Supporting Statement for the Paperwork Reduction Act Submission: Medicare and Medicaid Programs: Conditions of Participation for Hospices (OMB No. 0938-1067/CMS-10277)

A. Background

The purpose of this package is to request Office of Management and Budget (OMB) to reinstate, with change, the information collection requirements, titled "Medicare and Medicaid Programs: Conditions of Participation for Hospices (OMB No. 0938-1067/CMS-10277)."

Under the Medicare program, eligible beneficiaries may receive covered services in a hospice, provided that certain requirements are met by the hospice. Hospice care means a comprehensive set of services identified and coordinated by an interdisciplinary group to provide for the physical, psychosocial, spiritual and emotional needs of a terminally ill patient and/or family members, as delineated in a specific patient plan of care.

The information collection requirements (ICRs) described herein are needed to implement the Medicare Conditions of Participation (CoPs) for Medicare-participating hospices. The CoPs help assure an adequate level of patient health and safety in participating hospices and help ensure that Medicare hospice eligibility requirements are being met. CMS originally published the Hospice Conditions of Participation on June 5, 2008 (hereinafter "2008 Final Rule").[1] The regulations containing the information collection requirements are located at 42 CFR Part 418 of the Code of Federal Regulations, Subparts B, C and D.

This is an update of the information collection request that expires on February 28,2029. The previous iteration of this OMB Control Number 0938-1067 (approved August 28, 2025) had an annual burden of 4,032,329 hours and annual costs of $350,449,922. For this requested reinstatement, with changes, the total annual burden hours for industry is **4,095,725 hours** and the annual burden costs are **$354,496,106**. See **Table 56** below for summary of burden hours and costs to the industry. The 1.6%% increase in hours is primarily due to the increase in the number of hospices since the last iteration. See **Section 15** for details on the reasons for the change in burden.

Changes post March 2021

Since the last reinstatement was approved in March 2021, CMS revised one of the hospice CoPs at 42 CFR §418.76 in the proposed rule, *Medicare Program: FY 2022 Hospice Wage Index and Payment Rate Update, Hospice Conditions of Participation Updates, Hospice and Home Health Quality Reporting Program Requirements* published on April 14, 2021 (86 FR 19700). As CMS addressed in the final rule (CMS-1754-F) published on August 4, 2021 (86 FR 42528), the comments received supported the proposed revisions and did not require any changes to the original burden estimates in this PRA package. [2] This reinstatement incorporates the policy changes made to Section 418.76 through this rule and updates the associated burden estimates based on the original assumptions.

In November 2021, CMS required hospices to develop policies and procedures as a CoP to ensure all staff were fully vaccinated and the burden requirements were detailed in OMB 0938-0266.[3] However, CMS removed this

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[1] "Medicare and Medicaid Programs: Hospice Conditions of Participation," 73 FR 32088 (June 5, 2008). See also, NPRM "Medicare and Medicaid Programs: Hospice Conditions of Participation," 70 FR 30840 (May 27, 2005).

[2] See 86 FR 42528, 42600-01.

[3] "Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination," 86 FR 61555, 61590 (November 5, 2021).

requirement and related burden for hospices (and other facilities) in June 2023.[4]

Changes post August 2025

Since the last reinstatement was approved in August 2025, CMS proposed revisions to the hospice payment regulations at 42 CFR §§ 418.24(b), (c), and (d) in the proposed rule, *Medicare Program: FY 2027 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Program Requirements* published on April XX, 2026 (XX FR XXXX). The collection of information for the election statement and the addendum is already accounted for in the hospice CoP burden estimates in its information collection request (OMB control number: 0938-1067) that was re-approved in November 2017. Additionally, the burden estimates completed in FY 2020 (84 FR 38484) already assumed that hospices would provide the addendum to all beneficiaries; however, we have updated the burden estimates in the FY 2027 hospice proposed rule with more recent data on the estimated hospice burden associated with the proposed mandatory election statement addendum for all elections. This update incorporates the policy changes proposed in Sections 418.24(b), (c), and (d) of the FY 2027 proposed rule and updates the associated burden estimates related to completing the hospice addendum based on more recent data available, while utilizing the original assumptions presented in the March 2021 iteration and the March 2025 reinstatement of this OMB Control Number 0938-1067.

B. Justification

1. Need and Legal Basis

Under the authority of section 1861(dd) of the Social Security Act (the Act), the Secretary has established the Conditions of Participation (CoPs) that a hospice must meet to participate in Medicare and/or Medicaid, the scope of covered services and the conditions for Medicare payment for hospice services. The CoPs, set forth at 42 CFR part 418, Subparts B, C and D, apply to a hospice as an entity as well as to the services furnished to each individual under hospice care. Section 1861(dd) of the Act also requires the Secretary to ensure compliance of 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 applicable 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 facility 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.

Section 1814(d)(1) of the Act requires that the eligible individual must elect to receive hospice care in order for Medicare to pay for such services. And section 1814(d)(2)(A) of the Act requires that upon the election of hospice care, the individual waives all rights to have Medicare payment made for hospice care provided by another hospice program (unless under arrangement), services related to the terminal illness and related conditions, and services duplicative of hospice care.

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 or that dietary therapy be

provided by hospice employees (§418.74). 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).

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

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[4] "Medicare and Medicaid Programs; Policy and Regulatory Changes to the Omnibus COVID–19 Health Care Staff Vaccination Requirements; Additional Policy and Regulatory Changes to the Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals With Intellectual Disabilities (ICFs–IID) To Provide COVID–19 Vaccine Education and Offer Vaccinations to Residents, Clients, and Staff; Policy and Regulatory Changes to the Long Term Care Facility COVID–19 Testing," 88 FR 36485, 36510 (June 5, 2023).

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 through the survey process, whether a hospice qualifies for approval or re-approval under Medicare. Surveyors make an in-person visit to hospices to conduct their survey.

CMS and its contractors will use this information 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. Lastly, the information will be used by hospices for assuring their own compliance with all requirements to assist in guiding their patient care and quality programs. There were 7,356 hospice providers in Fiscal Year 2023 that must meet the CoPs in order to receive payment for services provided to Medicare patients.

3. Improved Information Technology

Hospices may use various information technologies to comply with the requirements and store and manage patient medical records as long as they are consistent with the existing confidentiality in record-keeping regulations at 42 CFR §418.104(c). Hospices are encouraged to take advantage of any technological advances that they find appropriate for their needs.

4. Duplication of Efforts

There is no duplication of information. These requirements are specified in a way that does not require facilities to duplicate their efforts. If a facility already meets the requirements and maintains these general records, regardless of format, they are in compliance. The general nature of the requirements makes variations in the substance and format of these records, from one facility to another, acceptable.

5. Small Business

This information collection affects small businesses. However, the general nature of the requirements allows the flexibility for small businesses to meet the requirements in a way that is consistent with their existing operations.

6. Less Frequent Collection

Less frequent information collection would impede efforts to establish compliance with the Medicare Conditions for Participation (CoPs), which in turn, would jeopardize the health and safety of hospice patients and provision of quality healthcare. CMS does not collect information directly from hospices and instead relies on State surveyors (employed by State survey agencies) to review the collection of information at the time of their certification and at the time of their periodic facility visit necessary for their recertification.

7. Special Circumstances

There are no special circumstances.

8. Federal Register Notice/Outside Consultation

A Notice of Proposed Rulemaking (Medicare Program: FY 2027 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Program Requirements - (CMS-1851-P)) published on April 6, 2026 (91 FR 17338). This update incorporates changes proposed in this proposed rule.

9. Payments or Gifts to Respondents

There will not be any payments or gifts provided to respondents for the collection of this information.

10. Confidentiality

Standard medical confidentiality practices, such as the Privacy Act of 1974 (5 U.S.C. § 552a) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA), assure the confidentiality of this information. The requirements of this regulation must be in compliance with HIPAA Privacy Rules at 45 CFR §§ 160 and 164, which protect the privacy and security of an individual's protected health information. We do not pledge confidentiality of aggregate data.

11. Sensitive Questions

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

12. Burden Estimates (Hours and Wages)

The information collections are broken out into the following sub-sections: Subpart B, Eligibility, Election and Duration of Benefits, 42 CFR §§ 418.20-418.30; Subpart C, Conditions of Participation: Patient Care 42 CFR §§ 418.52-418.78, Subpart D, Conditions of Participation: Organizational Environment, 42 CFR §§ 418.100-418.116.

Burden estimates are identified by each information collection (IC). First, we provide the global assumptions used to calculate the burden estimates herein.

Assumptions

Wages

The burden for information collections described below uses salary data located in Table 1. This salary data is based on the U.S. Department of Labor Bureau of Labor Statistics (BLS) May 2023 Industry-Specific Occupational Employment and Wage Estimates (OEWS) for Home Health Care Services Industry (NAICS 621600)[5]. We first identified typical positions for those who provide home health care services, and then matched those positions with labor categories use by BLS. We then identified the mean hourly salary wage for that labor category and estimated at 100 percent markup to account for fringe and overhead. We also rounded the numbers up to the next dollar where appropriate.

Table 1. Salary Data

Personnel	BLS Occupation Title	Occupation Code	Mean Hourly Wage	Wages w/Benefits
Hospice Administrator	Chief Executives	11-1011	$84.74	**$169**
Hospice Clinical Manager	Medical and Health Services Managers	11-9111	$52.55	**$105**
Hospice Medical Director	Physician	29-1210	$107.94	**$216**
Physician	Physician	29-1210	$107.94	**$216**
Hospice RN	Registered Nurse	29-1141	$42.04	**$84**
Nurse Practitioner	Nurse Practitioner	29-1171	$70.60	**$141**
Hospice MSW/Social Worker	Health Care Social Worker	21-1022	$35.09	**$70**
QAPI Coordinator	Registered Nurse	29-1141	$42.04	**$84**
Clerical Staff/Administrative Assistant	Medical Secretaries and Administrative Assistants	43-9000	$20.19	**$40**
Hospice Executive Assistant	Executive Administrative Assistant	43-6011	$30.99	**$62**

Hospice Data

In addition to salary data, the burden estimates also use Hospice specific data, located in Table 2. This data was obtained from: 1)Aggregate Medicare Fee-For-Service claims data, Fiscal Year (FY) 2023, or from the enrollment database on elections for Medicare hospice patients with FY 2023 claims; 2) Medicare's Certification and Survey Provider Enhanced Reporting (CASPER) for Calendar Year 2023 via the data reports available at Quality, Certification and Oversight Report (QCOR) at https://qcor.cms.gov. We assume the number of newly certified facilities remains consistent over the 3-year period.

Table 2. Hospice Specific Data

Hospice Data Item	Number
# of Medicare-participating hospices, FY 2023 per CASPER *(a)*	7,356
# of New Medicare-participating hospices, FY 2023 per CASPER	546
# of Medicare-billing hospices per FY 2023 claims *(b)*	6,414

[5] U.S. Bureau of Labor Statistics Occupational Employment and Wage Statistics. *U.S. Bureau of Labor Statistics.* Last Modified Date: April 3, 2024. https://www.bls.gov/oes/current/naics4_621600.htm. Accessed March 31, 2025.

# of hospice patients who are Medicare Beneficiaries nationwide, FY 2023 *(c)*	1,760,040
# of patients per average hospice *(d) = (c)/(a)*	239
# of Medicare hospice patients per FY 2023 claims *(e)*	1,776,013
# of Medicare patients per hospice per FY 2023 claims *(f) = (e)/(b)*	277
# of New Medicare-billing hospices per FY 2023 claims	860
# of annual certifications & recertifications, FY 2023 per Medicare Enrollment Database (EDB)	2,957,691
# of initial certifications, FY 2023 per EDB	1,346,961
# of recertifications for the 2nd benefit period, FY 2023 per EDB	380,106
# of annual recertifications for the 3rd or later benefit period, FY 2023	1,230,624
# of elections per FY 2023 claims	1,516,946
Revocations/beneficiary per FY 2023 claims	0.057

Burden estimates below may use facility totals based on Fee-For-Service billing data or CASPER based on the assumptions required for the specific information collection requirement.

Note: For all burden calculations herein, the burden amounts are rounded to the nearest hour and dollar amount.

Subpart B: Eligibility, Election and Duration of Benefits
42 CFR §§ 418.20-418.30

This sub-section is broken out by IC-1 to IC-6.

§418.22 Certification of terminal illness,

Hospices may develop their own form for certifications and recertifications, provided the form conforms to the requirements at §418.22(b). Requirements include a statement which specifies that the individual's prognosis is for a life expectancy of 6 months or less if the terminal illness were to run its normal course. The form is to be signed, dated, and include the benefit period dates to which the certification or recertification applies. Additionally, the form includes space for the physician's narrative and narrative attestation of face-to-face encounter.

The burdens associated with information collection requirements for this CoP includes:

- IC-1a: the one-time burden for hospices to develop their own certification form;
- IC-1b: the time for the physician to complete the narrative and its attestation;
- IC-2: the time for physician or nurse practitioner to complete the face-to-face attestation; and
- IC-3: the time for the physician to sign and date the form, and the physician or nurse to include the benefit period dates.

IC-1a: One-time Development of Certification Form – § 418.22(b)

The one-time cost of form development only falls on new hospices that begin filing Medicare claims. To estimate the burden, we estimate that according to Medicare claims data in FY 2023, there were 546 new hospices that began filing Medicare claims in FY 2023. We estimate that a Hospice Administrator would be the person responsible to develop a certification or recertification form within 45 minutes (0.75 hours). We also estimate that it would take an Administrative Assistant 15 minutes (0.25 hours) to prepare the certification or recertification form.

Table 3 below lists the number of applicable hospices that would need to develop a one-time certification form, the number of times each hospice would have to develop this form, the staff responsible to complete form, the hourly wage rates for each staff member, and the estimated time needed to complete one response.

Table 3. Annual One-Time Development of Hospice Certification Form

# of Applicable Hospices	# of Responses Per Hospice	Staff	Hourly Cost ($)	Time Per Response (mins)
546	1 form	Hospice Administrator	$169	45 mins. (0.75 hrs.)
546	1 form	Administrative Assistant	$40	15 mins. (0.25 hrs.)

Table 4 calculates the time burden and the cost burden per hospice as well as all hospices. The burden amounts are rounded to the nearest hour and dollar amount: The total annual burden for the industry would be 546 hours ((0.75 hour x 546 hospices = 409.5 hrs.) + (0.25 x 546 hospices = 136.50 hrs.)) and cost $74,667 (($169/hr. x 409.5 hours = $69,206) + ($40/hr. x 136.5 hours = $5,460)).

Table 4. IC-1a: Hour and Cost Burden for One-time Development of Certification Form – § 418.22(b)

# of Applicable Hospices	# of Responses Per Hospice	Total Time Per Hospice (mins/hrs.)	Total Cost per Hospice ($)	Total Time for All Hospices (hrs.)	Total Costs for All Hospices ($)
546	1	45 mins. (0.75 hrs.)	$126.75 ($169 x 0.75)	409.5 hours (546 x 0.75)	$69,206 ($169 x 409.5)
546	1	15 mins (0.25 hrs.)	$10.00 ($40 x0.25)	136.50 (546 x 0.25)	$5,460 ($40 x 136.50)
TOTAL BURDEN	**1**	**60 mins/1 hr.**	**$136.75**	**546 hrs.**	**$74,667**

IC-1b: Compose a Narrative for Certifications and Recertifications – § 418.22(b)(3)

Per Section 418.22(b)(3), the physician must include a brief narrative that provide an explanation of the clinical findings that supports a life expectancy of 6 months or less and 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.

