

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405 and 418

[CMS–1609–F]

RIN 0938–AS10

Medicare Program; FY 2015 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements and Process and Appeals for Part D Payment for Drugs for Beneficiaries Enrolled in Hospice

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule will update the hospice payment rates and the wage index for fiscal year (FY) 2015 and continue the phase-out of the wage index budget neutrality adjustment factor (BNAF). This rule provides an update on hospice payment reform analyses, potential definitions of “terminal illness” and “related conditions,” and information on potential processes and appeals for Part D payment for drugs while beneficiaries are under a hospice election. This rule will specify timeframes for filing the notice of election and the notice of termination/revocation; add the attending physician to the hospice election form, and require hospices to document changes to the attending physician; require hospices to complete their hospice aggregate cap determinations within 5 months after the cap year ends, and remit any overpayments; and update the hospice quality reporting program. In addition, this rule will provide guidance on determining hospice eligibility; information on the delay in the implementation of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM); and will further clarify how hospices are to report diagnoses on hospice claims. Finally, the rule will make a technical regulations text change.

DATES: *Effective Date:* These regulations are effective on October 1, 2014.

FOR FURTHER INFORMATION CONTACT:

Debra Dean-Whittaker, (410) 786–0848 for questions regarding the CAHPS® Hospice Survey.

Roxanne Dupert-Frank, (410) 786–9667 for questions regarding the hospice quality reporting program.

Deborah Larwood, (410) 786–9500 for questions regarding process and appeals

for Part D payment for drugs while beneficiaries are under a hospice election.

Owen Osaghae, (410) 786–7550 for questions regarding the hospice inpatient and aggregate cap determinations.

For general questions about hospice payment policy, please send your inquiry via email to: hospicepolicy@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

Wage index addenda will be available only through the internet on the CMS Web site at: (<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/index.html>.) Readers who experience any problems accessing any of the wage index addenda related to the hospice payment rules that are posted on the CMS Web site identified above should contact Hillary Loeffler at 410–786–0456.

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Acronyms

Because of the many terms to which we refer by acronym in this final rule, we are listing the acronyms used and their corresponding meanings in alphabetical order below:

- ACA—Affordable Care Act
- APU Annual Payment Update
- BBA Balanced Budget Act of 1997
- BIPA Benefits Improvement and Protection Act of 2000
- BNAF Budget Neutrality Adjustment Factor
- BLS Bureau of Labor Statistics
- CAHPS® Consumer Assessment of Healthcare Providers and Systems
- CBSA Core-Based Statistical Area
- CCW Chronic Conditions Data Warehouse
- CFR Code of Federal Regulations
- CHC Continuous Home Care
- CMS Centers for Medicare & Medicaid Services
- COPD Chronic Obstructive Pulmonary Disease
- CoPs Conditions of Participation
- CR Change Request
- CVA Cerebral Vascular Accident
- CWF Common Working File
- CY Calendar Year
- DDE Direct Data Entry
- DME Durable Medical Equipment
- DRG Diagnosis Related Group
- DTRR Daily Transaction Reply Report
- ED Emergency Department
- FEHC Family Evaluation of Hospice Care
- FR **Federal Register**
- FY Fiscal Year
- GAO Government Accountability Office
- GIP General Inpatient Care
- HCFA Healthcare Financing Administration
- HHS Health and Human Services
- HIPAA Health Insurance Portability and Accountability Act
- HIS Hospice Item Set
- HQRP Hospice Quality Reporting Program
- IACS Individuals Authorized Access to CMS Computer Services
- ICD–9–CM International Classification of Diseases, Ninth Revision, Clinical Modification
- ICD–10–CM International Classification of Diseases, Tenth Revision, Clinical Modification
- ICR Information Collection Requirement
- IDG Interdisciplinary Group
- IPPS Inpatient Prospective Payment System
- IRC Inpatient Respite Care
- LCD Local Coverage Determination
- MAC Medicare Administrative Contractor
- MAP Measure Applications Partnership
- MedPAC Medicare Payment Advisory Commission
- MFP Multi-factor Productivity
- MSA Metropolitan Statistical Area
- NCPDP National Council for Prescription Drug Programs
- NHPCO National Hospice and Palliative Care Organization
- NF Long Term Care Nursing Facility
- NOE Notice of Election
- NOTR Notice of Termination/Revocation
- NP Nurse Practitioner
- NPI National Provider Identifier
- NQF National Quality Forum
- OIG Office of the Inspector General
- OACT Office of the Actuary
- OIG Office of Inspector General
- OMB Office of Management and Budget
- ONC Office of the National Coordinator for Health Information Technology
- PA Prior Authorization
- PBM Pharmacy Benefit Manager
- PDE Prescription Drug Event
- PRA Paperwork Reduction Act
- PRRB Provider Reimbursement Review Board
- PS&R Provider Statistical and Reimbursement Report
- Pub. L Public Law
- QAPI Quality Assessment and Performance Improvement
- QIO Quality Improvement Organization
- QRP Quality Reporting Program
- RFA Regulatory Flexibility Act
- RHC Routine Home Care
- SAF Standard Analytic File
- SBA Small Business Administration
- SNF Skilled Nursing Facility
- TEFRA Tax Equity and Fiscal Responsibility Act of 1982
- TEP Technical Expert Panel
- TrOOP True Out-of-Pocket
- U.S.C. United States Code

I. Executive Summary

A. Purpose

This final rule will update the payment rates for hospices for fiscal year (FY) 2015 as required under section 1814(i) of the Social Security Act (the Act), based on the hospital market basket update, less reductions mandated for hospices by the Patient Protection and Affordable Care Act (Pub. L. 111–148) as amended by the Health Care and Education Reconciliation Act (Pub. L. 111–152) (the Affordable Care Act). This final rule also will update the hospice wage index using updated hospital wage index data, and will apply the 6th year of the 7-year Budget Neutrality Adjustment Factor (BNAF) phase-out. In addition, section 3004(c) of the Affordable Care Act established a quality reporting program for hospices. Starting in FY 2014, hospices that failed to meet quality reporting requirements received a two percentage point reduction to their market basket update.

The Affordable Care Act also requires the Secretary to implement revisions to the hospice payment methodology no earlier than October 1, 2013; as such, this final rule updates the public on our hospice payment reform activities. This final rule also discusses potential definitions of “terminal illness” and “related conditions,” and information on potential processes and appeals for Part D payment for drugs while beneficiaries are under a hospice election. This rule will specify the timeframes for filing the hospice notice of election and the notice of termination/revocation; will require that the attending physician be identified on the hospice election form and will require changes in the attending physician be documented; will require expedited hospice self-reporting of their aggregate cap determinations; and will provide updates to the hospice quality reporting program. Additionally, this rule provides guidance on determining a patient’s eligibility for hospice; discusses the delay in the implementation of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM); clarifies how hospices will report diagnoses, in accordance with current ICD–9–CM guidelines, on hospice claims; and will make a technical regulations text change.

B. Summary of the Major Provisions

In section III.A of this final rule, we provide information on hospice behavior and trends that raises program integrity concerns, including reform analyses related to beneficiaries dying without skilled visits at the end of life; utilization of General Inpatient Care (GIP), Continuous Home Care (CHC), or Inpatient Respite Care (IRC); live discharges; and non-hospice spending for hospice beneficiaries during a hospice election. The findings discussed raise questions about whether some hospices are operating within the intent of the Medicare Hospice benefit established by the Congress. In 2010, section 3132(a) of the Affordable Care Act amended section 1814(i)(6) of the Act to authorize the Secretary of the Department of Health and Human Services (the Secretary) to collect additional data and information determined appropriate to revise payments for hospice care (no earlier than October 1, 2013) and for other purposes. An initial step of hospice payment reform is to clarify hospice payment policy, and when necessary, to enforce policies to safeguard beneficiaries and the Medicare hospice benefit.

In response to the concerning trends and comments received in response to prior rulemaking, in section III.B, we solicited comments on the definitions of “terminal illness” and “related conditions” to strengthen and clarify the current concepts of holistic and comprehensive hospice care under the Medicare hospice benefit. In addition, we solicited comments on processes that Part D plan sponsors could use to coordinate with Medicare hospices in determining coverage of drugs for hospice beneficiaries and resolving disagreements between the parties.

We provide guidance on determining the beneficiary’s eligibility for hospice in section III.C.

In section III.D, we will require that hospices complete their aggregate cap determination using a pro-forma spreadsheet and payment data not earlier than 3 months after the cap year end, to determine their cap overpayment no later than 5 months after the cap year, and remit any overpayments at that time. Given concerns about hospices’ increasingly exceeding their aggregate cap, along with the increases in the average overpayment per beneficiary, we believe that this procedural change is necessary to better safeguard the Medicare Trust Fund.

In section III.E, we will require hospices to file both the notice of election (NOE) and the notice of

termination/revocation (NOTR) on behalf of beneficiaries within 5 calendar days after the effective date of election or of discharge/revocation, respectively. If an NOE is not filed timely, the days from the effective date of election to the date of filing the NOE will be the financial responsibility of the hospice. We will allow a waiver of this consequence of late-filing an NOE in certain exceptional circumstances.

In section III.F, we will require the hospice to identify the attending physician on the election form and to document changes to the attending physician.

This final rule will update the hospice wage index with more current wage data, and the BNAF will be reduced by an additional 15 percent for a total cumulative BNAF reduction of 85 percent as described in section III.G.2. The total BNAF phase-out will be complete by FY 2016. This final rule will also update the hospice payment rates for FY 2015 by 2.1 percent as described in section III.G.3.

In section III.H of this final rule, we discuss updates to the hospice quality reporting program, including participation requirements for CY 2015 regarding the CAHPS® Hospice Survey, and remind the hospice industry that last year we set the July 1, 2014 implementation date for the Hospice Item Set and the January 1, 2015

implementation date for the CAHPS® Hospice Survey.

More than seven new quality measures will be derived from these tools; therefore, no new measures were proposed this year. Section III.H of this rule also will make changes related to the reconsideration process, extraordinary circumstance extensions or exemptions, and hospice quality reporting program (HQRP) eligibility requirements for newly certified hospices.

In section III.I, we solicit comments on processes that Part D plan sponsors could use to coordinate with Medicare hospices in determining coverage of drugs for hospice beneficiaries and resolving disagreements between the parties.

In section III.J, we discuss the delay in the implementation of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) and clarify appropriate diagnosis reporting on hospice claims per ICD–9–CM Coding Guidelines. Claims will be returned to the provider if the claim listed a non-specific symptom diagnosis as the principal hospice diagnosis.

Finally, we will make a technical regulations text change in section III.K pertaining to the definition of “social worker”.

C. Summary of Impacts

TABLE 1—IMPACT SUMMARY TABLE

Provision description	Transfers
FY 2015 Hospice Wage Index and Payment Rate Update	The overall economic impact of this final rule is estimated to be \$230 million in increased payments to hospices during FY 2015.
	Total costs
New Quality Reporting Requirements for Hospices (FY 2015) and Aggregate cap Filing Requirements.	\$8.85 million.

II. Background

A. Hospice Care

Hospice care is an approach to treatment that recognizes that the impending death of an individual warrants a change in the focus from curative care to palliative care for relief of pain and for symptom management. The goal of hospice care is to help terminally ill individuals continue life with minimal disruption to normal activities while remaining primarily in the home environment. A hospice uses an interdisciplinary approach to deliver medical, nursing, social, psychological, emotional, and spiritual services through use of a broad spectrum of professionals and other caregivers, with

the goal of making the individual as physically and emotionally comfortable as possible. Hospice is compassionate patient and family-centered care for those who are terminally ill. It is a comprehensive, holistic approach to treatment that recognizes that the impending death of an individual necessitates a change from curative to palliative care.

Medicare regulations define palliative care as “patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering.” Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy,

access to information, and choice (42 CFR 418.3). Palliative care is at the core of hospice philosophy and care practices, and is a critical component of the Medicare hospice benefit. As stated in the June 5, 2008 Hospice Conditions of Participation final rule (73 FR 32088), palliative care is an approach that “optimizes quality of life by anticipating, preventing, and treating suffering.” The goal of palliative care in hospice is to improve the quality of life of individuals, and their families, facing the issues associated with a life-threatening illness through the prevention and relief of suffering by means of early identification, assessment and treatment of pain and

other issues. This is achieved by the hospice interdisciplinary team working with the patient and family to develop a comprehensive care plan focused on coordinating care services, reducing unnecessary diagnostics or ineffective therapies, and offering ongoing conversations with individuals and their families about changes in the disease. It is expected that this comprehensive care plan will shift over time to meet the changing needs of the patient and family as the individual approaches the end-of-life.

Medicare hospice care is palliative care for individuals with a prognosis of living 6 months or less if the terminal illness runs its normal course. As generally accepted by the medical community, the term "terminal illness" refers to an advanced and progressively deteriorating illness, and that the illness is diagnosed as incurable (see section III.B for a discussion). When an individual is terminally ill, many health problems are brought on by underlying condition(s), as bodily systems are interdependent. In the June 5, 2008 Hospice Conditions of Participation final rule (73 FR 32088), we stated that "the medical director must consider the primary terminal condition, related diagnoses, current subjective and objective medical findings, current medication and treatment orders, and information about unrelated conditions when considering the initial certification of the terminal illness." As referenced in our regulations at § 418.22(b)(1), to be eligible for Medicare hospice services, the patient's attending physician (if any) and the hospice medical director must certify that the individual is terminally ill, that is, the individual's prognosis is for a life expectancy of 6 months or less if the terminal illness runs its normal course as defined in section 1861(dd)(3)(A) of the Act and our regulations at § 418.3. The certification of terminal illness must include a brief narrative explanation of the clinical findings that supports a life expectancy of 6 months or less as part of the certification and recertification forms, as stated in § 418.22(b)(3).

The goal of hospice care is to make the hospice patient as physically and emotionally comfortable as possible, with minimal disruption to normal activities, while remaining primarily in the home environment. Hospice care uses an interdisciplinary approach to deliver medical, nursing, social, psychological, emotional, and spiritual services through the use of a broad spectrum of professional and other caregivers and volunteers. While the goal of hospice care is to allow for the

individual to remain in his or her home environment, circumstances during the end-of-life may necessitate short-term inpatient admission to a hospital, skilled nursing facility (SNF), or hospice facility for procedures necessary for pain control or acute or chronic symptom management that cannot be managed in any other setting. These acute hospice care services are to ensure that any new or worsening symptoms are intensively addressed so that the individual can return to his or her home environment under a home level of care. Short-term, intermittent, inpatient respite services are also available to the family of the hospice patient when needed to relieve the family or other caregivers. Additionally, an individual can receive continuous home care during a period of crisis in which an individual requires primarily continuous nursing care to achieve palliation or management of acute medical symptoms so that the individual can remain at home. Continuous home care may be covered on a continuous basis for as much as 24 hours a day, and these periods must be predominantly nursing care per our regulations at § 418.204. A minimum of 8 hours of nursing, or nursing and aide, care must be furnished on a particular day to qualify for the continuous home care rate (§ 418.302(e)(4)).

Hospices are expected to comply with all civil rights laws, including the provision of auxiliary aids and services to ensure effective communication with patients or patient care representatives with disabilities consistent with Section 504 of the Rehabilitation Act of 1973 and the Americans with Disabilities Act, and to provide language access for such persons who are limited in English proficiency, consistent with Title VI of the Civil Rights Act of 1964. Further information about these requirements may be found at <http://www.hhs.gov/ocr/civilrights>.

B. History of the Medicare Hospice Benefit

Before the creation of the Medicare hospice benefit, hospice was originally run by volunteers who cared for the dying. During the early development stages of the Medicare hospice benefit, hospice advocates were clear that they wanted a Medicare benefit available that provided all-inclusive care for terminally-ill individuals, provided pain relief and symptom management, and offered the opportunity to die with dignity in the comfort of one's home

rather than in an institutional setting.¹ As stated in the August 22, 1983 proposed rule entitled "Medicare Program; Hospice Care" (48 FR 38146), "the hospice experience in the United States has placed emphasis on home care. It offers physician services, specialized nursing services, and other forms of care in the home to enable the terminally ill individual to remain at home in the company of family and friends as long as possible." The concept of a patient "electing" the hospice benefit and being certified as terminally ill were two key components in the legislation responsible for the creation of the Medicare Hospice Benefit (section 122 of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA), (Pub. L. 97-248)). Section 122 of TEFRA created the Medicare Hospice Benefit, which was implemented on November 1, 1983. Under sections 1812(d) and 1861(dd) of the Social Security Act (the Act), codified at 42 U.S.C. 1395d(d) and 1395x(dd), we provide coverage of hospice care for terminally ill Medicare beneficiaries who elect to receive care from a Medicare-certified hospice. Our regulations at § 418.54(c) stipulate that the comprehensive hospice assessment must identify the patient's physical, psychosocial, emotional, and spiritual needs related to the terminal illness and related conditions, and address those needs in order to promote the hospice patient's well-being, comfort, and dignity throughout the dying process. The comprehensive assessment must take into consideration the following factors: the nature and condition causing admission (including the presence or lack of objective data and subjective complaints); complications and risk factors that affect care planning; functional status; imminence of death; and severity of symptoms (§ 418.54(c)). The Medicare hospice benefit requires the hospice to cover all reasonable and necessary palliative care related to the terminal prognosis and related conditions, as described in the patient's plan of care. The December 16, 1983 Hospice final rule (48 FR 56008) requires hospices to cover care for interventions to manage pain and symptoms. Clinically, related conditions are any physical or mental conditions that are related to or caused by either the terminal illness or the medications used to manage the terminal illness.²

¹ Connor, Stephen. (2007) Development of Hospice and Palliative Care in the United States. OMEGA. 56(1), p89-99.

² Harder, PharmD, CGP, Julia. (2012). To Cover or Not To Cover: Guidelines for Covered Medications in Hospice Patients. The Clinician. 7(2), p1-3.

See section III.B of this final rule for a discussion on a possible Medicare hospice definition of “related conditions.” Additionally, the hospice Conditions of Participation at § 418.56(c) require that the hospice must provide all reasonable and necessary services for the palliation and management of the terminal illness, related conditions and interventions to manage pain and symptoms. Therapy and interventions must be assessed and managed in terms of providing palliation and comfort without undue symptom burden for the hospice patient or family.³ For example, a hospice patient with lung cancer (the principal terminal diagnosis) may receive inhalants for shortness of breath (related to the terminal condition). The patient may also suffer from metastatic bone pain (a related condition) and will be treated with opioid analgesics. As a result of the opioid therapy, the patient may suffer from constipation (a related condition) and require a laxative for symptom relief. It is often not a single diagnosis that represents the terminal prognosis of the patient, but the combined effect of several conditions, which could include not only the physical, but the emotional, psychosocial and spiritual, that makes the patient’s condition terminal. In the December 16, 1983 Hospice final rule (48 FR 56010 through 56011), regarding what is related versus unrelated to the terminal illness, we stated: “. . . we believe that the unique physical condition of each terminally ill individual makes it necessary for these decisions to be made on a case-by-case basis. It is our general view that hospices are required to provide virtually all the care that is needed by terminally ill patients.” Therefore, unless there is clear evidence that a condition is unrelated to the terminal prognosis, all services will be considered related. It is also the responsibility of the hospice physician to document why a patient’s medical needs will be unrelated to the terminal prognosis.

As stated in the December 16, 1983 Hospice final rule, the fundamental premise upon which the hospice benefit was designed was the “revocation” of traditional curative care and the “election” of hospice care for end-of-life symptom management and maximization of quality of life (48 FR 56008). After electing hospice care, the patient typically returns to the home from an institutionalized setting or

remains in the home, to be surrounded by family and friends, and to prepare emotionally and spiritually for death while receiving expert symptom management and other supportive services. Election of hospice care also includes waiving the right to Medicare payment for curative treatment for the terminal prognosis, and instead receiving palliative care to manage pain or symptoms.

The benefit was originally designed to cover hospice care for a finite period of time that roughly corresponded to a life expectancy of 6 months or less. Initially, beneficiaries could receive three election periods: two 90-day periods and one 30-day period. Currently, Medicare beneficiaries can elect hospice care for two 90-day periods and an unlimited number of subsequent 60-day periods; however, the expectation remains that beneficiaries have a life expectancy of 6 months or less if the terminal illness runs its normal course.

C. Services Covered by the Medicare Hospice Benefit

One requirement for coverage under the Medicare Hospice Benefit is that hospice services must be reasonable and necessary for the palliation and management of the terminal illness and related conditions. Section 1861(dd)(1) of the Act establishes the services that are to be rendered by a Medicare certified hospice program. These covered services include: nursing care; physical therapy; occupational therapy; speech-language pathology therapy; medical social services; home health aide services (now called hospice aide services); physician services; homemaker services; medical supplies (including drugs and biologics); medical appliances; counseling services (including dietary counseling); short-term inpatient care (including both respite care and procedures necessary for pain control and acute or chronic symptom management) in a hospital, nursing facility, or hospice inpatient facility; continuous home care during periods of crisis and only as necessary to maintain the terminally ill individual at home; and any other item or service which is specified in the plan of care and for which payment may otherwise be made under Medicare, in accordance with Title XVIII of the Act.

Section 1814(a)(7)(B) of the Act requires that a written plan for providing hospice care to a beneficiary who is a hospice patient be established before care is provided by, or under arrangements made by, that hospice program and that the written plan be periodically reviewed by the beneficiary’s attending physician (if

any), the hospice medical director, and an interdisciplinary group (described in section 1861(dd)(2)(B) of the Act). The services offered under the Medicare hospice benefit must be available, as needed, to beneficiaries 24 hours a day, 7 days a week (section 1861(dd)(2)(A)(i) of the Act). Upon the implementation of the hospice benefit, the Congress expected hospices to continue to use volunteer services, though these services are not reimbursed by Medicare (see Section 1861(dd)(2)(E) of the Act and (48 FR 38149)). As stated in the August 22, 1983 Hospice proposed rule, the hospice interdisciplinary group should be comprised of paid hospice employees as well as hospice volunteers (48 FR 38149). This expectation is in line with the history of hospice and philosophy of holistic, comprehensive, compassionate, end-of-life care.

Before the Medicare hospice benefit was established, the Congress requested a demonstration project to test the feasibility of covering hospice care under Medicare. The National Hospice Study was initiated in 1980 through a grant sponsored by the Robert Wood Johnson and John A. Hartford Foundations and CMS (then, the Health Care Financing Administration (HCFA)). The demonstration project was conducted between October 1980 and March 1983. The project summarized the hospice care philosophy as the following:

- Patient and family know of the terminal condition.
- Further medical treatment and intervention are indicated only on a supportive basis.
- Pain control should be available to patients as needed to prevent rather than to just ameliorate pain.
- Interdisciplinary teamwork is essential in caring for patient and family.
- Family members and friends should be active in providing support during the death and bereavement process.
- Trained volunteers should provide additional support as needed.

The cost data and the findings on what services hospices provided in the demonstration project were used to design the Medicare hospice benefit. The identified hospice services were incorporated into the service requirements under the Medicare hospice benefit. Importantly, in the August 22, 1983 hospice proposed rule, we stated “the hospice benefit and the resulting Medicare reimbursement is not intended to diminish the voluntary spirit of hospices” (48 FR 38149).

³Paolini, DO, Charlotte. (2001). Symptoms Management at End of Life. *JAOA*. 101(10). p609–615.

D. Medicare Payment for Hospice Care

Sections 1812(d), 1813(a)(4), 1814(a)(7), 1814(i), and 1861(dd) of the Act, and our regulations in part 418, establish eligibility requirements, payment standards and procedures, define covered services, and delineate the conditions a hospice must meet to be approved for participation in the Medicare program. Part 418, subpart G, provides for a per diem payment in one of four prospectively-determined rate categories of hospice care (routine home care, continuous home care, inpatient respite care, and general inpatient care), based on each day a qualified Medicare beneficiary is under hospice care (once the individual has elected). This per diem payment is to include all of the hospice services needed to manage the beneficiaries' care, as required by section 1861(dd)(1) of the Act. There has been little change in the hospice payment structure since the benefit's inception. The per diem rate based on level of care was established in 1983, and this payment structure remains today with some adjustments, as noted below:

1. Omnibus Budget Reconciliation Act of 1989

Section 6005(a) of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101-239) amended section 1814(i)(1)(C) of the Act and provided for the following two changes in the methodology concerning updating the daily payment rates: (1) effective January 1, 1990, the daily payment rates for routine home care and other services included in hospice care were increased to equal 120 percent of the rates in effect on September 30, 1989; and (2) the daily payment rate for routine home care and other services included in hospice care for fiscal years beginning on or after October 1, 1990, were the payment rates in effect during the previous Federal fiscal year increased by the hospital market basket percentage increase.

2. Balanced Budget Act of 1997

Section 4441(a) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33) amended section 1814(i)(1)(C)(ii)(VI) of the Act to establish updates to hospice rates for FYs 1998 through 2002. Hospice rates were updated by a factor equal to the hospital market basket percentage increase, minus 1 percentage point. Payment rates for FYs from 2002 have been updated according to section 1814(i)(1)(C)(ii)(VII) of the Act, which states that the update to the payment rates for subsequent FYs will be the hospital market basket percentage increase for the FY. The Act requires us

to use the inpatient hospital market basket to determine hospice payment rates.

3. FY 1998 Hospice Wage Index Final Rule

In the August 8, 1997 FY 1998 Hospice Wage Index final rule (62 FR 42860), we implemented a new methodology for calculating the hospice wage index based on the recommendations of a negotiated rulemaking committee. The original hospice wage index was based on 1981 Bureau of Labor Statistics hospital data and had not been updated since 1983. In 1994, because of disparity in wages from one geographical location to another, the Hospice Wage Index Negotiated Rulemaking Committee was formed to negotiate a new wage index methodology that could be accepted by the industry and the government. This Committee was comprised of representatives from national hospice associations; rural, urban, large and small hospices, and multi-site hospices; consumer groups; and a government representative. The Committee decided that in updating the hospice wage index, aggregate Medicare payments to hospices would remain budget neutral to payments calculated using the 1983 wage index, to cushion the impact of using a new wage index methodology. To implement this policy, a Budget Neutrality Adjustment Factor (BNAF) will be computed and applied annually to the pre-floor, pre-reclassified hospital wage index when deriving the hospice wage index, subject to a wage index floor.

4. FY 2010 Hospice Wage Index Final Rule

Inpatient hospital pre-floor and pre-reclassified wage index values, as described in the August 8, 1997 Hospice Wage Index final rule, are subject to either a budget neutrality adjustment or application of the wage index floor. Wage index values of 0.8 or greater are adjusted by the (BNAF). Starting in FY 2010, a 7-year phase-out of the BNAF began (August 6, 2009 FY 2010 Hospice Wage Index final rule, (74 FR 39384)), with a 10 percent reduction in FY 2010, an additional 15 percent reduction for a total of 25 percent in FY 2011, an additional 15 percent reduction for a total 40 percent reduction in FY 2012, an additional 15 percent reduction for a total of 55 percent in FY 2013, and an additional 15 percent reduction for a total 70 percent reduction in FY 2014. The phase-out will continue with an additional 15 percent reduction for a total reduction of 85 percent in FY 2015, and an additional 15 percent reduction

for complete elimination in FY 2016. We note that the BNAF is an adjustment which increases the hospice wage index value. Therefore, the BNAF reduction is a reduction in the amount of the BNAF increase applied to the hospice wage index value. It is not a reduction in the hospice wage index value or in the hospice payment rates.

5. The Affordable Care Act

Starting with FY 2013 (and in subsequent fiscal years), the market basket percentage update under the hospice payment system referenced in sections 1814(i)(1)(C)(ii)(VII) and 1814(i)(1)(C)(iii) of the Act will be annually reduced by changes in economy-wide productivity, as specified in section 1886(b)(3)(B)(xi)(II) of the Act, as amended by section 3132(a) of the Patient Protection and Affordable Care Act (Pub. L. 111-148) as amended by the Health Care and Education Reconciliation Act (Pub. L. 111-152) (the Affordable Care Act)). In FY 2013 through FY 2019, the market basket percentage update under the hospice payment system will be reduced by an additional 0.3 percentage point (although for FY 2014 to FY 2019, the potential 0.3 percentage point reduction is subject to suspension under conditions as specified in section 1814(i)(1)(C)(v) of the Act).

In addition, sections 1814(i)(5)(A) through (C) of the Act, as amended by section 3132(a) of the Affordable Care Act, require hospices to begin submitting quality data, based on measures to be specified by the Secretary, for FY 2014 and subsequent fiscal years. Beginning in FY 2014, hospices which fail to report quality data will have their market basket update reduced by 2 percentage points.

Section 1814(a)(7)(D)(i) of the Act was amended by section 3132 (b)(2)(D)(i) of the Affordable Care Act, and requires, effective January 1, 2011, that a hospice physician or nurse practitioner have a face-to-face encounter with the beneficiary to determine continued eligibility of the beneficiary's hospice care prior to the 180th-day recertification and each subsequent recertification, and to attest that such visit took place. When implementing this provision, we decided that the 180th-day recertification and subsequent recertifications corresponded to the recertification for a beneficiary's third or subsequent benefit periods (CY 2011 Home Health Prospective Payment System final rule (75 FR 70435)). Further, section 1814(i)(6) of the Act, as amended by section 3132(a)(1)(B) of the Affordable Care Act, authorizes the Secretary to

collect additional data and information determined appropriate to revise payments for hospice care and other purposes. The types of data and information suggested in the Affordable Care Act would capture accurate resource utilization, which could be collected on claims, cost reports, and possibly other mechanisms, as the Secretary determines to be appropriate. The data collected may be used to revise the methodology for determining the payment rates for routine home care and other services included in hospice care, no earlier than October 1, 2013, as described in section 1814(i)(6)(D) of the Act. In addition, we are required to consult with hospice programs and the Medicare Payment Advisory Commission (MedPAC) regarding additional data collection and payment revision options.

6. FY 2012 Hospice Wage Index Final Rule

When the Medicare Hospice Benefit was implemented, the Congress included an aggregate cap on hospice payments, which limits the total aggregate payments any individual hospice can receive in a year. The Congress stipulated that a “cap amount” be computed each year. The cap amount was set at \$6,500 per beneficiary when first enacted in 1983 and is adjusted annually by the change in the medical care expenditure category of the consumer price index for urban consumers from March 1984 to March of the cap year (section 1814(i)(2)(B) of the Act). The cap year is defined as the

period from November 1st to October 31st. As we stated in the August 4, 2011 FY 2012 Hospice Wage Index final rule (76 FR 47308 through 47314), for the 2012 cap year and subsequent cap years, the hospice aggregate cap will be calculated using the patient-by-patient proportional methodology, within certain limits. We will allow existing hospices the option of having their cap calculated via the original streamlined methodology, also within certain limits. New hospices will have their cap determinations calculated using the patient-by-patient proportional methodology. The patient-by-patient proportional methodology and the streamlined methodology are two different methodologies for counting beneficiaries when calculating the hospice aggregate cap. A detailed explanation of these methods is found in the August 4, 2011 FY 2012 Hospice Wage Index final rule (76 FR 47308 through 47314). If a hospice’s total Medicare reimbursement for the cap year exceeded the hospice aggregate cap, then the hospice must repay the excess back to Medicare.

E. Trends in Medicare Hospice Utilization

Since the implementation of the hospice benefit in 1983, and especially within the last decade, there has been substantial growth in hospice utilization. The number of Medicare beneficiaries receiving hospice services has grown from 513,000 in FY 2000 to over 1.3 million in FY 2013. Similarly, Medicare hospice expenditures have

risen from \$2.9 billion in FY 2000 to an estimated \$15.1 billion in FY 2013. Our Office of the Actuary (OACT) projects that hospice expenditures are expected to continue to increase, by approximately 8 percent annually, reflecting an increase in the number of Medicare beneficiaries, more beneficiary awareness of the Medicare Hospice Benefit for end-of-life care, and a growing preference for care provided in home and community-based settings. However, this increased spending is partly due to an increased average lifetime length of stay for beneficiaries, from 54 days in 2000 to 86 days in 2011, an increase of 59 percent.

There have also been noted changes in the diagnosis patterns among Medicare hospice enrollees. Specifically, there were notable increases between 2002 and 2007 in neurologically-based diagnoses, including various dementia diagnoses. Additionally, there have been significant increases in the use of non-specific, symptom-classified diagnoses, such as “debility” and “adult failure to thrive.” In FY 2012, “debility” and “adult failure to thrive” were the first and third most common hospice diagnoses, respectively. “Debility” and “adult failure to thrive” continue to be among the most common hospice principal diagnoses (14 percent), and those, combined with “dementia” and Alzheimer’s disease constituted approximately 30 percent of all claims-reported principal diagnosis codes reported in FY 2013 (see Table 2 below).

TABLE 2—THE TOP TWENTY PRINCIPAL HOSPICE DIAGNOSES, FY 2002, FY 2007, FY 2012, FY 2013

Rank	ICD-9/Reported principal diagnosis	Count	Percentage
Year: FY 2002			
1	162.9 Lung Cancer	73,769	11
2	428.0 Congestive Heart Failure	45,951	7
3	799.3 Debility Unspecified	36,999	6
4	496 COPD	35,197	5
5	331.0 Alzheimer’s Disease	28,787	4
6	436 CVA/Stroke	26,897	4
7	185 Prostate Cancer	20,262	3
8	783.7 Adult Failure To Thrive	18,304	3
9	174.9 Breast Cancer	17,812	3
10	290.0 Senile Dementia, Uncomp	16,999	3
11	153.0 Colon Cancer	16,379	2
12	157.9 Pancreatic Cancer	15,427	2
13	294.8 Organic Brain Synd Nec	10,394	2
14	429.9 Heart Disease Unspecified	10,332	2
15	154.0 Rectosigmoid Colon Cancer	8,956	1
16	332.0 Parkinson’s Disease	8,865	1
17	586 Renal Failure Unspecified	8,764	1
18	585 Chronic Renal Failure (End 2005)	8,599	1
19	183.0 Ovarian Cancer	7,432	1
20	188.9 Bladder Cancer	6,916	1
Year: FY 2007			
1	799.3 Debility Unspecified	90,150	9

TABLE 2—THE TOP TWENTY PRINCIPAL HOSPICE DIAGNOSES, FY 2002, FY 2007, FY 2012, FY 2013—Continued

Rank	ICD-9/Reported principal diagnosis	Count	Percentage
2	162.9 Lung Cancer	86,954	8
3	428.0 Congestive Heart Failure	77,836	7
4	496 COPD	60,815	6
5	783.7 Adult Failure To Thrive	58,303	6
6	331.0 Alzheimer's Disease	58,200	6
7	290.0 Senile Dementia Uncomp	37,667	4
8	436 CVA/Stroke	31,800	3
9	429.9 Heart Disease Unspecified	22,170	2
10	185 Prostate Cancer	22,086	2
11	174.9 Breast Cancer	20,378	2
12	157.9 Pancreas Unspecified	19,082	2
13	153.9 Colon Cancer	19,080	2
14	294.8 Organic Brain Syndrome NEC	17,697	2
15	332.0 Parkinson's Disease	16,524	2
16	294.10 Dementia In Other Diseases w/o Behav. Dist	15,777	2
17	586 Renal Failure Unspecified	12,188	1
18	585.6 End Stage Renal Disease	11,196	1
19	188.9 Bladder Cancer	8,806	1
20	183.0 Ovarian Cancer	8,434	1

Year: FY 2012

1	799.3 Debility Unspecified	161,163	12
2	162.9 Lung Cancer	89,636	7
3	783.7 Adult Failure To Thrive	86,467	7
4	428.0 Congestive Heart Failure	84,333	6
5	496 COPD	74,786	6
6	331.0 Alzheimer's Disease	64,199	5
7	290.0 Senile Dementia, Uncomp	56,234	4
8	429.9 Heart Disease Unspecified	32,081	2
9	436 CVA/Stroke	31,987	2
10	294.10 Dementia In Other Diseases w/o Behavioral Dist	27,417	2
11	174.9 Breast Cancer	22,421	2
12	153.9 Colon Cancer	22,197	2
13	157.9 Pancreatic Cancer	22,007	2
14	332.0 Parkinson's Disease	21,183	2
15	185 Prostate Cancer	21,042	2
16	294.8 Other Persistent Mental Dis.-classified elsewhere	17,762	1
17	585.6 End Stage Renal Disease	17,545	1
18	518.81 Respiratory Failure	12,962	1
19	294.11 Dementia In Other Diseases w/Behavioral Dist	11,751	1
20	188.9 Bladder Cancer	10,511	1

Year: FY 2013

1	799.3 Debility Unspecified	127,415	9
2	428.0 Congestive Heart Failure	96,171	7
3	162.9 Lung Cancer	91,598	6%
4	496 COPD	82,184	6
5	331.0 Alzheimer's Disease	79,626	6
6	783.7 Adult Failure to Thrive	71,122	5
7	290.0 Senile Dementia, Uncomp	60,579	4
8	429.9 Heart Disease Unspecified	36,914	3
9	436 CVA/Stroke	34,459	2
10	294.10 Dementia In Other Diseases w/o Behavioral Dist	30,963	2
11	332.0 Parkinson's Disease	25,396	2
12	153.9 Colon Cancer	23,228	2
13	294.20 Dementia Unspecified w/o Behavioral Dist	23,224	2
14	174.9 Breast Cancer	23,059	2
15	157.9 Pancreatic Cancer	22,341	2
16	185 Prostate Cancer	21,769	2
17	585.6 End-Stage Renal Disease	19,309	1
18	518.81 Acute Respiratory Failure	15,965	1
19	294.8 Other Persistent Mental Dis.-classified elsewhere	14,372	1
20	294.11 Dementia In Other Diseases w/Behavioral Dist	13,687	1

Note(s): The frequencies shown represent beneficiaries that had a least one claim with the specific ICD-9-CM code reported as the principal diagnosis. Beneficiaries could be represented multiple times in the results if they have multiple claims during that time period with different principal diagnoses.

Source: FY 2002, 2007, and 2012 hospice claims data from the Chronic Conditions Data Warehouse (CCW), accessed on February 14 and February 20, 2013. FY 2013 hospice claims data from the CCW, accessed on June 26, 2014.

III. Provisions of the Proposed Regulations and Responses to Comments

On May 8, 2014, we published a proposed rule in the **Federal Register** (79 FR 26538–26587) entitled, FY 2015 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements and Process and Appeals for Part D Payment for Drugs for Beneficiaries Enrolled in Hospice (herein referred to as the FY 2015 Hospice Wage Index proposed rule). The FY 2015 Hospice Wage Index proposed rule updated the public on several issues and set forth the following proposals:

- We discussed recent payment reform analyses related to beneficiaries dying without skilled visits at the end of life; utilization of General Inpatient Care (GIP), Continuous Home Care (CHC), or Inpatient Respite Care (IRC); live discharges; and non-hospice spending for hospice beneficiaries during a hospice election.

- We solicited comments on the definition of “terminal illness” and “related conditions.”

- We provided guidance on determining eligibility for hospice care.

