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Medicare Program; FY 2017 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 418

[CMS–1652–F]

RIN 0938–AS79

Medicare Program; FY 2017 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements

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

ACTION: Final rule.

SUMMARY: This final rule will update the hospice wage index, payment rates, and cap amount for fiscal year (FY) 2017. In addition, this rule changes the hospice quality reporting program, including adopting new quality measures. Finally, this final rule includes information regarding the Medicare Care Choices Model (MCCM).

DATES: These regulations are effective on October 1, 2016.

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

Michelle Brazil, (410) 786–1648 for questions regarding the hospice quality reporting program.

Hillary A. Loeffler, (410) 786–0456 for questions regarding hospice payment policy.

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*.)

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Acronyms

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

APU Annual Payment Update
ASPE Assistant Secretary of Planning and Evaluation
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
CCN CMS Certification Number
CCW Chronic Conditions Data Warehouse
CFR Code of Federal Regulations
CHC Continuous Home Care
CHF Congestive Heart Failure
CMMI Center for Medicare & Medicaid Innovation
CMS Centers for Medicare & Medicaid Services
COPD Chronic Obstructive Pulmonary Disease
CoPs Conditions of Participation
CPI Center for Program Integrity
CPI–U Consumer Price Index—Urban Consumers
CR Change Request
CVA Cerebral Vascular Accident
CWF Common Working File
CY Calendar Year
DME Durable Medical Equipment
DRG Diagnostic Related Group
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
HIPAA Health Insurance Portability and Accountability Act
HIS Hospice Item Set
HQRP Hospice Quality Reporting Program
IACS Individuals Authorized Access to CMS Computer Services
ICD–9–CM International Classification of Diseases, Ninth Revision, Clinical Modification
ICD–10–CM International Classification of Diseases, Tenth Revision, Clinical Modification
ICR Information Collection Requirement
IDG Interdisciplinary Group
IMPACT Act Improving Medicare Post-Acute Care Transformation Act of 2014
IOM Institute of Medicine
IPPS Inpatient Prospective Payment System
IRC Inpatient Respite Care

LCD Local Coverage Determination
LOS Length of Stay
MAC Medicare Administrative Contractor
MAP Measure Applications Partnership
MCCM Medicare Care Choices Model
MedPAC Medicare Payment Advisory Commission
MFP Multifactor Productivity
MSA Metropolitan Statistical Area
MSS Medical Social Services
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
OMB Office of Management and Budget
PEPPER Program for Evaluating Payment Patterns Electronic Report
PRRB Provider Reimbursement Review Board
PS&R Provider Statistical and Reimbursement Report
Pub. L. Public Law
QAPI Quality Assessment and Performance Improvement
RHC Routine Home Care
RN Registered Nurse
SBA Small Business Administration
SEC Securities and Exchange Commission
SIA Service Intensity Add-on
SNF Skilled Nursing Facility
TEFRA Tax Equity and Fiscal Responsibility Act of 1982
TEP Technical Expert Panel
UHDDS Uniform Hospital Discharge Data Set
U.S.C. United States Code

I. Executive Summary

A. Purpose

This final rule updates the hospice payment rates for fiscal year (FY) 2017, as required under section 1814(i) of the Social Security Act (the Act). This rule also finalizes new quality measures and provides an update on the hospice quality reporting program (HQRP) consistent with the requirements of section 1814(i)(5) of the Act, as added by 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) (collectively, the Affordable Care Act). In accordance with section 1814(i)(5)(A) of the Act, starting in FY 2014, hospices that have failed to meet quality reporting requirements receive a 2 percentage point reduction to their payments. Finally, this final rule shares information on the Medicare Care Choices Model developed in accordance with the authorization under section 1115A of the Act for the Center for Medicare and Medicaid Innovation (CMMI) to test innovative payment and service models that have the potential to reduce Medicare, Medicaid, or Children's Health Insurance Program (CHIP) expenditures while maintaining or improving the quality of care.

B. Summary of the Major Provisions

In section III.B.1 of this rule, we update the hospice wage index with updated wage data and make the application of the updated wage data budget-neutral for all four levels of hospice care. In section III.B.2 we discuss the FY 2017 hospice payment update percentage of 2.1 percent. Sections III.B.3 and III.B.4 update the hospice payment rates and hospice cap amount for FY 2017 by the hospice payment update percentage discussed in section III.B.2.

In section III.C of this rule, we discuss updates to HQRP, including two new quality measures as well as of the possibility of utilizing a new assessment instrument to collect quality data. As part of the HQRP, the new measures, effective April 1, 2017, will be: (1) Hospice Visits When Death is Imminent, assessing hospice staff visits to patients and caregivers in the last week of life; and (2) Hospice and Palliative Care Composite Process Measure, assessing the percentage of hospice patients who received care processes consistent with existing guidelines. In section III.C we will also discuss the enhancement of the current Hospice Item Set (HIS) data collection instrument to be more in line with other post-acute care settings. This new data collection instrument will be a comprehensive patient assessment instrument, rather than the current chart abstraction tool. Additionally, in this section we discuss our plans for sharing HQRP data publicly during calendar year (CY) 2016 as well as plans to provide public reporting via a Compare Site in CY 2017.

Finally, in section III.D, we are providing information regarding the Medicare Care Choices Model (MCCM). This model is testing a new option for Medicare and dual eligible beneficiaries with certain advanced diseases who meet the model's other eligibility criteria to receive hospice-like support services from MCCM participating hospices while receiving care from other Medicare providers for their terminal illness. This model is designed to: (1) Increase access to supportive care services provided by hospice; (2) improve quality of life and patient/family/caregiver satisfaction; and (3) inform new payment systems for the Medicare and Medicaid programs.

C. Summary of Impacts

TABLE 1—IMPACT SUMMARY TABLE

Provision description	Transfers
FY 2017 Hospice Wage Index and Payment Rate Update	The overall economic impact of this final rule is estimated to be $350 million in increased payments to hospices during FY 2017.

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 beneficiary as physically and emotionally comfortable as possible. Hospice is compassionate beneficiary 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 transition 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. Also, see Hospice Conditions of Participation final rule (73 FR 32088 June 5, 2008). The goal of palliative care in hospice is to improve the quality of life of beneficiaries, 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 that may arise. This is achieved by the hospice interdisciplinary group working with the beneficiary and family to develop a comprehensive care plan focused on coordinating care services, reducing unnecessary diagnostics, or ineffective therapies, and offering ongoing conversations with individuals and their families about changes in their condition. The beneficiary's comprehensive care plan will shift over time to meet the changing needs of the individual, family, and caregiver(s) 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. When a beneficiary is terminally ill, many health problems are brought on by underlying condition(s), as bodily systems are interdependent. In the 2008 Hospice Conditions of Participation final rule, we stated that the medical director or physician designee 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. (73 FR 32176). 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,'' as defined in section 1861(dd)(3)(A) of the Act and our regulations at § 418.3; that is, the individual's prognosis is for a life expectancy of 6 months or less if the terminal illness runs its normal course. 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 set out at § 418.22(b)(3).

While the goal of hospice care is to allow the beneficiary 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 treatment 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 beneficiary can return to his or her home environment. Limited, short-term, intermittent, inpatient respite services are also available to the family/caregiver of the hospice patient 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, in accordance with our regulations at § 418.204. A minimum of 8 hours of nursing care, or nursing and aide care, must be furnished on a particular day to qualify for the continuous home care rate (§ 418.302(e)(4)).

Hospices are expected to comply with all civil rights laws, including the provision of auxiliary aids and services to ensure effective communication with patients and 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/civil-rights.*

B. History of the Medicare Hospice Benefit

Before the creation of the Medicare hospice benefit, hospice programs were originally operated 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 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 titled ''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 beneficiary ''electing'' the hospice benefit and being certified as terminally ill were two key components of 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 Act, 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 beneficiary's physical, psychosocial, emotional, and spiritual needs related to the terminal illness and related conditions, and address those needs in order to promote the beneficiary'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, as described in the beneficiary'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. Additionally, the hospice Conditions of Participation (CoPs) at § 418.56(c) require that the hospice must provide all reasonable and necessary services for the palliation and management of the terminal illness, related conditions, and interventions to manage pain and symptoms. Therapy and interventions must be assessed and managed in terms of providing palliation and comfort without undue symptom burden for the hospice patient or family.[2] In the December 16, 1983 Hospice final rule (48 FR 56010), regarding what is related versus

[1] Connor, Stephen. (2007). Development of Hospice and Palliative Care in the United States. OMEGA. 56(1), p. 89–99.

[2] Paolini, DO, Charlotte. (2001). Symptoms Management at End of Life. JAOA. 101(10). p. 609–615.

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 conditions are considered to be related to the terminal prognosis and the responsibility of the hospice to address and treat.

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 beneficiary 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, if requested, for death while receiving expert symptom management and other supportive services. Election of hospice care also requires waiving the right to Medicare payment for curative treatment for the terminal prognosis, and instead receiving palliative care to manage pain or other 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, at the beginning of each period, a physician must certify that the beneficiary has 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 biologicals); medical appliances; counseling services (including dietary counseling); short-term inpatient care in a hospital, nursing facility, or hospice inpatient facility (including both respite care and procedures necessary for pain control and acute or chronic symptom management); 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 to beneficiaries as needed, 24 hours a day, 7 days a week (section 1861(dd)(2)(A)(i) of the Act). Upon the implementation of the hospice benefit, 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 comprise paid hospice employees as well as hospice volunteers (48 FR 38149). This expectation supports the hospice 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 the Centers for Medicare & Medicaid Services (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 and principles 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 (RHC), Continuous Home Care (CHC), 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 beneficiary's 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 RHC and other services included in

hospice care were increased to equal 120 percent of the rates in effect on September 30, 1989; and (2) the daily payment rate for RHC and other services included in hospice care for fiscal years (FYs) beginning on or after October 1, 1990, were the payment rates in effect during the previous Federal FY 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 composed 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) was 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 (FY 2010 Hospice Wage Index final rule, (74 FR 39384, August 6, 2009)), 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 continued with an additional 15 percent reduction for a total reduction of 85 percent in FY 2015, an additional, and final, 15 percent reduction for complete elimination in FY 2016. We note that the BNAF was an adjustment which increased the hospice wage index value. Therefore, the BNAF phase-out reduced the amount of the BNAF increase applied to the hospice wage index value. It was not a reduction in the hospice wage index value itself or in the hospice payment rates.

5. The Affordable Care Act

Starting with FY 2013 (and in subsequent FYs), 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 is subject to annual reductions related to changes in economy-wide productivity, as specified in section 1814(i)(1)(C)(iv) 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 specified in section 1814(i)(1)(C)(v) of the Act).

In addition, sections 1814(i)(5)(A) through (C) of the Act, as added 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 of the Department of Health and Human Services (the Secretary), for FY 2014 and subsequent FYs. 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, as added by section 3132(b)(2) of the Affordable Care Act, requires, effective January 1, 2011, that a hospice physician or nurse practitioner have a face-to-face encounter with the beneficiary to determine continued eligibility of the beneficiary's hospice care prior to the 180th-day recertification and each subsequent recertification, and to attest that such visit took place. When implementing this provision, we finalized in the CY 2011 Home Health Prospective Payment System final rule (75 FR 70435) that the 180th-day recertification and subsequent recertifications would correspond to the beneficiary's third or subsequent benefit periods. Further, section 1814(i)(6) of the Act, as added 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 could capture accurate resource utilization, which could be collected on claims, cost reports, and possibly other mechanisms, as the Secretary determined to be appropriate. The data collected could be used to revise the methodology for determining the payment rates for RHC 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 were 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, Congress included an aggregate cap on hospice payments, which limits the total aggregate payments any individual hospice can receive in a year. 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 has been 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 was defined as the period from November 1st to October 31st. 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, we announced that subsequently, the hospice aggregate cap would be calculated using the patient-by-patient proportional methodology. We allowed existing hospices the option of having their cap calculated via the original streamlined methodology. As of FY 2012, new hospices 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 exceeds the hospice aggregate cap, then the hospice must repay the excess back to Medicare.

7. FY 2015 Hospice Wage Index and Payment Rate Update Final Rule

When electing hospice, a beneficiary waives Medicare coverage for any care for the terminal illness and related conditions except for services provided by the designated hospice and attending physician. The FY 2015 Hospice Wage Index and Payment Rate Update final rule (79 FR 50452) finalized a requirement that requires the Notice of Election (NOE) be filed within 5 calendar days after the effective date of hospice election. If the NOE is filed beyond this 5-day period, hospice providers are liable for the services furnished during the days from the effective date of hospice election to the date of NOE filing (79 FR 50474). Similar to the NOE, the claims processing system must be notified of a beneficiary's discharge from hospice or hospice benefit revocation. This update to the beneficiary's status allows claims from non-hospice providers to be processed and paid. Late filing of the NOE can result in inaccurate benefit period data and leaves Medicare vulnerable to paying non-hospice claims related to the terminal illness and related conditions and beneficiaries possibly liable for any cost-sharing associated costs. Upon live discharge or revocation, the beneficiary immediately resumes the Medicare coverage that had been waived when he or she elected hospice. The FY 2015 Hospice Wage Index and Payment Rate Update final rule also finalized a requirement that requires hospices to file a notice of termination/revocation within 5 calendar days of a beneficiary's live discharge or revocation, unless the hospices have already filed a final claim. This requirement helps to protect beneficiaries from delays in accessing needed care (§ 418.26(e)).

A hospice ''attending physician'' is described by the statutory and regulatory definitions as a medical doctor, osteopath, or nurse practitioner whom the beneficiary identifies, at the time of hospice election, as having the most significant role in the determination and delivery of his or her medical care. We received reports of problems with the identification of the person's designated attending physician and a third of hospice patients had multiple providers submit Part B claims as the ''attending physician,'' using a claim modifier. The FY 2015 Hospice Wage Index and Payment Rate Update final rule finalized a requirement that the election form include the beneficiary's choice of attending physician and that the beneficiary provide the hospice with a signed document when he or she chooses to change attending physicians (79 FR 50479).

Hospice providers are required to begin using a Hospice Experience of Care Survey for informal caregivers of hospice patients surveyed in 2015. The FY 2015 Hospice Wage Index and Payment Rate Update final rule provided background and a description of the development of the Hospice Experience of Care Survey, including the model of survey implementation, the survey respondents, eligibility criteria for the sample, and the languages in which the survey is offered. The FY 2015 Hospice Rate Update final rule also set out participation requirements for CY 2015 and discussed vendor oversight activities and the reconsideration and appeals process for entities that failed to win CMS approval as vendors (79 FR 50496).

Finally, the FY 2015 Hospice Wage Index and Payment Rate Update final rule required providers to complete their aggregate cap determination not sooner than 3 months after the end of the cap year, and not later than 5 months after, and remit any overpayments. Those hospices that fail to timely submit their aggregate cap determinations will have their payments suspended until the determination is completed and received by the Medicare Administrative Contractor (MAC) (79 FR 50503).

8. IMPACT Act of 2014

The Improving Medicare Post-Acute Care Transformation Act of 2014 (Pub. L. 113–185) (IMPACT Act) became law on October 6, 2014. Section 3(a) of the IMPACT Act mandated that all Medicare certified hospices be surveyed every 3 years beginning April 6, 2015 and ending September 30, 2025. In addition, section 3(c) of the IMPACT Act requires medical review of hospice cases involving beneficiaries receiving more than 180 days care in select hospices that show a preponderance of such patients; section 3(d) of the IMPACT Act contains a new provision mandating that the cap amount for accounting years that end after September 30, 2016, and before October 1, 2025 be updated by the hospice payment update rather than using the consumer price index for urban consumers (CPI–U) for medical care expenditures.

9. FY 2016 Hospice Wage Index and Payment Rate Update Final Rule

In the FY 2016 Hospice Rate Update final rule, we created two different payment rates for RHC that resulted in a higher base payment rate for the first 60 days of hospice care and a reduced base payment rate for all subsequent days of hospice care (80 FR 47172). We also created a Service Intensity Add-on (SIA) payment payable for services during the last 7 days of the beneficiary's life, equal to the CHC hourly payment rate multiplied by the amount of direct patient care provided by a registered nurse (RN) or social worker that occurs during the last 7 days (80 FR 47177).

In addition to the hospice payment reform changes discussed, the FY 2016 Hospice Wage Index and Payment Rate Update final rule implemented changes mandated by the IMPACT Act, in which the cap amount for accounting years that end after September 30, 2016 and before October 1, 2025 is updated by the hospice payment update percentage rather than using the CPI–U. This was applied to the 2016 cap year, starting on November 1, 2015 and ending on October 31, 2016. In addition, we finalized a provision to align the cap accounting year for both the inpatient cap and the hospice aggregate cap with the FY, for FY 2017 and later (80 FR 47186). This allows for the timely implementation of the IMPACT Act changes while better aligning the cap accounting year with the timeframe described in the IMPACT Act.

Finally, the FY 2016 Hospice Wage Index and Payment Rate Update final rule clarified that hospices must report all diagnoses of the beneficiary on the hospice claim as a part of the ongoing data collection efforts for possible future hospice payment refinements. Reporting of all diagnoses on the hospice claim aligns with current coding guidelines as

well as admission requirements for hospice certifications (80 FR 47142).

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 benefit utilization. The number of Medicare beneficiaries receiving hospice services has grown from 513,000 in FY 2000 to nearly 1.4 million in FY 2015. Similarly, Medicare hospice expenditures have risen from $2.8 billion in FY 2000 to an estimated $15.5 billion in FY 2015.[3] Under the economic assumptions from the 2017 Mid-Session Review,[4] our Office of the Actuary (OACT) projects that hospice expenditures are expected to continue to increase, by approximately 7 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.

There have also been changes in the diagnosis patterns among Medicare hospice enrollees. Specifically, as described in Table 2, there have been notable increases between 2002 and 2015 in neurologically-based diagnoses, including various dementia and Alzheimer's diagnoses. Additionally, there had been significant increases in the use of non-specific, symptom-classified diagnoses, such as ''debility'' and ''adult failure to thrive.'' In FY 2013, ''debility'' and ''adult failure to thrive'' were the first and sixth most common hospice claims-reported diagnoses, respectively, accounting for approximately 14 percent of all diagnoses. Effective October 1, 2014, hospice claims are returned to the provider if ''debility'' and ''adult failure to thrive'' are coded as the principal hospice diagnosis as well as other ICD–9–CM (and as of October 1, 2015, ICD–10–CM) codes that are not permissible as principal diagnosis codes per ICD–9–CM (or ICD–10–CM) coding guidelines. In the FY 2015 Hospice Wage Index and Payment Rate Update final rule (79 FR 50452), we reminded the hospice industry that this policy would go into effect and claims would start to be returned to the provider effective October 1, 2014. As a result of this, there has been a shift in coding patterns on hospice claims. For FY 2015, the most common hospice principal diagnoses were Alzheimer's disease, Congestive Heart Failure, Lung Cancer, Chronic Airway Obstruction, and Senile Dementia which constituted approximately 35 percent of all claims-reported principal diagnosis codes reported in FY 2015. In Table 2 we have updated the information initially presented in the FY 2017 proposed rule (81 FR 25504–06).

TABLE 2—THE TOP TWENTY PRINCIPAL HOSPICE DIAGNOSES, FY 2002, FY 2007, FY 2013, FY 2015

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
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

[3] FY2000 figures from MedPAC analysis of the denominator file, the Medicare Beneficiary Database, and the 100 percent hospice claims standard analytic file from CMS (*http://www.medpac.gov/documents/reports/chapter-11-hospice-services-(march-2012-report).pdf?sfvrsn=4*). FY 2015 hospice claims data from the Chronic Conditions Data Warehouse (CCW), accessed on June 20, 2016.

[4] ''Mid-Session Review: Budget of the US Government.'' *Office of Management and Budget.* July 15, 2016. *https://www.whitehouse.gov/sites/default/files/omb/budget/fy2017/assets/17msr.pdf.*

TABLE 2—THE TOP TWENTY PRINCIPAL HOSPICE DIAGNOSES, FY 2002, FY 2007, FY 2013, FY 2015—Continued

Rank	ICD–9	Reported principal diagnosis	Count	Percentage
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 2013				
1	799.3	Debility Unspecified	127,415	9
2	428.0	Congestive Heart Failure	96,171	7
3	162.9	Lung Cancer	91,598	6
4	496	COPD	82,184	6
5	331.0	Alzheimer's Disease	79,626	6
6	783.7	Adult Failure to Thrive	71,122	5
7	290.0	Senile Dementia, Uncomp	60,579	4
8	429.9	Heart Disease Unspecified	36,914	3
9	436	CVA/Stroke	34,459	2
10	294.10	Dementia In Other Diseases w/o Behavioral Dist	30,963	2
11	332.0	Parkinson's Disease	25,396	2
12	153.9	Colon Cancer	23,228	2
13	294.20	Dementia Unspecified w/o Behavioral Dist	23,224	2
14	174.9	Breast Cancer	23,059	2
15	157.9	Pancreatic Cancer	22,341	2
16	185	Prostate Cancer	21,769	2
17	585.6	End-Stage Renal Disease	19,309	1
18	518.81	Acute Respiratory Failure	15,965	1
19	294.8	Other Persistent Mental Dis.-classified elsewhere	14,372	1
20	294.11	Dementia In Other Diseases w/Behavioral Dist	13,687	1
Year: FY 2015				
1	331.0	Alzheimer's disease	196,705	13
2	428.0	Congestive heart failure, unspecified	115,111	8
3	162.9	Lung Cancer	88,404	6
4	496	COPD	80,655	6
5	331.2	Senile degeneration of brain	46,843	3
6	332.0	Parkinson's Disease	34,957	2
7	429.9	Heart disease, unspecified	31,906	2
8	436	CVA/Stroke	29,172	2
9	437.0	Cerebral atherosclerosis	26,887	2
10	174.9	Breast Cancer	23,969	2
11	153.9	Colon Cancer	23,844	2
12	185	Prostate Cancer	23,293	2
13	157.9	Pancreatic Cancer	23,127	2
14	585.6	End stage renal disease	22,990	2
15	491.21	Obstructive chronic bronchitis with (acute) exacerbation	21,493	1
16	518.81	Acute respiratory failure	20,214	1
17	429.2	Cardiovascular disease, unspecified	16,937	1
18	434.91	Cerebral artery occlusion, unspecified with cerebral infarction	15,841	1
19	414.00	Coronary atherosclerosis of unspecified type of vessel	15,689	1
20	188.9	Bladder Cancer	11,648	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 and 2007 hospice claims data from the Chronic Conditions Data Warehouse (CCW), accessed on February 14 and February 20, 2013. FY 2013 hospice claims data from the CCW, accessed on June 26, 2014, and FY 2015 hospice claims data from the CCW, accessed on June 20, 2016.

While there has been a shift in the reporting of the principal diagnosis as a result of diagnosis clarifications, a significant proportion of hospice claims (49 percent) in FY 2014 only reported a single principal diagnosis, which may not fully explain the characteristics of Medicare beneficiaries who are approaching the end of life. To address this pattern of single diagnosis reporting, the FY 2015 Hospice Wage Index and Payment Rate Update final rule (79 FR 50498) reiterated ICD–9–CM coding guidelines for the reporting of the principal and additional diagnoses on the hospice claim. We reminded providers to report all diagnoses on the hospice claim for the terminal illness and related conditions, including those that affect the care and clinical management for the beneficiary. Additionally, in the FY 2016 Hospice Wage Index and Payment Rate Update final rule (80 FR 47201), we provided further clarification regarding diagnosis reporting on hospice claims. We clarified that hospices will report *all*

diagnoses identified in the initial and comprehensive assessments on hospice claims, whether related or unrelated to the terminal prognosis of the individual, effective October 1, 2015. Analysis of FY 2015 hospice claims show that only 37 percent of hospice claims include a single, principal diagnosis, with 63 percent submitting at least two diagnoses and 46 percent including at least three.

F. Use of Health Information Technology

The Department of Health and Human Services (HHS) believes that the use of certified health IT by hospices can help providers improve internal care delivery practices and advance the interoperable exchange of health information across care partners to improve communication and care coordination. HHS has a number of initiatives designed to encourage and support the adoption of health information technology and promote nationwide health information exchange to improve health care. The Office of the National Coordinator for Health Information Technology (ONC) leads these efforts in collaboration with other agencies, including CMS and the Office of the Assistant Secretary for Planning and Evaluation (ASPE). In 2015, ONC released a document entitled ''Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap'' (available at: *https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf*), which includes a near-term focus on actions that will enable a majority of individuals and providers across the care continuum to send, receive, find and use a common set of electronic clinical information at the nationwide level by the end of 2017. The 2015 Edition Health IT Certification Criteria (2015 Edition) builds on past rulemakings to facilitate greater interoperability for several clinical health information purposes and enables health information exchange through new and enhanced certification criteria, standards, and implementation specifications. The 2015 Edition also focuses on the establishment of an interoperable nationwide health information infrastructure. More information on the 2015 Edition Final Rule is available at: *https://www.healthit.gov/policy-researchers-implementers/2015-edition-final-rule*

III. Provisions of the Proposed Regulations

The proposed rule, titled ''Medicare Program; FY 2017 Hospice Payment Rate Update'' (81 FR 25497 through 25538), was published in the **Federal Register** on April 28, 2016, with a comment period that ended on June 20, 2016. In that proposed rule, we proposed to update the hospice wage index, payment rates, and cap amount for fiscal year (FY) 2017. In addition, the proposed rule proposed changes to the hospice quality reporting program, including new quality measures. The proposed rule also solicited feedback on an enhanced data collection instrument and described plans to publicly display quality measures and other hospice data beginning in the middle of 2017. Finally, the proposed rule included information regarding the Medicare Care Choices Model (MCCM). We received approximately 56 public comments on the proposed rule, including comments from MedPAC, hospice agencies, national provider associations, patient organizations, nurses, and advocacy groups.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the FY 2017 Hospice Payment Rate Update. Comments related to the paperwork burden are addressed in the ''Collection of Information Requirements'' section in this final rule. Comments related to the impact analysis are addressed in the ''Economic Analyses'' section in this final rule.

A. Monitoring for Potential Impacts—Affordable Care Act Hospice Reform

In the FY 2017 Hospice Wage Index and Rate Update proposed rule (81 FR 25497), we provided a summary of analysis conducted on pre-hospice spending, non-hospice spending, live discharge rates, and skilled visits in the last days of life. In addition, we also provided a summary of our plans to monitor for impacts of hospice payment reform. We will continue to monitor the impact of future payment and policy changes and will provide the industry with periodic updates on our analysis in future rulemaking and/or announcements on the Hospice Center Web page at: *https://www.cms.gov/Center/Provider-Type/Hospice-Center.html.*

We received several comments on the analysis and CMS's plans for future monitoring efforts with regards to hospice payment reform outlined in the proposed rule, which are summarized below.

Comment: A few commenters expressed concerns regarding whether pre-hospice spending is an appropriate standard for comparison for post-hospice spending for any diagnosis, including dementia. The commenters noted the illness trajectory of dementia is marked by a slow, progressive decline, differs from the illness trajectories of other hospice appropriate diagnoses, and results in care needs increasing and extending over longer periods of time. In turn, it may require higher spending. The commenters asked us to recognize the overall care needs of patients with dementia and other progressive neurological conditions, and the costs associated with these patients and their caregivers. Additionally, several commenters highlighted the challenges of and intensive resources required for short-stay patients, noting that the current payment system may not address the unique needs of that population.

Several commenters suggested that CMS consider payment refinements that help to incentivize appropriate timing on enrollment for hospice. Additional commenters noted their concern regarding a potential case-mix payment system for hospice, as the commenters believe that the hospice benefit differs from all other Medicare payment systems, as it is designed to account for the patient's full scope of Medicare needs.

With regards to non-hospice spending during a hospice election, several commenters suggested that CMS take action to educate other Medicare provider types in order to increase understanding of benefits coverage and claims processing after a beneficiary has elected hospice. Several commenters also suggested that CMS investigate options for preventing other Medicare providers from billing without checking the Common Working File and notifying the hospice for a determination as to whether or not the care is related to the terminal prognosis. Several commenters requested that a greater level of specificity for Part D data be supplied to hospice providers, such that they can track where the billing issues originate and begin to address them. The commenters suggested that a coordinated system would help address the non-hospice spending.

With regards to hospice live discharge rates, a few commenters noted concerns about the difference between two types of live discharges: A patient-initiated discharge or revocation versus a hospice-initiated discharge. The commenters suggested that analysis of live discharge rates should exclude the patient-initiated discharges or revocations. Commenters suggested that for hospice-initiated discharges, the reasons for such discharges should be reported so that hospice providers can

make adjustments in their admission and discharge practices.

With regards to skilled visits during the last days of life, the number of visits by RNs and social workers is anticipated to increase during the last 7 days of a beneficiary's life as a result of the service intensity add-on payment, implemented on January 1, 2016. A few commenters stated that hospices take their cues from patients and families, who should always have the option to decline a visit. As such, decisions regarding visits made by the patient and family ought to be considered and/or reflected in the data.

Finally, most commenters supported our planned analysis to monitor the impact of hospice payment reform and would like to use the monitoring results to target program integrity efforts to those aberrant individual providers.

Although the analysis and monitoring efforts described in the proposed rule did not relate to the timely filing requirement for the hospice Notice of Election (NOE), nevertheless a few commenters expressed concern about the timely filing requirement and lost revenue due to data entry errors that cannot be immediately corrected. Commenters encouraged CMS to continue to explore the possibility of transmitting NOEs through Electronic Data Interchange rather than through direct data entry and recommended that, in the meantime, when the hospice files the NOE in good faith within the 5-day requirement, but the MAC does not accept the NOE within 5 days, the payment for hospice services should be allowed back to the date of election, once the MAC has accepted the NOE.