Per Table 4 below, we estimate it will take a physician 5 minutes to compose the narrative; write, type, or dictate it; and sign any attachments. As indicated in Table 2 above, there were:

- 1,346,961 initial certifications,
- 380,106 recertifications of beneficiaries entering the second benefit period, and
- 1,230,624 recertifications for beneficiaries entering the 3rd or later benefit periods.
- 2,957,691 total certifications/recertifications
- 6,414 Medicare-billing hospices[6]

[6] Note for the number of applicable hospices, 6,414 is as the total number of hospices used for IC-1 to IC-6. For IC-7 to IC-26, 7,356 is the total number of hospices used. As noted in Table 2 above, the 6,414 number is based off Fee for Service (FFS), FY2023, claims data and the 7,356 number is based off CASPER, FY 2023 data. Both are sources of data to produce these burden estimates.

Tables 5 and 6 calculate the time and cost burdens per hospice as well as for all hospices. The burden amounts are rounded to the nearest hour and dollar amount.

Table 5. Completion of Certification/Recertification Narrative

# of Applicable Hospices	# of Responses Per Hospice	Staff	Hourly Cost ($)	Time Per Response (mins)
6,414	461	Hospice Medical Director	$216	5 mins. (0.083 hrs.)

Per Table 6, the total annual burden per hospice would be 38 hours (0.083 x 461 narratives/hospice) and cost $8,208 ($216/hr. x 38 hours). The total annual burden for the industry would be 243,732 hours (38 hours x 6,414 hospices) and cost $52,646,112 ($216/hr. x 243,732 hours or $8,208/hospice x 6,414 hospices).

Table 6. IC-1b: Hour and Cost Burden for Composing Narratives for Certifications and Recertifications – § 418.22(b)(3)

Staff	Hourly Cost	# of Certifications and Recertifications Narratives	Total Time per Narrative (mins./hrs.)	Total Time per Hospice (hrs.)	Total Cost per Hospice ($)	Total Time for All Hospices (hrs.)	Total Costs for All Hospices ($)
Hospice Medical Director	$216	2,957,691 or 461 per hospice (2,957,691/6,414)	5 mins. (5/60=0.083)	38 (461 x 0.083)	$8,208 ($216 x 38)	243,732 (6,414 x 38)	$52,646,112 ($216 x 243,732)
TOTAL BURDEN	-	-	**0.083 hrs.**	**38 hrs.**	**$8,208**	**243,732 hrs.**	**$52,646,112**

IC-2: Face-to-Face Encounter Attestation – § 418.22(b)(4)

Per Section 418.22(b)(4), 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 this requirement 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. As indicated in Table 2, there were:

- 275,329 recertifications for patients with lengths of stay of 180 days or longer, which would require a face-to-face encounter attestation statement
- 6,414 Medicare-billing hospices. [7]

[7] Id.

Tables 7 and 8 calculate the time burden and the cost burden per hospice as well as all hospices. The burden amounts are rounded to the nearest hour and dollar amount. The total annual burden for the industry would be 2,156 hours ((0.168 hours x 6,414 hospices = 1,078 hrs.) x 2 staff) and cost $384,846 (($216/hr. x 1,078 hrs.) + ($141/hr. x 1,078 hrs.)).

Table 7. Face-to-Face Encounter Attestation

# of Applicable Hospices	# of Responses Per Hospice	Staff	Hourly Cost	Time Per Response (secs./hrs.)
6,414	21	Hospice Medical Director	$216	30 secs. (0.008 hrs.)
6,414	21	Nurse Practitioner	$141	30 secs (0.008 hrs.)

Table 8. IC-2: Hour And Cost Burden for Face-to-Face Encounter Attestation – § 418.22(b)(4)

Staff	Hourly Cost	Time Per Attestation (mins.)	# of Attestations	Total Time per Hospice (hrs.)	Total Cost per Hospice ($)	Total Time for All Hospices (hrs.)	Total Costs for All Hospices ($)
Medical Director	$216	30 secs./0.5 min (0.008 hrs.)	137,665 or 21 per hospice (137,665/6,414) (represents half the attestations)	0.168 hrs. (21 x 0.008)	$36.29 ($216 x 0.168)	1,078 hrs. (6,414 x 0.168)	$232,848 ($216 x 1,078)
Nurse Practitioner	$141	30 secs./0.5 min (0.008 hrs.)	137,665 or 21 per hospice (137,665/6,414) (represents half the attestations)	0.168 hrs. (21 x 0.008)	$23.69 ($141 x 0.168)	1,078 hrs. (6,414 x 0.168)	$151,998 ($141 x 1,078)
TOTAL BURDEN		**1 min. (0.017 hrs.)**	**275,329**	**0.336 hrs.**	**$59.98**	**2,156 hrs.**	**$384,846**

IC-3: Certification of Benefit Periods – § 418.22(b)(5)

Per Section 418.22(b)(5), 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. As indicated in Table 2, there were:

- 2,957,691 certifications and recertifications completed in a year, with half the benefit period dates written in by physicians (1,478,846), and half by a nurse (1,478,846);
- 6,414 Medicare-billing hospices.[8]

Tables 9 and 10 calculate the time burden and the cost burden per hospice as well as for all hospices. The burden amounts are rounded to the nearest hour and dollar amount. The total annual burden for the industry would be 23,662 hours ((1,478,846 certifications x 0.0083/hr. = 11,831 hrs.) x 2 staff) and cost $3,549,300 (($216/hr. x 11,831 hrs.) + ($84/hr. x 11,831 hrs.)).

Table 9. Benefit Periods on Certification/Recertifications

# of Applicable Hospices	# of Responses Per Hospice	Staff	Hourly Cost ($)	Time Per Response (hrs.)
6,414	231	Hospice Medical Director	$216	30 secs. (0.008 hrs.)
6,414	231	RN	$84	30 secs. (0.008)

Table 10. IC-3: Hour And Cost Burden for Reporting Benefit Periods on Certifications/Recertifications – § 418.22(b)(5)

Staff	Hourly Cost	Time Per Certification and Recertification (mins)	# of Certification and Recertifications	Total Time per Hospice (hrs.)	Total Cost per Hospice ($)	Total Time for All Hospice Certifications and Recertifications (hrs.)	Total Costs for All Hospices Certifications and Recertifications (hrs.)
Medical Director	$216	30 secs./0.5 min (0.008 hrs.)	1,478,846 or 231 per hospice (1,478,846/6,414)	1.9 hrs. (231 x 0.008)	$410 ($216 x 1.9)	11,831 hrs. (1,478,846 x 0.008)	$2,555,496 ($216 x 11,831)
RN	$84	30 secs./0.5 min (0.008 hrs.)	1,478,846 or 231 per hospice (1,478,846/6,414)	1.9 hrs. (231 x 0.008)	$160 ($84 x 1.9)	11,831 hrs. (1,478,846 x 0.008)	$993,804 ($84 x 11,831)
TOTAL BURDEN		**1 min. (0.017 hrs.)**	**2,957,691**	**3.8 hrs.**	**$570**	**23,662 hrs.**	**$3,549,300**

[8] Id.

§418.24 Election of Hospice Care

An individual who meets the eligibility requirement of §418.20 may file an election statement with a particular hospice. If the individual is physically or mentally incapacitated, his or her representative (as defined in §418.3) may file the election statement. For hospice elections beginning on and after October 1, 2026, we proposed changes to the content requirements for the hospice election form.

(b) Content of election statement.

Per Section 418.24(b), the election statement must include the following:
(1) Identification of the particular hospice that will provide care to the individual.
(2) 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.
(3) Acknowledgment that coverage of certain Medicare services is waived by the election. For Hospice elections beginning on or after October 1, 2020, this would include providing the individual with information indicating that services unrelated to the terminal illness and related conditions are exceptional and unusual and hospice should be providing virtually all care needed by the individual who has elected hospice.
(4) The effective date of the election.
(5) Individual cost-sharing for hospice services for Hospice elections beginning on or after October 1, 2020.
(6) For Hospice elections beginning on or after October 1, 2026, the hospice must provide the individual (or representative) an election statement addendum, as set forth in paragraphs (c) and (d) of this section, which includes any conditions, items, services, and drugs the hospice has determined to be unrelated to the individual's terminal illness and related conditions and would not be covered by the hospice.
(7) The Beneficiary and Family Centered Care Quality Improvement Organization (BFCC-QIO), including the right to immediate advocacy and BFCC-QIO contact information for Hospice elections beginning on or after October 1, 2020.
(8) 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.

IC-4a: Election Form Development – § 418.24(b)

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 the updates to the election requirements have been in place since 2020 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.

Tables 11 and 12 list the number of applicable hospices that would need to develop a one-time election form, the number of times each hospice would have to develop this form, the staff responsible, their hourly cost and the time per response:

Table 11. One-Time Election Form Development

# of Applicable Hospices	# of Responses Per Hospice	Staff	Hourly Cost ($)	Time Per Response (hrs.)
546	1 form	Hospice Administrator	$169	1 hour

Per Table 12, the total annual burden per hospice would be 1 hour and cost $169. The total annual burden for the industry would be 546 hours (1 hour x 546 hospices) and cost $92,274 ($169/hr. x 546 hours or $169/hospice x 546 hospices).

Table 12. IC-4a: Hour And Cost Burden for One-Time Election Form Development – § 418.24(b)

Staff	Hourly Cost	# of Applicable Hospices	# of Responses Per Hospice	Total Time Per Hospice (hrs.)	Cost per Hospice	Total Time for All Hospices	Total Costs for All Hospices
Hospice Administrator	$169	546	1	1 hr.	$169 ($169 x 1 hr.)	546 hours (546 x 1 hr.)	$92,274 ($169 x 546)
TOTAL BURDEN		**546**	**1**	**1 hr.**	**$169**	**546 hours**	**$92,274**

IC-4b: Election Statement Explanation – § 418.24(b)

For existing hospices, we estimate it will take 15 minutes (0.25 hours) for an RN to explain the election statement form to beneficiaries, and to ensure the beneficiary understands what they are signing. Tables 13 and 14 calculate the time burden for the 6,414 Medicare billing hospices[9] and the cost burden per hospice and all hospices. Burden amounts are rounded to the nearest hour and dollar amount:

Table 13. Election Statement Explanation

# of Applicable Hospices	# of Responses Per Hospice	Staff	Hourly Cost ($)	Time Per Response (hrs.)
6,414	237	RN	$84	15 mins. (0.25 hrs.)

Per Table 14, the total annual burden per hospice would be 59 hours (0.25 hour x 237 statements/hospice) and cost $4,956 (59 hrs. x $84/hr.). The total annual burden for the industry would be 378,426 hours (59 hours x 6,414 hospices) and cost $31,787,784 ($84/hr. x 378,426 hours or $4,956 x 6,414 hospices).

[9] Id.

Table 14. IC-4b: Hour And Cost Burden for Election Statement Explanation – § 418.24(b)

Staff	Hourly Cost	# of Hospice Election Statements	Time Per Election Statement (mins.)	Total Time Per Hospice (hrs.)	Total Costs per Hospice ($)	Total Time for All Hospice Elections (hrs.)	Total Costs for All Hospice Elections ($)
RN	$84	1,516,946 or 237 election statements per hospice (1,516,946/6,414)	15 mins (0.25 hours)	59 hrs. (237 x 0.25)	$4,956 ($84 x 59)	378,426 hrs. (6,414 x 59)	$31,787,784 ($84 x 378,426)
TOTAL BURDEN	-	**1,516,946**	**15 mins.** (0.25 hours)	**59 hrs.**	**$4,956**	**378,426 hrs.**	**$31,787,784**

(c) Content of hospice election statement addendum.

The burden estimate for the modifications to the election statement for hospice elections beginning on and after October 1, 2026, is included in the election statement addendum estimates found below. The hospice must provide the individual (or representative) an election statement addendum (and its updates), as set forth in Sections 418.24(b), (c), (d), which includes any conditions, items, services, and drugs the hospice has determined to be unrelated to the individual's terminal illness and related conditions and would not be covered by the hospice.

The election statement addendum (and its updates) must include the following:

(1) The addendum must be titled “Patient Notification of Hospice Non-Covered Items, Services, and Drugs.”
(2) Name of the hospice.
(3) Individual's name and hospice medical record identifier.
(4) Identification of the individual's terminal illness and related conditions.
(5) A list of the individual's conditions present on hospice admission (or upon plan of care update) and the associated items, services, and drugs not covered by the hospice because they have been determined by the hospice to be unrelated to the terminal illness and related conditions.
(6) A written clinical explanation, in language the individual (or representative) can understand, as to why the identified conditions, items, services, and drugs are considered unrelated to the individual's terminal illness and related conditions and not needed for pain or symptom management. This clinical explanation must be accompanied by a general statement that the decision as to whether or not conditions, items, services, and drugs are related is made for each patient and that the individual should share this clinical explanation with other health care providers from which they seek items, services, or drugs unrelated to their terminal illness and related conditions.
(7) References to any relevant clinical practice, policy, or coverage guidelines.
(8) Information on the following:
    (i) *Purpose of Addendum.* The purpose of the addendum is to notify the individual (or representative), in writing, of those conditions, items, services, and drugs the hospice will not be covering because the hospice has determined they are unrelated to the individual's

terminal illness and related conditions.

(ii) *Right to Immediate Advocacy.* The addendum must include language that immediate advocacy is available through the Medicare Beneficiary and Family Centered Care-Quality Improvement Organization (BFCC-QIO) if the individual (or representative) disagrees with the hospice's determination.

(9) Name and signature of the individual (or representative) and date signed, along with a statement that signing this addendum (and its updates) is only acknowledgement of receipt of the addendum and not the individual's (or representative's) agreement with the hospice's determinations. If the beneficiary (or representative) refuses to sign the addendum, the hospice must document on the addendum the reason the addendum was not signed and the addendum would become part of the patient's medical record. The addendum must also be available for non-hospice providers and Medicare contractors, the non-hospice providers and Medicare contractors are not required to sign the addendum.

(10) Date the hospice furnished the addendum to the individual.

Timeframes for the hospice election statement addendum

(1) For hospice elections beginning on or after October 1, 2026, the hospice must provide the individual (or representative) an election statement addendum, in writing, as set forth in § 418.24(c), at the time of the hospice election (that is, within the first 5 days of the hospice effective date of the hospice election). The hospice must also file this information with the election statement, as set forth in § 418.24(a) and (b), to be available for the individual (or representative), non-hospice providers, and Medicare contractors.

(2) If there are any changes to the plan of care during the course of hospice care, the hospice must update the addendum, within 3 days, with the contents described in § 418.24(c), and provide these updates, in writing, to the individual (or representative), as well as update the addendum on file in order to communicate these changes to the individual (or representative), non-hospice providers, and Medicare contractors.