- We proposed to require that hospices determine their inpatient and/or aggregate cap overpayment within 5 months after the cap year, and proposed to further amend § 418.308 and § 405.371 to state that payments to a hospice would be suspended in whole or in part, for failure to file a self-determined inpatient and aggregate cap determination no later than 5 months after the end of the cap year (that is, by March 31st of each year).

- We proposed to amend § 418.24(a) to require that a hospice must file the Notice of Election (NOE) with its Medicare Administrative Contractor (MAC) within 3 calendar days after the hospice effective date of election. We also proposed that for those hospices that do not file the NOE timely (that is, within 3 calendar days after the effective date of election), Medicare would not cover and pay for days of hospice care from the effective date of election to the date of filing of the NOE. In addition, we proposed that these days be considered the financial responsibility of the hospice; the hospice could not bill the beneficiary for them.

- We proposed to revise the regulations at § 418.26 and § 418.28 to require hospices to file a Notice of Termination or Revocation (NOTR) within 3 calendar days after the effective date of a beneficiary's

discharge or revocation, if they have not already filed a final claim.

- We proposed to amend the regulations at § 418.24(b)(1) to require the election statement to identify the attending physician, and to include an acknowledgement that the attending physician was chosen by the patient. We also proposed that if a patient (or representative) wants to change his or her designated attending physician, he or she must file a statement with the hospice which identifies the new attending physician and includes the date the change is to be effective, the date that the statement is signed, and the patient's (or representative's) signature, along with an acknowledgement that this change in the attending physician is the patient's (or representative's) choice.

- We provided a preliminary update to the FY 2015 hospice wage index, continuing to use the hospital pre-floor, pre-reclassified wage index as the source data, and provided a preliminary update to the FY 2015 hospice payment rates.

- We proposed in § 418.312 that newly certified hospices that receive notice of their CMS certification number on or after November 1, 2014, for payments to be made in FY 2016, be excluded from the quality reporting requirements for the FY 2016 payment determination, as data submission and analysis would not be possible for a hospice receiving notification of their certification this late in the reporting time period. We also proposed that in future years, hospices that receive notification of certification on or after November 1 of the preceding year involved would continue to be excluded from any payment penalty for quality reporting purposes for the following FY.

- We proposed that approved survey vendors meet all of the minimum business requirements and follow the detailed technical specifications for survey administration as published in the CAHPS® Hospice Survey specifications manual. We proposed to codify the CAHPS® Hospice Survey vendor requirements to be effective with the FY 2017 Annual Payment Update (APU) (as proposed in § 418.312). We also proposed that no organization, firm, or business that owns, operates, or provides staffing for a hospice be permitted to administer its own Hospice CAHPS® survey or administer the survey on behalf of any other hospice in the capacity as a Hospice CAHPS® survey vendor.

- We described a potential coordination of benefits and appeals process for Part D payment for drugs while beneficiaries are under a hospice

election, and solicited comments to guide us in making a possible proposal in future rulemaking. We solicited comments on whether hospices need to determine, in a specific amount of time, a beneficiary's drug and biological needs and communicate with the Part D plan sponsor or to the other payer and/or provider, verbally or in writing, to ensure that there is no lapse of reasonable and necessary drugs and biologicals or other items or services for the palliation and management of the terminal illness and related conditions. We also solicited comments on steps a hospice could take to reconcile payment responsibility with Part D plans or with other payers or providers.

- We provided an update on the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) and coding guidelines for hospice claims reporting.

- We proposed to make a technical correction in § 418.3 to delete an obsolete definition for a “social worker.”

We provided for a 60 day comment period on the FY 2015 Hospice Wage Index proposed rule. We received 114 public comments from the Medicare Payment Advisory Commission, Medicare beneficiary advocacy groups, hospice providers, state and national hospice associations, hospice and end-of-life care organizations and experts, hospice financial experts and consultants, attorneys, Part D sponsors, pharmacy associations, private insurance plans, and private individuals. In general, commenters provided thoughtful and diverse comments on the proposed policies. We also received comments that are outside the scope of this rule. We will take these comments under consideration when evaluating current hospice policies.

Summaries of the public comments received on the proposals and our responses to those comments are provided in the appropriate sections in the preamble of this final rule.

A. Hospice Payment Reform: Research and Analyses

Section 3132(a) of the Affordable Care Act amended section 1814(i)(6) of the Act to authorize the Secretary to collect additional data and information determined appropriate to revise payments for hospice care and for other purposes. The data collected may be used to revise the methodology for determining the payment rates for routine home care and other services included in hospice care, no earlier than October 1, 2013, as described in section 1814(i)(6)(D) of the Act. We are also required to consult with hospice

programs and the Medicare Payment Advisory Commission (MedPAC) regarding additional data collection and payment revision options. Since 2010, we have been working with our hospice reform contractor, Abt Associates, to review the most current peer-reviewed literature; conduct research and analyses; identify potential vulnerabilities in the current payment system; and research and develop hospice payment model options. We recently required additional information on hospice claims regarding drugs and certain durable medical equipment, effective April 1, 2014; and are in the process of finalizing changes to the hospice cost report to better collect data on the costs of providing hospice care. The additional information on hospice claims and the hospice cost report will be used in our hospice payment reform efforts, once the data are available for analysis.

The research and analyses conducted thus far on available Medicare claims and cost report data have highlighted hospice utilization trends that raise concerns regarding the viability of the Medicare hospice program and the impact of beneficiary access to quality end of life care. In March 2009, the Medicare Payment Advisory Commission (MedPAC) recommended that Medicare improve its payment system for hospice services to address a misalignment between Medicare's payments and hospice's costs that created incentives for providers to enroll patients who are more likely to have long stays because those stays are more profitable than short ones (http://www.medpac.gov/chapters/Mar09_Ch06.pdf). MedPAC's June 2013 Report to Congress on Medicare and the Health Care Delivery System reiterated concerns about utilization trends and suggested that such trends were driven by a misalignment in the payment

system (http://www.medpac.gov/chapters/Jun13_Ch05.pdf). MedPAC's June 2013 report added that, while payment reform would better align payments with costs, additional administrative controls were necessary to balance incentives and strengthen provider compliance. As such, we believe that a critical goal of the Medicare hospice payment system is to strengthen and safeguard the current scope of the Medicare hospice benefit. This will provide a solid foundation on which to reform the methodology used to pay for Medicare hospice services. Program integrity is being addressed immediately while we develop further data and research to address payment reform in the near future.

Abt Associates, with its subcontractor Brown University, has developed a technical report entitled, "Medicare Hospice Payment Reform: Analyses to Support Payment Reform," dated May 1, 2014 (hereafter, referred to as the May 2014 Technical Report) that thoroughly describes the analytic file and extensive work performed on analyzing current hospice utilization data, of which many of the results of the analyses are presented in this final rule. Both the May 2014 Technical Report and an updated literature review are available on our hospice center Web page at: <http://www.cms.gov/Center/Provider-Type/Hospice-Center.html> in the "Research and Analyses" section. We further examined hospice utilization data and developed a provider-level file to identify aberrant hospice behavior. The provider-level file contains information on beneficiaries who were discharged (alive or deceased) in calendar year (CY) 2012 and includes claims data from January 1, 2010 through December 31, 2012. Some of the findings described in this section, are based on this provider-level file.

1. Beneficiaries Dying Without Skilled Visits in the Last Days of Life

Hospice clinicians are experts in recognizing changes as a patient is approaching the last few days of life and helping to prepare and support the patient and family. Most individuals approaching end-of-life have noted declines over the several days prior to death. As such, the expectation is that there would be an increased need for hospice services in the days leading up to the hospice beneficiary's death. Although we recognize that prognostication is not an exact science, there are hallmark physical, functional, nutritional, and cognitive changes that are typically present leading up to the hospice patient's death (see section III.C of this final rule).

When looking at skilled visits provided in the last days of life, as reported on the hospice claim, our analysis found that a relatively high percentage (28.9 percent) of hospice decedents who were receiving RHC on their last day of life did not receive a skilled visit on that day (see Table 3 below). This could be explained, in part, by sudden or unexpected death. Expanding this analysis to skilled visits provided in the last two to four days of life, we found that 14.4 percent of hospice decedents did not receive skilled visits in the last 2 days of life and 6.2 percent of hospice decedents did not receive skilled visits in the last 4 days of life. While this could also be explained, in part, by sudden or unexpected death, we are concerned with the possibility that those beneficiaries and their families are not receiving hospice care and support at the very end of life. If hospices are actively engaging with the beneficiary and the family throughout the election period, we would expect to see skilled visits during those last days of life.

TABLE 3—FREQUENCY AND PERCENTAGE OF DECEDENTS NOT RECEIVING SKILLED VISITS AT THE END OF LIFE, CALENDAR YEAR 2012

	Number of decedents	Percentage of decedents with no skilled visits
No skilled visits on last day (and last day was RHC)	656,355	28.9
No skilled visits on last two days (and last two days were RHC)	622,334	14.4
No skilled visits on last three days (and last three days were RHC)	585,648	9.1
No skilled visits on last four days (and last four days were RHC)	551,359	6.2

Note(s): Skilled visit was considered to be a visit from a social worker, therapist, or nurse. Source: Beneficiaries whose last days of hospice enrollment were billed to the RHC level of care using 100% of hospice days from the Hospice Standard Analytic File (SAF), Calendar Year (CY) 2012.

Further analysis of skilled visits during the last two days of life found that 10.3 percent of very short stay

decedents (5 days or less) did not receive skilled visits during the last two days of life. In contrast, 15.9 percent of

decedents with lengths of stay 181 days or longer did not receive visits in the last two days of life. Newer hospices (5

years or less since Medicare certification) were more likely to have decedents with no skilled visits during the last two days of life (17.8 percent) compared to older hospices (6 years or more since Medicare certification; 14.0 percent). We also found geographic differences in this analysis. The five states with the lowest percentage of decedents with no skilled visits on the last two days of life included: Wisconsin (5.7 percent), North Dakota (7.3 percent), Vermont (7.5 percent), Tennessee (7.5 percent), and Kansas (8.7 percent). The five states with the highest percentage of decedents with no skilled visits on the last two days of life included: New Jersey (23 percent), Massachusetts (22.9 percent), Oregon (21.2 percent), Washington (21 percent), and Minnesota (19.4 percent).

Using the provider-level file referenced above, we also found that, on average, hospices did not report any skilled visits in the last two days of life for 9.7 percent of their decedents who died receiving routine home care.⁴ Nearly 5 percent of hospices did not provide any skilled visits in the last two days of life to more than 50 percent of their decedents receiving routine home care on those last two days; the average lifetime length of stay among those decedents was 143 days. We note that the average lifetime length of stay in our provider-level file was 95.4 days (among beneficiaries who were discharged alive or deceased in CY 2012). Furthermore, we found that 34 hospices did not make any skilled visits in the last 48 hours of life to any of their decedents who died while receiving routine home care.

2. General Inpatient Care, Continuous Home Care, and Inpatient Respite Care Utilization

Medicare Conditions of Participation require hospices to demonstrate that they are able to provide all four levels of care—Routine Home Care (RHC), General Inpatient Care (GIP), Continuous Home Care (CHC) and Inpatient Respite Care (IRC) to be a certified Medicare hospice provider. As stated in our regulations at § 418.302(b)(4), a GIP day is a day in which an individual who has elected hospice care, receives general inpatient care in an inpatient facility for pain control or acute or chronic symptom management which cannot be managed in other settings. For FY 2014, the

payment rate for GIP was \$694.19 per day compared to \$156.06 for a day of RHC.

While the goal of hospice care is to allow for the individual to remain in his or her home environment, circumstances during the end-of-life may necessitate short-term inpatient admission to a hospital, skilled nursing facility (SNF), or hospice inpatient facility for procedures necessary for pain control or acute or chronic symptom management that cannot be managed in any other setting. These acute hospice care services are to ensure that any new or worsening symptoms are intensively addressed so that the individual can return to his or her home environment under a home level of care.

As part of our reform work, we analyzed CY 2012 data to better understand GIP utilization. We found that 77.3 percent of beneficiaries did not have any GIP care in 2012. Using provider-level data for beneficiaries discharged in 2012, we also found that 21.1 percent of hospices did not provide GIP care to any of their beneficiaries. While there are appropriate circumstances where a hospice provides no GIP (for example, when a provider only has a few patients, none of whom needs GIP), we are concerned that more than a fifth of hospices not providing any GIP may be an indication that hospice beneficiaries do not have adequate access to a necessary level of care for acute or chronic symptom management. We also found that there were site of service differences such that the longest GIP length of stay was in the inpatient hospice setting (6.1 days) and shortest at in the inpatient hospital setting (4.5 days). Over two-thirds of GIP days were provided in an inpatient hospice setting (68 percent), and about a quarter of GIP days were provided in an inpatient hospital (24.9 percent). Only 5.5 percent of GIP days were provided in a SNF.

As stated in our regulations at § 418.302(b)(2), a continuous home care day is a day on which an individual who has elected to receive hospice care, is not in an inpatient facility, and receives hospice care consisting predominantly of nursing care on a continuous basis at home. Home health aide (also known as a hospice aide) or homemaker services, or both, may also be provided on a continuous basis. Continuous home care is only furnished during brief periods of crisis as described in § 418.204(a), and only as necessary to maintain the terminally ill patient at home. Continuous home care may be covered on a continuous basis for as much as 24 hours a day, and these periods must be predominantly nursing

care per our regulations at § 418.204. A minimum of 8 hours of care must be furnished on a particular day to qualify for the continuous home care rate (§ 418.302(e)(4)).

As part of our reform work, we analyzed CY 2012 data to better understand CHC utilization. Overall, approximately 0.4 percent of all hospice days in 2012 were billed as CHC, but that percentage decreases to 0.2 when a large chain provider with a large percentage of its hospice days billed as CHC days was excluded. Although 42.7 percent of hospices billed at least 1 day of CHC, we found considerable variation in the share of CHC days among hospices that provided any CHC. Almost 90 percent of hospices that provided any CHC had less than 1 percent of their days billed as CHC, but four hospices billed more than 10 percent of their days as CHC. Forty hospices accounted for 46 percent of all CHC days and a single hospice accounted for over a quarter of all CHC days. Among hospices who billed for providing CHC, 9.4 percent provided over half of their CHC days to beneficiaries residing in a nursing home. For CHC, a hospice must provide a minimum of 8 hours of care during a 24-hour day, which begins and ends at midnight.

Finally, we analyzed inpatient respite care (IRC) utilization in CYs 2005 through 2012. IRC is provided in an approved facility, as needed, on an occasional basis to relieve the family caregivers for up to 5 consecutive days. Payment for IRC is subject to the requirement that it may not be provided consecutively for more than 5 days at a time. As stated in our regulations at § 418.302(e)(5), payment for the sixth and any subsequent day of respite care is made at the routine home care rate. Overall, while the percentage of beneficiaries receiving at least 1 day of IRC care increased from 1.44 percent in CY 2005 to 3.4 percent in CY 2012, only a small percentage of beneficiaries utilize IRC. We also found that 26 percent of hospices did not bill for any IRC days in CY 2012. IRC is a critical part of the Medicare hospice benefit, providing vital support and relief to the patient's caregiver and family. We will continue to monitor utilization of IRC level of care, over time, to ensure beneficiaries receiving hospice care have access to respite services for their caregivers.

The variation in the provision of GIP, CHC, and IRC could suggest that the level of hospice care that a beneficiary receives may not always be driven by patient factors. Medicare Conditions of Participation require hospices to

⁴ The provider-level analysis conducted on whether skilled visits were provided in the last two days of life only examined instances where the decedent was receiving routine home care in the last two days of life. We note that 21 providers did not have any decedents that died while on routine home care.

demonstrate that they are able to provide all four levels of care—RHC, GIP, CHC, and IRC—in order to be a certified Medicare hospice provider. We will continue to monitor GIP, CHC, and IRC use to identify hospices with aberrant utilization patterns, to identify hospices that may be in violation of the CoPs or of payment regulations, and to refer hospices identified through our analysis to Survey and Certification, to the Office of Financial Management, and to the Center for Program Integrity for further investigation.

3. Hospice Live Discharges

Currently, federal regulations allow a patient who has elected to receive Medicare hospice services to revoke that election at any time. That patient may re-elect hospice benefits at any time for any other election period that is still available. However, federal regulations provide limited opportunity for a Medicare hospice provider to discharge a patient from its care. In accordance with 418.26, discharge from hospice care is permissible when the patient moves out of the provider's service area, is determined to be no longer terminally ill, or for cause. Hospices may not automatically or routinely discharge the patient at its discretion, even if the care may be costly or inconvenient. Neither should the hospice request or demand that the patient revoke his/her election.

Our regulations also state that if the hospice patient (or his/her representative) revokes the hospice election, Medicare coverage of hospice care for the remainder of that period is forfeited. The patient may, at any time, re-elect to receive hospice coverage for any other hospice election period that he or she is eligible to receive (§ 418.28(c)(3) and § 418.24(e)). During the time period between revocation/discharge and the re-election of the hospice benefit, Medicare coverage would resume for those Medicare benefits previously waived.

Prior to 2012, claims data provided limited information about the reason a hospice patient was discharged from a hospice's care. Starting July 1, 2012, the discharge information collected on the Medicare claim was expanded to capture the reason for all types of discharge, that is, if the discharge was due to a death, revocation, transfer to another hospice, moving out of the hospice's service area, discharge for cause, or due to the patient no longer being considered terminally ill (that is, no longer qualifying for hospice services). Between 2000 and 2012, the overall rate of live discharges increased from 13.2 percent of hospice discharges to 18.1 percent in 2012. In 2010, the rate

of live discharges varied by state (from 12.8 percent in Connecticut to 40.5 percent in Mississippi) and by hospice provider (from a 25th percentile of 9.5 percent to 75th percentile of 26.4 percent). Furthermore, analysis of our provider-level file shows that of the 3,702 hospices in our file, 71 hospices had a live discharge on 100 percent of their beneficiaries. The average lifetime length of stay for these hospices was 193 days compared to the national average lifetime length of stay of 95.4 days (among beneficiaries who were discharged alive or deceased in CY 2012). We have shared this information with the Office of Financial Management and with the Center for Program Integrity for their review and follow-up.

One study of hospice live discharges in cancer patients noted that smaller hospices and for-profit hospices had a higher rate of hospice live discharges.⁵ Our subcontractors at Brown University studied 2010 hospice live discharges among all diagnoses, finding that not-for-profit hospice programs had a lower rate of hospice live discharges than for-profit hospice programs (14.6 percent vs. 22.4 percent, $p < .001$). Small for-profit hospices in operation 5 years or less had a higher rate of hospice live discharges compared to older, for-profit hospices (31.5 percent vs. 12.8 percent, $p < .001$). We are also concerned over patterns of revocations and elections of the Medicare hospice benefit for the purpose of potentially avoiding costly hospitalizations, expensive procedures, drugs, or services. In 2010, 13,770 out of the 182,172 live discharges had a pattern of hospice discharge, hospital admission, and hospice readmission. These cases accounted for \$126 million dollars in Medicare payments for the hospitalization between hospice election periods. Nearly half of these Medicare payments are accounted for in ten states with the highest rate of this pattern of discharges (that is, MS, OK, AL, SC, MD, VA, TX, NJ, GA, and LA accounted for \$56.0 million dollars of the hospitalization costs).

We understand that the rate of live discharges should not be zero, given the uncertainties of prognostication and the ability of patients and their families to revoke the hospice election at any time. However, Medicare hospice care is a comprehensive patient and family focused care model designed to optimize quality of life by anticipating, preventing, and treating pain and

symptoms. We are concerned that patterns of discharge, hospital admission, and hospice readmission do not provide a comprehensive, coordinated care experience for terminally ill patients.

4. Non-hospice Spending for Hospice Beneficiaries During an Election

When a beneficiary elects the Medicare hospice benefit, he or she waives the right to Medicare payment for services related to the terminal illness and related conditions, except for services provided by the designated hospice and the attending physician. However, Medicare payment is allowed for covered Medicare items or services which are unrelated to the terminal illness and related conditions. When a hospice beneficiary receives items or services unrelated to the terminal illness and related conditions from a non-hospice Part A or Part B provider, that provider can bill Medicare for the items or services, but must include on the claim a GW modifier (if billed on a professional claim) or condition code 07 (if billed on an institutional claim). When a hospice beneficiary with Part D coverage receives medications unrelated to the terminal illness and related conditions, Prescription Drug Events (PDEs) are billed to Part D and do not require a modifier or a condition code.

In follow up to our initial analysis of hospice drugs being paid through Part D (78 FR 48245–48246), we analyzed the magnitude of Medicare spending outside of the hospice benefit for items or services provided to hospice beneficiaries during a hospice election from Parts A, B, and D. In CY 2012, we found that Medicare paid \$710.1 million for Part A and Part B items or services while a beneficiary was receiving hospice care. We estimated that 76.5 percent of the \$710.1 million included either a GW modifier or a condition code 07 on the claim, which indicated that the services identified by the provider or supplier as unrelated to the terminal illness and related conditions. The remaining 23.5 percent of this \$710.1 million was for claims without a GW modifier or condition code 07, some of which may have been processed due to late filing of the notice of election (NOE).

The \$710.1 million paid for Part A and Part B items or services was for durable medical equipment (7.0 percent), inpatient care (care in long-term care hospitals, inpatient rehabilitation facilities, acute care hospitals; 28.6 percent), outpatient Part B services (16.9 percent), other Part B services (also known as physician, practitioner and supplier claims, such

⁵ Carlson MD, Herrin J, Du Q, et al. Hospice characteristics and the disenrollment of patients with cancer. *Health Serv Res.* Dec 2009;44(6):2004–2021.

as labs and diagnostic tests, ambulance transports, and physician office visits; 37.4 percent), skilled nursing facility care (5.7 percent), and home health care (4.5 percent). Part A and Part B non-hospice spending occurred mostly for hospice beneficiaries who were at home (43.3 percent). We also found that 28.3 percent of hospice beneficiaries were in a nursing facility, 14.1 percent were in an inpatient setting, 10.2 percent were in an assisted living facility, and 4.1 percent were in other settings. Although the average daily rate of expenditures outside the hospice benefit was \$7.91, we found differences amongst states where beneficiaries receive care. The highest rates per day occurred for hospice beneficiaries residing in West Virginia (\$13.91), or in the South (Florida (\$13.17), Texas (\$12.45), Mississippi (\$11.91), and South Carolina (\$10.16)).

Another area of concern in high non-hospice Medicare spending occurring during a hospice election is hospital emergency department (ED) visits and observation stays. Ninety-five percent of these ED visits and observation stays were billed and paid outside of the hospice benefit with condition code 07

on the claim. Using data on CY 2010 hospice admissions, followed through discharge or December 31, 2011 (whichever came first), we found that 8.8 percent of hospice beneficiaries had a total of 87,720 ED visits/observation stays billed to Medicare during their hospice election, at a cost of \$268.4 million. The majority of these beneficiaries (77.6 percent) only experienced a single ED visit/observation stay, but 20.9 percent had between 2 and 4 ED visits/observation stays during their election, and 1.4 percent had more than 5 ED visits/observation stays during their hospice election. Although some beneficiaries may go directly to the ED rather than contacting the hospice first, 22.3 percent had 2 or more ED visits; these results may indicate that the hospice is not aware of the beneficiary's condition, the hospice is not being responsive to beneficiary needs, or related conditions are being treated as if they were unrelated. Most ED visits/observation stays occurred in younger beneficiaries with non-cancer diagnoses, in beneficiaries in newer hospices, and in beneficiaries receiving care in the

South, with Mississippi and Oklahoma having the highest rates (21.1 and 20.5 ED visits/observation stays per 100 hospice admissions, respectively). The most frequently occurring Diagnosis Related Groups (DRGs) associated with these ED visits/observation stays were septicemia or severe sepsis, kidney and urinary tract infections, hip and femur procedures, simple pneumonia and pleurisy, and gastrointestinal hemorrhage. Some of these frequently occurring DRGs are conditions which are common at end-of-life, and could be attended to in the home or with a GIP level of care. This raises concerns about whether the ED visits/observation stays were actually related to the terminal illness and related conditions and should have been covered by the hospice.

In addition to analyzing data from Parts A and B of Medicare, we analyzed CY 2012 Part D data which showed \$417.9 million in total drug spending by Medicare, states, beneficiaries, and other payers, for hospice beneficiaries during a hospice election. Table 4 details the various components of Part D spending.

TABLE 4—DRUG COST SOURCES FOR HOSPICE BENEFICIARIES' 2012 DRUGS RECEIVED THROUGH PART D

Component	Description	\$ Total expenditures
Patient Pay Amount	The dollar amount the beneficiary paid that is not reimbursed by a third party	\$48,191,067
Low Income Cost-Sharing Subsidy	Medicare payments to plans to subsidize the cost-sharing liability of qualifying low-income beneficiaries at the point of sale.	117,558,814
Other True Out-of-Pocket Amount	Records all other third-party payments on behalf of beneficiary. Examples are state pharmacy assistance programs and charities.	2,366,896
Patient Liability Reduction due to Other Payer Amount.	Amount patient liability reduced due to other benefits. Examples are Veteran's Administration and TRICARE.	3,120,834
Covered Drug Plan Paid Amount	Contains the net amount the plan paid for standard benefits	217,370,068
Non-Covered Plan Paid Amount	Contains the net amount the plan paid beyond standard benefits. Examples include supplemental drugs, supplemental cost-sharing, and OTC drugs paid under plan administrative costs.	16,985,982
Components' Total	405,593,660
Unknown	Unreconciled/Unreported Difference between total Gross Drug Costs and Reported payer sources (includes sales taxes, drug dispensing fees, and drugs' ingredient costs).	12,307,603
Gross Total Drug Costs, Reported	417,901,263

Source: Abt Associates analysis of 100% 2012 Medicare Claim Files. For more information on the components above and on Part D data, go to the Research Data Assistance Center's (ResDAC's) Web site at <http://www.resdac.org/>.

The portion of the \$417.9 million total Part D spending which was paid by Medicare is the sum of the Low Income Cost-Sharing Subsidy and the Covered Drug Plan Paid Amount, or \$334.9 million.

Medicare Spending: In total, actual non-hospice Medicare expenditures occurring during a hospice election in CY 2012 were \$710.1 million for Parts A and B spending, plus \$334.9 million for Part D spending, or approximately

\$1 billion dollars. This figure is comparable to the estimated \$1 billion MedPAC reported during its December 2013 public meeting.⁶ Associated with this \$1 billion in Medicare spending were cost sharing liabilities such as co-payments and deductibles that beneficiaries incurred. Hospice

⁶ MedPAC, "Assessing payment adequacy and updating payments: hospice services", December 13 2013. Available at: http://www.medpac.gov/transcripts/hospice_December2013_Public.pdf.

beneficiaries had \$135.5 million in cost-sharing for items and services that were billed to Medicare Parts A and B, and \$48.2 million in cost-sharing for drugs that were billed to Medicare Part D, while they were in a hospice election. In total, this represents a 2012 beneficiary liability of \$183.7 million for Parts A, B, and D items or services provided to hospice beneficiaries during a hospice election. Therefore, the total non-hospice costs paid by Medicare or

due from beneficiaries for items or services provided to hospice beneficiaries during a hospice election were over \$1.2 billion in CY 2012.

All-Payer Spending: Under Part D, gross covered drug cost on a claim includes the amount paid by the Part D plan, the beneficiary's cost sharing, and any amounts paid by others on the beneficiary's behalf. These latter amounts include the low-income subsidy amount paid by Medicare for beneficiaries who are subsidy-eligible, amounts paid by other payers whose payments can be counted toward the beneficiary's true out-of-pocket (TrOOP) costs, and amounts paid by others whose payments, though not TrOOP-eligible, reduce the amount of the beneficiary's liability. Accumulated gross covered drug costs are used to establish the beneficiary's position in the benefit. That is, these costs determine when the beneficiary has met a plan's deductible, if any, and moves into the initial coverage period, and when his or her initial coverage period ends and the coverage gap begins. TrOOP, whether paid by the beneficiary or on the beneficiary's behalf by a TrOOP-eligible payer, determines when

the beneficiary has met the annual out-of-pocket threshold and moves into the catastrophic phase of the benefit. Thus, administration of the Medicare prescription drug benefit is dependent upon both gross covered drug costs and TrOOP. As such, we are also describing total non-hospice Part D spending, both Medicare and non-Medicare. Non-hospice Part D spending for hospice beneficiaries during a hospice election was incurred by Medicare, by States, by the Veterans Administration, by TRICARE, by charities, and by other payers, in addition to the cost-sharing liabilities incurred by beneficiaries.

Part D spending by all-payers that occurred for hospice beneficiaries during a hospice election, including beneficiary cost-sharing, totaled \$417.9 million in CY 2012. If this is added to the \$710.1 million in Medicare spending for Parts A and B, and \$135.5 million in cost sharing for Parts A and B, total non-hospice costs are \$1.3 billion. We do not have data on other payers' spending for Part A or Part B services. Of note, 51.6 percent of this \$1.3 billion is associated with 373 hospices, with an average total per

beneficiary of \$1,289 in non-hospice costs.

For the current guidance regarding the coordination between Part D sponsors and hospices, we refer readers to visit the Hospice Center Web page's Spotlight section or the Coordination of Benefit section at: <http://www.cms.gov/Center/Provider-Type/Hospice-Center.html>.

The dollars spent by Part D and by beneficiaries for drugs covered outside of the hospice benefit for hospice beneficiaries during a hospice election raise concerns about whether some of these drugs should have been paid for by the hospice. We examined drug costs incurred by hospices from 2004 to 2012, using hospice cost report data adjusted to constant 2010 dollars. We saw a declining trend in the drug costs per patient day, with costs declining from a mean of \$20 per patient-day in 2004 to \$11 per patient-day in 2012 (see Table 5 below). We recognize that many hospices have become more efficient in their operations, but we are concerned that the decline in drug costs is of a magnitude that could suggest that some hospices are not providing, and thus are not incurring the costs for, all needed patient medications.

TABLE 5—COSTS PER PATIENT-DAY BY YEAR, 2010 DOLLARS

	2004	2005	2006	2007	2008	2009	2010	2011	2012
Number	n = 1,047	n = 1,218	n = 1,490	n = 1,694	n = 1,834	n = 1,882	n = 1,929	n = 2,015	n = 2,054
Provider-level drug costs per patient-day									
Mean	\$20	\$18	\$17	\$15	\$14	\$13	\$12	\$11	\$11
Std dev	(10)	(11)	(11)	(9)	(9)	(9)	(7)	(6)	(6)
Median	\$20	\$17	\$16	\$15	\$14	\$13	\$12	\$11	\$10
Trimmed means									
1%–99%	\$21	\$19	\$17	\$16	\$15	\$14	\$13	\$12	\$11
5%–95%	\$20	\$18	\$16	\$15	\$14	\$13	\$12	\$11	\$10

Source: Freestanding hospice cost reports with HCRIS release date of 1/23/2014. The costs are averaged at the provider-level and adjusted to constant 2010 dollars using the Producer Price Index for prescription pharmaceuticals.

Notes: We excluded cost reports with period less than 10 months or greater than 14 months, missing information or negative reported values for total costs or payments, were in the top and bottom 1% of cost per day, were in the top and bottom 5% of provider margins, and where the aggregate of cost centers does not equal total costs as reported.

We will continue to monitor non-hospice Medicare spending for beneficiaries during hospice elections.

B. Solicitation of Comments on Definitions of “Terminal Illness” and “Related Conditions”

1. The Development of the Medicare Hospice Benefit

Dame Cicely Saunders introduced the idea of hospice care in the United States during a lecture at Yale University in 1963. During the same decade, the international best-seller, *On Death and Dying*, published in 1969, by Dr.

Elisabeth Kubler-Ross, helped to bring death out of secrecy and brought new public awareness and discussion about dying to health care policymakers. Her interviews with over 500 dying patients shed new light on the dying process, as well as the needs and treatment wishes of those who were at the end-of-life. Her hallmark work argued for end-of-life care provided in the home, rather than in an institution, and stressed the importance of patients' being an integral part of their treatment decision-

making.⁷ In 1970, there were no formal hospice programs in the United States. However, healthcare providers started to recognize the need for a care delivery model to address the needs of those individuals who no longer wanted to seek out the aggressive, medical, curative model of healthcare for advancing illnesses and injuries. They also focused on a care delivery model that would provide pain and symptom relief that would offer an alternative to

⁷ Story, P., Knight, C. (2004). *The Hospice/Palliative Medicine Approach to End-of-Life Care*, 2nd ed. UNIPAC One.

hospitalization and would focus on the “total person,” as he or she approached the end-of-life. The hospice model of care, which had been previously introduced to the United States by Cicely Saunders, was viewed to be the type of care delivery model that could offer those services.

In 1972, Dr. Elisabeth Kubler-Ross testified at the first national hearings on the subject of death with dignity, conducted by the U.S. Senate Special Committee on Aging, and the first hospice legislation was introduced in the United States Senate, but was not enacted.⁸ Florence Wald, the Dean of the Yale School of Nursing, who attended the 1963 lecture given by Cicely Saunders, along with two pediatricians and a chaplain, founded the first United States hospice, Connecticut Hospice, in 1974. Ongoing meetings between hospice providers and hospice leaders evolved into the formation of the National Hospice Organization in 1978 (now called the National Hospice and Palliative Care Organization, or NHPCO). The first “Standards of a Hospice Program of Care” were published by National Hospice Organization in 1979. Even during the early stages of hospice development, hospice leaders were working with key legislative leaders to develop a system to reimburse hospice care in the United States.⁹ However, it was evident that before governmental reimbursement could occur, data had to be collected and analyzed to demonstrate what hospices actually provided and what costs were involved in rendering hospice care. The Health Care Finance Administration (HCFA)—now known as the Centers for Medicare & Medicaid Services (CMS)—conducted a national demonstration of 26 hospices throughout the country to study the effect of reimbursed hospice care. The results of this demonstration, as well as those sponsored by the private health insurance sector and private foundations, and along with the testimony of multiple hospice industry leaders, legislators and hospice families, helped to form the structure of the Medicare Hospice Benefit.

During Congressional committee hearings regarding the development of a Medicare hospice benefit, testimony by Paul Willging, deputy administrator of HCFA, expressed caution about embracing benefit expansions that could

lead to unexpected consequences and said that HCFA “must clearly define what we would pay for and to whom, in order to meet our responsibilities to patients, providers and the taxpayers.”¹⁰ Other stakeholders agreed that a Medicare hospice benefit needed to be structured to promote an optimum movement from a point of view of controlling costs and offering the most appropriate means of service without the development of a system that focused on just getting maximum reimbursement from Medicare. Stakeholders also agreed that unique characteristics of hospice care should be maintained. The goal was not to have the Federal government provide total support to hospice programs; rather, legislation would be enacted that would supplement the continued support of the local community, private sector and other resources which allow hospices to maintain their unique identity, spirit of volunteerism and altruistic focus.¹¹ The National Hospice Organization president, Dr. Edwin Olsen, testified at the March 25, 1982 Congressional hearing that, at that time, most American hospices were community charities by design and intent, and that hospice offered an integrated service. Hospices functioned not as an add-on, but as a comprehensive alternative to the typical ways of caring for the terminally ill and their families. The hospice industry, as discussed in Dr. Olsen’s testimony, was very clear that their goal was to maintain that alternative service for those who were approaching end-of-life.

Hospice industry leaders also expressed the importance of hospice program accountability. Hospices would be accountable for and be able to control the quality and delivery of patients admitted for hospice care, instead of having to “broker” the patients out to other providers for reimbursement and convenience.¹² Hospice advocates stressed the importance of maintaining continuous clinical control over all aspects of care to ensure a successful hospice program and framers of the benefit recognized this fact by requiring professional management

responsibility.¹³ Although there were ongoing concerns by HCFA, the Congress, and the hospice industry about the potential misuse of a new hospice benefit,¹⁴ Section 122 of the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982 (Pub. L. 97–248, enacted on September 3, 1982) expanded the scope of Medicare benefits by authorizing coverage for hospice care for terminally ill beneficiaries.

2. Legislative History of the Medicare Hospice Benefit

After Medicare coverage of hospice care was authorized by the Congress, the General Accounting Office (now Government Accountability Office, or GAO) summarized the legislative intent of the Medicare hospice benefit in a July 13, 1983 letter. In this letter, the GAO acknowledged that there was no standard definition of what a hospice was or what services an organization must provide to be considered a hospice. However, the GAO stated that it was generally agreed upon that the hospice concept in the United States is one program of care in which an organized interdisciplinary team systematically provides palliative care (relief of pain and other symptoms) and supportive services to patients with terminal illnesses.¹⁶ This letter further stated that the hospice objective is to make a patient’s remaining days as comfortable and meaningful as possible and to help the family cope with the stress by making the necessary adjustments to the changes in the patient’s illness and death. The GAO letter also reiterated that hospices must directly provide certain core services including nursing care, physician services and counseling services and must either directly, or through arrangements, provide physical therapy, occupational therapy, speech-language pathology, home hospice aides, homemaker services, drugs, medical supplies and appliances and short-term inpatient care. The letter concluded by stating that the Congress would continue to monitor the effectiveness of

¹³ Health Care Financing Administration, Office of Research and Demonstrations. September, 1987. “Medicare Hospice Benefit Program Evaluation.” Health Care Financing Extramural Report. HCFA Pub. No. 03248.

¹⁴ Testimony by Paul Willging, deputy administrator of HCFA, to the Subcommittee on Health of the Committee of Ways and Means, House of Representatives, March 25, 1982.

¹⁵ Comments by Congressman Bill Gradison, at the Hearing before the Subcommittee on Health of the Committee of Ways and Means, House of Representatives, March 25, 1982.

¹⁶ “Hospice Care—A Growing Concept in the United States.” (HRD–79–50), March 6, 1979.

⁸ Cefalu, C., Ruiz, M. (2011). *The Medicare Hospice Benefit: A Changing Philosophy of Care?* Annals of Long Term Care: Clinical Care and Aging. 19 (1); 43–48.

⁹ Connor, S. (2007). *Development of Hospice and Palliative Care in the United States.* OMEGA. 56 (1); 89–99.

¹⁰ Testimony by Paul Willging, deputy administrator of HCFA, to the Subcommittee on Health of the Committee of Ways and Means, House of Representatives, March 25, 1982.

¹¹ Testimony by Congressman Leon Panetta, to the Subcommittee on Health of the Committee of Ways and Means, House of Representatives, March 25, 1982.

¹² Written testimony by Dr. Edwin J. Olsen, director of the National Hospice Organization, to the Subcommittee on Health of the Committee of Ways and Means, House of Representatives, March 25, 1982.

the hospice demonstration program, which was ongoing at the time of enactment, the equity of the reimbursement system, method and benefit structure put into effect under the hospice provision, including the feasibility and advisability of a prospective reimbursement system for hospice care and other aspects of the hospice program.¹⁷

Further description of the Medicare hospice benefit design was provided in a report prepared by the Congressional staff for the Senate Committee on Finance on September 9, 1983. In this report, four basic principles were presented, which according to hospice advocates, distinguish hospice care from the traditional health care system:

1. The patient and his/her family are considered the unit of care.
2. A multidisciplinary team is used to assess the physical, psychological and spiritual needs of the patient and family to develop an overall plan of care and to provide coordinated care.
3. Pain and collateral symptoms associated with the terminal illness and previous treatments are controlled, but no heroic efforts are made to cure the patient.
4. Bereavement follow-up is provided to help the family cope with their emotional suffering.¹⁸

It was also noted that the statute provides that an individual, upon making an election to receive hospice coverage, would be deemed to have waived payments for certain other benefits in addition to choosing a palliative mode of treatment, except in "exceptional and unusual circumstances" as the Secretary may provide (section 1812(d)(2)(A) of the Act). Furthermore, the hospice plan of care must include assessment of the individual's needs and identification of the services to meet those needs including the management of discomfort and symptom relief.

