

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 418

[CMS–1675–F]

RIN 0938–AT00

Medicare Program; FY 2018 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) 2018. Additionally, this rule includes new quality measures and provides an update on the hospice quality reporting program.

DATES: These regulations are effective on October 1, 2017.

FOR FURTHER INFORMATION CONTACT:

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

Cindy Massuda, (410) 786–0652 for questions regarding the hospice quality reporting program.

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

SUPPLEMENTARY INFORMATION: Wage index addenda will be available only through the internet on the CMS Web site at: (<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/index.html>).

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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
CASPER Certification and Survey Provider Enhanced Reports
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
CMS Centers for Medicare & Medicaid Services
COPD Chronic Obstructive Pulmonary Disease
CoPs Conditions of Participation
CPI–U Consumer Price Index–Urban Consumers
CVA Cerebral Vascular Accident
CWF Common Working File
CY Calendar Year
DME Durable Medical Equipment
DRG Diagnostic Related Group
FEHC Family Evaluation of Hospice Care
FR Federal Register
FY Fiscal Year
GAO Government Accountability Office
GIP General Inpatient Care
HCFA Healthcare Financing Administration
HEART Hospice Evaluation & Assessment Reporting Tool

HHS Health and Human Services
 HIS Hospice Item Set
 HQRP Hospice Quality Reporting Program
 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
 IPPS Inpatient Prospective Payment System
 IRC Inpatient Respite Care
 LCD Local Coverage Determination
 MAC Medicare Administrative Contractor
 MACRA Medicare Access and CHIP Reauthorization Act of 2015
 MAP Measure Applications Partnership
 MedPAC Medicare Payment Advisory Commission
 MFP Multifactor Productivity
 MLN Medicare Learning Network
 MSA Metropolitan Statistical Area
 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
 PRA Paperwork Reduction Act of 1995
 PRRB Provider Reimbursement Review Board
 PS&R Provider Statistical and Reimbursement Report
 Pub. L. Public Law
 POC Plan of Care
 QAPI Quality Assessment and Performance Improvement
 QIO Quality Improvement Organization
 QM Quality Measure
 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) 2018, as required under section 1814(i) of the Social Security Act (the Act). This rule also discusses 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. In accordance with section 1814(i)(5)(A) of the Act, hospices that fail to meet quality reporting requirements receive a

2 percentage point reduction to their payments.

B. Summary of the Major Provisions

Section III.B.1 of this final rule updates the hospice wage index with updated wage data and makes the application of the updated wage data budget neutral for all four levels of hospice care. In section III.B.2 of this final rule, we discuss the FY 2018 hospice payment update percentage of 1.0 percent. Sections III.B.3 and III.B.4 of this final rule update the hospice payment rates and hospice cap amount for FY 2018 by the hospice payment update percentage discussed in section III.B.2 of this final rule.

In section III.C of this final rule, we discuss comments on the appropriate source(s) of the required clinical information for certification of a medical prognosis of a life expectancy of 6 months or less.

Finally, in section III.D of this final rule, we discuss updates to HQRP, including changes to the Consumer Assessment of Healthcare Providers and Systems (CAHPS)[®] Hospice Survey measures as well as the possibility of utilizing a new assessment instrument to collect quality data. We also discuss the enhancements to the current Hospice Item Set (HIS) data collection instrument to be more in line with other post-acute care settings. The new data collection instrument would be a comprehensive patient assessment instrument, rather than the current chart abstraction tool. Finally, we discuss our plans for sharing HQRP data publicly later in calendar year (CY) 2017, as well as plans to provide public reporting via a Compare Site in CY 2017 and future years.

C. Summary of Impacts

The overall economic impact of this final rule is estimated to be \$180 million in increased payments to hospices during FY 2018.

II. Background

A. Hospice Care

Hospice care is a comprehensive, holistic approach to treatment that recognizes that the impending death of an individual, upon his or her choice, 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 a collaboration 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/caregiver-centered care for those who are terminally ill.