(3) If the individual dies, revokes, or is discharged within the required timeframe for providing the addendum (and its updates) (as outlined in § 418.24(d)(1) and (2)), and before the hospice has provided the addendum (and its updates), the addendum would not be required to be provided, in writing, to the individual (or representative); however, if completed, the hospice must still file the addendum (and its updates) with the election statement, as set forth in § 418.24(a) and (b), to be available for the individual (or representative), non-hospice providers, and Medicare contractors. The hospice must note the reason the addendum (and its updates) was not completed and/or provided, in writing, to the individual (or representative) and this note would become part of the patient's medical record.

(4) If the individual dies, revokes, or is discharged prior to signing the addendum (or its updates) (as outlined in § 418.24(d)(1) and (2) with the required contents described in § 418.24(c)), the addendum would not be required to be signed in order for the hospice to receive payment. The hospice must note (on the addendum itself) the reason the addendum (and any updates) was not signed and the addendum would become part of the patient's medical record.

Addendum Form Development & Completion

The burden associated with this requirement includes the cost of developing the addendum (for new hospices) and the cost of filling out the form. There is no associated burden for hospices to communicate/coordinate with non-hospice providers regarding the content of the addendum statement because the hospice CoPs at §418.56(e) have always required hospices to have a system of communication with non-hospice providers in place. We estimate that there would be 1,516,946 hospice elections in a year based on FY 2023 claims data. Hospices would not be required to complete the election statement addendum for those hospice beneficiaries that die

within 5 days of hospice election. Approximately 23 percent (0.77) of hospice beneficiaries die within the first 5 days after the hospice election date. This results in 1,092,201 elections that could receive the election statement addendum.

IC-5a: One-time Election Statement Addendum Form Development – § 418.24(c)

As shown in Table 15, we estimate a one-time burden for the development of an election statement addendum for new hospices. We estimate that it would take a hospice Administrative Assistant 15 minutes (15/60 = 0.25 hours) to develop the addendum with the required elements, and the hospice administrator 15 minutes (15/60 = 0.25 hours) to review the addendum.

Table 15. One-Time Election Statement Addendum Form Development

# of Applicable Hospices	# of Responses Per Hospice	Staff	Hourly Cost ($)	Time Per Response (hrs.)
546	1 form	Hospice Executive Assistant	$62	15 mins. (0.25 hrs.)
546	1 form	Hospice Administrator	$169	15 mins. (0.25 hrs.)

Table 16 below lists the number of applicable hospices that would need to develop a one-time election statement addendum form, the number of times each hospice would have to develop this form, the staff responsible and their hourly cost, and the time per response. The total annual burden for the industry would be 274 hours (((0.25 hours x 546 hospices) = 137 hrs.) x 2 staff) and cost $31,647 (($62/hr. x 137 hrs.) + ($169/hr. x 137 hrs.)).

Table 16. IC-5a: Hour And Cost Burden for One-Time Election Statement Addendum Form Development – § 418.24(c)

Staff	Hourly Cost	# of Applicable New Hospices in 2023	# of Responses Per Hospice	Total Time Per Hospice (mins.)	Total Time for All Hospices (hrs.)	Total Costs for All New Hospices ($)
Hospice Executive Assistant	$62	546	1	15 mins. (15/60 = 0.25 hrs.)	137 hrs. (546 x 0.25)	$8,494 ($62 x 137)
Hospice Administrator	$169	546	1	15 mins. (15/60 = 0.25 hrs.)	137 hrs. (546 x 0.25)	$ 23,153 ($169 x 137)

TOTAL BURDEN	**-**	**-**	**1**	**30 mins.** (0.5 hrs.)	**274 hrs.**	**$31,647**

IC-5b: Completion of Election Statement Addendum – § 418.24(c)

Section 418.24(c) requires an RN to conduct the initial assessment. We assume the same RN would be responsible for completing the addendum for each hospice election as part of the routine admission paperwork.

We estimate there would be 1,873,148 hospice elections in a year based on FY 2042 claims data. Hospices would not be required to complete the election statement addendum for those hospice beneficiaries that die within 5 days of hospice election. Approximately 19 percent (0.19) of hospice beneficiaries die within the first 5 days after the hospice election date. This results in 1,517,250 applicable hospice elections in FY 2024 that could receive the completed addendum. The estimated burden for the hospice RN to extrapolate this information from the existing documentation in the patient's hospice medical record and complete this addendum would be 10 minutes (10/60 = 0.167 hrs.).

Tables 17 and 18 calculate the time burden and the cost burden per hospice and for *all* hospices to complete the hospice election addendum. The burden amounts are rounded to the nearest hour and dollar amount.

Table 17. Completion of Hospice Election Statement Addendum

# of Applicable Hospices	# of Responses Per Hospice	Staff	Hourly Cost ($)	Time Per Response (hrs.)
6,732	225	RN	$79	10 mins. (0.167 hrs.)

Per Table 18, the total annual burden per hospice would be 38 hours (0.167 hrs. x 225) and cost $3,002 ($79/hr. x 38 hours). The total annual burden for the industry would be 255,816 hours (38 hours x 6,732 hospices) and cost $20,209,464 ($79/hr. x 255,816 hrs. or $3,002/hospice x 6,732 hospices).

Table 18. IC-5b: Hour And Cost Burden for Completion of Hospice Election Statement Addendum – § 418.24(c)

Staff	Hourly Cost	# of Hospice Elections per Hospice	Total Time Per Hospice (hrs.)	Total Cost per Hospice ($)	Total Time for All Hospices	Total Costs for All New Hospices
RN	$79	225 (1,517,250/ 6,732)	38 hrs. (225 x 0.167)	$3,002 ($79 x 38)	255,816 hrs. (38 x 6,732)	$20,209,464 ($79 x 255,816)
TOTAL BURDEN	**-**	**225**	**38 hrs.**	**$3,002**	**255,816 hrs.**	**$20,209,464**

§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 on his or her behalf for the remaining time in the period.

IC-6a: One-Time Revocation Form Development – § 418.28(d)

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 (0.25 hours) of the hospice administrator's time. Tables 19 and 20 list the number of applicable hospices that would need to develop a one-time revocation form, the number of times each hospice would have to develop this form, the staff responsible, the hourly cost for each

staff, and the time per response. The total annual burden per hospice would be 0.25 hours and cost $42 ($169/hr. x 0.25 hours). The total annual burden for the industry would be 137 hours (0.25 hours x 546 hospices) and cost $23,153 ($169/hr. x 137 hours).

Table 19. One-Time Revocation Form Development

# of Applicable Hospices	# of Responses Per Hospice	Staff	Hourly Cost ($)	Time Per Response (hrs.)
546	1 form	Hospice Administrator	$169	15 mins (0.25 hrs.)

Table 20. IC-6a: Hour And Cost Burden for One-Time Revocation Form Development – § 418.28(d)

Staff	Hourly Cost	# of Applicable New Hospices in 2023	Total Time Per Hospice (hrs.)	Total Cost per Hospice ($)	Total Time for All Hospices (hrs.)	Total Costs for All Hospices ($)
Hospice Administrator	$169	546	15 mins. (15/60 = 0.25 hours)	$42 ($169 x 0.25)	137 hrs. (546 x 0.25)	$23,153 ($169 x 137)
TOTAL BURDEN		**546**	**15 mins (15/60 = 0.25 hrs.)**	**$42**	**137 hrs.**	**$23,153**

IC-6b: Explanation of Revocation Form – § 418.28(d)

We also estimate that it would take about 5 minutes (0.083 hours) for an RN to explain the revocation form to the beneficiary. With 0.057 revocations per beneficiary and 1,776,013 beneficiaries in FY 2023, we estimate that there would be 101,233 revocations in a year. Tables 21 and 22 calculate the time burden and the cost burden per hospice as well as the time burden and cost burden for all hospices. The burden amounts are rounded to the nearest hour and dollar amount:

Table 21. Explanation of Revocation Form

# of Applicable Hospices	# of Responses Per Hospice	Staff	Hourly Cost ($)	Time Per Response (hrs.)
6,414	16	RN	$84	5 minutes (0.083 hrs.)

The total annual burden per hospice would be 1.3 hours and cost $109 ($84/hr. x 1.3 hours). The total annual burden for the industry would be 8,338 hours (1.3 hours x 6,414 hospices) and cost $700,392 ($84/hr. x 8,338 hours).

Table 22. IC-6b: Hour And Cost Burden for Explanation of Revocation Form – § 418.28(d)

Staff	Hourly Cost	Total Revocations	Total Time per Revocation (mins.)	Total Time Per Hospice (hrs.)	Total Cost per Hospice ($)	Total Time for All Hospices (hrs.)	Total Costs for All Hospices ($)
RN	$84	101,233 or 16 revocations per hospice (101,233/6,414)	5 mins. (5/60 = 0.083 hrs.)	1.3 hrs. (0.083 x 16)	$109 ($84 x 1.3 hrs.)	8,338 hrs. (1.3 x 6,414)	$700,392 ($84 x 8,338)
TOTAL BURDEN		**101,233**	**5 mins.** (0.083 hrs.)	**1.3 hrs.**	**$109**	**8,338 hrs.**	**$700,392**

Subpart C: Conditions of Participation: Patient Care
42 CFR §§ 418.52-418.78

This sub-section is broken out by IC-7 to IC-17.

418.52 Patient rights.

(a) Standard: Notice of rights and responsibilities

During the initial assessment visit, a hospice must provide patients or their representatives with written and verbal notice of the patient's rights and responsibilities, in a manner and language consistent with the patient's ability to comprehend the information. A hospice must also inform and distribute to the patient (or his/her representative) its policies on advance directives and obtain his/her signature to confirm receipt of the notice of rights and responsibilities.

IC-7a: One-time burden to Develop Patient Notification Form – § 418.52(a)(1)

The one-time burden associated with this notification requirement is the time and effort necessary for newly certified hospices to develop the notification form. Based on FY 2023 claims data, 546 hospices began participating in the Medicare program. For purposes of this information collection request, we assume the number of new hospices each year remains consistent.

Per Table 23 below, for each newly certified hospice, we estimate that a Hospice Administrator (BLS Occupation Code 11-1011) at a loaded hourly wage of $169 will take 8 burden hours to develop the form. The total one time burden for all newly certified hospices is 4,368 hours (8 hours x 546 new hospices) and an annual cost of $738,192 (($169/hr. x 4,368 hours) or ($1,352 x 546 hospices)).

Table 23. IC-7a: One-time burden to Develop Patient Notification Form – § 418.52(a)(1)

Burden/Hospice	Hourly Mean Wage	Hours/Task (hrs.)	Cost/Task ($)
Hospice Administrator (BLS Code 11-1011)	$169		
One-time burden per hospice		8.0	$1,352
Total one-time Burden/Costs for newly certified facilities	**546**	**4,368**	**$738,192**

IC-7b: Provide notice to patients – § 418.52(a)(3)

The burden associated with this CoP is the time and effort necessary for a hospice to provide the notice verbally and in writing to the patient or the patient's representative and obtain their signature confirming receipt of the notice.

Per Table 24 below, for all existing hospices, we estimate that it will take an RN approximately five (5) minutes per patient (or 0.083/hour) to provide verbal and written notice of the patient's rights and responsibilities and the policy on advance directives each year. Thus, the annual burden for each hospice to notify all of its patients of their rights as part of the informed consent process would be 20 hours per year (rounded [5 minutes x 239 patients]/ 60). The total annual burden hours for all existing hospices would be 147,120 (20 hours/hospice x 7,356 hospices). At a loaded hourly wage of $84 for an RN (BLS Occupation Code 29-1141), we estimate it will cost each hospice or $1,680 ($84 x 20 hours) and the total annual burden cost for all existing hospices would be $12,358,080 (($1,680/hospice x 7,356 hospices) or ($84/hr. x 147,120 hrs.)).

Table 24. IC-7b: Provide notice to patients – § 418.52(a)(3)

Burden Assumptions			
Hours/patient (5 min) *(a)*	0.083 hr.		
Avg # of patients/hospice FY 23 per CASPER *(b)*	239		
Hourly rate of RN (BLS Code 29-1141) *(c)*	$84		
Burden Hours/hospice *(d) = (a) x (b)*	20 hrs.		
Burden Cost/hospice *(e) = (c) x (d)*	$1,680		
Burden/Hospice		**Hours/Task (hrs.)** *(g) = (d) x (f)*	**Cost/Task ($)** *(h) = (e) x (f)*
Burden Hours/Cost per hospice		20	$1,680
# of Hospices *(f)*	7,356		
Total Annual Burden/Costs for all existing hospices		**147,120**	**$12,358, 080**

IC-8: Document & Investigate allegations – § 418.52(b)(4)

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

Under Section 418.52(b)(4)(ii), hospices must 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 to the appropriate State and local entities. Hospices must also take action to correct problems once they are identified. The burden associated with Section 418.52(b)(4) is the time and effort necessary to report, document, and investigate all alleged violations. We expect that a Hospice Administrator will investigate alleged patient rights violations.

Per Table 25 below, we estimate that, in a one year period, a hospice would need to conduct investigations for 5% of its patients for alleged violations, or 12 patients per year (239 average of patients x 5%). We estimate each investigation would require 1 hour of a Hospice Administrator's time, or a total of 12 hours per year per hospice (12 patients x 1 hour). The total annual burden hours for the industry would be 88,272 (12 hours x 7,356 hospices). At a loaded hourly wage of $169 for a Hospice Administrator (BLS Code 11-1011), the annual burden cost per hospice to perform investigations of patient violations would be $2,028 ($169 x 12 hours) and the total cost for all existing hospices would be $14,917,968 (($2,028 x 7,356 hospices) or ($169/hr. x 88,272 hours)).

Table 25. IC-8: Document & Investigate allegations - § 418.52(b)(4)

Burden Assumptions			
% of patients with alleged violations *(a)*	5%		
Avg # of patients/hospice FY 23 per CASPER *(b)*	239		
# of Patients w/alleged violations *(c) = (a) x (b)*	12		
Burden Hours/Patient *(d)*	1 hr.		
Burden Hours/Hospice *(e) = (c) x (d)*	12 hrs.		
Burden/Hospice	**Hourly Mean Wage**	**Hours/Task (hrs.)**	**Cost/Task ($)**
Hospice Administrator (BLS Code 11-1011)	$169		
Burden hours/cost per hospice		12	$2,028
# of Hospices	7,356		
Total Annual Burden Hours/Cost for all existing hospices		**88,272**	**$14,917,968**

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. The burden associated with this CoP is included in the burden calculations below in Section 418.58 for a hospice's QAPI program.

418.56 Interdisciplinary group (IDG), care planning and coordination of services.

(a) Standard: Approach to service delivery

A hospice is required to designate the IDG s 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. Because this burden is considered to be usual and customary, it is exempt from the PRA per 5 CFR § 1320.3(b)(2).

IC-9: Educate and train on Plan of Care – § 418.56(b)

(b) Standard: Plan of care

A hospice is required to designate an IDG 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).