Response: We appreciate these comments on the ongoing analysis presented and will continue to monitor hospice trends and vulnerabilities within the hospice benefit while also investigating means by which we can educate the larger provider community regarding appropriate billing practices. Additionally, we continue to explore options and strategies for addressing and responding to concerning behavior in the provider community. We will also consider these suggestions in any potential future policy and payment refinements.

With regards to the comments received regarding the NOE timely filing requirement, we recognize that inadvertent NOE errors, such as transposed numbers or incorrect admission dates, will not trigger the NOE to return to the hospice for correction. The hospice must wait until the incorrect information is fully processed by Medicare systems before they can correct it, and this could cause the NOE to be late. We strongly encourage hospices to have quality assurance measures in place regarding the accuracy of the NOE information to mitigate any potential untimely NOEs. Our expectation is that the information provided on the hospice NOE is accurate and free of transcribing errors. To aid in reducing the impact of these situations on hospices, CMS is currently conducting an analysis that aims to redesign the hospice benefit period data in our systems.

B. FY 2017 Hospice Wage Index and Rate Update

1. FY 2017 Hospice Wage Index

a. Background

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. Our regulations at § 418.306(c) require each labor market to be established using the most current hospital wage data available, including any changes made by the Office of Management and Budget (OMB) to the Metropolitan Statistical Areas (MSAs) definitions.

We use the previous FY's hospital wage index data to calculate the hospice wage index values. For FY 2017, the hospice wage index will be based on the FY 2016 pre-floor, pre-reclassified hospital wage index. This means that the hospital wage data used for the hospice wage index is not adjusted to take into account any geographic reclassification of hospitals including those in accordance with section 1886(d)(8)(B) or 1886(d)(10) of the Act. The appropriate wage index value is applied to the labor portion of the payment rate based on the geographic area in which the beneficiary resides when receiving RHC or CHC. The appropriate wage index value is applied to the labor portion of the payment rate based on the geographic location of the facility for beneficiaries receiving GIP or Inpatient Respite Care (IRC).

In the FY 2006 Hospice Wage Index final rule (70 FR 45130), we adopted the changes discussed in the OMB Bulletin No. 03–04 (June 6, 2003). This bulletin announced revised definitions for MSAs and the creation of micropolitan statistical areas and combined statistical areas. The bulletin is available online at *http://www.whitehouse.gov/omb/bulletins/b03-04.html.* When adopting OMB's new labor market designations in FY 2006, we identified some geographic areas where there were no hospitals, and thus, no hospital wage index data, on which to base the calculation of the hospice wage index. In the FY 2010 Hospice Wage Index final rule (74 FR 39386), we 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 FY 2016, the only CBSA without a hospital from which hospital wage data could be derived is 25980, Hinesville-Fort Stewart, Georgia.

In the 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. The term ''contiguous'' means 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 value 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. In this final rule, for FY 2017, we will continue to use the most recent pre-floor, pre-reclassified hospital wage index value available for Puerto Rico, which is 0.4047.

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 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 a 15 percent increase subject to a maximum wage index value of 0.8. For example, if County A has a pre-floor, pre-reclassified hospital wage index value of 0.3994, we would multiply 0.3994 by 1.15, which equals 0.4593. Since 0.4593 is not greater than 0.8, then County A's hospice wage index would be 0.4593. In another example, if County B has a pre-floor,

pre-reclassified hospital wage index value of 0.7440, we would multiply 0.7440 by 1.15 which equals 0.8556. Because 0.8556 is greater than 0.8, County B's hospice wage index would be 0.8.

b. FY 2016 Implementation of New Labor Market Delineations

OMB has published subsequent bulletins regarding CBSA changes. On February 28, 2013, OMB issued OMB Bulletin No. 13–01, announcing revisions to the delineation of MSAs, Micropolitan Statistical Areas, and Combined Statistical Areas, and guidance on uses of the delineation in these areas. A copy of this bulletin is available online at: *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf.* This bulletin states that it ''provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010, in the **Federal Register** (75 FR 37246 through 37252) and Census Bureau data.'' In the FY 2016 Hospice Wage Index final rule (80 FR 47178), we adopted the OMB's new area delineations using a 1-year transition. In the FY 2016 Hospice Wage Index and Payment Rate Update final rule (80 FR 47178), we stated that beginning October 1, 2016, the wage index for all hospice payments would be fully based on the new OMB delineations.

A summary of the comments we received regarding the wage index and our responses to those comments appears below.

Comment: Several commenters noted their support for the full adoption of the new labor market delineations.

Response: We appreciate the comments in support of the CBSA delineations finalized in last year's FY 2016 Hospice Wage Index and Payment Rate Update final rule (80 FR 47142).

Comment: One commenter disagreed with fully basing hospice geographic area wage adjustments on the new OMB delineations. The commenter was particularly concerned with the New York City CBSA and the fact that the CBSA contains counties from New Jersey.

Response: In the FY 2016 Hospice Wage Index and Rate Update final rule (80 FR 47178), we stated that a 1-year transition policy would apply to the FY 2016 payment rates and that, beginning in FY 2017, hospice payments would be fully-based on the new OMB delineations. In addition, we believe that the OMB's CBSA designations reflect the most recent available geographic classifications and are a reasonable and appropriate method of defining geographic areas for the purposes of wage adjusting the hospice payment rates. We do not see any compelling reason to deviate from the OMB designations.

Comment: A commenter was concerned with the continued use of the pre-floor, pre-reclassified hospital wage index to adjust the hospice payment rates, because this causes continuing volatility of the hospice wage index from one year to the next. The commenter believes that this volatility is often based on inaccurate or incomplete hospital cost report data.

Response: We believe that annual changes in the wage index reflect real variations in costs of providing care in various geographic locations. The wage index values are based on data submitted on the inpatient hospital cost reports. We utilize efficient means to ensure and review the accuracy of the hospital cost report data and resulting wage index. The hospice wage index is derived from the pre-floor, pre-reclassified wage index, which is calculated based on cost report data from hospitals paid under the Inpatient Prospective Payment System (IPPS). All IPPS hospitals must complete the wage index survey (Worksheet S–3, Parts II and III) as part of their Medicare cost reports. Cost reports will be rejected if Worksheet S–3 is not completed. In addition, our Medicare contractors perform desk reviews on all hospitals' Worksheet S–3 wage data, and we run edits on the wage data to further ensure the accuracy and validity of the wage data. We believe that our review processes result in an accurate reflection of the applicable wages for the areas given.

In addition, we believe that finalizing our proposal to adopt a hospice wage index standardization factor will provide a safeguard to the Medicare program as well as to hospices because it will mitigate fluctuations in the wage index by ensuring that wage index updates and revisions are implemented in a budget neutral manner.

Comment: A commenter was concerned with the lack of parity between different health care sectors, each of which utilizes some form of a hospital wage index, that experience differing wage index values for specific geographic areas. The commenter also stated that hospital reclassifications create labor market distortions in areas in which hospice costs are not reclassified.

Response: Several post-acute care payment systems utilize the pre-floor, pre-reclassified hospital wage index as the basis for their wage indexes (for example, the Home Health Prospective Payment System (HH PPS), the Skilled Nursing Facility Prospective Payment System (SNF PPS) and the Inpatient Rehabilitation Facility Prospective Payment System (IRF PPS)). The statutes that govern hospice payment do not provide any discretion to permit a mechanism for allowing hospices to seek geographic reclassification. The reclassification provision is found in section 1886(d)(10) of the Act. Section 1886(d)(10)(C)(i) of the Act states, ''The Board shall consider the application of any subsection (d) hospital requesting that the Secretary change the hospital's geographic classification . . .'' This provision is only applicable to hospitals, as defined at section 1886(d) of the Act. In addition, we do not believe that using hospital reclassification data would be appropriate as these data are specific to the requesting hospitals and the data may or may not apply to a given hospice in a given instance.

Comment: One commenter requested that CMS modify the wage index so that the area wage index applicable to any hospice that is located in an urban area of a state may not be less than the area wage index applicable to hospices located in rural areas in that State.

Response: Section 4410(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33) provides that the area wage index applicable to any hospital that is located in an urban area of a state may not be less than the area wage index applicable to hospitals located in rural areas in that state. This rural floor provision is specific to hospitals. Because the hospital rural floor applies only to hospitals, and not to hospices, we continue to believe the use of the previous year's pre-floor and pre-reclassified hospital wage index results in the most appropriate adjustment to the labor portion of the hospice payment rates. This position is longstanding and consistent with other Medicare payment systems (SNF PPS, IRF PPS, HH PPS, etc.).

Comment: A commenter requested that CMS explore a wholesale revision and reform of the hospice wage index.

Response: We are exploring other methodologies for future reform of the Medicare wage index. CMS' ''Report to Congress: Plan to Reform the Medicare Wage Index'' was submitted by the Secretary on April 11, 2012 and is available on our Wage Index Reform Web page at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-*

Payment/AcuteInpatientPPS/Wage-Index-Reform.html.

Final Action: After considering the comments received in response to the proposed rule and for the reasons discussed above, we are finalizing our proposal to use the pre-floor, pre-reclassified hospital inpatient wage index as the wage adjustment to the labor portion of the hospice rates. For FY 2017, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2011 and before October 1, 2012 (FY 2012 cost report data).

The wage index applicable for FY 2017 is available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/index.html.* As of FY 2012, the wage index values applicable for the upcoming fiscal year and subsequent fiscal years are no longer published in the **Federal Register** (77 FR 44242). The hospice wage index for FY 2017 will be effective October 1, 2016 through September 30, 2017.

2. 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 inpatient hospital market basket index set out under section 1886(b)(3)(B)(iii) of the Act, 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 inpatient 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. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period) (the ''MFP adjustment''). A complete description of the MFP projection methodology is available on our Web site at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html.*

In addition to the MFP adjustment, 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 hospice payment update percentage for FY 2017 is based on the estimated inpatient hospital market basket update of 2.7 percent (based on IHS Global Insight, Inc.'s second quarter 2016 forecast with historical data through the first quarter of 2016). Due to the requirements at sections 1886(b)(3)(B)(xi)(II) and 1814(i)(1)(C)(v) of the Act, the estimated inpatient hospital market basket update for FY 2017 of 2.7 percent must be reduced by a MFP adjustment as mandated by Affordable Care Act (currently estimated to be 0.3 percentage point for FY 2017). The estimated inpatient hospital market basket update for FY 2017 is reduced further by 0.3 percentage point, as mandated by the Affordable Care Act. In effect, the hospice payment update percentage for FY 2017 is 2.1 percent.

Currently, the labor portion of the hospice payment rates is as follows: For RHC, 68.71 percent; for CHC, 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 RHC, 31.29 percent; for CHC, 31.29 percent; for General Inpatient Care, 35.99 percent; and for Respite Care, 45.87 percent.

A summary of the comments we received regarding the payment rates and our responses to those comments appear below.

Comment: Several commenters noted their support of the hospice payment update percentage.

Response: We appreciate the comments in support of the hospice payment update percentage.

Comment: One commenter suggested the CMS eliminate the hospice payment update percentage to hospice payments for FY 2017, as the commenter maintains that payment adequacy for hospice providers is generally positive. Other commenters noted that the proposed hospice payment update percentage is not sufficient to keep pace with rising costs of providing hospice care and suggested that CMS revisit the proposed hospice payment update percentage for potential increase.

Response: The payment update percentage to the hospice rates is required by statute, as previously described in detail in this section, and we do not have regulatory authority to alter the payment update.

Final Action: We are implementing the hospice payment update percentage as discussed in the proposed rule. Based on IHS Global Insight, Inc.'s updated forecast, the hospice payment update percentage for FY 2017 will be 2.1 percent for hospices that submit the required quality data and 0.1 percent for hospices that do not submit the required quality data.

3. FY 2017 Hospice Payment Rates

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 RHC rate for each day the beneficiary is enrolled in hospice, unless the hospice provides continuous home care, IRC, or general inpatient care. CHC is provided during a period of patient crisis to maintain the person at home; IRC is short-term care to allow the usual caregiver to rest and be relieved from caregiving; and General Inpatient Care (GIP) is to treat symptoms that cannot be managed in another setting.

As discussed in the FY 2016 Hospice Wage Index and Payment Rate Update final rule (80 FR 47172), we implemented two different RHC payment rates, one RHC rate for the first 60 days and a second RHC rate for days 61 and beyond. In addition, in the final rule, we adopted a Service Intensity Add-on (SIA) payment, when direct patient care is provided by a RN or social worker during the last 7 days of the beneficiary's life. The SIA payment is equal to the CHC hourly rate multiplied by the hours of nursing or social work provided (up to 4 hours total) that occurred on the day of service. In order to maintain budget neutrality, as required under section 1814(i)(6)(D)(ii) of the Act, the new RHC rates were adjusted by a SIA budget neutrality factor.

As discussed in the FY 2016 Hospice Wage Index and Payment Rate Update final rule (80 FR 47177), we will continue to make the SIA payments budget neutral through an annual determination of the SIA budget neutrality factor (SBNF), which will then be applied to the RHC payment

rates. The SBNF will be calculated for each FY using the most current and complete FY utilization data available at the time of rulemaking. For FY 2017, the budget neutrality adjustment that applies to days 1 through 60 is calculated to be 1.0000. The budget neutrality adjustment that applies to days 61 and beyond is calculated to be 0.9999.

For FY 2017, we are applying a wage index standardization factor to the FY 2017 hospice payment rates in order to ensure overall budget neutrality when updating the hospice wage index with more recent hospital wage data. Wage index standardization factors are applied in other payment settings such as under home health Prospective Payment System (PPS), IRF PPS, and SNF PPS. Applying a wage index standardization factor to hospice payments will eliminate the aggregate effect of annual variations in hospital wage data. We believe that adopting a hospice wage index standardization factor will provide a safeguard to the Medicare program as well as to hospices because it will mitigate fluctuations in the wage index by ensuring that wage index updates and revisions are implemented in a budget neutral manner. To calculate the wage index standardization factor, we simulated total payments using the FY 2017 hospice wage index and compared it to our simulation of total payments using the FY 2016 hospice wage index. By dividing payments for each level of care using the FY 2017 wage index by payments for each level of care using the FY 2016 wage index, we obtain a wage index standardization factor for each level of care (RHC days 1–60, RHC days 61+, CHC, IRC, and GIP).

Lastly, the hospice payment rates for hospices that submit the required quality data will be increased by the full FY 2017 hospice payment update percentage of 2.1 percent as discussed in section III.C.3 of this final rule. The FY 2017 RHC rates are shown in Table 11. The FY 2017 payment rates for CHC, IRC, and GIP are shown in Table 12.

TABLE 11—FY 2017 HOSPICE RHC PAYMENT RATES

Code	Description	FY 2016 payment rates	SBNF	Wage index standardization factor	FY 2017 hospice payment update percentage	FY 2017 payment rates
651	Routine Home Care (days 1–60)	$186.84	× 1.0000	× 0.9989	× 1.021	$190.55
651	Routine Home Care (days 61+)	146.83	× 0.9999	× 0.9995	× 1.021	149.82

TABLE 12—FY 2017 HOSPICE CHC, IRC, AND GIP PAYMENT RATES

Code	Description	FY 2016 payment rates	Wage index standardization factor	FY 2017 hospice payment update percentage	FY 2017 payment rates
652	Continuous Home Care Full Rate = 24 hours of care. $40.19 = FY 2017 hourly rate.	$944.79	× 1.0000	× 1.021	$964.63
655	Inpatient Respite Care	167.45	× 1.0000	× 1.021	170.97
656	General Inpatient Care	720.11	× 0.9996	× 1.021	734.94

Sections 1814(i)(5)(A) through (C) of the Act require 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 for 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. The FY 2017 rates for hospices that do not submit the required quality data will be updated by the FY 2017 hospice payment update percentage of 2.1 percent minus 2 percentage points. These rates are shown in Tables 13 and 14.

TABLE 13—FY 2017 HOSPICE RHC PAYMENT RATES FOR HOSPICES THAT *DO NOT* SUBMIT THE REQUIRED QUALITY DATA

Code	Description	FY 2016 payment rates	SBNF	Wage index standardization factor	FY 2017 hospice payment update of 2.1% minus 2 percentage points = 0.1%	FY 2017 payment rates
651	Routine Home Care (days 1–60)	$186.84	× 1.0000	× 0.9989	× 1.001	$186.82
651	Routine Home Care (days 61+)	146.83	× 0.9999	× 0.9995	× 1.001	146.89

TABLE 14—FY 2017 HOSPICE CHC, IRC, AND GIP PAYMENT RATES FOR HOSPICES THAT *DO NOT* SUBMIT THE REQUIRED QUALITY DATA

Code	Description	FY 2016 payment rates	Wage index standardization factor	FY 2017 hospice payment update of 2.1% minus 2 percentage points = 0.1%	FY 2017 payment rates
652	Continuous Home Care Full Rate = 24 hours of care. $39.41 = FY 2017 hourly rate.	$944.79	× 1.0000	× 1.001	$945.73
655	Inpatient Respite Care	167.45	× 1.0000	× 1.001	167.62
656	General Inpatient Care	720.11	× 0.9996	× 1.001	720.54

A summary of the comments we received regarding the payment rates and our responses to those comments appear below.

Comment: A commenter asked if the application of the standardization factor is premature or is it part of the continued progression of hospice reimbursement from hybrid fee-for-service/health maintenance organization to a full case-mix or value-based purchasing (VBP) system.

Response: We believe that applying a wage index standardization factor to the hospice rates is appropriate. The application of the standardization factor will mitigate any potential effects due to the annual variations in hospital wage data. Moreover, this approach creates a level of protection for the Medicare program as well as to hospices, as it minimizes the impacts of any fluctuations in the wage index.

Comment: Several commenters requested that the SIA Payment eligibility requirements be modified to include additional hospice services, including visits from licensed practical nurses (LPNs), music therapists, and other professionals providing care during the last 7 days of life. In addition, several commenters requested that data be collected in order to determine if the SIA Payment increased the number of visits during beneficiaries' most intensive time of need for skilled care (specifically, the last 7 days of life).

Response: CMS finalized the SIA payment policy in the FY 2016 Hospice Wage Index and Payment Update final rule (80 FR 47141) and we did not solicit comments on a proposal to modify these policy parameters in the FY 2017 Hospice Wage Index and Payment Rate update proposed rule (81 FR 25498). However, we will continue to consider and monitor for potential refinements to this policy, including current monitoring efforts that were described in the FY 2017 Hospice Wage Index and Payment Rate Update proposed rule (81 FR 25498) in response to these policy changes, and we will take these comments into account as we continue to do so.

Comment: One commenter noted that there have been issues with the technical implementation of the SIA payment such that payment adjustments are not occurring as originally intended.

Response: While the technical implementations issues with regards to SIA payments have been minimal, we appreciate this comment and are working diligently with appropriate stakeholders to expedite the appropriate system remediation to ensure accurate payment to providers.

Comment: One commenter expressed concern that the RHC rate payment amount for Days 61 and beyond may lead to payment inadequacy for patients with long lengths of stay. One commenter noted that the episode gap required by the two RHC rates policy implemented for FY 2016 could have a negative impact on those hospices that accept patients via transfers. Moreover, the commenter noted that CMS should consider payment adjustments if a patient is transferred from one hospice to another, particularly at or near day 61 of a hospice episode.

Response: We appreciate the comments and the concern for appropriate payment for long stay beneficiaries as well as transfer patients. The creation of the two RHC rates (one for days 1–60 and a another for days 61 and beyond) was finalized in the FY 2016 Hospice Wage Index and Payment Rate Update final rule (80 FR 47141), and we did not propose any changes for FY 2017 nor did we solicit comments on any future changes. In response to public comments, we stated in the FY 2016 Hospice Wage Index and Payment Rate Update final rule that allowing for a higher payment for a new hospice election (or in transfer situations) without a gap in hospice care of greater than 60 days goes against our intent to mitigate the incentive to discharge and readmit patients (or transfer patients) at or around day 60 for the purposes of obtaining a higher payment (80 FR 47168). With regards to the commenter's concern regarding reimbursement for long lengths of stay, we refer the commenter to the FY 2016 Hospice Wage Index and Payment Rate Update final rule (80 FR 47142), where we discuss the rationale for the creation of a higher RHC rate for days 1–60 and a lower rate for days 61 and beyond. In that final rule, we noted that hospice stays manifest in a 'U-Shaped' pattern (that is, the intensity of services provided is higher both at admission and near death and, conversely, is relatively lower during the middle period of the hospice episode). Since hospice care is most profitable during the long, low-cost middle portions of an episode, longer episodes have very profitable, long middle segments (80 FR 47161). Therefore, in order to better align hospice payments with service intensity during a hospice episode of care, we implemented a higher RHC rate for days 1–60 and a lower rate for days 61 and beyond, effective January 1, 2016. We also implemented a service intensity add-on (SIA) payment policy that reimburses hospices for visits performed during the last 7 days of a beneficiary's life (in addition to RHC per diem payments), also effective January 1, 2016. We will continue to monitor for and consider potential refinements to these policies as appropriate.

Comment: A commenter noted that Medicaid agencies have encountered challenges in the implementation of the payment changes due to hospice reform.

Response: We appreciate this comment and are working diligently with appropriate stakeholders and State Agencies to facilitate effective implementation of hospice payment reform.

Final Action: We are implementing the updates to hospice payment rates as discussed in the proposed rule.

4. Hospice Cap Amount for FY 2017

As discussed in the FY 2016 Hospice Wage Index and Payment Rate Update final rule (80 FR 47183), we implemented changes mandated by the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act). Specifically, for accounting years that end after September 30, 2016 and before October 1, 2025, the hospice cap is updated by the hospice payment update percentage rather than using the consumer price index for urban consumers (CPI–U). As required by section 1814(i)(2)(B)(ii) of the Act, the hospice cap amount for the 2016 cap year, starting on November 1, 2015 and ending on October 31, 2016, is equal to the 2015 cap amount ($27,382.63) updated by the FY 2016 hospice payment update percentage of 1.6 percent. As such, the 2016 cap amount is $27,820.75.

In the FY 2016 Hospice Wage Index and Payment Rate Update final rule (80 FR 47142), we finalized aligning the cap accounting year with the federal FY beginning in 2017. Therefore, the 2017 cap year will start on October 1, 2016 and end on September 30, 2017. Table 26 in the FY 2016 Hospice Wage Index and Payment Rate Update final rule (80 FR 47185) outlines the timeframes for counting beneficiaries and payments during the 2017 transition year. The hospice cap amount for the 2017 cap year will be $28,404.99, which is equal to the 2016 cap amount ($27,820.75) updated by the FY 2017 hospice payment update percentage of 2.1 percent.

A summary of public comments and our responses to comments on the hospice cap are summarized below:

Comment: One commenter expressed concerns that the methodology used to calculate the hospice cap creates an incentive for rural hospices to inflate their utilization of the GIP level of care, as some rural hospices may do this to gain higher reimbursement by placing patients at the GIP level of care that may not qualify for that level of care.

Response: The hospice aggregate cap is calculated based on total reimbursement across all levels of care. In addition, the hospice inpatient cap limits total payments to the hospice for inpatient care (general or respite). Total payments are subject to a limitation that total inpatient care days for Medicare patients does not exceed 20 percent of the total days for which patients had elected hospice care. We urge providers to adhere to appropriate guidelines with respect to the hospice levels of care. We note that in a March 2016 Office of Inspector General (OIG) report, OIG found that hospices billed one-third of GIP stays inappropriately, costing Medicare $268 million in 2012. According to the report, ''hospices commonly billed for GIP when the beneficiary did not have uncontrolled pain or unmanaged symptoms.'' (*http://oig.hhs.gov/oei/reports/oei-02-10-00491.asp*) As such, we will continue to monitor the use of the various levels of care in order to identify any aberrant or problematic behavior.

Final Action: We are implementing the changes to the hospice cap amount as discussed in the proposed rule.

C. Proposed Updates to the Hospice Quality Reporting Program (HQRP)

1. Background and Statutory Authority

Section 3004(c) of the Affordable Care Act amended section 1814(i)(5) of 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 for 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 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.

2. General Considerations Used for Selection of Quality Measures for the HQRP

Any measures selected by the Secretary must be endorsed by the consensus-based entity, which holds a contract regarding performance measurement, including the endorsement of quality measures, 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. Our paramount concern is the successful development of an HQRP that promotes the delivery of high quality healthcare services. We seek to adopt measures for the HQRP that promote person-centered, high quality, and safe care. Our measure selection activities for the HQRP take into consideration input from the Measure Applications Partnership (MAP), convened by the NQF, as part of the established CMS pre-rulemaking process required 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.* 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, (*http://www.ahrq.gov/workingforquality/nqs/nqs2013annlrpt.htm*) and the CMS Quality Strategy (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html*). To the extent practicable, we have sought to adopt measures endorsed by member organizations of the National Consensus Project (NCP), recommended by multi-stakeholder organizations, and developed with the input of providers, purchasers and/or payers, and other stakeholders.

3. Policy for Retention of HQRP Measures Adopted for Previous Payment Determinations

For the purpose of streamlining the rulemaking process, we finalized our policy in the FY 2016 Hospice Wage Index final rule (80 FR 47187) that when we adopt measures for the HQRP beginning with a payment

determination year, these measures would automatically be adopted for all subsequent years' payment determinations, unless we proposed to remove, suspend, or replace the measures. Quality measures would be considered for removal by CMS for reasons including, but not limited to:

- Measure performance among hospices was so high and unvarying that meaningful distinction in improvements in performance could no longer be made;
- Performance or improvement on a measure did not result in better patient outcomes;
- A measure did not align with current clinical guidelines or practice;
- A more broadly applicable measure (across settings, populations, or conditions) for the particular topic was available;
- A measure that was more proximal in time to desired patient outcomes for the particular topic was available;
- A measure that was more strongly associated with desired patient outcomes for the particular topic was available; or
- Collection or public reporting of a measure led to negative unintended consequences.

For any such removal, the public would be given an opportunity to comment through the annual rulemaking process. However, if there were reason to believe continued collection of a measure raised potential safety concerns, we would take immediate action to remove the measure from the HQRP and not wait for the annual rulemaking cycle. The measures would be promptly removed, and we would immediately notify hospices and the public of such a decision through the usual CMS HQRP communication channels, including postings and announcements on the CMS HQRP Web site, Medicare Learning Network (MLN) eNews communications, national provider association calls, and announcements on Open Door Forums and Special Open Door Forums. In such instances, the removal of a measure would be formally announced in the next annual rulemaking cycle.

To further streamline the rulemaking process, we proposed to codify that if measures we are using in the HQRP have non-substantive changes in their specifications change as part of their NQF endorsement process, we would continue to utilize the measure with their new endorsed status in the HQRP. As mentioned previously, quality measures selected for the HQRP must be endorsed by the NQF unless they meet the statutory criteria for exception under section 1814(i)(5)(D)(ii) of the Act. The NQF is a voluntary consensus standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other healthcare stakeholder organizations. The NQF was established to standardize healthcare quality measurement and reporting through its consensus measure development process (*http://www.qualityforum.org/About_NQF/Mission_and_Vision.aspx*). The NQF undertakes review of: (a) New quality measures and national consensus standards for measuring and publicly reporting on performance, (b) regular maintenance processes for endorsed quality measures, (c) measures with time-limited endorsement for consideration of full endorsement, and (d) ad hoc review of endorsed quality measures, practices, consensus standards, or events with adequate justification to substantiate the review. Through NQF's measure maintenance process, NQF-endorsed measures are sometimes updated to incorporate changes that we believe do not substantially change the nature of the measure. Examples of such changes could be updated diagnosis or procedure codes, changes to exclusions to a particular patient/consumer population, or definitions. We believe these types of maintenance changes are distinct from more substantive changes to measures. Additionally, since the NQF endorsement and measure maintenance process is one that ensures transparency, public input, and discussion among representatives across the healthcare enterprise,[5] we believe that the NQF measure endorsement and maintenance process itself is transparent, scientifically rigorous, and provides opportunity for public input. Thus, we proposed to codify at § 418.312 that if the NQF makes only non-substantive changes to specifications for HQRP measures in the NQF's re-endorsement process, we would continue to utilize the measure in its new endorsed status. If NQF-endorsed specifications change and we do not adopt those changes, then we would propose the measure as an application. An application of a NQF-endorsed quality measure is utilized in instances when CMS has identified a need to use a NQF-endorsed measure in a QRP but need to use it with one or more modifications to the quality measure's specifications. These modifications pertain to, but are not limited to, one or more of the following aspects of a NQF-endorsed quality measure: (a) Numerator, (b) denominator, (c) setting, (d) look-back period, (e) calculation period, (f) risk adjustment, and (g) revisions to data elements used to collect the data required for the measure, etc. CMS may adopt a quality measure for the HQRP under section 1814(i)(5)(D)(ii) of the Act, which states, ''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 NQF], the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.'' Reasons for not adopting changes in measure specifications to a measure may include any of the aforementioned criteria in this section, including that the new specification does not align with clinical guidelines or practice or that the new specification leads to negative unintended consequences. Finally, we will continue to use rulemaking to adopt substantive updates made by the NQF to the endorsed measures we have adopted for the HQRP. We continue to make these determinations about what constitutes a substantive versus non-substantive change on a measure-by-measure basis. A change would be deemed substantive if the intent of the measure changes, the facility/setting changes, the data sources changes, the level of analysis changes, and/or the measure is removed. We will continue to provide updates about changes to measure specifications as a result of NQF endorsement or maintenance processes through the normal CMS HQRP communication channels, including postings and announcements on the CMS HQRP Web site, MLN eNews communications, national provider association calls, and announcements on Open Door Forums and Special Open Door Forums.

