DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405 and 418

[CMS-1609-P]

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: Proposed rule.

SUMMARY: This proposed rule would 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 and solicits comments on "terminal illness" and "related conditions" definitions, and on a process and appeals for Part D payment for drugs, while beneficiaries are under a hospice election. Also, this rule proposes timeframes for filing the notice of election and the notice of termination/revocation; adding the attending physician to the hospice election form; a requirement that hospices complete their hospice inpatient and aggregate cap determinations within 5 months after the cap year ends, and remit any overpayments; and updates for the hospice quality reporting program.

In addition, this rule would 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 would further clarify how hospices are

to report diagnoses on hospice claims. Finally, the rule proposes to make a technical regulatory text change.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on **[OFR--insert date 60 days after date of display in the Federal Register]**.

ADDRESSES: In commenting, please refer to file code CMS-1609-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to **http://www.regulations.gov**. Follow the "Submit a comment" instructions.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1609-P,

P.O. Box 8010,

Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1609-P,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

4. By hand or courier. Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Room 445-G, Hubert H. Humphrey Building,

200 Independence Avenue, SW.,

Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

7500 Security Boulevard,

Baltimore, MD 21244-1850

If you intend to deliver your comments to the Baltimore address, call telephone number

(410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

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

Robin Dowell, (410) 786-0060 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.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received

before the close of the comment period on the following Web site as soon as possible after they have been received: http://www.regulations.gov. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

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Acronyms

Because of the many terms to which we refer by acronym in this proposed 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	Diagnostic Related Group
DTRR	Daily Transaction Reply Report
ER	Emergency Room
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
HIPPA	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 for this Proposed Rule

A. Purpose

This rule proposes updates to the payment rates for hospices for fiscal year (FY) 2015 as required under section 1814(i) of the Social Security Act (the Act). The proposed updates incorporate the use of updated hospital wage index data, the 6th year of the 7-year Budget

Neutrality Adjustment Factor (BNAF) phase-out, and an update to the hospice payment rates by the hospice payment update percentage. In addition, section 3004(c) 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) 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 proposed rule provides an update of our hospice payment reform activities. This rule solicits comments on: definitions of "terminal illness" and "related conditions"; and process and appeals for Part D payment for drugs while beneficiaries are under a hospice election. This rule proposes timeframes for filing the hospice notice of election and the notice of termination/revocation; adding the attending physician to the hospice election form; expediting hospice inpatient and aggregate cap determinations; and updates to the hospice quality reporting program. Additionally, this proposed 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 would report diagnoses, in accordance with current ICD-9-CM guidelines, on hospice claims, and proposes a technical regulations text change.

B. Summary of the Major Provisions

In this rule we propose to update the hospice payment rates for FY 2015 by 1.3 percent as described in section III.G.3. The hospice wage index would be updated with more current wage data and the BNAF would be reduced by an additional 15 percent for a total BNAF reduction of

85 percent as described in section III.G.2. The total BNAF phase-out would be complete by FY 2016. 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 (no earlier than October 1, 2013) and for other purposes. An initial step of hospice payment reform in this proposed rule is to clarify and enforce hospice payment policy, when necessary, in order to safeguard beneficiaries and the Medicare hospice benefit. In section III.A, we provide information on hospice behavior and trends that raise program integrity concerns; the impact of beneficiary access to quality end of life care; and the effect of hospice providers' market driven goals rather than preserving the intent of the Medicare Hospice benefit. In response to the concerning trends and comments received in response to prior rulemaking, we are soliciting comments on definitions of "terminal illness" and "related conditions" in section III.B, in order to strengthen and clarify the current concepts of holistic and comprehensive hospice care under the Medicare hospice benefit. In section III.I, we are soliciting 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.E, we propose to require hospices to file both the notice of election (NOE) and the notice of termination/revocation (NOTR) on behalf of beneficiaries within 3 calendar days of admission/discharge. If an NOE is not filed timely, the days from the effective date of election to the date of filing the NOE would be the financial responsibility of the hospice. In section III.F, we propose to require the hospice to identify the attending physician on the election form. In section III.D, we propose that hospices complete their cap determinations, using a pro-forma spreadsheet, within 150 days after the cap period, and remit any overpayments at that time.

Given concerns about hospices increasingly exceeding their aggregate cap, along with the average overpayment per beneficiary, we believe that this procedural change is necessary in order to better safeguard the Medicare Trust Fund.

This proposed rule, in section III.H, discusses updates to the hospice quality reporting program, including participation requirements for CY 2015 regarding the CAHPS® Hospice Survey, and reminds 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 would be derived from these tools; therefore, no new measures are proposed this year. Section III.H of this rule also proposes changes related to the reconsideration process, extraordinary circumstance extensions or exemptions, and hospice quality reporting program (HQRP) eligibility requirements for newly certified hospices. Finally, this proposed rule provides: guidance on determining the beneficiary's eligibility for hospice in section III.C; discusses the delay in the implementation of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM); clarifies appropriate diagnosis reporting on hospice claims. We propose that, effective October 1, 2014, claims would be returned to the provider if the claim listed a non-specific symptom diagnosis as the principal hospice diagnosis in section III. J. We also propose 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 proposed rule is estimated to be $230 million in increased payments to hospices during FY 2015.
Provision Description	**Total Costs**
New Quality Reporting Requirements for Hospices (FY 2015)	$8.77 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, reduce 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 would 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 (please see section III.B for a discussion and solicitation of comments on a possible Medicare hospice definition of "terminal illness"). 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 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

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

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] See section III.B of this proposed rule for a discussion and solicitation of comments 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 services necessary 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

[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.

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

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 would 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 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 would be considered related. It is also the responsibility of the hospice physician to document why a patient's medical needs would 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, 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).

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 in 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) would 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 would 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. 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 an individual to determine continued eligibility of the individual for 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 would have to 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, both "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%
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%

Rank	*ICD-9/Reported Principal Diagnosis*		*Count*	*Percentage*
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	127,308	9%
2	428.0	Congestive Heart Failure	95,850	7%
3	162.9	Lung Cancer	91,263	6%
4	496	COPD	81,944	6%
5	331.0	Alzheimer's Disease	79,360	6%
6	783.7	Adult Failure to Thrive	71,033	5%
7	290.0	Senile Dementia, Uncomp.	60,441	4%
8	429.9	Heart Disease Unspecified	36,817	3%

Rank	*ICD-9/Reported Principal Diagnosis*		*Count*	*Percentage*
9	436	CVA/Stroke	34,330	2%
10	294.10	Dementia In Other Diseases w/o Behavioral Dist.	30,884	2%
11	332.0	Parkinson's Disease	25,308	2%
12	153.9	Colon Cancer	23,133	2%
13	294.20	Dementia Unspecified w/o Behavioral Dist.	23,108	2%
14	174.9	Breast Cancer	22,986	2%
15	157.9	Pancreatic Cancer	22,267	2%
16	185	Prostate Cancer	21,701	2%
17	585.6	End-Stage Renal Disease	19,212	1%
18	518.81	Acute Respiratory Failure	15,900	1%
19	294.8	Other Persistent Mental Dis.-classified elsewhere	14,337	1%
20	294.11	Dementia In Other Diseases w/Behavioral Dist.	13,648	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 February 27, 2014.

III. Provisions of the Proposed Rule

A. Hospice Payment Reform: Research and Analyses

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. 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 could 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 fully develop our 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 proposed rule. Both the May 2014 Technical Report and an updated literature review will be available on our hospice center web page in May, 2014 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 the hospice patient's death (see section III.C of this proposed 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 general inpatient care (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

[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.

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 any GIP care to 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 is increasing 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 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. 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 describe 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 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 operations 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 or expensive procedures. 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.

[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

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 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). Prescription Drug Events (PDEs) unrelated to the terminal illness and related conditions for which hospice beneficiaries are receiving hospice care 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 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 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 room (ER) visits and observation stays. Ninety-five percent of these ER 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 ER 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 ER visit/observation stay, but 20.9 percent had between 2 and 4 ER visits/observation stays during their election, and 1.4 percent had more than 5 ER visits/observation stays during their hospice election. Although some beneficiaries

may go directly to the ER rather than contacting the hospice first, 22.3 percent had 2 or more ER 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 ER 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 ER visits/observation stays per 100 hospice admissions, respectively). The most frequently occurring Diagnostic Related Groups (DRGs) associated with these ER 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 ER 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	Records all other third-party payments on behalf	$2,366,896

Amount	of beneficiary. Examples are state pharmacy assistance programs and charities.	
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) website 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 $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 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

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

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 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 occurs 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.