Per Table 26 below, we estimate that an RN (BLS Occupation Code 29-1141) at a loaded hourly wage of $84 would need 30 minutes per patient to educate and train the patient and caregivers. Assuming each hospice has an average of 239 patients per year, the annual burden hours would be 120 hours per hospice ([30 minutes x 239 patients]/60), at a cost of $10,080 ($84 x 120). For all hospices, the total annual burden hours would be 882,720 (120 x 7,356 hospices) at a cost of $74,148,480 (($10,080 x 7,356) or ($84/hr. x 882,720 hrs.)).

Table 26. IC-9: Educate & Train on Plan of Care – § 418.56(b)

Burden Assumptions			
Hours/patient (30 min) *(a)*	0.5 hr.		
Avg # of patients/hospice FY 23 per CASPER *(b)*	239		
Burden Hours/hospice *(c) = (a) x (b)*	120 hrs.		
Burden/Hospice	**Hourly Mean Wage**	**Hours/Task (hrs.)**	**Cost/Task ($)**
RN (BLS Code 29-1141)	$84		
Burden Hours/Cost per hospice		120	$10,080
# of Hospices	7,356		

Total Annual Burden/Costs for all existing hospices		**882,720**	**$74,148,480**

IC-10: Update Plan of Care – § 418.56(c)

(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 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 an 18 day median length of service in 2022, patients would likely receive one update per year to their plan of care.[10] The burden associated with these requirements is the time and effort associated with drafting, reviewing, revising, and maintaining the plan of care.

Per Table 27 below, we estimate an RN (BLS Code 29-1141) at a loaded hourly wage of $84 would require 10 minutes per patient every 18 days to update the patients' plan of care. Assuming each hospice has an average of 239 patients per year, the annual burden per hospice would be 40 hours ([10 minutes x 239 patients] /60) and at a cost of $3,360 ($84 x 40 hours). The total annual burden hours for all hospices would be 292,240 (40 x 7,356 hospices) at a cost of $24,716,160 (($3,360x 7,356 hospices) or ($84/hr. x 294,240 hrs.)).

Table 27. IC-10: Update Plan of Care – § 418.56(c)

Burden Assumptions			
# of updates to plan of care/year *(a)*	1		
Hours/patient (10 min) to update plan of care *(b)*	0.167 hr.		
Avg # of patients/hospice FY 23 per CASPER *(c)*	239		
Burden Hours/hospice *(d) = (a) x (b) x (c)*	40 hrs.		
Burden/Hospice	**Hourly Mean Wage**	**Hours/Task (hrs.)**	**Cost/Task ($)**
RN (BLS Code 29-1141)	$84		
Burden hours/cost per hospice		40	$3,360
# of Hospices	7,356		
Total Annual Burden/Costs for all existing hospices		**294,240**	**$24,716,160**

[10] Chapter 9, "March 2024 Report to the Congress: Medicare Payment Policy," MedPAC, March 15, 2024 at: https://www.medpac.gov/document/march-2024-report-

to-the-congress-medicare-payment-policy/

(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).

QAPI

418.58 Quality assessment and performance improvement (QAPI)

A hospice must develop, implement, and maintain an effective, ongoing, hospice-wide data-driven quality assessment and performance improvement (QAPI) program.

1. Specifically, the hospice's governing body is responsible for ensuring the following:
2. Develop an ongoing program for quality improvement related to improved palliative outcomes and hospice services; quality improvement related to improved palliative outcomes and hospice services.
3. Implementing and maintaining the program by: tracking adverse patient events, analyzing causes, and implementing preventative actions and mechanisms.
4. Tracking and evaluating performance improvement projects.

The hospice must maintain documentary evidence of its QAPI program and be able to demonstrate its operation to CMS.

IC-11a: Initial development of QAPI program – § 418.58(a)(2)

First, for newly certified hospices, there is a one-time burden to develop a data-driven QAPI program. This entails identifying quality domains and measurements that reflect a hospice's organizational complexity.

Per Table 28 below, we estimate that initial development of a QAPI program would be done by a hospice's governing body, consisting of: an RN (serving as a QAPI Coordinator)(BLS Occupation Code 29-1141), a Hospice Administrator (BLS Occupation Code 11-1011), and a Clinical Manager (BLS Occupation Code 11-9111). We estimate that the governing body would hold four (4) one-hour meetings for a total of 12 hours per hospice to identify quality domains and measures. The total burden for the industry is 6,552 hours (12 hours x 546 new hospices per year). Based on an average, loaded hourly wage for all 3 members of the governing body, the total annual cost per newly certified hospice would be $1,432 ([$84 + $169 + $105] x 4 hours = $1,432). The one-time burden for all newly certified hospices is $781,872 ($1,432 x 546 hospices).

Table 28. IC-11a: One-time development of QAPI program – § 418.58(a)(2)

Task	Hourly Mean Wage	Hours /Task (hrs.)	Cost/Task ($)
QAPI Coordinator/RN (BLS Code 29-1141)	$84	4	$336
Hospice Administrator (BLS Code 11-1011)	$169	4	$676
Clinical Manager (BLS Code 11-9111)	$105	4	$420
Burden Hours/Cost per hospice		12	$1,432
Total Annual Burden/Costs for all newly certified hospices	**546**	**6,552**	**$781,872**

Note: The additional activities for creating a new QAPI program – developing policies and procedures and educating staff - are usual and customary business practices and are exempt from the PRA per 5 CFR §1320.3(b)(2).[11] For example, a hospice can incorporate QAPI training into the regular in-service training program it is required to conduct for its employees in accordance with the in-service training requirement at existing § 418.64.

IC-11b: Collect & Record Quality Data – § 418.58(a)(2)

Per Section 418.58(a)(2), hospices must "enter data in patient clinical records during patient assessments" to collect quality indicators, adverse patient events, and other data to assess patient care and operations. Although assessing a patient is already standard practice, we believe that collecting quality measure data during the patient assessment will be a new practice for many hospices.

Per Table 29, we estimate a QAPI Coordinator/RN (BLS Occupation Code 29-1141) at each hospice would need 4 minutes per patient per assessment, or 8 minutes for 2 assessments each year, to collect and record quality data in a patient's clinical record. Assuming each existing hospice has an average of 239 patients per year, collecting QAPI related data would take 32 hours per hospice ([4 minutes per assessment x 2 assessments per patient x 239 patients]/60) and cost $2,688 per hospice based on a loaded hourly wage of $84 ($84 x 32 hours). For all existing hospices, the total annual burden would be 235,392 (32 hours x 7,356 hospices) and cost $19,772,928 (($2,688 x 7,356 hospices) or ($84/hr. x 235,392 hrs.)).

Table 29. IC-11b: Collect & Record Quality Data – § 418.58(a)(2)

Burden Assumptions	
Hours/patient/assessment (4 min/60 min)	0.067 hr.
# of patient assessment/year	2
Avg # of patients/hospice FY 23 per CASPER	239
Burden Hours/hospice	32 hrs.

Annual Burden Hours/Cost	**# of Hospices**	**Hours/Task (hrs.)**	**Cost/Task ($)**
QAPI Coordinator/RN (BLS Code 29-1141)	$84		
Annual Burden per Hospice	1	32	$2,688
Total Annual Burden Hours and Costs for all existing hospices	**7,356**	**235,392**	**$19,772,928**

IC-11c: Document Analysis – § 418.58(a)(2)

Per Section 418.58(a)(2), the hospice's inter-disciplinary group (IDG) must "document the results of the QAPI data analysis, including changes to patients' plan of care based on the specific quality measure data."[12] We believe that the RN assigned to coordinate the patient's plan of care is the individual most likely to document this information during each patient's IDG meeting, which would take 5 minutes per patient. We assume each hospice would hold two (2) IDG meetings per patient per year.

[11] 2008 Final Rule at 32194.

[12] Id.

Per Table 30 below, assuming each existing hospice has an average of 239 patients per year, the annual burden for each hospice would be 40 hours ([5 minutes per patient per meeting x 2 IDG meetings per year x 239 = 2,390 minutes]/60 min) and cost $3,360 based on a loaded hourly wage of $84 for a QAPI Coordinator/RN ($84 x 40 hours). For all existing hospices, the total annual burden would be 294,240 (40 hours x 7,356 hospices) and cost $24,716,160 ($3,360 x 7,356 hospices or $84/hr. x 294,240 hrs.).

Table 30. IC-11c: Document Analysis – § 418.58(a)(2)

Burden Assumptions to Document Data Analysis	
5 minutes/patient/per meeting	5
# of IDG meetings/patient/year	2
Avg # of patients/hospice FY 23 per CASPER	239
Total Minutes/Hospice/Year	2,390
Annual burden/hospice	40 hrs.

Annual Burden Hours/Cost	# of Hospices	Hours/Task (Hrs.)	Cost/Task ($)
QAPI Coordinator/RN (BLS Code 29-1141)	$84		
Annual Burden Per Hospice	1	40	$3,360
Total Burden Hours/Costs for all existing hospices	**7,356**	**294,240**	**$24,716,160**

IC-11d: Organize QAPI Data – § 418.58(b)(1)

Per Section 418.58(b)(1), hospices must gather and organize the patient-level data and other quality data from additional sources (e.g., human resource records, pharmacy records, etc.) in a meaningful way. We estimate that, in order to ensure that the volume of gathered data is manageable, a hospice will gather its data once a month. A hospice may choose to gather data on a more or less frequent basis to suit its needs and circumstances. Some hospices may choose to gather all patient-level data, while others may choose to gather data from a sample of all patient-level data. Likewise, some hospices may choose to gather data from a wide variety of administrative files, while others may choose to select only a few administrative data sources.

Per Table 31, we estimate that an Administrative Assistant (BLS Occupation Code 43-9000) at a loaded hourly wage of $40 would spend four (4) hours per month to gather and organize the data to be reported to the QAPI governing body for analysis. The annual burden per hospice would be 48 hours (4 hours x 12 months) and cost $1,920 ($40 x 48 hours). For all 7,356 existing hospices, the total annual burden would be 353,088 (48 hours x 7,356 hospices) and the cost $14,123,520 (($1,920 x 7,356 hospices) or ($40/hr. x 353,088 hrs.)).

Table 31. IC-11d: Organize QAPI Data – § 418.58(b)(1)

Burden Assumptions to Organize Data	
Hours/month	4 hrs.
Annual Burden Hours/hospice	48 hrs.

Burden Hours/Cost	# of Hospices	Hours/Task (hrs.)	Cost/Task ($)
Administrative Assistant (BLS Code 43-9000)	$40		

Burden per Hospice	1	48	$1,920
Total Annual Burden Hours and Costs for all existing hospices	**7,356**	**353,088**	**$14,123,520**

IC-11e: Analyze QAPI data & Identify New Measures – § 418.58(b)(2)

Once the data is aggregated, a hospice must analyze the data through charts, graphs, and various other methods to identify trends, patterns, outliers, areas of concerns that may be useful in targeting areas for improvement. We believe that this data analysis will be done by the QAPI governing body which would need to examine several months of data at the same time.

We assume that 3 members of the governing body - consisting of a QAPI Coordinator/RN (BLS Occupation Code 29-1141), a Hospice Administrator (BLS Occupation Code 11-1011), and a Clinical Manager (BLS Occupation Code 11-9111) would meet for one (1) hour every quarter (4 hours per year) to examine the data and make decisions based off of it. In addition, the same members of the governing body would need to spend an additional hour per year to identify new domains and measures that may replace or be in addition to the domains and measures already being monitored by the hospice based on the data analysis. Thus, analyzing the QAPI data and identifying new measures would take 5 hours per year for all 3 members of the governing body.

Per Table 32 below, the annual burden for each hospice would be 15 hours (5 hours per member x 3 members) and cost $1,790, based on an average loaded hourly wage for the 3 governing body members ([$84 + $169 + $105] x 15 hours = $1,790). For all existing hospices, the total annual burden would be 110,340 hours (15 hours x 7,356 hospices) and would cost $13,167,520 ($1,790 x 7,356 hospices).

Table 32. IC-11e: Analyze QAPI data & ID new measures - § 418.58(b)(2)

Task	# of Hospices	Hourly Mean Wage	Hours/Task (hrs.)	Cost/Task ($)
QAPI Coordinator/RN (BLS Code 29-1141)	-	$84	5	$420
Hospice Administrator (BLS Code 11-1011)	-	$169	5	$845
Clinical Manager (BLS Code 11-9111)	-	$105	5	$525
Total Annual Burden/Cost per hospice	1	-	15	$1,790
Total Annual Burden/Costs all existing hospices	**7,356**	**-**	**110,340**	**$13,167,240**

QAPI Performance Improvement -§ 418.58(d)(2)

Per §418.58(d)(2), all certified hospices must document what performance improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects. Since a hospice already makes an organized effort to improve patient care in all of its facets, and since providing safe and effective care at all times for all patients is the essential charge of all health care providers, including hospices, we believe that conducting both major and minor performance improvement projects is a usual and customary practice and thus exempt from the PRA per 5 CFR §1320.3(b)(2).[13]

418.60 Infection control.

Section 418.60(a) requires hospices to maintain and document an effective infection control program that protects patients, families, visitors, and hospice personnel by preventing and controlling infections and communicable diseases. Hospices must also educate employees, contracted providers, patients, and family members and other care givers regarding infection control. We believe the burden to develop, implement, document, and maintain an effective infection control program as well as educate others about the program is a usual, customary practice in the hospice care industry, and thus exempt from the PRA per 5 CFR §1320.3(b)(2). In addition, the burden imposed by this requirement would exist even in the absence of the Federal requirement.

418.62 - Condition of participation: Licensed professional services.

Along with providing patient care and education, licensed professionals of a hospice must participate in a hospice's ongoing interdisciplinary comprehensive assessments, its QAPI program and any in-service training. Because this is a usual and customary practice for health care professionals, any burden from this requirement is exempt from the PRA per 5 CFR §1320.3(b)(2).

CoPs Patient Care – Core Services

418.64 Core services.

416.64(a) - Hospices may enter into a written agreement with another Medicare-certified hospice program for the provision of the core services. The burden to develop, draft, sign, and maintain contracts and written agreements constitutes a usual and customary business practice and thus is exempt from the PRA per 5 CFR §1320.3(b)(2).

416.64(d) - Hospices must offer bereavement counseling to patients and families, which includes developing a bereavement plan of care and an assessment of the patient's and family's needs. Bereavement counseling must also be offered to appropriate residents of a SNF/NF or ICF/IID. We believe offering and subsequently providing bereavement services are usual and customary business practice, and thus the burden is exempt from the PRA per 5 CFR §1320.3(b)(2).

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

CMS can waive the requirement in §418.64(b) for a hospice to provide nursing services directly if: per §418.66(a)(1), the hospice is located in a non-urbanized area, and per §418.66(a)(2), the hospice was

[13] Id.

operational on or before January 1, 1983. To obtain a waiver, the hospice must provide evidence to CMS (as specified in §418.66(a)(3)) that it made good faith efforts to hire a sufficient number of nurses to provide services. The one-year waiver can be extended per §418.66(d),if the hospice submits a request to CMS prior to the waiver's expiration date and certifies 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. Because only a few of the currently certified hospices were in operation before 1983 and meet the criteria for this waiver, we believe this burden will affect less than 10 entities on an annual basis. Thus, this requirement is exempt from the PRA under 5 CFR §1320.3(c)(4).