Comment: CMS received two comments on our proposal to codify that if measures used in the HQRP undergo non-substantive changes as part of their NQF re-endorsement process, we would utilize the measure with their new endorsed status without going through a new notice-and-comment rulemaking process. One commenter supported the proposal to codify this policy. Another commenter was concerned that CMS's plan to adopt non-substantive change(s) approved through the NQF re-endorsement process without a notice-and-comment rulemaking process does not allow providers and vendors the

[5] ''NQF: How Endorsement Happens—National Quality Forum.'' 2010. 26 Jan. 2016 *http://www.qualityforum.org/Measuring_Performance/ABCs/How_Endorsement_Happens.aspx.*

opportunity to provide input on changes to measure specifications. Additionally, the commenter also had concerns that adopting non-substantive changes to measures outside of the rulemaking process would limit the ability for hospices and vendors to make necessary changes to data collection systems to implement non-substantive updates to measures.

Response: We thank commenters for their support of this proposal, and for their concerns raised. We agree that the opportunity for the public to provide input on all changes to measure specifications (both substantive and non-substantive) is vital to the measure development, endorsement, and maintenance process. We also agree with the commenter that vendors and the hospice community need ample time to implement changes to measure specifications, especially those that would warrant updates to Hospice Item Set (HIS) items or technical specifications. We would like to reassure commenters that, as stated in this rule, we will still propose substantive changes to measure through rulemaking. With regard to non-substantive measure changes that could occur as a result of the measure maintenance and re-endorsement process, we would like to clarify that the NQF processes for endorsement and maintenance of measures includes review by an expert Standing Committee, public and Member comment periods, Member voting, consideration by the Consensus Standards Approval Committee (CSAC), endorsement by the Board of Directors, and a 30-day appeals period. The NQF endorsement and maintenance (re-endorsement) process allows ample opportunity for NQF member and public input, during the measure development, endorsement and maintenance phases. We encourage hospices to participate in these NQF comment periods to offer their insights about potential impacts of changes to measures and measure specifications. We believe that in instances of non-substantive changes to measure specifications, maximizing the use of NQF opportunities for public input allows us to efficiently and expediently adopt non-substantive, but important changes to measures. Regarding the commenter's concern about whether this policy will allow providers ample time to implement and adopt non-substantive changes, we would like to point out that when non-substantive changes put forth by the NQF are adopted, we are not required to immediately implement those changes on the date of re-endorsement by NQF. Once a non-substantive change is endorsed by NQF, we will consider the time necessary for providers and vendors to implement the change. If newly endorsed non-substantive changes require updates to data collection mechanisms (for example, updates to HIS specifications) or associated training materials, we will allow ample time for providers and vendors to prepare and implement such changes. As noted in the rule, we will communicate the endorsement of non-substantive changes, decisions about whether to adopt non-substantive changes, and timeline for implementation of non-substantive changes through regular HQRP communication channels. Additionally, CMS welcomes comment on any non-substantive changes adopted under this mechanism through the appropriate sub-regulatory communication channels, including but not limited to: NQF public comment periods held as part of endorsement processes, feedback from providers on the Hospice Quality HelpDesk, and feedback from the provider community on ODFs and SODFs. CMS will make such comments and their responses available to the public under the appropriate sub-regulatory communication channels. Finally, we would like to note that this policy is consistent with similar policies in other QRPs.

Comment: We received a few comments on our previously finalized policy for measure retention. These commenters encouraged CMS's continued consideration of whether previously adopted quality measures are appropriate for retention in the HQRP. Commenters encouraged CMS to eliminate measures that are no longer considered to effectively measure quality.

Response: We thank commenters for their suggestions surrounding measure retention and removal. We agree that any quality measures proposed and retained in the HQRP should continue to provide meaningful data to providers and consumers on quality of care. We regularly conduct measure testing activities according to NQF guidelines and the Blueprint for the CMS Measures Management System Version 12.0 (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint-120.pdf*) to ensure that measures continue to demonstrate scientific acceptability (including reliability and validity) and meet the goals of the HQRP, which include distinguishing performance among hospices and contributing to better patient outcomes. As outlined in this section of the rule, we will propose a measure for removal if meaningful distinctions in quality of care can no longer be made from the measure due to high and unvarying performance.

Final Action: After consideration of the comments, we are codifying our policy that once a quality measure is adopted, it be retained for use in the subsequent fiscal year payment determinations until otherwise stated, as proposed.

4. Previously Adopted Quality Measures for FY 2017 and FY 2018 Payment Determination

As stated in the CY 2013 HH PPS final rule (77 FR 67068 through 67133), CMS expanded the set of 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. In response, CMS developed, tested, and implemented a hospice patient-level item set, the HIS. Hospices are required to submit a HIS-Admission record and a HIS-Discharge record for each patient admission to hospice since July 1, 2014. In developing the standardized HIS, we considered comments offered in response to the CY 2013 HH PPS proposed rule (77 FR 41548 through 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 6 NQF-endorsed measures and 1 modified measure for hospice:

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

To achieve a comprehensive set of hospice quality measures available for widespread use for quality improvement and informed decision making, and to carry out our commitment to develop a quality reporting program for hospices that uses standardized methods to collect data needed to calculate quality measures, we finalized the HIS effective July 1, 2014 (78 FR 48258). To meet the quality reporting requirements for hospices for the FY 2016 payment determination and each subsequent year, we require regular and ongoing

electronic submission of the HIS data for each patient admission to hospice after July 1, 2014, regardless of payer or patient age (78 FR 48234 through 48258). We finalized a requirement in the FY 2014 Hospice Wage Index final rule (78 FR 48258) that hospice providers collect data on all patients to ensure that all patients regardless of payer or patient age are receiving the same care and that provider metrics measure performance across the spectrum of patients.

Hospices are required to complete and submit a HIS-Admission and a HIS-Discharge record for each patient admission. Hospices failing to report quality data via the HIS for patient admissions occurring in 2016 will have their market basket update reduced by 2 percentage points in FY 2018 (beginning in October 1, 2017). In the FY 2015 Hospice Wage Index final rule (79 FR 50485 through 50487), we finalized the proposal to codify the HIS submission requirement at § 418.312. The System of Record (SOR) Notice titled ''Hospice Item Set (HIS) System,'' SOR number 09–70–0548, was published in the **Federal Register** on April 8, 2014 (79 FR 19341).

TABLE 15—PREVIOUSLY FINALIZED QUALITY MEASURES AFFECTING THE FY 2017 PAYMENT DETERMINATION AND SUBSEQUENT YEAR

Quality measure	NQF ID#	Type	Submission method	Data submission deadlines
Treatment Preferences	1641	Process Measure	Hospice Item Set	Within 30 days of patient admission or discharge (Event Date).
Beliefs/Values Addressed	1647			
Pain Screening	1634			
Pain Assessment	1637			
Dyspnea Screening	1639			
Dyspnea Treatment	1638			
Patients Treated with an Opioid who are Given a Bowel Regimen.	1617			

Comment: CMS received a comment regarding the retirement of the seven day length of stay (LOS) exclusion for six of the care process measures currently implemented in the HQRP. This commenter expressed concern that in eliminating the LOS exclusion, provider behavior may shift towards focusing on completing the HIS requirements and compliance at the expense of addressing the needs and preferences of imminently dying patients. Additionally, this commenter recommended that CMS reconsider eliminating the LOS exclusion or risk adjust for hospices with an excessive number of short-stay patients for patients.

Response: We appreciate the commenters' input on the retirement of the LOS exclusion specification for six of the quality measures currently implemented in the HQRP. Developing and adopting measures that are meaningful and do not lead to negative unintended consequences for patients or providers is important to us. At the time the measures were developed, technical experts recommended that short patient stays be excluded from those measures' denominators for assessing quality of care in hospices. However, no national data regarding the implications of the LOS exclusion was available to the Technical Expert Panel (TEP) at that time. CMS's contractor analyzed data from the HIS to examine the implications of the LOS exclusion on hospices' denominator size and quality measure (QM) scores. Additionally, this analysis examined the timing of when hospices perform the care processes assessed in the quality measures. These analyses were conducted using HIS-Admission and HIS-Discharge records for stays in July 1, 2014 through March 31, 2015. The results of these analyses demonstrated that the denominator sizes for the HQRP QMs are largely impacted by the current 7-day LOS exclusion used to calculate the QMs. Excluding stays with LOS less than 7 days prevents some hospices from being included in QM score calculations because they do not have any qualifying patient stays. Therefore, removing the LOS exclusion criteria will increase the number of patients included in the measures, and thus the number of hospices that are included in the QM calculation. The impact of the LOS exclusions on the distribution of hospices' scores is generally small for all of the QMs. In addition, these analyses revealed that the care processes targeted by the QMs are performed on the day of, or within one day of, admission for the vast majority of patient stays. For example, among patient admissions for which a pain screening was administered, approximately 92 percent of screenings occurred on the day of admission and close to 99 percent occurred within 1 day of admission. This suggested that including stays of less than 7 days in QM calculations (that is, removing the QM LOS exclusion) could be appropriate and would not create a burden on hospices. In response to these results, the individual QMs were submitted by the measures' stewards to the NQF Palliative Care and End of Life Project for re-endorsement in February 2016 and received preliminary approval. In sum, 6 of the 7 current HIS measures that were adopted in the FY 2014 Hospice Wage Index final rule excluded beneficiaries with a LOS of <7 days from the denominator. However, since these measures were adopted in the HQRP, they have undergone their endorsement maintenance with the NQF. As part of the maintenance endorsement, the LOS exclusion for the 6 HIS measures was proposed for removal. NQF has indicated initial support for the removal of the LOS exclusion, and pending NQF maintenance endorsement of the previously adopted measures, we anticipate that the entire set of the 7 HIS measures will no longer exclude any patients with LOS <7 days in future public reporting and use in the HQRP. We appreciate the commenters' recommendation to risk adjust these measures and will consider this recommendation for future measure development efforts.

Comment: CMS received one comment requesting additional items or response options on the HIS V1.00.0 to capture instances where data regarding preferences or other care processes captured on the HIS are not available for non-verbal patients admitted to hospice who do not have a formal caregiver or responsible party available.

Response: We thank the commenter for their comment. For additional information on how to respond to current HIS items when the patient is nonverbal and/or a caregiver is unavailable, we refer readers to the HIS Manual V1.02 available on the Hospice

Item Set portion of the CMS HQRP Web site: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Hospice-Item-Set-HIS.html.* Specifically, we refer readers to the HIS Manual Section F Item-Specific Tips, which specifies roles of responsible parties for patients unable to self-report. The HIS Manual states that the ''Responsible party'' refers to the legally responsible or authorized individual, such as the Health Care Power of Attorney or legal guardian. In the rare cases where there is no legal guardian or power of attorney identified, the hospice should use state law guidance to identify the appropriate surrogate decision-maker. Other items that require patient or caregiver input, such as the pain assessment items, can be completed for nonverbal patients using the nonverbal assessment processes described in the HIS Manual.

5. Proposed Removal of Previously Adopted Measures

As mentioned in section III.C.3, a measure that is adopted and implemented in the HQRP will be adopted for all subsequent years, unless the measure is proposed for removal, suspension, or replacement by CMS. Policies and criteria for removing a measure include those mentioned in section III.C.3 of this proposed rule. CMS is not proposing to remove any of the current HQRP measures at this time. Any future proposals regarding removal, suspension, or replacement of measures will be proposed in this section of future rules.

6. Proposed New Quality Measures for FY 2019 Payment Determinations and Subsequent Years and Concepts Under Consideration for Future Years

a. Background and Considerations in Developing New Quality Measures for the HQRP

As noted in section III.C.2 of this proposed rule, CMS's paramount concern is to develop quality measures that promote care that is person-centered, high quality, and safe. In identifying priority areas for future measure enhancement and development, CMS takes into consideration input from numerous stakeholders, including the MAP, the MedPAC, Technical Expert Panels (TEP), and national priorities, such as those established by the National Priorities Partnership, the HHS Strategic Plan, the National Strategy for Quality Improvement in Healthcare, and the CMS Quality Strategy. In addition, CMS takes into consideration vital feedback and input from research published by our payment reform contractor, as well as important observations and recommendations contained in the Institute of Medicine (IOM) report, titled ''Dying in America,'' released in September 2014.[6] Finally, the current HQRP measure set is also an important consideration for future measure development areas; future measure development areas should complement the current HQRP measure set, which includes HIS measures and Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Hospice Survey measures.

As stated in the FY 2016 Hospice Wage Index final rule (80 FR 47188), based on input from stakeholders, CMS identified several high priority areas for future measure development, including: A patient reported pain outcome measure; claims-based measures focused on care practices patterns, including skilled visits in the last days of life; responsiveness of the hospice to patient and family care needs; and hospice team communication and care coordination. Of the aforementioned measure areas, CMS has pursued measure development for two quality measures: Hospice Visits when Death is Imminent Measure Pair, and Hospice and Palliative Care Composite Process Measure-Comprehensive Assessment at Admission. These measures were included in CMS' List of Measures under Consideration (MUC) list for 2015 and discussed at the MAP meeting on December 14 and 15, 2015. All materials related to the MUC list and the MAP's recommendations for each measure can be found on the National Quality Forum Web site, MAP Post-Acute Care/Long-Term Care Workgroup Web page at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75370.* The MAP supported the direction of each proposed measure.

Comment: Many comments were received about the HQRP quality measures and concepts under consideration for future years. Overall, commenters were supportive of CMS's efforts to develop a more robust quality reporting program that includes development of two new quality measures, the Hospice Visits when Death is Imminent Measure Pair, and Hospice and Palliative Care Composite Process Measure-Comprehensive Assessment at Admission. In addition to the two measures we proposed, regarding measure development in future years, commenters urged CMS to focus on meaningful quality measures and encouraged CMS to move towards the development of outcome measures. Several commenters noted the complexities associated with developing outcomes measures. These commenters also recommended that CMS conduct regular measure testing activities to ensure that all measures currently implemented in the HQRP are relevant and meaningful to providers and consumers. Finally, some commenters recommended the development of future measures of hospice live discharge rates. Commenters believe that such measures could contribute to quality information and hospice performance.

Response: We appreciate the commenters' input and recommendations for future measure development areas for the HQRP. We plan to continue developing the HQRP to respond to the measure gaps identified by the MAP and others, and align measure development with the National Quality Strategy and the CMS Quality Strategy. We will take these comments into consideration in developing and implementing measures for future inclusion in the HQRP. We would like to assure commenters that we are pursuing opportunities related to the development of live-discharge measures through environmental scans, public engagement, and participation in special topic panels. We would also like to assure commenters that for all measures implemented in the HQRP, we regularly conduct measure testing activities according to the Blueprint for the CMS Measures Management System Version 12.0 (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint-120.pdf*). This ensures that measures continue to demonstrate scientific acceptability (including reliability and validity) and meet the goals of the HQRP, which include distinguishing performance among hospices and contributing to better patient outcomes. If measure testing activities reveal that a measure meets one of the conditions for removal that is listed in the proposed rule (measure performance among hospices high and unvarying, performance or improvement in a measure does not result in better patient outcomes, etc.), the measure will be considered for removal from the HQRP to avoid unintended consequences and to ensure that providers' data collection efforts are meaningful and are contributing to quality of care. Finally, we would like to assure commenters that we continue to explore opportunities to pursue

[6] IOM (Institute of Medicine). 2014. Dying in America: Improving quality and honoring individual preferences near the end of life. Washington, DC: The National Academies Press.

hospice outcome measures, and we appreciate the commenters' support for such development efforts.

b. New Quality Measures for the FY 2019 Payment Determination and Subsequent Years

We proposed two new quality measures for the HRQP for the FY 2019 payment determination and subsequent years: Hospice Visits when Death is Imminent Measure Pair, and Hospice and Palliative Care Composite Process Measure-Comprehensive Assessment at Admission.

(1) Proposed Quality Measure 1: Hospice Visits When Death Is Imminent Measure Pair

Measure Background. This measure set addresses whether a hospice patient and their caregivers' needs were addressed by the hospice staff during the last days of life. This measure is specified as a set of 2 measures. Measure 1 assesses the percentage of patients receiving at least 1 visit from registered nurses, physicians, nurse practitioners, or physician assistants in the last 3 days of life. Measure 2 assesses the percentage of patients receiving at least 2 visits from medical social workers, chaplains or spiritual counselors, licensed practical nurses, or hospice aides in the last 7 days of life. Measure 1 addresses case management and clinical care, while Measure 2 gives providers the flexibility to provide individualized care that is in line with the patient, family, and caregiver's preferences and goals for care and contributing to the overall well-being of the individual and others important in their life.

Measure Importance. The last week of life is typically the period in the terminal illness trajectory with the highest symptom burden. Particularly during the last few days before death, patients experience myriad physical and emotional symptoms, necessitating close care and attention from the integrated hospice team. Hospice responsiveness during times of patient and caregiver need is an important aspect of care for hospice consumers. In addition, clinician visits to patients at the end of life have been demonstrated to be associated with improved outcomes such as decreased risk of hospitalization, emergency room visits, hospital deaths, decreased distress for caregivers, and higher satisfaction with care.

Several organizations and panels have identified care of the imminently dying patient as an important domain of palliative and hospice care and established guidelines and recommendations related to this high priority aspect of healthcare that affects a large number of people. The NQF 2006 report *A Framework for Preferred Practices for Palliative Care Quality*[7] and the NCP Clinical Practice Guidelines for Quality Palliative Care[8] recommend that signs and symptoms of impending death are recognized, communicated and educated, and care appropriate for the phase of illness is provided. The American College of Physicians Clinical Practice Guidelines[9] recommend that clinicians regularly assess pain, dyspnea, and depression for patients with serious illness at the end of life. These measures address this high priority area by assessing hospice staff visits to patients and caregivers during the final days of life when patients and caregivers typically experience higher symptom and caregiving burdens, and therefore a higher need for care.

Measure Impact. The literature shows that health care providers' practice is responsive to quality measuring and reporting.[10] CMS feels this research, while not specific to hospices, reasonably predicts the effect of measures on hospice provider behavior. Collecting information about hospice staff visits for measuring quality of care, in addition to the requirement of reporting visits from some disciplines on hospice claims, will encourage hospices to visit patients and caregivers and provide services that will address their care needs and improve quality of life during the patients' last days of life.

Performance Gap. The 2014 Abt Medicare Hospice Payment Reform Report indicated that 28.9 percent of Routine Home Care hospice patients did not receive a skilled visit on the last day of life.[11] The Report defines a 'skilled visit' as a visit from a nurse, social worker, or therapist. This percentage could be, in part, a result of rapid decline and unexpected death. The report revealed variation in receipt of visits at the end of life related to multiple factors. Patients who died on a weekday rather than a weekend, patients with a very short length of stay (5 days or less), and patients aged 84 and younger were more likely to receive a skilled visit in the last 2 days of life. Smaller hospices and hospices in operation for 5 years or less were slightly less likely to provide a visit at the end of life. States with the lowest rates of no visits in the last days of life were some of the more rural states (ND, WI, TN, KS, VT), whereas states with the highest rates of no visits were more urban (NJ, MA, OR, WA, MN).

Existing Measures. This quality measure set will fill a gap by addressing hospice care provided at the end of life. No current HQRP measures address care beyond the hospice initial and comprehensive assessment period, nor do any current HQRP measures relate to the assessment of hospice staff visits to patients and caregivers in the last week of life.

Stakeholder Support. A TEP convened by our measure development contractor, RTI International, on May 7 and 8, 2015, provided input on the measure concept. The TEP agreed that hospice visits when death is imminent is an important concept to measure and supported data collection using the HIS. A second TEP was convened October 19 and 21, 2015, to provide input on the technical specifications of this quality measure pair. The TEP supported development of a measure set rather than a single measure, using different timeframes to measure the different types of care provided, and limiting the measures to patients receiving routine home care. The NQF MAP met on December 14 and 15, 2015, and provided input to CMS. The MAP encouraged continued development of the Hospice Visits when Death is Imminent Measure Pair in the HQRP. More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75370.* While this measure is not currently NQF endorsed, we recognize that the NQF endorsement process is an important part of measure development and plan to submit this measure pair for NQF endorsement.

Form, Manner, and Timing of Data Collection and Submission. Data for this measure would be collected via the existing data collection mechanism, the HIS. CMS has proposed that 4 new items be added to the HIS-Discharge record to collect the necessary data elements for this measure. CMS expects that data collection for this quality

[7] National Quality Forum. *A National Framework and Preferred Practices for Palliative and Hospice Care Quality.* 2006; Available from: *http://www.qualityforum.org/publications/2006/12/A_National_Framework_and_Preferred_Practices_for_Palliative_and_Hospice_Care_Quality.aspx.*

[8] National Consensus Project, *Clinical Practice Guidelines for Quality Palliative Care. 3rd edition.* 2013, National Consensus Project: Pittsburgh, PA.

[9] Qaseem, A., et al., *Evidence-Based Interventions to Improve the Palliative Care of Pain, Dyspnea, and Depression at the End of Life: A Clinical Practice Guideline from the American College of Physicians.* Annals of Internal Medicine, 2008. 148(2): p. 141–146.

[10] Werner, R., E. Stuart, and D. Polsky, *Public reporting drove quality gains at nursing homes.* Health Affairs, 2010. 29(9): p. 1706–1713.

[11] Plotzke, M., et al., *Medicare Hospice Payment Reform: Analyses to Support Payment Reform.* May 2014, Abt Associates Inc. Prepared for Centers for Medicare and Medicaid Services: Cambridge, MA.

measure via the 4 new HIS items would begin no earlier than April 1, 2017. Thus, under current CMS timelines, hospice providers would begin data collection for this measure for patient admissions and discharges occurring after April 1, 2017. Prior to the release of the new HIS data items, CMS will provide education and training to hospice providers to ensure all providers have adequate information and guidance to collect and submit data on this measure to CMS.

Since the data collection mechanism is the HIS, providers would collect and submit data using the same processes that are outlined in sections III.C.7c through III.C.7e of this rule. In brief, processes in section III.C.7c through III.C.7e specify that data for the measure would be submitted to the Quality Improvement and Evaluation System (QIES) Assessment Submission and Processing (ASAP) system, in compliance with the timeliness criterion and threshold set out in sections III.C.7c through III.C.7e.

For more information on the specifications and data elements for the measure set, Hospice Visits when Death is Imminent, we refer readers to the HQRP Specifications for the Hospice Item Set-based Quality Measures document, available on the ''Current Measures'' portion of the CMS HQRP Web site: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Current-Measures.html.* In addition, to facilitate the reporting of HIS data as it relates to the implementation of the new measure, we submitted a request for approval to OMB for the Hospice Item Set version 2.00.0 under the Paperwork Reduction Act (PRA) process. The new HIS data items that would collect this measure data are also available for public viewing in the PRA package available at: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

We received multiple comments pertaining to the Hospice Visits when Death is Imminent Measure Pair. The following is a summary of the comments we received on this topic and our responses:

Comment: We received many comments in support of our proposal to implement the Hospice Visits when Death is Imminent Measure Pair. Commenters emphasized the importance of visits at the end of life, and stated that this measure pair would provide a valuable measure of quality. Commenters also stated that they expect this measure will improve quality of life during patients' final days and that this measure could be useful to patients, families, and the Medicare program. One commenter said that hospice nurses are often aware when death is imminent because they are skilled at recognizing the final stages of a terminal condition, and that most individuals and families are aided and reassured by visits from some disciplines at the end of life.

Response: We thank the commenters for their support of the Hospice Visits when Death is Imminent Measure Pair in the HQRP. We agree that visits at the end of life are an important component of hospice care and that this measure can help to drive holistic, patient centered quality improvement. We believe that this information will be useful to consumers, providers, and payers.

Comment: Some commenters questioned whether the Hospice Visits when Death is Imminent Measure Pair would foster better quality for hospice care patients and requested evidence-based research showing the link between hospice visits and quality. One commenter emphasized the important role that hospices play in helping prepare patients and caregivers for the end of life, and stated that if hospices provide high quality preparation, then patients and families may need fewer visits at the end of life. The commenter stated that a focus on visits at the end of life may take focus away from empowering patients and caregivers. One commenter stated that, as a process measure, this measure pair does not adequately reflect high quality care, and urged CMS to conduct further testing of the measure. One commenter cautioned that, while sociodemographic differences in receipt of visits may appear to indicate differences in quality, one must also take into consideration possible differences in religious beliefs and cultural values that may affect desire for visits. One commenter noted that these measures alone might not be representative of the quality of care that hospice beneficiaries and their families receive.

Response: We thank the commenters for their feedback. We are committed to the ensuring that all quality measures implemented in the HQRP meet the goals of the program, which include distinguishing performance among hospices and contributing to better patient outcomes.

We believe that provision of hospice visits at the end of life is an important component of high quality hospice care for most patients. The last week of life is typically the period in the terminal illness trajectory with the highest symptom burden and the literature supports hospice visits when death is imminent as a high priority in end-of-life care. Clinician visits to patients at the end of life have been demonstrated to be associated with improved outcomes such as decreased risk of hospitalization, emergency room visits, and hospital death; and higher satisfaction with care.[12] [13] [14] Measurements of visits at the end of life are already used in the literature as quality indicators for end of life or hospice care.[15] [16] [17] Studies focusing on the expectations of patients and families also demonstrate the importance of care and attention from the hospice team in the days leading up to death. Caregivers of dying patients agree overwhelmingly with the importance of preparation at the end of life. Hospice assistance, ranging from legal to logistical to emotional, is paramount in preparing hospice patients and their families for imminent death.[18] Bereaved family members and friends from a variety of settings identified the provision of physical comfort and emotional support to dying patients and their families as fundamental aspects of high-quality care.[19]

The literature shows that health care providers' practices are responsive to

[12] Seow, H., Barbera, L., Howell, D., & Dy, S. M. (2010). Using more end-of-life homecare services is associated with using fewer acute care services: a population-based cohort study. *Med Care, 48*(2), 118–124. doi:10.1097/MLR.0b013e3181c162ef.

[13] Almaawiy, U., Pond, G. R., Sussman, J., Brazil, K., & Seow, H. (2014). Are family physician visits and continuity of care associated with acute care use at end-of-life? A population-based cohort study of homecare cancer patients. *Palliat Med, 28*(2), 176–183. doi:10.1177/0269216313493125.

[14] Pivodic, L., Harding, R., Calanzani, N., McCrone, P., Hall, S., Deliens, L. & Gomes, B. (2015). Home care by general practitioners for cancer patients in the last 3 months of life: An epidemiological study of quality and associated factors. *Palliat Med.* doi:10.1177/0269216315589213.

[15] Barbera, L., Seow, H., Sutradhar, R., Chu, A., Burge, F., Fassbender, K., . . . Potapov, A. (2015). Quality Indicators of End-of-Life Care in Patients With Cancer: What Rate Is Right? *J Oncol Pract, 11*(3), e279–287. doi:10.1200/jop.2015.004416.

[16] Gandhi, S. O. (2012). Differences between non-profit and for-profit hospices: patient selection and quality. *Int J Health Care Finance Econ, 12*(2), 107–127. doi:10.1007/s10754–012–9109-y.

[17] Lorenz, K. A., Ettner, S. L., Rosenfeld, K. E., Carlisle, D. M., Leake, B., & Asch, S. M. (2002). Cash and compassion: profit status and the delivery of hospice services. *J Palliat Med, 5*(4), 507–514. doi:10.1089/109662102760269742.

[18] Steinhauser, K. E., Christakis, N. A., Clipp, E. C., McNeilly, M., McIntyre, L., & Tulsky, J. A. (2000). Factors considered important at the end of life by patients, family, physicians, and other care providers. *Jama, 284*(19), 2476–2482.

[19] Steinhauser, K. E., Christakis, N. A., Clipp, E. C., McNeilly, M., McIntyre, L., & Tulsky, J. A. (2000). Factors considered important at the end of life by patients, family, physicians, and other care providers. *Jama, 284*(19), 2476–2482.

quality measurement and reporting.[20] We believe that this research, while not specific to hospices, reasonably predicts the effect of measures on hospice provider behavior. Collecting information about hospice staff visits for measuring quality of care, in addition to the requirement of reporting visits from some disciplines on hospice claims, will encourage hospices to visit patients and caregivers and provide services that will address their care needs and improve quality of life during the patients' last days of life. While we agree that a greater number of visits does not always indicate higher quality care, based on the published literature and expert input, we believe that most patients benefit from some visits near the end of life. For this reason, this measure set is specified to measure receipt of at least 1 clinician visit (Measure 1) and at least 2 visits from other staff (Measure 2), rather than measuring the total number of visits. A TEP held in October 19 and 21, 2015, by our contractor agreed that a measure of patients receiving at least a minimum number of visits would be a better indicator of quality than a measure of the total number of visits provided.

We agree with the commenter that this measure pair alone may not provide a full representation of the quality of care that hospices provide. The previously finalized measures in the HQRP address care processes at admission, and the Hospice CAHPS survey examines caregiver experience retrospectively. This measure pair fills an important gap in the HQRP by providing a measure of quality of care provided near the time of death, and it is intended to be interpreted along with the other measures in the HQRP to reflect quality of care provided by hospices across several domains of care that are important to patients and other stakeholders. CMS also plans to analyze the relationship between this quality measure pair and other quality measures to support the validity of this measure pair (that is, the measure reflects true quality of care).

Comment: One commenter expressed concern that the results of the Hospice Visits when Death is Imminent Measure Pair may be mischaracterized once they are publicly reported, if appropriate disclaimers are absent from the information provided. Another commenter requested that CMS remind measure users that patients/families have the right to decline services and that those declinations should not be considered an ''under-service'' by the hospice provider.

Response: We thank the commenters for their feedback regarding interpreting these measures. We agree that it is important to educate both providers and consumers on how to use and interpret these quality measures. Prior to public reporting of this measure, we will provide resources through the Hospice Compare Web site to aid consumers in interpreting the quality metrics reported there. CMS has carefully considered usability by consumers throughout the measure development process. The measure specifications take into account usability feedback from a TEP, caregiver workgroup, and clinical user panel. We recognize that some patients may decline services and that rapid and unanticipated patient declines do occur; thus, a score of 100% is not the expectation for this measure pair.