On December 6, 2013 and March 3, 2014, we issued memoranda to all Part D plan sponsors and Medicare hospice providers (available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Downloads/Hospice-PartD-Payment.pdf and http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Downloads/Part-D-Payment-Hospice-Final-2014-Guidance.pdf, respectively). These memoranda reiterated longstanding policy regarding the coverage of drugs in the Medicare hospice benefit, and Part D guidance regarding payment for drugs for hospice beneficiaries under Part D. These memoranda also contained new clarified guidance for addressing the determination of payment responsibility for Part D drugs for hospice beneficiaries in 2014 and the need for rulemaking to address the use of standardized processes for determining payment responsibility, recovering payment when the wrong party has paid, and resolving disputes regarding payment responsibility. We encourage providers to review these important memoranda at: http://www.cms.gov/Center/Provider-Type/Hospice-Center.html, and in section III.I in this proposed rule.

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 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 in 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 for the first time. 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 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

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

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

[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.

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

[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.

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], [15] 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 that the hospice concept in the United States is a 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 states 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 reiterates 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,

[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.

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 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]

[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, 24-525 0.

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

[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

response to recent home health rulemaking we received anecdotal comments that some home health agencies commented that they 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 without the beneficiary assuming responsibility for the associated 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 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

[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.nhpco.org/press-room/press-releases/nhpco-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 Long-Term Care: Clinical Care and Aging. 2011; 19(1): 43-48.

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 section 418.26(a) state the reasons a hospice can discharge a beneficiary from hospice services.

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[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.

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 it 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 imagining, and ambulance transports, to name just a few. 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-

[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.

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.

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. The most recent Part D guidance was provided in the March 10, 2014 memorandum entitled, 'Part D Payment for Drugs for Beneficiaries Enrolled in Hospice—Final

[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.

2014 Guidance' (http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Downloads/Part-D-Payment-Hospice-Final-2014-Guidance.pdf) In addition, this rule solicits 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 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 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

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

terminally ill patients" (48 FR 56010). Our expectation continues to be that hospices offer and provide comprehensive, virtually all-inclusive care, and in a better, more humane way, than is available in other healthcare settings. 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 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 that 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), articulates a set of requirements that do not delineate between pre-existing, chronic, nor controlled conditions. In order 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 §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. 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 means that

[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

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 solicits comments on defining "terminal illness" to mean: "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 six months or less".

We are soliciting comments on this definition for further discussion and consideration for potential future rulemaking.

5. Definition of "Related Conditions"

[35] Mosby's Medical Dictionary, 8th edition, 2009, Elsevier

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 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 solicits comments on defining "related conditions" to mean: "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 solicit comments on this definition for further discussion and consideration for potential future rulemaking.

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) (P.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 are 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 the clinical documentation supports or does not support 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 websites).

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 qualify 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 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 of 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 hospice services should continue. The QIO will determine if the beneficiary still needs 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 following the resumption of covered services the hospice believes that the patient is no longer hospice eligible, the provider should timely deliver a CMS-10123 to notify the patent 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.

D. Proposed Timeframe for Hospice Cap Determinations and Overpayment Remittances

As described in sections 1861(dd)(2)(A)(iii) and 1814(i)(2)(A) through (C) of the Act, when the Medicare hospice benefit was implemented, the Congress included 2 limits on payments to hospices: an inpatient cap and an aggregate cap. 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

[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

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 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]

Abt Associates, 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.

[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.

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 which will be posted in May, 2014 on our Hospice Center webpage 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 Fund, 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 propose 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 propose 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 150 days after the end of the cap year, we propose 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 propose 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.

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.

We invite comment on this proposal and the associated change in the regulation at §418.308 in section VI.

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

1. Proposed 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 that the hospice election be recorded in the claims processing system as soon as possible after the election occurs. A survey of the four Medicare hospice 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 hospice terminal illness. Prompt filing of the NOE also protects beneficiaries from

financial liability from deductibles and copayments for items or services provided during a hospice election which are related to the terminal prognosis.

Once an 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, Abt Associates, 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 which should have been provided by the hospice. 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. Approximately $100 million was from physician/supplier Part B claims that include claims from, for example, 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 hospice beneficiary liability was $135.5 million for Part A or B claims, and $48.2 million for Part D claims, for items or services provided to hospice beneficiaries during a hospice election. 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 proposed rule and the May 2014 Technical Report, which will be posted on the CMS Hospice Center webpage in May, 2014 for more details on Medicare payments made to non-hospice providers during a hospice election for hospice beneficiaries. The hospice center webpage 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).

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[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/MedicareAdvtgSpecRateStats/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.*

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 its billing for that beneficiary, to allow the previous hospice to input its NOE and billing; once the previous hospice files its claims and records 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 creates 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, to enable smooth and efficient operation of other Medicare benefits (like Part D), and to safeguard hospice beneficiaries from inappropriate financial liability due to copayments and deductibles for services related to the terminal prognosis. For all of these reasons, we propose that a hospice must file the NOE with its MAC 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). Hospices operate 24 hours per day, 7 days per week, so meeting this proposed requirement should be a part of normal business operations. Additionally, we believe

that this proposed requirement will relieve hospices of the burden created when some minority of hospices do not file their NOEs promptly, will avoid inappropriate payments to other Part A, Part B, or Part D providers, and will 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 propose 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 propose 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 and 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 MAC 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 MAC within the proposed 3-calendar-day timeframe after the effective date of election. Given the extremely low volume of NOEs filed by mail or messenger (an average of 68 per year), we do not believe this proposed 3-calendar day filing of the NOE

would be burdensome to hospices. 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 MAC.

We invite comment on this proposal and the associated change in the regulation at §418.24(a) in section VI.

2. Proposed Timeframe for Filing the Notice of Termination/Revocation

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 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 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, or NOTR.

We propose 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 have 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.

We invite comment on this proposal and the associated changes in the regulations at §418.26 and §418.28 in section VI.

F. Proposed 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):

"The term "attending physician" 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 statutory language above. 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 set out above. The hospice patient (or his or her representative) chooses the attending physician, not the hospice. This differs from some non-hospice settings, where an attending may be a clinician assigned to provide care to the patient. We stress that in hospice, the attending physician, who may be a nurse practitioner, is chosen by the patient (or his or her representative), and not by the hospice. This requirement is also included as part of the CoPs at §418.52(c)(4), which states 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. MACs 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 an NP.

To ensure the attending physician of record is properly documented in the patient's medical record, we propose 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 propose 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 propose 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.

We invite comment on this proposal and the associated changes in the regulations at §418.24(b)(1) and §418.24(f) in section VI.

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, 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 proposed 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 would use the 2014 pre-floor, pre-reclassified hospital wage index to derive the applicable wage index values for the FY 2015 hospice wage index. We would 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 proposed 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 proposed FY 2015 pre-floor, pre-reclassified hospital wage index does not contain OMB's new area delineations. CMS intends to propose 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.

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

This proposed rule would 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 proposed rule, that means estimating payments for FY 2015 using units (days or hours) from FY 2013 hospice claims data, and applying the 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 0.062060 (or 6.2060 percent). An 85 percent reduction to the BNAF is computed to be 0.009309 (or 0.9309 percent). For FY 2015, this is mathematically equivalent to taking 15 percent of the unreduced BNAF value, or multiplying 0.062060 by 0.15, which equals 0.009309 (0.9309 percent). The BNAF of 0.9309 percent reflects an 85 percent reduction in the BNAF. The 85 percent reduced BNAF (0.9309 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 0.009309, based on a full BNAF of 0.062060.