CoPs Patient Care – Non-Core Services

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 exempt from the PRA per 5 CFR §1320.3(b)(2) as usual and customary.

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 exempt from the PRA per 5 CFR §1320.3(b)(2) as usual and customary.

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. 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. Because we believe the requirement will affect less than 10 entities on an annual basis based on current data, this burden is exempt from the PRA under 5 CFR §1320.3(c)(4).

418.76 Hospice aide and homemaker services.

(a) Standard: Hospice aide qualifications.

All hospice aide services must be provided by individuals who meet the personnel requirements and training specified at 42 CFR §418.76(a).

IC-12a and 12b: Document new hospice aide qualifications - § 418.76(b)(4)

(b) Standard: Content and duration of hospice aide classroom and supervised practical training.

Per Section 418.76(b)(4), hospices must maintain documentation that their hospice aides meet the required qualifications specified at 418.76(a). We estimate below the burden to comply with this CoP based on the time to complete the required documentation for all hospice aides.

Per Table 33 below, we first estimate the number of hospice aides that must comply with the requirements and complete training. Based on the 2024 hospice employee turnover rate of 29.9 (rounded to 30%), we estimate for purposes of this analysis that the average hospice would replace 30% of its hospice aides in a given year.[14] Assuming each hospice employs five (5) hospice aides to serve their average number of patients (239 for FY 2023), we estimate one (1) hospice aide per hospice per year will need to undergo the required training. we estimate that it would take five (5) minutes (0.083 hr.) per newly hired hospice aide to document that new hospice aides met the training requirement and that an Administrative Assistant (BLS Occupation Code 43-9000) at a loaded hourly rate of $40 will complete this task.[15]

Table 33. Number of Hospice Aides to Complete Training

Burden Assumptions	
% Employee turnover	30%
Avg # of hospice aides/hospice	5
Hours/aide (5 min)	0.083 hr.
Administrative Assistant (BLS Code 43-9000)	$40

Per Table 34 below, we estimate that it would take each existing hospice 0.083 hours per year to document that one (1) hospice aide meets the qualification requirement (5 min per aide to document compliance x 1 = 5/60 min = 0.083 hour) at an annual cost of $3.32(0.083 hr. x $40/hr.). For all existing certified hospices, the annual burden would be 611 hours (0.083 hr. x 7,356 hospices) and cost $24,422 per year ($3.32 x 7,356 hospices)(IC-12a).

For newly certified hospice, we estimate that each newly certified hospice would have five (5) new hospice aides per year that would need their qualifications to be documented. The annual burden per hospice would be 0.415 hours (0.083 hr. per aide x 5 aides) and cost $16.60 per year ($3.32 per aide x 5 aides). The total annual burden for all 546 newly certified facilities would be 227 hours (0.415 hr. x 546 hospices) and cost $9,064 ($16.60 x 546 hospices)(IC-12b).

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[14] "Hospice aides and licensed practical nurses experienced turnover rates of 29.9% and 28.4%, respectively, in 2024" See "Hospices see declining turnover this year thanks, in part, to pay raises, salary survey finds," McKnight's Home Care, December 10, 2024 (restating data from "2024-2025 Hospice Salary and Benefits Report" by Hospital & Healthcare Compensation Service (HCS).)

[15] Note: Although CMS revised the hospice aide training standard in 2019, there was no change to the 5 minute per aide assumption for this ICR. See "Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care," 84 FR 51732, 51761 (September 30, 2019) at: https://www.federalregister.gov/documents/2019/09/30/2019-20736/medicare-and-medicaid-programs-regulatory-provisions-to-promote-program-efficiency-transparency-and#p-443 (stating "this change to the actual training and competency requirements would not alter the requirement to document the fact that a hospice aide meets one of the training and competency requirements set forth in the rule; therefore there would be no change to the existing collection of information estimates because the estimates relate to the unchanged documentation requirements rather than the actual training and competency requirements that would be revised by this change.")

Table 34. IC-12a & IC-12b: Document Hospice Aide Qualifications – § 418.76(b)(4)

IC-12a: Existing Hospices			
Per Hospice	**# of Hospice Aides**	**Hours/Task (hrs.)**	**Cost/Task ($)**
Administrative Assistant (BLS Code 43-9000)	$40		
# of new hospice aides' qualifications to document/year per existing hospice	1	0.083	$3.32
Total burden for all Existing Hospices	**7,356**	**611**	**$24,422**

IC-12b: Newly Certified Hospices			
Administrative Assistant (BLS Code 43-9000)	$40		
# of new hospice aides' qualifications to document/ per newly certified hospice for Year 1	5	0.415	$16.60
Total burden for all Newly Certified Facilities	**546**	**227**	**$9,064**

IC-13: Document hospice aide in-service training – § 418.76(d)(2)

(d) Standard: In-service training

Per Section 418.76(d)(2), hospices must maintain documentation that all hospice aides have received at least 12 hours of in-service training during each 12-month period. Per Table 35 below, we estimate it will take 2 hours each year for an Administrative Assistant (BLS Occupation Code 43-9000) at each hospice to document that all their current hospice aides completed the yearly in-service training at an annual cost of $80 (2 hours x $40/hour). For all existing certified hospices, the annual burden for this requirement would be 14,712 hours (2 hours x 7,356 hospices) and cost $588,480 (($80 x 7,356 hospices or $40/hr.) x (14,712 hrs.)).

Table 35. IC-13: Document hospice in-service training – § 418.76(d)(2)

Burden/Hospice	**Hourly Mean Wage**	**Hours/ Task (hrs.)**	**Cost/Task ($)**
Administrative Assistant (BLS Code 43-9000)	$40		
Burden per Hospice		2	$80
Total Annual Burden/Costs for all hospices	**7,356**	**14,712**	**$588,480**

418.76(g)(1) Standard: Hospice aide assignment and duties

A hospice aide is assigned to a patient by an RN who is a member of that patient's IDG. Per Section 418.76(g)(1), the supervising RN must provide a hospice aide written patient care instructions. We believe that preparing patient care instructions is a usual and customary business practice, and thus the burden is exempt from the PRA under 5 CFR §1320.3(b)(2).

418.76(h) Standard: Supervision of hospice aides

Under Section 418.76(h)(2), a RN must conduct an on-site visit annually to observe and assess each aide while he or she is performing care. The burden initially associated with this requirement was the time and effort necessary for an RN to make an annual on-site visit to observe and evaluate each hospice aide while they perform care and to document the evaluation.[16] However, we revised this burden in 2021 because "competency evaluations are a usual and customary business practice." [17] As a result, this requirement is exempt from the PRA under 5 CFR §1320.3(b)(2).

418.76(i)(1) 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. While this requirement is subject to the PRA, we believe the associated burden is exempt per 5 CFR §1320.3(b)(2) because it is a usual and customary business practice.

418.76(j) Standard: Homemaker qualifications

(k)(2)-(k)(3) 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. We believe the burden is exempt as stated in 5 CFR §1320.3(b)(2) because it is a usual and customary business practice.

418.78 Volunteers.

IC-14: Document volunteer training/orientation – § 418.78(a)

(a) Standard: Training

Per Section 418.78(a), 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 (6) times per year and that it would take five (5) minutes to document each orientation section, or a total of 30 minutes per year per hospice (5 minutes x 6 times per year) or 0.5 hours.

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[16] 2008 Final Rule at 32187.

[17] See NPRM "Medicare Program; FY 2022 Hospice Wage Index and Payment Rate Update, Hospice Conditions of Participation Updates, Hospice and Home Health Quality Reporting Program Requirements," 86 FR 19700, 19769 (April 14, 2021)(stating "that both the existing requirements and the proposed revisions to the requirements at § 418.76(h) are exempt from the PRA. We believe competency evaluations are a usual and customary business practice."). See also "Medicare Program; FY 2022 Hospice Wage Index and Payment Rate Update, Hospice Conditions of Participation Updates, Hospice and Home Health Quality Reporting Program Requirements", 86 FR 42528, 42601 (August 4, 2021)(stating "we believe that both the requirements at § 418.76(h) are exempt from the PRA. In accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2), we believe competency evaluations are a usual and customary business practice.")

Per Table 36 below, we estimate this requirement would be completed by an Administrative Assistant (BLS Occupation Code 43-9000) at a loaded hourly rate of $40 or $20 per year per hospice (0.5 hours x $40 = $20). For all existing certified hospices, the total annual burden would be 3,678 hours ([0.5 hours x 7,356) and cost $147,120 ($20 x 7,356 hospices or $40/hr. x 3,678 hrs.).

Table 36. IC-14: Document volunteer training/orientation – § 418.78(a)

Burden Assumptions			
# of Orientations/Trainings/Year	6		
Minutes/Training	5 mins		
Hours/hospice/year (30 min)	0.5 hr.		
Burden/Hospice	**Hourly Mean Wage**	**Hours/Task (hrs.)**	**Cost/Task ($)**
Administrative Assistant (BLS Code 43-9000)	$40		
Burden per Hospice		0.5	$20
Total Annual Burden/Costs for all existing hospices	**7,356**	**3,678**	**$147,120**

IC-15: Document volunteer recruitment – § 418.78(c)

(c) Standard: Recruiting and retaining

Per Section 418.78(c), a hospice is required to document and demonstrate viable and ongoing efforts to recruit and retain volunteers. Per Table 37 below, we estimate that it will take each hospice 3 hours per year for an Administrative Assistant (BLS Occupation Code 43-9000) at a loaded hourly rate of $40 to document its volunteer recruitment and retention efforts and cost of $120 (3 hours x $40 = $120) per hospice per year. For all existing hospices, the annual burden would be 22,068 hours (3 hours x 7,356 hospices)and cost $882,720 (($120 x 7,356 hospices) or ($40/hr. x 22,068 hrs.)).

Table 37. IC-15: Document volunteer recruitment – § 418.78(c)

Burden/Hospice	**Hourly Mean Wage**	**Hours/Task (hrs.)**	**Cost/Task ($)**
Administrative Assistant (BLS Code 43-9000)	$40		
Burden per hospice		3	$120
Total Annual Burden/Costs for existing hospices	**7,356**	**22,068**	**$882,720**

IC-16: Document cost-savings from volunteers – § 418.78(d)

(d) Standard: Cost saving

Per Section 418.78(d), a hospice is required to document the cost savings achieved through the use of volunteers. Per Table 389 below, we estimate that complying with this requirement will take three (3) hours per hospice per year for a Hospice Administrator (BLS Occupation Code 11-1011) at a loaded hourly rate of $169, or $507 per hospice (3 hours x $169/hour = $507). For all existing hospices, the annual burden hours would be 22,068 (3 hours x 7,356 hospices = 22,068 hours) and cost $3,729,492 per year (($507 x 7,356 hospices) or ($169/hr. x 22,068 hrs.)).

Table 38. IC-16: Document cost-savings from volunteers- § 418.78(d)

Burden/Hospice	Hourly Mean Wage	Hours/Task (hrs.)	Cost/Task ($)
Hospice Administrator (BLS Code 11-1011)	$169		
Burden per hospice		3	$507
Total Annual Burden/Costs for all existing hospices	**7,356**	**22,068**	**$3,729,492**

IC-17: Document use of volunteers – § 418.78(e)

(e) Standard: Level of activity

Per Section 418.78(e), 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. Per Table 39 below, we 48 hours per year per hospice for an Administrative Assistant (BLS Occupation Code 43-9000) at a loaded hourly rate of $40 to document the use of volunteers at an annual cost of $1,920 per hospice (48 hours x $40/hr.). For all existing hospices, the total annual burden would be 353,088 hours (48 hours x 7,356 hospices) and cost $14,123,520 (($1,920 x 7,356 hospices) or ($40/hr. x 353,088 hrs.)).

Table 39. IC-17: Document use of volunteers - 418.78(e)

Burden/Hospice	Hourly Mean Wage	Hours/Task (hrs.)	Cost/Task ($)
Administrative Assistant (BLS Code 43-9000)	$40		
Burden/Hospice		48	$1,920
Total Annual Burden/Costs for all hospices	**7,356**	**353,088**	**$14,123,520**

Subpart D: Conditions of Participation: Organizational Environment
42 CFR §§ 418.100-418.116

This sub-section is broken out by IC-18 to IC-26.

418.100 Organization and administration of services.

(e) Standard: Professional management responsibility

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

(f)(2) 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 considered to be usual and customary per 5 CFR §1320.3(b)(2) and is thereby exempt from the PRA.

(g) Standard: Training

Section 418.100(g)(2) requires a hospice to provide an initial orientation for each employee that addresses the employee's specific job duties. Section 418.100(g)(3) requires a hospice must have written policies and procedures regarding how competency is assessed and a written description of the in-service training provided during the previous 12 months. The burdens associated with the requirements of this section is considered to be usual and customary and thus exempt from the PRA under 5 CFR §1320.3(b)(2).

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. The burden associated with this requirement is considered to be usual and customary per 5 CFR §1320.3(b)(2) and thus exempt from the PRA.

(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. The burden associated with the requirement is considered to be usual and customary and thus exempt from the PRA per 5 CFR §1320.3(b)(2).

(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 this CoP is included at 42 CFR § 418.22(b)(3). See IC-1b.

(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. Because it is standard practice for the hospice medical director to lead and bear responsibility for the medical component of the hospice's patient care services, the burden associated with this requirement is considered to be usual and customary and this exempt from the PRA per 5 CFR §1320.3(b)(2).

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. Hospices must also protect and retain the Personal Health Information ("PHI") contained in the clinical record in accordance with 45 CFR parts 160 and 164. Because these requirements reflect standard hospice practices, the associated burden should be considered usual and customary and thus exempt from the PRA per 5 CFR §1320.3(b)(2).

(d) Standard: Retention of records

Clinical records must be retained 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. If a hospice discontinues operations, it must draft, implement, and maintain a record retention policy Because the development and maintenance of a record retention policy is a usual and customary business practice, this burden is exempt from the PRA per 5 CFR §1320.3(b)(2).

(e) Standard: Discharge or transfer of care

A hospice is required to prepare and send a comprehensive discharge summary for all patients who 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. Because discharge requirements reflect usual and customary industry practice, this burden is exempt from the PRA per 5 CFR
§1320.3(b)(2).

(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. Because this burden is considered usual and customary business practice, it is exempt from the PRA per 5 CFR §1320.3(b)(2).

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

(b) Standard: Ordering of drugs

Under 418.106(b), individuals receiving a drug order must record and sign it immediately and have the prescribing person sign it in accordance with State and Federal regulations. Because this requirement is a usual and customary business practice and required under state law, the burden is exempt from the PRA

under both 5 CFR §1320.3(b)(2) and 5 CFR §1320.3(b)(3).

(c)(2) 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. Because the requirement to develop, draft, implement, and maintain a written policy that promotes dispensing accuracy and to maintain controlled drug records is a usual and customary business practice, the burden is exempt from the PRA per 5 CFR §1320.3(b)(2).