Comment: Some commenters stated that it is not always known when a patient's death is imminent. One commenter stated that there is not always an opportunity for hospices to provide the visits specified in this measure set if a patient experiences a rapid and unanticipated decline.

Response: We understand that it is not always possible to accurately predict time of death. However, the last week of life is typically the period in the terminal illness trajectory with the highest symptom burden, especially during the last few days before death. We recognize that rapid and unanticipated patient declines do occur; thus, a score of 100 percent is not the expectation for this measure pair. We do expect that hospices delivering high quality care will be responsive to the patient and caregiver needs that arise during the last days of a patient's life. In order to address performance gaps in this measure, providers may be motivated to proactively assess symptom burden, resulting in improved symptom management and higher quality of life during the final days.

Comment: We received some comments related to the structure of the Hospice Visits when Death is Imminent Measure Pair and intent of each measure. Some comments indicated that commenters might have misinterpreted the intent of this measure pair. For example, one commenter stated that adoption of this measure pair would in fact create three visit metrics, and another commenter referenced the calculation of a composite measure for visits at the end of life. Some commenters interpreted the specifications as not including visits addressing spiritual or psychosocial suffering in the 3 days before death.

Some commenters requested clarification of the calculation of each of these measures and of the disciplines included in each. One commenter recommended that Measure 1 and Measure 2 be combined into one measure in order to streamline data collection. One commenter requested that RN visits be included in both Measure 1 and Measure 2 since some interventions to manage symptoms may only be provided by an RN.

Response: We wish to clarify the intent of this measure pair. The Hospice Visits when Death is Imminent Measure Pair will be calculated and reported as two separate measures. These measures are intended to be interpreted as a set. For more information on the specifications and data elements for the measure set, Hospice Visits when Death is Imminent Measure Pair, we refer readers to the HQRP Specifications for the Hospice Item Set-based Quality Measures document, available on the ''Current Measures'' portion of the CMS HQRP Web site: *https://www.cms.gov/Medicare/Quality-Initiatives-PatientAssessment-Instruments/HospiceQuality-Reporting/CurrentMeasures.html.*

The two measures are intended to capture distinct aspects of hospice care at the end of life. The inclusion of registered nurses, physicians, nurse practitioners, and physician assistants in Measure 1 is intended to capture the range of clinical disciplines that might visit a patient, depending on patient and hospice preferences, and uses a 3-day timeframe to reflect the active dying phase. The inclusion of medical social workers, chaplains or spiritual counselors, licensed practical nurses, and hospice aides in Measure 2 is intended to allow for flexible and individualized care in line with patient, family, and caregiver preferences. The 7-day time frame covers both the active dying phase and the transition period before, and thus could also capture important visits related to preparation for active dying. To clarify, the 7-day time frame is inclusive of the 3 days prior to death. Data collection is conducted at the discipline level in order to provide us with sufficient information to conduct reliability and validity testing and possible future measure refinement.

Comment: We received some comments regarding the types of visits included in the Hospice Visits when Death is Imminent Measure Pair. Some commenters requested that all visits on the date of death be included in the measures, including postmortem visits, as this is an important service that hospices provide. One commenter

[20] Werner, R., E. Stuart, and D. Polsky, Public reporting drove quality gains at nursing homes. *Health Affairs*, 2010. 29(9): p. 1706–1713.

recommended that a new, separate measure could look at postmortem visits. Some commenters requested that phone calls or videoconferencing be included in the measures. One commenter stated that phone calls may be an especially important form of contact in rural areas. A few commenters requested clarification of the definition of a visit counted for quality purposes, and one inquired what visit duration is expected.

Response: We thank the commenters for their feedback regarding the types of visits included in this measure pair. We agree that post mortem and bereavement visits are an important service for hospices to provide. However, we believe that these services are outside the scope of this quality measure pair, which focusses specifically on visits when death is imminent. These visits provided shortly prior to death are intended to address the increased symptom burden many patients experience when death is imminent and provide an opportunity for proactive assessment and communication.

We recognize that some providers use phone calls to supplement care provided in person and that these calls can be helpful in facilitating ongoing care and communication. However, in agreement with a TEP and based on the available evidence, we consider these calls as a supplement to, and not a replacement for, in-person care, particularly when death is imminent. For this reason, phone calls are not included in the definition of a visit for this measure pair. Prior to implementation of the HIS V2.00.0, we will provide hospices with guidance and training materials, including an updated version of the HIS Manual. These training materials will further clarify the types of visits included in this measure pair and other item coding information.

Comment: We received many comments regarding the disciplines included in each of the Hospice Visits when Death is Imminent measures. One commenter stated that this measure pair recognizes the value of the core interdisciplinary team members and maintains a holistic approach to care. Many commenters supported the inclusion of chaplains or spiritual counselors and aides in Measure 2, as they play an important role in the interdisciplinary team. Some commenters encouraged CMS to conduct further research on the types of visits provided at the end of life and present a clear rationale for inclusion or exclusion from this measure. One commenter recommended that both measures be amended to include any member of the hospice's interdisciplinary team.

Many commenters requested that visits from volunteers be included in Measure 2. The commenters pointed out that the use of volunteers is a Medicare requirement for hospices, and that volunteers play an important role in the delivery of hospice care. One commenter indicated that it might be burdensome to report data on volunteer visits, but that inclusion of volunteers would be valuable. A couple of commenters requested that visits from music therapists or massage therapists be included in Measure 2.

Several commenters noted that although physician assistant (PA) visits are included in this quality measure pair, this discipline is not identified by CMS as a core or non-core service of a hospice provider. Some of these commenters requested that PA visits be removed from the measure in order to align with the Conditions of Participation and Medicare payment practices. Some of these commenters supported the inclusion of PAs and recommended that their role be clarified. One commenter stated that since the use of PAs is limited, inclusion of PA visits would negatively skew the data.

One commenter noted that a Licensed Practicing Nurse's (LPN) scope of practice varies from state to state, and asked that CMS consider removing LPN visits from the measure to make the measure more uniform nation-wide. One commenter expressed appreciation for the inclusion of LPNs and stated that the discipline is frequently used.

Some commenters requested that bereavement coordinator or bereavement counselor visits be included in this measure pair. One commenter requested clarification of whether a visit from a provider contracted but not employed by a hospice program would be considered a visit under this measure pair.

Response: We thank the commenters for their support of the disciplines included in this measure, including chaplains or spiritual counselors and aides. This measure pair is designed to allow hospices flexibility to determine the most appropriate discipline or disciplines to visit a patient. The inclusion of registered nurses, physicians, nurse practitioners, and physician assistants in Measure 1 is intended to capture the range of clinical disciplines that might visit a patient, depending on patient and family preferences and emerging care needs in the last days of life. Similarly, the inclusion of medical social workers, chaplains or spiritual counselors, licensed practical nurses, and hospice aides in Measure 2 is intended to allow for flexible and individualized care in line with patient, family, and caregiver preferences. This measure is not intended to require visits from any given discipline, but aims to allow flexibility in the types of visits provided. The Hospice Conditions of Participation state that the interdisciplinary group must include, but is not limited to, a doctor of medicine or osteopathy, a registered nurse, a social worker, and a pastoral or other counselor. Visits from all of these disciplines are included in this measure pair, as well as from some additional disciplines. We have carefully researched the topic of which disciplines to include in this measure pair, including an environmental scan, pilot test of this measure in summer 2015, TEP discussions on May 7 and 8, 2015, and October 19 and 21, 2015, and input from our Clinical Users Panel and Caregiver Workgroup.

Regarding volunteer visits, we agree that volunteers play an important role in high quality hospice care and that their visits are important to patients and families. Visits from volunteers were included in an early version of this measure, which pilot tested for feasibility in summer 2015. Many of the hospices included in the pilot had trouble reporting data on visits from volunteers because the records of volunteer visits were often stored in a separate system and were frequently delayed. The data was unreliable, and hospices reported significant reporting burden. This topic was discussed with the TEP, held October 19 and 21, 2015. After reviewing the results from the pilot test and thoroughly discussing the issues, the TEP members did not support including visits from volunteers in this measure pair. For the same reasons, the TEP advised against including complementary and alternative therapists such as music or massage therapists in this measure pair, though they do provide important services.

Regarding physician assistant visits, although Medicare does not provide separate payments for visits from physician assistants, these services would be covered under the hospice per diem. Additionally, this measure is an all-payer measure and some states and other programs may authorize physician assistants to provide hospice care under separate payments. This measure pair is separate from payment and should focus on services provided by hospices and not be restricted by the terms of payment by Medicare. Therefore, the inclusion of physician assistants in the

measure specifications provides the flexibility for hospices that may have physician assistants to count these clinical visits as part of Measure 1. We wish to clarify that the absence of physician assistant visits will not negatively skew the data reported in this measure. Visits from physician assistants are one of the options included in Measure 1, but patients will also be included in the numerator of the measure if they receive a visit from a registered nurse, physician, or nurse practitioner.

We thank the commenters for their feedback regarding the inclusion of LPNs in Measure 2. Members of our TEP agreed that LPNs provide an important service in hospice care that is distinct from the role of RNs. For this reason, we have included visits from LPNs in Measure 2 of this measure pair.

We appreciate the commenters' recommendations to include bereavement coordinators, and agree that visits from these disciplines are important for many patients and families. However, we believe that bereavement services are outside the scope of this quality measure pair, which focusses specifically on visits, which may address the increased symptom burden many patients experience when death is imminent, and provide an opportunity for proactive assessment and communication.

Regarding contracted hospice staff, we clarify that visits from contracted staff may be included in this measure pair. As defined in the HIS Manual V1.02, hospice staff members may include volunteers, contractors, and affiliates.

Comment: Some commenters recommended changes to the Hospice Visits when Death is Imminent Measure Pair to further align the two measures. A few commenters suggested that both Measure 1 and Measure 2 be measured over a 7-day timeframe in order to improve consistency between the measures and simplify data collection for providers. A few commenters recommended that CMS consider altering Measure 2 such that it includes in the numerator patients who receive one visit from medical social workers, chaplains or spiritual counselors, licensed practical nurses or hospice aides in the final seven days of life.

Response: We thank the commenters for their feedback on the specifications of the two measures in this measure pair. As currently specified, Measure 1 uses a 3-day timeframe and Measure 2 uses a 7-day timeframe. A TEP meeting held October 19 and 21, 2015, provided input on the timeframes. The TEP indicated that the 3-day timeframe would be reflective of the active dying phase, and that it would be appropriate to measure clinical visits provided during the active dying phase. The 7-day time frame covers both the active dying phase and the transition period before, and thus could also capture important visits related to preparation for active dying. An analysis of Medicare claims indicates that most routine home care patients (94 percent) receive at least one skilled visit from a nurse, social worker, therapist or physician in the last four days of life.[21] Because of this, there may be a ceiling effect for these quality measures using a longer time frame.

The current specification of Measure 2 limits the numerator to patients who receive at least two visits from those disciplines in the final 7 days of life. Using two visits rather than one may also serve to reduce the expected ceiling effect that is likely to result from grouping multiple disciplines together in Measure 2.

Comment: Many commenters pointed out that, in keeping with the individualized and patient-centered focus of hospice care, patients and families have the option of declining visits from hospice providers if they deem them unnecessary or unwanted. Commenters indicated that patients and caregivers might decline a visit for various reasons: Desire for privacy at the end of life, adequate preparation for the end of life such that additional visits are not necessary, or patient is receiving receipt of similar services from outside of the hospice provider. Some commenters recommended that revisions be made to the HIS Discharge form to allow a hospice to indicate that a patient or family was offered a visit included in either Measure 1 or Measure 2, but refused or deferred the visit. Some commenters recommended that patients who refuse an offered visit be included in the measure numerator, while others recommended that these patients be excluded from the measure pair, and a few recommended that the measures be risk adjusted to reflect patient refusal of services.

Some commenters cautioned that this measure pair could result in an unintended consequence: Hospices might provide unnecessary or unwanted visits, thus undermining patient and family preferences and choice. One commenter cautioned that specifying when particular staff must visit would undermine the flexibility hospices have in customizing the plan of care. Some commenters pointed out that, by respecting the wishes of some patients to receive fewer visits, a hospice might have lower scores on this measure pair but that it would not reflect an issue with quality of care.

Response: We thank the commenter for their feedback about patients and families that may refuse a visit at the end of life. In a pilot study conducted by our measure development contractor, hospices reported that information on visit refusal is available, but is burdensome for hospices to report. In addition, fewer than 4 percent of patients in the pilot study refused a visit from a given discipline, and no patients refused all visits offered. By including multiple disciplines in each measure, the Hospice Visits when Death is Imminent Measure Pair is designed to allow hospices flexibility to determine the most appropriate discipline or disciplines to visit a patient, and to consider patient and family preferences. A TEP held by our measure development contractor did not expect that there would be wide variation in the rate of visit refusal across hospices. The TEP determined that the burden of data collection would outweigh the benefit of excluding patients who refuse visits. For these reasons, we determined not to require hospices to report data on visit refusals. Hospices may wish to track visit refusals internally for quality improvement purposes. This measure pair will be tested for reliability and validity prior to public reporting. We recognize that some patients may decline services and that rapid and unanticipated patient declines do occur; thus, the expectation is not for hospices to score 100 percent on this measure pair. We will take these comments into account during future measure development.

Comment: Some commenters recommended using risk adjustment or exclusions to account for patient characteristics in the Hospice Visits when Death is Imminent Measure Pair. Some commenters stated that patients with shorter lengths of stay will likely receive different visits than patients with longer lengths of stay. Commenters requested that CMS examine any differences, and some requested that the Hospice Visits when Death is Imminent Measure Pair be risk adjusted or stratified for length of stay in hospice. Another commenter requested that case mix adjustment be used in the calculation of this measure pair.

[21] Plotzke, M. C., T.J.; Axelrod, Elizabeth; Hunt, Meaghan; Muma, Allison; Gozalo, Pedro; Teno, Joan. (2015). *Medicare Hospice Payment Reform: Analysis of How the Medicare Hospice Benefit is Used.* Retrieved from *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Downloads/December-2015-Technical-Report.pdf.*

One commenter recommended that patients with a length of stay shorter than 5 days be excluded from Measure 2. This is the length of time allowed by Hospice Conditions of Participation requirements for the comprehensive assessments to be completed, and the commenter expects that some patients might not receive two visits from a medical social worker, chaplain or spiritual counselor, licensed practical nurse, or hospice aide before Day 5. Another commenter recommended that patients with a length of stay of three days or fewer be excluded from Measure 1 if the only visit received is the initial nursing assessment. The commenter expressed concern that for such short lengths of stay, the measure would function as an indicator of compliance rather than of quality.

Finally, one commenter requested clarification of whether this measure pair would be applied across all levels of care.

Response: We thank the commenters for their feedback. As currently specified, this measure set is not risk adjusted. A TEP convened by our measure development contractor discussed possible risk adjustment of this measure pair, including risk adjustment by diagnosis or length of stay. The TEP determined that diagnosis may not reliably predict symptom burden at the end of life and therefore may not reliably predict need for visits. The TEP members determined that it might be important to take length of stay into account in measure calculations. We will continue to consider this feedback, and will examine measure performance, including the potential need for risk adjustment in the future.

As currently specified, Measure 1 does not include a length of stay exclusion, while Measure 2 excludes patients with a length of stay less than or equal to one day (that is, admitted and discharged on the same day). The rationale for excluding patients with a very short length of stay from Measure 2 is that Measure 2 requires two visits from select hospice staff, and it may be difficult or possibly inappropriate to provide more than one such visit for patients receiving only one day of hospice care. We do not exclude these patients from Measure 1 because Measure 1 specifies at least one clinician visit, and it is reasonable to expect that a hospice would provide at least one such visit, even for patients with a very short length of stay. It is acceptable if this visit is the initial nursing assessment visit. One of the goals of this measure pair is to increase prospective assessment of patient needs and timely management of symptoms prior to death, and this can be accomplished during the initial nursing assessment visit as well as other types of visits provided in the final days to patients with longer length of stay. We do not intend to increase burden on providers or patients by requiring specific types of visits to meet the goals of this measure. Patients with short lengths of stay are expected to have high symptom burden throughout their short stay and can benefit from hospice visits. For these reasons, patients with short lengths of stay are included in this measure.

This measure pair currently includes only patients who received routine home care. It does not include patients who received general inpatient care, respite care, or continuous home care during the measure timeframes. Routine home care patients for whom the hospice receives a service intensity add-on payment are included in this measure, as this payment is an add-on to the routine home care rate.

Comment: Some commenters encouraged CMS to obtain NQF endorsement prior to proposing new measures. One commenter expressed appreciation that this measure development process has included input from the Measure Applications Partnership (MAP).

Response: We appreciate the commenters' input and support of the NQF endorsement process. Our paramount concern is the successful development of a HQRP that promotes the delivery of high quality healthcare services. We seek to adopt measures for the HQRP that promote patient-centered and high quality care. Our measure selection activities for the HQRP take into consideration input from the MAP, convened by the NQF, as part of the established CMS pre-rulemaking process required under section 1890A of the Act. The NQF MAP met on December 14th and 15th, 2015 and encouraged continued development of this measure pair. Additionally, while this measure is not currently NQF-endorsed, we recognize that the NQF endorsement process is an important part of measure development and plan to submit this measure for NQF endorsement. This quality measure will fill a gap by addressing quality of hospice care at the end of life. Furthermore, no current NQF-endorsed measures address hospice care when death is imminent, and this measure is a first step towards that goal. CMS is establishing the timeline for seeking NQF endorsement for this quality measure and will communicate this timeline to the public in future rulemaking cycles.

Comment: One commenter asked whether CMS would correlate the Hospice Visits when Death is Imminent Measure Pair with the Hospice CAHPS results. Another commenter recommended that CMS compare outcomes as measured by the HIS care processes and the CAHPS survey with the data collected on visits at the end of life to guide refinement of this measure pair.

Response: We plan to conduct reliability and validity testing of this measure pair as part of ongoing measure maintenance and refinement and to prepare for NQF endorsement. As part of those efforts, we will examine the correlations of the paired measures with other quality measures calculated from the HIS and possibly from the CAHPS.

Comment: Some commenters indicated that data collection for the Hospice Visits when Death is Imminent Measure Pair would be burdensome for providers, and potentially duplicative of the information about visits reported in Medicare claims. One commenter requested that claims data be used to calculate this measure pair in order to reduce provider burden of data collection. Another commenter encouraged CMS to establish a claims code for spiritual counselor/chaplain visits so that their visits can be reviewed for reimbursement and quality considerations. One commenter indicated that this measure pair would be calculated using claims data.

Response: We wish to clarify the data source for this measure pair. This measure will be calculated using data from the HIS V2.00.0, and will not be a claims-based measure. This HIS-based measure pair will expand upon information that would be available in Medicare hospice claims. The HIS includes data for all hospice patients, regardless of payment source, while claims data capture only Medicare Fee-for-service beneficiaries. Therefore, the use of assessment data allows the measure to be inclusive of all patients regardless of payer. Medicare claims capture visits from certain disciplines, including skilled nursing, medical social services, aides, physical therapy, occupational therapy, and speech therapy—language pathology. HIS items will capture hospice visits by members of additional disciplines that are not included in the Medicare hospice claims (for example, chaplains). Finally, visit information on the HIS can be assessed and reported in a timelier manner than Medicare claims, providing hospices with opportunities to review and improve care.

Comment: Some commenters requested that sufficient time be given

prior to measure implementation of the Hospice Visits when Death is Imminent Measure Pair to ensure time for software vendors to develop new processes, and hospices to upgrade their EMR systems, train staff, and conduct testing. One commenter recommended that CMS delay initiation of data collection for this measure pair until October 1, 2016. One commenter encouraged CMS to solicit feedback from the hospice industry and software vendors to determine whether necessary updates can be made by April 1, 2017. Other commenters recommended a period of data collection on the proposed measures prior to implementation of the measures.

Response: We appreciate the commenters' feedback regarding the timeline for implementation and public reporting of this measure pair. We would like to clarify the implementation date proposed in this rule; data used for calculation of this measure pair will be collected via the HIS V2.00.0. The HIS V2.00.0 is undergoing review as part of a PRA package under OMB number 0938–1153 and will be implemented April 1, 2017. This measure pair is proposed for the FY 2019 payment determination and subsequent years. The HIS V2.00.0 is currently available for review by software vendors and hospice providers. Some of the activities that are necessary prior to implementation can be done concurrently. For example, hospice education and training in the new items and data abstraction can be conducted at the same time as vendor development of software. As stated in section III.C.7.c, providers may also use the Hospice Abstraction Reporting Tool (HART) software, which is free to download and use. HART provides an alternative option for hospice providers to collect and maintain facility, patient, and HIS Record information for subsequent submission to the QIES ASAP system. We agree it is critical to establish the reliability and validity of the quality measures prior to public reporting. We plan to conduct data analysis to demonstrate the ability of the quality measures to distinguish the quality of services provided. More detail on public display is provided in section III.C.11 of this rule.

Comment: Some commenters drew connections between the Hospice Visits when Death is Imminent Measure Pair and the Service Intensity Add-on payment. Some commenters recommended delaying implementation of this measure pair until the impact of the SIA payment is better understood. One commenter recommended that CMS use the data obtained for Measure 2 to update the payment of the SIA payment to include visits by licensed practical nurses and other disciplines. One commenter stated that CMS should align financial payment and quality measures.

Response: We thank the commenters for their feedback regarding the Hospice Visits when Death is Imminent Measure Pair and the SIA. CMS adopted SIA payments to address the observed misalignment between resource use and associated Medicare payments and to improve patient care through the promotion of skilled visits at end of life with minimal claims processing systems changes. While it may be good for payment and quality to align when possible, this measure pair is a measure of quality, not of practice driven by reimbursement structure. We will take into consideration using measure data for further refinement of the SIA.

Final Action: After consideration of the comments, we are finalizing our proposal to implement the Hospice Visits when Death is Imminent Measure Pair effective April 1, 2017. Data will be collected starting on such date, and will, if not reported, affect payments for FY 2019.

(2) Proposed Quality Measure 2: Hospice and Palliative Care Composite Process Measure—Comprehensive Assessment at Admission

Measure Background. The Hospice and Palliative Care Composite Process Measure—Comprehensive Assessment at Admission is a composite measure that assesses whether a comprehensive patient assessment is completed at hospice admission by evaluating the number of individual care processes completed upon admission for each hospice patient stay. A composite measure, as defined by the NQF, is a combination of two or more component measures, each of which individually reflects quality of care, fashioned into a single performance measure with a single score.[22] For more information on composite measure definitions, guiding principles, and measure evaluation criteria, we refer readers to the NQF Composite Performance Measure Evaluation Guidance Publication available at *https://www.qualityforum.org/Publications/2013/04/Composite_Performance_Measure_Evaluation_Guidance.aspx.* A total of 7 individual care processes will be captured in this composite measure, which include the 6 NQF-endorsed quality measures and 1 modified NQF-endorsed quality measure currently implemented in the HQRP. Thus, the Hospice and Palliative Care Composite Process quality measure will use the current HQRP quality measures as its components. These individual component measures address care processes around hospice admission that are clinically recommended or required in the hospice CoPs.[23] This measure calculates the percentage of patients who received all care processes at admission. To calculate this measure, the individual components of the composite measure are assessed separately for each patient and then aggregated into one score for each hospice.

Measure Importance. This composite quality measure for comprehensive assessment at admission addresses high priority aspects of quality hospice care as identified by both leading hospice stakeholders and beneficiaries receiving hospice services. The NCP for Quality Palliative Care Clinical Practice Guidelines for Quality Palliative Care established 8 core palliative care domains, and this composite measure captures 4 of those domains.[24] The 4 domains captured by this composite measure are the Structure and Process of Care Domain; the Physical Aspects of Care Domain; the Spiritual, Religious, and Existential Aspects of Care Domain, and the Ethical and Legal Aspects of Care Domain. The NCP guidelines placed equal weight on both the physical and psychosocial domains, emphasizing a comprehensive approach to patient care. For more information on the NCP domains for palliative care, refer to *http://www.nationalconsensusproject.org/guidelines_download2.aspx.* In addition, the Medicare Hospice CoPs require that hospice comprehensive assessments identify patients' physical, psychosocial, emotional, and spiritual needs and address them to promote the hospice patient's comfort throughout the end-of-life process. Furthermore, the person-centered, family, and caregiver perspective align with the domains identified by the CoPs and NCP, as patients and their families/caregivers also place value on physical symptom management and spiritual/psychosocial care as important factors at the end of

[22] National Quality Forum. (2013). Composite Performance Measure Evaluation Guidance: National Quality Forum.

[23] Medicare and Medicaid Programs: Hospice Conditions of Participation, Part 418 subpart 54. Centers for Medicare and Medicaid Services, June 5, 2008.

[24] The National Consensus Project for Quality Palliative Care Clinical Practice Guidelines for Quality Palliative Care 3rd edition 2013.

life.[25] [26] A composite measure serves to ensure all hospice patients receive a comprehensive assessment for both physical and psychosocial needs at admission.

Measure Impact. The literature indicates that health care providers' practice is responsive to quality measures reported.[27] CMS feels this research, while not specific to hospices, reasonably predicts the effect of measures on hospice provider behavior. Collecting information about the total number of care processes conducted for each patient will incentivize hospices to conduct all desirable care processes for each patient and provide services that will address their care needs and improve quality during the time he or she is receiving hospice care. Additionally, creating a composite quality measure for comprehensive assessment at admission will provide consumers and providers with a single measure regarding the overall quality and completeness of assessment of patient needs at hospice admission, which can then be used to meaningfully and easily compare quality across hospice providers and increase transparency.

Performance Gap. Analyses conducted by our measure development contractor, RTI International, show that hospice performance scores on the current 7 HQRP measures are high (a score of 90 percent or higher on most measures); however, these analyses also revealed that, on average, a much lower percentage of patient stays in a hospice had documentation that all of these desirable care processes were completed at admission. Thus, by assessing hospices' performance of comprehensive assessment, the composite measure sets a higher standard of care for hospices and reveals a larger performance gap. A similar effect has been shown in the literature where facilities are achieving more than 90 percent compliance with individual measures, but compliance numbers decrease when multiple measures are combined as one.[28] [29] The performance gap identified by the composite measure creates opportunities for quality improvement and may motivate providers to conduct a greater number of high priority care processes for as many patients as possible upon admission to hospice.

Existing Measures. The Family Evaluation of Hospice Care (FEHC), NQF #0208, is a precursor of the Hospice CAHPS®. The surveys cover some similar domains. However, a major difference between them is the detailed requirements for survey administration of the CAHPS® Hospice Survey, which allow for comparison of hospice programs, The Hospice CAHPS® survey quality measure is not yet endorsed by NQF. CMS has recently submitted the CAHPS® Hospice Survey (experience of care) measure (NQF #2651) to be considered for endorsement under the Palliative and End-of-Life Care Project 2015–2016. For more information regarding this project and the measure submitted, we refer readers to *https://www.qualityforum.org/ProjectMeasures.aspx?projectID=80663.* In addition, we refer readers to section III.C.9 of this rule for more information on the Hospice CAHPS® survey and associated quality measures. The CAHPS®-based quality measures submitted to NQF include patient and caregiver experience of care outcome measures and CMS plans to propose these measures as part of the HQRP measure set in future rulemaking cycles. A key difference between the FEHC, Hospice CAHPS® and the Hospice and Palliative Care Composite Process Measure is that the FEHC and Hospice CAHPS® focus on the consumer's perspective of their health agency and experience, whereas the Hospice and Palliative Care Composite Process Measure focuses on the clinical care processes that are actually delivered by the hospice to each patient.

Stakeholder Support. A TEP convened by our measure development contractor, RTI International, on December 2, 2015, provided input on this measure concept. The TEP unanimously agreed that a comprehensive hospice composite measure is an important measure and supported data collection using the HIS. The NQF MAP met on December 14th and 15th, 2015 and provided input to CMS. In their final recommendation, the MAP encouraged continued development of the Hospice and Palliative Care Composite Process Measure—Comprehensive Assessment at Admission measure. More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75370.*

While this measure is not currently NQF-endorsed, we recognize that the NQF endorsement process is an important part of measure development and plan to submit this measure for NQF endorsement. As noted, this quality measure will fill a gap by holding hospices to a higher standard of care and will motivate providers to conduct a greater number of high priority care processes for as many beneficiaries as possible upon admission as hospice patients. Furthermore, no current NQF-endorsed measures address the completion of a comprehensive care assessment at hospice admission.

Form, Manner, and Timing of Data Collection and Submission. The data source for this measure will be currently implemented HIS items that are currently used in the calculation of the 7 component measures. These items and quality measure algorithms for the 7 component measures can be found in the HQRP Specifications for the Hospice Item Set-based Quality Measures document, which is available in the ''Downloads'' section of the ''Current Measures'' portion of the CMS HQRP Web site: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Current-Measures.html.* Since the proposed measure is a composite measure whose components are currently adopted HQRP measures, no new data collection will be required; data for the composite measure will come from existing items from the existing 7 HQRP component measures. CMS proposes to begin calculating this measure using existing data items, beginning April 1, 2017; this means patient admissions occurring after April 1, 2017 would be included in the composite measure calculation.

Since the composite measure components are existing HIS data items, providers are already collecting the data needed to calculate the composite measure. Data collection will continue in accordance with processes outlined in sections III.C.7c through III.C.7e of this rule.

For more information on the specifications and data elements for the measure, Hospice and Palliative Care Composite Process Measure-Comprehensive Assessment at Admission, we refer readers to the *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Current-Measures.html* document, available on the ''Current Measures''

[25] Singer PA, Martin DK, Kelner M. Quality End-of-Life Care: Patients' Perspectives. JAMA. 1999;281(2):163–168. doi:10.1001/jama.281.2.163.