Hospital wage index values which are less than 0.8 are subject to the hospice floor calculation. For example, if in FY 2014, 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 0.062060, less 85 percent, or 0.009309) 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 x 1.009309 = 0.4031); Pre-floor, pre-reclassified hospital wage index value below 0.8 multiplied by 1 + hospice floor: (0.3994 x 1.15 = 0.4593). Based on these calculations, County A's hospice wage index would be 0.4593. The BNAF may be updated for the final rule based on availability of more complete data.

An addendum A and Addendum B with the FY 2015 wage index values for rural and urban areas will not be published in the **Federal Register**. The 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 proposed rule includes the BNAF reduction and would be effective October 1, 2014 through September 30, 2015.

3. Proposed 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 proposed hospice payment update percentage for FY 2015 is based on the estimated inpatient hospital market basket update of 2.7 percent (based on IHS Global Insight, Inc.'s first quarter 2014 forecast with historical data through the fourth quarter of 2013). Due to the requirements at 1886(b)(3)(B)(xi)(II) and 1814(i)(1)(C)(v) of the Act, the estimated inpatient hospital market basket update for FY 2015 of 2.7 percent must be reduced by a productivity adjustment as mandated by Affordable Care Act (currently estimated to be 0.4 percentage point for FY 2015). The estimated 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 proposed hospice payment update percentage for FY 2015 is 2.0 percent. We are also proposing that if more recent data are subsequently available (for example, a more recent estimate of the inpatient hospital market basket and productivity adjustment), we would use such data, if appropriate, to determine the FY 2015 market basket update and the multi-factor productivity MFP adjustment in the 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.

4. Proposed 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 FY 2015 payment rates would be the FY 2014 payment rates, increased by 2.0 percent, which is the proposed hospice payment update percentage for FY 2015 as discussed in

section III.G.3. The preliminary FY 2015 hospice payment rates would 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 Proposed Hospice Payment Update Percentage

Code	Description	FY 2014 Payment Rates	Multiply by the FY 2015 proposed hospice payment update of 2.0 percent	FY 2015 Preliminary Payment Rate
651	Routine Home Care	$156.06	x1.02	$159.18
652	Continuous Home Care Full Rate = 24 hours of care $=38.71 hourly rate	$910.78	x1.02	$929.00
655	Inpatient Respite Care	$161.42	x1.02	$164.65
656	General Inpatient Care	$694.19	x1.02	$708.07

We reiterate in this proposed rule, that 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 proposed rule.

Table 7: FY 2015 Hospice Payment Rates Updated by the Proposed Hospice Payment Update Percentage for Hospices That <u>DO NOT</u> Submit the Required Quality Data

Code	Description	FY 2014 Payment Rates	Multiply by the FY 2015 hospice payment update percentage of 2.0 percent minus 2 percentage points (-0.2)	FY 2015 Preliminary Payment Rate
651	Routine Home care	$156.06	X1.00	$156.06
652	Continuous Home Care Full Rate= 24 hours of care $=37.95 hourly rate	$910.78	X1.00	$910.78
655	Inpatient Respite Care	$161.42	X1.00	$161.42
656	General Inpatient Care	$694.19	X1.00	$694.19

A Change Request with the finalized hospice payment rates, a finalized hospice wage index, the Pricer for FY 2015, and the hospice cap amount for the cap year ending October 31, 2014 will be issued in the summer.

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 website at http://www.cms.gov/Center/Provider-Type/Hospice-Center.html. Please refer to section III.D of this proposed rule on the proposal to expedite hospice cap determinations.

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 Social Security 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 the current accounting year (in this case, March

2014). The CPI-U for medical care expenditures for 1984 to present is available from the Bureau of Labor Statistics (BLS) website at: http://www.bls.gov/cpi/home.htm.

Step 1) From the BLS website 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 x 4.111660= $26,725.79

H. Proposed 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 efficient and safer care. Our measure selection activities for the HQRP takes 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), to meet 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 that is 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 FY2015 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 wide spread 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 that the HIS will be implemented in 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 are proposing to codify the HIS submission requirements at §418.312 in this proposed 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).

Hospice programs will be evaluated for purposes of the quality reporting program based on whether or not they submit data, not on their performance level on required measures. We have provided hospices with information and details about use of the HIS through postings on the Hospice Quality Reporting Program webpage, 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 will also provide reports to individual hospices on their performance on the measures calculated from data submitted via the HIS. The specifics of the reporting system and precisely when specific measures will be made available have not yet been determined. 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 propose 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 propose 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 propose to codify this requirement at §418.312.

As is common in other quality reporting programs, we propose 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 propose 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 propose a process that, in the event that a hospice requests 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 Website 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 propose that we may 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 are proposing 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/.

4. Future Measure Development

We are not proposing any new measures for the HQRP at this time. 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. We welcome comments and input on future measure development.

CMS is 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 are soliciting 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 are also interested in public comment on the need to develop and the benefits and limitations of implementing electronic clinical quality measures for hospice providers.

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.) The Department 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-certification-regulations

http://www.healthit.gov/facas/FACAS/health-it-policy-committee/hitpc-workgroups/certificationadoption

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

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

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 website. 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, as noted, the Affordable Care Act requires that reporting be made public on a CMS website 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, we anticipate that 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 welcome public comment on what we should consider when developing future proposals related to public reporting.

6. Proposed 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. Please refer 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 48261-482-66).

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 will include 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.

Thirty-three hospice programs from 29 hospice organizations participated in the field test, which was designed to assess survey administration procedures among hospices of varying size, geographic region, chain status, ownership, and urbanicity. Respondents were primary caregivers of patients who died while receiving hospice care in the prior 2 to 5 months. In all, 1,136 respondents, representing the three main settings of hospice care (home, nursing home, and inpatient, including freestanding hospice inpatient unit, and acute care hospitals), completed the field test survey. Field test survey data were analyzed to identify for removal survey questions which exhibited little variation between hospices or for which there was little room for hospice improvement. Field test survey data were further analyzed to identify composite

measures of hospice performance, including Communication, Care Coordination, Getting Timely Care, Treating Your Family Member with Respect, Providing Emotional Support, and Getting Help for Symptoms.

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 (two to three 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. These include communications with hospice staff, treatment of symptoms, pain medication, cooperation among caregivers, treating patients with dignity and respect, and spiritual support offered by the hospice. 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. As part of national implementation we will launch a web site intended as the primary information resource for hospices and vendors (www.hospicecahpssurvey.org). The web site is expected to launch in the summer of 2014. The launch date will be announced at the Home Health, Hospice, and Durable Medical Equipment Open Door forum conducted by CMS (http://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/ODF_HHHDME.html).

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 decedents 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 decedents in the prior year (n = 2,326 in 2012) will be required to survey all cases. For large hospices with 700 or more decedents in the prior year (n = 274 in 2012), a sample of 700 will be drawn under an equal-probability design.

For national implementation, we have assumed an eligibility rate of 85% and a response rate of 50%, 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 large

hospice (700 or more decedents in the calendar year) and between 21 and 300 completed questionnaires for hospices with between 50 and 699 decedents 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 the CAHPS® Hospice Survey website 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 www.hospicecahpssurvey.org. In this rule we propose 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 below. 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 9: 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

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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?

In order 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 of proposed §418.312(e).

In the FY 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 will be 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 would be 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) will be required to meet the pay for reporting requirement of the 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 proposed deadlines for data submission occur quarterly and are shown in Table 9 below. Deadlines are final. No late submissions will be accepted. Hospice providers are responsible for making sure that their vendors are submitting data in a timely manner.

Table 10: 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 exempted very small hospices from CAHPS® Hospice Survey requirements. Hospices that have fewer than 50 survey-eligible deceased patients in the period from January 1, 2014 through December 31, 2014 will be 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 (www.hospicecahpssurvey.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 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 propose 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.

We propose to exempt very small hospices. Hospices that have fewer than 50 deceased patients in the period from January 1, 2015 through December 31, 2015 will be 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 on the CAHPS® Hospice Survey web site (www.hospicecahpssurvey.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 is August 10, 2016.

d. Vendor Participation Requirements for the 2017 APU

We have previously stated that 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 propose 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 website. In addition, to the specifications manual, the website will include information and updates regarding survey implementation and technical assistance.

We propose to codify the CAHPS® Hospice Survey vendor requirements to be effective with the FY 2017 APU (as proposed in §418.312). We propose that applicants that wish 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 (e.g. mailings) from a residence in order to ensure the confidentiality of data.