Several Senators testified at a September 15, 1983 Hearing before the Subcommittee on Health of the Committee on Finance regarding ongoing concerns with the new Medicare hospice benefit. These Senators made it clear that the new healthcare delivery system—hospice—was to offer an alternative to institutionalized care for the terminally ill. Concerns were expressed over the

possibility that "store front" hospices would crop up as a result of Medicare reimbursement being made available for this service. The Senators stated that they wanted to maintain flexibility within the benefit without creating incentives for fraud and abuse.¹⁹ Similarly, industry advocates were also concerned that availability of Medicare reimbursement would attract interest from those simply interested in a new source of revenue. The hospice industry agreed that the Medicare hospice benefit was created, not as a new revenue source for providers, but as a benefit choice for patients and their families.²⁰ Terminally ill Medicare beneficiaries could decide not to elect hospice care, and they would continue to be able to receive all other Medicare services available, such as home health services that include skilled nursing and home health aide care, inpatient hospital services, supplies, medications, and DME. For example, in response to recent home health rulemaking, we received anecdotal comments that some home health agencies are providing palliative care to homebound terminally ill individuals who have not elected the hospice benefit. In those instances, the patient is receiving home health aide services, nursing care, and supplies needed under the home health benefit, and the DME and medications that the patient needs are still covered under Medicare Parts B and D. However, we note that, with the exception of home health, these services typically have associated co-payments and would be rendered through various different providers or suppliers, perhaps with a lack of continuity and coordination that would be provided under the Medicare hospice benefit. Under the Medicare hospice benefit, the hospice-eligible individual would receive all of those services, and more, with the hospice provider assuming the clinical and professional responsibility of coordinating all of the necessary care and services with minimal beneficiary cost sharing required outside of the hospice benefit.

3. Hospice Care Today

The Medicare hospice benefit was a unique addition to the U.S. health care system. Prior to the implementation of

the Medicare hospice benefit, the government reimbursed providers based on the cost of delivering care. Reimbursement under the Medicare hospice benefit is a fixed, per day, per level of care prospective payment structure. By creating a fixed payment for hospice care, the provider is at risk for costs that exceed the payment amount; and, if the fixed payment exceeds the cost of care, the hospice is allowed to keep the gain. Under the Medicare hospice benefit, the provider has clinical flexibility in how hospices can render care to best meet the needs of the individual patient and his or her family. This is viewed as a joint partnership between the providers of care and the federal government to provide services and the financial payment for those services for those who are dying. Hospice advocates, during the development of the benefit, welcomed this type of reimbursement structure for the flexibility it afforded in providing individualized hospice services.²¹ The hospice industry continues to recognize that the Medicare hospice benefit has always been a risk-based clinical and economic model of care stating that the fixed reimbursement model means "a fixed sum for all-inclusive end of life care."²² Similar to the more recent medical home model for primary care, hospice has always been patient-centered, comprehensive, team-based, coordinated, accessible, focused on quality and safety, and extends throughout the continuum of care.

Throughout the development of the Medicare hospice benefit, experts in the hospice field believed that the success or failure of hospice, under Medicare, would depend on the hospice plan of care, appropriate implementation of the plan of care, and the hospice team sharing the same philosophy of patient-centered, comprehensive, and holistic care.²³ A coordinated, collaborative approach to each and every hospice patient and his or her family was considered to be the most important component of the success of the Medicare hospice benefit.²⁴ During the

²¹ Testimony by Dr. Daniel Hadlock, Hospice, Inc, before the Select Committee on Aging, House of Representatives, May 25, 1983.

²² "NHPCO Comments on Washington Post Article", Retrieved on December 27, 2013. <http://www.nhpcoco.org/press-room/press-releases/nhpcoco-responds-washington-post>.

²³ Cefalau, C., Ruiz, M. The Medicare Hospice Benefit: A Changing Philosophy of Care? *Annals of Long-Term Care: Clinical Care and Aging*. 2011; 19(1): 43–48.

²⁴ Cefalau, C., Ruiz, M. The Medicare Hospice Benefit: A Changing Philosophy of Care? *Annals of*

¹⁷ GAO Letter, "Comments on the Legislative Intent of Medicare's Hospice Care Benefit," GAO-HRD-83-72, July 12, 1983.

¹⁸ "Background Materials on Medicare Hospice Benefit Including Description of Proposed Implementing Regulations," September 9, 1983. Committee on Finance, United States Senate, S. Prt. 98-88, p. 1.

¹⁹ Testimony by Senators George Mitchell and Roger W. Jepsen. Testimony before the Subcommittee on Health of the Committee on Finance, United States Senate, September 15, 1983.

²⁰ Position paper submitted by Donald J. Gaetz, president, National Hospice Organization. "Subcontracting for Nursing Services under the Medicare Hospice Benefit." Testimony before the Subcommittee on Health of the Committee on Finance, United States Senate, September 15, 1983.

development of the Medicare hospice benefit, there were concerns by both the Congress and the hospice industry regarding the potential for fraud and abuse by some providers resulting from the enactment of a Medicare hospice benefit.²⁵ One drafter of the legislation expressed that he wanted to maintain benefit flexibility by allowing hospices to render individualized care, promoting access to needed services, and providing high quality care while maintaining fiscal integrity of the Medicare Trust Funds.²⁶ This was a benefit founded in trust—trust that hospices would provide the comprehensive care and services promised during the benefit development and trust that Medicare would be a partner in helping to share the costs.²⁷ It was very clear throughout the development, and years after the implementation of the Medicare hospice benefit, that hospices were expected to make good on their promise to do a better job than conventional Medicare services for those who were at end-of-life.²⁸ Deliberately, the law made no provision for discharging a hospice patient except under very limited circumstances and only after making attempts to rectify those circumstances.²⁹ This meant that once a beneficiary elected hospice and was under one of the three 60-day election periods, a hospice could not just discharge a patient for the sake of cost or convenience. Currently, there are two 90-day election periods and unlimited 60-day election periods, as long as the beneficiary continues to meet eligibility criteria. However, hospices are still limited in the reasons for discharge, and still cannot discharge a hospice

beneficiary for cost or convenience. Our regulations at § 418.26(a) state the reasons a hospice can discharge a beneficiary from hospice services.

Since the implementation of the Medicare hospice benefit, hospice utilization continues to grow. More Medicare beneficiaries are becoming aware and educated of the benefits of hospice care. In recent years, the percentage of Medicare deaths for patients under a hospice election has increased from 20 percent in 2000 to 44 percent in 2012. Total expenditures have increased from over \$9.2 billion in 2006 to over \$15.1 billion in 2013. This observed growth far outpaces the annual market basket increases and is not solely reflective of an increase in utilization. We note that average spending per beneficiary has increased substantially between 2006 and 2013 from approximately \$9,833 in 2006 to \$11,458 in 2013.³⁰

Section 3132(a) of the Affordable Care Act provides statutory authority for CMS to reform the hospice payment system no earlier than October 1, 2013. We presented data in the FY 2014 Hospice Wage Index and Payment Rate Update Final Rule, regarding diagnosis reporting on hospice claims and opioids paid under Part D for beneficiaries in a hospice election (78 FR 48234). Recent analysis of other Part A, Part B and Part D spending in 2012 (including beneficiary cost-sharing payments of \$135.5 million for Parts A and B and \$48.2 million for Part D) shows that there was an additional \$1 billion in total Medicare spending during a hospice election (see section III.A.4). This includes Part A payments for inpatient hospitalizations and SNF stays, as well as Part B payments for outpatient and physician services, diagnostic tests and imaging, and ambulance transports. There is concern that many of these services should have been provided under the Medicare hospice benefit as they very likely were for services related to the terminal illness and related conditions. This strongly suggests that hospice services are being “unbundled”, negating the hospice philosophy of comprehensive, holistic care and shifting the costs to other parts of Medicare, and creating additional cost-sharing burden to those vulnerable Medicare beneficiaries who are at end-of-life. Duplicative payments for hospice-covered services also threaten the program integrity and fiscal viability of the hospice benefit.

³⁰ Calendar year 2013 expenditures and average spending per beneficiary were calculated using hospice claims data from the Chronic Conditions Data Warehouse (CCW), accessed on February 27, 2014.

Reports by both the Medicare Payment Advisory Committee (MedPAC) and the Office of the Inspector General (OIG) expressed similar concerns regarding the unbundling of services meant to be covered under the hospice per diem, capitated payment system. Similar to the analysis presented above, MedPAC also analyzed non-hospice utilization and spending patterns through Parts A, B and D for Medicare hospice beneficiaries. MedPAC also concluded that over \$1 billion FFS spending was attributed to providing services reported as unrelated to the terminal conditions of hospice enrollees. MedPAC went on to state that 58 percent of Medicare hospice enrollees received a service or drug outside of the hospice benefit over the course of a hospice episode. The highest shares of spending were on drugs and inpatient services.³¹ In addition, the OIG reported in June of 2012 that Medicare could be paying twice for prescription drugs for beneficiaries receiving services under the Medicare hospice benefit and recommended that CMS increase its oversight to make sure that Part D is not paying for medications already included in the Medicare hospice per diem payment rates.³² As a result of the OIG report, the CMS' Center for Program Integrity (CPI) began recoupment efforts for analgesics from Part D plan sponsors.

Ongoing Part D memo guidance has also been issued to clarify existing coverage and payment policies. All Part D memo guidance can be found on the Hospice Center Web page under “Coordination of Benefits” at <http://www.cms.gov/Center/Provider-Type/Hospice-Center.html>. In addition, the proposed rule solicited comments on processes that could be developed to address the inappropriate Part D reimbursement for medications that should be covered under the Medicare hospice per diem (see Section III.I). The purpose of these Part D guidance memos, in response to OIG reports of possible duplication of payment for drugs under the hospice per diem and Part D plans, was to outline the expectations regarding coordination of benefits and coverage responsibility between Part D plan sponsors and hospices. The ongoing concern is that

³¹ MedPAC, “Assessing payment adequacy and updating payments: hospice services”, December 13 2013. Available at: http://www.medpac.gov/transcripts/hospice_December2013_Public.pdf.

³² Office of the Inspector General, Department of Health and Human Services. Medicare Could be Paying Twice for Prescription Drugs for Beneficiaries in Hospice. June, 2012. A-06-10-00059.

Long-Term Care: Clinical Care and Aging. 2011; 19(1): 43–48.

²⁵ Comments by Congressman Bill Gradison, at the Hearing before the Subcommittee on Health of the Committee of Ways and Means, House of Representatives, March 25, 1982; Testimony by Rosemary Johnson-Hurzeler, CEO, The Connecticut Hospice, Testimony before the Subcommittee on Health of the Committee on Finance, United States Senate, September 15, 1983; Testimony by Margaret Cushman, MSN, RN, Chairman of Governmental Affairs, National Association of Home Health and Hospice Care (NAHC) before the Subcommittee on Health of the Committee on Finance, United States Senate, September 15, 1983.

²⁶ Comments by Congressman Bill Gradison, at the Hearing before the Subcommittee on Health of the Committee of Ways and Means, House of Representatives, March 25, 1982.

²⁷ Testimony by Congressman Leon Panetta, to the Subcommittee on Health of the Committee of Ways and Means, House of Representatives, March 25, 1982.

²⁸ Hoyer, T. (1998). A History of the Medicare Hospice Benefit. *The Hospice Journal*, 13(1–2), 61–69.

²⁹ Hoyer, T. (1998). A History of the Medicare Hospice Benefit. *The Hospice Journal*, 13(1–2), 61–69.

hospices are not providing the broad range of medications required by hospice beneficiaries during a hospice election, especially for those drugs classified as analgesics, antianxiolytic, antiemetics and laxatives (generally considered essential medications for palliation in a hospice population).³³ Comments received, regarding this memo guidance, highlighted that there are multiple interpretations as to the meaning of what are considered “related conditions.” Additionally, it was noted in these comments that the terms, “terminal illness”, “terminal diagnosis”, “qualifying terminal diagnosis”, and “terminal prognosis” were used interchangeably and with varying interpretations as to their meanings.

We believe the summary of the “Development of the Hospice Benefit” and the “Legislative history of the Medicare Hospice Benefit” clearly captures the expectation that hospices are to provide holistic and comprehensive services under the Medicare hospice benefit. As stated in the 1983 proposed and final rules, and reiterated in the FY 2014 Hospice Wage Index and Rate Update proposed and final rules: “It is our general view that the waiver required by law is a broad one and that hospices are required to provide virtually all of the care that is needed by terminally ill patients” (48 FR 56010). Our expectation continues to be that hospices offer and provide comprehensive, virtually all-inclusive care, and with a patient-centered approach. In order to preserve the Medicare hospice benefit and ensure that Medicare beneficiaries continue to have access to comprehensive, high-quality and appropriate end-of-life hospice care, we will continue to examine program vulnerabilities and implement appropriate safeguards in the Medicare hospice benefit, when appropriate.

4. Definition of “Terminal Illness”

Since the implementation of the Medicare hospice benefit, we have defined a “terminally ill” individual to mean “that the individual has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course” (§ 418.3). We have always interpreted “terminally ill” to mean a time frame of life expectancy and expect that the individual’s whole condition plays a role in that prognosis. Comments received in response to prior years’ proposed rules state that longstanding, preexisting conditions

should not be considered related to a patient’s terminal illness or related conditions and that chronic, stable conditions play little to no role in a patient’s terminal illness or related conditions. Commenters have also stated that controlled pain and symptoms are not considered to be related to a patient’s terminal illness or related conditions, that not all pain is related to the terminal illness and related conditions, and that comorbidities and the maintenance of comorbidities are not related to a patient’s terminal illness or related conditions. These commenters believed these types of conditions should not be included in the bundle of services covered under the Medicare hospice benefit. As previously stated in response to those comments, we believe these conditions are included in the bundle of covered hospice services. The original implementing regulations of the Medicare hospice benefit, beginning with the 1983 Hospice proposed and final rules (48 FR 38146 and 48 FR 56008), articulate a set of requirements that do not delineate between pre-existing, chronic, or controlled conditions. To be eligible to receive hospice services under the Medicare hospice benefit, the individual must be entitled to Part A and must be certified as being terminally ill, meaning that his or her medical prognosis is a life expectancy of 6 months or less if the illness runs its normal course. We have recognized throughout the federal regulations at 42 CFR Part 418 that the total person is to be assessed, including acute and chronic conditions, as well as controlled and uncontrolled conditions, in determining an individual’s terminal prognosis. All body systems are interrelated; all conditions, active or not, have the potential to affect the total individual. The presence of comorbidities is recognized as potentially contributing to the overall status of an individual and should be considered when determining the terminal prognosis. The National Hospice and Palliative Care Organization (NHPCO) defines “comorbidity,” as: “known factors or pathological disease impacting on the primary health problem and generally attributed to increased risk for poor health status outcomes.”³⁴

We have defined “palliative care”—the nature of the care provided under the hospice benefit—in our regulations

at § 418.3 to mean patient and family-centered care that optimizes quality of life by anticipating, preventing and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social and spiritual needs and to facilitate patient autonomy, access to information and choice. Note that, in this definition, palliative care is to anticipate and prevent, as well as treat, suffering. This indicates that hospices are to be proactive in their care approach and not just reactive to pain and symptoms after they arise.

Because hospice care is unique in its comprehensive, holistic, and palliative philosophy and practice, we want to ensure that the hospice services under the Medicare hospice benefit are preserved and not diluted, or unbundled in any way. For context, the definition of illness means “an abnormal process in which aspects of the social, physical, emotional, or intellectual condition and function of a person are diminished or impaired compared with that person’s previous condition”.³⁵ An intensive review of the history of hospice, hospice philosophy and legislative actions described above provided the basis for discussion among several CMS clinical leaders across several agency components as to the meaning of “terminal illness” within the context of the Medicare hospice benefit. After a review of all of the history listed above, the clinical collaborative effort across CMS solicited comments on the following definition of “terminal illness”: “Abnormal and advancing physical, emotional, social and/or intellectual processes which diminish and/or impair the individual’s condition such that there is an unfavorable prognosis and no reasonable expectation of a cure; not limited to any one diagnosis or multiple diagnoses, but rather it can be the collective state of diseases and/or injuries affecting multiple facets of the whole person, are causing progressive impairment of body systems, and there is a prognosis of a life expectancy of 6 months or less”. We did not propose any definitions but asked for public input on this definition for possible future rulemaking.

5. Definition of “Related Conditions”

Section 1812(d)(2) of the Act provides that an individual, upon making an election to receive hospice coverage, would be deemed to have waived payments for certain other benefits

³³ World Health Organization. (January, 2013). Essential Medications in Palliative Care.

³⁴ National Hospice and Palliative Care Organization: “Standards of Practices for Hospice Programs”, 2010. Retrieved on February 20, 2014 from: <http://www.nhpco.org/nhpco-standards-practice>.

³⁵ Mosby’s Medical Dictionary, 8th edition, 2009, Elsevier.

except in “exceptional and unusual circumstances as the Secretary may provide.” Comments received on the 1983 Hospice proposed rule specifically asked for further CMS clarification regarding the concept of “related conditions.” Specifically, the commenters suggested a more detailed definition of what constitutes care for a patient’s terminal illness or related conditions (which is the responsibility of the hospice) and what constitutes care for unrelated conditions (for which out-of-hospice Medicare payment may be made) (48 FR 56010). Our response was: “. . . we have not received any suggestions for identifying ‘exceptional or unusual’ circumstances that warranted the inclusion of a specific provision in the regulations to accommodate them. Most of the comments that were made attempted to suggest this exception as a means of routinely providing non-hospice Medicare financing for the expense of costly services needed by hospice patients, and we do not view this as an appropriate interpretation of the law” (48 FR 56011). The law allows for circumstances in which services needed by a hospice beneficiary would be completely unrelated to the terminal illness and related conditions, but we believe that this situation would be the rare exception rather than the norm. We reiterated this position in the FY 2014 Hospice Wage Index and Rate Update proposed rule (78 FR 27826) as a reminder of the expectation of the holistic nature of hospice services that shall be provided under the hospice benefit, as well as to remind hospices about diagnosis reporting on hospice claims.

Therefore, in keeping with the tenets of hospice philosophy described in this section, the intent of the Medicare hospice benefit, expectations of comprehensive care, and in response to previous and ongoing stakeholder comments, the CMS clinical collaborative effort solicited comments on the following definition of “related conditions”: “Those conditions that result directly from terminal illness; and/or result from the treatment or medication management of terminal illness; and/or which interact or potentially interact with terminal illness; and/or which are contributory to the symptom burden of the terminally ill individual; and/or are conditions which are contributory to the prognosis that the individual has a life expectancy of 6 months or less.” We did not propose any new regulations but asked for public input on this definition for possible future rulemaking.

We received a significant number of comments representing diverse stakeholder groups on the definitions of “terminal illness” and “related conditions” and the impact it may have on the stakeholder groups whom provided comments. We will consider these comments and the issues raised for possible future rulemaking.

We also received several comments from End Stage Renal Disease (ESRD) stakeholder groups, noting that the solicitation of comments on the definition of “terminal illness” and “related conditions” would impede access to hospice services for ESRD beneficiaries with non-renal terminal conditions. These commenters stated that many hospices do not admit patients with ESRD because they do not want to bear the financial liability for covering dialysis. These commenters went on to say that if CMS proposes these definitions, that there should be an exception to allow those patients receiving dialysis to continue to do so under Part B while receiving hospice care under Part A. We would like to clarify that the solicitation of comments regarding the definitions of “terminal illness” and “related conditions” was not intended to address ESRD beneficiary access to hospice services with non-renal terminal conditions. As such, the current policy at Chapter 11 of the Medicare Benefit Policy Manual (Pub. 100–02), which states: “If the patient’s terminal condition is not related to ESRD, the patient may receive covered services under both the ESRD benefit and the hospice benefit. Hospice agencies can provide hospice services to patients who wish to continue dialysis treatment”, remains in effect.

C. Guidance on Determining Beneficiaries’ Eligibility for Hospice

An individual must be certified by the hospice medical director and the individual’s attending physician (if designated by the individual) as being terminally ill, meaning that the individual has a medical prognosis of a life expectancy of 6 months or less in order to receive the Medicare hospice benefit. However, we also have recognized the challenges in prognostication. It has always been our expectation that the certifying physicians will use their best clinical judgment, based on the initial and updated comprehensive assessments and collaboration with the hospice interdisciplinary group (IDG) to determine if the individual has a life expectancy of six months or less with each certification and recertification. As stated in previous rules, in reaching a decision to certify that the patient is

terminally ill, the hospice medical director must consider at least the following information per our regulations at § 418.25(b):

- Diagnosis of the terminal condition of the patient.
- Other health conditions, whether related or unrelated to the terminal condition.
- Current clinically relevant information supporting all diagnoses.

We do recognize that making a prognosis is not an exact science. Section 322 of the Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) amended section 1814(a) of the Act by clarifying that the certification of an individual who elects hospice “shall be based on the physician’s or medical director’s clinical judgment regarding the normal course of the individual’s illness.” The amendment clarified that the certification is based on a clinical judgment regarding the usual course of a terminal illness, and recognizes the fact that making medical prognostications regarding life expectancy is not exact. However, the amendment regarding the physician’s clinical judgment does not negate the fact that there must be a clinical basis for a certification. A hospice is required to make certain that the physician’s clinical judgment can be supported by clinical information and other documentation that provide a basis for the certification of 6 months or less if the illness runs its normal course.

While the expectation remains that the hospice physician will determine a beneficiary’s eligibility for hospice, this is not to say that this decision cannot be reviewed if there is a question as to whether or not the clinical documentation supports a patient’s hospice eligibility as hospice services provided must be reasonable and necessary for the palliation and management of the terminal illness and related conditions. The goal of any review for eligibility is to ensure that hospices are thoughtful in their eligibility determinations so that hospice beneficiaries are able to access their benefits appropriately. CMS’ right to review clinical documentation that supports physician certifications has been established in federal court and by the agency in an administrative ruling. (See, for example, HCFA Ruling, 93–1 *Weight to be Given to a Treating Physician’s Opinion in Determining Medicare Coverage of Inpatient Care in a Hospital or Skilled Nursing Facility* (May 18, 1993); *Maximum Comfort, Inc. v. Leavitt* (512 F.3d 1081 (9th Cir. 2007)); *MacKenzie Medical Supply v. Leavitt* (506 F.3d 341 (4th Cir. 2007))). In order

to be covered under Medicare Part A, the care must also be reasonable and necessary. There has always been a statutory prohibition (section 1862 (a)(1)(C) of the Act) against payment under the Medicare program for services which are not reasonable and necessary for the palliation or management of terminal illness. Additionally, section 1869(a)(1) of the Act makes clear that the Secretary makes determinations concerning entitlement, coverage and payment of benefits under part A and part B of Medicare.

We are reminding providers that there are multiple public sources available to assist in determining whether a patient meets Medicare hospice eligibility criteria (that is, industry-specific clinical and functional assessment tools and information on MAC Web sites). Additionally, we expect that hospices will use their expert clinical judgment in determining eligibility for hospice services. We expect that documentation supporting a 6-month or less life expectancy is included in the beneficiary's medical record and available to the MACs when requested.

If a beneficiary improves and/or stabilizes sufficiently over time while in hospice such that he/she no longer has a prognosis of 6 months or less from the most recent recertification evaluation or definitive interim evaluation, that beneficiary should be considered for discharge from the Medicare hospice benefit. Such beneficiaries can be re-enrolled for a new benefit period when a decline in their clinical status is such that their life expectancy is again 6 months or less. On the other hand, beneficiaries in the terminal stage of their illness that originally qualified for the Medicare hospice benefit but stabilize or improve while receiving hospice care, yet have a reasonable expectation of continued decline for a life expectancy of less than 6 months, remain eligible for hospice care. The hospice medical director must assess and evaluate the full clinical picture of the Medicare hospice beneficiary to make the determination whether the beneficiary still has a medical prognosis of 6 months or less, regardless of whether the beneficiary has stabilized or improved. There are prognostication tools available for hospices to assist in thoughtful evaluation of Medicare beneficiaries for determining terminally ill eligibility for the Medicare hospice benefit. We expect hospice providers to use the full range of tools available, including guidelines, comprehensive assessments, and the complete medical record, as necessary, to make responsible and thoughtful

determinations regarding terminally ill eligibility.

We have always acknowledged the uniqueness of every Medicare beneficiary and support thorough and thoughtful evaluation in determining whether beneficiaries meet the eligibility criteria for being certified as terminally ill. We continue to support the concept of shared decision-making, patient choice and the right care at the right time to allow Medicare beneficiaries full and appropriate access to their Medicare benefits, including hospice care. Furthermore, Medicare hospice beneficiaries have certain guaranteed rights. If the hospice or designated attending physician believes that the hospice beneficiary is no longer eligible for hospice care because his or her condition has improved, and the beneficiary does not agree with that determination, the hospice beneficiary has the right to ask for a review of his or her case. The hospice should provide the hospice beneficiary with a notice that explains his or her right to an expedited review by a contracted independent reviewer hired by Medicare, called a Quality Improvement Organization (QIO). If the hospice beneficiary asks for this appeal, the QIO will determine if the beneficiary continues to meet eligibility requirements for hospice services. The provider is expected to continue to provide services for the patient following a favorable decision by a QIO. In the QIO decision, the QIO should advise the provider as to why it disagrees with the hospice, which should help the provider to re-evaluate the discharge decision. If at another point in time during a hospice election, the hospice believes that the patient is no longer hospice eligible, the provider should timely deliver a CMS-10123 to notify the patient of its decision to discharge. The patient could again appeal to the QIO. Medicare beneficiaries have the right to be included in decisions about their care, the right to a fair process to appeal decisions about payment of services, and the right to privacy and confidentiality. No proposals were made regarding hospice eligibility nor were comments solicited. This discussion only provides background information regarding current procedures for determining eligibility for hospice services under the Medicare hospice benefit and beneficiary appeal rights.

D. Timeframe for Hospice Cap Determinations and Overpayment Remittances

When the Medicare hospice benefit was implemented, the Congress

included 2 limits on payments to hospices: an inpatient cap and an aggregate cap, as described in sections 1861(dd)(2)(A)(iii) and 1814(i)(2)(A) through (C) of the Act. The hospice inpatient cap limits the total number of Medicare inpatient days to no more than 20 percent of a hospice's total Medicare hospice days. The intent of the inpatient cap was to ensure that hospice remained a home-based benefit. The hospice aggregate cap limits the total aggregate payment any individual hospice can receive in a year. The intent of the hospice aggregate cap was to protect Medicare from spending more for hospice care than it would for conventional care at the end of life.

The aggregate cap amount was set at \$6,500 per beneficiary when first enacted in 1983; this was an amount hospice advocates agreed was well above the average cost of caring for a hospice patient.³⁶ The \$6,500 amount is adjusted annually by the change in the medical care expenditure category of the consumer price index for urban consumers from March 1984 to March of the cap year. For the 2013 cap year, the cap amount was \$26,157.50 per beneficiary. The cap year is defined as the period from November 1st to October 31st, and was set in place in the December 16, 1983 hospice final rule (48 FR 56022).

The cap amount is multiplied by the number of Medicare beneficiaries who received hospice care from a particular hospice during the year, resulting in its hospice aggregate cap, which is the allowable amount of total Medicare payments that hospice can receive for that cap year. There are two different methods for counting a hospice's beneficiaries: the streamlined and the patient-by-patient proportional methods. Which method a hospice can use to count beneficiaries depends on a number of factors, as described in our regulations at § 418.309 and in section 90.2.3 of the hospice Benefit Policy Manual (IOM 100-02, chapter 9, available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c09.pdf>). A hospice's total Medicare payments for the cap year cannot exceed the hospice's aggregate cap. If its aggregate cap is exceeded, then the hospice must repay the excess back to Medicare.

While hospices rarely exceed the inpatient cap, in its March 2012 Report to the Congress, MedPAC reported that

³⁶ National Hospice and Palliative Care Organization (NHPCO), "A Short History of the Medicare Hospice Cap on Total Expenditures." Retrieved on February 19, 2014 at: http://www.nhpco.org/sites/default/files/public/regulatory/History_of_Hospice_Cap.pdf

an increasing number of hospices are exceeding the aggregate cap. MedPAC also noted that above-cap hospices were almost all for-profit with very long lengths of stay, high live discharge rates, and very high profit margins before the return of cap overpayments.³⁷ The percentage of hospices exceeding the aggregate cap rose from 2.6 percent in 2002 to a peak of 12.5 percent in 2009. In 2010, the percentage of hospices exceeding the aggregate cap decreased to 10.1 percent.³⁸

Our hospice reform contractor also performed analysis on the number of hospices exceeding the aggregate cap with results similar to MedPAC's, where an increasing percentage of hospices exceeded their caps from 2006 (9.1 percent) to a peak in 2009 (12.8 percent), followed by a decline through 2011 (10.5 percent). However, the analysis shows an increase in 2012, with 11.6 percent of hospices exceeding their aggregate caps. Additionally, analysis of above-cap hospices showed that the average overpayment per beneficiary has increased over time, up 35.2 percent from 2006 (\$7,384) to 2012 (\$9,983). Using above-cap hospices, we also found that the average overpayment amount went from \$732,103 in 2006 to \$440,727 in 2011, but that this downward trend is estimated to change in 2012, when the average overpayment amount is estimated to increase to \$547,011.

We also compared hospices' year-end percentage of their aggregate cap total that they had received in Medicare payments over time. Specifically, we examined where hospices ended their cap year in terms of Medicare reimbursements received, relative to that year's aggregate cap limit, by comparing the 2006 cap year to the 2012 cap year. Analysis revealed that more hospices ended the 2012 cap year "just below" their aggregate cap than in 2006. The cap analyses which are referenced in this section are available in the May 2014 Technical Report was posted in May, 2014 on our Hospice Center Web page at: <http://www.cms.gov/Center/Provider-Type/Hospice-Center.html>.

The results from these recent analyses on the hospice aggregate cap highlight the importance of hospices monitoring their aggregate cap and ensuring that the beneficiaries under their care are truly eligible for hospice services. In the FY 2010 hospice wage index proposed rule, we solicited comments on the aggregate hospice cap (74 FR 18920–18922). Many

commenters wanted more timely notification of cap overpayments. Many also requested that hospices be given access to beneficiaries' full hospice utilization history, as having this information would enable hospices to better manage their aggregate cap. In response to concerns from hospices, we redesigned the Provider Statistical and Reimbursement (PS&R) system in 2011, so that hospices can now easily manage their inpatient and aggregate caps. The redesigned PS&R enables hospices to calculate estimated caps to monitor their cap status at different points during the cap year, and also enables them to calculate their caps after the cap year ends.

Our current practice is for the Medicare Administrative Contractors (MACs) to complete the hospice cap determinations for both the inpatient and the aggregate caps 16 to 24 months after the cap year in order to demand any overpayment. We are concerned about this long timeframe, particularly given that the percentage of hospices exceeding the aggregate cap is increasing, along with the average overpayment per beneficiary. To better safeguard the Medicare Trust Funds, we believe that demands for cap overpayments should occur sooner. This is now possible due to the redesigned PS&R system.

Therefore, for the 2014 cap year and subsequent cap years, we proposed to amend § 418.308 and require that hospices complete their inpatient and aggregate caps determination within 5 months after the cap year ends (that is, by March 31) and remit any overpayments at that time. We proposed that the MACs would then reconcile all payments at the final cap determination. If a provider fails to file its inpatient and aggregate cap determination 5 months after the end of the cap year, we proposed that payments to the provider would be suspended in whole or in part until the self-determined cap is filed with the Medicare contractor. We proposed to further amend § 418.308 and § 405.371 to state that payments to a hospice would be suspended in whole or in part, for failure to file a self-determined inpatient and aggregate cap determination. This is similar to the current practice followed by all other provider types that file cost reports with MACs.

We proposed that hospices would be provided a pro-forma spreadsheet that they would use to calculate their caps to remit any overpayments. The redesigned PS&R system provides the inpatient days, total days, beneficiary counts, and Medicare payments that are needed to calculate any inpatient or

aggregate cap overpayments. The redesigned system can provide needed data whether a hospice uses the streamlined method or the patient-by-patient proportional method for its aggregate cap calculation. All hospices are required to register in Individuals Authorized Access to CMS Computer Services (IACS) and obtain their PS&R report from the PS&R system. Hospices experiencing difficulties can request a copy of their PS&R report from their MAC.

Twenty six public comments and our responses are summarized below.

Comment: Several commenters suggested that the Medicare Administrative Contractors (MACs) should complete the initial cap determination instead of the hospices. Some of the concerns are that the proposal would increase the hospices administrative costs, and this would be especially burdensome for small hospices. There were suggestions that CMS establish criteria to target providers that are more likely to exceed the cap if the concern was about the MACs workload.

Response: The reason for this proposal is for hospices to determine and remit any overpayment. We do not believe this proposal would be overly burdensome to the hospices; some hospices are already using the information needed to complete the self-determined cap to manage their cap. The net reimbursement and beneficiary count needed to calculate the cap overpayment are reported on the Provider Statistical & Reimbursement (PS&R) report. A pro-forma spreadsheet for calculating the cap will be provided. The MACs are still required to issue the final cap determination and reconcile any overpayments received.

Comment: Some commenters suggested that the cap calculation should be integrated with the cost report that hospices are currently required to file in order to minimize the administrative burden on the hospices.

Response: This suggestion is not practical at this time. The hospice cap period of November 1–October 31 is not aligned with the hospices' various cost reporting fiscal years, and the hospice cap calculation is not based on the Medicare cost report.

Comment: Commenters were concerned that the proposal for hospices to file a self-determined cap calculation and remit any overpayment within 5 months after the cap period would not achieve the stated goal of protecting the Medicare Trust Funds. Early calculation of the hospice cap liability will underestimate the amount owed by hospices that are over the cap. The 5

³⁷ MedPAC, "Report to Congress: Medicare Payment Policy", March 2012, pp. 293–295, 302.

³⁸ MedPAC, "Report to Congress: Medicare Payment Policy", March 2013, p. 276.

months proposed for hospices to file their self-determined cap is vulnerable to gaming because a hospice could choose to perform its cap calculation immediately after the close of the cap year when its cap liability will be lowest. Some commenters suggested that CMS should instruct providers not to request data to calculate their cap liability earlier than 90 days after the end of the cap period in order to allow for most of the hospice claims to be processed before the completion of the cap calculation.

Response: We agree that allowing up to 5 months to calculate the cap without a minimum time for allowing claims to process is vulnerable to “gaming” by hospices. The goal is to require the hospices to submit an accurate cap determination within 5 months of the end of the cap year. In order to increase the reliability of the determination, we will require that hospices use payment data not earlier than 3 months after the cap year to determine their cap overpayment due 5 months after the cap year. This will improve the accuracy of the calculation by ensuring that most claims have been processed, while still allowing a reasonable period of time for the hospice to complete the calculation.

For example, the cap year ending October 31, 2015 would result in the hospice providing its cap determination and any associated overpayment to their MAC by March 31, 2016. In order to allow a reasonable number of claims to be processed, the hospice shall wait at least 3 months after the end of the cap year, or January 31, 2016, before attempting to calculate the cap overpayment. Thus, the cap determination would be calculated after January 31, 2016 but before March 31, 2016 and the overpayment would be submitted at the same time as the cap determination.

We plan to continue to monitor hospices that may be “gaming” the system, and CMS has the option of performing a cap review at any time after the end of the cap year, if needed. In addition, MACs will review the hospices’ cap determinations at a later time in order to ensure that they are accurate and to reconcile them with updated claims data.

Comment: Several commenters suggested that CMS should not recoup any overpayment as a result of the self-determined cap calculation until the MACs issue the final cap determination.

Response: While completing the self-determined calculation as proposed will inform hospices about whether or not they are over the cap as early as possible, it will not protect the Medicare Trust Fund if the overpayments are not

recouped. Other provider types that file Medicare cost reports 5 months after the cost reporting year end are required to remit any overpayments at the time the cost reports are filed. Sometimes the final settlements of Medicare cost reports are issued 2 to 3 years after the cost reports were filed. The same process is proposed for hospice providers, since the cap calculations are not reconciled on the cost reports themselves. MACs will reconcile the final payments when it issues the final cap determination. The final cap determination includes the appeal rights for the hospice.

Comment: Several commenters were concerned that the proposal did not address the availability of the Extended Repayment Schedule (ERS) for providers that exceed the cap.

Response: This proposal is not changing the current ERS availability. Providers that have overpayments as a result of the self-determined cap calculation will follow the same overpayment processes that were in effect prior to this requirement.

Comment: A commenter suggested that CMS should consider eliminating the requirement that hospices determine the inpatient cap overpayment because the calculation involved is more complex than those required for determining the aggregate cap. Since most providers do not exceed the inpatient cap, they are not experienced in performing the calculation required.

Response: We agree with the commenter that most providers do not exceed the inpatient cap limitation, and that calculation of the inpatient cap is more complex than the aggregate cap calculation. We are eliminating the requirement that hospices complete a self-determined inpatient cap liability in order to address stakeholders concerns regarding the complexity of the calculation. The Medicare contractors will continue to calculate the inpatient cap limitation. We will continue to monitor the inpatient cap and consider implementing in the future if needed. However, the self-determined aggregate cap calculation proposal is being implemented in this final rule.

Comment: Some commenters suggested that the MACs be required to review the providers’ submitted self-determined cap amounts and alert hospices of any discrepancies in the calculation or provide notice of acceptance of the hospices calculations. Some commenters suggested that a formal adjudication process should be included in the proposal if there is discrepancy between the providers’ data and the Providers Statistical and Reimbursement (PS&R) system.

Response: The MACs will review the submitted self-determined cap calculation for errors but not necessarily recalculate the submitted cap in all cases for accuracy. The MACs will issue a final cap determination at a later date. Under the current process, providers have the option of using their data to file the cap report if they disagree with the PS&R report. Providers using their data to file their cap calculation will need to provide documentation to support the calculations. The MAC will subsequently issue a final cap determination, which will include appeal rights for the hospice.

Comment: A commenter suggested that the MACs should provide advance notification to the hospices regarding the requirement to file a cap determination and the due date.

Response: We are not requiring the MACs to send advance notification to the hospices at this time. We will work with the MACs in order to distribute educational material regarding the calculation of the cap, and access to the PS&R. While all providers have been instructed to obtain their own PS&R reports, some may not have used such reports. Hospices will be informed of their requirements through various educational materials.