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. For more information, see “Medicare and Medicaid Programs: 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 and caregivers through early identification and management of pain and other issues associated with a life limiting condition. The hospice interdisciplinary group works with the beneficiary, family, and caregivers to develop a coordinated, comprehensive care plan; reduce unnecessary diagnostics or ineffective therapies; and maintain ongoing communication with individuals and their families about changes in their condition. The beneficiary’s 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 related to the underlying condition(s), as bodily systems are interdependent. In the 2008 Hospice Conditions of Participation final rule, we stated that “the [hospice] medical director must consider the primary terminal condition, related diagnoses, current subjective and objective medical findings, current medication and treatment orders, and information about unrelated conditions when considering the initial certification of the terminal illness” (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 regulations at § 418.22(b)(3) require that the certification and recertification forms include a brief narrative explanation of the clinical findings that support a life expectancy of 6 months or less.

While the goal of hospice care is to allow the beneficiary to remain in his or her home, circumstances during the end of life may necessitate short-term inpatient admission to a hospital, skilled nursing facility (SNF), or hospice facility for necessary pain control or acute or chronic symptom management that cannot be managed in any other setting. These acute hospice care services ensure that any new or worsening symptoms are intensively addressed so that the beneficiary can return to his or her home. Limited, short-term, intermittent, inpatient respite care (IRC) is also available because of the absence or need for relief of the family or other caregivers. Additionally, an individual can receive continuous home care (CHC) during a period of crisis in which an individual requires continuous care to achieve palliation or management of acute medical symptoms so that the individual can remain at home. Continuous home care may be covered 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. Additionally, they must provide language access for such persons who are limited in English proficiency, consistent with Title VI of the Civil Rights Act of 1964. Further information about these requirements may be found at <http://www.hhs.gov/ocr/civilrights>.

B. History of the Medicare Hospice Benefit

Before the creation of the Medicare hospice benefit, hospice 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 entitled “Medicare Program; Hospice Care” (48 FR 38146), “the hospice experience in the United States has placed emphasis on home care. It offers physician services, specialized nursing services, and other forms of care in the home to enable the terminally ill individual to remain at home in the company of family and friends as long as possible.” The concept of a 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 well as, care for interventions to manage pain and symptoms, as described in the beneficiary’s plan of care. 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 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 home from an institutional 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.

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.

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, the Congress expected hospices to continue to use volunteer services, though these services are not reimbursed by Medicare (see section 1861(dd)(2)(E) of the Act). 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 community based, holistic, comprehensive, and compassionate end-of-life care.

Before the Medicare hospice benefit was established, the Congress requested a demonstration project to test the

feasibility of covering hospice care under Medicare.³ 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. Most 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 (IRC), and general inpatient care (GIP)), 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 and items 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

³ Greer, D., Mor, V., Sherwood, S. (1983) National hospice study analysis plan. *Journal of Chronic Diseases*, Vol 36, 11, 737-780. [https://doi.org/10.1016/0021-9681\(83\)90069-3](https://doi.org/10.1016/0021-9681(83)90069-3).

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, were subject to either a budget neutrality adjustment or application of the wage index floor. Wage index values of 0.8 or greater were 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, and 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 that fail to report quality data will have their market basket percentage increase 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, the Congress included an aggregate cap on hospice payments, which limits the total aggregate payments any individual hospice can receive in a year. The Congress stipulated that a "cap amount" be computed each year. The cap amount was set at \$6,500 per beneficiary when first enacted in 1983 and 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, within certain limits. We allowed existing hospices the option of having their cap calculated via the original streamlined methodology, also within certain limits. 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 payments for the cap year exceed 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 of 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. Over time, we have 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 as of 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 Wage Index and Payment 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 Wage Index and Payment 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 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 fiscal year 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.