The following are examples of data collection activities would not satisfy the requirement of valid survey experience for approved vendors as defined for the CAHPS® Hospice Survey, and these would 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 propose 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.

e. Annual Payment Update

The Affordable Care 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 the FY, unless covered by specific exemptions. Any such reduction would not be cumulative and would not be taken into account in computing the payment amount for subsequent FYs. We propose 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 a dry run for at least 1 month of the first quarter of CY 2015 (January 2015, February 2015, March 2015) and 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 HQRP 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 in order to qualify for the full APU.

f. CAHPS® Hospice Survey Oversight Activities

We propose that vendors and hospice providers be required to 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 propose that the reconsiderations and appeals process for hospices that fail 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: www.hospicecahpssurvey.org. The launch date for this web site will be announced at the Home Health, Hospice & Durable Medical Equipment Open Door Forum. We expect the web site to be launched during the summer of 2014. You can contact CMS hospice team at hospicesurvey@cms.hhs.gov.

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 two percentage point reduction in their annual payment update. The process for filing a request for reconsideration is described on the CMS website at:

http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Reconsideration-Requests.html. We propose to codify this process at §418.312.

Finally, we also propose 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.

We invite public comment on all of the proposals in this section and the associated regulations text at §418.312 and in §418.306 in section VI.

I. 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, claims data presented in section III.A.4 in this proposed rule shows that in 2012 there was over $1 billion in additional Medicare spending for beneficiaries during a hospice election. Gross covered drug costs 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. This suggests that hospice services are possibly being "unbundled," resulting in duplicate costs to the Medicare program. To ensure that only costs for drugs that are unrelated to the terminal illness and related conditions are covered under Part D, we are considering defining "terminal

illness" and "related conditions" in the regulations at §418.3 (see section III.B for more information on the definitions we are considering).

CMS has previously issued a number of policy documents addressing our expectations concerning how Part D sponsors are to ensure that Part D drugs are provided only when those drugs are not covered under Part A or B as so prescribed and dispensed or administered for that individual. Since the hospice benefit was created with the expectation that virtually all care that is needed by the terminally ill patient and all drug needs at end of life would be covered by the hospice benefit, we believed that Part D coverage would be rare, and that hospices would make appropriate determinations consistent with the 1983 Hospice final rule (48 FR 56010 through 56011). Prior to the 2014 Final Call Letter, our guidance included an October 22, 2010 memorandum (titled, "Preventing Part D Payment for Hospice Drugs) and a 2012 Call Letter (dated April 4, 2011 and available at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Announcement2012final.pdf) instructing Part D sponsors that they should pay for drugs that may be covered under the hospice per-diem payment, and retrospectively determine payment responsibility ("pay and chase"). On June 28, 2012, the HHS Office of Inspector General (OIG) issued a final report documenting the findings of its review of Medicare payments for prescription drugs for beneficiaries who had elected hospice[41]. The OIG's review focused on four categories of drugs typically used to treat symptoms generally experienced by beneficiaries in hospice at end of life and concluded the Medicare program could be paying twice for prescription drugs for hospice beneficiaries. The OIG recommended that CMS require Part D sponsors to develop controls to prevent Part D payment for drugs included in the hospice per diem payments. Therefore, in the 2014 Call

41 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.

Letter, we stated that when a sponsor receives a Daily Transaction Reply Report (DTRR) from CMS showing a beneficiary has elected hospice, the sponsor must have controls in place to comply with the requirement that Part D does not pay for drugs and biologicals that can be covered under the Medicare Part A per-diem payment to a hospice. Although we strongly encouraged sponsors to place beneficiary-level prior authorization (PA) requirements on the four categories of prescription drugs identified by the OIG, including: analgesics, antinauseants (antiemetics), laxatives, and antianxiety drugs, we permitted sponsors to use other approaches, such as pay-and-chase, to resolve payment responsibility in these scenarios.

Following the issuance of this guidance, we received questions indicating our policy statements were being misinterpreted by some parties. The hospice industry expressed uncertainty with the definitions of "terminal condition" and "related conditions," and Part D sponsors were thus uncertain about whether payment should be the responsibility of either the hospice (Part A) or the plan (Part D). Therefore, on December 6, 2013, we issued a memorandum (titled, "Part D Payment for Drugs for Beneficiaries Enrolled in Hospice") providing clarified guidance for review and requesting comment on whether the industry's questions had been addressed. We received 130 comments, with many requesting that CMS undertake rulemaking to clarify for all parties what is, and is not, related to the terminal illness and related conditions, thereby providing the basis for clear criteria for determining payment responsibility between the hospice benefit and Part D. Therefore, we are considering defining "terminal illness" and "related conditions" (see section III.B of this proposed rule).

1. Part D Sponsor Coordination of Payment with Hospice Providers

Many commenters on the December 6, 2013 guidance also requested that CMS establish and require the use of standardized processes for determining payment responsibility, recovering payment when the wrong party has paid, and resolving disputes regarding payment responsibility. We agree with these commenters as well as those who suggested we seek stakeholder input. Thus, we are not proposing any requirements at this time, but are only soliciting comments on processes we are considering to facilitate the coordination of payment between Part D sponsors and hospices.

Specifically, we are considering amending §423.464 by adding a new paragraph (i): "Coordination with Medicare hospices," which would require that a Part D sponsor communicate and coordinate with Medicare hospices in determining coverage for drugs whenever a coverage determination process is initiated or a hospice furnishes information regarding a beneficiary's hospice election and/or drug profile. We are not considering establishing a requirement that the Part D sponsor initiate such communication and coordination. Rather, we are considering requiring that the Part D sponsor communicate and coordinate once the hospice initiates communication with the Part D sponsor to report information concerning a hospice election and/or drug profile, or the beneficiary or the beneficiary's appointed representative or the prescriber initiates a coverage determination request. In other words, a hospice may initiate the communication by reporting a beneficiary's hospice status, which would include the notice of election (NOE) or the notice of termination/revocation (NOTR). The hospice may also provide drug profile information, meaning identification of any drug that the hospice has determined is unrelated to the terminal illness or related conditions and an explanation of why the drug is unrelated. Hospices may identify a beneficiary's Part D plan by asking the beneficiary for the plan information on his or her member identification card or by requesting the hospice pharmacy

submit a standard electronic eligibility transaction (that is, an E1) to the CMS Part D Transaction Facilitation contractor. The Facilitator will seek to match the beneficiary's identifying information on the E1 request to the contractor's Medicare Part D enrollment data. If a match is found, the transaction response will identify the Part D plan and provide on-line billing information and the sponsor's help desk telephone number.

To facilitate the communication and coordination, CMS reports hospice election information to Part D plan sponsors on the Daily Transaction Reply Report (DTRR). This information includes a hospice indicator, a hospice start date and a hospice termination date. Updated data are reported to reflect a new benefit period or a termination/revocation date. Because communication and coordination between the Part D sponsor and the hospice are necessary to determine coverage for drugs for beneficiaries who elect hospice, we expect that sponsors will promptly upload the DTRR data into their systems. As noted previously in CMS-issued Part D guidance, only a single hospice benefit period can be reported on the DTRR. As a result, sponsors need to store the hospice data in their systems so historical data are available when needed for claims adjudication and adjustments. Sponsors also can access additional hospice data via the Medicare Advantage and Prescription Drug system (MARx) User Interface, including the hospice provider number, prior benefit period start and end dates, and the hospice termination/revocation indicator.

Although we are proposing changes in this rule at section III.E that are expected to result in improvement to the timeliness of the CMS' reporting of the hospice election information, some time lag will remain in hospices filing their election information and plan sponsors' ability to access that information. One approach, recommended by hospice organizations, to address the time lag is to permit hospices to initiate communication with the beneficiary's Part D sponsor

prior to a claim submission, such as at hospice election, to provide early notice of the election. When hospices provide this information, we are considering requiring Part D sponsors to accept it and use it to adjudicate requests for coverage until the official notice via the DTTR is received from CMS. We would expect sponsors to have processes in place to monitor receipt of the information from CMS and communicate with the hospice to resolve discrepancies between hospice-reported information and CMS-reported data.