Comment: A commenter that supported the proposal suggested that CMS delay this requirement to allow providers time to prepare for the changes, and allow those that currently do not have access to the PS&R system to register. Another suggested that CMS phase-in the proposal over a three year period.

Response: We do not believe phasing the requirement that hospices calculate their cap overpayment over a three year period will reduce the burden on hospices and will ensure hospices’ ability to calculate the cap accurately. We appreciate the commenter’s concern about providers who are not currently registered to obtain their PS&R report. Providers have received instructions regarding access to the PS&R system on numerous occasions, and we will work with the MACs to remind providers how to access the PS&R system, and explain how to access and utilize the hospice reports.

Comment: Some commenters raised concern about the ability of hospices that are not registered in CMS’ authentication and authorization system (IACS) to obtain a copy of their PS&R report. A commenter stated that since most providers only access the PS&R system once in a year, their accounts are deactivated after six months of inactivity and would be unable to obtain a copy of their PS&R report. The

commenter suggested that CMS change the deactivation of account after six months of inactivity.

Response: The security protocol of the CMS authentication and authorization system needed to access the PS&R system is beyond the scope of this proposal. It should be noted, however, that accounts are not deactivated after six months of inactivity. Accounts are only deactivated when a user fails to recertify its account, which is usually once a year. The system sends out several notification emails 45 days prior to the recertification date, and everyday 15 days prior to the due date. Providers that failed to change their password every 60 days need only to complete the specific password steps in order to reset their password. Since the PS&R reports will be a source of information for calculation of the caps, we do not expect problems with system inactivity subsequent to the issuance of this final rule.

Comment: A commenter suggested that the CMS employ electronic delivery of important notices, like overpayment determinations.

Response: This is outside the scope of this proposal.

Comment: A commenter was concerned that providers are not able to obtain the beneficiary count for patients served by more than one provider, and that this information is only available to the MACs.

Response: This statement is not accurate. The PS&R report provides summary beneficiary count for patients served by more than one hospice, and the summary report is available for providers to request.

Comment: Some commenters suggested that CMS should include in the proposal a time frame for the MACs to complete the final cap reviews

Response: We are not proposing a requirement at this time. We will continue to work with the MACs regarding this process.

Comment: A commenter noted that the proposed rulemaking under the Affordable Care Act required that Medicare providers and suppliers to report and return overpayments 60 days from the date the liability is identified. CMS should provide hospices 60 days from 150 days to refund any overpayment as a result of the self-cap determination.

Response: We agree that the Affordable Care Act requires that providers and suppliers report and refund overpayments within 60 days from when identified. The Overpayment rule resulting from the Affordable Care Act has not been finalized as of the date this rule was finalized; and therefore, is

outside of the scope of this proposal. As noted above, the requirement that hospices pay the overpayment when they file their cap determination is similar to the requirement for other provider types that final payment reconciliation are completed on the Medicare cost report.

Comment: Some commenters applauded the proposal stating that it allows hospices to better manage their cap, and they will be aware of their cap situation soon after the cap year in order to implement changes to better manage their cash flow in light of hospices' responsibility to reconcile their overpayments with amounts allowed by CMS.

Response: We agree with the commenters and thank them for their support.

Final action: We are finalizing the proposal to require hospices to submit the aggregate cap determination 5 months after the end of the cap year and refund any overpayment with the filed cap determination. We are eliminating the proposal that hospices complete the self-determined inpatient cap limitation as part of this proposal, but will continue to monitor the inpatient cap and consider implementing in the future if needed. In addition, we are requiring hospices to wait at least 3 months after the end of the cap year to calculate the self-determined aggregate cap, in order to include a reasonable number of claims. Finally, we are finalizing the proposal that hospices which fail to file their self-determined cap determination will have their payments suspended.

E. Timeframes for Filing the Notice of Election and Notice of Termination/Revocation

1. Timeframe for Filing the Notice of Election

A distinctive characteristic of the Medicare hospice benefit is that it requires patients (or their representative) to intentionally choose hospice care through an election. As part of that election, patients (or their representative) acknowledge that they fully understand the palliative, rather than curative, nature of hospice care. Another important aspect of the election is a waiver of beneficiary rights to Medicare payment for any Medicare services related to the terminal illness and related conditions during a hospice election except when provided by, or under arrangement by, the designated hospice, or by the individual's attending physician if he/she is not employed by the designated hospice (§ 418.24(d)).

Because of this waiver, providers other than the designated hospice or

attending physician cannot receive payment for services to a hospice beneficiary unless those services are unrelated to the terminal illness and related conditions. For our claims processing system to properly enforce this waiver, it is necessary for the hospice election to be recorded in the claims processing system as soon as possible after the election occurs. A survey of the four Medicare Administrative Contractors (MACs) revealed that 16.2 percent of NOEs are filed within 2 days of the effective date of election, 39.2 percent of NOEs are filed within 5 days of the effective date of election, and 62.1 percent of NOEs are filed within 10 days of the effective date of election. Prompt recording of the notice of election (NOE) prevents inappropriate payments, as claims filed by providers other than the hospice or the attending physician will be rejected by the system, unless those claims are for items or services unrelated to the terminal illness and related conditions. Prompt filing of the NOE also protects beneficiaries from financial liability from deductibles and cost sharing for items or services provided during a hospice election which are related to the terminal prognosis.

Once a NOE is filed, the hospice election and benefit period are established in the Common Working File (CWF) and in the Daily Transaction Reply Report (DTRR). The CWF is used by Part A and Part B providers, and the DTRR is used by Part D plan sponsors, to determine whether a beneficiary is a hospice patient. This information is necessary for providers and suppliers to properly handle claims for beneficiaries under a hospice election.

Our hospice reform contractor has performed analyses of Medicare expenditures for drugs and services provided to hospice beneficiaries during a hospice election. These analyses found that Medicare Part D was paying for many drugs that should have been provided by the hospice during a hospice election. We also found that Parts A and B were paying claims for items or services from non-hospice providers during a hospice election (See section III.A.4), though some of these claims may have been appropriate. Once a hospice election is established in the CWF, in order for claims from other providers to process, the claim must be from the attending physician and coded with a "GV" modifier, or for items or services unrelated to the terminal illness and related conditions and must be coded with either a condition code of "07" or a "GW" modifier. However, in calendar year 2012, 10,500 claims and 2.4 million line items, totaling \$159

million were processed without the condition code or modifier. Of this \$159 million, approximately \$100 million was from physician/supplier Part B claims that include claims from physicians, laboratories, and ambulance companies, and approximately \$46 million was billed as durable medical equipment. This suggests that these claims may have been processed in the time between when the beneficiary elected hospice and when the hospice filed its NOE. When Parts A, B, or D pay claims for items or services during a hospice election, there is typically an associated beneficiary liability (such as deductibles or copayments). For example, in 2012 the hospice beneficiary liability for items or services provided to hospice beneficiaries during a hospice election was \$135.5 million for Part A or B claims, and \$48.2 million for Part D claims. We want to safeguard hospice beneficiaries from inappropriate financial liability during a hospice election for items or services that should be provided by the hospice. Please see section III.A.4 of this final rule and the May 2014 Technical Report, which was posted on the CMS Hospice Center Web page in May 2014, for more details on Medicare payments made to non-hospice providers during a hospice election for hospice beneficiaries. The hospice center Web page can be accessed at <http://www.cms.gov/Center/Provider-Type/Hospice-Center.html>.

In the April 1, 2013 CMS Part D Final Call Letter, it was noted that delays in the flow of hospice election information cause retroactive updates to the information sent to Part D plan sponsors on the DTRR, and plan sponsors requested that CMS improve the timeliness of the hospice data on the DTRR.³⁹ More recently, CMS issued a memorandum on December 6, 2013 entitled “Part D Payment for Drugs for Beneficiaries Enrolled in Hospice,” which sought to clarify the criteria for determining payment responsibility for drugs for hospice beneficiaries.⁴⁰ Industry commenters described the lag time in the notification of Part D plan sponsors that the beneficiary had elected hospice, revoked hospice, or

been discharged alive from hospice as a key problem in determining payment responsibility. Commenters suggested that CMS require that the NOE be filed within a short timeframe of election (for example, within 48 hours).

The CWF is also used by hospices to identify the current benefit period, which helps hospices determine when a face-to-face encounter is required. We have received requests for assistance from hospices where a beneficiary was previously admitted to and then discharged from another hospice, which had not yet filed the NOE, creating a problem for the current hospice in determining the correct benefit period. This can lead to the current hospice not meeting the face-to-face requirement. Additionally, because of sequential billing requirements, the current hospice would have to cancel its NOE and all of its billing for that beneficiary to allow the previous hospice to input its NOE and billing. Once the previous hospice had filed its claims and recorded the beneficiary's discharge, the current hospice could then resubmit its NOE and its claims. The failure of the first hospice to file its NOE promptly created an administrative burden for the second hospice.

In summary, prompt filing of the NOE avoids compliance problems with the statutorily mandated face-to-face requirement. It also avoids creating burdensome situations for hospices when sequential billing requirements are not met. Finally, because Medicare payments for services related to the terminal illness and related conditions are waived once a hospice election is in place, it is crucial that the NOE be filed promptly to safeguard the integrity of the Medicare Trust Fund and enable smooth and efficient operation of other Medicare benefits (like Part D), and to safeguard hospice beneficiaries from inappropriate financial liability due to cost sharing and deductibles for services related to the terminal prognosis. For all of these reasons, we proposed that a hospice must file the NOE with its Medicare contractor within 3 calendar days after the hospice effective date of election, regardless of how the NOE is filed (by direct data entry, or sent by mail or messenger). We believe that this proposed requirement would relieve hospices of the burden created when some minority of hospices do not file their NOEs promptly, would avoid inappropriate payments to other Part A, Part B, or Part D providers, and would safeguard beneficiaries from inappropriate liability for copayments or deductibles.

Currently, payment for hospice services begins on the effective date of

the hospice election, regardless of when the NOE was filed. A commenter on the December 6, 2013 CMS memorandum clarifying drug payment responsibility between Part D, hospice, and beneficiaries suggested that without enforcement actions, hospices would not file NOEs within a short timeframe. We agree that providing a consequence for failing to file NOEs timely would encourage compliance. Therefore, we proposed that for those hospices that do not file the NOE timely (that is, within 3 calendar days after the effective date of election), Medicare would not cover and pay for days of hospice care from the effective date of election to the date of filing of the NOE. We proposed that these days be considered the financial responsibility of the hospice; the hospice could not bill the beneficiary for them. We believe that this is a reasonable step, which would not be burdensome to hospices, would help us to safeguard the integrity of the Medicare Trust Fund, and help protect beneficiaries from inappropriate liability.

Once filed, the process of posting an NOE to the CWF after direct data entry (DDE) takes 1 to 5 days, depending on the host site. If an NOE is not submitted by DDE, the current policy requires hospices to send it to the Medicare contractor by mail or messenger. This policy remains in place; however, hospices may need to use overnight mail or an overnight messenger to ensure that paper NOEs are received by the Medicare contractor within the required timeframe after the effective date of election (On average, only 68 NOEs are filed by mail or messenger per year). Using a speedier form of delivery will ensure that a paper NOE's filing is not delayed by the transit time needed to get the document from the hospice to the Medicare contractor.

2. Timeframe for Filing the Notice of Termination/Revocation

In accordance with 42 CFR 418.26, hospices may discharge patients for only three reasons: (1) Due to cause; (2) due to the patient's no longer being terminally ill; or (3) due to the patient's moving outside the hospice's service area. In contrast, hospice patients are free to revoke their election to hospice care at any time. Upon discharge or revocation, a beneficiary resumes the Medicare coverage that had previously been waived by the hospice election. It is important for hospices to record the beneficiary's discharge or revocation in the claims processing system in a timely manner. As previously noted, a number of those commenting on the December 6, 2013 CMS memorandum clarifying

³⁹ CMS, “Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter,” issued April 1, 2013; available at <http://www.cms.gov/Medicare/Health-Plans/MedicareAdvgtSpecRateStats/downloads/Announcement2014.pdf>.

⁴⁰ Tudor CG, Wilson L, and Majestic M. “Part D Payment for Drugs for Beneficiaries Enrolled in Hospice—Request for Comments,” memorandum issued December 6, 2013, available at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Downloads/Hospice-PartD-Payment.pdf>.

drug payment responsibility between Part D, hospices, and beneficiaries wrote that it was critical for beneficiary revocations and live discharges from hospice to be recorded as soon as possible within CMS claims processing systems. Commenters on this Part D memorandum wrote that prompt recording of revocations or discharges is necessary to ensure that the beneficiary is able to access needed items or services, and to ensure that payment for the item or service is from the appropriate source. Providers are allowed 12 months to file a claim, so if a hospice is not prepared to file a final claim quickly, it should instead file a termination/revocation of election notice, so that the claims processing systems are updated to no longer show the beneficiary as being under a hospice election. Hereafter, we will refer to this as a Notice of Termination or Revocation (NOTR).

We proposed to revise the regulations at § 418.26 and § 418.28 to require hospices to file a NOTR within 3 calendar days after the effective date of a beneficiary's discharge or revocation, if they had not already filed a final claim. This would safeguard beneficiaries from any delays or difficulties in accessing needed drugs, items, or services that could occur if the CWF or DTRR continued to show a hospice election in place when in fact it was revoked or a discharge occurred. It would also avoid costs and administrative burden to non-hospice providers and to the claims processing system that would occur for claims for items or services provided after discharge or revocation, which would be rejected if the claims processing systems continued to show the beneficiary as being under a hospice election.

Comments we received with regard to the proposals to file the NOE and NOTR within 3 calendar days and the consequence for filing the NOE late are summarized below.

Comment: Nearly all commenters supported placing timeframes around the NOE and NOTR for the reasons noted in the proposed rule, but hospices cited circumstances that would make it difficult for them to comply within the proposed timeframe and some requested we phase-in the proposal. Hospice commenters suggested using business days instead of calendar days, or timeframes of 5 to 10 calendar days. Primarily beneficiary advocacy groups, pharmacy groups, and Part D plan sponsors supported 3 calendar days, with one commenter supporting 2 calendar days for the NOE and the NOTR to be filed. These commenters

also identified administrative burden issues and beneficiary impact concerns if the NOE and NOTR are not filed as soon as possible. A few commenters asked us to clarify the timeframe for NOE filing and for when a revocation begins. Another suggested that the NOE filing statistics in the rule demonstrated that hospices could not file their NOEs within a short timeframe.

Response: In response to comments received, we are finalizing the requirement for hospices to file the NOE within 5 calendar days after the effective date of the election and to file the NOTR within 5 calendar days after the date of the discharge or revocation (unless the hospice has already submitted the final claim). A timely-filed NOE is one that is submitted to, and accepted by, the Medicare contractor within 5 calendar days after the effective date of election. A timely-filed NOTR is one that is submitted to, and accepted by, the Medicare contractor within 5 calendar days after the effective date of discharge or revocation. While a timely-filed NOE or NOTR is one that is submitted to and accepted by the Medicare contractor within 5 calendar days after the hospice election or hospice discharge/revocation, posting to the CWF may not occur within that same time frame. The date of posting to the CWF is not a reflection of whether the NOE or NOTR is considered timely-filed. We believe these timeframes provide an appropriate balance of concerns expressed by the diverse comments received on the proposal, and eliminates the need to phase-in the required timeframe implemented in this final rule. Prompt filing of the NOE and NOTR is essential to protecting the Medicare Trust Fund; minimizing the effect on beneficiaries' cost-sharing; and preserving access to non-hospice services. We considered the feasibility of using business days versus calendar days; however, the Medicare claims processing system cannot distinguish between calendar days and business days. Therefore, we are not able to consider counting business days for this policy. The NOE filing timeframe statistics included in the proposed rule only indicate historical filing practices and do not indicate hospices' inability to file NOEs in a more timely fashion once a filing timeframe is implemented. As described in the existing CMS Claims Processing Manual (IOM 100-04, Chapter 11, Section 20.1.1), hospices are to submit the NOE "as soon as possible". This final policy imposes an upper limit as to when the NOE is to be submitted without the imposition of provider

liable days due to late filing of the NOE. We encourage hospices to submit the NOE and NOTR (if a final claim has not been submitted) as soon as possible and not wait until the 5th calendar day after the effective date of the election or discharge/revocation. For revocations, existing policy requires that the beneficiary must provide the hospice with a signed statement that he or she is revoking the benefit, including the effective date of the revocation, which cannot be a date earlier than the date the revocation is made, as described at 42 CFR 418.28.

Some hospice commenters identified various technical reasons as to why an NOE or NOTR may not be timely-filed. We encourage hospices to consider available electronic means of transmitting data that nurses in the field may utilize to send the election statement to their administrative office. For example, secure fax or secure email is an easily accessible means of secure data transmission. We believe that it is prudent for hospices, as a business, to establish contingency plans for situations where administrative staff who normally file the NOEs or NOTRs are on vacation, unavailable due to illness, or are unexpectedly unavailable.

We will continue to monitor the filing of NOEs and NOTRs, and will consider shortening the timeframe for what would be considered a timely-filed NOE or NOTR in future rulemaking.

Comment: A few commenters opposed the proposed consequence for late NOEs. Some commenters felt it would be unfair for hospices to experience financial consequences due to exceptional circumstances that are beyond the control of the hospice, which cause the NOE to be filed untimely. Several commenters suggested that the provider liable days resulting from failing to meet the 3 calendar day timeframe for NOE filing could cause unintended consequences, including delaying admissions.

Response: We agree that there are some circumstances that may be beyond the control of the hospice where it may not be possible to timely-file the NOE within 5 calendar days after the effective date of election or timely-file the NOTR within 5 calendar days after the effective date of a beneficiary's discharge or revocation, and appreciate the variety of examples to illustrate such exceptional circumstances. Therefore, we are finalizing an exception policy for the timely filing of the NOE, which would waive the consequences for failure to timely-file a NOE. The four circumstances that may qualify the hospice for an exception to the consequences of filing the NOE more

than 5 calendar days after the effective date of election are as follows:

1. Fires, floods, earthquakes, or other unusual events that inflict extensive damage to the hospice's ability to operate;
2. an event that produces a data filing problem due to a CMS or Medicare contractor systems issue that is beyond the control of the hospice;
3. a newly Medicare-certified hospice that is notified of that certification after the Medicare certification date, or which is awaiting its user ID from its Medicare contractor; or,
4. other circumstances determined by CMS to be beyond the control of the hospice.

If one of the four circumstances described above prevents a hospice from timely-filing its NOE, the hospice must document the circumstance to support a request for an exception, which would waive the consequences of filing the NOE late. Using that documentation, the hospice's Medicare contractor will determine if a circumstance encountered by a hospice qualifies for an exception to the consequences for filing an NOE more than 5 calendar days after the effective date of election. If the request for an exception is denied, the Medicare contractor will retain the decision of the denial. Hospices retain their usual appeal rights on the claim for payment. The Medicare contractors will provide hospices with information on how to request an exceptional circumstance and a waiver of the consequence of filing the NOE late after the publication of this final rule. Sub-regulatory guidance will detail the procedures a hospice would follow.

Based on the exceptions described above, examples such as personnel issues; internal IT systems issues that the hospice may experience; the hospice not knowing the requirements; and failure of the hospice to have back-up staff to file the NOE are not acceptable circumstances that meet the exceptions. Therefore, late-filing consequences would be applied. For those hospices which do not timely-file the NOE (that is, the NOE is submitted to, and accepted by, the Medicare contractor within 5 calendar days after the effective date of election), Medicare will not cover and pay for the days of hospice care from the effective date of election up to the date the NOE is submitted to, and accepted by, the Medicare contractor. The date the NOE is submitted to, and accepted by, the Medicare contractor would be a covered day.

Given the longer timeframe for timely-filing the NOE and the exceptional

circumstances that we are implementing, we do not believe that hospices would delay admitting beneficiaries to avoid provider liable days. We will monitor for any unintended consequences of the policy.

Under the Medicare hospice benefit, hospices are responsible for providing all care and services to the beneficiary for the palliation and management of the terminal illness and related conditions from the effective date of election to the date of death, or effective date of discharge/revocation, even if some of those days are a provider liability due to a late-filed NOE. The hospice remains responsible for covering all hospice medical, nursing, counseling, social work, and aide services, as well as all hospice drugs, DME, supplies, etc. as needed by the patient, in accordance with the plan of care, during provider liable days.

Comment: Multiple commenters suggested a consequence for NOTRs filed late because they considered the filing of the NOTR as more critical from a beneficiary access to care standpoint. Late-filing of the NOTR could create problems for beneficiaries in accessing Part D medications or critical Medicare services, with a few commenters recommending a shorter timeframe than that for the NOE.

Response: We appreciate the comments recommending a consequence for late-filing of NOTRs in order to protect the beneficiary's access to timely care and ensuring that the appropriate party is responsible for care and services. We are not implementing consequences for the late-filing of the NOTR at this time, but will consider doing so in future rulemaking.

Comment: Many commenters described systems issues which make filing NOEs and NOTRs cumbersome, or which lead to delays in posting NOE or NOTR data to CMS systems such as the CWF or Part D's DTRR. Some of these commenters noted concerns with the DDE filing system, the inability to batch and transmit data directly from electronic health records, the inability of FISS to accept electronic files, sequential billing requirements, and also offered other recommendations. Several commenters suggested that CMS address its systems issues, suggesting that CMS systems be required to post NOE information to CWF within 1 to 3 days. Several comments requested various technical clarifications and/or shared concerns with CMS's data systems to support the proposal to timely-file the NOE and NOTR. One commenter asked if NOTR filing procedures should be consistent with current instructions for reporting

occurrence codes in claims submissions so that the reason for the discharge would be clear.

Response: Before the implementation of the HIPAA transactions and code sets standards in 2003, CMS accepted hospice NOEs via Electronic Data Interchange (EDI) batch submission using the UB-92 flat file claim format. HIPAA implementation eliminated the UB-92 flat file format for claims processing, replacing it with the 837 Institutional (837I) claim transaction. The 837I format requires reporting at least one delivered service and other data elements that are not appropriate to an NOE, so an EDI claim transaction could no longer be used for this purpose. At that time, a great majority of hospice NOEs were already being processed via Direct Data Entry (DDE) into Medicare claims processing systems. CMS determined that DDE submission of NOEs met the business needs of Medicare and most hospices. While many hospices have now adopted electronic health record technology that could facilitate the creation and submission of electronic NOEs, no standard for such submission currently exists. There would be significant implementation challenges associated with creating an interface between any new non-claim format and Medicare claims processing systems. CMS plans to explore options to resume electronic batch submission of hospice NOEs in the future and welcomes input from the hospice industry regarding how electronic submission of NOEs could be feasible.

Commenters who stated that sequential billing requirements prevent timely filing of NOEs are in error. While sequential billing requirements continue to apply, if a previous hospice has not filed any or all of its claims for a beneficiary, the current hospice is not prevented by CMS's claims processing systems from timely-filing its NOE (bill type 8xA). Similarly, there is no restriction within CMS claims processing systems on a current hospice's ability to file its NOTR if a previous hospice has not filed any or all of its claims for that beneficiary. We are investigating possible improvements or process changes within CMS systems to increase the timeliness of updates. As part of that, we are open to discussions with the industry regarding sequential billing requirements or the Electronic Data Interchange (EDI). Finally, since the claims processing function of the NOTR is simply to post a revocation date for the beneficiary in the CWF, additional information identifying the reason for the discharge is not necessary. This information would

duplicate what is provided when the claim is filed.

Comment: One commenter asked if the proposals related to the NOE filing that we finalize would apply when Medicare is a secondary payer.

Response: The timely-filing NOE requirement applies whether Medicare is the primary or secondary payer.

Comment: We received comments in the context of coordinating Part D and hospice. These comments provided recommendations for various processes for information flow to be considered.

Response: We appreciate the comments received related to coordination between hospices and Part D sponsors. We will consider these in the overall development of a coordination process, which we solicited comments on in Section III.I.

Comments: A few hospice commenters stated that they may not know the principal diagnosis or the attending physician to include with the NOE within the proposed 3 calendar days after the effective date of election, and noted that the comprehensive assessment occurs over a 5 day period.

Response: As noted previously, we are finalizing a timely-filing NOE policy that requires the NOE to be submitted to, and accepted by, the Medicare contractor within 5 calendar days after the effective date of hospice election, which is 2 days longer than the proposed timeframe. Since beneficiaries must be certified as terminally ill by the hospice physician and the patient's attending physician (if any) within 2 calendar days after the effective date of election, the principal diagnosis and attending physician chosen by the beneficiary are known to the hospice prior to the end of the timely-filing NOE timeframe. In addition, coding guidelines are very clear as to how to determine a primary diagnosis when multiple potential principle diagnoses may exist. These coding guidelines can be found at: http://www.cdc.gov/nchs/data/icd/icd9cm_guidelines_2011.pdf. We also disagree that the comprehensive assessment must be completed for the hospice to know which diagnosis is the principal diagnosis. The initial assessment would determine the patient's immediate care and support needs within 48 hours after the election of hospice care, as described in 418.54, and would be completed within the timely-filing NOE timeframe. The initial assessment should support the information documented by hospice and/or attending physician (if any) during the patient certification of eligibility for hospice care. The hospice physician and/or attending physician should be

able to provide that information because they have had to review the beneficiary's medical documentation to determine whether or not to certify the patient as eligible for hospice care. While the comprehensive assessment may determine the breadth of specific needs of the patient, it would not be the primary driver in determining the beneficiary's principal diagnosis to be included on the NOE.

Final action: We are finalizing a timely-filing NOE policy that requires the NOE to be submitted to, and accepted by, the Medicare contractor within 5 calendar days after the effective date of election, and a timely-filing NOTR policy that requires the NOTR to be submitted to, and accepted by, the Medicare contractor within 5 calendar days after the effective date of the discharge/revocation (unless the hospice has already filed a final claim). We are finalizing provider liable days for late filing of NOEs, as proposed. We are also finalizing specific exceptions that, if applicable, would allow for a waiver of the provider liable days for not filing NOEs within 5 days after the effective date of election. We emphasize that prompt filing of the NOE and the NOTR is essential to protecting the Medicare Trust Fund; minimizing the effect on beneficiaries' cost-sharing; and preserving access to non-hospice services. This finalized policy imposes an upper limit as to when the NOE is to be submitted without the imposition of provider liable days due to late filing of the NOE and an upper limit to when the NOTR is to be submitted after the discharge or revocation of the hospice beneficiary. As such, we strongly encourage hospices to submit the NOE and NOTR as soon as possible and not wait until the 5th calendar day after the date of the election or discharge/revocation. We will continue to monitor the filing of NOEs and NOTRs, and will consider shortening the timeframe for what would be considered a timely-filed NOE or NOTR in future rulemaking. We have changed the regulatory text shown at the end of this final rule to reflect the policies described above.

F. Addition of the Attending Physician to the Hospice Election Form

The term "attending physician" is defined differently in different health care settings. For the Medicare hospice benefit, "attending physician" has a specific definition found in the Social Security Act at 1861(dd)(3)(B) that the term means, with respect to an individual, the physician (as defined in subsection (r)(1)) or nurse practitioner (as defined in subsection (aa)(5)), who may be employed by a hospice program,

whom the individual identifies as having the most significant role in the determination and delivery of medical care to the individual at the time the individual makes an election to receive hospice care.

Our regulations at § 418.3 include a definition for "attending physician," based on the above mentioned statutory language. We define it as either 1) a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she performs that function or action; or 2) a nurse practitioner who meets the training, education, and experience requirements described elsewhere in our regulations. The definition also sets out the requirement that the patient identify the attending physician at the time he or she elects to receive hospice care, as having the most significant role in the determination and delivery of the individual's medical care.

We require that the National Provider Identifier (NPI) of the attending physician be included on the NOE and on each claim. An attending physician can be a physician or a nurse practitioner, as long as he or she meets the requirements outlined in our regulations discussed above. The hospice patient (or his or her representative), not the hospice, chooses the attending physician. This differs from some non-hospice settings, where an attending may be a clinician assigned to provide care to the patient. This requirement is included as part of the CoPs at § 418.52(c)(4), which state that the patient has the right to choose his or her attending physician. The hospice CoPs at § 418.64(a)(3) further require that if the attending physician is unavailable, the hospice medical director, hospice contracted physician, and/or hospice physician employee is responsible for meeting the medical needs of the patient. Therefore, the patient should receive all needed care, whether that care is provided by hospice doctors, hospice nurse practitioners (NPs), or by the designated attending physician. Hospices can bill Part A for reasonable and necessary physician services provided to hospice beneficiaries by its doctors, regardless of whether those doctors are the designated attending. However, our regulations at § 418.304(e) do not permit Medicare to be billed for reasonable and necessary physician services provided by NPs unless the NP is the attending physician, as defined in § 418.3.

We have recently heard anecdotal reports of hospices changing a patient's attending physician when the patient moves to an inpatient setting for inpatient care, often to a nurse

practitioner. We have also heard reports of hospices assigning an attending physician based upon whoever is available. Medicare contractors noted that the NPI of the attending physician reported on claims was sometimes changing, and differed from that reported on the NOE. Additionally, using CY 2010 and CY 2011 data, we found that 35 percent of beneficiaries had Part B claims during their hospice election from more than one physician who claimed to be their designated attending physician. The reports of hospices changing a patient's attending physician are of great concern since the statute emphasizes that the attending physician must be chosen by the patient (or his or her representative). Finally, we have also received anecdotal reports that some hospices are not getting the signature of the attending physician on the initial certification. If a beneficiary has designated an attending physician, that physician must sign the initial certification for Medicare to cover and pay for hospice services, unless the attending is a NP.

To ensure the attending physician of record is properly documented in the patient's medical record, we proposed to amend the regulations at § 418.24(b)(1) and require the election statement to include the patient's choice of attending physician. The proposed information identifying the attending physician should be recorded on the election statement in enough detail so that it is clear which physician or NP was designated as the attending physician. Hospices have the flexibility to include this information on their election statement in whatever format works best for them, provided the content requirements in § 418.24(b) are met. The language on the election form should include an acknowledgement by the patient (or representative) that the designated attending physician was the patient's (or representative's) choice.

In addition, we further proposed that if a patient (or representative) wants to change his or her designated attending physician, he or she must follow a procedure similar to that which currently exists for changing the designated hospice. Specifically, the patient (or representative) must file a signed statement with the hospice that identifies the new attending physician in enough detail so that it is clear which physician or NP was designated as the new attending physician. Additionally, we proposed that the statement include the date the change is to be effective, the date that the statement is signed, and the patient's (or representative's) signature, along with an acknowledgement that this change in

the attending physician is the patient's (or representative's) choice. The effective date of the change in attending physician cannot be earlier than the date the statement is signed. We believe that such a change would help ensure that any changes in the identity of the attending physician would be the result of the patient's free choice.

Public comments and our response to comments regarding the changes to § 418.24(b)(1) and 418.24(f) requiring the election statement to include the patient's choice of attending physician and other requirements are summarized below.

Comments: Nearly all commenters wrote that they supported protecting beneficiary choice of the attending physician. The majority of commenters supported our proposal to identify the attending physician on the election form, with several affirming that they already follow this procedure. The main objection to identifying the attending physician on the election form was concern that the patient may not know whom he or she would like to serve as his or her attending physician at the time of election, and that this requirement could delay admission. One commenter asked that the hospice physician or NP be allowed to act as the attending until the patient's choice could be determined. One commenter suggested that we require the election form to state that the beneficiary (or representative) has the right to choose his or her attending physician, and that the chosen physician does not need to be employed by the hospice. Another commenter asked that we use "provider neutral" language, and refer to the "attending clinician" rather than the attending physician, as the attending could be a physician (MD or DO) or an advanced practice nurse. Two commenters suggested we determine patient and family satisfaction with the attending physician before implementing new requirements.

Some commenters felt that the proposal would not change existing behavior and that the proposed requirements increase administrative burden on the hospice. A few commenters encouraged Medicare contractor and/or hospice survey oversight rather than a regulation change.

Response: We appreciate the comments supporting our proposal and the protection of beneficiary choice, and are implementing the requirement to identify the attending physician on the election form as proposed. Regarding comments that the beneficiary might not know the attending at the time of election, the definition of "attending

physician" in the Medicare statute requires that the beneficiary identify the attending physician "at the time of election". Therefore, this timeframe for identifying the attending physician was not part of our proposal but is an existing statutory requirement at section 1861(dd)(3)(B) of the Act. Most beneficiaries have had encounters with physicians prior to their decision to elect hospice care and many typically have longstanding relationships with their healthcare providers. If a hospice beneficiary has had a physician actively involved in their care prior to a hospice election, it is reasonable to expect that the hospice beneficiary will not have difficulty identifying that physician who has the most significant role in the determination and delivery of medical care to them. And, for those individuals who do not have any established and/or longstanding relationships with a healthcare provider, he/she may choose not to identify an attending physician, or may choose to identify a hospice physician or NP as his or her attending physician. We do not prohibit a patient (or representative) from choosing a hospitalist as the attending physician, though we suggest that the hospice explain to the patient (or representative) that a hospitalist only follows patients who are hospitalized.

As indicated in our regulations at 42 CFR 418.20, in order to be eligible to elect hospice care, the beneficiary must be certified as terminally ill. That certification process occurs before election, and involves the patient's attending physician (if any). We did not receive any comments raising concerns about identifying the attending physician at the time of election when the definition of "attending physician" was first proposed in 1983 (48 FR 56009). The definition of "attending physician" was changed in section 408 of the Medicare Modernization Act of 2003, and the hospice regulations were updated in the August 4, 2005 FY 2006 Hospice Wage Index Final rule (70 FR 45139-45140). There were no comments received about this longstanding timeframe in the discussion of the changes to the definition of "attending physician" in this final rule. The June 5, 2008 Hospice Conditions of Participation final rule (73 FR 32089 through 32090) also discussed the definition of "attending physician", and again, there were no comments that raised concerns regarding this timeframe. Since identifying an attending physician at time of hospice election has been a requirement in place for over 30 years, and has not appeared to cause any delay in admission, we do

not believe that including the information that identifies the attending physician on the election form would now begin to create delays in admission to hospice care.

In the proposed rule, we gave hospices the flexibility to include this information identifying the attending physician on their election statement in whatever format works best for them, provided the content requirements in § 418.24(b) are met. We wrote that the language on the election form should include an acknowledgement by the patient (or representative) that the designated attending physician was the patient's (or representative's) choice. We believe that this language remains sufficient, and do not agree with the commenters that asked that the acknowledgement also include language indicating that the chosen attending physician need not be an employee of the hospice. The decision as to who is or is not the attending physician belongs solely to the patient (or representative) regardless of that attending physician's employment relationship (or lack thereof) with the hospice. We do not prohibit attending physicians from being hospice employees as long as it is the patient's choice to decide whether or not to have an attending physician and who that attending physician will be during the patient's hospice care.

Because "attending physician" is defined in the statute, we are also unable to use provider neutral language such as "attending clinician" to describe this position. As articulated in this section, the statutory definition of the "attending physician" at section 1861(dd)(3)(B) of the Act means either a physician or a nurse practitioner, and does not permit broadening the term to include other health care professionals.

We do not agree that we should wait to consider patient or family satisfaction data before implementing any new requirements related to the attending physician. While a few commenters suggested that we not make this regulatory change to the election statement, but instead allow Medicare contractors and survey enforcement to deal with any failure to comply with the regulations, we expect this policy to improve Medicare contractor enforcement and oversight activities as well as State survey activities. The hospice CoPs at § 418.52 include regulations related to the choice of attending physician and are enforced by State surveys.

Comment: While some commenters supported having changes in the attending physician documented by the hospice, many commenters felt that this would cause undue burden to the

hospice and to patients or their families during a period of crisis. A number of commenters asked that we clarify what constitutes a change in the attending physician, and mentioned scenarios when changes frequently occur, such as when the patient receives GIP care. A number of commenters wrote that most changes come about because the attending is unwilling or unavailable to continue following the patient, particularly as the patient's care becomes more complex and the hospice physician's role increases.

Some commenters asked that we allow verbal changes, or changes from representatives by email or by fax. One wrote that it would be unfair for an NP to provide physician services, and for the hospice not to be able to bill for those services because that NP is not the designated attending physician. One commenter was concerned that our proposal implied that changing the attending physician is not appropriate.

Response: We recognize that there are many legitimate reasons for a patient to change an attending physician. However, the choice of the new attending physician belongs solely to the patient (or representative), and the intent of this proposal is to further safeguard and protect that beneficiary choice. A patient cannot be required or coerced to change his or her attending physician.

The hospice should document, in the medical record, situations where the attending physician is no longer willing or available to follow the patient. The hospice can then inform the patient or representative that he or she may choose someone else to serve in that role. In making such a choice, the patient or representative should be informed that he or she can choose a physician or a nurse practitioner as the attending physician, and that this individual could be from the community or from the hospice. Because the attending physician is typically someone with whom the patient had a relationship before electing to receive hospice care, the role of the attending physician is to provide a long term perspective on the patient and family that takes into account their medical and personal history. Ideally, this conversation with the patient (or representative) would occur when the patient is stable, and the patient (or representative) is able to make a decision without the stress of a medical crisis or in the midst of a transition to inpatient care. The patient is not required to make a change, and if he or she chooses not to do so, then the hospice physician or NP would step in to provide all needed care.

We are concerned that many commenters appear to believe that it is necessary to change the attending physician when a patient transitions to GIP or other inpatient care, and that changing the attending physician would cause undue burden to the hospice and to patients or their families during a period of crisis. A hospice patient is not required to change his or her attending physician in order to receive inpatient care, regardless of the setting. If the attending physician does not have privileges at the hospital(s) the hospice contracts with for inpatient care, or does not wish to care for the patient in an inpatient setting, then according to our CoPs at § 418.64(a)(3), the hospice physician or NP must provide any needed physician's services. The patient does not need to designate the hospice physician or NP as his or her attending physician for this to occur. However, while the hospice can bill Medicare Part A for its employed or contracted physicians providing needed physician services to its patients, it can only do so for its NPs if the NP is the designated attending physician. This limitation on hospice NP billing is in the hospice regulations at § 418.304(e) and is based on the statutory language surrounding physician billing. The statutory definition of "physician services" at section 1861(q) of the Act requires that the individual performing the services be a physician. "Physicians" are defined at section 1861(r) of the Act, and do not include NPs. However the statute does permit attending physicians to bill for their services at section 1812(d)(2)(A) of the Act, and defines attending physicians to include NPs at section 1861(dd)(3)(B) of the Act.

We noted in the preamble of the proposed rule that "attending physician" is defined differently in different settings. If the patient is in a hospital, the hospital may assign a hospitalist to the patient, and the hospital may consider that hospitalist to be the "attending physician." However, that individual does not meet the hospice definition of "attending physician" unless the beneficiary chooses the hospital assigned attending physician to be their hospice attending physician. The clinician who meets the hospice definition of "attending physician" should provide needed care to the hospice patient in the hospital. If that hospice attending physician is unavailable, then the hospice physician or NP would need to do so. The hospice should coordinate the patient's care during the inpatient stay by communicating with the hospitalist. If the hospice attending physician is

involved in the patient's care during an inpatient stay, that hospice attending physician will need to coordinate with any hospitalists that the hospital may have assigned, and of course with the hospice.