[26] Steinhauser KE, Christakis NA, Clipp EC, McNeilly M, McIntyre L, Tulsky JA. Factors Considered Important at the End of Life by Patients, Family, Physicians, and Other Care Providers. JAMA. 2000;284(19):2476–2482. doi:10.1001/jama.284.19.2476.

[27] Werner, R., E. Stuart, and D. Polsky, *Public reporting drove quality gains at nursing homes.* Health Affairs, 2010. 29(9): p. 1706–1713.

[28] Nolan, T., & Berwick, D. M. (2006). All-or-none measurement raises the bar on performance. JAMA [H.W. Wilson—GS], 295(10), 1168.

[29] Agency for Healthcare Research and Quality. (2004). National Healthcare Quality Report.

portion of the CMS HQRP Web site: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Current-Measures.html.*

We received multiple comments pertaining to the Hospice and Palliative Care Composite Process Measure. The following is a summary of the comments we received on this topic and our responses.

Comment: CMS received many comments in support of the proposed Hospice and Palliative Care Composite Process Measure—Comprehensive Assessment at Admission quality measure. Commenters appreciated that the measure demonstrates greater variation in hospice performance than the individual component measures, and that it can be used to differentiate performance across hospices. Commenters also appreciated that CMS's measure selection activities for the HQRP take into consideration input from stakeholders such as the Measure Applications Partnership (MAP). Several commenters were supportive of CMS's approach to quality measure development in the HQRP, specifically, the use of Technical Expert Panels (TEP) to obtain expert and other stakeholder input.

Response: We thank commenters for their support of the proposed Hospice and Palliative Care Composite Process Measure—Comprehensive Assessment at Admission quality measure, herein after referred to as the 'Composite QM'.

Comment: Many comments were received regarding the retirement of the seven day length of stay exclusion for six of the care process measures that comprise the Composite QM. Commenters' primary concern focused on the impact of removing this exclusion on provider behavior; specifically, commenters suggested that eliminating the LOS exclusion may inappropriately incentivize providers to focus on completion and compliance with the HIS requirements at the expense of addressing the needs and preferences of imminently dying patients. Commenters noted that upon admission for imminently dying patients, a comprehensive assessment is not in the interest of patients and caregivers, nor may it be feasible for hospices to deliver because the focus is on appropriately directed to other priorities. One commenter stated that the level and intensity of hospices services are different for patients with short LOS and that the items captured in this measure are not reflective of quality of care for patients imminently dying. Finally, one commenter indicated that this measure might complicate data collection efforts and processes already in place at hospices, noting that different members of the interdisciplinary team often complete different sections of the HIS at different times. This commenter believed that hospices would therefore need to establish new data collection processes when addressing urgent patient/family needs should be the priority. In response to these concerns, commenters requested that provisions be made to account for patients with short LOS and suggested alternative approaches to do so. Namely, commenters recommended that CMS risk adjust or stratify for patients with a 2-day or less, 3-day or less, or 5-day or less LOS, while other comments recommended that CMS maintain the current 7-day LOS exclusion. Another commenter recommended that a new measure be created to capture data for short LOS patients, rather than including them in this measure. Commenters requested clarification on why the measure was not created with risk adjustment in its current specifications.

Response: We appreciate the commenters' input on the Composite QM LOS exclusion specifications. Developing and adopting measures that benefit patient outcomes and do not lead to negative unintended consequences of the utmost importance to CMS. We would like to take this opportunity to respond to commenters' concerns about the impact of retiring the LOS exclusion, first by describing the history of the LOS exclusion and the reason for retiring it from the individual measures. As many commenters noted, 6 of the 7 component quality measure (QMs) exclude patient stays that are less than 7 days from the measure denominator. At the time the measures were developed, no national data regarding the implications of the LOS exclusion was available at that time, and technical experts recommended that short patient stays be excluded from those measures' denominators for assessing quality of care. Since the implementation of the HIS, we have performed descriptive analyses to examine the implications of the LOS exclusion on hospices' denominator size and QM scores. Additionally, this analysis also examined the timing of when hospices perform the care processes assessed in the quality measures. The results of these analyses demonstrated that the denominator sizes for the HQRP QMs are largely impacted by the current 7 day LOS exclusion used to calculate the QMs. Excluding stays with LOS less than 7 days result in many hospices not having sufficient denominator size to allow for public display of their quality scores. Although the LOS exclusion has a sizable impact on the number of hospices eligible to have their data publicly displayed, the impact of the LOS exclusions on the distribution of hospices' scores is generally small for all of the QMs. Therefore, removing the LOS exclusion criteria will increase the number of hospices eligible for public reporting while having a minimal impact on the QM scores. In addition, these analyses revealed that the care processes targeted by the QMs are performed on the day of or within one day of admission for the vast majority of patient stays. For example, among patient admissions for which a pain screening was administered, approximately 92 percent of screenings occurred on the day of admission and close to 99 percent occurred within 1 day of admission. This suggests that including stays of less than 7 days in QM calculations (that is, removing the QM LOS exclusion) may be appropriate and would not create a burden on hospices. In response to these results, the measure developer and steward submitted the individual QMs to the NQF Palliative Care and End of Life Project for re-endorsement in February 2016 without the LOS exclusion. Because of the anticipated removal of the LOS exclusion for the current HQRP measures (component measures for this Composite QM), this Composite QM was proposed without the LOS exclusion in order to be consistent with the individual measure components. Our contractor convened a TEP in December 2015 to inform the development of the Composite QM. The TEP, presented with the results of the LOS analysis, strongly recommended that the Composite QM maintain the same measure specifications as the individual measures. Additionally, this TEP considered the creation of a separate measure specifically for short LOS patients, as recommended by a commenter, but ultimately agreed that such a measure would not capture comprehensive care for short LOS patients as the current proposed measure would. Furthermore, we remind commenters that because the Composite QM is based on the 7 current HIS measures that are already endorsed by NQF, risk adjustment for the Composite QM will be consistent with any risk adjustment created and applied for the individual measures. Any additional risk adjustment applied to the individual measures will first be developed and tested for in coordination with the NQF prior to

implementation. We will keep the commenters' recommendations and concerns regarding short LOS in mind for future development efforts and data analysis.

Comment: CMS received comments regarding the contribution of this measure to quality of care. While commenters did not object to the development and implementation of this measure, many were concerned whether this measure is truly reflective of comprehensive care at admission and whether it will provide patients and families with meaningful information.

Response: We appreciate the commenters' concern regarding the impact and relevance of the Composite QM. We are committed to the ensuring that all quality measures implemented in the HQRP meet the goals of the HQRP, which include distinguishing performance among hospices and improving patient outcomes. We regularly conduct measure testing and evaluation activities to ensure that measures continue to demonstrate improvements in-patient care. We would like to convey to commenters that a primary motivation in developing the Composite QM is to provide interpretable and meaningful information to consumers. We believe that, above and beyond information provided by the individual component QMs, the Composite QM accomplishes this by providing consumers with a single measure regarding the overall quality and completeness of assessment of patient needs at hospice admission, which can then be used to compare quality across hospice providers and increase transparency, while also accessing information about hospice performance on each of the individual measures that comprise the Composite QM. As also noted in this rule, the Composite QM demonstrates greater variation in hospice performance than individual measures. Hospice performance scores on the current 7 HQRP measures are high (a score of 90 percent or higher on most measures); however, on average, a much lower percentage of patient stays in a hospice had documentation that all 7 of these care processes were completed at admission. Additionally, we would like to reiterate that the Composite QM for comprehensive assessment at admission addresses high priority aspects of comprehensive quality hospice care as identified by both leading hospice stakeholders and beneficiaries receiving hospice services, all of which emphasize attention to physical, psychosocial, emotional, and spiritual needs of patients.

Comment: CMS received a few comments recommending that CMS attain NQF endorsement of the Composite QM prior to implementation.

Response: We appreciate the commenters' input and support of the NQF endorsement process. Our paramount concern is the successful development of a HQRP that promotes the delivery of high quality healthcare services. We seek to adopt measures for the HQRP that promote patient-centered and high quality care. Our measure selection activities for the HQRP take into consideration input from the Measure Applications Partnership (MAP), convened by the NQF, as part of the established CMS pre-rulemaking process required under section 1890A of the Act. The NQF MAP met on December 14th and 15th, 2015 and encouraged continued development of this measure. Additionally, while this measure is not currently NQF-endorsed, we recognize that the NQF endorsement process is an important part of measure development and plan to submit this measure for NQF endorsement. This quality measure will fill a gap by holding hospices to a higher standard of care and will motivate providers to conduct a greater number of high priority care processes for as many beneficiaries as possible upon admission as hospice patients—a unique contribution to hospices. Furthermore, no current NQF-endorsed measures address the completion of a comprehensive care assessment at hospice admission, and this measure is a first step towards that goal. We are establishing the timeline for seeking NQF endorsement for this quality measure and will communicate this timeline to the public in future rulemaking cycles.

Comment: CMS received one comment requesting clarification on the logic behind including NQF #1617 Patients Treated with an Opioid Who Are Given a Bowel Regimen measure as a component measure of the proposed Composite QM. This commenter indicated that the NQF #1617 measure does not collect data representative of comprehensive care on the first day of admission and, therefore, does not serve this measure well as a component.

Response: We would like to clarify that the Composite QM is not designed to focus on care processes completed on the first day of admission; rather, this measure is intended to capture all comprehensive assessment activities around the time of hospice admission. This timeframe is in line with guidelines identified the Medicare Hospice Conditions of Participation (CoPs).[30] The Medicare CoPs mandate that an initial assessment be completed within 48 hours after the election of hospice care and that a comprehensive assessment be completed no later than 5 calendar days after the election of hospice care is in accordance with § 418.24. Therefore, by collecting data beyond the first day of admission, this measure aligns with the practices recommended by the CoPs and with national guidelines and clinical recommendations. The Medicare CoPs require that both the hospice initial and comprehensive assessments identify patients' physical needs and address them to promote the hospice patients' well-being and comfort throughout the dying process. Additionally, the Quality Palliative Care Clinical Practice Guidelines [31] produced by the National Consensus Project (NCP) established eight core palliative care domains, one of which emphasizes the assessment and management of pain and/or other physical symptoms. This measure captures care processes related to bowel management and opioid use. Most patients prescribed opioids to manage pain or other symptoms develop some degree of constipation after opioid initiation or dose increases. Reducing opioid-induced constipation can reduce patient discomfort and improve quality of life. Properly assessing and managing symptoms related to bowel management are critical components of the comprehensive assessment. Therefore, by including the NQF #1617 measure in this comprehensive assessment, we address high priority aspects of quality hospice care as identified by leading hospice stakeholders.

Comment: CMS received one comment recommending that the title of this measure, specifically the term ''at admission'', be clarified or replaced. The commenter believed that the use of the phrase ''at admission'' was misleading since it seemed to imply that the measure captures care processes completed on the day of admission. Since the composite measure in fact captures care processes completed during the initial and/or comprehensive assessment (which, per CoP requirements, must be completed within 2 and 5 days from admission, respectively), the commenter believed the title of the measure could be misleading since care processes that are components of the measure may be completed beyond the day of admission.

[30] Medicare and Medicaid Programs: Hospice Conditions of Participation, Part 418 subpart 54. Centers for Medicare and Medicaid Services (2008).

[31] Clinical Practice Guidelines for Quality Palliative Care. National Consensus Project for Quality Palliative Care (2013).

Response: We would like to thank this commenter for their recommendation. We would like to clarify that this measure title was developed based on the CoP requirement for the comprehensive assessment. While it is true that the CoPs require the first comprehensive assessment to be completed within 5 days of admission, the CoPs also require hospices to update the comprehensive assessment as frequently as the condition of the patient requires, but no less frequently than every 15 days. Thus, we used the phrase Comprehensive Assessment ''at Admission'' to denote that this measure and the data it captures refers to care processes delivered during the *first* comprehensive assessment completed upon admission to hospice and not any subsequent comprehensive assessment updates.

Comment: CMS received a few comments regarding the measure specifications of the Composite QM. Commenters requested clarification on the composite measure score calculation, construction, and components.

Response: The Composite QM is a composite measure that assesses whether a comprehensive patient assessment is completed at hospice admission by evaluating whether seven critical individual care processes were completed upon admission for each hospice patient stay. A composite measure, as defined by the NQF, is a combination of two or more component measures, each of which individually reflects quality of care, into a single performance measure with a single score. For more information on composite measure definitions, guiding principles, and measure evaluation criteria, we refer readers to the NQF Composite Performance Measure Evaluation Guidance Publication available at *https://www.qualityforum.org/Publications/2013/04/Composite_Performance_Measure_Evaluation_Guidance.aspx.* A total of 7 individual care processes will be captured in this Composite QM, which include the 6 NQF endorsed quality measures and 1 modified NQF endorsed quality measure currently implemented in the HQRP. This Composite QM calculates the percentage of patients who received all applicable care processes at admission. For additional details on the draft Composite QM specifications, we refer readers to the HQRP Specifications for HIS-Based QM document, available on the ''Current Measures'' portion of the CMS HQRP Web site: *https://www.cms.gov/Medicare/Quality-Initiatives-PatientAssessment-Instruments/HospiceQuality-Reporting/CurrentMeasures.html.* This measure, therefore, reflects the variation in hospices' performance on all 7 quality measures for each patient at admission. We will continue the development and analyses of the Composite QM. Potential refinement to the measure specifications will be communicated with the public via HQRP communication channels, including postings and announcements on the CMS HQRP Web site, MLN eNews communications, national provider association calls, and announcements on Open Door Forums and Special Open Door Forums.

Comment: CMS received a few comments recommending that CMS be mindful of public awareness of differences between process and outcome measures when creating a composite measure. Two commenters stated that although this measure concept is valuable and consistent with existing clinical guidelines, knowledge about differences in hospice measure types is minimal among the public. The commenter noted that the public might not be able to understand the relationship of hospice performance on the Composite QM to quality of care delivery at the hospice. Additionally, two commenters recommended that to aid consumer understanding of information from the Composite QM, CMS should supplement this data with information from the hospice CAHPS survey.

Response: We appreciate the commenters' feedback on public usability of the Composite QM. We would like to highlight that one primary motivation for creating this Composite QM was to provide interpretable and meaningful information to consumers. We believe the Composite QM may be easier for consumers to understand because it provides the public with a single metric regarding care processes at admission as compared to the individual component QMs. As such, QM scores can be easily used to compare quality across providers and make informed decisions. We are committed to providing all users with the necessary information to understand the intent and application of measures in the HQRP. As with other measures, we will conduct measure testing and reportability analysis to determine if the Composite QM is appropriate for public reporting. Should we determine the Composite QM is appropriate for public reporting, we would take necessary steps to ensure that any data publicly reported is meaningful and understandable by the public. Such steps may include usability testing and cognitive interviewing. We also plan to make hospice CAHPS quality measures publicly available to consumers.

Final Action: After consideration of the comments, we are finalizing our proposal to implement the Hospice and Palliative Care Composite Process Measure—Comprehensive Assessment at Admission effective April 1, 2017.

TABLE 16—PROPOSED QUALITY MEASURES AND DATA COLLECTION PERIOD AFFECTING THE FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Quality measure	NQF ID No.	Type	Submission method	Data collection to begin
Hospice Visits when Death is Imminent	TBD	Process Measure	Hospice Item Set	04/01/2017
Hospice and Palliative Care Composite Process Measure	TBD.			

7. Form, Manner, and Timing of Quality Data Submission

a. Background

Section 1814(i)(5)(C) of the Act requires that each hospice submit data to the Secretary on quality measures specified by the Secretary. Such data must be submitted in a form and manner, and at a time specified by the Secretary. Section 1814(i)(5)(A)(i) of the Act requires that beginning with the FY 2014 and for 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 for that FY.

b. Previously Finalized Policy for New Facilities To Begin Submitting Quality Data

In the FY 2015 Hospice Wage Index final rule (79 FR 50488), we finalized a policy stating that any hospice that receives its CMS Certification Number (CCN) (also known as the Medicare Provider Number) notification letter

dated on or after November 1 of the preceding year involved is excluded from any payment penalty for quality reporting purposes for the following FY. This requirement was codified at § 418.312.

In the FY 2016 Hospice Wage Index final rule (80 FR 47189), we further clarified and finalized our policy for the timing of new providers to begin reporting data to CMS. The clarified policy finalized in the FY 2016 Hospice Wage Index final rule (80 FR 47189) distinguished between when new hospice providers are required to begin submitting HIS data and when providers will be subject to the potential 2 percentage point annual payment update (APU) reduction for failure to comply with HQRP requirements. In summary, the policy finalized in the FY 2016 Hospice Wage Index final rule (80 FR 47189 through 47190) clarified that providers *must begin submitting HIS* data on the date listed in the letterhead of the CCN Notification letter received from CMS but will be subject to the APU reduction based on whether the CCN Notification letter was dated before or after November 1 of the reporting year involved. Thus, beginning with the FY 2018 payment determination and for each subsequent payment determination, we finalized our policy that a new hospice be responsible for HQRP quality data submission beginning on the date of the CCN notification letter; we retained our prior policy that hospices not be subject to the APU reduction if the CCN notification letter was dated after November 1 of the year involved. For example, if a provider receives their CCN notification letter and the date in the letterhead is November 5, 2016, that provider will begin submitting HIS data for patient admissions occurring after November 5, 2016. However, since the CCN notification letter was dated after November 1st, they would not be evaluated for, or subject to any payment penalties for, the relevant FY APU update (which in this instance is the FY 2018 APU, which is associated with patient admissions occurring 1/1/16–12/31/16).

This policy allows CMS to receive HIS data on all patient admissions on or after the date a hospice receives their CCN notification letter, while at the same time allowing hospices flexibility and time to establish the necessary accounts for data submission before they are subject to the potential APU reduction for a given reporting year. Currently, new hospices may experience a lag between Medicare certification and receipt of their actual CCN Number. Since hospices cannot submit data to the QIES ASAP system without a valid CCN Number, CMS proposed that new hospices begin collecting HIS quality data beginning on the date noted on the CCN notification letter. We believe this policy will provide sufficient time for new hospices to establish appropriate collection and reporting mechanisms to submit the required quality data to CMS. Requiring quality data reporting beginning on the date listed in the letterhead of the CCN notification letter aligns CMS policy for requirements for new providers with the functionality of the HIS data submission system (QIES ASAP).

c. Previously Finalized Data Submission Mechanism, Collection Timelines, and Submission Deadlines for the FY 2017 Payment Determination

In the FY 2015 Hospice Wage Index final rule (79 FR 50486), we finalized our policy requiring that, for the FY 2017 reporting requirements, hospices must complete and submit HIS records for all patient admissions to hospice after July 1, 2014. For each HQRP program year, we require that hospices submit data on each of the adopted measures in accordance with the reporting requirements specified in sections III.C.7c through III.C.7e of that rule for the designated reporting period. This requirement applies to previously finalized and adopted measures, as well as new measures proposed through the rulemaking process. Electronic submission is required for all HIS records. Although electronic submission of HIS records is required, hospices do not need to have an electronic medical record to complete or submit HIS data. In the FY 2014 Hospice Wage Index final rule (78 FR 48258), we finalized a provision requiring that providers can use either the Hospice Abstraction Reporting Tool (HART) (which is free to download and use) or vendor-designed software to complete HIS records. HART provides an alternative option for hospice providers to collect and maintain facility, patient, and HIS Record information for subsequent submission to the QIES ASAP system. Once HIS records are complete, electronic HIS files must be submitted to CMS via the QIES ASAP system. Electronic data submission via the QIES ASAP system is required for all HIS submissions; there are no other data submission methods available. Hospices have 30 days from a patient admission or discharge to submit the appropriate HIS record for that patient through the QIES ASAP system. CMS will continue to make HIS completion and submission software available to hospices at no cost. We provided details on data collection and submission timing under the downloads section of the HIS Web site on the *CMS.gov* Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Hospice-Item-Set-HIS.html*.

The QIES ASAP system provides reports upon successful submission and 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, home health agencies, 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), Outcome Assessment Information Set (OASIS), and Long-Term Care Hospital Continuity Assessment Record & Evaluation Data Set (LTCH CARE), respectively. We have provided hospices with information and details about use of the HIS through postings on the HQRP Web site, Open Door Forums, announcements in the CMS MLN Connects Provider e-News (E-News), and provider training.

d. Previously Finalized Data Submission Timelines and Requirements for FY 2018 Payment Determination and Subsequent Years

Hospices are evaluated for purposes of the quality reporting program based on whether or not they submit data, not on their substantive performance level for the required quality measures. In order for CMS to appropriately evaluate the quality reporting data received by hospice providers, it is essential HIS data be received in a timely manner.

The submission date is the date on which the completed record is submitted and accepted by the QIES ASAP system. In the FY 2016 Hospice Wage Index final rule (80 FR 47191), CMS finalized our policy that beginning with the FY 2018 payment determination hospices must submit all HIS records within 30 days of the event date, which is the patient's admission date for HIS-Admission records or discharge date for HIS-Discharge records.

For HIS-Admission records, the submission date must be no later than the admission date plus 30 calendar days. The submission date can be equal to the admission date, or no greater than 30 days later. The QIES ASAP system will issue a warning on the Final Validation Report if the submission date is more than 30 days after the patient's admission date.

For HIS-Discharge records, the submission date must be no later than the discharge date plus 30 calendar days. The submission date can be equal to the discharge date, or no greater than 30 days later. The QIES ASAP system will issue a warning on the Final Validation Report if the submission date is more than 30 days after the patient's discharge date.

The QIES ASAP system validation edits are designed to monitor the timeliness of submission and ensure that providers' submitted records conform to the HIS data submission specifications. Providers are notified when timing criteria have not been met by warnings that appear on their Final Validation Reports. A standardized data collection approach that coincides with timely submission of data is essential to establish a robust quality reporting program and ensure the scientific reliability of the data received.

In the FY 2016 Hospice Wage Index final rule (80 FR 47191), CMS also clarified the difference between the completion deadlines and the submission deadlines. Current sub-regulatory guidance produced by CMS (for example, HIS Manual, HIS trainings) states that the completion deadlines for HIS records are 14 days from the Event Date for HIS-Admission records and 7 days from the Event Date for HIS-Discharge records. Completion deadlines continue to reflect CMS guidance only; these guidelines are not statutorily specified and are not designated through regulation. These guidelines are intended to offer clear direction to hospice agencies in regards to the timely completion of HIS-Admission and HIS-Discharge records. The completion deadlines define only the latest possible date on which a hospice should complete each HIS record. This guidance is meant to better align HIS completion processes with clinical workflow processes; however, hospices may develop alternative internal policies to complete HIS records. Although it is at the discretion of the hospice to develop internal policies for completing HIS records, CMS continues to recommend that providers complete and attempt to submit HIS records early, prior to the previously finalized submission deadline of 30 days, beginning in FY 2018. Completing and attempting to submit records early allows providers ample time to address any technical issues encountered in the QIES ASAP submission process, such as correcting fatal error messages. Completing and attempting to submit records early will ensure that providers are able to comply with the 30 day submission deadline.

HQRP guidance documents, including the CMS HQRP Web site, HIS Manual, HIS trainings, Frequently Asked Questions, and Fact Sheets, continue to offer the most up-to-date CMS guidance to assist providers in the successful completion and submission of HIS records. Availability of updated guidance will be communicated to providers through the usual CMS HQRP communication channels, including postings and announcements on the CMS HQRP Web site, MLN eNews communications, national provider association calls, and announcements on Open Door Forums and Special Open Door Forums.

e. Previously Finalized HQRP Data Submission and Compliance Thresholds for the FY 2018 Payment Determination and Subsequent Years

To accurately analyze quality reporting data received by hospice providers, it is imperative we receive ongoing and timely submission of all HIS-Admission and HIS-Discharge records. In the FY 2016 Hospice Wage Index final rule (80 FR 47192), CMS finalized the timeliness criteria for submission of HIS-Admission and HIS-Discharge records. The finalized timeliness criteria was in response to input from our stakeholders seeking additional specificity related to HQRP compliance affecting FY payment determinations and, due to the importance of ensuring the integrity of quality data submitted.

Last year, we finalized our policy (80 FR 47191 through 47192) that beginning with the FY 2018 payment determination and subsequent FY payment determinations, all HIS records would have to be submitted within 30 days of the event date, which is the patient's admission date or discharge date. In conjunction with this requirement, we also finalized our policy (80 FR 47192) to establish an incremental threshold for compliance over a 3-year period. To be compliant for the FY 2018 APU determination, hospices must submit no less than 70 percent of their total number of HIS-Admission and HIS-Discharge records by no later than 30 days from the event date. The timeliness threshold is set at 80 percent for the FY 2019 APU determination and at 90 percent for the FY 2020 APU determination and subsequent years. The threshold corresponds with the overall amount of HIS records received from each provider that fall within the established 30 day submission timeframes. Our ultimate goal is to require all hospices to achieve a compliance rate of 90 percent or more.

To summarize, in the FY 2016 Hospice Wage Index final rule (80 FR 47193), we finalized our policy to implement the timeliness threshold requirement beginning with all HIS admission and discharge records that occur after January 1, 2016, in accordance with the following schedule.

- Beginning January 1, 2016 to December 31, 2016, hospices must submit at least 70 percent of all required HIS records within the 30 day submission timeframe for the year or be subject to a 2 percentage point reduction to their market basket update for FY 2018.
- Beginning January 1, 2017 to December 31, 2017, hospices must submit at least 80 percent of all required HIS records within the 30 day submission timeframe for the year or be subject to a 2 percentage point reduction to their market basket update for FY 2019.
- Beginning January 1, 2018 to December 31, 2018, hospices must submit at least 90 percent of all required HIS records within the 30 day submission timeframe for the year or be subject to a 2 percentage point reduction to their market basket update for FY 2020.

Timely submission of data is necessary to accurately analyze quality measure data received by providers. To support the feasibility of a hospice to achieve the compliance thresholds, CMS's measure development contractor conducted some preliminary analyses of Quarter 3 and Quarter 4 HIS data from 2014. According to this analysis, the vast majority of hospices (92 percent) would have met the compliance thresholds at 70 percent. Moreover, 88 percent and 78 percent of hospices would have met the compliance thresholds at 80 percent and 90 percent, respectively. CMS believes this analysis is further evidence that the compliance thresholds are reasonable and achievable by hospice providers.

The current reports available to providers in the Certification and Survey Provider Enhanced Reports (CASPER) system do allow providers to track the number of HIS records that are submitted within the 30 day submission timeframe. Currently, submitting an HIS record past the 30 day submission timeframe results in a non-fatal (warning) error. In April 2015, CMS made available 3 new Hospice Reports in CASPER, which include reports that can list HIS Record Errors by Field by Provider and HIS records with a specific error number. CMS is working on expanding this functionality of CASPER reports to include a timeliness compliance threshold report that

providers could run to determine their preliminary compliance with the timeliness compliance requirement. CMS expects these reports to be available by late fall of 2016.

In the FY 2016 Hospice Wage Index final rule (80 FR 47192 through 47193), CMS provided clarification regarding the methodology used in calculating the 70 percent/80 percent/90 percent compliance thresholds. In general, HIS records submitted for patient admissions and discharges occurring during the reporting period (January 1st to December 31st of the reporting year involved) will be included in the denominator for the compliance threshold calculation. The numerator of the compliance threshold calculation would include any records from the denominator that were submitted within the 30 day submission deadline. In the FY 2016 Hospice Wage Index final rule (80 FR 47192), CMS also stated we would make allowances in the calculation methodology for two circumstances. First, the calculation methodology will be adjusted following the applicable reporting period for records for which a hospice is granted an extension or exemption by CMS. Second, adjustments will be made for instances of modification/inactivation requests (Item A0050. Type of Record = 2 or 3). Additional helpful resources regarding the timeliness compliance threshold for HIS submissions can be found under the downloads section of the Hospice Item Set Web site at CMS.gov at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Hospice-Item-Set-HIS.html.* Lastly, as further details of the data submission and compliance threshold are determined by CMS, we anticipate communicating these details through the regular CMS HQRP communication channels, including postings and announcements on the CMS HQRP Web site, MLN eNews communications, national provider association calls, and announcements on Open Door Forums and Special Open Door Forums.

Comment: A few commenters commented on our previously finalized policies for form, manner, and timing of data collection. One commenter raised concern about the ability of hospices to comply with the incremental 70 percent/80 percent/90 percent timeliness compliance threshold in cases of natural disasters. Specifically, the commenter was concerned that in the case of protracted natural disasters (for example, Hurricane Sandy), hospice organizations may not be able to email CMS within the 30-day timeframe to request an extension or exemption as appropriate, and that, in turn, failure to submit a timely request for extension or exemption may put a hospice at risk of non-compliance with the timeliness threshold. Another commenter stated they believed the process for HIS data collection and submission, which relies heavily on chart abstraction, was error-ridden and outdated. The commenter encouraged CMS to automate data collection and submission processes via electronic submission of HIS data.