We also are considering requiring that a Part D sponsor determine Part A versus Part D coverage at point-of-sale for any drugs for beneficiaries who have elected the hospice benefit as of the date the prescription is presented to be filled. By this we mean Part D sponsors would use HIPAA standard transactions to effectuate the Part D prior authorization requirement. The point of sale transaction related to Part A versus Part D coverage begins when a Part D sponsor receives a pharmacy claim for a beneficiary who has elected hospice, and rejects the claim with the following National Council for Prescription Drug Programs (NCPDP)-approved reject coding. Currently, this consists of: (1) reject code A3 "This Product May Be Covered Under Hospice – Medicare A"; (2) reject code 75 "Prior Authorization Required"; and (3) reject code 569 "Provide Notice: Medicare Prescription Drug Coverage and Your Rights." In addition to the reject coding, sponsors would employ point-of-sale messaging that indicates a hospice is involved and that an explanation is needed that the drug is unrelated to the terminal illness and related conditions. The point-of-sale messaging must also include the 24-hour pharmacy help desk phone number to call with questions.

The beneficiary, the beneficiary's appointed representative, or the prescriber must contact the sponsor to initiate a coverage determination request which would require the plan sponsor to obtain information from the hospice provider that the drug is unrelated to the terminal illness and

related conditions. The standardized pharmacy notice instructs the enrollee on how to contact his or her plan and explains an enrollee's right to receive, upon request, a coverage determination (including a detailed written decision) from the Part D sponsor regarding his or her Part D prescription drug benefits. Part D sponsors must arrange with their network pharmacies (including mail-order and specialty pharmacies) to distribute the standardized notice.

After the Part D sponsor receives the coverage determination request and the PA process is initiated, the Part D sponsor would expect to receive either a verbal explanation or a completed PA form from the hospice within the timeframes proposed in this rule in §418.305. Upon receiving either a verbal explanation of why the prescribed drug is unrelated to the beneficiary's terminal illness and related conditions or the completed PA form from the hospice, the Part D sponsor would be required to use the criteria described in the definitions of "terminal illness" and "related conditions", as we indicate we are considering in in this rule in section III.B, to determine whether the documentation establishes that the drug as prescribed and dispensed or administered is unrelated to the terminal illness and related conditions and, thus, satisfies the beneficiary-level hospice PA. If it does, the Part D sponsor would instruct the pharmacy on how to override the edit or provide coding to the pharmacy that would permit the claim transaction to process. Whenever an explanation of why the prescribed drug is unrelated to the beneficiary's terminal illness and related conditions is provided verbally, CMS is considering requiring the Part D sponsor to accurately document the date and content of the notice and explanation and to retain that documentation.

If the sponsor disagrees with the hospice's determination that the drug is unrelated to the terminal illness and related conditions, or determines that the documentation is insufficient to satisfy the beneficiary-level hospice PA, the Part D sponsor would initiate communication with

the hospice and attempt to resolve the dispute. If the Part D sponsor and the hospice are unable to reach a resolution, the Part D sponsor may request a review by the independent review entity (IRE) we indicate in this rule we are considering.

Since the plan sponsor's decision about whether the PA is satisfied is a coverage determination, the Part D sponsor must notify the enrollee (and, if applicable, the prescriber) of its decision in accordance with the applicable adjudication timeframes and notice rules in Part 423, Subpart M. For example, if an enrollee, the enrollee's representative, or the prescriber's request is processed as an expedited coverage determination, the plan sponsor must provide notice of its decision as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the request or, for an exceptions request, the prescriber's supporting statement. If an appeal is requested following an adverse coverage determination decision, an expedited redetermination (plan level appeal) requires the plan to notify the enrollee (and prescriber, if appropriate) of the decision as expeditiously as the enrollee's health condition requires, but no later than 72 hours from receiving the request. The 72 hour expedited timeframe also applies to the IRE reconsideration level of review.

In those instances in which the Part D sponsor disagrees with the hospice's determination that the prescribed drug is unrelated to the terminal illness and related conditions, the denial notice would explain the Part D sponsor's intention to seek independent review of the hospice's determination, if applicable. Since Part D coverage of a drug depends on whether the drug is covered under the hospice benefit, if the hospice does not respond or refuses to provide the required explanation regarding why the drug is unrelated to the terminal illness and related conditions, Part A coverage cannot be ruled out and the PA would be unfulfilled.

In addition to providing early notice of a hospice election or termination/revocation, the hospice may identify any drugs determined to be coverable under Part D for a beneficiary and provide an explanation of why the drugs are unrelated to the terminal illness and related conditions. When the hospice furnishes the documentation to satisfy the PA, prior to a claim submission, we are considering requiring Part D sponsors to accept the information from the hospice either verbally or on the PA form. Once the information is received from the hospice provider, the Part D sponsor would determine whether it is sufficient to establish that the drug as prescribed and dispensed or administered is unrelated to the terminal illness and related conditions. If it does, the Part D sponsor would reflect that the PA is satisfied for this drug in their system. If the Part D sponsor determines that the explanation provided is unsatisfactory, the Part D sponsor would communicate this to the hospice. The Part D sponsor and hospice may attempt to resolve the coverage issue, but should they be unable to do so, the plan sponsor would be able to seek review by the IRE.

We also are considering requiring that a Part D sponsor process retrospective claims adjustments and issue requests for repayment and or refunds for drugs that are excluded from Part D by virtue of their being covered under the hospice benefit in accordance with the timeframes in §423.466(a). The amount requested for repayment and subsequently repaid would be the total amount paid to the pharmacy, including the negotiated price for the drug paid by the Part D sponsor, the beneficiary cost sharing and any other payments made on the claim as reported by the sponsor on the prescription drug event record to CMS, such as the low-income subsidy and payments made by supplemental insurers. Under the process we are considering, the Part D sponsor would be responsible for refunding beneficiary cost-sharing as well as the amounts paid by supplemental payers on claims for which the sponsor received an NCPDP

reporting (that is, Nx) transaction. The Part D sponsor would also be responsible for refunding amounts the hospice has paid to the pharmacy for drugs that should have been covered under Part D, including any beneficiary cost-sharing.

We believe that the definitions of "terminal illness" and "related conditions" in section III.B of this proposed rule would guide hospices, prescribers, and Part D sponsors by clarifying and strengthening the concepts of holistic and comprehensive hospice care. Thus, through a good faith effort, Part D sponsors and hospices would be able to resolve issues of payment responsibility for prescription drugs using the processes under consideration and outlined in this proposed rule.

While we expect the overwhelming preponderance of cases involving payment coverage responsibility to be resolved using the communication and coordination of benefits processes we are considering, we recognize that there may be some instances where the Part D sponsor and the hospice will be unable to agree on which entity is responsible for covering a prescription drug. Therefore, we are considering enabling the Part D sponsor to request review from the IRE that has contracted with CMS. As noted above, drugs available under Part A as prescribed and dispensed or administered are excluded by statute from coverage under Part D. We believe that the coverage exclusion set forth at section 1860D-2(e)(2)(B) of the Act provides CMS with the authority to implement a process whereby the Part D sponsor can request an independent review of a disagreement over payment responsibility with a Part A hospice. In addition, section 1860D-24 of the Act requires Part D sponsors to coordinate with other drug plans, including 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. We believe these statutory provisions support the coordination and independent review processes

being considered, as these processes would help ensure that payment responsibility is properly determined and that drugs are not being inappropriately covered and paid for by the Part D program.

The independent review process considered would be made part of the regulations at 42 CFR Part 423, Subpart J, given the nexus between the coordination of benefits processes considered for inclusion at §423.464(i) and the right to request an independent review if the Part D sponsor disagrees with the information provided by the hospice or prescriber. Under the provisions being considered, the Part D sponsor would have to communicate and coordinate with Medicare hospices in determining coverage for prescription drugs. As part of this process, the hospice would be required to furnish information regarding why the drug is unrelated to the terminal illness and related conditions to satisfy the beneficiary-level hospice prior authorization (PA) requirements. The independent review process we are considering would be separate and distinct from the enrollee appeals process and would not affect the rights of an enrollee, the enrollee's representative or the enrollee's prescriber to request an appeal under the administrative appeal provisions set forth in 42 CFR Part 423, subpart M and subpart U.