We believe that commenters' concerns about stress on families during times of transition, and the burden of additional paperwork, resulted from hospices' erroneously believing that the attending physician must be changed for each GIP stay. With the clarification provided in this rule, we do not believe that the procedures we proposed for documenting a change in attending physician need to be revised, and are implementing the proposal without changes. When an attending physician is changed by the beneficiary (or representative), the required information documenting that change can be securely faxed or emailed to the hospice.

We reiterate that if the attending physician cannot provide needed physician services, then the hospice physician or NP is required by the hospice CoPs to do so.

Comment: Several commenters felt that the proposals surrounding changes in the attending physician would still not address situations where different non-hospice physicians are filing claims as the attending physician. A few suggested we educate community physicians as well as hospices about the attending physician. Some commenters stated, that given the hospices' role as the beneficiaries' care coordinators, hospices should have a role in addressing the issue of patients seeing multiple community physicians and others suggested notifying the patients' community physicians of the hospice election. However, one commenter expressed concern over whether this approach would complicate referral relationships with community physicians. Suggestions for billing edits for claims processing were also made.

Response: We agree that our proposals will not completely resolve the issues related to inappropriate physician billing. We expect that the hospice beneficiary receives all needed items and services for the palliation and management of the terminal illness and related conditions from the hospice or the attending physician. However, sometimes hospice beneficiaries decide to seek continued treatment without the knowledge of the hospice for their terminal illness and related conditions, utilizing items or services provided by or through entities other than the hospice or the designated attending physician. The hospice may need to remind beneficiaries of the waiver of

Medicare payment for services related to the terminal illness and related conditions provided by non-hospice providers (other than the attending physician), which is part of their election, and of their liability for those related services. Hospice beneficiaries also retain their right to use non-hospice providers for items or services unrelated to the terminal illness and related conditions, and Medicare will pay for those covered items or services.

The hospice CoPs at § 418.56(e) require that hospices "ensure that the interdisciplinary group maintains responsibility for directing, coordinating, and supervising the care and services provided" whether the care and services are provided directly or under arrangement and to "provide ongoing sharing of information with other non-hospice healthcare providers furnishing services unrelated to the terminal illness and related conditions." Therefore, the care coordination role of hospices is one that is to be collaborative with all providers of a beneficiary's care, including non-hospice providers. The expectation is that hospices would have established collaborative care coordination and communication relationships with other providers to ensure the best interests of its patients.

We also agree that more education is needed around this issue to hospices and to physicians, and will be issuing a MedLearn Matters article and possibly other Medicare education products on the topic. We also plan to address Part B billing by physicians inappropriately using the attending physician modifier on claims in the future. Finally, we will update informational materials on the hospice benefit that Medicare makes available to beneficiaries to increase awareness of the choices available to them related to the attending physician.

Comment: A commenter asked if a new election should be completed for each change in attending, or if the NOE should be updated in the claims processing system. One commenter was supportive that we are not limiting the number of times a change in attending physician occurs, but others noted that more than one attending could be in place during a billing period. Another commenter asked if CMS expected the same attending to sign off on all services provided for the date range of the claim, asked for clarification whether the attending physician shown on claims should be based on the statutory definition of attending physician or the 5010 TR3 manual definition of attending physician, and asked which definition would take precedence in an audit.

Response: If the patient (or representative) chooses to make a change in the attending physician, then the patient (or representative) would need to file a signed statement with the hospice that identifies the new attending physician in enough detail so that it is clear which physician or NP was designated as the new attending physician. For example, "Dr. Smith" is likely not specific enough, as there could be more than one physician named "Dr. Smith" in the area. The hospice should include information such as the physician's full name, office address, or NPI number on the election form when needed to correctly identify the attending physician chosen by the beneficiary. The statement should include the date the change is to be effective, the date that the statement is signed, and the patient's (or representative's) signature, along with an acknowledgement that this change in the attending physician is the patient's (or representative's) choice. The effective date of the change in attending physician cannot be earlier than the date the statement is signed. The patient (or representative) does not need to complete a new election form. At this time, the hospice does not need to update the claims processing system with changes in the attending physician.

When a change in attending physician occurs, Medicare could be billed for services provided by more than one attending physician during any given month. Hospices should follow the statutory definition of "attending physician" given in this final rule when recording attending physicians or billing for attending physicians on hospice claims. That definition is already included in the hospice claims processing manual (IOM 100-04, chapter 11, sections 40.1.2 and 40.1.3), and takes precedence in an audit.

Comment: A commenter was concerned by anecdotal reports indicating that when services are being provided in a skilled nursing facility or other long term care facility, the hospices bypass the nursing facility medical directors or attending physicians and write new medical orders. This commenter wrote that the long-term care facility's attending physician or medical director should retain primary responsibility for the patient except in unusual circumstances. This commenter asked that hospices not be permitted to change medical orders without the involvement or permission of the long term care facility's attending physician.

Response: The hospice CoPs at 418.56 require that the hospice be responsible for coordinating provision of the

patient's care and services in all settings. When a hospice patient resides in a nursing facility, the CoPs at 418.112 require that the hospice assume responsibility for professional management of the resident's hospice services provided, in accordance with the hospice plan of care. There must be a written agreement in place between the hospice and the facility which addresses care coordination with the facility staff. The CoPs at § 418.112(e) requires the hospice IDG to designate one of its members to coordinate the patient's hospice care with representatives of the SNF/NF or ICF/MR. The designated IDG member must also communicate with representatives of the SNF/NF or ICF/MR and any other health care providers to ensure quality care for the patient. Additionally, the designated IDG member must ensure that the hospice IDG communicates with the SNF/NF or ICF/MR medical director, the patient's attending physician, and any other physicians caring for the patient as needed to coordinate the patient's hospice care with the care provided by other entities. Through these mechanisms, the hospice maintains responsibility for all of its care and services for all of its patients and ensures that the care that it is providing complements the care being provided by others. In addition, the establishment of the written agreements and communication systems with SNFs, NFs, and ICFs/MR when hospices are furnishing hospice care to residents of those facilities promotes clear communication between the hospice and the SNF/NF or ICF/MR and will help hospices ensure that they are meeting their responsibility to furnish the care necessary to meet the needs of its patients. We believe that this coordinated process actively involves and engages all members of the patient's care team, both within the hospice and the facility, in care planning, and delivery.

Comment: A commenter suggested that the attending physician be responsible for communicating with the beneficiary's pharmacy regarding which of a hospice beneficiary's drugs should be discontinued.

Response: We appreciate this comment related to Part D coordination with pharmacies. We will consider this comment in the overall development of a coordination process which we solicited comments on in Section III.I and will address this comment in future rulemaking.

Final action: We are implementing all the proposals related to the attending physician as proposed.

G. FY 2015 Hospice Wage Index and Rates Update

1. FY 2015 Hospice Wage Index

The hospice wage index is used to adjust payment rates for hospice agencies under the Medicare program to reflect local differences in area wage levels based on the location where services are furnished. The hospice wage index utilizes the wage adjustment factors used by the Secretary for purposes of section 1886(d)(3)(E) of the Act for hospital wage adjustments, and our regulations at § 418.306(c) require each labor market to be established using the most current hospital wage data available, including any changes by the Office of Management and Budget (OMB) to the Metropolitan Statistical Areas (MSAs) definitions. We have consistently used the pre-floor, pre-reclassified hospital wage index when deriving the hospice wage index. In our August 4, 2005 FY 2006 Hospice Wage Index final rule (70 FR 45130), we began adopting the revised labor market area definitions as discussed in the OMB Bulletin No. 03-04 (June 6, 2003). This bulletin announced revised definitions for MSAs and the creation of Core-Based Statistical Areas (CBSAs). The bulletin is available online at <http://www.whitehouse.gov/omb/bulletins/b03-04.html>.

In the FY 2006 Hospice Wage Index final rule, we implemented a 1-year transition policy using a 50/50 blend of the CBSA-based wage index values and the MSA-based wage index values for FY 2006. The one-year transition policy ended on September 30, 2006. For FY 2007 and beyond, we have used CBSAs exclusively to calculate wage index values. OMB has published subsequent bulletins regarding CBSA changes. The most recent CBSA changes used for the FY 2015 hospice wage index are found in OMB Bulletin 10-02, available at: <http://www.whitehouse.gov/sites/default/files/omb/assets/bulletins/b10-02.pdf>.

When adopting OMB's new labor market designations in FY 2006, we identified some geographic areas where there were no hospitals, and thus, no hospital wage index data on which to base the calculation of the hospice wage index. We also adopted the policy that for urban labor markets without a hospital from which hospital wage index data could be derived, all of the CBSAs within the state would be used to calculate a statewide urban average pre-floor, pre-reclassified hospital wage index value to use as a reasonable proxy for these areas in our August 6, 2009 FY 2010 Hospice Wage Index final rule (74 FR 39386). In FY 2015, the only CBSA

without a hospital from which hospital wage data could be derived is 25980, Hinesville-Fort Stewart, Georgia.

In our August 31, 2007 FY 2008 Hospice Wage Index final rule (72 FR 50214), we implemented a new methodology to update the hospice wage index for rural areas without a hospital, and thus no hospital wage data. In cases where there was a rural area without rural hospital wage data, we used the average pre-floor, pre-reclassified hospital wage index data from all contiguous CBSAs to represent a reasonable proxy for the rural area. In our August 31, 2007 FY 2008 Hospice Wage Index final rule, we noted that we interpret the term "contiguous" to mean sharing a border (72 FR 50217). Currently, the only rural area without a hospital from which hospital wage data could be derived is Puerto Rico. However, our policy of imputing a rural pre-floor, pre-reclassified hospital wage index based on the pre-floor, pre-reclassified hospital wage index (or indices) of CBSAs contiguous to a rural area without a hospital from which hospital wage data could be derived does not recognize the unique circumstances of Puerto Rico. While we have not identified an alternative methodology for imputing a pre-floor, pre-reclassified hospital wage index for rural Puerto Rico, we will continue to evaluate the feasibility of using existing hospital wage data and, possibly, wage data from other sources. For FY 2008 through FY 2013, we have used the most recent pre-floor, pre-reclassified hospital wage index available for Puerto Rico, which is 0.4047. In this final rule, for FY 2015, we continue to use the most recent pre-floor, pre-reclassified hospital wage index value available for Puerto Rico, which is 0.4047.

For FY 2015, we used the 2014 pre-floor, pre-reclassified hospital wage index to derive the applicable wage index values for the FY 2015 hospice wage index. We continue to use the pre-floor, pre-reclassified hospital wage data as a basis to determine the hospice wage index values because hospitals and hospices both compete in the same labor markets, and therefore, experience similar wage-related costs. We believe the use of the pre-floor, pre-reclassified hospital wage index data, as a basis for the hospice wage index, results in the appropriate adjustment to the labor portion of the costs. The FY 2015 hospice wage index values presented in this final rule were computed consistent with our pre-floor, pre-reclassified hospital (IPPS) wage index policy (that is, our historical policy of not taking into account IPPS geographic reclassifications in determining

payments for hospice). The FY 2015 pre-floor, pre-reclassified hospital wage index does not reflect OMB's new area delineations, based on the 2010 Census, as outlined in OMB Bulletin 13-01, released on February 28, 2013.

Moreover, the final FY 2015 pre-floor, pre-reclassified hospital wage index does not contain OMB's new area delineations. CMS proposed changes to the FY 2015 hospital wage index based on the newest CBSA changes in the FY 2015 IPPS proposed rule. Therefore, if CMS incorporates OMB's new area delineations, based on the 2010 Census, in the FY 2015 hospital wage index, those changes would also be reflected in the FY 2016 hospice wage index.

We received 3 comments regarding the wage index proposals.

Comment: A commenter suggests that CMS implement a policy whereby the area wage index applicable to any hospice that is located in an urban area of a State may not be less than the area wage index applicable to hospices located in rural areas in that State.

Response: The wage index is based on hospital wage data from each urban CBSA and rural area. Therefore, the wage index for each geographic area (whether urban or rural) should be an accurate reflection of hospital wages in that area. We will continue to monitor the effects of the wage index, look into whether or not we would have the authority to implement such a policy, and determine the appropriateness of such a policy before possibly considering this recommendation in future rulemaking.

Comment: A commenter suggests placing Montgomery County, Maryland into CBSA 47894 "Washington-Arlington-Alexandria, DC-VA-MD-WV". Montgomery County, along with Frederick County, Maryland, is in CBSA 13644 "Bethesda-Rockville-Frederick, MD". The commenter states that the cost of living in Montgomery County is no lower than the cost of living in the counties which comprise CBSA 47894.

Response: The geographic area delineations are based on labor market definitions established by OMB. We proposed and finalized the adoption of the revised labor market area definitions as discussed in the OMB Bulletin No. 03-04 (June 6, 2003) in our August 4, 2005 FY 2006 Hospice Wage Index final rule (70 FR 45130). Any revisions to the labor market area definitions will reflect updates to the geographic area delineations established by OMB.

Comment: One commenter requests that the new OMB delineations be considered when computing the FY 2015 wage index for hospices, just as they are for other provider types such as

inpatient hospital, SNF and home health.

Response: As in previous years, the hospice wage index will be based on the previous year's IPPS hospital pre-floor, pre-reclassified wage index. For FY 2015, the hospice wage index will use the FY 2014 IPPS hospital pre-floor, pre-reclassified wage index subject to either a budget neutrality adjustment or application of the hospice floor. The FY 2014 IPPS hospital wage index did not utilize the new OMB delineations. Therefore, the FY 2015 hospice wage index will not incorporate them in this rule. The new OMB delineations will be incorporated into the FY 2015 IPPS hospital wage index. We expect to propose to adopt those changes to the hospice wage index in future rulemaking.

Final action: We are implementing the hospice wage index as discussed in the proposed rule.

2. FY 2015 Hospice Wage Index With an Additional 15 Percent Reduced Budget Neutrality Adjustment Factor (BNAF)

In the FY 2015 Hospice Wage Index proposed rule, we proposed to update the hospice wage index values for FY 2015 using the FY 2014 pre-floor, pre-reclassified hospital wage index. As described in the August 8, 1997 Hospice Wage Index final rule (62 FR 42860), the pre-floor and pre-reclassified hospital wage index is used as the raw wage index for the hospice benefit. These raw wage index values are then subject to either a budget neutrality adjustment or application of the hospice floor to compute the hospice wage index used to determine payments to hospices. Pre-floor, pre-reclassified hospital wage index values below 0.8 are adjusted by either: (1) the hospice budget neutrality adjustment factor (BNAF); or (2) the hospice floor subject to a maximum wage index value of 0.8; whichever results in the greater value.

The BNAF is calculated by computing estimated payments using the most recent, completed year of hospice claims data. The units (days or hours) from those claims are multiplied by the updated hospice payment rates to calculate estimated payments. For the FY 2015 Hospice Wage Index final rule, that means estimating payments for FY 2015 using units (days or hours) from FY 2013 hospice claims data, and applying the final FY 2015 hospice payment rates. The FY 2015 hospice wage index values are then applied to the labor portion of the payments. The procedure is repeated using the same units from the claims data and the same payment rates, but using the 1983 Bureau of Labor Statistics (BLS)-based

wage index instead of the updated raw pre-floor, pre-reclassified hospital wage index (note that both wage indices include their respective floor adjustments). The total payments are then compared, and the adjustment required to make total payments equal is computed; that adjustment factor is the BNAF.

The August 6, 2009 FY 2010 Hospice Wage Index final rule finalized a provision to phase out the BNAF over 7 years, with a 10 percent reduction in the BNAF in FY 2010, and an additional 15 percent reduction in each of the next 6 years, with complete phase out in FY 2016 (74 FR 39384). Once the BNAF is completely phased out, the hospice floor adjustment would simply consist of increasing any wage index value less than 0.8 by 15 percent, subject to a maximum wage index value of 0.8. Therefore, in accordance with the FY 2010 Hospice Wage final rule, the BNAF for FY 2015 will be reduced by an additional 15 percent for a total BNAF reduction of 85 percent (10 percent from FY 2010, an additional 15 percent from FY 2011, an additional 15 percent for FY 2012, an additional 15 percent for FY 2013, an additional 15 percent in FY 2014, and an additional 15 percent in FY 2015).

The unreduced BNAF for FY 2015 is 0.062084 (or 6.2084 percent). An 85 percent reduction to the BNAF is computed to be 0.009313 (or 0.9313 percent). For FY 2015, this is mathematically equivalent to taking 15 percent of the unreduced BNAF value, or multiplying 0.062084 by 0.15, which equals 0.009313 (0.9313 percent). The BNAF of 0.9313 percent reflects an 85 percent reduction in the BNAF. The 85 percent reduced BNAF (0.9313 percent) was applied to the pre-floor, pre-reclassified hospital wage index values of 0.8 or greater. The 10 percent reduced BNAF for FY 2010 was 0.055598, based on a full BNAF of 0.061775; the additional 15 percent reduced BNAF FY 2011 (for a cumulative reduction of 25 percent) was 0.045422, based on a full BNAF of 0.060562; the additional 15 percent reduced BNAF for FY 2012 (for a cumulative reduction of 40 percent) was 0.035156, based on a full BNAF of 0.058593; the additional 15 percent reduced BNAF for FY 2013 (for a cumulative reduction of 55 percent) was 0.027197, based on a full BNAF of 0.060438; the additional 15 percent reduced BNAF for FY 2014 (for a cumulative reduction of 70 percent) was 0.018461, based on a full BNAF of 0.061538 and the additional 15 percent reduced BNAF for FY 2015 (for a cumulative reduction of 85 percent) is

0.009313, based on a full BNAF of 0.062084.

Hospital wage index values which are less than 0.8 are subject to the hospice floor calculation. For example, if in FY 2015, County A had a pre-floor, pre-reclassified hospital wage index (raw wage index) value of 0.3994, we would perform the following calculations using the budget-neutrality factor (which for this example is an unreduced BNAF of 0.062084, less 85 percent, or 0.009313) and the hospice floor to determine County A's hospice wage index: Pre-floor, pre-reclassified hospital wage index value below 0.8 multiplied by 1 + 85 percent reduced BNAF: $(0.3994 \times 1.009313 = 0.4031)$; Pre-floor, pre-reclassified hospital wage index value below 0.8 multiplied by 1 + hospice floor: $(0.3994 \times 1.15 = 0.4593)$. Based on these calculations, County A's hospice wage index would be 0.4593.

An Addendum A and Addendum B with the final FY 2015 wage index values for rural and urban areas will not be published in the **Federal Register**. The final FY 2015 wage index values for rural areas and urban areas are available via the internet at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/index.html>. The hospice wage index for FY 2015 set forth in this final rule includes the BNAF reduction and would be effective October 1, 2014 through September 30, 2015.

3. Hospice Payment Update Percentage

Section 4441(a) of the Balanced Budget Act of 1997 (BBA) amended section 1814(i)(1)(C)(ii)(VI) of the Act to establish updates to hospice rates for FYs 1998 through 2002. Hospice rates were to be updated by a factor equal to the market basket index, minus 1 percentage point. Payment rates for FYs since 2002 have been updated according to section 1814(i)(1)(C)(ii)(VII) of the Act, which states that the update to the payment rates for subsequent FYs must be the market basket percentage for that FY. The Act requires us to use the inpatient hospital market basket to determine the hospice payment rate update. In addition, section 3401(g) of the Affordable Care Act mandates that, starting with FY 2013 (and in subsequent FYs), the hospice payment update percentage will be annually reduced by changes in economy-wide productivity as specified in section 1886(b)(3)(B)(xi)(II) of the Act. In addition, section 3401(g) of the Affordable Care Act also mandates that in FY 2013 through FY 2019, the hospice payment update percentage will be reduced by an additional 0.3 percentage point (although for FY 2014

to FY 2019, the potential 0.3 percentage point reduction is subject to suspension under conditions specified in section 1814(i)(1)(C)(v) of the Act). The final hospice payment update percentage for FY 2015 will be the inpatient hospital market basket update of 2.9 percent (based on IHS Global Insight, Inc.'s second quarter 2014 forecast with historical data through the first quarter of 2014), less any mandated adjustments. Due to the requirements at 1886(b)(3)(B)(xi)(II) and 1814(i)(1)(C)(v) of the Act, the inpatient hospital market basket update for FY 2015 of 2.9 percent must be reduced by a productivity adjustment as mandated by Affordable Care Act (currently estimated to be 0.5 percentage point for FY 2015). The inpatient hospital market basket for FY 2015 is reduced further by a 0.3 percentage point, as mandated by the Affordable Care Act. In effect, the final hospice payment update percentage for FY 2015 is 2.1 percent. We used the most recent data available (for example, the most recent inpatient hospital market basket and productivity adjustment), to determine the FY 2015 market basket update and the multi-factor productivity MFP adjustment in this FY 2015 Hospice PPS final rule.

Currently, the labor portion of the hospice payment rates is as follows: for Routine Home Care, 68.71 percent; for Continuous Home Care, 68.71 percent; for General Inpatient Care, 64.01 percent; and for Respite Care, 54.13 percent. The non-labor portion is equal to 100 percent minus the labor portion for each level of care. Therefore, the non-labor portion of the payment rates is as follows: for Routine Home Care, 31.29 percent; for Continuous Home Care, 31.29 percent; for General Inpatient Care, 35.99 percent; and for Respite Care, 45.87 percent.

We received 3 comments regarding the proposed payment update.

Comment: The commenters stated that the proposed update is misleading and inaccurate due to cuts through the BNAF phase-out and sequestration. Commenters claim that hospices are incurring significant, additional regulatory costs and are forced to take dollars for these costs out of patient care. Some examples of additional regulatory burdens cited by the commenters include: the costs of CR 8358 "Additional Data Reporting Requirements for Hospice Claims", the Experience of Care Survey which will be required in 2015, the burden of Part D prior authorization or appeal, and the proposed new cost report requiring new financial reporting systems and additional staff.

Response: The comments on sequestration are outside the scope of this rule. We note that the impact analysis does reflect estimated reductions in FY 2015 payments to hospice as a result of the 6th year of the 7-year BNAF phase-out.

Final action: We are implementing the hospice payment update as discussed in the proposed rule and consistent with the updated data to the hospital market basket update and multi-factor productivity (MFP) adjustment.

4. FY 2015 Hospice Payment Rates

Historically, the hospice rate update has been published through a separate administrative instruction issued annually in the summer to provide adequate time to implement system change requirements; however, beginning in FY 2014 and for subsequent fiscal years, we are using rulemaking as the means to update payment rates. This change was proposed in the FY 2014 Hospice Wage Index and Payment Rate Update proposed rule and finalized in the FY 2014 Hospice Wage Index and Payment Rate Update final rule (78 FR 48270). It is consistent with the rate update process in other Medicare benefits, and provides rate information to hospices as quickly as, or earlier than, when rates are published in an administrative instruction.

There are four payment categories that are distinguished by the location and intensity of the services provided. The base payments are adjusted for geographic differences in wages by multiplying the labor share, which varies by category, of each base rate by the applicable hospice wage index. A hospice is paid the routine home care rate for each day the beneficiary is enrolled in hospice, unless the hospice provides continuous home care, inpatient respite care, or general inpatient care. Continuous home care is provided during a period of patient crisis to maintain the patient at home; inpatient respite care is short-term care to allow the usual caregiver to rest; and general inpatient care is to treat symptoms that cannot be managed in another setting.

The final FY 2015 payment rates will be the FY 2014 payment rates, increased by 2.1 percent, which is the final hospice payment update percentage for FY 2015 as discussed in section III.G.3. The final FY 2015 hospice payment rates will be effective for care and services furnished on or after October 1, 2014, through September 30, 2015 (see Table 6 below).

TABLE 6—FY 2015 HOSPICE PAYMENT RATES UPDATED BY THE FINAL HOSPICE PAYMENT UPDATE PERCENTAGE

Code	Description	FY 2014 payment rates	Increase by the FY 2015 final hospice payment update of 2.1 percent	FY 2015 final payment rate
651	Routine Home Care	\$156.06	×1.021	\$159.34
652	Continuous Home Care	910.78	×1.021	929.91
	Full Rate applies to 24 hours of care			929.91
	Hourly rate = \$38.75			
655	Inpatient Respite Care	161.42	×1.021	164.81
656	General Inpatient Care	694.19	×1.021	708.77

The Congress required in sections 1814(i)(5)(A) through (C) of the Act that hospices begin submitting quality data, based on measures to be specified by the Secretary. In the FY 2012 Hospice Wage Index final rule (76 FR 47320 through 47324), we implemented a Hospice Quality Reporting Program (HQRP) as required by section 3004 of the

Affordable Care Act. Hospices were required to begin collecting quality data in October 2012, and submit that quality data in 2013. Section 1814(i)(5)(A)(i) of the Act requires that beginning with FY 2014 and each subsequent FY, the Secretary shall reduce the market basket update by 2 percentage points for any hospice that does not comply with the

quality data submission requirements with respect to that FY.). We remind hospices that this applies to payments in FY 2015 (See Table 7 below). For more information on the HQRP requirements please see section III.H in this final rule.

TABLE 7—FY 2015 HOSPICE PAYMENT RATES UPDATED BY THE FINAL HOSPICE PAYMENT UPDATE PERCENTAGE FOR HOSPICES THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

Code	Description	FY 2014 payment rates	Increase by the FY 2015 hospice payment update percentage of 2.1 percent minus 2 percentage points = 0.1	FY 2015 final payment rate
651	Routine Home care	\$156.06	×1.001	\$156.22
652	Continuous Home Care.	910.78	×1.001	911.69
	Full Rate applies to 24 hours of care			911.69
	Hourly rate = \$37.99.			
655	Inpatient Respite Care	161.42	×1.001	161.58
656	General Inpatient Care	694.19	×1.001	694.88

To assist the hospice industry in planning and budgeting, CMS is informing the hospice industry of the aggregate cap amount for the 2014 cap year in advance of the formal CMS administrative notice, which will be issued this summer. Additionally, we have included information about how we calculate the aggregate cap amount so that hospices can compute the amount themselves in the future if they so desire. This information is also in CMS' Internet-Only Manual 100–2, chapter 9, section 90.2.6. The manual can be accessed from the “Manuals and Transmittals” section of CMS' hospice Web site at <http://www.cms.gov/Center/Provider-Type/Hospice-Center.html>.

The hospice aggregate cap amount for the 2014 cap year will be \$26,725.79. The cap amount is calculated according to § 1814(i)(2)(B) of the Act. The cap amount for a given year is \$6,500 multiplied by the change in the Consumer Price Index for All Urban Consumers (CPI-U) Medical Care

expenditure category, from the fifth month of the 1984 accounting year (March 1984) to the fifth month of the current accounting year (in this case, March 2014). The CPI-U for Medical Care expenditures (BLS series code CUUR0000SAM) for 1984 to present is available from the Bureau of Labor Statistics (BLS) Web site at: <http://www.bls.gov/cpi/home.htm>.

(Step 1) From the BLS Web site given above, the March 2014 CPI-U for Medical Care expenditures is 433.369 and the 1984 CPI-U for Medical Care expenditures was 105.4.

(Step 2) Divide the March 2014 CPI-U for Medical Care expenditures by the 1984 CPI-U for medical care expenditures to compute the change.

$$433.369/105.4 = 4.111660$$

(Step 3) Multiply the original cap base amount (\$6,500) by the result from step 2) to get the updated aggregate cap amount for the 2014 cap year.

$$\$6,500 \times 4.111660 = \$26,725.79$$

H. Updates to the Hospice Quality Reporting Program

1. Background and Statutory Authority

Section 3004 of the Affordable Care Act amended the Act to authorize a quality reporting program for hospices. Section 1814(i)(5)(A)(i) of the Act requires that beginning with FY 2014 and each subsequent FY, the Secretary shall reduce the market basket update by 2 percentage points for any hospice that does not comply with the quality data submission requirements with respect to that FY. Depending on the amount of the annual update for a particular year, a reduction of 2 percentage points could result in the annual market basket update being less than 0.0 percent for a FY and may result in payment rates that are less than payment rates for the preceding FY. Any reduction based on failure to comply with the reporting requirements, as required by section 1814(i)(5)(B) of the

Act, would apply only for the particular FY involved. Any such reduction would not be cumulative or be taken into account in computing the payment amount for subsequent FYs.

Section 1814(i)(5)(C) of the Act requires that each hospice submit data to the Secretary on quality measures specified by the Secretary. The data must be submitted in a form, manner, and at a time specified by the Secretary. Any measures selected by the Secretary must have been endorsed by the consensus-based entity which holds a contract regarding performance measurement with the Secretary under section 1890(a) of the Act. This contract is currently held by the National Quality Forum (NQF). However, section 1814(i)(5)(D)(ii) of the Act provides that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the consensus-based entity, the Secretary may specify measures that are not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus-based organization identified by the Secretary.

The successful development of a Hospice Quality Reporting Program (HQRP) that promotes the delivery of high quality healthcare services is our paramount concern. We seek to adopt measures for the HQRP that promote more efficient and safer care. Our measure selection activities for the HQRP take into consideration input we receive from the Measure Applications Partnership (MAP), convened by the National Quality Forum (NQF), as part of a pre-rulemaking process that we have established and are required to follow under section 1890A of the Act. The MAP is a public-private partnership comprised of multi-stakeholder groups convened by the NQF for the primary purpose of providing input to CMS on the selection of certain categories of quality and efficiency measures, as required by section 1890A(a)(3) of the Act. By February 1st of each year, the NQF must provide that input to CMS. Input from the MAP is located at: (http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx). For more details about the pre-rulemaking process, see the FY 2013 IPPS/LTCH PPS final rule (77 FR 53376).

We also take into account national priorities, such as those established by the National Priorities Partnership at (<http://www.qualityforum.org/npp/>), the HHS Strategic Plan (<http://www.hhs.gov/secretary/about/priorities/priorities.html>), the National Strategy

for Quality Improvement in Healthcare located at (<http://www.ahrq.gov/workingforquality/nqs/nqs2013annlrpt.htm>) and the CMS Quality Strategy at (<http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html>).

To the extent practicable, we have sought to adopt measures that have been endorsed by the national consensus organization, recommended by multi-stakeholder organizations, and developed with the input of providers, purchasers/payers, and other stakeholders.

2. Measures for Hospice Quality Reporting Program and Data Submission Requirements for Payment Years FY 2014 and FY 2015.

As stated in the FY 2012 Hospice Wage Index final rule (76 FR 47302, 47320), to meet the quality reporting requirements for hospices for the FY 2014 payment determination and in the CY 2013 Home Health Prospective Payment System (HH PPS) final rule (77 FR 67068, 67133), the quality reporting requirements for hospices for the FY 2015 payment determination, as set forth in section 1814(i)(5) of the Act, we finalized the requirement that hospices report two measures:

- An NQF-endorsed measure related to pain management, NQF #0209. The data for this measure are collected at the patient level, but are reported in the aggregate for all patients cared for within the reporting period, regardless of payer.
- A structural measure that is not endorsed by NQF: Participation in a Quality Assessment and Performance Improvement (QAPI) program that includes at least three quality indicators related to patient care.

3. Quality Measures for Hospice Quality Reporting Program and Data Submission Requirements for Payment Year FY 2016 and Beyond

In the FY 2014 Hospice Wage Index and Payment Rate Update final rule (78 FR 48234, 48256), we finalized that the structural measure related to QAPI indicators and the NQF #0209 pain measure would not be required for the HQRP beyond data submission for the FY 2015 payment determination. The data submission period for the FY 2015 payment determination closed on April 1, 2014.

As stated in the CY 2013 HH PPS final rule (77 FR 67068, 67133), we considered an expansion of the required measures to include additional

measures endorsed by NQF. We also stated that to support the standardized collection and calculation of quality measures by CMS, collection of the needed data elements would require a standardized data collection instrument. We developed and tested a hospice patient-level item set, the Hospice Item Set (HIS) to be used by all hospices to collect and submit standardized data items about each patient admitted to hospice.

In developing the standardized HIS, we considered comments offered in response to the CY 2013 HH PPS proposed rule (77 FR 41548, 41573). In the FY 2014 Hospice Wage Index final rule (78 FR 48257), and in compliance with section 1814(i)(5)(C) of the Act, we finalized the specific collection of data items that support the following six NQF endorsed measures and one modified measure for hospice:

- NQF #1617 Patients Treated with an Opioid who are Given a Bowel Regimen
- NQF #1634 Pain Screening
- NQF #1637 Pain Assessment
- NQF #1638 Dyspnea Treatment
- NQF #1639 Dyspnea Screening
- NQF #1641 Treatment Preferences
- NQF #1647 Beliefs/Values Addressed (if desired by the patient) (modified)

To achieve a comprehensive set of hospice quality measures available for widespread use for quality improvement and informed decision making, and to carry out our commitment to develop a quality reporting program for hospices that uses standardized methods to collect data needed to calculate quality measures, we finalized the HIS effective July 2014 (78 FR 48257). To meet the quality reporting requirements for hospices for the FY 2016 payment determination and each subsequent year, we will require regular and ongoing electronic submission of the HIS data for each patient admission to hospice on or after July 1, 2014, regardless of payer or patient age (78 FR 48234, 48258). Collecting data on all patients will provide CMS with the most robust, accurate reflection of the quality of care delivered to Medicare beneficiaries as compared with non-Medicare patients. Therefore, to measure the quality of care that is delivered to Medicare beneficiaries in the hospice setting, we will collect quality data necessary to calculate the adopted measures on all patients. We are requiring in our regulation that hospices collect data on all patients in hospice in order to ensure that all patients, regardless of payer, are receiving the same care and that provider metrics measure performance

across the spectrum of patients (78 FR 48258).

Hospices are required to complete and submit an admission HIS and a discharge HIS for each patient admission. Hospices failing to report quality data via the HIS in 2014 will have their market basket update reduced by 2 percentage points in FY 2016. Although this has been implemented thus far pursuant to instructions set out in our preamble statements, we proposed to codify the HIS submission requirements at § 418.312 in this final rule. The System of Record (SOR) Notice for the HIS, SOR number 09–07–0548, was published in the **Federal Register** on April 8, 2014 (79 FR 19341).

Comment: Several commenters believed that hospices should not be subject to a reduction in the annual market basket update if they are unable to achieve 100 percent timely data submission during the FY 2015 submission period.

Response: We thank the commenters for their concern; however, we did not make any proposals regarding timely data submission. We also recognize that new hospices that receive their CCN after the yearly submission deadline are still required to submit the HIS for each patient, but those HIS submissions would fall after the submission deadline. If a hospice realizes that it will not meet the timeliness criteria for any given record, for whatever reason, it should still complete and submit that record. Late completion and submission of HIS records will result in a non-fatal warning error in the Quality Improvement and Evaluation System. However, the records can still be accepted by the system.

Comment: Several commenters asserted that the Quality Reporting Program should be restricted to Medicare patients and stated that requiring data reporting on patients covered by other payers is outside CMS's regulatory authority.

Response: We respectfully disagree with the commenters' assertions. We have proposed to codify the HIS submission requirements at § 418.312. Section 3004 of the ACA requires quality reporting, and CMS has required all facilities subject to quality reporting requirements to submit data on its entire patient population, including hospitals and inpatient rehabilitation facilities. The delivery of high quality care in hospice is imperative, regardless of payer. We believe that collecting quality data on all patients in the hospice setting supports CMS' mission to ensure quality care for Medicare beneficiaries and ensures that all patients, regardless of payer, are receiving the same care.

Comment: Several commenters noted that the cost of the mandated quality program must be reflected in hospice reimbursement rates.

Response: We thank the commenters for their concern; however, the cost of quality improvement programs should be reported on the cost reports. Cost report data may be considered in future payment reform.

Comment: One commenter reported that more time is required to assure the quality of HIS information than the time it takes to collect it. While this situation may be the result of the newness of the tool and the learning curve required for implementation, the production of reliable and meaningful quality measures depends on the quality of the data collected.

Response: We thank the commenters for taking the time to express their concerns regarding the HIS collection. Collection began on July 1st, 2014 and we understand the commenter's perception that the newness of the process may make the process feel more burdensome. We appreciate the commenters' diligence ensuring quality and accuracy of the data submitted.

Comment: A few commenters expressed disagreement with our estimate of the amount of regulatory burden on hospice agencies to carry out the HIS admission and discharge submissions.

Response: We thank the commenters for taking the time to express these views and suggestions. CMS attempts to reduce the regulatory burden of our quality reporting programs to the greatest extent possible. As required by OMB, the burden to complete the HIS is included in the actual HIS (http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Downloads/HIS_Admission_Final_4-8-2014.pdf). Specifically, CMS estimates 19 minutes per response for the Admission HIS and 10 minutes per response for the Discharge HIS. Details regarding the estimate can be found at: <http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1252151.html?DLPage=1&DLSort=1&DLSortDir=descending>. Comments concerning the accuracy of the time estimate(s) or suggestions for improving the HIS can be directed to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4–26–05, Baltimore, Maryland 21244–1850.

Final action: After consideration of the comments, we are finalizing our proposal to codify the HIS submission requirements at § 418.312 in this final rule as proposed without change.

Hospice programs will be evaluated for purposes of the quality reporting program based on whether or not they submit data, not on their substantive performance level with respect to the required measures. We have provided hospices with information and details about use of the HIS through postings on the Hospice Quality Reporting Program Web page, Open Door Forums, announcements in the CMS MLN Connects Provider e-News (E-News), and provider training. Electronic data submission is required for HIS submission in CY 2014 and beyond; there are no other data submission methods available. CMS will make available submission software for the HIS to hospices at no cost. We intend to report to providers on the seven finalized measures on a schedule to be determined.

We provided details on data collection and submission timing at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Hospice-Item-Set-HIS.html>.

Submission of the HIS on all patient admissions to hospice, regardless of payer or patient age, is required. The data submission system provides reports upon successful submission and successful processing of the HIS records. The final validation report may serve as evidence of submission. This is the same data submission system used by nursing homes, inpatient rehabilitation facilities and long-term care hospitals for the submission of Minimum Data Set Version 3.0 (MDS 3.0), Inpatient Rehabilitation Facility—Patient Assessment Instrument (IRF—PAI), and Long-Term Care Hospital Continuity Assessment Record & Evaluation Data Set (LTCH CARE), respectively.

We also proposed that newly certified hospices that receive notice of their CMS certification number on or after November 1, 2014 for payments to be made in FY 2016 be excluded from the quality reporting requirements for the FY 2016 payment determination, as data submission and analysis would not be possible for a hospice receiving notification of their certification this late in the reporting time period.

We proposed that in future years, hospices that receive notification of certification on or after November 1 of the preceding year involved would continue to be excluded from any payment penalty for quality reporting purposes for the following FY. We proposed to codify this requirement at § 418.312.

Comment: Several commenters support the proposal that hospices that

receive notification of certification on or after November 1 of the preceding year involved would continue to be excluded from any payment penalty for quality reporting purposes for the following FY and to codify this requirement at § 418.312.

Response: We thank commenters for taking the time to support our proposal.

Final action: We are finalizing our proposal that hospices that receive notification of certification on or after November 1 of the preceding year involved would continue to be excluded from any payment penalty for quality reporting purposes for the following FY and to codify this requirement at § 418.312.