10. FY 2017 Hospice Wage Index and Payment Rate Update Final Rule

In the FY 2017 Hospice Wage Index and Payment Rate Update final rule, we finalized several new policies and requirements related to the HQR. First, we codified our policy that if the National Quality Forum (NQF) makes non-substantive changes to specifications for HQR measures as part of the NQF's re-endorsement process, we will continue to utilize the measure in its new endorsed status, without going through new notice-and-comment rulemaking (81 FR 52160). We will continue to use rulemaking to adopt substantive updates made by the NQF to the endorsed measures we have adopted for the HQR; determinations about what constitutes a substantive versus non-substantive change will be made on a measure-by-measure basis. Second, we finalized two new quality measures for the HQR 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 (81 FR 52173). The data collection mechanism for both of these measures is the HIS, and the measures are effective April 1, 2017. Regarding the CAHPS® Hospice Survey, we finalized a policy that hospices that receive their CMS Certification Number (CCN) after January 1, 2017 for the FY 2019 Annual Payment Update (APU) and January 1, 2018 for the FY 2020 APU will be exempted from the Hospice CAHPS® requirements due to newness (81 FR 52182). The exemption is

determined by CMS and is for 1 year only.

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 2016. Similarly, Medicare hospice expenditures have risen from \$2.8 billion in FY 2000 to approximately \$16.5 billion in FY 2016. 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 2016 in neurologically-based diagnoses, including diagnoses of Alzheimer’s disease. Additionally, there have been significant increases in the use of non-specific, symptom-classified diagnoses, such as “debility” and “adult failure to thrive.” In FY 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 2016, the most common hospice principal diagnoses were Alzheimer’s disease, Heart Failure, Chronic Obstructive Pulmonary Disease, Lung Cancer, and Senile Degeneration of the Brain, which constituted approximately 30 percent of all claims-reported principal diagnosis codes reported in FY 2016 (see Table 2).

TABLE 2—THE TOP TWENTY PRINCIPAL HOSPICE DIAGNOSES, FY 2002, FY 2007, FY 2013, FY 2016

| 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 | 153.0 | Colon Cancer | 19,080 | 2 |
| 14 | 294.8 | Organic Brain Syndrome NEC | 17,697 | 2 |
| 15 | 332.0 | Parkinson’s Disease | 16,524 | 2 |
| 16 | 294.10 | Dementia In Other Diseases w/o Behavior. 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 |

TABLE 2—THE TOP TWENTY PRINCIPAL HOSPICE DIAGNOSES, FY 2002, FY 2007, FY 2013, FY 2016—Continued

| Rank | ICD-9/Reported principal diagnosis | | Count | Percentage |
|----------------------|------------------------------------|--|---------|------------|
| 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 2016 | | | | |
| 1 | G30.9 | Alzheimer's disease, unspecified | 162,845 | 11 |
| 2 | I50.9 | Heart failure, unspecified | 84,088 | 6 |
| 3 | J44.9 | Chronic obstructive pulmonary disease, unspecified | 74,131 | 5 |
| 4 | C34.90 | Malignant Neoplasm Of Unsp Part Of Unsp Bronchus Or Lung | 57,077 | 4 |
| 5 | G31.1 | Senile degeneration of brain, not elsewhere classified | 55,305 | 4 |
| 6 | G20 | Parkinson's disease | 37,245 | 2 |
| 7 | I25.10 | Atherosclerotic heart disease of native coronary art without angina pectoris | 33,647 | 2 |
| 8 | J44.1 | Chronic obstructive pulmonary disease with (acute) exacerbation | 32,851 | 2 |
| 9 | G30.1 | Alzheimer's disease with late onset | 29,223 | 2 |
| 10 | I67.2 | Cerebral atherosclerosis | 27,629 | 2 |
| 11 | C61 | Malignant neoplasm of prostate | 24,576 | 2 |
| 12 | N18.6 | End stage renal disease | 22,261 | 1 |
| 13 | C18.9 | Malignant neoplasm of colon, unspecified | 22,203 | 1 |
| 14 | I51.9 | Heart disease, unspecified | 21,868 | 1 |
| 15 | C25.9 | Malignant neoplasm of pancreas, unspecified | 20,400 | 1 |
| 16 | I63.9 | Cerebral infarction, unspecified | 18,546 | 1 |
| 17 | I67.9 | Cerebrovascular disease, unspecified | 14,879 | 1 |
| 18 | C50.919 | Malignant neoplasm of unspecified site of unspecified female breast | 14,022 | 1 |
| 19 | A41.9 | Sepsis, unspecified organism | 12,723 | 1 |
| 20 | I50.22 | Chronic systolic (congestive) heart failure | 12,083 | 1 |