The changes we are considering at §423.464(i)(4) would enable the Part D sponsor to request an independent review if the hospice has furnished information as part of the coordination of benefits and PA process indicating that the drug is not a covered drug under the Part A hospice benefit, and the Part D sponsor disagrees with that determination. To satisfy the beneficiary-level hospice PA requirement, the hospice would be required to notify the Part D sponsor, verbally or in writing, of the determination as to whether the need for the prescription drug is related to the beneficiary's terminal illness and related conditions and provide a clinical explanation to support that determination. If the need for the drug is unrelated to the

beneficiary's terminal illness and related conditions, the drug may be covered under Part D. If the Part D sponsor disagrees with the hospice or prescriber's explanation, the Part D sponsor would have the right to file a written request for review with the IRE within 5 calendar days of the date of notice provided by the hospice or prescriber. If the hospice or prescriber provides verbal notice of its determination, we are considering requiring the Part D sponsor to accurately document the date and content of the notice and explanation and retain that documentation. We believe that 5 calendar days (from the date the hospice provider furnishes notice to the plan sponsor that the drug is unrelated to the beneficiary's terminal illness and related conditions) would be a reasonable period of time for the hospice provider and plan sponsor to attempt to resolve any disagreement over payment responsibility via the coordination processes being considered. In the interest of promptly resolving disputes over payment responsibility, we do not believe a longer timeframe for requesting IRE review would be appropriate, but solicit comments on this 5 calendar day timeframe.

We are considering requiring that the written request for independent review include relevant clinical documentation and the explanation provided by the hospice. The IRE would be responsible for obtaining any additional information it believes is necessary to determine whether the disputed drug is the payment responsibility of the hospice or the Part D sponsor. The IRE would notify the hospice (and prescriber, as appropriate), the Part D sponsor, and the enrollee of its decision in writing. The IRE's decision would be binding on the Part D sponsor and the hospice. Decisions made through this review would not be subject to appeal, but could be reviewed and revised at the discretion of CMS. We are considering a corresponding change at 418.305(b) specifying the hospice would be bound by the decision made by the IRE under the change being considered at 423.464(i). If the IRE review process we are considering were to be

proposed and finalized through future rulemaking, additional guidance related to the IRE's review, such as adjudication timeframes and specific notice requirements, would be established in manual guidance or rulemaking.

The following chart summarizes the existing and new requirements under consideration for Part D sponsor coordination with hospices:

Process		Timeframes
Communication/Coordination	Part D sponsors would be required to communicate and coordinate with a hospice when: • The hospice furnishes information regarding a beneficiary's hospice election or plan of care; and • The Part D coverage determination process is initiated.	A hospice would be able to furnish information to the Part D sponsor at any time. This communication/coordination process would begin when the beneficiary, the beneficiary's appointed representative or the prescriber requests a coverage determination.
Prior Authorization	Part D sponsors would implement beneficiary-level hospice PAs and NCPDP reject coding at point-of-sale (POS) for drugs for beneficiaries who have elected hospice. When a claim rejects at POS, the beneficiary would be provided with a notice explaining the right to request a coverage determination from the plan.	When a coverage determination is requested, sponsors would be required to comply with the existing timeframes of 72 hours for standard requests and 24 hours for expedited requests, as specified in Federal regulation at §423.568 and §423.572 respectively.
Payment Recovery	When a Part D sponsor has paid for drugs prior to receiving notification of the beneficiary's hospice election, the sponsor would be required to determine payment responsibility for the drugs, process retrospective claims	Once payment responsibility is determined, the sponsor would be required to process any adjustments and issue refunds or recovery notices within 45 days, as specified in Federal regulations at §423.466(a).

	adjustments, and issue refunds or recovery requests.	
Independent Review	If a sponsor disagrees with a hospice determination that a drug is unrelated, the sponsor would be able to request an IRE review. IRE decisions would be binding on the sponsor and hospice.	Sponsors would be required to request an IRE review within 5 business days of receiving the hospice's explanation of why a drug is unrelated and not covered under the hospice benefit.

In formulating the requirements under consideration, we have become 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 of or provision *of Part D* (emphasis added) prescription drugs. As a result, 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 as noted above, drugs covered as so prescribed and dispensed or administered under Part A are excluded from the definition of a covered Part D drug. Since 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 are 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 solicit comments on the changes under consideration regarding the coordination of benefits process and appeals for Part D payment for drugs while beneficiaries are under a hospice election.

2. 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). Additionally, 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)).

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.

In addition, several hospices have stated that pre-existing, chronic and/or controlled conditions are not related to the prognosis of the hospice beneficiary and should not be the responsibility of the hospice—a concept which is contrary to the hospice philosophy of providing comprehensive coordinated care to patients at end of life as described in sections II

and III.B of this proposed rule. One hospice illustrated the issue with an example, a patient that was admitted with a primary terminal diagnosis of COPD. In the example, the patient also has diabetes which pre-dates the COPD; the patient uses corticosteroids to manage the COPD. The diabetes is well managed with an oral hypoglycemic agent and the patient needs to continue the medication to manage the diabetes. The hospice argues that since the diabetes is unrelated to the COPD, the oral hypoglycemic agent medication should not be covered by hospice. However, increased glucose levels are a common manifestation of corticosteroid use. While the hospice states that the admission to hospice is a result of COPD, treatment for the COPD has the potential to affect glucose levels, and hence the hypoglycemic agent would be covered by the hospice and not through Part D. As we stated above, and as required by §418.202(f), hospices are to cover all drugs which are reasonable and necessary to meet the needs of the patient in order to provide palliation and symptom management of the individual's terminal illness and related conditions. 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.

As outlined in section III.A.4, $1.2 billion in non-hospice Medicare spending and beneficiary cost-sharing occurred in CY 2012 for beneficiaries in hospice elections. In addition, we examined drug costs incurred by hospices from 2004 to 2012 using hospice cost report data adjusted to constant 2010 dollars. That analysis revealed 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. As of 2010, MedPAC reports that the aggregate hospice Medicare margin was 7.5 percent, up from 7.4 percent in 2009. Margins varied widely across the sector. For example,

MedPAC reports that the Medicare margins were 19.9 percent at the 75th percentile.[42] This may suggest that some hospices could be unbundling items, services, and drugs included in the per-diem hospice payments they are receiving, and other parts of the Medicare program are being billed for services that the hospice should have provided. For example, during a hospice election hospice beneficiaries have received care and/or services from hospitals, laboratories, DME suppliers, non-hospice clinicians, which were billed to Medicare as being unrelated to the terminal illness and related conditions. We believe that most of these claims were likely related to the hospice terminal illness and related conditions.

To safeguard the integrity of the Medicare Trust Funds and encourage hospices to coordinate with other providers and payers, and to ensure that beneficiaries have access to needed services and medications, we are considering how hospices can coordinate with Part D plan sponsors and comply with a standardized process for determining payment responsibility (prior authorization (PA) process), for recovering payment when the wrong party has paid, and for resolving disputes regarding payment responsibility. We are not proposing any requirements at this time, but are soliciting comments on approaches to these issues.

Currently, 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 expect that any PA process would result in minimal disruption to access to the drugs presumed to be unrelated to the terminal illness or related conditions. It would be vital for the hospice to provide information to respond to a PA as soon as possible to minimize any potential disruption to the medication needs of the beneficiary. We believe the information necessary to satisfy a request from any payer or non-

[42]MedPAC "Report to the Congress: Medicare Payment Policy", March 2013, pp.278.

hospice provider would be readily available, since hospices are required to maintain clinical records per the regulations at §418.104. We expect the beneficiary's needs for drugs and biologicals at the end of life would be addressed as soon as possible to maximize quality of care and access to critical drugs and biologicals. We are soliciting 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 there is no lapse of reasonable and necessary drugs and biologicals or other items or services for the beneficiary. We are particularly interested in the experiences of Part D sponsors and hospices that successfully communicate with each other and how both parties ensured that the beneficiary did not experience any delay in drug coverage. While the solicitation of comments is focused on coordination between the hospice and Part D sponsor, the solicitation would apply broadly to any payer or non-hospice provider.