As is common in other quality reporting programs, we proposed to make accommodations in the case of natural disaster or other extenuating circumstances. Our experience with other quality reporting programs has shown that there are times when providers are unable to submit quality data due to extraordinary circumstances beyond their control (for example, natural or man-made disasters). A disaster may be widespread or impact multiple structures or be isolated and impact a single site only. We do not wish to penalize providers in these circumstances or to unduly increase their burden during these times. Therefore, we proposed a process, for the FY 2016 payment determination and subsequent payment determinations, for hospices to request and for CMS to grant extensions/exceptions with respect to the reporting of required quality data when there are extraordinary circumstances beyond the control of the provider. When an extension/exception is granted, a hospice will not incur payment reduction penalties for failure to comply with the requirements of the HQRP.

Under the proposed process for the FY 2016 payment determination and subsequent payment determinations, a hospice may request an extension/exception of the requirement to submit quality data for a specified time period. We proposed a process that, in the event that a hospice requested an extension/exception for quality reporting purposes for the FY 2016 payment determination and subsequent payment determinations, the hospice would submit a written request to CMS. Requirements for requesting an extension/exception will be available on the Hospice Quality Reporting Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/index.html>.

This proposal does not preclude us from granting extensions/exceptions to hospices that have not requested them when we determine that an extraordinary circumstance, such as an act of nature, affects an entire region or locale. We also proposed that we could grant an extension/exception to a hospice if we determine that a systemic problem with our data collection systems directly affected the ability of the hospice to submit data. If we make the determination to grant an extension/exception to hospices in a region or locale, we proposed to communicate this decision through routine communication channels to hospices and vendors, including, but not limited to, Open Door Forums, E-News and notices on <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/>.

Public comments and our response to comments are summarized below. All comments received were supportive of the proposed extension/exception policy.

Comment: Several commenters supported the proposal to allow hospices to request and for CMS to grant extensions/exceptions with respect to the reporting of required quality data when there are extraordinary circumstances beyond the control of the provider.

Response: We thank the commenters for taking the time to express their support for this proposal.

Final action: After consideration of the public comments, we are finalizing our proposal without change to allow hospices to request and for CMS to grant extensions/exceptions with respect to the reporting of required quality data when there are extraordinary circumstances beyond the control of the provider.

4. Future Measure Development

We did not propose any new measures for the HQRP in the FY 2015 Hospice Wage Index and Payment Rate Update proposed rule. However, we believe future development of the HQRP should address existing measure gaps by focusing on two primary opportunities: to expand measures already in use in other quality reporting programs that could apply to the HQRP and to develop new measures if no suitable measures are ready for implementation or expansion. We are particularly interested in outcome measures for symptom management, particularly pain. We are also interested in measures of patient reported outcomes. In the proposed rule, we solicited comments

and input on future measure development.

Comment: Many comments were generally supportive of the Hospice Quality Reporting Program (HQRP), and quality measurement in general. Commenters indicated they were pleased that CMS was not proposing additional new measures for implementation at this time, and cautioned against implementing additional measures before the end of at least one full year of data collection using the current Hospice Item Set (HIS), allowing hospices time to focus on HIS implementation and the proposed CAHPS® Hospice Survey implementation. Commenters supported the addition of measures in the future, and agreed that pain outcome and patient reported measures are an important area of focus for measure development. Several commenters highlighted the need for additional measures to capture a more comprehensive picture of hospice quality of care.

One commenter underscored the importance of developing and implementing quality measures that address the biopsychosocial model of distress, addressing depression, anxiety, personality and behavioral symptoms. In prioritizing future measure development areas, commenters recommended that CMS consider measure recommendations made by the NQF-convened Measures Application Partnership and developments in other initiatives including the “Measuring What Matters” consensus project. In addition, commenters emphasized that measures should address matters that are important to patients and caregivers and meet the information needs of Medicare beneficiaries.

Commenters specifically recommended measures that captured the following aspects of quality hospice care for patients with a variety of symptoms and diagnoses including: dementia; symptom management to comfortable or acceptable level; medication reconciliation; shared decision making and person and family-centered care; use of the interdisciplinary team; avoidance of unwanted CPR; avoidance of hospitalization and Emergency Department use; access and availability of hospice services, particularly time between initial referral and start of hospice care; appropriate staff training, degrees, or certifications; assessment of behavioral symptoms; assessment and management of caregiver burden; and assessment and management of caregiver and patient quality of life.

Another commenter suggested that CMS, along with other stakeholders, develop outcome measures to address areas such as pain, dyspnea, bowel management, and/or caregiver satisfaction. A few commenters indicated concerns that quality measures based on symptoms (for example, measures related to pain, and dyspnea) only represent a subset of hospice patients (those with that particular symptom) and due to this smaller sample size may limit usefulness of the measures, particularly for public reporting.

In addition, one commenter suggested that CMS reconsider the removal of the NQF #0209 measure from the HQRP, stating that it should be retained while CMS works with the measure steward to revise the measure to address the concerns CMS raised in last year's rule.

Other commenters reiterated their support of CMS's decision to remove the NQF #0209 from the HQRP. Another commenter encouraged CMS to implement a patient assessment instrument in the future to collect quality measure data at defined time points.

Finally, one commenter indicated that quality of care should be measured across settings.

Response: CMS appreciates commenters' input and recommendations for future measure development areas for the HQRP. We plan to continue developing the HQRP to respond to the measure gaps identified by the Measures Application Partnership and others, and align measure development with the National Quality Strategy and the CMS Quality Strategy. We will take these comments into consideration in developing and implementing measures for future inclusion in the HQRP.

We are also interested in understanding the current state of electronic health record (EHR) adoption and usage and Health Information Exchange (HIE) in the hospice community. Therefore, we solicited feedback and input from providers on topics such as decision support, whether hospices have adopted an EHR, if so, what functional aspects of the EHR do hospices find most important (for example, the ability to send or receive transfer of care information, ability to support medication orders/medication reconciliation); does the EHR used in the hospice setting support interoperable document exchange with other healthcare providers (for example, acute care hospitals, physician practices, and skilled nursing facilities)? In addition to seeking public input on the feasibility and desirability of

electronic health record adoption and use of HIE in hospices, we solicited comments on the need to develop and the benefits and limitations of implementing electronic clinical quality measures for hospice providers.

The Department of Health and Human Services (HHS) believes all patients, their families, and their healthcare providers should have consistent and timely access to their health information in a standardized format that can be securely exchanged between the patient, providers, and others involved in the patient's care. (HHS August 2013 Statement, Principles and Strategies for Accelerating Health Information Exchange.) HHS is committed to accelerating health information exchange (HIE) through the use of electronic health records (EHRs) and other types of health information technology (HIT) across the broader care continuum through a number of initiatives including: (1) alignment of incentives and payment adjustments to encourage provider adoption and optimization of HIT and HIE services through Medicare and Medicaid payment policies; (2) adoption of common standards and certification requirements for interoperable HIT; (3) support for privacy and security of patient information across all HIE-focused initiatives; and (4) governance of health information networks. These initiatives are designed to encourage HIE among all health care providers, including professionals and hospitals eligible for the Medicare and Medicaid EHR Incentive Programs and those who are not eligible for the EHR Incentive Programs, and are designed to improve care delivery and coordination across the entire care continuum. To increase flexibility in the Office of the National Coordinator for Health Information Technology's (ONC) HIT Certification Program and expand HIT certification, ONC has issued a proposed rule concerning a voluntary 2015 Edition EHR certification criteria which would more easily accommodate certification of HIT used in other types of health care settings where individual or institutional health care providers are not typically eligible for incentive payments under the Medicare and Medicaid EHR Incentive Programs, such as long-term and post-acute care and behavioral health settings.

We believe that HIE and the use of certified EHRs by Hospice (and other types of providers that are ineligible for the Medicare and Medicaid EHR Incentive Programs) can effectively and efficiently help providers improve internal care delivery practices, support management of patient care across the

continuum, and enable the reporting of electronically specified clinical quality measures (eCQMs). More information on the identification of EHR certification criteria and development of standards applicable to Hospice can be found at:

[http://healthit.gov/policy-researchers-implementers/standards-and-](http://healthit.gov/policy-researchers-implementers/standards-and-certification-regulations)

<http://www.healthit.gov/facas/FACAS/health-it-policy-committee/>

<http://wiki.siframework.org/>

<http://wiki.siframework.org/LCC+LTPAC+Care+Transition+SWG>

<http://wiki.siframework.org/Longitudinal+Coordination+of+Care>

Summaries of the public comments and our responses to comments on the current state of electronic health record (EHR) adoption and usage and Health Information Exchange (HIE) in the hospice community are provided below:

Comment: Commenters expressed support of the adoption and use of EHRs in the hospice setting, noting that it may lead to more consistent care and better symptom management.

Response: We thank the commenters for their support.

Comment Summary: CMS received several comments in response to its solicitation for input related to Electronic Health Record (EHR) adoption and usage and Health Information Exchange (HIE) in the hospice community. Most commenters noted that EHRs are important to aid in quality outcomes, and in general supported the use of certified EHRs if given sufficient time and resources for implementation. A commenter expressed that EHR adoption exists among hospices, however they lack standardization. Some commenters conveyed the importance of EHR and HIE adoption and use for patient coordination, and that information exchange should be required and available across providers; noting that it may lead to more consistent care and better symptom management. A commenter noted continued use of fax and mail services for the delivery of patient information. Several commenters supported EHR use, but suggested that there are current limitations related to the lack of decision support software and adequate health information exchange amongst the providers. In addition, they expressed concerns related to barriers to EHR and HIE adoption, as well as electronic quality measures.

Commenters suggested that specific barriers and limitations pertained to funding, feasibility, and adequate interoperability. Commenters suggested that a major barrier to the adoption of EHR technology in the hospice setting is

that hospice EHRs are not always interoperable with the technology used by hospitals and/or physicians. The commenters recommended that government officials review and adjust regulations that inhibit the exchange of electronic health information and that CMS mandate the development and use of uniform standards to govern the Health Information Exchange. All commenters suggested that funding incentives/levers could enable adoption of EHR technology. Some commenters recommended that CMS consider the establishment of financial incentives, (for example, funding tied to quality improvement/cost savings for hospices to implement EHR technology), noting that small and/or rural hospices have lower financial margins and lack of capital to implement EHR technology. One commenter suggested low-interest loans programs to aid in the funding of EHR technology. Additional commenters expressed that all EHR/HIE systems should include adequate education and system testing to ensure data integrity and the protection of confidential information, and that CMS should facilitate health information technology that includes tele-health technology. One commenter stated that CMS should not develop electronic clinical quality measures for the hospice setting until a framework is developed that includes the certification of electronic medical records for post-acute care providers and the financial assistance to support system implementation.

Response: We thank the commenters for their support of EHR and HIE utilization and for their recommendations. We are encouraged to learn about hospice adoption of EHRs and their efforts related to interoperability. We believe that the recommendations provided (for example, testing, education, use of uniform standards, exchange of appropriate information across providers), as well as the concerns that were conveyed related to barriers in EHR and HIE adoption (for example, adequate information exchange and interoperability, feasibility, testing and financial barriers), are important considerations related to EHR adoption and HIE usage in the hospice setting.

5. Public Availability of Data Submitted

Under section 1814(i)(5)(E) of the Act, the Secretary is required to establish procedures for making any quality data submitted by hospices available to the public. Measures reported publicly will not display patient identifiable information. The procedures ensure that a hospice would have the opportunity to

review the data regarding the hospice's respective program before it is made public. In addition, under section 1814(i)(5)(E) of the Act, the Secretary is authorized to report quality measures that relate to services furnished by a hospice on the CMS Web site. We recognize that public reporting of quality data is a vital component of a robust quality reporting program and are fully committed to developing the necessary systems for public reporting of hospice quality data. We also recognize that it is essential that the data made available to the public be meaningful and that comparing performance between hospices requires that measures be constructed from data collected in a standardized and uniform manner. The development and implementation of a standardized data set for hospices must precede public reporting of hospice quality measures. Once hospices have implemented the standardized data collection approach, we will have the data needed to establish the scientific soundness of the quality measures that can be calculated using the standardized data collection. It is critical to establish the reliability and validity of the measures prior to public reporting in order to demonstrate the ability of the measures to distinguish between the quality of services provided. To establish reliability and validity of the quality measures, at least four quarters of data will need to be analyzed. Typically the first two quarters of data reflect the learning curve of the providers as they adopt a standardized data collection; these data are not used to establish reliability and validity. This means that, since we will begin data collection in CY 2014 (Q3), the data from CY 2014 (Q3, Q4) will not be used for assessing validity and reliability of the quality measures. Data collected by hospices during Q1–3 CY 2015 will be analyzed starting in CY 2015. Decisions about whether to report some or all of the quality measures publicly will be based on the findings of analysis of the CY 2015 data. In addition, the Affordable Care Act requires that reporting be made public on a CMS Web site and that providers have an opportunity to review their data prior to public reporting. CMS will develop the infrastructure for public reporting, and provide hospices an opportunity to review their data. In light of all the steps required prior to data being publicly reported, public reporting will not be implemented in FY 2016. Public reporting may occur during FY 2017, allowing ample time for data analysis, review of measures' appropriateness for use for public

reporting, and allowing hospices the required time to review their own data prior to public reporting. We will announce the timeline for public reporting of data in future rulemaking. We solicited comments on what we should consider when developing future proposals related to public reporting.

Summaries of the public comments and our responses to comments are provided below:

Comment: One commenter suggested that CMS delay public reporting until a full year of the HIS submission so that data can better reflect the totality of hospice, and another stated that reporting in 2017 may be too soon. They believe that the HIS needs to be more fully developed to include additional outcome measures in order to provide a more complete picture of the care provided by hospices. The data from the CAHPS® Hospice Survey should be included in public reporting.

Response: We recognize the importance of providing patients and families/caregivers and other stakeholders accurate, scientifically sound, usable, and relevant information to support their decision-making regarding hospice care.

Comment: Several commenters recommended that CMS continue to ask for stakeholder input concerning the reliability and validity of the measures and maintain frequent communication with the hospice provider community prior to public reporting.

Response: We thank the commenters for this recommendation. CMS encourages stakeholder involvement throughout the measure development process. CMS considers input from the NQF Measure Applications Partnership (MAP) as part of the measure selection and maintenance process. The MAP is composed of multi-stakeholder groups convened by NQF for the primary purpose of providing input to CMS on the selection of certain categories of quality and efficiency measures, as required by section 1890(a)(3) of the Act. The MAP was created to provide input to the Department of Health and Human Services (HHS) on the selection of performance measures for public reporting and performance-based payment programs, and will continue to provide input to CMS as the HQRP moves toward public reporting. Additional information about the MAP can be found at: http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx

Comment: One commenter supported public reporting of hospice quality data, but strongly believes that public reporting must be preceded by valid

benchmarking to ensure data are collected in a standardized way to be more meaningful to the public.

Response: We thank the commenter for this suggestion and will consider these comments as we begin planning for public reporting.

6. Adoption of the CAHPS® Hospice Survey for the FY 2017 Payment Determination

In the FY 2014 Hospice Wage Index and Payment Rate Update final rule (78 FR 48234), we stated that CMS would start national implementation of the CAHPS® Hospice Survey as of January 1, 2015. (Previously, known as the Hospice Experience of Care Survey, HECS) We are maintaining our existing policy and are moving forward with national implementation of this survey. The CAHPS® Hospice Survey is a component of CMS' quality reporting program that emphasizes the experiences of hospice patients and their primary caregivers listed in the hospice patients' records. Measures from the survey will be submitted to the National Quality Forum (NQF) for approval as hospice quality measures. We refer readers to our extensive discussion of the Hospice Experience of Care Survey in the Hospice Wage Index FY 2014 final rule for a description of the measurements involved and their relationship to the statutory requirement for hospice quality reporting (78 FR 48261–48266).

a. Background and Description of the Survey

Before the development of the CAHPS® Hospice Survey, there was no official national standard hospice experience of care survey that included standard survey administration protocols. The CAHPS® Hospice Survey includes detailed survey administration protocols which will allow for fair comparisons across hospices.

CMS developed the CAHPS® Hospice Survey with input from many stakeholders, including other government agencies, industry stakeholders, consumer groups and other key individuals and organizations involved in hospice care. The Survey was designed to measure and assess the experiences of patients who died while receiving hospice care as well as the experiences of their informal caregivers. The goals of the survey are to—

- Produce comparable data on patients' and caregivers' perspectives of care that allow objective and meaningful comparisons between hospices on domains that are important to consumers;

- Create incentives for hospices to improve their quality of care through public reporting of survey results; and

- Hold hospice care providers accountable by informing the public about the providers' quality of care.

The development process for the survey began in 2012 and included a public request for information about publically available measures and important topics to measure (78 FR 5458); a review of the existing literature on tools that measure experiences with end-of-life care; exploratory interviews with caregivers of hospice patients; a technical expert panel attended by survey development and hospice care quality experts; cognitive interviews to test draft survey content; incorporation of public responses to **Federal Register** notices (78 FR 48234) and a field test conducted by CMS in November and December 2013.

The CAHPS® Hospice Survey treats the dying patient and his or her informal caregivers (family members or friends) as the unit of care. The Survey seeks information from the informal caregivers of patients who died while enrolled in hospices. Caregivers will be identified using hospice records. Fielding timelines give the respondent some recovery time (2 to 3 months), while simultaneously not delaying so long that the respondent is likely to forget details of the hospice experience. The survey focuses on topics that are important to hospice users and for which informal caregivers are the best source for gathering this information. Caregivers will be presented with a set of standardized questions about their own experiences and the experiences of the patient in hospice care. During national implementation of this survey, hospices are required to conduct the survey to meet the hospice quality reporting requirements, but individual caregivers will respond only if they voluntarily choose to do so. We have launched a Web site as part of national implementation which is intended as the primary information resource for hospices and vendors (www.hospicecahpsurvey.org). The CAHPS® Hospice Survey will initially be available in English and Spanish. CMS will provide additional translations of the survey over time in response to suggestions for any additional language translations. Requests for additional language translations should be made to the CMS Hospice CAHPS® Project Team at hospicesurvey@cms.hhs.gov.

In general, hospice patients and their caregivers are eligible for inclusion in the survey sample with the exception of the following ineligible groups: primary

caregivers of patients under the age of 18 at the time of death; primary caregivers of patients who died within 48 hours of admission to hospice care; patients for whom no caregiver is listed or available, or for whom caregiver contact information is not known; patients whose primary caregiver is a legal guardian unlikely to be familiar with care experiences; patients for whom the primary caregiver has a foreign (Non-US or US Territory address) home address; patients or caregivers of patients who request that they not be contacted (those who sign "no publicity" requests while under the care of hospice or otherwise directly request not to be contacted). Identification of patients and caregivers for exclusion will be based on hospice administrative data.

Hospices with fewer than 50 survey-eligible decedents/caregivers during the prior calendar year are exempt from the CAHPS® Hospice Survey data collection and reporting requirements for payment determination. Hospices with 50 to 699 survey-eligible decedents/caregivers in the prior year will be required to survey all cases. For hospices with 700 or more survey-eligible decedents/caregivers in the prior year, a sample of 700 will be drawn under an equal-probability design.

Survey-eligible decedents/caregivers are defined as that group of decedent and caregiver pairs that meet all the criteria for inclusion in the survey sample.

For national implementation, we have assumed an eligibility rate of 85 percent and a response rate of 50 percent based on experience in the 2013 field test of the CAHPS® Hospice Survey instrument. These rates will result in an estimated 300 completed questionnaires for each hospice with 700 or more survey-eligible decedents/caregivers in the calendar year and between 21 and 300 completed questionnaires for hospices with between 50 and 699 survey-eligible decedents/caregivers during the calendar year. Assuming a total of 300 completes within each hospice and an intraclass correlation coefficient (ICC) of 0.01, which measures the amount of variability between hospices, we would achieve an interunit reliability of 0.75. Note that in Medicare CAHPS® a reliability of 0.75 is regarded as a minimal acceptable standard.

We will move forward with a model of national survey implementation which is similar to that of other CMS patient experience of care surveys. Medicare-certified hospices will contract with a third-party vendor that is CMS-trained and approved to

administer the survey on their behalf. Hospices are required to contract with independent survey vendors to ensure that the data are unbiased and collected by an organization that is trained to collect this type of data. It is important that survey respondents feel comfortable sharing their experiences with an interviewer not directly involved in providing the care. We have successfully used this mode of data collection in other settings, including for Medicare-certified home health agencies. The goal is to ensure that we have comparable data across all hospices.

Hospices will be required to provide their vendor with the sampling frame on a monthly basis. Participation requirements for the survey begin January 1, 2015 for the FY 2017 Annual Payment Update. For hospices, this means they will have to start conducting the survey as of January 1, 2015 and will incur the costs of hiring a survey vendor. The survey vendor would be the business associate of the hospice.

A list of approved vendors will be provided on <http://www.hospicecahpsurvey.org> closer to the launch of national implementation.

Beginning summer 2014, interested vendors may apply to become approved CAHPS® Hospice Survey vendors. The application process will be online at <http://www.hospicecahpsurvey.org>. Vendors conducting the survey are required to offer a toll free assistance line which respondents can call for help. This help could include reading the survey to a respondent. The toll free line must have staff that can respond to questions in any language in which the vendor is offering the survey. Vendors must accommodate alternate telephone communications, including TTY.

In the FY 2015 Hospice Wage Index proposed rule we proposed to codify the requirements for being an approved CAHPS® Hospice Survey vendor for the FY 2017 APU.

Consistent with many other CMS CAHPS® surveys that are publicly reported on CMS Web sites, CMS will publicly report hospice data when at least 12 months of data are available, so that valid comparisons can be made across hospice providers in the United States, to help patients, family and friends choose a hospice program for themselves or their loved ones.

b. Participation Requirements To Meet Quality Reporting Requirements for the FY 2017 APU

In section 3004 of the Affordable Care Act, the Secretary is directed to establish quality reporting requirements for Hospice Programs. The CAHPS® Hospice Survey is a component of the CMS Quality Reporting Requirements for the FY 2017 APU and subsequent years.

The CAHPS® Hospice Survey is the only nationally implemented survey of civilian patient and caregiver experiences with hospice that includes both a standard questionnaire and standard survey administration protocols. Such standardization is needed in order to establish that the resulting survey data is comparable across hospices and is suitable for public reporting.

The CAHPS® Hospice Survey includes the measures detailed in *Table 8*. The measures map directly to the CAHPS® Hospice Survey. The individual survey questions that comprise each measure are listed under the measure. These measures are in the process of being submitted to the National Quality Forum (NQF).

TABLE 8—HOSPICE EXPERIENCE OF CARE SURVEY QUALITY MEASURES AND THEIR ITEMS

Hospice Team Communication

- How often did the hospice team listen carefully to you when you talked with them about problems with your family member's hospice care?
- While your family member was in hospice care, how often did the hospice team listen carefully to you?
- While your family member was in hospice care, how often did the hospice team explain things in a way that was easy to understand?
- While your family member was in hospice care, how often did the hospice team keep you informed about your family's condition?
- While your family member was in hospice care, how often did the hospice team keep you informed about when they would arrive to care for your family member?

Getting Timely Care

- While your family member was in hospice care, when you or your family member asked for help from the hospice team, how often did you get help as soon as you needed it?
- How often did you get the help you needed from the hospice team during evenings, weekends, or holidays?

Treating Family Member with Respect

- While your family member was in hospice care, how often did the hospice team treat your family member with dignity and respect?
- While your family member was in hospice care, how often did you feel that the hospice team really cared about your family member?

Providing Emotional Support

- In the weeks after your family member died, how much emotional support did you get from the hospice team?
- While your family member was in hospice care, how much emotional support did you get from the hospice team?

Getting Help for Symptoms

- How often did your family member receive the help he or she needed from the hospice team for feelings of anxiety or sadness?
- Did your family member get as much help with pain as he or she needed?
- How often did your family member get the help he or she needed for constipation?
- How often did your family member get the help he or she needed for trouble breathing?

Information Continuity

- While your family member was in hospice care, how often did anyone from the hospice team give you confusing or contradictory information about your family member's condition or care?

Understanding the Side Effects of Pain Medication

- Side effects of pain medicine include things like sleepiness. Did any member of the hospice team discuss side effects of pain medicine with you or your family member?

Getting Hospice Care Training (Home Setting of Care Only)

- Did the hospice team give you enough training about what to do if your family member became restless or agitated?
- Did the hospice team give you enough training about if and when to give more pain medicine to your family member?
- Did the hospice team give you enough training about how to help your family member if he or she had trouble breathing?
- Did the hospice team give you enough training about what side effects to watch for from pain medicine?

To comply with CMS's quality reporting requirements, hospices will be required to collect data using the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Hospice Survey. Hospices would be able to comply by utilizing only CMS-approved third party vendors that are in compliance with the provisions at § 418.312(e).

In the FY 2014 Hospice Wage Index and Rate Update final rule (78 FR 48234), we stated that national implementation of the CAHPS® Hospice Survey will begin with a "dry run" in the first quarter of CY 2015. Hospices are required to contract with an approved survey vendor to conduct a dry run of the survey for at least one month during January 2015, February 2015, or March 2015. During this period

the survey vendor will follow all the national implementation procedures, but the data will not be publicly reported. The dry run will provide hospices and their vendors with the opportunity to work together under test circumstances.

Beginning April 1, 2015, all hospices are required to participate in the survey on an ongoing monthly basis. This means hospices need to contract with a survey vendor to conduct the survey monthly on their behalf. Participation for at least 1 month during the dry run, plus monthly participation for the 9 months between April 2015 and December 2015 (inclusive) is required to meet the pay for reporting requirement of the Hospice Quality Reporting Program (HQRP) for the FY 2017 APU.

Approved CAHPS® Hospice Survey vendors will submit data on the hospice's behalf to the CAHPS® Hospice Survey Data Center. The deadlines for data submission occur quarterly and are shown in *Table 9* below. Deadlines are final; no late submissions will be accepted. However in the event of extraordinary circumstances beyond the control of the provider, the provider will be able to request an exemption as previously noted in the Quality Measures for Hospice Quality Reporting Program and Data Submission Requirements for Payment Year FY 2016 and Beyond section. Hospice providers are responsible for making sure that their vendors are submitting data in a timely manner.

TABLE 9—DATA SUBMISSION DATES 2015–2016 FOR CAHPS® HOSPICE SURVEY

Sample months	Quarterly data submission deadlines
Dry Run (January–March 2015)	August 12, 2015
Monthly data collection April–June 2015 (Q2)	November 1, 2015
Monthly data collection July–September 2015 (Q3)	February 10, 2016
Monthly data collection October–December 2015 (Q4)	May 11, 2016

In the FY 2014 Hospice Wage Index and Rate Update final rule, we stated that we would exempt very small hospices from CAHPS® Hospice Survey requirements. Hospices that have fewer than 50 survey-eligible decedents/caregivers in the period from January 1, 2014 through December 31, 2014 are exempt from CAHPS® Hospice Survey data collection and reporting requirements for the 2017 APU. To qualify for the survey exemption for FY 2017, hospices must submit an exemption request form. This form will be available on the CAHPS® Hospice Survey Web site <http://www.hospicecahpsurvey.org>. Hospices are required to submit to CMS their total unique patient count for the period of January 1, 2014 through December 31, 2014. The due date for submitting the exemption request form for the FY 2017 APU is August 12, 2015.

c. Participation Requirements To Meet Quality Reporting Requirements for the FY 2018 APU

To meet participation requirements for the FY 2018 APU, we proposed that hospices collect data on an ongoing monthly basis from January 2016 through December 2016 (inclusive). Data submission deadlines for the 2018 APU will be announced in future rulemaking.

Hospices that have fewer than 50 survey-eligible decedents/caregivers in the period from January 1, 2015 through December 31, 2015 are exempt from CAHPS® Hospice Survey data collection and reporting requirements for the FY 2018 payment determination. To qualify, hospices must submit an exemption request form. This form will be available in first quarter 2016 on the CAHPS® Hospice Survey Web site <http://www.hospicecahpsurvey.org>.

Hospices are required to submit to CMS their total unique patient count for the period of January 1, 2015 through December 31, 2015. The due date for submitting the exemption request form for the FY 2018 APU is August 10, 2016.

Summaries of the public comments and our responses to comments are summarized below:

Comment: For the CAHPS® Hospice Survey we received multiple comments concerning CMS' proposed exclusion of respondents who were family caregivers of patients who died within 48 hours or less of their admission to hospice care. Commenters were concerned that we were excluding this group's experience.

Response: We appreciate these comments because they show a concern for evaluating the hospice care experience for all patients, regardless of the time spent in hospice care. CMS used the 48 hours or less exclusion because of the history of the Family

Evaluation of Care Survey (FEHC) which has been in use in the industry for several years. The FEHC also recommended exclusion of patients with less than two days of hospice care. We set similar timeframe exclusions for other CAHPS® surveys such as the Medicare CAHPS® Health Plans Survey, where respondents need to be in the plans for at least six months, and the ICH CAHPS® survey where the respondents need to have at least three months of dialysis experience at the facility before they are eligible. If caregiver respondents do not have enough experience with the hospice, they will not be able to easily or reliably answer the questions on the current survey. Our technical expert panel also stated that shorter-stay patients would have difficulty answering the current questions on the survey and recommended developing a shorter questionnaire for shorter-stay respondents. In national implementation, we will move forward with the 48-hour or less exclusion, but we will closely track the number of patients being excluded. We will consider developing and implementing an abbreviated CAHPS® Hospice Survey, depending upon the number of people affected.

Comment: One commenter stated that it is important that the CAHPS® Hospice Survey document the length of stay, and

its relationship to the profit/non-profit status of the hospice, in order to provide an accurate picture of the caregiver's perception of the quality of care the hospice provided and to publicly report the data by length of stay.

Response: We have not determined how the survey results will be publicly reported for hospices. However, we are aware that both length of stay and for-profit/non-profit status may have an impact on patient/caregiver experiences. We would not control for for-profit or non-profit status when we publicly report the data since that is under the control of the facility. If length of stay is a function of for-profit or non-profit status, it also should not be controlled for. During national implementation we will document the length of stay for sampled patients as part of the administrative data we obtain for all sampled patients. CMS will conduct analyses of the impact of length of stay and profit/non-profit status on the survey results to see if any adjustments are needed for length of stay.

Comment: A small number of commenters said there should be no participation exemptions for hospices reporting fewer than 50 deaths per year.

Response: We proposed to exempt hospices with fewer than 50 survey-eligible decedents/caregivers annually because very small hospices will not have a sufficient number of survey responses to produce reliable measures. Survey data collected for very small samples tends to be unstable and can be influenced by relatively small changes in responses. This could result in the smallest hospices experiencing substantial variations in scores each year, not due to changes in care, but because only a small number of caregivers are answering the questions.

Comment: One commenter said that the CAHPS® Hospice Survey should include a method for finding the respondent who is the most knowledgeable about the patient experience and noted that this person may not be the patient's closest relative.

Response: The family caregiver listed in hospice administrative records is the individual who will be contacted to respond to the CAHPS® Hospice Survey. We agree this person may or may not be the most knowledgeable about the patient's care. However, for sampling purposes we must be able to objectively and clearly define our target population and we must have contact information to reach them by mail or telephone.

Comment: One commenter stated that very few hospices experience fewer than 50 deaths a year. Conversely, 700 deaths are not necessarily indicative of a large

hospice requiring only a sample survey. The commenter also stated that CMS may wish to analyze the sampling ranges in the year following initial implementation to determine if these ranges are appropriate, particularly for sampling.

Response: We are excluding hospices with fewer than 50 survey-eligible decedents/caregivers annually because small samples will not produce reliable results. The choice of 700 survey-eligible decedents/caregivers annually is not intended to define a large hospice, but only to allow hospices with this many deaths (or more) to conduct a sample rather than require them to survey a census of all eligible caregivers. CMS will continuously monitor survey responses and vendor activities. We will revisit these ranges if we find evidence that we need to do so.

Comment: One commenter stated that the CAHPS® Hospice Survey is too long and is not written in health literacy terms.

Response: The CAHPS® Hospice Survey includes 47 items, not all of which apply to all respondents. This does make the survey slightly longer than the Hospital CAHPS® Survey (32 items) and the Home Health CAHPS® Survey (34 items). However, the hospice survey had to ask demographic questions for both the patient and the family caregiver, which partially accounts for its longer length. In addition, some items are only for patients in particular settings (for example, home care). The CAHPS® Hospice Survey was cognitively tested to learn how well respondents understood the items. The questionnaire was revised based upon the results of the cognitive testing. The text of the current instrument and the final reports on the testing of the instrument can be found at: <http://www.hospicecahpsurvey.org>.

Comment: One commenter was concerned that the survey is missing specific references to mental/behavior health, psychosocial concerns and related occupations.

Response: The CAHPS® Hospice Survey does not seek to address experiences with specific professional occupations, but rather asks about the entire hospice team. Items on the survey concern communication with the hospice team, as well as the patients' experience of anxiety and agitation. The survey also asks about spiritual and emotional support provided by the hospice. The survey was designed to capture topic areas that are most important from the perspective of family members/caregivers of the patients.

Comment: One commenter said they understood that the proposal required that three different CAHPS surveys be distributed, based on the patient's location at the time of death. The commenter strongly disagreed with implementing the survey in this manner.

Response: The CAHPS® Hospice survey consists of a single survey instrument for all settings in which hospice care is provided. The questionnaire will include a few items applicable only to certain settings of care (for example, home-based hospice) along with clear directions for the respondent. We do not limit our questions only to the final setting of care.

Comment: One commenter said that for some questions in the survey, the use of choices such as never, sometimes, usually or always could affect the results. The commenter noted that some respondents may believe there is room for improvement and may be reluctant to choose "always" as an answer. The commenter stated that a five-point rating scale may be a better choice.

Response: The "never to always" scale has been tested extensively and used in CAHPS® surveys for many years. We are unaware of any evidence indicating respondents are reluctant to choose "always" as a response. In addition, we do not believe a 5-point rating scale would offer a significant improvement over the existing CAHPS® survey response methodology.

Comment: One commenter stated that the CAHPS® Hospice Survey should include patients as respondents rather than exclusively interview informal caregivers.

Response: CMS is aware of the value of collecting survey data on patients' experiences. During the survey development process we carefully considered the logistics of conducting surveys with two different populations: hospice patients and their informal caregivers. CMS concluded that attempting to survey two populations would pose additional logistical problems and burdens because it was not clear the same questionnaire could be used for both groups. It is also not clear how the two groups should be publicly reported. Other considerations include —(1) the difficulty of determining which hospice patients are capable of participating in the survey and; (2) the risk of upsetting families if a survey addressed to a patient were to arrive soon after the patient died. In addition, hospice patients cannot provide information about the totality of the hospice care provided. For these reasons, CMS decided to survey only

primary caregivers of deceased hospice patients.

Comment: One commenter said that the hospice survey questionnaire should not be sent more than two months after the death of the patient, as the family member(s) may have difficulty recalling the experience. The commenter also noted that a prolonged delay in completion of the survey questionnaire could result in diminished recall by the patient's clinicians.

Response: CMS is aware that a significant delay in the completion of the survey questionnaire following the death of a patient can diminish the ability of survey respondents to accurately recall events. However, sending the survey shortly after a patient's death has the potential to generate grief and pain for the respondent. Based on discussions with our technical expert panel and stakeholders, CMS has chosen to include what we believe is an appropriate period of delay following the death of the patient and survey administration procedures to provide a time for family members to grieve, but still respond regarding the particulars of hospice care. CMS has built in a two-month lag after the death before any contact is made with the potential respondent. Currently, the CAHPS® Hospice Survey does not consider clinicians as survey respondents, thus the commenter's concerns regarding their ability to recall patient care for the survey is outside the scope of the comment.

Comment: Approximately one-third of commenters supported the CAHPS® Hospice Survey.

Response: We thank the commenters for their support.

Comment: One commenter recommended that the definition of criteria for exclusion be clarified for consistent interpretation and implementation.

Response: Details of the groups that are ineligible for survey participation can be found under subsection a. Background and Description of the Survey in this rule.

Final Action: As a result of these comments, we are finalizing the requirements as proposed. Hospices must participate in and report data from the Dry Run for at least 1 month in the first quarter of CY 2015 (January 2015, February 2015, or March 2015). Continuous monthly data collection begins in April 1, 2015, continues through December 31, 2015, and continues in subsequent years.

d. Vendor Participation Requirements for the 2017 APU

CMS will train and approve vendors to administer CAHPS® Hospice Survey on behalf of hospices (78 FR 48233). In addition we stated that hospices will be required to contract with an approved survey vendor and to provide the sampling frame to the approved vendor on a monthly basis.

We proposed that approved survey vendors must meet all of the minimum business requirements and follow the detailed technical specifications for survey administration as published in the CAHPS® Hospice Survey specifications manual, which will be posted on the Survey Web site: <http://hospicecahpsurvey.org>. In addition, to the specifications manual, the Web site will include information and updates regarding survey implementation and technical assistance, and a copy of the questionnaire.

We proposed to codify the CAHPS® Hospice Survey vendor requirements to be effective with the FY 2017 APU (as proposed in § 418.312). We proposed that applicants wishing to become approved CAHPS® Hospice Survey vendors must have been in business for a minimum of 4 years and have conducted surveys for a minimum of 3 years using each the modes of survey administration for which they are applying. In addition the organization must have been conducting "surveys with patients" for at least 2 years immediately preceding the application to become a survey vendor for the CAHPS® Hospice Survey. For purposes of the approval process for CAHPS® Hospice Survey vendors, a "survey of individual patients" is defined as the collection of data from at least 600 individual patients selected by statistical sampling methods and the data collected are used for statistical purposes.

Vendors may not use home-based or virtual interviewers to conduct the CAHPS® Hospice Survey, nor may they conduct any survey administration processes (for example, mailings) from a residence to ensure the confidentiality of data.

The following are examples of data collection activities will not satisfy the requirement of valid survey experience for approved vendors as defined for the CAHPS® Hospice Survey, and these will not be considered as part of the experience required of an approved vendor for CAHPS® Hospice Survey.

- Focus groups, cognitive interviews, or any other qualitative data collection activities;

- Surveys of fewer than 600 individuals;

- Surveys conducted that did not involve using statistical sampling methods;

- Internet or Web-based surveys; and
- Interactive Voice Recognition Surveys.

We also proposed that no organization, firm, or business that owns, operates, or provides staffing for a hospice is permitted to administer its own Hospice CAHPS® survey or administer the survey on behalf of any other hospice in the capacity as a Hospice CAHPS® survey vendor. Such organizations will not be approved by CMS as CAHPS® Hospice Survey vendors.

Summaries of the public comments and our responses to those comments are summarized below:

Comment: CMS received no comments regarding Vendor Participation Requirements for the 2014 APU.