Response: We thank the commenters for their comments on our previously finalized policies for form, manner, and timing of data collection. Regarding the first commenter's concern about ability to submit a timely extension or exemption request to maintain compliance with the 70/80/90 timeliness compliance thresholds in the case of extended natural disasters, CMS refers readers to our previously finalized policies for extensions and exemptions, addressed in section III.C.8 of this rule. As noted in section III.C.8, in instances of extraordinary circumstances (like widespread natural disasters), we may grant an extension/exemption to hospices that have not requested them, which may include instances where hospices are unable to make the request within the 30-day timeframe due to extenuating circumstances. Regarding the second commenter's request for electronic data collection and submission processes for the HIS, we would like to clarify that, as noted in section III.C.7.c of this rule, electronic submission of HIS records is already required; no other data submission methods are available. Hospices are required to submit all HIS records through the QIES ASAP system. We also provide electronic software to hospices free of charge that allows hospices to complete HIS records electronically; alternatively, hospices may choose to use vendor-designed software to complete HIS records. As noted by the commenter, we believe this electronic process of data completion and submission minimizes burden on providers and helps ensure data quality through the HIS record validation process. We refer readers to section III.C.7.c for more information on mechanisms of data submission for the HIS.

f. New Data Collection and Submission Mechanisms Under Consideration for Future Years

CMS has made great progress in implementing the objectives set forth in the quality reporting and data collection activities required by sections 3004 of the Affordable Care Act. To date, CMS has established the HQRP, which includes 7 NQF-endorsed quality measures that are collected via the HIS. As stated in this rule, data on these measures are expected to be publicly reported sometime in 2017. Additionally, CMS has also implemented the Hospice CAHPS® as part of the HQRP to gather important input on patient experience of care in hospice. Over the past several years, CMS has conducted data collection and analysis on hospice utilization and trends to help reform the hospice payment system. In the FY 2016 Hospice Wage Index final rule, we finalized payment reform measures, including changes to the RHC payment rate and the implementation of a Service Intensity Add-On (SIA) payment, effective January 1st, 2016. As part of payment reform and ongoing program integrity efforts, we will continue ongoing monitoring of utilization trends for any future refinements.

To facilitate continued progress towards the requirements set forth in section 3004 of the Affordable Care Act, CMS is considering developing a new data collection mechanism for use by hospices. This new data collection mechanism would be a hospice patient assessment instrument, which would serve 2 primary objectives concordant with the Affordable Care Act legislation: (1) To provide the quality data necessary for HQRP requirements and the current function of the HIS; and (2) provide additional clinical data that could inform future payment refinements.

CMS believes that the development of a hospice patient assessment tool could offer several benefits over the current mechanisms of data collection for quality and payment purposes, which include the submission of HIS data and the submission of claims data. For future payment refinements, a hospice patient assessment tool would allow CMS to gather more detailed clinical information, beyond the patient diagnosis and comorbidities that are currently reported on hospice claims. As stated in the FY 2016 Hospice Wage Index final rule (80 FR 47203), detailed patient characteristics are necessary to determine whether a case mix payment system could be achieved. A hospice patient assessment tool would allow CMS to capture information on symptom burden, functional status, and patient, family, and caregiver preferences, all of which will inform future payment refinements.

While systematic assessment is vital throughout the continuum of care, including palliative and end-of-life care, documentation confirming completion

of systematic assessment in hospice settings is often inadequate or absent.[32] The value of the introduction of structured approaches via a clinical assessment is well established, as it enables a more comprehensive and consistent way of identifying and meeting patient needs.[33]

Moreover, symptoms are the leading reason that people seek medical care in the first place and frequently serve as the basis for establishing a diagnosis. Measures of physical function and disease burden have been used to identify older adults at high-risk for excess health care utilization, disability, or mortality.[34] Currently, data collected on claims includes line-item visits by discipline, General Inpatient Care (GIP) visit reporting to hospice patients in skilled nursing facilities or hospitals, post-mortem visits, injectable and non-injectable drugs and infusion pumps. Industry representatives have communicated to CMS that required claims information is not sufficiently comprehensive to accurately reflect the provision and the cost of hospice care.

For quality data collection, a hospice patient assessment instrument would support the goals of the HQRP as new quality measures are developed and adopted. Since the current quality data collection tool (HIS) is a chart abstraction tool, not a hospice patient assessment instrument, CMS is limited in the types of data that can be collected via the HIS. Instead of retrospective data collection elements, a hospice patient assessment tool would include data elements designed to be collected concurrent with provision of care. As such, CMS believes a hospice patient assessment tool would allow for more robust data collection that could inform development of new quality measures that are meaningful to hospice patients, their families and caregivers, and other stakeholders.

Finally, a hospice patient assessment tool that provides clinical data that is used for both payment and quality purposes would align the hospice benefit with other care settings that use similar approaches, such as nursing homes, inpatient rehabilitation facilities, and home health agencies which submit data via the MDS 3.0, IRF–PAI, and OASIS, respectively.

CMS envisions the hospice patient assessment tool itself as an expanded HIS. The hospice patient assessment tool would include current HIS items, as well as additional clinical items that could be used for payment refinement purposes or to develop new quality measures. The hospice patient assessment tool would not replace existing requirements set forth in the Medicare Hospice CoPs (such as the initial nursing and comprehensive assessment), but would be designed to complement data that are collected as part of normal clinical care. If such a patient assessment were adopted, the new data collection effort would replace the current HIS, but would not replace other HQRP data collection efforts (that is, the Hospice CAHPS® survey), nor would it replace regular submission of claims data. CMS envisions that patient assessment data would be collected upon a patient's admission to and discharge from any Medicare-certified hospice provider; additional interim data collection efforts are also possible. Should CMS develop and implement a hospice patient assessment tool, CMS would provide several training opportunities to ensure providers are able to comply with any new requirements.

CMS is not proposing a hospice patient assessment tool at this time; we are still in the early stages of development of an assessment tool to determine if it would be feasible to implement under the Medicare Hospice Benefit. In the development of such a hospice patient assessment tool, CMS will continue to receive stakeholder input from MedPAC and ongoing input from the provider community, Medicare beneficiaries, and technical experts. It is of the utmost importance to CMS to develop a hospice patient assessment tool that is scientifically rigorous and clinically appropriate, thus we believe that continued and transparent involvement of stakeholders is critical. Additionally, it is of the utmost importance to CMS to minimize data collection burden on providers; in the development of any hospice patient assessment tool, CMS will ensure that patient assessment data items are not duplicative or overly burdensome to providers, patients, caregivers, or their families.

We received multiple comments pertaining to a potential hospice patient assessment tool to collect quality, clinical and other data with the ability to be used to inform future payment refinement efforts. The following is a summary of the comments we received on this topic and our responses.

Comment: CMS received many comments about the potential new data collection mechanism—a comprehensive, standardized hospice patient assessment instrument—under consideration for future years. Overall, the vast majority of commenters were supportive of CMS's efforts to develop a patient assessment tool. Commenters believed that a patient assessment tool capturing information on symptom burden, functional status, and patient, family, and caregiver preferences has the potential to more accurately inform future payment refinements and quality measure development based on the needs of the populations served. Commenters noted that the development of a patient assessment tool would be an integral step in improving care management and coordination across settings, providing standardized data on the services that patients and families receive to better understand the complex patient characteristics. One of the commenters, MedPAC, supported the development of a patient assessment instrument, noting its potential value in capturing more meaningful quality data, as well as providing more detailed clinical information that might be useful for payment policy.

Commenters offered several suggestions for CMS to consider in moving forward with the development of a patient assessment tool. Suggestions focused on two main themes: (1) Considerations for the content of any patient assessment tool (2) considerations for the process used by CMS to develop and test a patient assessment tool. Beyond these two themes, commenters also listed other considerations, including cross-setting considerations (experience with other assessment tools and relationship to the IMPACT Act), burden and costs, use for future payment refinements, and general concerns.

Regarding considerations for the content of a patient assessment tool, overall, commenters emphasized the unique nature and care goals of hospice, urging CMS to bear in mind these complexities in the development of a patient assessment. Specifically, commenters stated that the patient assessment tool should reflect the holistic nature of hospice care delivery to the patient and their loved ones and should include physical, psychosocial, and spiritual components. Commenters also noted that the unit of care in hospice is the patient and family, and that the initial and ongoing assessment, as well as care planning and

[32] McMillan, S., Small, B., & Haley, W. (2011). Improving Hospice Outcomes through Systematic Assessment: A Clinical Trial. *Cancer Nursing,* 34(2), 89–97.

[33] Bourbonnais, F.F., Perreault, A., & Bouvette, M. (2004). Introduction of a pain and symptom assessment tool in the clinical setting—lessons learned. *Journal of Nursing Management,* 12(3), 194–200.

[34] Sha, M., Callahan, C., Counsell, S., Westmoreland, G., Stump, T., Kroenke, K. (2005). Physical symptoms as a predictor of health care use and mortality among older adults. 118, 301–306.

interventions, address the holistic care needs of both the patient and family. Commenters urged CMS not to limit the focus of a patient assessment tool to the clinical, ''head-to-toe'' nursing assessment, since care plans in hospice are often ''more personal than medical'' with emphasis on the patient's family and environment. Similarly, commenters pointed out the interdisciplinary nature of hospice, and recommended that any patient assessment tool include information from the entire hospice team. In consideration of all of these factors, commenters ultimately urged CMS to develop data elements that are relevant and meaningful to hospice practice.

In addition to comments about the nature and goals of hospice care, several commenters also had specific content suggestions for CMS to consider in the development of a patient assessment tool:

- Several commenters recommended that the assessment tool recognize the patient's right to refuse or defer offered services and the importance of an individualized plan of care.
- Several commenters recommended that the assessment tool accommodate care delivered in various settings, including nursing homes, assisted living facilities, hospitals, hospice facilities, and the patient's home.
- Several commenters recommended that the assessment tool allow for modified assessment of patients who are imminently dying to facilitate a focus on the urgent and immediate needs of the patient and family. Commenters noted that for imminently dying patients, the focus is the management of symptoms and the family's emotions, not necessarily a detailed medical history and physical assessment of the patient.
- Several commenters noted that the assessment tool should preserve the integrity of the hospice philosophy by allowing hospice interdisciplinary team members to individualize assessments and care based on their best clinical judgment. Additionally, commenters recommended that CMS not place overly restrictive limits on members of the interdisciplinary team that are permitted to complete the assessment tool. Commenters recommended that CMS allow several disciplines to contribute patient information and goals on the assessment, noting that this was a limitation of other assessment tools.
- One commenter recommended that CMS collect assessment data beyond the admission and discharge time points discussed in the proposed rule (81 FR 25528). The commenter noted the importance of measuring care throughout the entire stay, not just at admission and discharge.
- Commenters recommended that any outcome measure derived from the assessment be risk-adjusted.
- A couple of commenters suggested that any ''Reason for Discharge'' item(s) on the assessment tool differentiate the reason behind any live discharges (for example, revoked vs. moved out of service area).
- One commenter recommended CMS consider the International Classification of Function (ICF), in the development of a patient assessment tool. The commenter noted that the ICF provides a scientific basis for understanding health and health-related states as well as outcomes, related to both physical as well as social determinants, and could be a way to determine appropriate outcomes more quickly. Finally, the commenter noted that the ICF is already integrated into the ICD–10 and ICD–11 taxonomy internationally.
- Another commenter recommended that CMS align any new hospice assessment tool with the National Consensus Project for Quality Palliative Care Clinical Practice Guidelines for Quality Palliative Care.

Commenters had several suggestions regarding the process for development of any patient assessment tool. The majority of comments on the process for assessment tool development focused on systematically and comprehensively gathering input from hospice providers and other stakeholders with respect to what is appropriate and relevant to include in the assessment tool. Commenters offered specific suggestions of ways to involve the provider community, including CMS-convened technical expert panels (TEP) that include representation from hospices, physicians, and other members of the hospice Interdisciplinary Team (IDT). In addition to TEPs, one commenter suggested that CMS consider extending opportunities for input beyond TEPs and employ widespread processes for gathering provider input. Commenters also had suggestions for testing and refinement of a patient assessment tool. Commenters recommended piloting the tool with a wide variety of hospices, to ensure that the assessment tool is tested with variation in hospice size, rurality, state regulatory environments, and organization type (that is, hospital based, freestanding, those with inpatient facilities vs. those who contract for inpatient care, etc.). Commenters recommended a pilot testing process that is thorough and includes a dry-run period or phased-in implementation approach. Finally, commenters encouraged CMS to provide thorough and ongoing education and support for hospices as the patient assessment tool is implemented. Commenters specifically requested that educational materials include clear definitions of patient assessment items and data collection procedures.

Several commenters also discussed their experience with assessment tools in other care settings (for example, the OASIS in home health and the MDS in nursing homes). Some commenters expressed concerns about potential overreliance on existing assessment instrument items citing the difference in care goals between hospice and other post-acute care settings. These commenters emphasized the importance of creating an assessment tool tailored to the unique needs of hospice. On the other hand, commenters also urged CMS to create an assessment tool that is aligned and consistent with other assessment tools to facilitate care coordination and planning across the care continuum.

A few commenters offered considerations on potential burden and costs of a new assessment instrument. Commenters urged CMS to pursue efforts that would limit administrative burden, reduce redundancy, and ensure the use of definitions consistent with other assessment tools. Commenters noted that the assessment would likely be completed by different staff than those who are currently completing the HIS-Admission and HIS-Discharge records and that the assessment would likely be more time-intensive than the current HIS. Commenters urged CMS to consider increased costs to providers and to take into consideration the time and resources necessary to complete the assessment.

One commenter suggested that CMS—as appropriate—consider harmonizing measures from the IMPACT Act. The commenter noted that such harmonization would facilitate communication among providers and to measure the care of patient populations across setting measures. With respect to use of the patient assessment for future payment refinements, a few commenters noted the importance of rigorous testing of assessment items for inter-rater reliability and validity.

Beyond the support and suggestions offered, some commenters did raise concerns about a patient assessment tool. Commenters cautioned against a patient assessment tool that would lead to ''checklist'' assessments and undue restrictions on patient eligibility and the freedom to employ clinical judgment. Finally, one commenter had concerns about the flexibility of electronic medical record systems to capture

assessment items in a structured and minimally burdensome manner.

Response: First, we thank the commenters for their support of the development of a patient assessment tool. We agree that development of a patient assessment tool is a critical next step in refining quality data collection efforts and to inform future refinements to the hospice payment system. Second, we greatly appreciate the thoughtful input and recommendations from the hospice community. We believe the initial input from our stakeholders regarding the content and process for development of a patient assessment tool is aligned with our vision and guiding principles for moving forward with developing this new data collection mechanism. We would like to assure the provider community that we wholeheartedly agree with commenters regarding the unique nature of hospice care, and we intended to keep the hospice philosophy as the foundation of the patient assessment tool. We seek to develop an assessment tool that reflects the distinctive aspects of hospice care, including the palliative, rather than curative, focus of hospice care. We agree with the points raised by commenters about the overall focus of an assessment tool and aims to develop a tool that addresses the holistic nature of hospice, incorporating important medical, psychosocial, spiritual, and other aspects of care that are important for patients and their caregivers. We also appreciate commenters' specific suggestions regarding the content of a patient assessment tool including the need for a flexible assessment, which would incorporate input from various members of the IDT and accommodate circumstances unique to hospice such as care of the imminently dying and patient/caregivers' right to decline services or treatment.

With respect to commenters' suggestions about the process for development of a patient assessment tool, we would again like to thank the hospice community for their detailed input and careful consideration. Again, we would like to assure the provider community that it is our intent to use a development process that is transparent and includes multiple opportunities for stakeholder input. Feedback from the provider community is vital to the development of a patient assessment tool that is meaningful and not unduly burdensome on providers. As noted by commenters and discussed in this rule, CMS plans to hold TEPs to inform the development, testing, and refinement of the patient assessment. CMS also plans to provide other opportunities for stakeholders to provide input through venues such as special open door forums and other regular HQRP communication channels. We are committed to a development process that will ensure rigorous and iterative testing of the patient assessment tool in hospices with varying organizational characteristics, patient populations, settings of care delivery, and levels of care. We recognize the emphasis that we will need to place on thorough testing and analysis of items for reliability and validity, particularly for purposes of any future payment refinements. Finally, we agree that ongoing training and education will be vital, and we will ensure access to regular HQRP education and outreach outlets, such as training webinars, manuals and access to various Helpdesks.

We also appreciate commenters' suggestions on cross-setting harmonization and for sharing their experience with assessment tools in other care settings. We would like to assure commenters that we recognize the unique nature of hospice care; it is not our intent to develop an assessment tool that inappropriately relies on items from existing tools, such as the Minimum Data Set (MDS) and Outcome and Information Assessment Information Set (OASIS). We will work diligently with the provider community to gather information on current assessment practices in hospice and to ensure that a hospice assessment tool would capture the goals of hospice care and be complementary to current clinical practice. Regarding the commenters' suggestion to harmonize assessment items and resulting quality measure with the IMPACT Act quality measures, we appreciate the commenter's suggestion and will take it under consideration for future measure and assessment development.

Finally, with respect to concerns raised by commenters about costs and administrative burden, as stated in the rule, it is our goal to minimize data collection burden on providers and ensure that patient assessment items are not duplicative or overly burdensome to providers, patients, or their families. We believe that regular, ongoing input from the provider community will aide in the development of an assessment that is not overly burdensome. We expect that development of the patient assessment will take into account the ongoing movement toward use of certified EHRs and other interoperable health IT across all patient settings. We expect that our consultations with providers and with technical experts including health IT experts will include assessing and taking advantage of opportunities to develop and deploy the instrument in a way that integrates with hospice work flows and with the potential of health IT to help providers improve care, communication and coordination across the interdisciplinary care team while reducing burden on clinicians and other care team members by streamlining data collection and management. In addition, any patient assessment tool would be submitted to OMB as required by the Paperwork Reduction Act, the purpose of which is to ensure that Federally-sponsored data collection efforts pose no undue burden on the public.

We appreciate the input from the public regarding the development of a patient assessment tool for hospice. We will continue to inform our stakeholders on any progress and proposals regarding the patient assessment tool through future rulemaking cycles.

8. HQRP Submission Exemption and Extension Requirements for the FY 2017 Payment Determination and Subsequent Years

In the FY 2015 Hospice Wage Index final rule (79 FR 50488), we finalized our proposal to allow hospices to request, and for CMS to grant, exemptions/extensions for the reporting of required HIS quality data when there are extraordinary circumstances beyond the control of the provider. When an extension/exemption is granted, a hospice will not incur payment reduction penalties for failure to comply with the requirements of the HQRP. For the FY 2016 payment determination and subsequent payment determinations, a hospice may request an extension/exemption of the requirement to submit quality data for a specified time period. In the event that a hospice requests an extension/exemption for quality reporting purposes, the hospice would submit a written request to CMS. In general, exemptions and extensions will not be granted for hospice vendor issues, fatal error messages preventing record submission, or staff error.

In the event that a hospice seeks to request an exemptions or extension for quality reporting purposes, the hospice must request an exemption or extension within 30 days of the date that the extraordinary circumstances occurred by submitting the request to CMS via email to the HQRP mailbox at *HospiceQRPReconsiderations@cms.hhs.gov.* Exception or extension requests sent to CMS through any other channel will not be considered valid. The request for an exemption or extension must contain all of the finalized requirements as outlined on our Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-*

Quality-Reporting/Extensions-and-Exemption-Requests.html.

If a hospice is granted an exemption or extension, timeframes for which an exemption or extension is granted will be applied to the new timeliness requirement so such hospices are not penalized. If a hospice is granted an exemption, we will not require that the hospice submit any quality data for a given period of time. By contrast, if we grant an extension to a hospice, the hospice will still remain responsible for submitting quality data collected during the timeframe in question, although we will specify a revised deadline by which the hospice must submit these quality data.

This process does not preclude us from granting extensions/exemptions 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 may grant an extension/exemption 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/exemption to hospices in a region or locale, we will communicate this decision through routine CMS HQRP communication channels, including postings and announcements on the CMS HQRP Web site, MLN eNews communications, national provider association calls, and announcements on Open Door Forums and Special Open Door Forums.

9. Hospice CAHPS® Participation Requirements for the 2019 APU and 2020 APU

National Implementation of the Hospice CAHPS® Survey started January 1, 2015 as stated in the FY 2015 Hospice Wage Index and Payment Rate Update final rule (79 FR 50452). The CAHPS® Hospice Survey is a component of CMS' Hospice Quality Reporting Program that emphasizes the experiences of hospice patients and their primary caregivers listed in the hospice patients' records. Readers who want more information are referred to our extensive discussion of the Hospice Experience of Care Survey in the Hospice Wage Index FY 2015 final rule for a description of the measurements involved and their relationship to the statutory requirement for hospice quality reporting (79 FR 50450 also refer to 78 FR 48261).

a. Background and Description of the Survey

The CAHPS® Hospice Survey is the first national hospice experience of care survey that includes standard survey administration protocols that allow for fair comparisons across hospices. 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, in order to help patients, family, friends, and caregivers choose the right hospice program.

The goals of the CAHPS® Hospice Survey are to:

- Produce comparable data on hospice 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.
- Hold hospice care providers accountable by informing the public about the providers' quality of care.

Details regarding CAHPS® Hospice Survey national implementation, and survey administration as well as participation requirements, exemptions from the survey requirement, hospice patient and caregiver eligibility criteria, fielding schedules, sampling requirements, and the languages in which is questionnaire, are available on the CAHPS® Web site, *www.HospiceCAHPSsurvey.org* and in the Quality Assurance Guidelines (QAG) manual, which is also on the same site and is available for download. Measures from the survey will be submitted to the NQF for endorsement.

b. Participation Requirements To Meet Quality Reporting Requirements for the FY 2019 APU

To meet participation requirements for the FY 2019 APU, hospices must collect survey data on an ongoing monthly basis from January 2017 through December 2017 (inclusive). Data submission deadlines for the 2019 APU can be found in Table 17. The data must be submitted by the deadlines listed in Table 17 by the hospice's authorized approved CMS vendor.

Hospices provide lists of the patients who died under their care to form the sample for the Hospice CAHPS® Survey. We emphasize the importance of hospices providing complete and accurate information to their vendors in a timely manner. Hospices must contract with an approved Hospice CAHPS® Survey vendor to conduct the survey on their behalf. The hospice is responsible for making sure their vendor meets all data submission deadlines. Vendor failure to submit data on time will be the responsibility of the hospice.

TABLE 17—CAHPS® HOSPICE SURVEY DATA SUBMISSION DATES FY 2018 APU, FY 2019 APU, AND FY 2020 APU

Sample months (that is, month of death) [1]	Quarterly data submission deadlines [2]
FY 2018 APU	
January–March 2016 (Q1)	August 10, 2016.
April–June 2016 (Q2)	November 9, 2016.
July–September 2016 (Q3)	February 8, 2017.
October–December 2016 (Q4)	May 10, 2017.
FY 2019 APU	
January–March 2017 (Q1)	August 9, 2017.
April–June 2017 (Q2)	November 8, 2017.
July–September 2017 (Q3)	February 14, 2018.
October–December 2017 (Q4)	May 9, 2018.
FY 2020 APU	
January–March 2018 (Q1)	August 8, 2018.

TABLE 17—CAHPS® HOSPICE SURVEY DATA SUBMISSION DATES FY 2018 APU, FY 2019 APU, AND FY 2020 APU—Continued

Sample months (that is, month of death) [1]	Quarterly data submission deadlines [2]
April–June 2018 (Q2)	November 14, 2018.
July–September 2018 (Q3)	February 13, 2019.
October–December 2018 (Q4)	May 8, 2019.

[1] Data collection for each sample month initiates 2 months following the month of patient death (for example, in April for deaths occurring in January).

[2] Data submission deadlines are the second Wednesday of the submission months, which are Augst, November, February, and May.

Hospices that have fewer than 50 survey-eligible decedents/caregivers in the period from January 1, 2016 through December 31, 2016 are exempt from CAHPS® Hospice Survey data collection and reporting requirements for the FY 2019 payment determination. To qualify, hospices must submit an exemption request form. This form will be available in first quarter 2017 on the CAHPS® Hospice Survey Web site *http://www.hospiceCAHPSsurvey.org.* Hospices that want to claim the size exemption are required to submit to CMS their total unique patient count for the period of January 1, 2016 through December 31, 2016. The due date for submitting the exemption request form for the FY 2019 APU is August 10, 2017.

CMS proposed that hospices that received their CCN after January 1, 2017 are exempted from the FY 2019 APU Hospice CAHPS® requirements due to newness. This exemption will be determined by CMS. The exemption is for 1 year only.

c. Participation Requirements To Meet Quality Reporting Requirements for the FY 2020 APU

To meet participation requirements for the FY 2020 APU, hospices must collect survey data on an ongoing monthly basis from January 2018 through December 2018 (inclusive). Data submission deadlines for the 2020 APU can be found in Table 17. The data must be submitted by the deadlines in Table 17 by the hospice's authorized approved CMS vendor.

Hospices that have fewer than 50 survey-eligible decedents/caregivers in the period from January 1, 2017 through December 31, 2017 are exempt from CAHPS® Hospice Survey data collection and reporting requirements for the FY 2020 payment determination. To qualify, hospices must submit an exemption request form. This form will be available in first quarter 2018 on the CAHPS® Hospice Survey Web site *http://www.hospiceCAHPSsurvey.org.* Hospices that want to claim the size exemption are required to submit to CMS their total unique patient count for the period of January 1, 2017 through December 31, 2017. The due date for submitting the exemption request form for the FY 2020 APU is August 10, 2018.

CMS proposed that hospices that received their CCN after January 1, 2018 are exempted from the FY 2020 APU Hospice CAHPS® requirements due to newness. This exemption will be determined by CMS. The exemption is for 1 year only.

d. Annual Payment Update

The Affordable Care Act requires that beginning with FY 2014 and each subsequent fiscal year, the Secretary shall reduce the market basket update by 2 percentage points for any hospice that does not comply with the quality data submission requirements for that fiscal year, unless covered by specific exemptions. Any such reduction will not be cumulative and will not be taken into account in computing the payment amount for subsequent fiscal years. In the FY 2015 Hospice Wage Index final rule, we added 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 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 to qualify for the full APU.
- To meet the HQRP requirements for the FY 2019 payment determination, hospices would collect survey data on a monthly basis for the months of January 1, 2017 through December 31, 2017 to qualify for the full APU.
- To meet the HQRP requirements for the FY 2020 payment determination, hospices would collect survey data on a monthly basis for the months of January 1, 2018 through December 31, 2018 to qualify for the full APU.

e. Hospice CAHPS® Reconsiderations and Appeals Process

Hospices are required to monitor their respective Hospice CAHPS® Survey vendors to ensure that vendors submit their data on time. The hospice CAHPS® data warehouse provides reports to vendors and hospices, including reports on the status of their data submissions. Details about the reports and emails received after data submission should be referred to the Quality Assurance Guidelines Manual. If a hospice does not know how to retrieve their reports, or lacks access to the reports, they should contact Hospice CAHPS® Technical Assistance at *hospiceCAHPSsurvey@hcqis.org* or call them at 1–844 –472 –4621. Additional information can be found on page 113 of the Hospice CAHPS® Quality Assurance Guidelines manual Version 2.0 which is available on the Hospice CAHPS® Web site, *www.hospicecahpssurvey.org.*

In the FY 2017 payment determination and subsequent years, reporting compliance is determined by successfully fulfilling both the Hospice CAHPS® Survey requirements and the HIS data submission requirements. Providers would use the same process for submitting a reconsideration request that are outlined in section III.C.10 of this rule.

We received multiple comments pertaining to the Hospice CAHPS® Survey. The following is a summary of the comments we received on this topic and our responses.

Comment: One commenter expressed concern about the length of the survey and described it as a tool that is 36 pages in length and fraught with arduous stipulations of its delivery. In addition, the commenter stated that it would be very difficult for CMS to monitor compliance with how hospices are portraying the survey and described the survey as cumbersome for bereaved families to complete.

Response: The Hospice CAHPS Survey consists of a total of 47

questions, some of which are only asked when the patient received services in a specific setting. The Hospice CAHPS Survey has fewer questions than NHPCO's well-known Family Evaluation of Hospice Care (FEHC) survey, which has 54 items. We offer a 36-page document on the CAHPS Survey Web site that contains survey materials (*www.hospicecahpssurvey.org*). The document packages three copies of the questionnaire, each set up for a different optical scanning program. This is offered for the convenience of the survey vendors. Vendors will use only one of these versions. In addition, the file includes some sample letters for vendors' use. We have implemented detailed specifications for the survey vendors to follow. This ensures standardization of survey administration procedures across vendors. Standardization is important for accurate data quality and to ensure that the data from different vendors is comparable for public reporting. While it is true that we have no way to monitor the way hospices are portraying the survey, we offer guidelines in the Quality Assurance Guidelines manual on the survey Web site (*www.hospicecahpssurvey.org*). We rely on the professionalism of the providers to cooperate with the survey's requirements.

The commenter also states that the survey is burdensome for bereaved families to complete. We thank the commenters for their comments; we have not received complaints from respondents regarding the survey being burdensome. Responses are voluntary and at the discretion of the person receiving the survey. If they find the survey too burdensome, they simply do not need to respond.

Comment: A few commenters stated that it is unclear whether public reporting will use only the eligible HIS quality measures or will also use the Hospice CAHPS results. Commenters claim that the inclusion of Hospice CAHPS results is essential if Hospice Compare is to provide a meaningful reflection of hospice care quality.

Response: We thank the commenters for their comments. We are currently building the infrastructure for the new Hospice Compare site and are evaluating the best method to include both the Hospice Item Set measures and the results of the Hospice CAHPS Survey.

Comment: One commenter made the point that, for smaller hospices, Hospice CAHPS data is likely to be more vulnerable to variations numerator size and variability than comparable data for larger hospices.

Response: We agree that smaller hospices may be subject to greater variability than large ones. We plan to report an eight-quarter rolling average for Hospice CAHPS public reporting. For the initial report, we may include fewer quarters, but we will build up to eight quarters and continue on an ongoing basis. These plans are intended to counterbalance concerns about variability of the data while at the same time including as many hospices as possible on the Compare site.

Comment: One commenter recommended that CMS conduct analysis to determine how CAHPS results are affected by survey eligibility requirements and response rates. Specifically, they express concern about the relationship between Hospice CAHPS data and the data that would be obtained if survey eligibility rules were modified.