IC-18: Notify and Educate Patient of Controlled Drug Policy – § 418.106(e)(2)(i)(C)

(e) Standard: Labeling, disposing and storing of drugs and biologicals
Per Section 418.106(e)(2)(i), a hospice must have a policy for how patients should manage and dispose of controlled drugs in their home, which it must then discuss and provide to the patient representative and their family and document this in the patient's clinical record. These are usual and customary business practices for a hospice. However, per 418.106(e)(2)(i)(C), a hospice must also document in a patient's clinical record that its controlled drug policy and procedures was provided and discussed with the patient and patient's representative at the time when a controlled drug is first ordered.[18]

We estimate that it will take an RN at a loaded hourly wage of $84 five (5) minutes per patient to document the controlled drug policy was provided and discussed. Per Table 40 below, assuming each hospice has an average of 239 patients per year, the annual burden would be 20 hours ([5 minutes x 239 patients = 1,195 minutes]/60) and cost$1,680 (20 hours x $84 = $1,680) per hospice. For all existing hospices, the total annual burden would be 147,120 (20 hours x 7,356 hospices = 147,120 hours) and cost $12,358,080 (($1,680 x 7,356 hospices) or ($84/hr. x 147,120 hrs.).

Table 40. IC-18: Notify & Educate Patient of Controlled Drug Policy – § 418.106(e)(2)(i)(C)

Burden Assumptions	
Minutes/Patient	5 mins
Avg # of patients/hospice FY 23 per CASPER	239
Total Minutes/Hospice/Year	1,195 mins
Annual burden/hospice	20 hrs.

Burden/Hospice	**# of Hospices**	**Hours/Task (hrs.)**	**Cost/Task ($)**
RN (BLS Code 29-1141)	$84		
Burden per Hospice	1	20	$1,680
Total Annual Burden Hours and Costs for all existing hospices	**7,356**	**147,120**	**$12,358,080**

[18] 2008 Final Rule at 32198.

(e)(3)(ii) - Storing of drugs and biologicals

Per Section 418.106(e)(3)(ii), for hospices that provide inpatient care in their facility, the hospice's Pharmacist and the Administrator must investigate discrepancies involving controlled drugs and must document in writing an account of the investigation to provide state or federal officials. We estimate it would take 1 hour per incident for both staff members to thoroughly investigate and complete a report.

Of the 4,459 deficiencies issued by State Surveyors for FY 2023-2024, there were only 4 condition-level citations related to 42 CFR 418.106.[19] Based on the current data, the need to investigate and document drug discrepancies does not regularly occur. Although this requirement is subject to the PRA, the burden is exempt under 5 CFR §1320.3(c)(4)because it would impact less than 10 persons or entities.

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

Per Section 418.106(f)(1), 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. Because proper maintenance of equipment is standard practice, this burden is exempt from the PRA per 5 CFR §1320.3(b)(2).

Per Section 418.106(f)(2), 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. Because providing proper instruction on the use of durable medical equipment to patient, family members, and caregivers is a usual and customary business, this burden is exempt from the PRA per 5 CFR §1320.3(b)(2).

418.108 Short term inpatient care.

Per Section 418.108(a), short-term inpatient care must be available for pain control, symptom management, and respite purposes, and must be provided in a participating Medicare or Medicaid facility. Because this is a usual and customary business practice, this requirement is exempt from the PRA per 5 CFR § 1320.3(b)(2).

(c) Standard: Inpatient care provided under arrangement – Written Agreement

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. Because having written agreements between providers is a usual and customary business practice, this requirement is exempt from the PRA per 5 CFR §1320.3(b)(2).

[19] Condition-level deficiencies are the most serious type of deficiency and are issued when a hospice violates one or more standards and the hospice's capacity to furnish adequate care is substantially limited or adversely affects the health and safety of patients.

IC-19: Patient plan of care – § 418.108(c)(1)

Per Section 418.108(c)(1), if a hospice has a written agreement with a facility to provide for short-term inpatient care, the written agreement should specify that the hospice must provide a copy of the patient's plan of care and the details of the short-term inpatient services to be provided by the facility. The plan of care is typically from two to five pages long. The burden associated with this requirement is the time needed to provide a copy of the patient's plan of care. Per Table 41 below, we initially estimate the number of hospice patients with short-term in-patient stays. Based on CY 2023 data, there were 289,331 out of a total of 1,773,559 hospice patients with "General Inpatient (GIP) utilization, or 16.3%.[20] Based on an average of 239 patients/hospice x 16.3%, there are an average of 39 patients per hospice that receive in-patient services and require a plan of care.

Table 41. Number of Hospice Patients with Short-term Inpatient Stays

# of Short-Term Inpatient Patients/Hospice		
# of beneficiaries with General in-patient (GIP) utilization FFS claims (CY 2023)	*(a)*	289,331
Total # of hospice patients (CY 2023)	*(b)*	1,773,559
% of hospice patients w/short-term inpatient stays	*(c) = (a)/(b)*	16.3%
Avg # of patients/hospice FY 23 per CASPER	*(d)*	239
Avg # of patients/hospice with inpatient stays	*(e) = (c) x (d)*	**39**

Per Table 42 below, we estimate the burden hours and costs per hospice to provide an in-patient plan of care. We estimate this would require an Administrative Assistant (BLS Occupation Code 43-9000) at a loaded hourly wage of $40 to spend 10 minutes or 0.167 hours and $6.68 (0.167 hours/patient x $40) per patient's plan of care. Assuming each hospice would need to provide a short-term inpatient plan of care for 39 patients per year, the annual burden for each hospice would be 6.5 hours (0.167 hours per patient x 39 patients per hospice) and $261 ($6.68 patient x 39 patients). For all existing hospices, the annual burden would be 47,814 hours (6.5 hours per hospice x 7,356 hospices) and cost $1,919,916 ($261 per hospice x 7,356 hospices).

Table 42. IC-19: Short-Term Inpatient Plan of Care – § 418.108(c)(1)

Burden Assumptions			
Hours/Patient (10 min)	0.167 hr.		
Avg # of Inpatient patients/hospice (Table 41)	39		
Hours/Hospice	6.5 hrs.		
Administrative Assistant (BLS Code 43-9000)	$40		
Cost/Patient	$6.68		
Burden/Hospice	**# of Hospices**	**Hours/Task (hrs.)**	**Cost/Task ($)**
Burden per hospice	1	6.5	$261
Total Annual Burden Hours/Costs for all existing hospices	**7,356**	**47,814**	**$1,919,916**

[20] Number of beneficiaries with General Inpatient (GIP) utilization is based on CY 2023 FFS claims, as of March 3, 2025 provided by Hospice group. Total number of hospice beneficiaries for CY 2023 is based on "Hospice Monitoring Report April 2024," Centers for Medicare and Medicaid Services, accessed at: https://www.cms.gov/files/document/hospice-monitoring-report-2024.pdf. Note CMS Revenue Codes for Inpatient Respite Care (IRC) is 0655 and for General Inpatient Care (GIP) is 0656.

IC-20: Short-Term Inpatient Discharge Summary – § 418.108(c)(3)

Per Section 418.108(c)(3), at the time of a patient's discharge, a hospice should provide a patient's clinical record for all inpatient services furnished and events regarding care that occurred at the facility as well as a copy of the discharge summary. The burden associated with this requirement is the time needed by the inpatient facility to prepare and provide a copy of the patient's clinical record and discharge summary at the time the patient is discharged.

Per Table 43, we estimate that it will take an Administrative Assistant (BLS Occupation Code 43-9000) of a short-term inpatient facility at a loaded hourly wage of $40, 5 minutes (or 0.083 hours) and cost $3.32 per patient (0.083 hours x $40 = $3.32) to provide a copy of the patient's clinical record and discharge summary to the patient's hospice. Assuming there are an average of 39 patients per hospice that will be discharged per year per Table 41, the annual burden for each hospice would be 3.2 hours (.083 hours/patient x 39 patients) and cost $130 ($3.32 per patient x 39 patients). For all existing hospices, the annual burden would be 23,539 (3.2 hours per hospice x 7,356 hospices) and cost of $956,280 ($130 per hospice x 7,356 hospices).

Table 43. IC-20: Short-Term Inpatient Discharge Summary – § 418.108(c)(3)

Burden Assumptions			
Hours/Patient (5 min)	0.083 hr.		
Avg # of Inpatient patients/hospice (Table 41)	39		
Hours/Hospice	3.2 hrs.		
Administrative Assistant (BLS Code 43-9000)	$40		
Cost/Patient	$3.32		
Burden/Hospice	**# of Hospices**	**Hours/Task (hrs.)**	**Cost/Task ($)**
Burden per hospice	1	3.2	$130
Total for all existing hospices	**7,356**	**23,539**	**$956,280**

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 an RN on each shift to provide direct patient care has been in place since the inception of the Medicare hospice Conditions of Participation and is thus standard practice. Because the requirement is usual and customary, the burden is exempt from the PRA per 5 CFR §1320.3(b)(2).

(c) Standard: Physical environment.

A hospice must develop procedures for managing physical plant issues and address physical plant issues. Because this requirement is usual and customary practice, the burden is exempt from the PRA per 5 CFR §1320.3(b)(2).

(d) Standard: Fire protection
(e) Standard: Building Safety
(f) Standard: Patient areas
(g) Standard: Patient rooms
(h) Standard: Toilet and bathing
(i) Standard: Plumbing facilities
(j) Standard: Infection control
(k) Standard: Sanitary environment
(l) Standard: Linen
(m) 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. Because these requirements are standard practice in hospice-operated inpatient facilities, the burden is exempt from the PRA per 5 CFR §1320.3(b)(2).

(n)(3) - Standard: Restraint or seclusion

Per Section 418.100(n)(3), restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient, a staff member, or others from harm. Use of restraint or seclusion must be in accordance with State law as well as safe and appropriate techniques as determined by hospice policy, a physician's order and written modification of a patient's plan of care. 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. Because these requirements are usual and customary practice and must comply with State law, the burden is exempt from the PRA per 5 CFR §1320.3(b)(2) and §1320.3(b)(3).

IC-21: Documentation of restraint/seclusion – §§ 418.110(n)(11) and (n)(15)(i)

Per Section 418.110(n)(11), when restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen face-to-face within 1 hour after the initiation of the intervention by a physician or RN. If the evaluation is done by the RN, the RN must consult with the medical director or physician afterwards. Per Section 418.110(n)(15)(i), this intervention must be documented in the patient's clinical record. The burden associated with this requirement is the time required to document the face-to-face intervention that is required after a patient is restrained in the patient's clinical record.

Per Table 44 below, we initially estimate the number of hospice patients with short-term in-patient stays that may be required to be restrained or secluded. Because reported use of seclusion and restraint techniques is very rare, we believe that less than 1% of patients with inpatient stays will need to be restrained or secluded. Based on CY 2023 data, there were 289,331 hospice patients with "General Inpatient (GIP) utilization claims.[21] For purposes of this analysis, we estimate that only 0.5% (.005) of the 289,331 hospice patients with in-patient stays, or 1,447 hospice patients per year for all existing hospices, will need to have an in-person intervention of their seclusion or restraint documented in their record per Section 418.110(n)(11).

[21] Number of beneficiaries with General Inpatient (GIP) utilization is based on CY 2023 FFS claims, as of March 3, 2025 provided by Hospice group. Note CMS Revenue Codes for General Inpatient Care (GIP) is 0656.

Table 44. Number of Restrained/Secluded Patients per Year

# of Impacted Patients	
# of hospice beneficiaries with General Inpatient (GIP) utilization FFS claims CY 2023 *(a)*	289,331
% of hospice patients who are restrained/secluded per year *(b)*	0.5%
# of inpatient restrained/secluded per year across all hospices *(c) = (a) x (b)*	**1,447**

Per Table 45 below, we estimate that an RN (BLS Occupation Code 29-1141) at a loaded hourly rate of $84 would spend 45 minutes (0.75 hours) at a cost of $63 (0.75 hours per patient x $84) per patient to complete the required documentation in the patient's clinical record. For the 1,447 patients who are restrained or secluded per year across all currently certified hospices, the annual burden for all existing hospices would be 1,085 hours (0.75 hours per patient x 1,447 patients) and cost of $91,161 ($63 per patient x 1,447 patients = $91,161).

Table 45. IC-21: Document restraint/seclusion – §§ 418.110(n)(11) & (n)(15)

Burden Assumptions			
Burden Hours per patient (45 min)	0.75 hr.		
RN (BLS Code 29-1141)	$84		
Burden/Hospice	**# of Patients**	**Hours/Task (hrs.)**	**Cost/Task ($)**
Per patient	1	0.75	$63
Total for all patients in existing hospices	**1,447**	**1,085**	**$91,161**

IC-22: One-Time Development of Restraint or seclusion staff Training – § 418.110(o)(2)

Per Section 418.110(o)(2), all 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. The one-time burden for newly certified hospices is the time to develop a staff-wide training program.

Per Table 46 below, for each newly participating hospice, we estimate that developing a staff-wide training program will require 40 hours for an RN (serving as a Trainer)(BLS Occupation Code 29-1141) at a loaded hourly rate of $84 at a cost of $3,360 ($84 x 40 hours) per each newly certified hospice. The total one time burden for all newly certified hospices would be 21,840 hours (40 hours per hospice x 546 hospices) and cost of $1,834,560 (($3,360 x 546 hospices) or ($84/hr. x 21,840 hrs.)).

Table 46. IC-22: One-Time Development of Restraint/Seclusion Staff Training – § 418.110(o)(2)

Burden/Hospice	Hourly Mean Wage	Hours/Task (hrs.)	Cost/Task ($)
RN (BLS Code 29-1141)	$84		
Burden per newly certified hospice		40	$3,360
Total Annual Burden/Costs for all newly certified facilities	**546**	**21,840**	**$1,834,560**

IC-23: Document completion of staff restraint/seclusion training – § 418.110(o)(4)

Per Section 418.110(o)(4), hospices must document in each trained individual's personnel record that he or she has successfully completed the required training on restraint and seclusion. To reduce burden and create a reasonable requirement while assuring patient safety, we have mandated that only those staff who are involved in the application of restraint or seclusion or performing associated monitoring and assessment of or providing care for restrained or secluded patients have this training. While we expect physicians to be trained in the proper use of restraint or seclusion, we do not expect that they will be trained with the other hospice staff. Thus, we have not included physicians in the burden associated with these requirements.

Instead, we require the remaining hospice staff who have direct contact with patients must be trained in restraint or seclusion use.

Per Table 47, we estimate that it will take an Administrative Assistant (BLS Occupation Code 43-9000) 5 minutes per trainee (0.083 hours) to document each participant's completion of the training. For purposes of this analysis, we assume that 12 hospice employees per hospice will be trained each year and need documentation. The annual burden for each hospice would be 1 hour (0.083 hour/trainee x 12 trainees) at a cost of $40 ($40 x 1 hour). For all existing certified hospices, the total annual burden would be 7,356 hours (1 hour/hospice x 7,356 hospices) and cost $294,240 (($40 per hospice x 7,356 hospices) or ($40/hr. x 7,356 hrs.)).