Final Action: We are finalizing the requirements as proposed without change.

e. Annual Payment Update

The Affordable Care Act requires that beginning with FY 2014 and each subsequent fiscal year, the Secretary shall reduce the market basket update by 2 percentage points for any hospice that does not comply with the quality data submission requirements with respect to the fiscal year, unless covered by specific exemptions. Any such reduction will not be cumulative and will not be taken into account in computing the payment amount for subsequent fiscal years. In the FY 2015 Hospice Wage Index proposed rule, we proposed to add the CAHPS® Hospice Survey to the Hospice Quality Reporting Program requirements for the FY 2017 payment determination and determinations for subsequent years.

- To meet the FY 2017 requirements, hospices will participate in the Dry Run for at least 1 month of the first quarter of CY 2015 (January 2015, February 2015, March 2015). Hospices must collect the survey data on a monthly basis for the months of April 1, 2015 through December 31, 2015 in order to qualify for the full APU.

- To meet the HQR requirements for the FY 2018 payment determination, hospices would collect survey data on a monthly basis for the months of January 1, 2016 through December 31, 2016 to qualify for the full APU.

Summaries of the public comments and our responses to comments are summarized below:

Comment: A few commenters stated that the timeframe for implementing the CAHPS® Hospice Survey may not be sufficient to adequately finalize the survey questions, approve, train and hire vendors, complete the Dry Run and correct any concerns that may arise from the Dry Run.

Response: We are aware that the timeframe for implementing the CAHPS® Hospice Survey is shorter than for other CAHPS® surveys. However, we have taken steps to mitigate the impact on hospices. The survey can be found on the CAHPS® Hospice Survey Web site, www.hospicecahpsurvey.org. We will post the Quality Assurance Guidelines technical manual in August 2014. We will also open the vendor application and approval process on the Web site in August 2014. This should provide hospice programs with ample time to contact and select a vendor. Hospices may contact vendors prior to this time if they wish to do so. The Dry Run will occur over the first quarter of 2015 (January–March 2015). We encourage hospices to participate in the Dry Run as early as possible and collaborate with their vendors to resolve any potential issues.

Comment: A few commenters noted the cost of conducting the CAHPS® Hospice Survey imposes regulatory burden on hospice providers requiring the allocation of resources from patient care and potentially result in higher costs to the Medicare program due to patients being shifted to higher levels of care due to limited hospice staffing.

Response: We respectfully disagree with the commenter's assertions. Similar to other CAHPS® surveys, the CAHPS® Hospice Survey will allow three modes of data collection, with each mode of data collection varying in price. The modes are: mail-only, telephone-only, and mixed mode (mail with telephone follow-up). We urge hospices to call multiple vendors to discuss prices and services since the cost does vary by vendor and the extra services that they provide. It is unacceptable to change a patient's level of care due to staffing issues; such a change should be based on the patient's and family's needs, should meet the regulatory requirements for that level of care, and should be documented in the plan of care.

Comment: One commenter noted that CMS should refrain from using data for public reporting until 2016.

Response: We have not finalized plans for public reporting of CAHPS® Hospice Survey data. However, we will not publicly report data until we have accumulated a baseline data set of at least four quarters of data.

Comment: One commenter said that CMS should ensure that public reporting will meet the needs of Medicare beneficiaries and their family caregivers. Among other things, the information should be beneficiary friendly and address matters of particular concern to beneficiaries and their families.

Response: We agree that public reporting of data obtained from surveys should meet the needs of Medicare beneficiaries and their families. Prior to publicly reporting the data, the displays will be tested with potential users of the information. We thank the commenter for the reminder of the importance of public reporting to beneficiaries and their families.

Comment: One commenter said that CMS should delay public reporting until the HIS is more fully developed and the data from the Hospice CAHPS is available.

Response: CMS has not stated when public reporting of hospice survey results will commence. We will provide details on the schedule for public reporting in subsequent rulemaking.

Comment: CMS should also consider instituting a hospice star rating system where hospice providers will be measured based on these quality metrics so family members/care givers are able to shop for hospice benefits based on quality rating.

Response: We appreciate the comment and will take it under consideration as public displays are developed.

Final Action: We are finalizing the requirements as proposed without change.

f. CAHPS® Hospice Survey Oversight Activities

We proposed a requirement that vendors and hospice providers participate in CAHPS® Hospice Survey oversight activities to ensure compliance with Hospice CAHPS® technical specifications and survey requirements. The purpose of the oversight activities is to ensure that hospices and approved survey vendors follow the CAHPS® Hospice Survey technical specifications and thereby ensure the comparability of CAHPS® Hospice Survey data across hospices.

We proposed that the reconsiderations and appeals process for hospices failing to meet the Hospice CAHPS® data collection requirements will be part of the Reconsideration and Appeals process already developed for the Hospice Quality Reporting program. We encourage hospices interested in learning more about the CAHPS® Hospice Survey to visit the CAHPS®

Hospice Survey Web site: <http://www.hospicecahpsurvey.org>.

Summaries of the public comments and responses to comments regarding the reconsiderations and appeals process for hospices that fail to meet the Hospice CAHPS® data collection requirements regarding are summarized below:

Comment: CMS received no comments regarding CAHPS® Hospice Survey Oversight Activities

Final Action: We are finalizing the requirements as proposed without change.

7. Procedures for Payment Year 2016 and Subsequent Years

In the FY 2014 Hospice Wage Index and Payment Rate Update final rule (78 FR 48267), we notified hospice providers of the opportunity to seek reconsideration of our initial non-compliance decision for the FY 2014 and FY 2015 payment determinations. We stated that we will notify hospices found to be non-compliant with the HQRP reporting requirements that they may be subject to the 2 percentage point reduction in their annual payment update. The process for filing a request for reconsideration is described on the CMS Web site at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Reconsideration-Requests.html>. We proposed to codify this process at § 418.312.

Finally, we proposed to codify at § 418.306 that beginning with FY 2014 and each subsequent FY, the Secretary shall reduce the market basket update by 2 percentage points for any hospice that does not comply with the quality data submission requirements with respect to that FY and solicited comments on all of the proposals in this section and the associated regulations text at § 418.312 and in § 418.306 in section VI.

Summaries of the public comments and our responses to comments are summarized below:

Comment: CMS received no comments regarding Procedures for Payment Year 2016 and Subsequent Years.

Final Action: We are finalizing the requirements as proposed without change.

I. Solicitation of Comments on Coordination of Benefits Process and Appeals for Part D Payment for Drugs While Beneficiaries are Under a Hospice Election

The statutory definition of the term “covered Part D drug”, as specified in section 1860D–2(e)(2)(B) of the Social

Security Act, excludes a drug if payment for such a drug, as so prescribed and dispensed or administered with respect to a Part D eligible individual, is available (or would be available but for the application of a deductible) under Part A or B for that individual. Therefore, drugs and biologicals for which coverage is available under the Medicare Part A per-diem payment to a hospice program are excluded from coverage under Part D. Our previous understanding was that hospice coverage of drugs was very broad and very inclusive. Therefore, Part D payment for drugs furnished to hospice beneficiaries would be rare and the need for controls was not critical.

Section 1861(dd) of the Act states the hospice is responsible for covering all drugs or biologicals for the palliation and management of the terminal illness and related conditions. Our stated intention in the 1983 Hospice final rule (48 FR 56010) was that the hospice benefit provides virtually all care for the terminally ill individual. Despite our intention for a comprehensive and holistic benefit, gross covered drug costs in 2012 under Part D for beneficiaries during a hospice election totaled \$417.9 million. Of this total, Medicare reimbursed approximately \$334.9 million, and beneficiaries contributed \$48.2 million in possibly unnecessary cost-sharing.

1. Part D Sponsor Coordination of Payment with Hospice Providers

In the proposed rule, we described various requirements we were considering to facilitate the coordination of payment between Part D sponsors and hospices and solicited comments on them. We refer you to the proposed rule (79 FR 26570 through 26575) for the discussion of the requirements we were considering and sought comment on. Prior to the proposed rule, we had issued interim guidance on March 10, 2014 (<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Downloads/Part-D-Payment-Hospice-Final-2014-Guidance.pdf>) and, as a result of feedback from stakeholders, we amended the guidance on July 18, 2014. In the interim guidance, we encourage Part D sponsors and Medicare hospices to take several of the actions that we stated in the proposed rule we are considering requiring. Our July 18, 2014 guidance can be accessed at (<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Downloads/2014-PartD-Hospice-Guidance-Revised-Memo.pdf>); we plan that this guidance will remain in effect

until requirements are finalized. The revised guidance expects Part D sponsors to use hospice prior authorization only on the four categories of drugs that the Office of Inspector General (<http://oig.hhs.gov/oas/reports/region6/61000059.pdf>), in consultation with hospice providers, identified as nearly always covered under the hospice benefit. These categories of drugs will require hospice prior authorizations analgesics, anti-nauseants, laxatives, and anti-anxiety drugs. Hospices may use the "Hospice Information for Medicare Part D" (<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Downloads/Hospice-Info-PartD.pdf>) form to provide the necessary information generally requested by Medicare Part D sponsors.

We appreciate the comments we received on the processes we were considering to facilitate the coordination of payment between Part D sponsors and hospices and will consider those comments in future rulemaking.

In formulating the changes we were considering, we became aware that the regulatory requirement for a Part D sponsor to coordinate with other health benefit plans or programs at § 423.464(f)(1)(ix) is narrower than the requirement specified in statute. Section 1860D–24 of the Act requires Part D sponsors to coordinate with other drug plans, including, as specified in paragraph § 423.464(b)(5), with other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of Part D eligible individuals. However, in codifying this requirement in the regulations at § 423.464(f)(1)(ix), we specified that the other plans or programs are those that provide coverage or financial assistance for the purchase or provision of Part D (emphasis added) prescription drugs. The regulation does not include the requirement for Part D sponsors to coordinate with providers of drugs covered under Part A, such as hospices, since those drugs prescribed, dispensed, or administered under Part A are excluded from the definition of a covered Part D drug. Because coordination between Part D sponsors and the Medicare hospices is essential to ensure Part D statutory coverage requirements are met, to reduce the potential for erroneous payment under Part D, and to facilitate the recovery of erroneous payments when they do occur, we also were considering amending the Part D regulations at § 423.464(f) to align the definition of other prescription drug coverage in

paragraph § 423.464(f)(1)(ix) with the statute by removing the phrase "Part D." We did not propose to amend the Part D regulations at § 423.464(f), but rather solicited comments on this change. We appreciate the comments received in response to our solicitation and will consider those comments in future rulemaking.

2. Solicitation of Comments on Hospice Coordination of Payment with Part D Sponsors and Other Payers

As specified in section 1861(dd) of the Act, and in regulation at 42 CFR Part 418, the hospice is responsible for covering all drugs and biologicals for the palliation and management of the terminal illness and related conditions. As noted in 418.202(f), drugs and biologicals for palliation of pain and symptom management are included in the Medicare Part A per-diem payment to a hospice. Therefore, such drugs and biologicals are excluded from coverage under Part D (see section III.I.1). Our payment regulations at § 418.200 require that, to be covered, hospice services must be consistent with the plan of care, which must include the drugs and treatment necessary to meet the needs of the patient (§ 418.56(c)(2)). Additionally, the CoPs at § 418.56(e)(5) require hospices to share information with other non-hospice healthcare providers furnishing services unrelated to the terminal illness and related conditions. As described in § 418.100(c)(2), hospices must be available 24 hours a day and 7 days a week to address beneficiary and family needs.

We have received anecdotal reports from Medicare hospice beneficiaries that they are not receiving medications related to their terminal illness and related conditions from their hospice because, among other stated reasons, those medications are not on the hospice's formulary. These reports also have stated that hospice beneficiaries were advised to obtain drugs related to the terminal illness and related conditions from their Part D prescription drug plans. Per the regulations at § 418.202(f), hospices must provide all drugs which are reasonable and necessary to meet the needs of the patient in order to provide palliation and symptom management of the terminal illness and related conditions. If the drugs on the hospice formulary are not providing the relief needed, then the hospice must provide alternatives in order to relieve pain and symptoms, even if it means providing drugs that are not on their formularies. Treatment decisions should not be driven by costs, as opposed to clinical

appropriateness. Hospices should use thoughtful clinical judgment, with a patient-centered focus, when developing the hospice plan of care, including the recommendations for medication management.

We did not propose any requirements, but we described various requirements we are considering to facilitate coordination of payment responsibility between hospices and other payers and operational considerations. We refer you to the May 8, 2014 FY 2015 Hospice proposed rule (79 FR 26570–26575) for the discussion of the requirements we sought comments on. As articulated above in section I.1, the July 18, 2014 interim guidance (<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Downloads/2014-PartD-Hospice-Guidance-Revised-Memo.pdf>) has been issued, and we plan that this guidance will remain in effect until requirements are finalized. We appreciate the comments on these issues and will consider the comments in future rulemaking.

3. Beneficiary Rights and Appeals

Sometimes a beneficiary requests a certain medication that a hospice cannot or will not provide because the hospice has deemed that the specific medication is not reasonable and necessary for the palliation and management of the terminal illness and related conditions. Coverage of such medication would not be permissible under Part D coverage since the medication is not for any condition completely separate and distinct from the terminal illness and related conditions, nor is it covered under Part A, since it is not reasonable and necessary for the palliation and management of the terminal illness and related conditions. If the hospice does not provide the medication, the hospice is not obligated to provide any notice of non-coverage (including the Advance Beneficiary Notice of Non-coverage or ABN). If the hospice provides medication it believes is not reasonable and necessary for the palliation and management of the terminal illness and related conditions, the hospice must first issue an ABN in order to charge the beneficiary for the cost of such medication. Regardless of whether or not the hospice furnishes the drug, if the beneficiary independently obtains the drug, but believes that the Medicare hospice should have furnished or covered the cost of the drug as part of the hospice benefit, the beneficiary may submit a claim for the medication directly to Medicare on Form CMS–1490S (<http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-Items/CMS012949.html>). If the claim is

denied, the beneficiary may file an appeal of that determination under the appeals process set forth in part 405, subpart I.

There may also be instances where a beneficiary prefers a non-formulary drug because, for example, he or she believes it to be more efficacious than the formulary drug prescribed by the hospice. In such instances, the hospice may have determined that the formulary drug prescribed is reasonable and necessary for the palliation and management of the terminal illness and related conditions; however, the beneficiary may prefer another brand of such drug that is off formulary, which the hospice believes is not reasonable and necessary, or more expensive but no more effective than the drug in the formulary. In those cases, the beneficiary may submit quality of care complaints to a Quality Improvement Organization. We plan to increase our beneficiary outreach efforts to advise beneficiaries and their families/caregivers of their rights and the available appeals process described in this section.

J. Update on the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) and Coding Guidelines for Hospice Claims Reporting

3. International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM)

On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93), was enacted. Section 212 of PAMA, titled “Delay in Transition from ICD–9 to ICD–10 Code Sets,” provides that “[t]he Secretary of Health and Human Services may not, prior to October 1, 2015, adopt ICD–10 code sets as the standard for code sets under section 1173(c) of the Social Security Act (42 U.S.C. 1320d–2(c)) and section 162.1002 of title 45, Code of Federal Regulations.” On May 1, 2014, the Secretary announced plans to release an interim final rule in the near future that will include a new compliance date to require the use of ICD–10–CM beginning October 1, 2015. The interim final rule will also require HIPAA covered entities to continue to use ICD–9–CM through September 30, 2015. Although the Department has not yet published the rule, we are proceeding in accordance with the announcement. This means that ICD–9–CM diagnosis codes will continue to be used for hospice claims reporting until October 1, 2015, the new implementation date for ICD–10–CM. Diagnosis reporting on hospice claims

must adhere to ICD–9–CM coding conventions and guidelines regarding the selection of principal diagnosis and the reporting of additional diagnoses. Additionally, the CMS’ Hospice Claims Processing manual (Pub 100–04, chapter 11) requires that hospice claims include the reporting of additional/other diagnoses as required by ICD–9–CM coding guidelines.

In the HIPAA regulations at 45 CFR 162.1002, the Secretary adopted the ICD–9–CM code set, including the Official ICD–9–CM Guidelines for Coding and Reporting. The current ICD–9–CM Coding Guidelines use the International Classification of Diseases, 9th Edition, Clinical Modification (ICD–9–CM) and are available through the CMS Web site at: <http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html> or on the CDC’s Web site at <http://www.cdc.gov/nchs/icd/icd9cm.htm>.

4. Coding Guidelines for Hospice Claims Reporting

In the FY 2014 Hospice Wage Index and Payment Rate Update, we reiterated that diagnosis reporting on hospice claims should include the appropriate selection of principal diagnoses as well as the other, additional and coexisting diagnoses related to the terminal illness and related conditions (78 FR 48254). Additionally, in the July 27, 2012, FY 2013 Hospice Wage Index notice (77 FR 44247), we provided in-depth information regarding longstanding, existing ICD–9–CM Coding Guidelines. We also discussed related versus unrelated diagnosis reporting on claims and clarified that “all of a patient’s coexisting or additional diagnoses” related to the terminal illness and related conditions should be reported on the hospice claim. The expectation was that hospices would report all diagnoses related to the terminal illness and related conditions on hospice claims to provide accurate information regarding the hospice beneficiaries for which they are providing hospice services.

In the FY 2014 Hospice Wage Index and Payment Rate Update final rule, we stated that beginning on October 1, 2014, any claims with “debility” or “adult failure to thrive” in the principal diagnosis field will be returned to the provider for more definitive coding (78 FR 48252). “Debility” and “adult failure to thrive” do not provide enough information to accurately describe Medicare hospice beneficiaries and the conditions that hospices are managing. Once these claims are resubmitted with more appropriate diagnosis codes,

following the ICD–9–CM Coding Guidelines, these claims will be processed accordingly. This is a reminder that claims with “debility” and “adult failure to thrive” coded in the principal diagnosis field will be returned to providers for more definitive coding effective October 1, 2014 (for those claims submitted on and after October 1, 2014).

Also in the FY 2014 Hospice Wage Index and Payment Rate Update final rule, we advised hospice providers to pay particular attention to dementia diagnoses which are found under two separate ICD–9–CM classifications: “Mental, Behavioral, and Neurodevelopmental Disorders” and “Diseases of the Nervous System and Sense Organs” (78 FR 48252–48253). Many of the codes relating to dementia manifestations found under the ICD–9–CM classification, “Mental, Behavioral, and Neurodevelopmental Disorders”, are not appropriate as principal diagnoses because of etiology/manifestation guidelines or sequencing conventions under the ICD–9–CM Coding Guidelines. ICD–9–CM Coding Guidelines for this classification state that dementia is most commonly a secondary manifestation of an underlying causal condition. Codes found under this classification identify the common behavioral disturbances of dementia manifestations. Many of the dementia codes under the ICD–9–CM classification, “Mental, Behavioral and Neurodevelopmental Disorders” have coding conventions that require to code first the associated neurological condition. Many of the associated neurological conditions can be found under the classification, “Diseases of the Nervous System”, including such conditions as “Alzheimer’s disease” and “Senile Degeneration of the Brain”. We advise hospices to pay close attention to the various coding and sequencing conventions found within The Official ICD–9–CM Guidelines for Coding and Reporting when reporting diagnoses on hospice claims.

To ensure additional compliance with ICD–9–CM Coding Guidelines we will implement certain edits from Medicare Code Editor (MCE), which detect and report errors in the coding of claims data, for all hospice claims effective October 1, 2014 (for those claims submitted on or after October 1, 2014). Hospice claims containing inappropriate principal or secondary diagnosis codes, per ICD–9–CM coding conventions and guidelines, will be returned to the provider and will have to be corrected and resubmitted to be processed and paid.

We will implement edits related to etiology/manifestation code pairs from the MCE; therefore, it is important for hospice providers to follow the ICD–9–CM Coding Guidelines regarding codes that fall under this coding convention. The etiology/manifestation coding convention states that there are certain conditions which have both an underlying cause (etiology) and subsequent multiple body system manifestations. For such conditions, ICD–9–CM coding convention requires the underlying condition be sequenced first, followed by the manifestation. Whenever such a combination exists, there is a “use additional code” note at the etiology code and a “code first” note at the manifestation code. These instructional notes indicate the proper sequencing order of the codes. In most cases, the manifestation codes will have in the code title, “in diseases classified elsewhere.” “In diseases classified elsewhere” codes are never permitted to be used as first-listed or principal diagnosis codes. They must be used in conjunction with an underlying condition code and they must be listed following the underlying condition. An example of this can be found under the category 294, “Persistent mental disorders due to conditions classified elsewhere.” However, there are manifestation codes that do not have “in diseases classified elsewhere” in the title. For such codes, there is “use an additional code” note at the etiology code and a “code first” note at the manifestation code and the rules for sequencing apply.

There are sequencing conventions under ICD–9–CM coding guidelines that are not accounted for in the MCE edits. There are several dementia codes under the classification, “Mental Behavioral and Neurodevelopmental Disorders” that have a sequencing convention that require the underlying physiological condition to be coded first, but for which there is no edit in the MCE. We will be issuing technical guidance through a Change Request to include these codes for edits in the MCE to be consistent for claims processing under ICD–9–CM Coding Guidelines. We are reminding providers to utilize the ICD–9–CM coding guidelines when submitting hospice claims to ensure they are following the appropriate guidelines for coding so that claims are not returned to providers as a result of MCE edits. Following the ICD–9–CM coding guidelines will help hospice providers with appropriate code selection for hospice claims processing. This is not to say that hospice beneficiaries with various dementia

conditions are not appropriate for hospice services, rather, this is merely a clarification regarding the ICD–9–CM coding guidelines for claims processing. We expect hospice providers to follow ICD–9–CM coding guidelines to ensure that the most accurate information is provided regarding the patients for whom hospices are providing services.

Additional details describing the specific MCE edits that will be applied will be announced through a change request, an accompanying Medicare Learning Network article, and other CMS communication channels, such as the Home Health, Hospice, and DME Open Door Forum.

We have clarified in previous rules that hospice providers are expected to report on hospice claims all ICD–9–CM codes to provide an accurate description of the patients’ conditions. In the Hospice Wage Index for Fiscal Year 2013 (77 FR 44247) and again in the Hospice Wage Index for Fiscal Year 2014 (78 FR 48240), we reminded providers to follow ICD–9–CM Coding Guidelines for reporting diagnoses on hospice claims. HIPAA, federal regulations, and the Medicare claims processing manual all require that ICD–9–CM Coding Guidelines be applied to the coding and reporting of diagnoses on hospice claims. In the FY 2013 hospice notice, we reported that our analyses showed that 77.2 percent of hospice claims from 2010 only reported a single, principal diagnosis. We provided in-depth information regarding longstanding, existing ICD–9–CM Coding Guidelines that require the reporting of all additional or co-existing diagnoses on hospice claims. We went on to state that coexisting or additional diagnoses could be related or unrelated to the hospice patient’s terminal illness. As the Medicare hospice benefit covers hospice services for the palliation and management of the terminal illness and related conditions, we said, at that time, that hospice providers “should report on hospice claims all coexisting or additional diagnoses that are related to the terminal illness; they should not report coexisting or additional diagnoses that are unrelated to the terminal illness” (77FR 44248). We also stated that we do not believe that requiring reporting of coexisting or additional diagnoses that are related to the terminal illness would create a burden for hospice and that some providers already report these diagnoses on their claims.

In the FY 2014 Hospice Wage Index and Payment Rate Update final rule, we reported that for the first quarter of FY 2013 (October 1, 2012 through December 31, 2012) 72 percent of

hospice claims only reported a single, principal diagnosis (78 FR 48240). We also discussed related versus unrelated diagnosis reporting on claims and clarified that “all of a patient’s coexisting or additional diagnoses” related to the terminal illness or related conditions should be reported on the hospice claim. Information on a patient’s related and unrelated diagnoses should already be included as part of the hospice comprehensive assessment and appropriate interventions should be incorporated into the patient’s plan of care, as determined by the hospice IDG.

Analysis conducted on FY 2013 hospice claims shows that 67 percent of hospice claims still only report a single, principal hospice diagnosis.⁴¹ Though this is a trend in the right direction, there still appears to be some confusion by the majority of hospice providers as to the requirements for diagnosis reporting on hospice claims. We are reminding providers to follow the ICD–9–CM Coding Guidelines, per longstanding policy, in regard to diagnosis reporting on claims.

The ICD–9–CM Official Guidelines for Coding and Reporting state that for accurate reporting of ICD–9–CM diagnosis codes, “The documentation should describe the patient’s condition, using terminology which includes specific diagnoses, as well as symptoms, problems, and reasons for the encounter. List first the ICD–9–CM code for the diagnosis, condition, problem, or other reason for the encounter/visit shown in the medical record to be chiefly responsible for services provided.” The coding guidelines also state to code all documented conditions that coexist at the time of the encounter/visit and require or affect patient care treatment or management. Therefore, this is a reminder that all diagnoses should be reported on the hospice claim for the terminal illness and related conditions, including those that can affect the care and management of the beneficiary. We will condition to monitor hospice claims to see if all conditions are being reported as required by ICD–9–CM Coding Guidelines. While we did not make any proposals regarding ICD–9–CM Coding Guidelines in the proposed rule, we received two comments requesting rapid dissemination of the ICD–9–CM diagnostic codes that will prompt an edit to return to the provider for more definitive coding. As mentioned above, more specific information will be

provided, including the diagnostic codes, in sub-regulatory guidance after the publication of this final rule. We will also issue provider education describing the specific MCE edits.

K. Technical Regulatory Text Change

In the FY 2015 Hospice Wage Index proposed rule, we proposed to make a technical correction in § 418.3 to delete the definition for a “social worker.” This definition is no longer accurate, and we intended to remove it as part of the June 5, 2008 final rule that amended the conditions of participation (CoPs) for hospices (73 FR 32088). The 2008 final rule established new requirements for social workers at § 418.114(b)(3), making the definition of “social worker” at § 418.3 obsolete. However, the technical amendatory language included in the 2008 final rule did not instruct the **Federal Register** to delete the “social worker” definition.

Public comments and our response to comments regarding the technical correction to delete the definition of social worker from § 418.3 are summarized below.

Comment: Three commenters acknowledged and agreed with this technical correction.

Response: We appreciate the commenters support.

Final action: We will implement the technical correction as proposed.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for this section of this document that contains information collection requirements (ICRs). This section includes ICR information on data collection (A) related to hospice

payment policy, including changes to the election statement and changes to aggregate cap determination reporting; and (B) related to the CAHPS® Hospice Survey.

A. Changes Related to Hospice Payment Policy

Sections A.1 and A.2 are associated with the information collection request (ICR) previously approved under OMB control number as 0938–1067. We are currently seeking to have the ICR reinstated under notice and comment periods separate from those associated with the FY 2015 Hospice Wage Index proposed rule. The following assumptions were used in estimating the burden for the proposed changes related to hospice payment policy:

TABLE 10—HOSPICE PAYMENT POLICY BURDEN ESTIMATE ASSUMPTIONS

Number of Medicare-participating hospices nationwide, CY 2012	3,897
Number of Medicare-billing hospices, from CY 2012 claims	3,727
Number of Part D prescriptions per hospice, from CY 2012 claims	481
Hourly rate of registered nurse	\$41
Hourly rate of accountant	\$40
Hourly rate of office employee	\$17
Hourly rate of administrator	\$63

Note: CY = Calendar year.

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

1. Changes to the Election Statement (§ 418.24)

Section 1812(d) of the Act requires that patients elect hospice care in order for Medicare to cover and pay for hospice services. Section 1861(dd)(3)(B) of the Act defines an attending physician and requires that the patient, not the hospice, designate an attending physician at the time of election. Our regulations at § 418.24 outline current requirements for completion of a hospice election statement, but do not require that the attending physician designated by the patient be identified. To safeguard the patient’s right to choose his or her attending physician, we proposed and have now finalized a change to our regulations at § 418.24(b) to require that the election statement be modified to identify the attending physician chosen by the patient and to include language that the patient acknowledges that the attending

⁴¹ FY 2013 hospice claims data from the Chronic Conditions Data Warehouse (CCW) accessed on February 26, 2014.

physician was his or her choice. All Medicare and Medicaid hospice patients are required to elect the benefit. Since election requirement is particular to the Medicare and Medicaid hospice benefits, hospices are free to establish a similar starting point for non-Medicare and Medicaid patients in their own policies, based on the needs of the hospice, its community, and any applicable State and local laws and regulations.

We estimated that the burden for this requirement is the one-time burden to modify the election statement to include a place for identifying the attending physician and acknowledging that he or she was chosen by the patient or representative. Hospices are currently required to explain these processes to patients, so we do not believe there is any additional burden for discussing that part of the election statement with patients or their representatives. We estimate that it will take a hospice clerical staff person 20 minutes ($20/60 = 0.33333$ hours) to modify the election form, and the hospice administrator 15 minutes ($15/60 = 0.25$ hours) to review the revised form. The clerical time plus administrator time equals a one-time burden of 35 minutes or ($35/60 = 0.58333$ hours per hospice; for all 3,897 hospices, the total time required is $(0.58333 \times 3,897) = 2,273$ hours. At \$17 per hour for an office employee, the cost per hospice is $(0.33333 \times \$17) = \5.66 . At \$63 per hour for the administrator's time, the cost per hospice will be $(0.25 \times \$63) = \15.75 . Therefore, the total one-time cost per hospice is \$21.41, and the total one-time cost for all hospices is $(\$21.41 \times 3,897) = \$83,435$.

Because of concerns related to the potential inappropriate changing of attending physicians by hospices, we also proposed and have now finalized a policy to add paragraph (f) to our regulations at § 418.24, to require that the patient (or representative) provide a statement identifying the new attending physician and the date the change is to be effective, and that the patient (or representative) sign and date the form. The form should also include an acknowledgement that this change is the patient's choice. The one-time burden to hospices is the time to develop a form for the patient to use. We estimate that it will take a hospice clerical staff person 20 minutes ($20/60 = 0.33333$ hours) to develop this form, and the hospice administrator 15 minutes ($15/60 = 0.25$ hours) to review the new form. The clerical time plus administrator time equals a one-time burden of 35 minutes or ($35/60 = 0.58333$ hours per hospice; for all 3,897 hospices, the total time required is $(0.58333 \times 3,897) =$

2,273 hours. At \$17 per hour for an office employee, the cost per hospice is $(0.33333 \times \$17) = \5.66 . At \$63 per hour for the administrator's time, the cost per hospice is $(0.25 \times \$63) = \15.75 . Therefore, the total one-time cost per hospice to develop this new form for changing attending physicians is \$21.41, and the total one-time cost for all hospices is $(\$21.41 \times 3,897) = \$83,435$.

Comment: Two commenters asked CMS to clarify the sentence from the proposed rule which read, "Note that all hospices, including those that are not Medicare-participating, are required by the Conditions of Participation to have patients elect hospice care."

Response: All Medicare and Medicaid hospice patients are required to elect the benefit. Since the election requirement is particular to the Medicare and Medicaid hospice benefits, hospices are free to establish a similar starting point for non-Medicare and Medicaid patients in their own policies, based on the needs of the hospice, its community, and any applicable State and local laws and regulations. We have rephrased the sentence in this final rule to read as written in this response.

2. Changes to Aggregate Cap Determination Reporting (§ 418.308)

Congress mandated two caps on hospice payments: an inpatient cap and an aggregate cap. The hospice cap year is November 1 through October 31. Medicare contractors complete the hospice cap determination approximately twelve to eighteen months after the cap year in order to demand any overpayments from the hospices. A cap determination consists in determining whether a hospice exceeds the inpatient cap and the aggregate hospice cap. Medicare hospice inpatient stays in excess of twenty percent of total Medicare hospice days are to be reimbursed at the routine homecare rate; the hospice must be repay any excess due to receiving payments at the higher inpatient rates for the excess inpatient days. Additionally, Medicare hospice payments are limited by an aggregate cap, which is computed by multiplying the "cap amount" by the number of beneficiaries. If the actual Medicare payments exceed the aggregate cap, the hospice must repay the difference. We proposed to change our regulations at § 418.308(c) to require hospices to calculate their inpatient and aggregate caps five months after the cap year and remit any overpayment. We finalized a policy that only requires hospices to calculate their aggregate cap five months after the cap year and remit any overpayment (please see section III.D of

this final rule for more specifics). This is similar to the process in § 413.24(f), which requires other provider types that file a Medicare cost report to file their cost reports five months after the end of their cost reporting year. The regulation at § 413.24(f) also requires other provider types that file a Medicare cost report to remit any amount due the program at the time of the cost report filing. Although hospices file cost reports, the cap determination is not based on the cost report; the hospice caps serve to limit total Medicare payments similar to the way cost reports limit those payments for other provider types that file a Medicare cost report. Requiring hospices to complete a cap determination and remit any overpayment is consistent with what is currently required of all other provider types that file a Medicare cost report.

We expect that it will take a hospice about 1.5 hours to complete its cap determination. All information needed to file the cap determination is available in the Provider Statistical and Reimbursement (PS&R) system. For all 3,727 hospices that bill Medicare, this is $(1.5 \times 3,727) = 5,591$ hours. We estimate that it will take one hour for an accountant to complete the cap determination worksheet provided by CMS for the cap year. At \$40 per hour for an accountant, the cost is $(1 \times \$40) = \40 per hospice, and $(3,727 \times \$40) = \$149,080$ for all hospices. We estimate that it will take a half hour for the administrator to review the worksheet prepared by the accountant. At \$63 per hour for the administrator's time, the cost per hospice is $(0.5 \times \$63) = \31.50 , and for all hospices is $(3,727 \times \$31.50) = \$117,401$. Therefore the total estimated cost per hospice is $(\$40 + \$31.50) = \$71.50$, and the total cost for all hospices is $(3,727 \times \$71.50) = \$266,481$.

B. CAHPS® Hospice Survey

This section is associated with a new information collection request that is required to start in January 2015. The Hospice Survey data collected in 2015 is required for the FY 2017 HQR quality reporting requirements along with the submission of the clinical structural measures for the same payment period. This is a new information collection request seeking approval to assess experiences of care with hospice reported by primary caregivers (that is, bereaved family members of friends) of patients who died while receiving hospice care. This information data collection request is required to (1) assess experience of care at the respondent (caregiver) level, and (2) provide sufficient response to

generate hospice experience reports. Here are the estimates for the approximate annual cost of the CAHPS® Survey (Table 11).

TABLE 11—ASSUMPTIONS AND ESTIMATES FOR CAHPS® HOSPICE SURVEY

Approximate Number of hospices required to do the CAHPS® Survey annually.	2,600
Approximate Cost to each hospice annually for the CAHPS® Survey.	\$3,300
Approximate Cost for all CAHPS® Hospices annually for the CAHPS® Survey.	\$8.58 million
Respondent Cost burden	\$2.19 million
Approximate Total Cost of CAHPS® Survey annually.	\$10.77 million

In implementing the HQRP, we seek to collect measure information with as little burden to the providers as possible, but which reflects the full spectrum of quality performance. As such, we are moving forward toward the implementation of the CAHPS® Hospice Survey to provide data to the public about the patients' families' and friends' perspectives of care of their loved ones who passed way while in hospices.

The CAHPS® Hospice Survey data will provide the peoples' voices to hospice care in the United States. Based

on the criteria outlined in the Preamble, some hospices that are too new and very small will be exempt from the HQRP. We estimate that 2,600 hospices will qualify to participate in the survey. From CMS experiences with surveys, we estimate an annual cost of \$3,300 per hospice to participate in the CAHPS® Hospice Survey. The cost of \$3,300 includes the preparation of a monthly sampling frame for their approved vendor, as well as estimated vendor costs to conduct the data collection. The estimated annual cost for all hospices to do the survey is \$8.58 million. As part of the survey requirement, all participating hospices will contract with an approved hospice survey vendor, and each hospice will be required to submit a monthly list of deceased patients' caregivers contact information, for patients that passed away in the hospice care two months prior to the date of the list. This list (essentially the sampling frame) for most hospices can be generated from existing databases with minimal effort. For some small hospices, preparation of a monthly sample frame may require more time. However, data elements needed on the sample frame will be kept at a minimum to reduce the burden on the hospices.

The survey contains 47 items and is estimated to require an average administration time of 10.4 minutes in English, and 12.5 minutes in Spanish,

for an average response time of 10.505 minutes or 0.175 hours, assuming that 5 percent of the survey respondents complete the survey in Spanish. These burden estimates are based on CMS' experiences with surveys of similar lengths that were fielded with Medicare beneficiaries. We estimate that approximately six surveys can be done an hour, at an hourly wage of \$22.77. (We used the mean hourly wage from the "National Compensation Survey: All United States December 2009—January 2011," U.S. Department of Labor, Bureau of Labor Statistics. This was the most recent survey available at the time of OMB submission). With a total estimate of 550,000 respondents, we estimate a total respondent burden by multiplying 550,000 respondents by an estimated hourly burden per respondent of 0.175 hours to produce the total estimated number of burden hours (96,250). We then multiplied the number of hours (96,250) by \$22.77 which equals at \$2.19 million. The respondent burden does not represent an additional cost to the hospices, but instead refers to the time burden borne by respondents; the cost to the participating hospices is \$8.58 million. Table 12 below provides a summary of the burden and cost estimates associated with both the hospice payment policy changes and the CAHPS® Hospice Survey requirements.

TABLE 12—BURDEN AND COST ESTIMATES ASSOCIATED WITH ALL INFORMATION COLLECTION REQUIREMENTS

Regulation section(s)	OMB control No.	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting (\$)	Total labor cost of reporting (\$)	Total cost (\$)
418.24(b)	0938–1067.	3,897	3,897	0.583333	2,273	21.41	83,435	83,435
418.24(f) ..	0938–1067.	3,897	3,897	0.583333	2,273	21.41	83,435	83,435
418.308(c)	0938–1067.	3,727	3,727	1.500000	5,591	71.50	266,481	266,481
418.312 ...	0938–New	1,100,000	550,000	0.175	96,250	22.77	2,191,612	2,191,612
Totals	1,107,624	561,521	106,387	2,624,963

There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 12.

If you comment on these information collection and recordkeeping requirements, please submit your comments electronically as specified in the ADDRESSES section of this final rule.

Please identify which Collection of Information requirement you are commenting on by indicating whether it is from subsection:

- A.1. Changes to the Election Statement (§ 418.24);
- A.2. Changes to Aggregate Cap Determination Reporting (§ 418.308); or
- B. CAHPS® Hospice Survey (§ 418.312).

Comment: A commenter said the rates used in Table 10 do not reflect salary information in all regional areas, and therefore underestimate the administrative burden. This commenter felt that the time estimates were under-reported but did not suggest specific changes to the estimates.

Response: We use salary data from the Bureau of Labor Statistics that is a national average, which reflects the variation in wages across the country. Our time estimates are based on the time an efficient hospice would require to complete a particular activity.