Response: We thank the commenter for their comments. When a sample is taken, it is a random sample to represent the care of all eligible hospice patients. We do exclude patients who have been in hospice care for fewer than 48 hours since their caregivers do not have enough experience to evaluate the care provided by the hospice. We intend to conduct a variety of special and ongoing analyses of Hospice CAHPS data, as well as other related data available to the agency, including analyses of how non-responders differ from responders to determine if we need to control for non-response bias. Generally, the adjustment is already completed for differences in the mix of patients across providers also controls for any non-response bias. We will, however, continue to monitor how eligibility requirements and response rates impact the character of the data reported and whether changes in requirements need to be made.

Comment: A few commenters commented that hospices not included in public reporting might be disadvantaged.

Response: As mentioned previously, we are aware that hospices might want to be included in the Hospice Compare Web site. We are increasing the number of quarters included in the rolling average that will be reported on the public reporting site. The goal of this process is to make it possible for a larger proportion of hospices to be included on the site, while at the same time limiting the variability of the results for smaller hospices.

Comment: One commenter requested that CMS use two individual questions from the survey, the hospice rating item and the ''willingness to recommend'' item, on the Hospice Compare Web site.

Response: We plan to include both the hospice rating question and the willingness to recommend question as part of the Hospice CAHPS data reported on Hospice Compare.

Final Action: After consideration of comments, we are finalizing our proposals that hospices that receive their CCN after January 1, 2017 for the FY 2019 APU and January 1, 2018 for the FY 2020 APU are exempted from the Hospice CAHPS® requirements due to newness.

10. HQRP Reconsideration and Appeals Procedures for the FY 2017 Payment Determination and Subsequent Years

In the FY 2015 Hospice Wage Index final rule (79 FR 50496), we notified hospice providers on how to seek reconsideration if they received a noncompliance decision for the FY 2016 payment determination and subsequent years. 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 period.

We clarified that any hospice that wishes to submit a reconsideration request must do so by submitting an email to CMS containing all of the requirements listed on the HQRP Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Reconsideration-Requests.html*. Electronic email sent to *HospiceQRPReconsiderations@cms.hhs.gov* is the only form of submission that will be accepted. Any reconsideration requests received through any other channel including the United States Postal Service or phone will not be considered as a valid reconsideration request. We codified this process at § 418.312(h). In addition, we codified at § 418.306(b)(2) 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 for that FY and solicited comments on all of the proposals and the associated regulations text at § 418.312 and in § 418.306 in section VI. Official instructions regarding the payment reduction reconsideration process can be located under the Regulations and Guidance, Transmittals, 2015 Transmittals Web site at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2015-Transmittals-Items/*

R52QRI.html?DLPage=1&DLEntries=10&DLSort=4&DLSortDir=descending.

In the past, only hospices found to be non-compliant with the reporting requirements set forth for a given payment determination received a notification from CMS of this finding along with instructions for requesting reconsideration in the form of a United States Postal Service (USPS) letter. In the FY 2016 Hospice Wage Index final rule (80 FR 47198), we stated that we would use the QIES CASPER reporting system as an additional mechanism to communicate to hospices regarding their compliance with the reporting requirements for the given reporting cycle. We will implement this additional communication mechanism via the QIES CASPER timeliness compliance reports referenced in section III.C.7e of this final rule. As stated in section III.C.7e of the rule, these QIES CASPER reports will be automated reports that hospices will be able to generate at any point in time to determine their preliminary compliance with HQRP requirements, specifically, the timeliness compliance threshold for the HIS. We believe the QIES CASPER timeliness compliance reports meet CMS's intent of developing a method to communicate as quickly, efficiently, and broadly as possible with hospices regarding their preliminary compliance with reporting requirements. We will continue to send notification of noncompliance via delivery of a letter via the United States Postal Service. Requesting access to the CMS systems is performed in 2 steps. Details are provided on the QIES Technical Support Office Web site at *https://www.qtso.com/hospice.html.* Providers may access the CMS QIES Hospice Users Guides and Training by going to the QIES Technical Support Office Web site and selecting Hospice and then selecting the CASPER Reporting Users Guide at *https://www.qtso.com/hospicetrain.html.* Additional information about how to access the QIES CASPER reports will be provided prior to the availability of these new reports.

We proposed to disseminate communications regarding the availability of hospice compliance reports in CASPER files through CMS HQRP communication channels, including postings and announcements on the CMS HQRP Web site, MLN eNews communications, national provider association calls, and announcements on Open Door Forums and Special Open Door Forums. We further proposed to publish a list of hospices who successfully meet the reporting requirements for the applicable payment determination on the CMS HQRP Web site *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/index.html.* We proposed updating the list after reconsideration requests are processed on an annual basis. We clarified that the published list of compliant hospices on the CMS HQRP Web site would include limited organizational data, such as the name and location of the hospice. Finalizing the list of compliant providers for any given year is most appropriately done after the final determination of compliance is made. It is our intent for the published list of compliant hospices to be as complete and accurate as possible, giving recognition to all providers who were compliant with HQRP requirements for that year. Finalizing the list after requests for reconsideration are reviewed and a final determination of compliance is made allows for a more complete and accurate listing of compliant providers than developing any such list prior to reconsideration. Developing the list after the final determination of compliance has been made allows providers whose initial determination of noncompliance was reversed to be included in the list of compliant hospices for that year. We believe that finalizing the list of compliant hospices annually after the reconsideration period will provide the most accurate listing of hospices compliant with HQRP requirements.

11. Public Display of Quality Measures and Other Hospice Data for the HQRP

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. Such procedures shall ensure that a hospice program has the opportunity to review the data that is to be made public for the hospice program prior to such data being made public. The Secretary shall report quality measures that relate to hospice care provided by hospice programs on the CMS Web site.

We recognize that public reporting of quality data is a vital component of a robust quality reporting program and are fully committed to developing the necessary systems for transparent 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. Hospices have been required to use a standardized data collection approach (HIS) since July 1, 2014. Data from July 1, 2014 onward is currently being used to establish the scientific soundness of the quality measures prior to the onset of public reporting of the 7 quality measures implemented in the HQRP. We believe it is critical to establish the reliability and validity of the quality measures prior to public reporting to demonstrate the ability of the quality measures to distinguish the quality of services provided. To establish reliability and validity of the quality measures, at least four quarters of data will be analyzed. Typically, the first 1 or 2 quarters of data reflect the learning curve of the facilities as they adopt standardized data collection procedures; these data often are not used to establish reliability and validity. We began data collection in CY 2014; the data from CY 2014 for Quarter 3 (Q3) was not used for assessing validity and reliability of the quality measures. We analyzed data collected by hospices during Quarter 4 (Q4) CY 2014 and Q1 through Q3 CY 2015. Preliminary analyses of HIS data show that all 7 quality measures that can be calculated using HIS data are eligible for public reporting (NQF #1634, NQF #1637, NQF #1639, NQF #1638, NQF #1641, modified NQF #1647, NQF #1617). Based on analyses conducted to establish reportability of the measures, 71 percent through 90 percent of all hospices would be able to participate in public reporting, depending on the measure. For additional details regarding analysis, we refer readers to the Measure Testing Executive Summary document available on the ''Current Measures'' section of the CMS HQRP Web site: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Current-Measures.html.* Although analyses show that many hospices perform well on the 7 measures from the HIS measure set, the measures still show variation, especially among hospices with suboptimal performance, indicating that these measures are still meaningful for comparing quality of care across hospice providers. In addition to conducting quantitative analysis to establish scientific acceptability of the HIS measures, CMS's measure development contractor conducted interviews with family and caregivers of hospice patients. The purpose of these interviews was to determine what information patients and caregivers would find useful in selecting hospices, as well as gathering input about patient and caregiver experience with hospice

care. Results from these interviews indicate that all 7 HIS quality measures provide consumers with useful information. Interview participants stated that quality measure data would be especially helpful in identifying poor quality outliers that inform beneficiaries, families, caregivers, and other hospice stakeholders.

To inform which of the HIS measures are eligible for public reporting, CMS's measure development contractor, RTI International, examined the distribution of hospice-level denominator size for each quality measure to assess whether the denominator size is large enough to generate the statistically reliable scores necessary for public reporting. This goal of this analysis is to establish the minimum denominator size for public reporting, which is referred to as ''reportability'' analysis. Reportability analysis is necessary since small denominators may not yield statistically meaningful QM scores. Thus, for other quality reporting programs, such as Nursing Home Compare,[35] CMS sets a minimum denominator size for public reporting, as well as the data selection period necessary to generate the minimum denominator size. Reportability analysis showed that calculating and publicly displaying measures based on 12 months of data would allow for sufficient measure denominator size. Having ample denominator size ensures that quality measure scores that are publicly reported are reliable and stable; a minimum sample size of 20 stays is commonly applied to assessment-based quality measures in other reporting programs. The 12-month data selection period produced significantly larger mean and median sample sizes among hospices, which will generate more reliable quality measure scores. Additionally, our analysis revealed that when applying a minimum sample size of 20 stays, using rolling 12 months of data to create QMs would only exclude about 10 percent through 29 percent of hospices from public reporting, depending on the measure. For more information on analyses conducted to determine minimum denominator size and data selection period, we refer readers to the Reportability Analysis Section of the Measure Testing Executive Summary, available on the ''Current Measures'' portion of the CMS HQRP Web site: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Current-Measures.html*.

Based on reportability analysis and input from other stakeholders, we have determined that all 7 HIS measures are eligible for public reporting. Thus, we plan to publicly report all 7 HIS measures on a CMS Compare Web site for hospice agencies. For more details on each of the 7 measures, including information on measure background, justification, measure specifications, and measure calculation algorithms, we refer readers to the HQRP QM User's Manual, which is available on the downloads portion of the Current Measures CMS HQRP Web site: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Current-Measures.html*. Individual scores for each of the 7 HIS measure scores would be reported on a new publicly available CMS Hospice Compare Web site. Current reportability analysis indicates that a minimum denominator size of 20 based on 12 rolling months of data would be sufficient for public reporting of all HIS quality measures. Under this methodology, hospices with a quality measure denominator size of smaller than 20 patient stays would not have the quality measure score publicly displayed since a quality measure score on the basis of small denominator size may not be reliable. We will continue to monitor quality measure performance and reportability and will adjust public reporting methodology in the future if needed.

Reportability analysis is typically conducted on a measure-by-measure basis. We would like to clarify that any new measure adopted as part of the HQRP will undergo reportability analysis to determine: (1) If the measure is eligible for public reporting; and (2) the data selection period and minimum denominator size for the measure. Results of reportability analyses conducted for new measures will be communicated through future rulemaking.

In addition, the Affordable Care Act requires that reporting be made public on a CMS Web site and that providers have an opportunity to review their data prior to public reporting. We are currently developing the infrastructure for public reporting and will provide hospices an opportunity to review their quality measure data prior to publicly reporting information about the quality of care provided by Medicare-certified hospice agencies throughout the nation. These quality measure data reports or ''preview reports'' will be made available in the CASPER system prior to public reporting and will offer providers the opportunity to review their quality measure data prior to public reporting on the CMS Compare Web site for hospice agencies. Under this process, providers would have the opportunity to review and correct data they submit on all measures that are derived from the Hospice Item Set. Reports would contain the provider's performance on each measure calculated based on HIS submission to the QIES ASAP system. The data from the HIS submissions would be populated into reports with all data that have been submitted by the provider. CMS will post preview reports with sufficient time for providers to be able to submit, review data, make corrections to the data, and view their data. Providers are encouraged to regularly evaluate their performance in an effort to ensure the most accurate information regarding their agency is reflected.

We also plan to make available additional provider-level feedback reports, which are separate from public reporting and will be for provider viewing only, for the purposes of internal provider quality improvement. As is common in other quality reporting programs, quality reports would contain feedback on facility-level performance on quality metrics, as well as benchmarks and thresholds. For the CY 2015 Reporting Cycle, several new quality reporting provider participation reports were made available in CASPER. Providers can access a detailed list and description of each of the 12 reports currently available to hospices on the QIES Web site, under the Training & Education Selections, CASPER Reporting Users Guide at *https://www.qtso.com/hospicetrain.html.* We anticipate that providers would use the quality reports as part of their Quality Assessment and Performance Improvement (QAPI) efforts.

Furthermore, to meet the requirement for making such data public, we are developing a CMS Hospice Compare Web site, which will provide valuable information regarding the quality of care provided by Medicare-certified hospice agencies throughout the nation. Consumers would be able to search for all Medicare approved hospice providers that serve their city or zip code (which would include the quality measures and CAHPS® Hospice Survey results) and then find the agencies offering the types of services they need, along with provider quality information. Based on the efforts necessary to build the infrastructure for public reporting, we anticipate that public reporting of the eligible HIS quality measures on the CMS Compare Web site for hospice

[35] ''CMS Nursing Home Quality Initiative—Centers for Medicare . . .'' 2011. 25 Jan. 2016 *https://www.cms.gov/nursinghomequalityinits/45_nhqimds30trainingmaterials.asp*.

agencies will begin sometime in the spring/summer of CY 2017. To help providers prepare for public reporting, we will offer opportunities for stakeholder engagement and education prior to the rollout of a Hospice Compare site. We will offer outreach opportunities for providers through the MLN eNews, Open Door Forums and Special Open Door Forums; we will also post additional educational materials regarding public reporting on the CMS HQRP Web site. Finally, we will offer training to all hospice providers on the systems and processes for reviewing their data prior to public reporting; availability of trainings will be communicated through the regular CMS HQRP communication channels, including postings and announcements on the CMS HQRP Web site, MLN eNews communications, national provider association calls, and announcements on Open Door Forums and Special Open Door Forums.

Like other CMS Compare Web sites, the Hospice Compare Web site will, in time, feature a quality rating system that gives each hospice a rating of between 1 and 5 stars. Hospices will have prepublication access to their own agency's quality data, which enables each agency to know how it is performing before public posting of data on the Hospice Compare Web site. Public comments regarding how the rating system would determine a hospice's star rating and the methods used for calculations, as well as a proposed timeline for implementation will be announced via regular CMS HQRP communication channels, including postings and announcements on the CMS HQRP Web site, MLN eNews communications, provider association calls, and announcements on Open Door Forums and Special Open Door Forums. We will announce the timeline for development and implementation of the star rating system in future rulemaking.

Lastly, as part of our ongoing efforts to make healthcare more transparent, affordable, and accountable for all hospice stakeholders, the HQRP is prepared to post hospice data on a public data set, the Data.Medicare.gov Web site, and directory located at *https://data.medicare.gov.* This site includes the official datasets used on the Medicare.gov Compare Web sites provided by CMS. In addition, this data will serve as a helpful resource regarding information on Medicare-certified hospice agencies throughout the nation. In an effort to move toward public reporting of hospice data, we will initially post demographic data of hospice agencies that have been registered with Medicare. This list will include high-level demographic data for each agency including, provider name, address, phone numbers, ownership type, CMS Certification Number (CCN), profit status, and date of original CMS certification. The posting of this new hospice data directory occurred on June 14, 2016. Information can be located at *https://data.medicare.gov/data/hospice-directory*. Additional details regarding hospice datasets will be announced via regular CMS HQRP communication channels, including postings and announcements on the CMS HQRP Web site, MLN eNews communications, national provider association calls, and announcements on Open Door Forums and Special Open Door Forums. In addition, we have provided the list of CASPER/ASPEN and Regional Office coordinators in the event the Medicare-certified agency is either not listed in the database or the characteristics/administrative data (name, address, phone number, services, or type of ownership) are incorrect or have changed. To continue to meet Medicare enrollment requirements, all Medicare providers are required to report changes to their information in their enrollment application as outlined in the Provider-Supplier Enrollment Fact Sheet Series located at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/MedEnroll_InstProv_FactSheet_ICN903783.pdf.*

Comment: CMS received several comments that were supportive of public reporting of hospice quality measures. Commenters noted that they were in favor of CMS's efforts to publicly report hospice quality data to support the timely and transparent reporting of HQRP data. One commenter shared that public reporting of valid and reliable quality data demonstrates value, underpins compliance, and provides structure for hospice care. Several commenters did have suggestions, recommendations, and concerns about specific aspects of the public display of hospice quality measure data. These specific comments are summarized below.

Response: We appreciate the commenters' support of public reporting of hospice quality measures. We address commenters' specific concerns with respect to public reporting reports below.

Comment: CMS received a few comments expressing concerns that many hospice providers have high scores on the current HIS measures and some Hospice CAHPS measures. The potential lack of variation in scores for these measures may make differentiating between hospice providers' performance challenging for consumers. Given the limited range of scores, commenters thought that presenting data as rankings or percentiles may present results in a way that does not provide valuable information to consumers. One commenter suggested that CMS consider risk-adjusting quality measures reported on the Compare Web site.

Response: We agree that all publicly reported data should be presented in a manner that is meaningful and understandable to the general public. We will take steps and use recognized practices to ensure that any publicly reported data is displayed in an appropriate and meaningful manner. We are developing the format and content for public display of quality measure data on the Hospice Compare site. We appreciate the commenters input on how to most meaningfully display quality measure data and will take these suggestions into consideration as we finalize the format of public reporting (that is, whether to report scores or the percentiles for each quality measure (QM)).

Regarding commenters' concerns about the lack of variation in current HIS measure scores, the overall distribution and variability of the seven currently adopted HIS QMs is an indicator that most hospices are providing the required and recommended care to the majority of the patients around hospice admission, demonstrating overall high quality of care. However, the seven measures demonstrate room for improvement. Analysis conducted by our measure development contractor demonstrates that a low percentage of hospices have perfect scores for most measures and a small percentage of hospices have very low scores. We believe this is valuable and important information to communicate to consumers as well as to providers to motivate quality improvement. Additionally, we are working on the specific format for publicly reporting these 7 QMs and will take commenters' suggestions into consideration. We agree that given the skewed distribution, presenting hospice scores in formats like percentiles may provide misleading information. Presenting hospices' quality scores may provide information that is more straightforward for consumers and providers. Finally, input that we have received from hospice caregivers will also inform our strategy for public reporting of quality measure data. Our measure development contractor interviewed hospice caregivers about public display of quality data and what

types of data would be most meaningful to consumers. In these interviews, respondents supported the continued data collection and reporting of the individual HIS measures, noting that information on the individual measures is valuable to consumers. Respondents also noted that although overall performance on the 7 HIS measures is high, public display of these scores would still be meaningful as a way to identify low-performing hospices.

With respect to the commenter's suggestion to risk adjust quality measures reported on the Hospice Compare Web site, we would like to point out that both the current HIS measure set (NQF #1634, NQF #1637, NQF #1639, NQF #1638, NQF #1617, NQF #1641 and NQF #1647) and Hospice CAHPS quality measures are currently under review by the National Quality Forum (NQF) for maintenance endorsement and endorsement, respectively. NQF criteria for review and endorsement includes consideration of risk adjustment. As stated in section III.C.3 of this rule, it is CMS's intent to implement endorsed quality measures, using the specifications as endorsed by the NQF.

Comment: A few commenters suggested that CMS provide quarterly benchmark data to hospices for at least 1 year in advance of publicly reporting the data. Commenters believed the benchmark data would demonstrate to individual hospices how they perform compared to all hospices on the existing measures and allow opportunity for improvement prior to the onset of public reporting. One commenter shared that hospices have found stable benchmark scores for comparison to be far more useful for setting goals and tracking performance improvement.

Response: We appreciate the commenters' suggestion to provide quarterly benchmark data. As we previously stated, we plan to make available additional provider-level feedback reports prior to public reporting; these reports will help hospices with their quality assessment and performance improvement efforts. As is common in other quality reporting programs, these reports would provide feedback on facility-level performance on quality metrics, as well as national benchmarks. Additionally, national means of the HIS quality measures, based on Q4 2014 through Q3 2015 HIS data, are reported in the Hospice Quality Reporting Program: Executive Summary of Measure Testing and Validation, available on the ''Current Measures'' portion of the CMS HQRP Web site: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Current-Measures.html.*

Comment: One commenter urged CMS to not only showcase quality measures from HIS and Hospice CAHPS, but also demonstrate the scope and level of services provided by different hospice programs. The commenter stated that while hospices are required to be able to provide certain services, patient and family access to these services varies, especially for the non-clinical services. In addition, this commenter stated that there is variation in how well hospices meet the requirements. Moreover, the commenter stated that and a lack of enforcement allowed lower quality programs to minimally comply with requirements, if at all. For example, many hospice programs send mailings to families on bereavement; while this technically meets the bereavement requirements under the benefit; other hospices offer and provide robust, individualized bereavement support. The commenter thought that it would be important for consumers to have information about these services to help them select a hospice.

Response: We appreciate the commenter's recommendation to report quality metrics and hospice information beyond HIS and Hospice CAHPS measures. We recognize that information regarding the scope and level services provided would be valuable to consumers and hospice providers; however, we note that such information may not be readily available to us through billing records or other reporting mechanisms, and we are cognizant of the burden additional reporting could place on providers. We will take this recommendation into consideration as we move forward with the development for future HQRP measures.

Comment: The majority of commenters supported the minimum denominator size for public reporting. Although commenters were generally supportive of this requirement, some commenters had concerns about the possible negative impact on small hospices for which quality information is not included in public reporting due to not meeting the minimum denominator size. Commenters noted that hospices who do not meet the threshold of 20 stays for the HIS-based QMs or the size exemption for Hospice CAHPS® Survey, which is less than 50-survey eligible patients in the previous year, would not be included in all or part of public reporting. Commenters raised concerns that a lack of displayed data on Hospice Compare may disadvantage these smaller providers. Commenters believed that consumers using Hospice Compare to search for a provider might disregard hospices that do not have some or all of their data displayed due to size issues, and that, in turn, consumers may be more likely to seriously consider only those hospices for which quality information is presented. One commenter expressed concerns that there are some important statistical considerations, in addition to denominator size, that should be addressed in creating a means for public display of hospice quality data. Specifically, the commenter noted that a small denominator that meets the minimum denominator size is more sensitive to fluctuations in the numerator than a large denominator. Smaller hospices are likely to have smaller denominators and are more vulnerable to numerator size and variability than larger hospices. The commenters suggested that CMS create a means to counterbalance the potential negative consequences for those hospices for which quality information is not included in public reporting.

Response: We thank the commenters for their support of our recommendation to set a minimum denominator size for public reporting. We appreciate commenters sharing concerns regarding the possible negative impact on small hospices. To establish the minimum denominator size, we examined the national hospice-level denominator size for the HIS quality measures. The determination of the minimum denominator size balanced the necessity of yielding statistically meaningful QM scores and the goal of allowing as many hospices to have their quality measure scores publicly displayed as possible. To be consistent with other quality reporting programs' public reporting policies, we set a minimum denominator size for public reporting of quality measures, as well as the data selection period necessary to generate the minimum denominator size. The minimum denominator size is determined based on a hospice's patient stays over a 12-month period. Analysis conducted by RTI International shows that only about 10 percent of hospices would not have accumulated 20 patient stays to have any HIS quality measure publicly displayed. RTI's analysis also shows that quality measures calculated based on 12 months of data are stable and robust against fluctuation. These results were summarized in the Measure Testing Executive Summary document referenced in this section of the rule and posted on the ''Current Measures'' portion of the CMS HQRP Web site:

https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Current-Measures.html. On the Hospice Compare Web site, CMS plans to indicate in some manner (for example, through a footnote or some other statement) instances where data is not displayed due to denominator size issues. We believe this will minimize any potential negative impact on small providers and signal to consumers that in such instances, the lack of data is a result of the hospice having too few admissions to allow for reporting of a valid quality measure, and is not in and of itself an indicator of hospice quality. Finally, we will take the commenters suggestion regarding creating a means to counterbalance the potential negative consequences for small hospices as we move forward with the development and launch of Hospice Compare.

Comment: CMS received several comments regarding data sources that would be included in the launch of Hospice Compare. Overall, commenters offered two main considerations. First, commenters brought up concerns about the limitations of HIS data for consumer decision-making. Second, commenters requested clarification from and encouraged CMS to include Hospice CAHPS data in the launch of Hospice Compare. Regarding the first concern, commenters noted that HIS data alone might provide inadequate information to aid in consumer decision-making. Commenters noted that all HIS measures are process of care measures and, as such, do not address important issues such as whether the patient/family was treated with respect or felt supported by the hospice team. They strongly recommended that the Hospice CAHPS results be reported along with HIS measures to provide consumers with the most meaningful and comprehensive picture of quality of care. Finally, commenters encouraged CMS to provide appropriate disclaimers about the hospice quality data and information, outlining the limitations of the data and its utility.

Response: We appreciate the commenters' feedback on public reporting of HIS and Hospice CAHPS data. We agree with commenters that HIS and Hospice CAHPS data are complementary and, together, provide a more meaningful and comprehensive view of quality of care provided by hospices. As noted in section III.C.9 of this rule, we plan to include both HIS and Hospice CAHPS data in the launch of Hospice Compare. Reporting both data sources will address commenters' concerns and mirrors the approach for public reporting used in other CMS Compare sites. We will communicate additional plans for the public reporting of hospice quality data through the usual CMS HQRP communication channels, including postings and announcements on the CMS HQRP Web site, MLN eNews communications, national provider association calls, and announcements on Open Door Forums and Special Open Door Forums.

Comment: A few commenters expressed concerns that consumers will not understand the difference between a process measure and an outcome measure and be able to draw conclusions about the experience of hospice care from just the composite process measure. One commenter shared that CMS needs to provide education and resources to help the public understand what the measures mean.

Response: We agree that any publicly reported data should be presented in a manner that is meaningful and understandable by the public. We intend to take steps and use recognized practices to ensure that any publicly reported data is displayed in an appropriate and meaningful manner. We intend to work with our Web site development contractor to ensure that the Hospice Compare site has been tested for usability, readability, and navigation, and that consumers and stakeholders are continuously involved and have opportunities for input throughout the development process. We will write in plain language, with awareness of variations in health and general literacy, and solicit input from key stakeholders and technical experts in the development of the presentation of publicly available quality data.

Comment: CMS received a few comments regarding concerns about the publicly reported HIS measures because they are constructed using HIS data that is self-reported by hospice providers. Commenters had concerns about the validity of this data and encouraged CMS to determine methods to monitor the veracity of the data being submitted. Commenters noted that the launch of Hospice Compare might create perverse incentives for hospices to submit false data to avoid unfavorable scores being publicly reported on the Compare Web site.

Response: We acknowledge commenters' concerns regarding the validity of self-reported HIS measures. Publicly reported quality measure data relies on the submission of valid and reliable data at the patient level. Our measure development contractor conducts ongoing testing and validation of the quality measure data to identify data irregularities and trends. We will consider additional validation processes for future rulemaking cycles.

Comment: CMS received a few comments expressing providers' desire to review data prior to publication. One commenter inquired about the process for correcting data errors.

Response: We appreciate the commenters' interest in reviewing data prior to public reporting. We would like to take this opportunity to clarify the processes available to providers for reviewing and making changes to HIS data, and for previewing QM scores prior to public display. First, as outlined in the HIS Manual, providers have the opportunity to make corrections to HIS data through HIS record modification and inactivation processes. HIS record modifications and inactivations are available if a provider finds an error in HIS data that has been submitted and accepted by the QIES ASAP system. Further details on processes for modifications and inactivations are available in Chapter 3 of the HIS Manual, available on the HIS portion of the CMS HQRP Web site: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Hospice-Item-Set-HIS.html.* It is vital for providers to correct any errors in HIS data to ensure information in the QIES ASAP system accurately reflects the patient's hospice record and HIS-related care processes delivered to the patient; this initial corrections process for errors in HIS data helps ensure QM scores and any publicly displayed data are accurate.

In addition to modification and inactivation processes available in QIES ASAP, as we previously stated, we are currently developing the infrastructure to provide hospices with the opportunity to view their quality measure data via CASPER provider-level feedback reports. These internal provider-level feedback reports will provide hospices an initial opportunity to review QM *score* data in CASPER. Provider-level feedback reports are confidential and separate from the public reporting processes. The purpose of provider-level feedback reports is to provide hospices with QM score data that can be used at the individual facility level and for internal quality improvement. We are planning for release of the QM provider-level feedback reports sometime in December of 2016. Availability of the new CASPER QM reports will be communicated to providers through the usual CMS HQRP communication channels, including postings and announcements on the CMS HQRP Web site, MLN eNews communications,

national provider association calls, and announcements on Open Door Forums and Special Open Door Forums.

Finally, we will ensure providers have the opportunity to preview QM score data to be displayed on Hospice Compare, prior to public posting of the data. Prior to public reporting, quality measure data ''preview'' reports will be made available in CASPER system. Hospices will have a 30-day preview period prior to public display during which they can preview the performance information on their measures that will be made public. The ''preview'' reports will be made available using the Certification and Survey Provider Enhanced Reporting (CASPER) System because hospices are familiar with this system. In line with other PAC QRPs, hospices will have 30 days to review this information, beginning from the date on which they can access the preview report. Corrections to the underlying data would not be permitted during this time; however, hospices would be able to ask for a correction to their measure calculations during the 30-day preview period. If we determine that the measure, as it is displayed in the preview report, contains a calculation error, we would suppress the data on the public reporting Web site, recalculate the measure and publish the corrected rate at the time of the next scheduled public display date. This process is consistent with informal processes used in the Hospital IQR and other PAC programs. Technical details for how and when providers may contest their measure calculations, as well as the process for submitting a suppression request will be conveyed through the usual CMS HQRP communication channels.

Comment: CMS received a comment in support of the initiative to make available additional provider-level feedback reports in the CASPER reporting system. The commenter requested CMS consider additional reports to display quality metric scores that would be available 2 days after HIS records are submitted and accepted by the QIES ASAP system.

Response: We appreciate the commenter's support of the initiative to provide additional provider-level feedback reports in CASPER. We agree that providing timely feedback to hospice providers is a critical step in the process of quality improvement since providers need data about their performance to inform QAPI and other performance improvement efforts. We will continue to refine the provider-level feedback reports to make timely data available to providers within the CASPER system.