Table 47. IC-23: Document completion of restraint/seclusion staff training – § 418.110(o)(4)

Burden Assumptions			
Burden Hours/Employee (5 minutes)	0.083 hr.		
# of Employees/Hospice/Year	12		
Hours/hospice/year	1.0 hr.		
Burden/Hospice	**Hourly Mean Wage**	**Hours/Task (hrs.)**	**Cost/Task ($)**
Administrative Assistant (BLS Code 43-9000)	$40		
Burden per hospice		1	$40
Total Annual Burden/Costs for all existing hospices	**7,356**	**7,356**	**$294,240**

418.110(p) Standard: Death reporting requirements

Per Section 418.110(p), a hospice must report deaths associated with the use of restraint or seclusion. The hospice staff must document in the decedent's clinical record the date and time the death and report the death to CMS by telephone no later than the close of business the next business day following knowledge of the patient's death. The number of reported deaths associated with use of restraint or seclusion remains less than 10, thus the burden is exempt from the PRA per 5 CFR §1320.3(c)(4).

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

(a) Standard: Resident eligibility

Medicare patients residing in a SNF, NF, or ICF/IID must meet Medicare hospice eligibility criteria in order to receive hospice services. Because verifying patient eligibility is a usual and customary business practice, the burden from this requirement is exempt from the PRA per 5 CFR §1320.3(b)(2).

(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. Because this requirement is a usual and customary business practice, the burden is exempt from the PRA per 5 CFR §1320.3(b)(2).

(c) Standard: Written agreement

A hospice and SNF/NF or ICF/IID 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/IID 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/IID if the hospice is caring for a resident of the facility. Hospices must document that this communication has occurred to ensure that the hospice has made all necessary efforts to consult facility representatives in hospice care planning activities. The burden associated with this requirement is the time and effort necessary to develop, draft, sign, and maintain the written agreement. Because written agreements between providers are a usual and customary business practice, the associated burden is exempt from the PRA per 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/IID representatives. The burden associated with this requirement is part of the burden for Section 418.56(c). See IC-10.

IC-24: Coordinate Services between Hospice & Nursing Facility – § 418.112(e)(3)

Per Section 418.112(e)(3), in order to coordinate services for residents of a SNF, NF, or ICF/IID, a hospice must provide to the SNF/NF or ICF/IID specific information including: most recent hospice plan of care for each patient, the patient's hospice election form, advance directives, physician certification forms, contact information for pertinent hospice personnel and hospice's 24-hour on-call system, patient's medication, and physician's orders.

Per Table 48 below, we first estimate the number of hospice patients residing in nursing facilities whose services need to be coordinated by a hospice. For FY 2023, there were a total of 1,760,040 hospice patients nationally based on Fee-for-Service claims. Based on 2006 and 2009 CMS data, 31% of hospice patients nationwide resided in a SNF or other nursing facility, or a total of 545,612 patients across all existing hospices (1,760,040 patients x 31%).[22] Therefore, each hospice has on average 74 patients residing in a SNF/NF or an ICF/IID each year (545,612 patients nationwide/ 7,356 hospices).

Table 48. Hospice patients whose services need coordination

# of Hospice patients in SNF/NF	
Total # of hospice patients in US *(a)*	1,760,040
% of hospice patients in SNF/NF *(b)*	31%
# of hospice patients in SNF/NF *(c) = (a) x (b)*	545,612
Total # of hospices *(d)*	7,356
Avg # of patients SNF/NF per hospice *(e) = (c)/(d)*	**74**

Per Table 49 below, we estimate an Administrative Assistant at a loaded hourly wage of $40 at each hospice would need 10 minutes (0.167 hours) or $6.68 per patient (0.167 hours x $40) to send the required documents to the nursing facility to coordinate services. The annual burden for each hospice would be 12 hours (0.167 hours x 74 patients) and cost $494 per hospice (74 patients x $6.68/patient). For all existing hospices, the total burden would be 88,272 hours (12 hours/hospice x 7,356 hospices) and cost $3,633,864 ($494 x 7,356 hospices).

Table 49. IC-24: Coordinate Services between Hospice & Nursing Facility – § 418.112(e)(3)

Burden Assumptions	
Patients/Hospices (Table 48) *(e)*	74
Hours/Patient (10 min) *(f)*	0.167 hr.
Burden Hours/Hospice/Year *(g) = (e) x (f)*	12 hrs.
Administrative Assistant (BLS Code 43-9000) *(h)*	$40
Cost/Patient *(i) = (f) x (h)*	$6.68
Cost/Hospice/Year *(j) = (e) x (i)*	$494

Burden Hospice	**# of Hospices**	**Hours/Task (hrs.)**	**Cost/Task ($)**
Burden Per Hospice (for Avg of 74 patients/hospice)	1	12	$494
Total Annual Burden Hours/Costs for all existing hospices	**7,356**	**88,272**	**$3,633,864**

[22] Medicare Hospices That Focus on Nursing Facility Residents (OEI-02-10-00070), HHS Office of Inspector General, July 2011at: https://oig.hhs.gov/reports/all/2011/medicare-hospices-that-focus-on-nursing-facility-residents (citing 2009 data); Medicare Hospice Care for Beneficiaries in Nursing Facilities: Compliance With Medicare Coverage Requirements (OEI-02-06-00221), HHS Office of Inspector General, September 2009 (citing 2006 data) at: https://oig.hhs.gov/reports/all/2009/medicare-hospice-care-for-beneficiaries-in-nursing-facilities-compliance-with-medicare-coverage-requirements/

(f) Standard: Orientation and training of staff

Per Section 418.112(f), a hospice must consult with and thus share responsibility with the SNF/NF or ICF/IID facility to provide orientation and training to their staff. Hospice staff must "assure" that SNF/NF or ICF/IID facility staff understand the hospice philosophy, including hospice policies and procedures regarding methods of comfort, pain control, symptom management as well as 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. Thus, hospices are to use nursing facility staff in the same way that they would use home caregivers to implement the patient's plan of care. While facility staff presumably possess more sophisticated health care skills than home caregivers, they may not be used to perform functions more frequently, or with a greater degree of complexity, than the hospice would utilize home caregivers under similar circumstances.

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), orienting nursing facility staff would be a usual and customary practice and any additional burden would be minimal. This requirement is exempt from the PRA per 5 CFR §1320.3(b)(2).

418.113 - Condition of participation: Emergency preparedness

Per Section 418.113, hospices must comply with all applicable Federal, State, and local emergency preparedness requirements and must establish and maintain an emergency preparedness program that includes developing: a) an emergency plan; b) policies and procedures; c) a communication plan; and d) a testing and training program.

The associated ICRs and burden estimates for this CoP for hospices are included in a separate PRA submission under OMB Control No 0938-1325, along with other Medicare certified facilities as an "omnibus" package. For details, see the Supporting Statement titled "*Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers (0938-1325/CMS-10578).*"

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. Because this is a usual and customary business practice, this burden is exempt from the PRA per 5 CFR §1320.3(b)(2).

IC-25: MSW Supervision of Social Workers – § 418.114(b)(3)(i)(B)

Per Section 418.114(b)(3)(i)(B), if a hospice employs a social worker with a baccalaureate degree in social work, psychology, sociology, or other field related to social work (BSW), the BSW must be supervised by a Social Worker with a Master of Social Work degree (MSW). This supervision may occur in person, over the telephone, through electronic communication, or any combination thereof.

The burden associated with this CoP is the time and cost to document the MSW supervision of a BSW. Per Table 50 below, we first determine how many hospices must comply with this IC. Based on data from CMS' Quality, Certification and Oversight Reports (QCOR), the number of hospices who were surveyed for this CoP and the number which did not comply (based on the number of citations for L0594 "Medical Social Services") for the Calendar Year (CY) were as follows:

Table 50. Number of Hospices with Supervision of BSW Required

	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022
# of L0594 "Medical Social Services" Citations	23	12	17	17	9
# of Hospices Surveyed	2,414	2,317	2,007	2,975	1,237
% of Hospices Surveyed with citations	0.95%	0.52%	0.85%	0.57%	0.73%

Based on this data from CY 2018-2022, we estimate that 1% of the hospices are not in compliance with having a MSW supervise a social worker with a bachelor's degree. We originally estimated that 33% of the hospices were subject to this requirement, but we revise our assumption that this IC applies to 1% of all hospices based on the above data and because this CoP has been in place for more than a decade.[23]

Per Table 51 below, we estimate that one (1) percent of all existing hospices or 74 (7,356 x 0.01) hospices must comply with this IC because they have a social worker who needs to be supervised by a hospice MSW. Assuming there is one MSW supervisor per hospice, we estimate that a hospice MSW (Health Care Social Worker (BLS Occupation Code 21-1022)) at a loaded hourly rate of $70 would spend 4 hours per month documenting supervision activities. The annual burden per hospice would be 48 hours (4 hrs. x 12 months) and cost $3,360 (48 hours x $70). Therefore, the annual burden for the 74 affected hospices that must comply with this requirement would be 3,552 hours (48 hours x 74 hospices) and cost $248,640 ($3,360 per hospice x 74 hospices).

Table 51. IC-25: Supervision of social worker by MSW – § 418.114(b)(3)(i)(B)

Burden Assumptions	
Total # of Hospices *(a)*	7,356
% of Hospices with social workers who need supervision *(b)*	1%
# of Hospices w/social workers who need supervision *(c) = (a) x (b)*	74
# of MSWs per Hospice	1
# of Hours/Month to document supervision	4 hrs.
Hours/hospice/year	48 hrs.

Burden/Hospice	**Hourly Mean Wage**	**Hours/ Task (hrs.)**	**Cost/Task ($)**
Health Care Social Worker (BLS Code 21-1022)	$70		
Burden per hospice		48	$3,360

[23] 2008 Final Rule at 32202.

Total Annual Burden/Costs for all applicable hospices	**74**	**3,552**	**$248,640**

IC-26a and 26b: Criminal Background Checks – § 418.114(d)

Per Section 418.114(d), hospices must obtain a background check for each employee including contract employees, who have direct patient contact or access to patient records.

Existing Hospices

Per Table 52 below, first we determine the number of current hospice employees who must comply with this CoP in the existing 7,356 hospices who will need to be replaced due to turnover. According to the U.S. Bureau of Labor Statistics, for the home healthcare industry (NAICS 621600), there are a total of 946,000 employees in 2023 and the growth rate is 20.6%.[24] For purposes of this analysis, we estimate that half of these employees work in hospices with the other half working in home health agencies, for a total of 473,000. Applying the 20.6% growth rate, there are currently 570,438 hospice employees in all existing hospices across all states (473,000 x 1.206). Thus, there are an average of 78 employees per hospice (570,438 total employees/7,356 hospices) or 11,409 hospice employees per state (570,438 employees/50 states).

Based on reported data from the hospice industry, the current turnover rate for hospice employees is 25.15%.[25] As a result, 20 employees (78 employees x 0.252 per hospice, or 2,869 employees (11,409 employees x 0.252) per state would need to be replaced each year.

Table 52. Number of Replacement Staff at Existing Hospices

# of Replacement Staff at Existing Hospices	
Current total # of hospice employees *(a)*	473,000
% of employee growth *(b)*	20.6%
Estimated total # of employees *(c) = (a) x (b)*	570,438
Total # of existing hospices *(d)*	7,356
Avg # of employees per hospice *(e) = (c)/(d)*	78
Avg # of employees/state *(f) = (c)/50 states*	11,409
% of employee turnover *(g)*	25.15%
# of employees who would need to be replaced/hospice *(h) = (e) x (g)*	20
# of employees who would need to be replaced/state *(i) = (f) x (g)*	2,869

Per Table 53 below, we estimate the number of criminal background checks required in existing hospices for replacement hospice staff. Based on CMS data, 47 of the 50 states currently have state requirements to conduct criminal background checks for hospice employees.[26] In the three (3) of the 50 states that do not

[24] See "BLS Employment Projections for Home health and personal care aides (31-1120)," U.S. Bureau of Labor Statistics, at: https://data.bls.gov/projections/nationalMatrix?queryParams=31-1120&ioType=o.

[25] See e.g., Vossel, H. "Hospice Leaders: Dollars Alone Won't Solve the Turnover Conundrum," Hospice News, March 21, 2023 at: https://hospicenews.com/2023/03/21/hospice-leaders-dollars-alone-wont-solve-the-turnover-conundrum/

[26] See also, "State Requirements for Conducting Background Checks on Home Health Agency Employees," U.S. Department of Health and Human Services Office of Inspector General, May 29, 2014, Report Number: OEI-07-14-00131, accessed at: https://oig.hhs.gov/reports/all/2014/state-requirements-for-conducting-background-checks-on-home-health-agency-employees/

have their own criminal background check requirement for hospice workers, we estimate that 100% of the replacement staff in each of those states, or a total of 8,607 (2,869 replacement employees per state x 3 states), would require a background check to comply with this CoP. In the 47 states that have existing state requirements for background checks, for purposes of this analysis, we estimate that half of those employees being replaced in each of those states, or 1,435 employees per state (50% x 2,869 replacement employees per state) or 67,445 in 47 states (1,435 employees x 47 states) would need to complete background checks. The total number of hospice employees in existing hospices who as replacement staff would be required to complete background checks in all 50 states would be 76,052 (8,607 in 3 states + 67,445 in 47 states).

Table 53. Number of Hospice Employees Requiring Background Checks in Existing Hospices

# of Existing Hospice Employees Requiring Background Checks	**No State Required Background Checks**	**State Required Background Checks**	**Total**
# of hospice employees/state to be replaced *(a)*	2,869		-
# of States *(b)*	3	47	50
% of replacement staff who need background check *(c)*	100%	50%	-
# of replacement staff/state who need background checks *(d) = (a) x (c)*	2,869	1,435	-
Total # of employees requiring background checks in existing hospices *(e) = (b) x (d)*	8,607	67,445	**76,052**

Newly certified hospices

Per Table 54 below, we estimate the number of newly hired employees for newly certified hospices who will need to undergo background checks. For FY 2023, there were 546 newly certified hospices or approximately 10 per state. Although the average number of employees for existing hospices is 78 based on current data (see Table 52), we believe that these new hospices as start-up businesses will have significantly smaller staffs than existing hospices. For purposes of this analysis only, we assume that each new hospice will have 15 employees who will need criminal background checks and that 100% of these employees will need background checks regardless of which state the hospice is in Assuming there will be 10 new hospices per state each year over the next three year period, there will be 11,250 hospice employees (15 new employees per hospice x 10 newly certified hospices per state x 50 states) hired in newly certified hospices each year who will need background checks.

Table 54. Number of New Hires at Newly Certified Hospices Requiring Background Checks

# of New Hires at Newly Certified Hospices Requiring Background Checks	
# of Newly Certified Hospices *(a)*	546
Estimated # of newly certified hospice per state *(b) = (a)/50 states*	10
Estimated # of new hires per newly certified hospice *(c)*	15
Total newly hired hospice employees per state *(d) = (b) x (c)*	225
Total new hospice employees at newly certified hospices requiring background checks *(e) = (d) x 50 states*	**11,250**

Total Annual Burden for Background Checks

Finally, we estimate the annual burden hours and cost for the industry for conducting required background checks. See Table 55 below.