The PA process described in Section III.I.1 would be a mechanism that would emphasize the recognition of the hospice and hospice physician as the clinical point of contact and enable the hospice and hospice physician to better maintain the professional and clinical responsibility for hospice patients. Hospices are health care leaders in coordinating care for beneficiaries at the end of life, and thus we believe this solicitation fits well within a hospice's usual care paradigm. The solicitations outlined, above in section III.I.1, could ensure that hospices and hospice physicians are notified of any beneficiary medications prescribed by a non-hospice provider, as well as non-hospice care the beneficiary has initiated without the hospice's knowledge.

We are also soliciting comments on the steps hospices should take to reconcile payment responsibility within a specified timeframe that could be similar to an established timeframe set forth in Part 423, Subpart M, which also requires that payment responsibility be resolved within

45 days. We are soliciting comments on whether the determination of payment responsibility should be resolved within 45 days from the date of receipt of a repayment request from either the Part D plan sponsor or the hospice. We are soliciting comments on whether the hospice would issue a request for a refund from the other payer or provider for the total amount paid for the item or service within a specific timeframe and refund to the beneficiary any associated cost-sharing.

As described in section III.I.1, we believe a majority of cases involving payment coverage responsibility could be resolved under the communication and coordination of benefits process. However, we recognize that there may be instances where the hospice and the Part D sponsor will be unable to agree on which entity is responsible for the prescription drug. We are soliciting comments on the impact to hospices regarding the potential independent review process described in section III.I.1.

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.
Beneficiaries who disagree with such medication coverage determinations may use the Medicare fee-for-service appeals process if the determination relates to Part A or B coverage, and the Part D appeals process if the determination relates to Part D coverage.

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." As of now, the Secretary has not implemented this provision under HIPAA. This means that ICD-9-CM diagnosis codes will continue to be used for hospice claims reporting until an implementation date for ICD-10-CM is announced. 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 Revision, 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 FR48252). “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 FR48252-48253). 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 (77FR 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.[43] 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.

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

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.

K. Technical Regulatory Text Change

We propose to make at technical correction in §418.3 to delete the definition for "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. We propose this technical correction in order to remedy this oversight.

We invite comments on this technical correction and associated change in the regulations at §418.3 in section VI.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-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 proposed changes to the election statement and proposed changes to inpatient and aggregate cap determination reporting; and B) related to the CAHPS® Hospice Survey.

A. Proposed Changes Related to Hospice Payment Policy

Sections A.1, A.2, and A.3 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

this notice of proposed rulemaking. 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

# of Medicare-participating hospices nationwide, CY 2012	3,897
# of Medicare-billing hospices, from CY 2012 claims	3,727
# 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) website 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. Proposed 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 to change 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 physician was his or her choice. Note that all hospices, including those that are not Medicare-participating, are required by the Conditions of Participation to have patients elect hospice care.

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 would 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 would be (0.58333 x 3,897) = 2,273 hours. At $17 per hour for an office employee, the cost per hospice would be (0.33333 x $17) = $5.66. At $63 per hour for the administrator's time, the cost per hospice would be (0.25 x $63) = $15.75. Therefore, the total one-time cost per hospice would be $21.41, and the total one-time cost for all hospices would be ($21.41 x 3,897) = $83,435.

Because of concerns related to the potential inappropriate changing of attending physicians by hospices, we also proposed 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 would 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

would be (0.58333 x 3,897) = 2,273 hours. At $17 per hour for an office employee, the cost per hospice would be (0.33333 x $17) = $5.66. At $63 per hour for the administrator's time, the cost per hospice would be (0.25 x $63) = $15.75. Therefore, the total one-time cost per hospice to develop this new form for changing attending physicians would be $21.41, and the total one-time cost for all hospices would be ($21.41 x 3,897) = $83,435.

2. Proposed Changes to Inpatient and 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 are proposing to change our regulations as §418.308(c) to require hospices to calculate their inpatient and aggregate caps five months after the cap year and remit any overpayment. 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 would 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 would be (1.5 x 3,727) = 5,591 hours. We estimate that it would 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 would be (1 x $40) = $40 per hospice, and (3,727 x $40) = $149,080 for all hospices. We estimate that it would 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 would be (0.5 x $63) = $31.50, and for all hospices would be (3,727 x $31.50) = $117,401. Therefore the total estimated cost per hospice would be ($40 + $31.50) = $71.50, and the total cost for all hospices would be (3,727 x $71.50) = $266,481.

C. 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 HQRP 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 (i.e., bereaved family members of friends) of patients who died while receiving hospice care. This

information data collection request are 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 # 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	$8.5 million
Respondent Cost burden	$3.8 million
Approximate Total Cost of CAHPS® Survey annually	**$12.3 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 $8.5 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. With a total estimate of 550,000 respondents, we estimate a total respondent burden at $3.8 million. This cost is not an additional cost to the hospices; the cost to the participating hospices is $8.5 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	95,029.55	$22.77	$2,163,823	$2,163,823
Totals		1,107,624	561,521		105,167		$2,597,174	$2,597,174

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 13.

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

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

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

V. Regulatory Impact Analysis

A. Statement of Need

This proposed 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 proposed rule also updates payment rates for each of the categories of hospice care described in §418.302(b) for FY 2015as 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 proposed rule provides an update on hospice payment reform analysis.

This proposed rule also proposes that, in accordance with section 1814(i)(2)(A) through (C), that providers complete their hospice aggregate cap determination within 5 months after the cap year ends and remit any overpayments at that time. 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. This proposed rule, in accordance with sections 1860D-24 and 1861(dd) of the Act, solicits comments on a coordination of benefits process and appeals for Part D payment for drugs and biologicals while beneficiaries are under a hospice election. At this time, we are not making 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 proposed 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 proposed rule is an estimated net increase in Federal payments to hospices of $230 million, or 1.3 percent, for FY 2015. This estimated impact on hospices is a result of the proposed hospice payment update percentage for FY 2015 of 2.0 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 0.009309 (or 0.9309 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 would 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 ($-110 million). This estimate does not take into account the proposed hospice payment update percentage of 2.0 percent (+$360 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 proposed hospice payment update percentage of 2.0 percent. The proposed 2.0 percent hospice payment update percentage is based on a 2.7 percent estimated inpatient hospital market basket update for FY 2015 reduced by a 0.4 percentage point productivity adjustment and by 0.3 percentage point as mandated by the Affordable Care Act. The estimated effect of the 2.0 percent proposed hospice payment update percentage is an increase in payments to hospices of approximately $360 million. Taking into account the 2.0 percent proposed hospice payment update percentage (+$360 million), the use of updated wage data ($-20 million), and the additional 15 percent reduction in the BNAF ($-110 million), it is estimated that hospice payments would increase by $230 million in FY 2015 ($360 million - $20 million -$110 million = $230 million) or 1.3 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 proposed 2.0 percent hospice payment update percentage for FY 2015. This proposed 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 proposed 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 December 31, 2013) 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 proposed 2.0 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 proposed rule and the proposed 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 2.0 Percent Hospice Payment Update Percentage, Compared to the FY 2014 Hospice Wage Index with a 70 Percent BNAF Reduction