Comment: One commenter expressed concerns regarding consumers leaving anonymous negative comments or grievances on the Hospice Compare Web site. The commenter noted that there is no manner for the hospice to respond to or rebut negative comments or grievances.

Response: We would like to thank the commenters for taking the time to convey their concerns regarding consumers leaving anonymous negative comments or grievances on the Hospice Compare Web site. Consumers will only be able to search for hospice providers and review quality data; they will not be able to post comments or grievances on the CMS Hospice Compare Web site.

Comment: Though commenters were generally supportive of public reporting of quality data, several commenters expressed concerns over the methodology for the star rating system to be used in the future as part of the Hospice Compare Web site. One commenter urged CMS to be conservative and cautious about the use of star ratings when applied to Hospice CAHPS data because patient and family experience with care data is typically positively skewed. A few commenters cautioned CMS against evaluating hospice providers along a bell curve rather than on a grading scale when developing star ratings for hospice providers. They shared that the use of a bell curve creates confusion for consumers and may misrepresent the quality of the care provided by hospices. Commenters encouraged CMS to develop a star-rating methodology that incorporates both HIS and Hospice CAHPS data. A few commenters suggested that CMS provide sufficient time for stakeholders to review the star ratings model. One commenter voiced concerns about star-rating methodologies used in other care settings and recommended CMS take into consideration lessons learned about unintended consequences when developing the hospice star rating system. One commenter recommended that CMS take a criterion approach to constructing the CMS Hospice Compare Web site and determining the methodology to be used for calculating star ratings. Another commenter stated that any star rating system developed should reflect care provided by the entire interdisciplinary team and should be risk adjusted to account for individualized care, short lengths of stay and patient right to refuse care.

Response: We appreciate the thorough and detailed input on the development of a Hospice Compare Web site and the future development of a star rating system for hospices. We would like to assure commenters that it is of paramount concern to develop a star rating methodology that is valid, is reliable, and presents quality data that is meaningful to stakeholders. As with the development of star methodology in other care programs, we will allow continued opportunities for the provider community and other stakeholders to comment on and provide input to the proposed rating system. In addition to regular HQRP communication channels, we will solicit input from the public regarding star methodology through special listening sessions, invitation to submit comments via a Help Desk mailbox, Open Door Forums, a Technical Expert Panel, and other opportunities. Additionally, we will benefit from lessons learned from the development and implementation of star ratings in other QRPs to help guide the hospice star rating initiative.

D. The Medicare Care Choices Model

We want to remind the provider community that the Medicare Care Choices Model (MCCM) is testing a new option for Medicare beneficiaries with certain advanced diseases to receive hospice-like support services from MCCM hospices while receiving care from other Medicare providers for their terminal condition. This 5 year model is being tested to encourage greater and earlier use of the Medicare and Medicaid hospice benefit to determine whether it can improve the quality of life and care received by Medicare beneficiaries, increase beneficiary, family, and caregiver satisfaction, and reduce Medicare or Medicaid expenditures. Participation in the model is limited to Medicare and dual eligible beneficiaries with advanced cancers, chronic obstructive pulmonary disease, congestive heart failure, and Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome who qualify for the Medicare or Medicaid hospice benefit and meet the eligibility requirements of the model. The model includes more than 130 hospices from 39 states across the country and is projected to serve 100,000 beneficiaries by 2020. The first cohort of MCCM participating hospices began providing services under the model in January 2016, and the second cohort will begin to provide services under the model in January 2018. The last patient will be accepted into the model 6 months before the December 31, 2020 model end date.

For more information, see the MCCM Web site: *https://innovation.cms.gov/initiatives/Medicare-Care-Choices/.*

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. 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 solicited public comment on each of the following information collection requirements (ICRs).

A. Information Collection Requirements

Section 1814(i)(5)(C) of the Act requires that each hospice submit data to the Secretary on quality measures specified by the Secretary. Such data must be submitted in a form, manner, and at a time specified by the Secretary. 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).

Data for the aforementioned 7 measures is collected via the HIS. Data collection for the 7 NQF-endorsed measures via the HIS V1.00.0 was approved by the Office of Management and Budget April 3, 2014 (OMB control number 0938–1153—Hospice Quality Reporting Program). As outlined in this final rule, we continue data collection for these 7 NQF-endorsed measures.

In this final rule, we finalized the implementation of two new measures. The first measure is the Hospice and Palliative Care Composite Process Measure—Comprehensive Assessment at Admission. Seven individual care processes will be captured in this composite measure, which includes the six NQF-endorsed quality measures and one modified NQF-endorsed quality measure currently implemented in the HQRP. Thus, the Hospice and Palliative Care Composite Process quality measure will use the current HQRP quality measures as its components. The data source for this measure will be currently implemented HIS items that are currently used in the calculation of the 7 component measures. Since the measure is a composite measure created from components, which are currently adopted HQRP measures, no new data collection will be required; data for the composite measure will come from existing items from the existing 7 HQRP component measures. CMS will begin calculating this measure using existing data items, beginning April 1, 2017; this means patient admissions occurring on or after April 1, 2017 will be included in the composite measure calculation.

The second measure is the Hospice Visits when Death is Imminent Measure Pair. Data for this measure will be collected via the existing data collection mechanism, the HIS. Four new items will be added to the HIS-Discharge record to collect the necessary data elements for this measure. CMS expects that data collection for this quality measure via the 4 new HIS items will begin no earlier than April 1, 2017. Thus, under current CMS timelines, hospice providers will begin data collection for this measure for patient admissions and discharges occurring on or after April 1, 2017.

The HIS V2.00.0 will fulfill the data collection requirements for the 7 currently adopted NQF measures and the 2 new measures. The HIS V2.00.0 contains:

- All items from the HIS V1.00.0, which are necessary to calculate the 7 adopted NQF measures (and thus the composite measure), plus the HIS V1.00.0 administrative items necessary for patient identification and record matching,
- One new item for measure refinement of the existing measure NQF #1637 Pain Assessment,
- New items to collect data for the Hospice Visits when Death is Imminent measure pair,
- New administrative items for patient record matching and future public reporting of hospice quality data.

Hospice providers will submit an HIS-Admission and an HIS-Discharge for each patient admission. Using HIS data for assessments submitted October 1, 2014 through September 30, 2015, we have estimated that there will be approximately 1,248,419 discharges across all hospices per year and, therefore, we would expect that there should be 1,248,419 Hospice Item Sets (consisting of one admission and one discharge assessment per patient) submitted across all hospices yearly. Over a three-year period, we expect 3,745,257 Hospice Item Sets across all hospices. There were 4,259 certified hospices in the U.S. as of January 2016; [36] we estimate that each individual hospice will submit on average 293 Hospice Item Sets annually, which is approximately 24 Hospice Items Sets per month or 879 Hospice Item Sets over 3 years.

The Hospice Item Set consists of an admission assessment and a discharge assessment. As noted above, we estimate that there will be 1,248,419 hospice admissions across all hospices per year. Therefore, we expect there to be 2,496,838 Hospice Item Set assessment submissions (admission and discharge assessments counted separately) submitted across all hospices annually, which is 208,070 across all hospices monthly, or 7,490,514 across all hospices over three years. We further estimate that there will be 586 Hospice Item Set submissions by each hospice annually, which is approximately 49 submissions monthly or 1,759 submissions over three years.

For the Admission Hospice Item Set, we estimate that it will take 14 minutes of time by a clinician, such as a Registered Nurse, at an hourly wage of $67.10 [37] to abstract data for Admission Hospice Item Set. This would cost the facility approximately $15.66 for each admission assessment. We further estimate that it will take 5 minutes of time by clerical or administrative staff person, such as a medical data entry clerk or medical secretary, at an hourly wage of $32.24 [38] to upload the Hospice Item Set data into the CMS system. This would cost each facility approximately $2.69 per assessment. For the Discharge Hospice Item Set, we estimate that it

[36] Quality Improvement and Evaluation System (QIES) List of Hospice Providers, January 2016.

[37] The adjusted hourly wage of $67.10 per hour for a Registered Nurse was obtained using the mean hourly wage from the U.S. Bureau of Labor Statistics, $33.55. This mean hourly wage is adjusted by a factor of 100 percent to include fringe benefits. See *http://www.bls.gov/oes/current/oes291141.htm.*

[38] The adjusted hourly wage of $32.24 per hour for a Medical Secretary was obtained using the mean hourly wage from the U.S. Bureau of Labor Statistics, $16.12. This mean hourly wage is adjusted by a factor of 100 percent to include fringe benefits. See *http://www.bls.gov/oes/current/oes436013.htm.*

will take 9 minutes of time by a clinician, such as a nurse, at an hourly wage of $67.10 to abstract data for Discharge Hospice Item Set. This would cost the facility approximately $10.07. We further estimate that it will take 5 minutes of time by clerical or administrative staff, such as a medical data entry clerk or medical secretary, at an hourly wage of $32.24 to upload data into the CMS system. This would cost each facility approximately $2.69. The estimated cost for each full Hospice Item Set submission (admission assessment and discharge assessment) is $31.10.

We estimate that the total nursing time required for completion of both the admission and discharge assessments is 23 minutes at a rate of $67.10 per hour. The cost across all hospices for the nursing/clinical time required to complete both the admission and discharge Hospice Item Sets is estimated to be $32,111,417 annually, or $96,334,252 over 3 years, and the cost to each individual hospice is estimated to be $7,539.66 annually, or $22,618.98 over 3 years. The estimated time burden to hospices for a medical data entry clerk to complete the admission and discharge Hospice Item Set assessments is 10 minutes at a rate of $32.24 per hour. The cost for completion of the both the admission and discharge Hospice Item Sets by a medical data entry clerk is estimated to be $6,708,171 across all hospices annually, or $20,124,514 across all hospices over 3 years, and $1,575.06 to each hospice annually, or $4,725.17 to each hospice over 3 years.

The total combined time burden for completion of the Admission and Discharge Hospice Item Sets is estimated to be 33 minutes. The total cost across all hospices is estimated to be $38,819,589 annually or $116,458,766 over 3 years. For each individual hospice, this cost is estimated to be $9,114.72 annually or $27,344.16 over 3 years. See Table 18 for breakdown of burden and cost by assessment form.

TABLE 18—SUMMARY OF BURDEN HOURS AND COSTS

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 ($)	Total cost ($)
Hospice Item Set Admission Assessment.	0938–1153	4,259	1,248,419 per year.	0.233 clinician hours; 0.083 clerical hours.	395,333 hours ...	Clinician at $67.10 per hour; Clerical staff at $32.24 per hour.	$22,900,166
Hospice Item Set Discharge Assessment.	0938–1153	4,259	1,248,419 per year.	0.150 clinician hours; 0.083 clerical hours.	291,298 hours ...	Clinician at $67.10 per hour; Clerical staff at $32.24 per hour.	15,919,423
3-year Total	0938–1153	4,259	7,490,514	0.55 hours	2,059,891 hours	Clinician at $67.10 per hour; Clerical staff at $32.24 per hour.	116,458,766

C. Submission of PRA-Related Comments

We have submitted a copy of this final rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by the OMB.

To obtain copies of the supporting statement and any related forms for the collections discussed above, please visit CMS's Web site at *https://www.cms.gov/RegulationsandGuidance/Legislation/PaperworkReductionActof1995/PRAListing.html*, or call the Reports Clearance Office at 410–786–1326.

We invited public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **ADDRESSES** section of this final rule and identify the rule (CMS–1652–F) the ICR's CFR citation, CMS ID number, and OMB control number.

Public Comments Received for PRA Package (CMS Form Number—CMS–R–245)

Comment: CMS received one supportive comment indicating that the additional data sought by CMS for the calculation of the Hospice Visits when Death is Imminent Measure Pair does not represent a significant burden on providers and may result in useful information. Other commenters stated that CMS's burden estimates underestimate the costs of completing the HIS. One commenter stated that the typical admission assessment time is 45 minutes to 1 hour, and that staff travel can significantly increase costs. Another commenter stated that the costs of training and operational processes to support valid data abstraction should be included in the burden estimate.

Response: We thank the commenters for their feedback regarding the burden of the HIS V2.00.0, and the support of the new items used to collect data for the Hospice Visits when Death is Imminent Measure Pair. Regarding the cost estimates for the HIS Admission form, the HIS is a set of data elements that can be used to calculate 7 NQF endorsed quality measures and 2 new measures adopted in this rule. The HIS is not a patient assessment that would be directly administered to the patient and/or family or caregivers during the initial assessment or comprehensive assessment visit. Since the HIS is not intended to replace the initial/comprehensive assessment, the PRA burden estimates, by definition, do not include the time spent assessing the patient. HIS PRA burden estimates are intended to reflect only the time needed to complete HIS items, independent of clinical time spent assessing the patient. Similarly, PRA burden estimates include the Annualized Cost to the Federal Government related to the HIS V2.00.0 for provider training, preparation of HIS V2.00.0 manuals and materials, receipt and storage of data, data analysis, and upkeep of data submission software. In order to mitigate costs of operational processes, providers may use the Hospice Abstraction Reporting Tool (HART) software, which is free to download and use, to collect and maintain facility, patient, and HIS Record information for subsequent submission to the QIES

ASAP system. Burden estimates for completing the HIS data items were based on the HIS V1.00.0 and HIS V2.00.0 pilot tests. We recognize additional activities and efforts will be required to implement and use the HIS V2.00.0 as part of the quality reporting program. We agree that it is important for hospices to learn about and understand the new HIS, and we plan to provide hospices with training resources to facilitate implementation of the HIS.

Comment: One commenter stated that the addition of new items to the HIS Discharge record will require vendor software development and testing, hospice implementation, education and training, and internal validation. The commenter stated that the target implementation date of April 1, 2017 may not provide adequate time for implementation.

Response: We appreciate the commenter's feedback regarding the timeline for implementation and of the HIS V2.00.0. The HIS V2.00.0 is undergoing review as part of a PRA package under OMB number 0938–1153 and will be implemented April 1, 2017. We believe the April 1, 2017 implementation date will allow sufficient time for providers to update their clinical documentation systems and train staff on new HIS items. The timeline for implementation of the HIS V2.00.0 is consistent with the timeline from prior years when the HIS V1.00.0 was implemented. We expect training and implementation activities to take considerably less time for the HIS V2.00.0 compared to the HIS V1.00.0 since the HIS V2.00.0 can capitalize on existing infrastructures used by stakeholders for the HIS V1.00.0 and contains only 17 new item components (compared to the 60 item components that were implemented in the HIS V1.00.0). Moreover, we encourage providers to begin preparations for HIS V2.00.0 implementation as soon as possible. The HIS V2.00.0 is currently available for review by software vendors and hospice providers. Some of the activities that are necessary prior to implementation can be done concurrently. For example, hospice education and training on the new items and data abstraction can be conducted at the same time as vendor development of software.

We are aware of the effort hospices and vendors will have to make to prepare for implementation of the HIS. The HIS pilot showed that implementing the HIS is feasible and that hospices are most likely already collecting the information needed to complete the HIS data items. A draft version of the HIS technical data specifications was posted on the CMS Web site on May 19, 2016. Thus, vendors have been provided with more than adequate time to develop products for their clients. We expect vendors to begin reviewing the draft technical data specifications as soon as they are posted. We encourage vendors to submit questions and comments to the HIS technical email box: *HospiceTechnicalIssues@cms.hhs.gov.* Software vendors should not be waiting for final technical data specifications to be posted to begin development of their own products. Therefore, we believe that vendors have been provided with adequate time and resources to meet the April 1, 2017 implementation date of the HIS. For providers that currently use a vendor-designed software to complete HIS records, if a provider has concerns about the timeliness of release of HIS V2.00.0 items in vendor-designed software, CMS reminds providers that alternative means of completing HIS records (HART software) are available to all providers free of charge. Although electronic submission of HIS records is required, hospices do not need to have an electronic medical record to complete or submit HIS data. In the FY 2014 Hospice Wage Index, final rule (78 FR 48258) we finalized that to complete HIS records providers can use either the HART software, which is free to download and use, or vendor-designed software. HART provides an alternative option for hospice providers to collect and maintain facility, patient, and HIS Record information for subsequent submission to the QIES ASAP system. Once HIS records are complete, electronic HIS files must be submitted to CMS via the QIES ASAP system. Electronic data submission via the QIES ASAP system is required for all HIS submissions; there are no other data submission methods available. Hospices have 30 days from a patient admission or discharge to submit the appropriate HIS record for that patient through the QIES ASAP system. We will continue to make HIS completion and submission software available to hospices at no cost. We provided details on data collection and submission timing under the downloads section of the HIS Web page on the CMS.gov Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-AssessmentInstruments/Hospice-Quality-Reporting/Hospice-Item-Set-HIS.html.*

Comment: One commenter stated that although the burden associated with the HIS assessment may not be unduly burdensome, the collective burden of various reporting requirements makes a large fiscal impact on hospices.

Response: We thank the commenters for taking the time to convey their concerns about the burden and cost of data collection for the HQRP and other regulatory requirements. We attempted to reduce the regulatory burden of our quality reporting programs to the greatest extent possible. The estimated burden for completing the HIS V2.00.0 can be viewed here: (*https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html*). Specifically, CMS estimates 19 minutes per response for the Admission HIS and 14 minutes per response for the Discharge HIS. Details regarding the estimate can be found at *http://cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.* Comments concerning the accuracy of the time estimate(s) or suggestions for improving the HIS can be directed to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4–26–05, Baltimore, Maryland 21244–1850. With respect to the commenter's concern about additional expenses incurred as part of quality reporting, any additional costs incurred as part of quality reporting programs should be reported on the cost reports. Cost report data may be considered in future payment reform.

Comment: One commenter stated that the addition of the J0905 Pain Active Problem item to the HIS V2.00.0 would be burdensome to hospice providers since it requires an update to the Admission HIS documentation and the item will not be used in calculation of the Pain Assessment measure. The commenter suggested adding the item when a Patient Reported Outcome Pain Measure is implemented or when a Hospice Patient Assessment Instrument is developed.

Response: We thank the commenter for their comments regarding the new item J0905, Pain Active problem. CMS would like to clarify our reasoning and intent behind the addition of the J0905 Pain Active Problem item. Since the HIS V1.00.0 was implemented on July 1, 2014, CMS has received an overwhelming amount of feedback from the provider community regarding the items in Section J: Pain of the HIS V1.00.0 (J0900. Pain Screening and J0910. Comprehensive Pain Assessment). These items correspond to the National Quality Forum (NQF) #1634 Pain Screening quality measure and the NQF #1637 Pain Assessment quality measure, respectively. NQF #1634 calculates the percentage of

patients who were screened for pain within two days of admission. Patients who screen positive for pain are included in the denominator for NQF #1637, which measures the percentage of patients who screened positive for pain who received a comprehensive pain assessment within 1 day.

Under current specifications for NQF #1634 and NQF #1637, if a patient is *not* in pain at the time of the first screening, that patient is not included in the denominator for NQF #1637—even if pain is an active problem for the patient. As such, if a patient is not in current pain at the time of the first pain screening, HIS V1.00.0 skip patterns direct providers to skip Item J0910, the comprehensive pain assessment item. RTI received feedback from the provider community that the measure specifications and associated skip pattern between J0900 and J0910 do not align with clinical practice, as clinicians will often complete a comprehensive pain assessment for patients when pain is an active problem but the patient is not in pain at the time of the screening. Providers further noted that some vendor-designed software built HIS skip patterns into clinical documentation systems and the skip pattern between J0900 and J0910 was thus restricting the ability of clinicians to document comprehensive assessments that were conducted per clinical best practice but not required for the purposes of the HIS pain quality measures. Due to these factors, CMS has received feedback from the provider community to consider changing items in the pain section to align HIS pain items with current clinical practice.

Thus, directly in response to feedback from providers, CMS added the J0905 Pain Active Problem item to the HIS V2.00.0. We believe this addition will actually reduce burden on providers since it is better aligned with current clinical practice. The addition of J0905 also better aligns items in the pain section with items in Section J: Respiratory Status. CMS plans to analyze data from J0905 to inform future potential refinements to the NQF-endorsed pain quality measures.

ICR-related comments are due October 4, 2016.

V. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

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

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This final rule has been designated as economically significant under section 3(f)(1) of Executive Order 12866 and thus a major rule under the Congressional Review Act. Accordingly, we have prepared a regulatory impact analysis (RIA) that, to the best of our ability, presents the costs and benefits of the rulemaking. This final rule was also reviewed by OMB.

2. Statement of Need

This final rule meets the requirements of our regulations at § 418.306(c), which requires annual issuance, in the **Federal Register**, of the hospice wage index based on the most current available CMS hospital wage data, including any changes to the definitions of Core-Based Statistical Areas (CBSAs), or previously used Metropolitan Statistical Areas (MSAs). This final rule will also update payment rates for each of the categories of hospice care described in § 418.302(b) for FY 2017 as required under section 1814(i)(1)(C)(ii)(VII) of the Act. The payment rate updates are subject to changes in economy-wide productivity as specified in section 1886(b)(3)(B)(xi)(II) of the Act. In addition, the payment rate updates may be reduced by an additional 0.3 percentage point (although for FY 2014 to FY 2019, the potential 0.3 percentage point reduction is subject to suspension under conditions specified in section 1814(i)(1)(C)(v) of the Act). In 2010, the Congress amended section 1814(i)(6) of the Act with section 3132(a) of the Affordable Care Act. The amendment authorized the Secretary to 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. In the FY 2016 Hospice Wage Index and Rate Update final rule (80 FR 47164), we finalized the creation of two different payment rates for RHC that resulted in a higher base payment rate for the first 60 days of hospice care and a reduced base payment rate for days 61 and over of hospice and created a SIA payment, in addition to the per diem rate for the RHC level of care, equal to the CHC hourly payment rate multiplied by the amount of direct patient care provided by an RN or social worker that occurs during the last 7 days of a beneficiary's life, if certain criteria are met. 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.

3. Overall Impacts

We estimate that the aggregate impact of this final rule will be an increase of $350 million in payments to hospices, resulting from the hospice payment update percentage of 2.1 percent. The impact analysis of this final rule represents the projected effects of the changes in hospice payments from FY 2016 to FY 2017. Using the most recent data available at the time of rulemaking, in this case FY 2015 hospice claims data, we apply the current FY 2016 wage index and labor-related share values to the level of care per diem payments and SIA payments for each day of hospice care to simulate FY 2016 payments. Then, using the same FY 2015 data, we apply the FY 2017 wage index and labor-related share values to simulate FY 2017 payments. 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.

4. Detailed Economic Analysis

The FY 2017 hospice payment impacts appear in Table 19. We tabulate the resulting payments according to the classifications in Table 19 (for example, facility type, geographic region, facility ownership), and compare the difference between current and proposed payments to determine the overall impact.

The first column shows the breakdown of all hospices by urban or rural status, census region, hospital-based or freestanding status, size, and type of ownership, and hospice base. The second column shows the number of hospices in each of the categories in the first column.

The third column shows the effect of the annual update to the wage index. This represents the effect of using the FY 2017 hospice wage index. The aggregate impact of this change is zero percent, due to the hospice wage index standardization factor. However, there are distributional effects of the FY 2017 hospice wage index.

The fourth column shows the effect of the hospice payment update percentage for FY 2017. The 2.1 percent hospice payment update percentage for FY 2017 is based on an estimated 2.7 percent inpatient hospital market basket update, reduced by a 0.3 percentage point productivity adjustment and by a 0.3 percentage point adjustment mandated by the Affordable Care Act, and is constant for all providers.

The fifth column shows the effect of all the changes on FY 2017 hospice payments. It is projected that aggregate payments will increase by 2.1 percent, assuming hospices do not change their service and billing practices in response.

As illustrated in Table 19, the combined effects of all the proposals vary by specific types of providers and by location. For example, due to the changes in this rule, the estimated impacts on FY 2017 payments range from a 1.1 percent increase for hospices providing care in the rural West North Central region to a 2.8 percent increase for hospices providing care in the rural Pacific region.

TABLE 19—PROJECTED IMPACT TO HOSPICES FOR FY 2017

(1)	Number of providers (2)	Updated wage data (%) (3)	Proposed hospice payment update (%) (4)	FY 2017 total change (%) (5)
All Hospices	4,177	0.0	2.1	2.1
Urban Hospices	3,179	0.0	2.1	2.1
Rural Hospices	998	−0.1	2.1	2.0
Urban Hospices—New England	138	0.4	2.1	2.5
Urban Hospices—Middle Atlantic	252	0.2	2.1	2.3
Urban Hospices—South Atlantic	422	−0.1	2.1	2.0
Urban Hospices—East North Central	399	−0.1	2.1	2.0
Urban Hospices—East South Central	162	−0.1	2.1	2.0
Urban Hospices—West North Central	220	−0.5	2.1	1.6
Urban Hospices—West South Central	616	−0.2	2.1	1.9
Urban Hospices—Mountain	313	−0.3	2.1	1.8
Urban Hospices—Pacific	618	0.6	2.1	2.7
Urban Hospices—Outlying	39	−0.7	2.1	1.4
Rural Hospices—New England	23	−0.4	2.1	1.7
Rural Hospices—Middle Atlantic	42	−0.2	2.1	1.9
Rural Hospices—South Atlantic	136	0.2	2.1	2.3
Rural Hospices—East North Central	141	0.1	2.1	2.2
Rural Hospices—East South Central	129	−0.1	2.1	2.0
Rural Hospices—West North Central	186	−1.0	2.1	1.1
Rural Hospices—West South Central	184	−0.1	2.1	2.0
Rural Hospices—Mountain	107	−0.2	2.1	1.9
Rural Hospices—Pacific	47	0.7	2.1	2.8
Rural Hospices—Outlying	3	−0.2	2.1	1.9
0–3,499 RHC Days (Small)	912	0.0	2.1	2.1
3,500–19,999 RHC Days (Medium)	2,004	0.0	2.1	2.1
20,000+ RHC Days (Large)	1,261	0.0	2.1	2.1
Non-Profit Ownership	1,071	0.1	2.1	2.2
For Profit Ownership	2,553	−0.1	2.1	2.0
Govt Ownership	160	0.5	2.1	2.6
Other Ownership	393	−0.1	2.1	2.0
Freestanding Facility Type	3,184	0.0	2.1	2.1
HHA/Facility-Based Facility Type	993	0.2	2.1	2.3

Source: FY 2015 hospice claims data from the Standard Analytic Files for CY 2014 (as of June 30, 2015) and CY 2015 (as of March 31, 2016).

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.

5. Alternatives Considered

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 2.1 percent hospice payment update percentage for FY 2017 is based on a 2.7 percent inpatient hospital market basket update for FY 2017, reduced by a 0.3 percentage point productivity adjustment and by an

additional 0.3 percentage point. Payment rates since FY 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 years must be the market basket percentage for that FY. Section 3401(g) of the Affordable Care Act also mandates that, starting with FY 2013 (and in subsequent years), 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 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 considered not adopting a hospice wage index standardization factor. However, as discussed in section III.C.1 of this final rule, we believe that adopting a hospice wage index standardization factor would provide a safeguard to the Medicare program, as well as to hospices, because it will mitigate changes in overall hospice expenditures due to annual fluctuations in the hospital wage data from year-to-year by ensuring that hospice wage index updates and revisions are implemented in a budget neutral manner. We estimate that if the hospice wage index standardization factor is not finalized, total payments in a given year would increase or decrease by as much as 0.3 percent or $50 million.

6. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table 20, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule. Table 20 provides our best estimate of the possible changes in Medicare payments under the hospice benefit as a result of the policies in this final rule. This estimate is based on the data for 4,177 hospices in our impact analysis file, which was constructed using FY 2015 claims available as of March 31, 2016. All expenditures are classified as transfers to hospices.

TABLE 20—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS, FROM FY 2016 TO FY 2017

[in $Millions]

Category	Transfers
FY 2017 Hospice Wage Index and Payment Rate Update	
Annualized Monetized Transfers.	$350 *
From Whom to Whom?	Federal Government to Medicare Hospices.

* The net increase of $350 million in transfer payments is a result of the 2.1 percent hospice payment update percentage compared to payments in FY 2016.

7. Conclusion

We estimate that aggregate payments to hospices in FY 2017 would increase by $350 million, or 2.1 percent, compared to payments in FY 2016. We estimate that in FY 2017, hospices in urban and rural areas would experience, on average, a 2.1 percent and a 2.0 percent increase, respectively, in estimated payments compared to FY 2016. Hospices providing services in the urban Pacific and rural Pacific regions would experience the largest estimated increases in payments of 2.7 percent and 2.8 percent, respectively. Hospices serving patients in rural areas in the West North Central region would experience the lowest estimated increase of 1.1 percent in FY 2017 payments.

B. 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. 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 $7.5 million to $38.5 million in any 1 year), or being nonprofit organizations. For purposes of the RFA, we consider all hospices as small entities as that term is used in the RFA. 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. The effect of the final FY 2017 hospice payment update percentage results in an overall increase in estimated hospice payments of 2.1 percent, or $350 million. Therefore, the Secretary has determined that this final rule will not create a significant economic impact on a substantial number of small entities.

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

C. 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 2016, that threshold is approximately $146 million. This final rule is not anticipated to have an effect on State, local, or tribal governments, in the aggregate, or on the private sector of $146 million or more.

VI. Federalism Analysis

Executive Order 13132, Federalism (August 4, 1999) requires an agency to provide federalism summary impact statement when it promulgates a proposed rule (and subsequent final rule) that has federalism implications and which imposes substantial direct requirement costs on State and local governments which are not required by statute. We have reviewed this final rule under these criteria of Executive Order 13132, and have determined that it will not impose substantial direct costs on state or local governments.

Dated: July 18, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: July 25, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

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