V. Regulatory Impact Analysis

A. Statement of Need

This final rule follows § 418.306(c) which requires annual issuance, in the **Federal Register**, of the hospice wage

index based on the most current available CMS hospital wage data, including any changes to the definitions of Core-Based Statistical Areas (CBSAs), or previously used Metropolitan Statistical Areas (MSAs). This final rule also updates payment rates for each of the categories of hospice care described in § 418.302(b) for FY 2015 as required under section 1814(i)(1)(C)(ii)(VII) of the Act. The payment rate updates are subject to changes in economy-wide productivity as specified in section 1886(b)(3)(B)(xi)(II) of the Act. In addition, the payment rate updates may be reduced by an additional 0.3 percentage point (although for FY 2014 to FY 2019, the potential 0.3 percentage point reduction is subject to suspension under conditions specified in section 1814(i)(1)(C)(v) of the Act). In 2010, the Congress amended section 1814(i)(6) of the Act with section 3132(a) of the Affordable Care Act. The amendment authorized the Secretary to collect additional data and information determined appropriate to revise payments for hospice care and for other purposes. The data collected may be used to revise the methodology for determining the payment rates for routine home care and other services included in hospice care, no earlier than October 1, 2013, as described in section 1814(i)(6)(D) of the Act. In accordance with section 1814(i)(6)(D) of the Act, this final rule provides an update on hospice payment reform analysis.

Section 1814(i)(2)(A) through (C) limits total Medicare payments a hospice can receive through the aggregate cap. This final rule also requires that providers submit their hospice aggregate cap determination to their Medicare Administrative Contractor (MAC) within 5 months after the cap year ends, but not sooner than 3 months after the cap year ends, and remit any overpayments at that time. Hospices that fail to comply will be subject to suspension of payments.

Section 1812(d) of the Act requires that hospice beneficiaries waive their right to Medicare payments for services related to the terminal illness and provided during a hospice election, except when provided by the hospice or by the attending physician. To properly enforce that requirement, it is necessary that a beneficiary's hospice status be up-to-date in the claims processing systems. Therefore, this final rule requires that hospice Notice of Elections (NOEs) and Notice of Terminations/ Revocations (NOTRs) be filed with the Medicare contractor within 5 days after the effective date of election or the effective date of discharge/revocation. Hospices will be subject to provider-

liable days when they file an NOE late, though we will allow for a waiver of these provider-liable days when late-filing is due to certain circumstances beyond the control of the hospice.

Furthermore, in accordance with section 1860D–24 of the Act, drugs and biologicals that may be covered under the Medicare Part A per-diem payment to a hospice program are excluded from coverage under Part D. Section 1861(dd) of the Act states the hospice is responsible for covering all drugs or biologicals for the palliation and management of the terminal illness and related conditions. The FY 2015 Hospice Wage Index proposed rule, in accordance with sections 1860D–24 and 1861(dd) of the Act, solicited comments on a coordination of benefits process and appeals for Part D payment for drugs and biologicals while beneficiaries are under a hospice election. We did not make any proposals on the coordination of benefits process and appeals for Part D payment for drugs and biologicals while beneficiaries are under a hospice election.

Finally, section 3004 of the Affordable Care Act amended the Act to authorize a quality reporting program for hospices, and this rule discusses changes in the requirements for the hospice quality reporting program in accordance with section 1814(i)(5) of the Act.

B. Introduction

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA, March 22, 1995; Pub. L. 104–4), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100

million or more in any 1 year). This final rule has been designated as economically significant under section 3(f)(1) of Executive Order 12866 and thus a major rule under the Congressional Review Act. Accordingly, we have prepared a regulatory impact analysis (RIA) that to the best of our ability, presents the costs and benefits of the rulemaking. Finally, this rule has been reviewed by OMB.

C. Overall Impact

The overall impact of this final rule is an estimated net increase in Federal payments to hospices of \$230 million, or 1.4 percent for FY 2015. This estimated impact on hospices is a result of the final hospice payment update percentage for FY 2015 of 2.1 percent and changes to the FY 2015 hospice wage index, including a reduction to the BNAF by an additional 15 percent, for a total BNAF reduction of 85 percent (10 percent in FY 2010, and 15 percent per year for FY 2011 through FY 2015). An 85 percent reduced BNAF is computed to be 0.009313 (or 0.9313 percent). The BNAF reduction is part of a 7-year BNAF phase-out that was finalized in the FY 2010 Hospice Wage Index final rule (74 FR 39384), and is not a policy change.

1. Detailed Economic Analysis

Column 4 of Table 13 shows the combined effects of the updated wage data (the 2013 pre-floor, pre-reclassified hospital wage index) and of the additional 15 percent reduction in the BNAF (for a total BNAF reduction of 85 percent), comparing estimated payments for FY 2014 to estimated payments for FY 2015. The FY 2014 payments used for comparison have a 70 percent reduced BNAF applied. We estimate that the total hospice payments for FY 2015 will decrease by 0.7 percent. This 0.7 percent is the result of a 0.1 percent reduction due to the use of updated wage data (–\$20 million), and a 0.6 percent reduction due to the additional 15 percent reduction in the BNAF (–\$100 million). This estimate does not take into account the final hospice payment update percentage of 2.1 percent (+\$350 million) for FY 2015.

Column 5 of Table 13 shows the combined effects of the updated wage data (the 2013 pre-floor, pre-reclassified hospital wage index), the additional 15 percent reduction in the BNAF (for a total BNAF reduction of 85 percent), and the final hospice payment update percentage of 2.1 percent. The final 2.1 percent hospice payment update percentage is based on a 2.9 percent inpatient hospital market basket update for FY 2015 reduced by a 0.5 percentage

point productivity adjustment and by 0.3 percentage point as mandated by the Affordable Care Act. The estimated effect of the 2.1 percent final hospice payment update percentage is an increase in payments to hospices of approximately \$350 million. Taking into account the 2.1 percent final hospice payment update percentage (+\$350 million), the use of updated wage data (– \$20 million), and the additional 15 percent reduction in the BNAF (– \$100 million), it is estimated that hospice payments will increase by \$230 million in FY 2015 (\$350 million – \$20 million – \$100 million = \$230 million) or 1.4 percent in FY 2015.

a. Effects on Hospices

This section discusses the impact of the projected effects of the hospice wage index and the effects of a final 2.1 percent hospice payment update percentage for FY 2015. This final rule continues to use the CBSA-based pre-floor, pre-reclassified hospital wage index as a basis for the hospice wage

index and continues to use the same policies for treatment of areas (rural and urban) without hospital wage data. The final FY 2015 hospice wage index is based upon the FY 2013 pre-floor, pre-reclassified hospital wage index and the most complete hospice claims data available (FY 2013 hospice claims submitted as of March 31, 2014) with an additional 15 percent reduction in the BNAF (for a total BNAF reduction of 85 percent).

For the purposes of our impacts, our baseline is estimated FY 2014 payments with a 70 percent BNAF reduction, using the FY 2012 pre-floor, pre-reclassified hospital wage index. Our first comparison (column 3 of Table 13) compares our baseline to estimated FY 2015 payments (holding payment rates constant) using the updated wage data (FY 2013 pre-floor, pre-reclassified hospital wage index). Consequently, the estimated effects illustrated in column 3 of Table 13 show the distributional effects of the updated wage data only. The effects of using the updated wage

data combined with the additional 15 percent reduction in the BNAF are illustrated in column 4 of Table 13.

We have included a comparison of the combined effects of the additional 15 percent BNAF reduction, the updated wage data, and the final 2.1 percent hospice payment update percentage for FY 2015 (Table 13, column 5). Presenting these data gives the hospice industry a more complete picture of the effects on their total revenue based on changes to the hospice wage index and the BNAF phase-out as discussed in this final rule and the final FY 2015 hospice payment update percentage. Certain events may limit the scope or accuracy of our impact analysis, because such an analysis is susceptible to forecasting errors due to other changes in the forecasted impact time period. The nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon hospices.

TABLE 13—ANTICIPATED IMPACT ON MEDICARE HOSPICE PAYMENTS OF UPDATING THE PRE-FLOOR, PRE-RECLASSIFIED HOSPITAL WAGE INDEX DATA, REDUCING THE BUDGET NEUTRALITY ADJUSTMENT FACTOR (BNAF) BY AN ADDITIONAL 15 PERCENT (FOR A TOTAL BNAF REDUCTION OF 85 PERCENT) AND APPLYING A 2.1 PERCENT HOSPICE PAYMENT UPDATE PERCENTAGE, COMPARED TO THE FY 2014 HOSPICE WAGE INDEX WITH A 70 PERCENT BNAF REDUCTION

	Number of hospices	Number of routine home care days in thousands	Percent change in hospice payments due to FY2014 wage index change	Percent change in hospice payments due to wage index change, additional 15% reduction in budget neutrality adjustment	Percent change in hospice payments due to wage index change, additional 15% reduction in budget neutrality adjustment and market basket update
	(1)	(2)	(3)	(4)	(5)
ALL HOSPICES	3,752	88,006	–0.1	–0.7	1.4
URBAN HOSPICES	2,779	77,199	–0.1	–0.7	1.4
RURAL HOSPICES	973	10,808	–0.2	–0.5	1.6
BY REGION—URBAN:					
NEW ENGLAND	128	2,783	0.0	–0.7	1.4
MIDDLE ATLANTIC	252	7,920	0.5	–0.1	2.0
SOUTH ATLANTIC	391	16,855	–0.6	–1.2	0.9
EAST NORTH CENTRAL	363	12,012	–0.1	–0.8	1.3
EAST SOUTH CENTRAL	156	4,494	–0.3	–0.7	1.4
WEST NORTH CENTRAL	210	4,775	–0.8	–1.4	0.7
WEST SOUTH CENTRAL	558	10,459	–0.2	–0.8	1.3
MOUNTAIN	278	6,639	–0.3	–0.9	1.2
PACIFIC	408	10,039	0.9	0.2	2.3
OUTLYING	35	1,222	0.7	0.7	2.8
BY REGION—RURAL:					
NEW ENGLAND	24	238	–0.1	–0.7	1.4
MIDDLE ATLANTIC	44	571	0.3	–0.3	1.8
SOUTH ATLANTIC	137	2,330	–0.6	–1.0	1.1
EAST NORTH CENTRAL	137	1,783	–0.7	–1.3	0.8
EAST SOUTH CENTRAL	132	1,916	0.0	0.0	2.1
WEST NORTH CENTRAL	181	1,228	0.4	–0.1	2.0
WEST SOUTH CENTRAL	174	1,530	–0.3	–0.3	1.8
MOUNTAIN	96	693	0.5	0.1	2.2
PACIFIC	47	504	0.8	0.1	2.2
OUTLYING	1	13	0.0	0.0	2.1

TABLE 13—ANTICIPATED IMPACT ON MEDICARE HOSPICE PAYMENTS OF UPDATING THE PRE-FLOOR, PRE-RECLASSIFIED HOSPITAL WAGE INDEX DATA, REDUCING THE BUDGET NEUTRALITY ADJUSTMENT FACTOR (BNAF) BY AN ADDITIONAL 15 PERCENT (FOR A TOTAL BNAF REDUCTION OF 85 PERCENT) AND APPLYING A 2.1 PERCENT HOSPICE PAYMENT UPDATE PERCENTAGE, COMPARED TO THE FY 2014 HOSPICE WAGE INDEX WITH A 70 PERCENT BNAF REDUCTION—Continued

	Number of hospices	Number of routine home care days in thousands	Percent change in hospice payments due to FY2014 wage index change	Percent change in hospice payments due to wage index change, additional 15% reduction in budget neutrality adjustment	Percent change in hospice payments due to wage index change, additional 15% reduction in budget neutrality adjustment and market basket update
	(1)	(2)	(3)	(4)	(5)
BY SIZE/DAYS:					
0–3499 DAYS (small)	668	1,135	0.1	–0.4	1.7
3500–19,999 DAYS (medium)	1,797	18,352	0.0	–0.5	1.6
20,000+ DAYS (large)	1,287	68,519	–0.1	–0.7	1.4
TYPE OF OWNERSHIP:					
VOLUNTARY	1,032	29,283	–0.1	–0.6	1.5
PROPRIETARY	2,195	48,857	–0.1	–0.7	1.4
GOVERNMENT	525	9,866	–0.1	–0.7	1.4
HOSPICE BASE:					
FREESTANDING	2797	73,257	–0.1	–0.7	1.4
HOME HEALTH AGENCY	489	9,129	0.1	–0.5	1.6
HOSPITAL	444	5,380	0.2	–0.4	1.7
SKILLED NURSING FACILITY	22	241	0.2	–0.4	1.7

Source: FY 2013 Hospice claims data from the Standard Analytic Files for CY 2012 (as of June 30, 2013) and CY 2013 (as of March 31, 2014) and the Provider of Service (POS) file (as of March 2014).

Note: The final 2.1 percent hospice payment update percentage for FY 2015 is based on a 2.9 percent inpatient hospital market basket update, reduced by a 0.5 percentage point productivity adjustment and by 0.3 percentage point. Starting with FY 2013 (and in subsequent fiscal years), the market basket percentage update under the hospice payment system as described in section 1814(i)(1)(C)(ii)(VII) or section 1814(i)(1)(C)(iii) of the Act will be annually reduced by changes in economy-wide productivity as set out at section 1886(b)(3)(B)(xi)(II) of the Act. In FY 2013 through FY 2019, the market basket percentage update under the hospice payment system will be reduced by an additional 0.3 percentage point (although for FY 2014 to FY 2019, the potential 0.3 percentage point reduction is subject to suspension under conditions set out under section 1814(i)(1)(C)(v) of the Act).

Region Key:

New England=Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont; **Middle Atlantic**=Pennsylvania, New Jersey, New York; **South Atlantic**=Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia; **East North Central**=Illinois, Indiana, Michigan, Ohio, Wisconsin; **East South Central**=Alabama, Kentucky, Mississippi, Tennessee; **West North Central**=Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota; **West South Central**=Arkansas, Louisiana, Oklahoma, Texas; **Mountain**=Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming; **Pacific**=Alaska, California, Hawaii, Oregon, Washington; **Outlying**=Guam, Puerto Rico, Virgin Islands

Table 13 shows the results of our analysis. In column 1, we indicate the number of hospices included in our analysis as of March 31, 2014, which had also filed claims in FY 2013. In column 2, we indicate the number of routine home care days that were included in our analysis, although the analysis was performed on all types of hospice care. Columns 3, 4, and 5 compare FY 2014 estimated payments with those estimated for FY 2015. The estimated FY 2014 payments incorporate a BNAF, which has been reduced by 70 percent. Column 3 shows the percentage change in estimated Medicare payments for FY 2015 due to the effects of the updated wage data only, compared with estimated FY 2014 payments. The effect of the updated wage data can vary from region to region

depending on the fluctuations in the wage index values of the pre-floor, pre-reclassified hospital wage index. Column 4 shows the percentage change in estimated hospice payments from FY 2014 to FY 2015 due to the combined effects of using the updated wage data and reducing the BNAF by an additional 15 percent. Column 5 shows the percentage change in estimated hospice payments from FY 2014 to FY 2015 due to the combined effects of using updated wage data, an additional 15 percent BNAF reduction, and the final 2.1 percent hospice payment update percentage.

The impact of changes in this final rule has been analyzed according to the type of hospice, geographic location, type of ownership, hospice base, and size. Table 13 categorizes hospices by

various geographic and hospice characteristics. The first row of data displays the aggregate result of the impact for all Medicare-certified hospices. The second and third rows of the table categorize hospices according to their geographic location (urban and rural). Our analysis indicated that there are 2,779 hospices located in urban areas and 973 hospices located in rural areas. The next two row groupings in the table indicate the number of hospices by census region, also broken down by urban and rural hospices. The next grouping shows the impact on hospices based on the size of the hospice’s program. We determined that the majority of hospice payments are made at the routine home care rate. Therefore, we based the size of each individual hospice’s program on the

number of routine home care days provided in FY 2013. The next grouping shows the impact on hospices by type of ownership. The final grouping shows the impact on hospices defined by whether they are provider-based or freestanding.

As indicated in column 1 of Table 13, there are 3,752 hospices included in the regulatory impact analysis (the number of hospices in Table 13 differs from the number of hospices shown in Table 10 because the data were obtained from different sources). Approximately 41.5 percent of Medicare-certified hospices are identified as voluntary (non-profit) or government agencies; a majority (58.5 percent) are proprietary (for-profit), with 1,557 designated as non-profit or government hospices, and 2,195 as proprietary. In addition, our analysis shows that most hospices are in urban areas and provide the vast majority of routine home care days, most hospices are medium-sized, and the vast majority of hospices are freestanding.

b. Hospice Size

Under the Medicare hospice benefit, hospices can provide four different levels of care. The majority of the days provided by a hospice are routine home care (RHC) days, representing about 97 percent of the services provided by a hospice. Therefore, the number of RHC days can be used as a proxy for the size of the hospice, that is, the more days of care provided, the larger the hospice. We currently use three size designations to present the impact analyses. The three categories are—(1) small agencies having 0 to 3,499 RHC days; (2) medium agencies having 3,500 to 19,999 RHC days; and (3) large agencies having 20,000 or more RHC days. The FY 2015 updated wage data before any BNAF reduction are anticipated to decrease payments to large hospices by 0.1 percent, and increase 0.1 for small hospices. Medium hospices' payments are anticipated to stay stable (column 3). The updated wage data and the additional 15 percent BNAF reduction (for a total BNAF reduction of 85 percent) are anticipated to decrease estimated payments to small hospices by 0.4 percent, to medium hospices by 0.5 percent, and to large hospices by 0.7 percent (column 4). Finally, the updated wage data, the additional 15 percent BNAF reduction (for a total BNAF reduction of 85 percent), and the final 2.1 percent hospice payment update percentage are projected to increase estimated payments by 1.7 percent for small hospices, by 1.6 percent for medium hospices, and by 1.4 percent for large hospices (column 5).

c. Geographic Location

Column 3 of Table 13 shows the estimated impact of using updated wage data without the BNAF reduction. Urban hospices are anticipated to experience a decrease of 0.1 percent and rural hospices are anticipated to experience a decrease of 0.2 percent in payments. Urban hospices can anticipate an increase in payments in Middle Atlantic of 0.5 percent, in the Pacific of 0.9 percent and in the Outlying area of 0.7 percent. Urban hospices can anticipate a decrease in payments ranging from 0.8 percent in the West North Central region to 0.1 percent in the East North Central region. Urban hospices in New England are not anticipated to be affected by the updated wage data.

Rural hospices are estimated to see a decrease in payments in four regions, ranging from 0.7 percent in the East North Central region to 0.1 percent in the New England region. Rural hospices can anticipate an increase in payments in four regions ranging from 0.3 percent in the Middle Atlantic region to 0.8 percent in the Pacific region. There is no anticipated change in payments for the East South Central and Outlying regions due to the use of updated wage data.

Column 4 shows the combined effect of the updated wage data and the additional 15 percent BNAF reduction on estimated payments, as compared to the FY 2014 estimated payments using a BNAF with a 70 percent reduction. Overall, hospices are anticipated to experience a 0.7 percent decrease in payments, with urban hospices experiencing an estimated decrease of 0.7 percent and rural hospices experiencing an estimated decrease of 0.5 percent. All urban areas other than Outlying and Pacific are estimated to see decreases in payments, ranging from 1.4 percent in the West North Central region to 0.7 percent in the New England and East South Central regions. The urban Pacific and Outlying regions are anticipated to see increases in payments of 0.2 percent and 0.7 percent, respectively.

Rural hospices are estimated to experience a decrease in payments in six regions, ranging from 1.3 percent in the East North Central region to 0.1 percent in the West North Central region. Payments in the rural Mountain and Pacific regions are anticipated to increase by 0.1 percent, while payments in the rural Outlying and East South Central regions are anticipated to stay relatively stable.

Column 5 shows the combined effects of the updated wage data, the additional 15 percent BNAF reduction, and the

final 2.1 percent hospice payment update percentage on estimated FY 2015 payments as compared to estimated FY 2014 payments. Overall, hospices are anticipated to experience a 1.4 percent increase in payments, with urban hospices anticipated to experience a 1.4 percent increase in payments, and rural hospices anticipated to experience a 1.6 percent increase in payments. Urban hospices are anticipated to experience an increase in estimated payments in every region, ranging from 0.7 percent in the West North Central region to 2.8 percent in Outlying area. Rural hospices in every region are estimated to see an increase in payments ranging from 0.8 percent in East North Central to 2.2 percent in the Mountain and Pacific regions.

d. Type of Ownership

Column 3 demonstrates the effect of the updated wage data on FY 2015 estimated payments, versus FY 2014 estimated payments. We anticipate that using the updated wage data will decrease estimated payments to proprietary (for-profit), voluntary (non-profit), and Government hospices by 0.1 percent. Column 4 demonstrates the combined effects of the updated wage data and of the additional 15 percent BNAF reduction. Estimated payments to voluntary (non-profit), proprietary (for-profit), and government hospices are anticipated to decrease by 0.6 percent, 0.7 percent and 0.7 percent, respectively. Column 5 shows the combined effects of the updated wage data, the additional 15 percent BNAF reduction (for a total BNAF reduction of 85 percent), and the final 2.1 percent hospice payment update percentage on estimated payments, comparing FY 2015 to FY 2014. Estimated FY 2015 payments are anticipated to increase for voluntary (non-profit) hospices by 1.5 percent, for proprietary (for-profit) hospices by 1.4 percent, and government hospices by 1.4 percent.

e. Hospice Base

Column 3 demonstrates the effect of using the updated wage data, comparing estimated payments for FY 2015 to FY 2014. Estimated payments are anticipated to decrease for freestanding hospices by 0.1 percent. Estimated payments are anticipated to increase for home health agency, hospital, and skilled nursing facility based hospices by 0.1 percent, 0.2 percent, and by 0.2 percent, respectively. Column 4 shows the combined effects of the updated wage data and reducing the BNAF by an additional 15 percent, comparing estimated payments for FY 2015 to FY 2014. All hospice facilities are

anticipated to experience decrease in payments ranging from 0.7 percent for freestanding hospices to 0.4 percent for hospital and skilled nursing facility based hospices. Column 5 shows the combined effects of the updated wage data, the additional 15 percent BNAF reduction, and the final 2.1 percent hospice payment update percentage on estimated payments, comparing FY 2015 to FY 2014. Estimated payments are anticipated to increase for all hospices, ranging from 1.4 percent for freestanding hospices to 1.7 percent for hospital and skilled nursing facility based hospices.

f. Effects on Other Providers

This final rule will only affect Medicare hospices, and therefore has no effect on other provider types. We note that our suggested approaches with respect to Part D coordination with hospice payments may ultimately have an effect on Part D spending, if subsequently proposed and adopted.

g. Effects on the Medicare and Medicaid Programs

This final rule only affects Medicare hospices, and therefore has no effect on Medicaid programs. As described previously, estimated Medicare payments to hospices in FY 2015 are anticipated to decrease by \$20 million due to the update in the wage index data, and to decrease by \$100 million due to the additional 15 percent reduction in the BNAF (for a total 85 percent reduction in the BNAF). However, the final hospice payment update percentage of 2.1 percent is anticipated to increase Medicare payments by \$350 million. Therefore, the total effect on Medicare hospice payments is estimated to be a \$230 million increase (1.4 percent).

h. Alternatives Considered

In continuing the reduction to the BNAF by an additional 15 percent, for a total BNAF reduction of 85 percent (10 percent in FY 2010, and 15 percent per year for FY 2011 through FY 2015), and implementing the hospice payment update percentage and the updated wage index, the aggregate impact will be a net increase of \$230 million in payments to hospices. In the proposed rule for FY 2015, we did not consider discontinuing the additional 15 percent reduction to the BNAF as the 7-year phase-out of the BNAF was finalized in the FY 2010 Hospice Wage Index final rule (74 FR 39384). However, if we were to discontinue the reduction to the BNAF by an additional 15 percent, Medicare will pay an estimated \$100 million more to hospices in FY 2015.

Since the hospice payment update percentage is determined based on statutory requirements, we did not consider updating the hospice payment rates by a percentage less than the payment update percentage. The final 2.1 percent hospice payment update percentage for FY 2015 is based on a final 2.9 percent inpatient hospital market basket update for FY 2015, reduced by a 0.5 percentage point productivity adjustment and by an additional 0.3 percentage point. Payment rates for FYs since 2002 have been updated according to section 1814(i)(1)(C)(ii)(VII) of the Act, which states that the update to the payment rates for subsequent FYs must be the market basket percentage for that FY. The Act requires us to use the inpatient hospital market basket to determine the hospice payment rate update. In addition, section 3401(g) of the Affordable Care Act mandates that, starting with FY 2013 (and in subsequent FYs), the hospice payment update percentage will be annually reduced by changes in economy-wide productivity as specified in section 1886(b)(3)(B)(xi)(II) of the Act. In addition, section 3401(g) of the Affordable Care Act also mandates that in FY 2013 through FY 2019, the hospice payment update percentage will be reduced by an additional 0.3 percentage point (although for FY 2014 to FY 2019, the potential 0.3 percentage point reduction is subject to suspension under conditions specified in section 1814(i)(1)(C)(v) of the Act).

Regarding alternative timeframes for timely-filing of the Notice of Election (NOE) and of the Notice of Termination/Revocation (NOTR), we considered using 4 days after the effective date of election or of discharge/revocation, but decided to allow 5 days. We will continue to monitor the filing of NOEs and NOTRs, and will consider shortening the timeframe for what would be considered a timely-filed NOE or NOTR in future rulemaking. To ensure the attending physician of record is properly documented in the patient's medical record, we finalized, in section III.F, changes to the regulations at § 418.24(b)(1) requiring the election statement to include the patient's choice of attending physician. We considered limiting the number of times that a beneficiary can change his/her attending to once per election period (similar to the current regulations at § 418.30(a) that only allows a beneficiary to change a hospice provider once during an election period). However, we first want to conduct additional analyses of hospice Part A billing for physician

services provided by nurse practitioners and Part B attending physician billing to determine how frequently beneficiaries change attending physicians.

i. Accounting Statement

As required by OMB Circular A-4 (available at <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>), in Table 14 below, we have prepared an accounting statement showing the classification of the expenditures associated with this final rule. Table 14 provides our best estimate of the increase in Medicare payments under the hospice benefit as a result of the changes presented in this final rule for 3,752 hospices in our impact analysis file constructed using FY 2013 claims as of March 31, 2014. Table 14 also includes the costs associated with (1) a hospice accountant to complete the cap determination worksheet, and for a hospice administrator to review the final worksheet, for a total annual burden of \$266,481 as noted in section IV.A; and (2) the cost to hospices to participate in the CAHPS® survey, including the preparation of a monthly sampling frame for their approved vendor, as well as estimated survey vendor costs, for an estimated total annual cost of \$8.58 million to all hospices in the survey. Table 14 below does not reflect a one-time cost of modifying the current hospice election statement to record the patient's choice of attending physician (\$83,435) and the one-time cost of creating a new hospice form for changing the attending physician (\$83,435), for a total one-time burden of \$166,870 as noted in section IV.B.

TABLE 14—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS, FROM FY 2014 TO FY 2015

[in \$Millions]	
Category	Transfers
FY 2015 Final Rule Hospice Wage Index and Payment Rate Update	
Annualized Monetized Transfers.	\$230
From Whom to Whom?	Federal Government to Hospices
Category	Costs
Annualized Monetized Costs for Hospice Providers ¹ .	\$8.85

¹ Costs associated with hospice aggregate cap reporting and with the CAHPS® Hospice Survey.

j. Conclusion

In conclusion, the overall effect of this final rule is an estimated \$230 million increase in Medicare payments to hospices due to the wage index changes (including the additional 15 percent reduction in the BNAF) and the final hospice payment update percentage of 2.1 percent. Also, starting in FY 2015, hospices are estimated to incur annual burden costs of \$266,481 for a hospice accountant to complete the cap determination worksheet, and for a hospice administrator to review the final worksheet. Finally, starting in FY 2015 hospices are estimated to incur annual burden costs of \$8.58 million for participation in the CAHPS® hospice survey.

2. Regulatory Flexibility Act Analysis

The RFA requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that almost all hospices are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities by meeting the Small Business Administration (SBA) definition of a small business (in the service sector, having revenues of less than \$7.0 million to \$35.5 million in any 1 year), or being nonprofit organizations. While the SBA does not define a size threshold in terms of annual revenues for hospices, it does define one for home health agencies (\$14 million; see [http://www.sba.gov/sites/default/files/files/Size_Standards_Table\(1\).pdf](http://www.sba.gov/sites/default/files/files/Size_Standards_Table(1).pdf)). For the purposes of this final rule, because the hospice benefit is a home-based benefit, we are applying the SBA definition of “small” for home health agencies to hospices; we will use this definition of “small” in determining if this final rule has a significant impact on a substantial number of small entities (for example, hospices). We estimate that 95 percent of hospices have Medicare revenues below \$14 million or are nonprofit organizations and therefore are considered small entities.

HHS’s practice in interpreting the RFA is to consider effects economically “significant” only if they reach a threshold of 3 to 5 percent or more of total revenue or total costs. As noted above, the combined effect of the updated wage data, the additional 15 percent BNAF reduction, and the final FY 2015 hospice payment update percentage of 2.1 percent results in an increase in estimated hospice payments of 1.4 percent for FY 2015. For small

and medium hospices (as defined by routine home care days), the estimated effects on revenue when accounting for the updated wage data, the additional 15 percent BNAF reduction, and the final FY 2015 hospice payment update percentage reflect increases in payments of 1.7 percent and 1.6 percent, respectively. Therefore, the Secretary has determined that this final rule will not create a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This final rule only affects hospices. Therefore, the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

3. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2014, that threshold is approximately \$141 million. This final rule is not anticipated to have an effect on State, local, or tribal governments, in the aggregate, or on the private sector of \$141 million or more.

VI. Federalism Analysis

Executive Order 13132 on Federalism (August 4, 1999) establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this final rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have substantial direct effects on the rights, roles, and responsibilities of States, local or tribal governments.

VII. Waiver of 60-Day Delay in the Effective Date

We ordinarily provide a 60-day delay in the effective date of the provisions of a rule in accordance with the

Administrative Procedure Act (APA) (5 U.S.C. 553(d)), which requires a 30-day delayed effective date, and the Congressional Review Act (5 U.S.C. 801(a)(3)), which requires a 60-day delayed effective date for major rules. However, we can waive the delay in the effective date if the Secretary finds, for good cause, that the delay is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons in the rule issued. 5 U.S.C. 553(d)(3); 5 U.S.C. 808(2).

The hospice payment system is a fiscal year payment system, and we typically issue the final rule by August 1 of each year to both comply with the requirement to annually review and update these payment systems and ensure that the payment policies for these systems are effective, following the required 60-day delay in the effective date, on October 1, the first day of the fiscal year to which the policies are intended to apply. If the agency finds, for good cause, that a 60-day delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued, the agency may specify an earlier effective date. The timeframes for developing annual rules are extremely compressed and processing issues complicated this year’s rule. We believe it would be contrary to the public interest to delay the effective date of the hospice payment system. We therefore specify that those portions of the rule will be effective October 1.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare and Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Subpart C—Suspension of Payment, Recovery of Overpayments, and Repayment of Scholarships and Loans

- 1. The authority citation for part 405, subpart C continues to read:

Authority: Secs. 1102, 1815, 1833, 1842, 1862, 1866, 1870, 1871, 1879 and 1892 of the Social Security Act (42 U.S.C. 1302, 1395g, 1395l, 1395u, 1395y, 1395cc, 1395gg, 1395hh, 1395pp and 1395ccc) and 31 U.S.C. 3711.

■ 2. Section 405.371 is amended by revising paragraph (c)(1) and adding paragraph (e) to read as follows:

§ 405.371 Suspension, offset, and recoupment of Medicare payments to providers and suppliers of services.

* * * * *

(c) * * * (1) Except as provided in paragraphs (d) and (e) of this section, CMS or the Medicare contractor suspends payments only after it has complied with the procedural requirements set forth at § 405.372.

* * * * *

(e) *Suspension of payment in the case of unfiled hospice cap determination reports.* (1) If a provider has failed to timely file an acceptable hospice cap determination report, payment to the provider is immediately suspended in whole or in part until a cap determination report is filed and determined by the Medicare contractor to be acceptable.

(2) In the case of an unfiled hospice cap determination report, the provisions of § 405.372 do not apply. (See § 405.372(a)(2) concerning failure to furnish other information.)

PART 418—HOSPICE CARE

■ 3. The authority citation for part 418 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 418.3 [Amended]

■ 4. Section 418.3 is amended by removing the definition of “Social worker”.

■ 5. Section 418.24 is amended by revising paragraphs (a) and (b)(1) and adding paragraph (f) to read as follows:

§ 418.24 Election of hospice care.

(a) *Filing an election statement.* (1) *General.* 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.

(2) *Notice of election.* The hospice chosen by the eligible individual (or his or her representative) must file the Notice of Election (NOE) with its Medicare contractor within 5 calendar days after the effective date of the election statement.

(3) *Consequences of failure to submit a timely notice of election.* When a hospice does not file the required Notice of Election for its Medicare patients within 5 calendar days after the effective date of election, Medicare will not cover and pay for days of hospice care from the effective date of election to the date of filing of the notice of election. These days are a provider liability, and the provider may not bill the beneficiary for them.

(4) *Exception to the consequences for filing the NOE late.* CMS may waive the consequences of failure to submit a timely-filed NOE specified in paragraph (a)(2) of this section. CMS will determine if a circumstance encountered by a hospice is exceptional and qualifies for waiver of the consequence specified in paragraph (a)(3) of this section. A hospice must fully document and furnish any requested documentation to CMS for a determination of exception. An exceptional circumstance may be due to, but is not limited to the following:

- (i) Fires, floods, earthquakes, or similar unusual events that inflict extensive damage to the hospice’s ability to operate.
- (ii) A CMS or Medicare contractor systems issue that is beyond the control of the hospice.
- (iii) A newly Medicare-certified hospice that is notified of that certification after the Medicare certification date, or which is awaiting its user ID from its Medicare contractor.
- (iv) Other situations determined by CMS to be beyond the control of the hospice.

(b) * * * (1) Identification of the particular hospice and of the attending physician that will provide care to the individual. The individual or representative must acknowledge that the identified attending physician was his or her choice.

* * * * *

(f) *Changing the attending physician.* To change the designated attending physician, the individual (or representative) must file a signed statement with the hospice that states that he or she is changing his or her attending physician.

(1) The statement must identify the new attending physician, and include the date the change is to be effective and the date signed by the individual (or representative).

(2) The individual (or representative) must acknowledge that the change in the attending physician is due to his or her choice.

(3) The effective date of the change in attending physician cannot be before the date the statement is signed.

■ 6. Section 418.26 is amended by adding a new paragraph (e) to read as follows:

§ 418.26 Discharge from hospice care.

* * * * *

(e) *Filing a notice of termination of election.* When the hospice election is ended due to discharge, the hospice must file a notice of termination/revocation of election with its Medicare contractor within 5 calendar days after the effective date of the discharge, unless it has already filed a final claim for that beneficiary.

■ 7. Section 418.28 is amended by adding a new paragraph (d) to read as follows:

§ 418.28 Revoking the election of hospice care.

* * * * *

(d) When the hospice election is ended due to revocation, the hospice must file a notice of termination/revocation of election with its Medicare contractor within 5 calendar days after the effective date of the revocation, unless it has already filed a final claim for that beneficiary.

■ 8. Section 418.306 is amended by adding paragraph (b)(6) to read as follows:

§ 418.306 Determination of payment rates.

* * * * *

(b) * * * (6) For FY 2014 and subsequent fiscal years, in the case of a Medicare-certified hospice that does not submit hospice quality data, as specified by the Secretary, the payment rates are equal to the rates for the previous fiscal year increased by the applicable market basket percentage increase, minus 2 percentage points. Any reduction of the percentage change will apply only to the fiscal year involved and will not be taken into account in computing the payment amounts for a subsequent fiscal year.

* * * * *

■ 9. Section 418.308 is amended by revising paragraph (c) to read as follows:

§ 418.308 Limitation on the amount of hospice payments.

* * * * *

(c) The hospice must file its aggregate cap determination notice with its Medicare contractor no later than 5 months after the end of the cap year (that is, by March 31st) and remit any overpayment due at that time. Hospices shall file the aggregate cap using data no earlier than 3 months after the end of

the cap period. The Medicare contractor will notify the hospice of the final determination of program reimbursement in accordance with procedures similar to those described in § 405.1803 of this chapter. If a provider fails to file its self-determined cap determination with its Medicare contractor within 5 months after the cap year, payments to the hospice will be suspended in whole or in part, until a self-determined cap determination is filed with the Medicare contractor, in accordance with § 405.371(e) of this chapter.

* * * * *

■ 10. Subpart G is amended by adding a new § 418.312 to read as follows:

§ 418.312 Data submission requirements under the hospice quality reporting program.

(a) *General rule.* Except as provided in paragraph (g) of this section, Medicare-certified hospices must submit to CMS data on measures selected under section 1814(i)(5)(C) of the Act in a form and manner, and at a time, specified by the Secretary.

(b) *Submission of Hospice Quality Reporting Program data.* Hospices are required to complete and submit an admission Hospice Item Set (HIS) and a discharge HIS for each patient admission to hospice, regardless of payer or patient age. The HIS is a standardized set of items intended to capture patient-level data.

(c) A hospice that receives notice of its CMS certification number before November 1 of the calendar year before the fiscal year for which a payment

determination will be made must submit data for the calendar year.

(d) Medicare-certified hospices must contract with CMS-approved vendors to collect the CAHPS® Hospice Survey data on their behalf and submit the data to the Hospice CAHPS® Data Center.

(e) If the hospice's total, annual, unique, survey-eligible, deceased patient count for the prior calendar year is less than 50 patients, the hospice is eligible to be exempt from the CAHPS® Hospice Survey reporting requirements in the current calendar year. In order to qualify for this exemption the hospice must submit to CMS its total, annual, unique, survey-eligible, deceased patient count for the prior calendar year.

(f) Vendors that want to become CMS-approved CAHPS® Hospice Survey vendors must meet the minimum business requirements. Survey vendors must have been in business for a minimum of 4 years, have conducted surveys in the approved survey mode for a minimum of 3 years, and have conducted surveys of individual patients for a minimum of 2 years. For Hospice CAHPS®, a "survey of individual patients" is defined as the collection of data from at least 600 individual patients selected by statistical sampling methods, and the data collected are used for statistical purposes. Vendors may not use home-based or virtual interviewers to conduct the CAHPS® Hospice Survey, nor may they conduct any survey administration processes (for example, mailings) from a residence.

(g) No organization, firm, or business that owns, operates, or provides staffing

for a hospice is permitted to administer its own Hospice CAHPS® survey or administer the survey on behalf of any other hospice in the capacity as a Hospice CAHPS® survey vendor. Such organizations will not be approved by CMS as CAHPS® Hospice Survey vendors.

(h) *Reconsiderations and appeals of Hospice Quality Reporting Program decisions.* (1) A hospice may request reconsideration of a decision by CMS that the hospice has not met the requirements of the Hospice Quality Reporting Program for a particular reporting period. A hospice must submit a reconsideration request to CMS no later than 30 days from the date identified on the annual payment update notification provided to the hospice.

(2) Reconsideration request submission requirements are available on the CMS Hospice Quality Reporting Web site on CMS.gov.

(3) A hospice that is dissatisfied with a decision made by CMS on its reconsideration request may file an appeal with the Provider Reimbursement Review Board under part 405, subpart R of this chapter.

Dated: July 24, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Approved: July 30, 2014.

Sylvia M. Burwell

Secretary, Department of Health and Human Services.

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