Per Table 53, we estimated 76,052 employees per year in existing hospices who would need a criminal background check due to turnover. Per Table 54, we estimated 11,250 new hires at newly certified hospices per year would require background checks. Thus, for purposes of our analysis, there would be 87,302 background checks required for newly certified and existing hospices. (76,052 background checks in existing hospices + 11,250 background checks newly certified hospices).

Per Table 55 below, we estimate a pre-employment background check would cost $50 based on current data.[27] In addition, based on our original burden assumptions in the 2008 Rule, we estimate that it would take 0.10 hours (6 minutes) for an Administrative Assistant (BLS Occupation Code 43-9000) at a loaded hourly wage of $40 to electronically submit each background check request. Thus, for each background check, the burden would be 0.10 hours and cost $54 ($50 background check fee + $4.00 of an Administrative Assistant's time (0.10 hours x $40/hour = $4.00)).

Assuming the total number of background checks required for existing hospices would be 76,052 per Table 53 above, the annual burden for *all* existing hospices (IC-26a) would be 7,605 hours (0.10 hours x 76,052 background checks) and would cost $4,106,808 ($54 x 76,052 background checks). Assuming the total number of background checks required for newly certified hospices would be 11,250 per Table 53 above, the annual burden for *all* newly certified hospices (IC-26b) would be 1,125 hours (0.10 hours x 11,250 background checks) and would cost $607,500 ($54 x 11,250 background checks). The total annual burden for all existing and newly certified hospices would be 8,730 hours (0.10 hours x 87,302 background checks) and cost $4,714,308 ($54 x 87,302 background checks).

Table 55. IC-26a and IC-26 –Burden for Background Checks – § 418.114(d)

Assumptions per Background Check		
Administrative Assistant (BLS Code 43-9000) *(a)*	$40	
6 min per background Check *(b)*	0.10 hr.	
	Hours/ Task	**Cost/Task**
Cost for staff to submit background check *(c) = (a) x (b)*		$4.00
Fee/Background Check *(d)*		$50
Total Cost/Background Check *(e) = (c) + (d)*	**0.10**	**$54**

Burden/Hospice	**# of Hospices** *(f)*	**# Background Checks** *(g)*	**Hours/Task (hrs.)** *(h) = (b) x (g)*	**Cost/Task ($)** *(i) = (e) x (g)*
Existing Hospices				
IC-27a: Total Annual Burden for Background Checks for all existing hospices	**7,356**	**76,052 (Table 51)**	**7,605**	**$4,106,808**
Newly Certified Hospices				

[27] See e.g., Walsh, B. "How Much Does a Background Check Cost? A Quick Guide," The Justice Collaborative, May 17, 2024 accessed on April 1, 2025 at https://thejusticecollaborative.com/how-much-does-a-background-check-cost/; "Understanding Background Check Costs (2025)," GCheck accessed on March 27, 2025 at: https://gcheck.com/blog/how-much-does-a-background-check-cost.

IC-27b: Total Annual Burden for Background Checks for all newly certified hospices	**546**	**11,250 (Table 52)**	**1,125**	**$607,500**
Total Burden Hours/Costs	**-**	**87,302**	**8,730**	**$4,714,308**

418.116 - Compliance with Federal, State, and local laws and regulations related to the health and safety of patients.

This is exempt from the PRA per 5 CFR § 1320.3(b)(3).

Per Table 56 on the next page, the total annual burden to the hospice industry is **4,095,725 hours** and the annual cost is **$354,496,106**.

Table 56. Total Annual Burden and Cost Estimates for Industry

Information Collection No.	CFR	# of Respondents	# of Responses	Total Burden Hours	Total Burden Costs	Reference Table
IC-1a: Certification Form Development	§418.22(b)	546	546	546	$74,667	4
IC-1b: Certification Content	§418.22(b)(3)	6,414	2,957,691	243,732	$52,646,112	6
IC-2: Face to Face Attestation	§418.22(b)(4)	6,414	275,329	2,156	$384,846	8
IC-3: Benefit Period Certification	§418.22(b)(5)	6,414	2,957,691	23,662	$3,549,300	10
IC-4a: Election Form Development	§418.24(b)	546	546	546	$92,274	12
IC-4b: Election Statement Explanation	§418.24(b)	6,414	1,516,946	378,426	$31,787,784	14
IC-5a: Addendum Form Development	§418.24(c)	546	546	274	$31,647	16
IC-5b: Addendum Form Completion	§418.24(c)	6,732	1,517,250	255,816	$20,209,464	18
IC-6a: Revocation Form Development	§418.28(d)	5460	546	,137	$23,153	20
IC-6b: Revocation Form Explanation	§418.28(d)	6,414	101,233	8,338	$700,392	22
IC-7a: Develop Patient Notification Form	§418.52(a)(1)	546	546	4,368	$738,192	23
IC-7b: Provide notice	§418.52(a)(3)	7,356	7,356	147,120	$12,358,080	24
IC-8: Document & investigate patient allegations	§418.52(b)(4)	7,356	7,356	88,272	$14,917,968	25
IC-9: Educate & Train on Plan of Care	§418.56(b)	7,356	7,356	882,720	$74,148,480	26
IC-10: Update Plan of Care	§418.56(c)	7,356	7,356	294,240	$24,716,160	27
IC-11a: One time development of QAPI program	§418.58(a)(2)	546	546	6,552	$781,872	28
IC-11b: Collect & Record Quality Data	§418.58(a)(2)	7,356	7,356	235,392	$19,772,928	29
IC-11c: Document Analysis	§418.58(a)(2)	7,356	7,356	294,240	$24,716,160	30
IC-11d: Organize QAPI Data	§418.58(a)(2)	7,356	7,356	353,088	$14,123,520	31
IC-11e: Analyze QAPI & ID new measures	§418.58(a)(2)	7,356	7,356	110,340	$13,167,240	32
IC-12a: Hospice Aide Training - Existing facilities	§418.76(b)(4)	7,356	7,356	611	$24,422	34
IC-12b: Hospice Aide Training - Newly certified facilities	§418.76(b)(4)	546	546	227	$9,064	34
IC-13: Hospice Aide In-Service Training	§418.76(d)(2)	7,356	7,356	14,712	$588,480	35
IC-14: Volunteer Training	§418.78(a)	7,356	7,356	3,678	$147,120	36
IC-15: Volunteer Recruitment	§418.78(c)	7,356	7,356	22,068	$882,720	37
IC-16: Volunteer Cost-Savings	§418.78(d)	7,356	7,356	22,068	$3,729,492	38
IC-17: Use of Volunteers	§418.78(e)	7,356	7,356	353,088	$14,123,520	39
Information Collection No.	**CFR**	**# of Respondents**	**# of Responses**	**Total Burden Hours**	**Total Burden Costs**	**Reference Table**

IC-18: Notify and Educate Patient of Controlled Drug Policy	418.106(e)(2)(i)(C)	7,356	7,356	147,120	$12,358,080	40
IC-19: Short-term inpatient plan of care	418.108(c)(1)	7,356	7,356	47,814	$1,919,916	42
IC-20: Short-term inpatient discharge summary	418.108(c)(3)	7,356	7,356	23,539	$956,280	43
IC-21: Document restraint/seclusion for inpatient hospices	418.110(n)(11) & (n)(15)	1,447	1,447	1,085	$91,161	45
IC-22: Develop staff training content on restraint/seclusion - newly certified facilities	418.110(o)(2)	546	546	21,840	$1,834,560	46
IC-23: Document staff training completion	418.110(o)(4)	7,356	7,356	7,356	$294,240	47
IC-24: Coordinate services for patients in SNF/NF	418.112(e)(3)	7,356	7,356	88,272	$3,633,864	49
IC-25: MSW Supervision of BSW	418.114(b)(3)(i)(B)	74	74	3,552	$248,640	51
IC-26a: Criminal Background checks - Existing Facilities	418.114(d)	7,356	76,052	7,605	$4,106,808	55
IC-26b:Criminal Background checks - Newly Certified Facilities	418.114(d)	546	11,250	1,125	$607,500	55
Total Annual Burden Hours and Costs for Industry	**-**	**192,357**	**9,559,095**	**4,095,725**	**$354,496,106**	**56**

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

The burden and costs to the federal government for this information collection are estimated to include the time spent by CMS State Surveyors to complete CoP compliance evaluations. There are multiple points in time when CMS conducts evaluations of certified facilities for compliance with CoPs. First, each facility undergoes a CMS compliance review at the time of initial application for Medicare approval. Subsequent surveys for every hospital are conducted an average of every 4.5 years, but it varies between 3 and 6 years.

The burden to the federal government for completing these responsibilities was calculated using a mean loaded hourly wage of $64 for a State Survey Agency reviewer (BLS Occupation Code 19-3022) which includes benefits and overhead.[28] For the initial compliance review, we estimate the cost to the Federal government to ensure each facility's compliance to be 4 hours, with a net cost of $256 per facility (4 hours x $64). For ongoing compliance, we estimate the cost to the Federal government to ensure each facility's compliance to be 1 hour, with a net cost of $64 per facility (1 hour x $64).

Per Table 57 below, the burden to the Federal government for each applicable information collection (IC) is calculated below with only those facilities that are impacted by each IC. The total burden hours is 207,099 and the burden cost is $**13,254,308**.

[28] U.S. Bureau of Labor Statistics National Occupational Employment and Wage Statistics. *U.S. Bureau of Labor Statistics.* Last Modified Date: April 3, 2024. https://www.bls.gov/oes/current/oes_nat.htm#00-0000. Accessed March 31, 2025.

Table 57. Total Burden and Cost Estimates for Federal Government

Information Collection No.	CFR	# of Facilities	Hourly Wage	Hours/ Task	Total Burden Hours	Total Burden Costs
IC-1a: Certification Form Development	§418.22(b)	546	$64	4	2,184	$139,776
IC-1b: Certification Content	§418.22(b)(3)	6,414	$64	1	6,414	$410,496
IC-2: Face to Face Attestation	§418.22(b)(4)	6,414	$64	1	6,414	$410,496
IC-3: Benefit Period Certification	§418.22(b)(5)	6,414	$64	1	6,414	$410,496
IC-4a: Election Form Development	§418.24(b)	546	$64	4	2,184	$139,776
IC-4b: Election Statement Explanation	§418.24(b)	6,414	$64	1	6,414	$410,496
IC-5a: Addendum Form Development	§418.24(c)	546	$64	4	2,184	$139,776
IC-5b: Addendum Form Completion	§418.24(c)	6,732	$64	1	6,732	$430,848
IC-6a: Revocation Form Development	§418.28(d)	546	$64	4	2,184	$139,776
IC-6b: Revocation Form Explanation	§418.28(d)	6,414	$64	1	6,414	$410,496
IC-7a: Develop Patient Notification Form	§418.52(a)(1)	546	$64	4	2,184	$139,776
IC-7b: Provide notice	§418.52(a)(3)	7,356	$64	1	7,356	$470,784
IC-8: Document & investigate patient allegations	§418.52(b)(4)	7,356	$64	1	7,356	$470,784
IC-9: Educate & Train on Plan of Care	§418.56(b)	7,356	$64	1	7,356	$470,784
IC-10: Update Plan of Care	§418.56(c)	7,356	$64	1	7,356	$470,784
IC-11a: One time development of QAPI program	§418.58(a)(2)	546	$64	4	2,184	$139,776
IC-11b: Collect & Record Quality Data	§418.58(a)(2)	7,356	$64	1	7,356	$470,784
IC-11c: Document Analysis	§418.58(a)(2)	7,356	$64	1	7,356	$470,784
IC-11d: Organize QAPI Data	§418.58(a)(2)	7,356	$64	1	7,356	$470,784
IC-11e: Analyze QAPI & ID new measures	§418.58(a)(2)	7,356	$64	1	7,356	$470,784
IC-12a: Hospice Aide Training - Existing facilities	§418.76(b)(4)	7,356	$64	1	7,356	$470,784
IC-12b: Hospice Aide Training - Newly certified facilities	§418.76(b)(4)	546	$64	4	2,184	$139,776
IC-13: Hospice Aide In-Service Training	§418.76(d)	7,356	$64	1	7,356	$470,784
IC-14: Volunteer Training	§418.78(a)	7,356	$64	1	7,356	$470,784
IC-15: Volunteer Recruitment	§418.78(c)	7,356	$64	1	7,356	$470,784
IC-16: Volunteer Cost-Savings	§418.78(d)	7,356	$64	1	7,356	$470,784
IC-17: Use of Volunteers	§418.78(e)	7,356	$64	1	7,356	$470,784
IC-18: Notify and Educate Patient of Controlled Drug Policy	418.106(e)(2)(i)(C)	7,356	$64	1	7,356	$470,784
Information Collection No.	**CFR**	**# of Facilities**	**Hourly Wage**	**Hours/ Task**	**Total Burden Hours**	**Total Burden Costs**

IC-19: Short-term inpatient plan of care	418.108(c)(1)	7,356	$64	1	7,356	$470,784
IC-20: Short-term inpatient discharge summary	418.108(c)(3)	7,356	$64	1	7,356	$470,784
IC-21: Document restraint/seclusion for inpatient hospices	418.110(n)(11) and (n)(15)	1,447	$64	1	1,447	$92,608
IC-22: Develop staff training content on restraint/seclusion - newly certified facilities	418.110(o)(2)	546	$64	4	2,184	$139,776
IC-23: Document staff training completion	418.110(o)(4)	7,356	$64	1	7,356	$470,784
IC-24: Coordinate services for patients in SNF/NF	418.112(e)(3)	7,356	$64	1	7,356	$470,784
IC-25: MSW Supervision of BSW	418.114(b)(3)(i)(B)	74	$64	1	74	$4,708
IC-26a: Criminal Background checks - Existing Facilities	418.114(d)	7,356	$64	1	7,356	$470,784
IC-26b:Criminal Background checks - Newly Certified Facilities	418.114(d)	546	$64	4	2,184	$139,776
Total Federal Government Burden Hours and Costs	-	**192,357**	n/a	n/a	**207,099**	**$13,254,308**

15. Changes to Burden

Per Table 56 above, this package has been updated to reflect changes in information collection requirements related to new or revised Conditions of Participation. For this reinstatement, the total annual burden hours for industry are **4,095,725 hours** and the annual burden costs are **$354,496,106**.

The annual burden hours to industry increased 1.6% from 4,032,329 to 4,095,725. The reasons for the change in annual burden hours are due to the following:

- The overall number of applicable hospice elections per year continues to increase. The prior version estimated 1,168,048 applicable hospice elections per year while current estimates expect 1,517,250 applicable hospice elections per year.
- The current number of applicable hospices is 6,732 while the prior reinstatement documented that 6,414 applicable hospices were providing Medicare hospice services.
- The hospice facilities, the number of hospice patients, and the number of responses per hospice subject to the payment regulation changes have increased, thereby increasing burden hours across the industry.

16. Publication and Tabulation Dates

There are no plans to publish the information collected.

17. Expiration Date

CMS will publish a notice in the Federal Register to inform the public of the updated information; however, there is no change to the expiration date. Please note that the information collection does not contain a collection instrument but educational materials and websites that discuss these requirements will include the OMB control number and the expiration date.

18. Certification Statement

There is no exception to the certification.