	Number of Hospices (1)	Number of Routine Home Care Days in Thousands (2)	Percent Change in Hospice Payments due to FY2014 Wage Index Change (3)	Percent Change in Hospice Payments due to Wage Index Change, additional 15% Reduction in Budget Neutrality Adjustment (4)	Percent Change in Hospice Payments due to Wage Index Change, additional 15% Reduction in Budget Neutrality Adjustment and Market Basket Update (5)
ALL HOSPICES	3,702	87,456	-0.1%	-0.7%	1.3%
URBAN HOSPICES	2,736	76,784	-0.1%	-0.7%	1.3%
RURAL HOSPICES	966	10,672	-0.2%	-0.5%	1.5%
BY REGION – URBAN:					
NEW ENGLAND	128	2,771	0.0%	-0.7%	1.3%
MIDDLE ATLANTIC	252	7,880	0.5%	-0.1%	1.9%
SOUTH ATLANTIC	388	16,778	-0.6%	-1.2%	0.8%
EAST NORTH CENTRAL	358	11,949	-0.1%	-0.8%	1.2%
EAST SOUTH CENTRAL	156	4,467	-0.3%	-0.7%	1.2%
WEST NORTH CENTRAL	209	4,775	-0.8%	-1.4%	0.5%
WEST SOUTH CENTRAL	545	10,402	-0.2%	-0.8%	1.2%
MOUNTAIN	276	6,596	-0.3%	-0.9%	1.1%
PACIFIC	389	9,964	0.9%	0.2%	2.2%
OUTLYING	35	1,201	0.7%	0.7%	2.7%
BY REGION – RURAL:					
NEW ENGLAND	24	236	-0.1%	-0.7%	1.3%
MIDDLE ATLANTIC	44	567	0.3%	-0.3%	1.7%
SOUTH ATLANTIC	136	2,308	-0.6%	-1.0%	1.0%
EAST NORTH CENTRAL	137	1,763	-0.7%	-1.3%	0.7%
EAST SOUTH CENTRAL	131	1,888	0.0%	0.0%	2.0%
WEST NORTH CENTRAL	180	1,190	0.4%	-0.1%	1.9%
WEST SOUTH CENTRAL	172	1,526	-0.3%	-0.3%	1.7%
MOUNTAIN	94	681	0.5%	0.1%	2.1%
PACIFIC	47	500	0.8%	0.1%	2.1%
OUTLYING	1	13	0.0%	0.0%	2.0%
BY SIZE/DAYS:					
0- 3499 DAYS (small)	631	1,113	0.1%	-0.4%	1.6%
3500–19,999 DAYS (medium)	1795	18,345	0.0%	-0.5%	1.5%
20,000+ DAYS (large)	1276	67,998	-0.1%	-0.7%	1.3%
TYPE OF OWNERSHIP:					
VOLUNTARY	1042	29,537	0.0%	-0.6%	1.4%
PROPRIETARY	2142	48,415	-0.1%	-0.7%	1.3%
GOVERNMENT	518	9,505	-0.2%	-0.7%	1.3%
HOSPICE BASE:					
FREESTANDING	2734	72,437	-0.1%	-0.7%	1.3%
HOME HEALTH AGENCY	502	9,435	0.1%	-0.5%	1.5%

HOSPITAL	445	5,345	0.2%	-0.4%	1.6%
SKILLED NURSING FACILITY	21	238	0.2%	-0.4%	1.6%

Source: FY 2013 Hospice claims data from the Standard Analytic Files for CY 2012 (as of June 30, 2013) and CY 2013 (as of December 31, 2013).

Note: The proposed 2.0 percent hospice payment update percentage for FY 2015 is based on an estimated 2.7 percent inpatient hospital market basket update, reduced by a 0.4 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 December 31, 2013, 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 proposed 2.0 percent hospice payment update percentage.

The impact of changes in this proposed 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 2,736 hospices located in urban areas and 966 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 3,702 hospices included in the regulatory impact analysis. Approximately 42.1 percent of Medicare-certified hospices are identified as voluntary (non-profit) or government agencies; a majority (57.9 percent) are proprietary (for-profit), with 1,560 designated as non-profit or government hospices, and 2,142 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 payment would 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 proposed 2.0 percent hospice payment update percentage are projected to increase estimated payments by 1.6 percent for small hospices, by 1.5 percent for medium hospices, and by 1.3 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 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 region. 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 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 proposed 2.0 percent hospice payment update percentage on estimated FY 2015 payments as compared to estimated FY 2014 payments. Overall, hospices are anticipated to experience a 1.3 percent increase in payments, with urban hospices anticipated to experience a 1.3 percent increase in payments, and rural hospices anticipated to experience a 1.5 percent increase in payments. Urban hospices are anticipated to experience an increase in estimated payments in every region, ranging from 0.5 percent in the West North Central region to 2.2 percent in Outlying area. Rural hospices in every region are estimated to see an increase in payments ranging from 0.7 percent in East North Central to 2.1 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 would decrease estimated payments to proprietary (for-profit) and Government hospices by 0.1 percent and 0.2 percent, respectively. Voluntary (non-profit) hospices are expected to have no change in payments. 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 proposed 2.0 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 1.4 percent, for proprietary (for-profit) hospices by 1.3 percent, and government hospices by 1.3 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 proposed 2.0 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 1.3 percent for freestanding hospices to 1.6 percent for hospital and skilled nursing facility based hospices.

f. Effects on Other Providers

This proposed rule would 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 proposed and adopted.

g. Effects on the Medicare and Medicaid Programs

This proposed 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 $110 million due to the additional 15 percent reduction in the BNAF (for a total 85 percent reduction in the BNAF). However, the proposed hospice payment update percentage of 2.0 percent is anticipated to increase Medicare payments by $360 million. Therefore, the total effect on Medicare hospice payments is estimated to be a $230 million increase (1.3 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 would pay an estimated $110 million more to hospices in FY 2015.

Since the hospice payment update percentage is determined based on statutory requirements, we did not consider not updating hospice payment rates by the payment update percentage. The proposed 2.0 percent hospice payment update percentage for FY 2015 is based on a proposed 2.7 percent inpatient hospital market basket update for FY 2015, reduced by a 0.4 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).

We also considered proposing a waiver of the consequences for not filing the NOE within 3 calendar days after the effective date of election, to account for exceptional circumstances. However, since hospices are to operate 24 hours a day, 7 days a week, and should have back-up systems in place so that they can care for their patients without interruption, we did not believe that this would be necessary.

To ensure the attending physician of record is properly documented in the patient's medical record, we proposed, in section III.F, to amend the regulations at §418.24(b)(1) and require 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 proposed 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 proposed rule for 3,702 hospices in our impact analysis file constructed using FY 2013 claims as of December 31, 2013. 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 proposed in section III.D; 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 $8.5 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 proposed in section III.E.

TABLE 14-- Accounting Statement: Classification of Estimated Transfers, From

FY 2014 to FY 2015 [in $Millions]

Category	Transfers
FY 2015 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]	$8.77

[1] Costs associated with hospice cap reporting and with the CAHPS® Hospice Survey

j. Conclusion

In conclusion, the overall effect of this proposed 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 proposed hospice payment update percentage of 2.0 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 $8.5 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). For the purposes of this proposed 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 proposed 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 proposed FY 2015 hospice payment update percentage of 2.0 percent results in an increase in estimated hospice payments of 1.3 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 proposed FY 2015 hospice payment update percentage reflect increases in payments of 1.6 percent and 1.5 percent, respectively. Therefore, the Secretary has determined that this proposed 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 proposed rule only affects hospices. Therefore, the Secretary has determined that this proposed rule would 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 proposed 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 and Regulations Text

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 proposed 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.

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 proposes to amend 42 CFR chapter IV as set forth below:

PART 405 —FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

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 is revised to read as follows:

Authority: Secs. 1102, 1812(a)(5), 1812(d), 1813(a)(4), 1814(a)(7), 1814(i), and 1861(dd) 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--

A. Revising paragraph (a).

B. Revising paragraph (b)(1).

C. Adding a new paragraph (f).

The addition and revisions read as follows:

§418.24 Election of hospice care.

(a) Filing an election statement. (1) 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) The hospice chosen by the eligible individual (or his or her representative) must file the Notice of Election with its Medicare claims processing contractor within 3 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 3 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 NOE. These days are a provider liability, and the provider may not bill the beneficiary for them.

(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 prior to 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 claims processing contractor within 3 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) Filing a Notice of Revocation of Election. When the hospice election is ended due to revocation, the hospice must file a notice of termination/revocation of election with its Medicare claims processing contractor within 3 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 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. 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 150 days after the cap year, payments to the hospice would 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).

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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.

General rule. Except as provided in paragraph (f) 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.

(a) 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.

(b) 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.

(c) 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.

(d) 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.

(e) 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 (e.g. mailings) from a residence.

(f) 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.

(g) 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 website 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: April 18, 2014.

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Marilyn Tavenner,

Administrator,

Centers for Medicare & Medicaid Services.

Approved: April 22, 2014.

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Kathleen Sebelius,

Secretary,

Department of Health and Human Services.

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