Note(s): The frequencies shown represent beneficiaries that had a least one claim with the specific ICD-9-CM/ICD-10 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 2016 hospice claims data from the CCW, accessed and merged with ICD-10 codes on January 9, 2017.

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 2016 hospice claims show that 100 percent of hospices reported one diagnosis, 86 percent submitted at least two diagnoses, and 77 percent included at least three diagnoses.

III. Provisions of the Final Rule

On May 3, 2017, we published the FY 2018 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements proposed rule in the **Federal Register** (82 FR 20750 through 20792) and provided a 60 day comment period. In that proposed rule, we proposed to update the hospice wage index, payment rates, and cap amount for fiscal year (FY) 2018. In addition, we

proposed changes to the hospice quality reporting program. 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. We received approximately 89 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 2018 Hospice Payment Rate Update and Hospice Quality Reporting Requirements. Comments related to the paperwork burden are addressed in section IV "Collection of Information Requirements" of this final rule. Comments related to the impact analysis are addressed in section V "Regulatory Impact Analysis" of this final rule.

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

In the FY 2018 Hospice Wage Index and Payment Rate Update proposed rule (82 FR 20750), we provided a summary of analysis conducted on hospice length of stay, live discharge rates, skilled visits in the last days of life, and non-hospice spending. Additionally, we discussed initial analyses of data from recently revised cost reports. 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.

The comments and our responses are set forth below.

Comment: Many commenters expressed continued support for our plans to monitor the impact of hospice payment reform and suggested the use of monitoring results in order to better target program integrity efforts. Commenters suggested CMS ensure hospices with a high number of live discharges receive the appropriate training on hospice eligibility requirements, which may help reduce their number of live discharges to a threshold more aligned with other hospices with similar demographics. With regards to skilled visits during the

last days of life, a few commenters stated that hospices continue to 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. With regards to the initial analysis of newly-revised cost report data, several commenters encouraged CMS to approach further analysis in a deliberate fashion, taking into account the "newness" of the data collected, further educate providers on appropriate completion of the cost report forms, and audit cost reports before moving forward with any further research. Several commenters suggested that CMS take action to educate other Medicare provider types to increase understanding of benefits coverage and claims processing after a beneficiary has elected hospice and encouraged Medicare systems changes that could shorten the time frame for updates to the beneficiary's status in all systems. Several commenters recommended that CMS make more data available to the hospice providers and other stakeholders, especially with regards to Part D billing, and consider clarifying the responsibilities for prescription medications to decrease Part D non-hospice spending.

Response: We appreciate these comments on the ongoing analysis presented and we will continue to monitor hospice trends and vulnerabilities within the hospice benefit, while also investigating the means by which we can educate the provider community regarding the hospice benefit and appropriate billing practices. We will also consider these suggestions for future monitoring efforts and for potential policy or payment refinements. We are currently working on a process to allow NOEs to be submitted via electronic data interchange while simultaneously working on a redesign of hospice benefit period data in our systems. Allowing NOEs to be submitted via an electronic data interchange and the hospice benefit period data redesign should help with more timely beneficiary status updates in the Medicare systems.

B. FY 2018 Hospice Wage Index and Rate Update

1. FY 2018 Hospice Wage Index

The hospice wage index is used to adjust payment rates for hospice agencies under the Medicare program to reflect local differences in area wage levels, based on the location where services are furnished. The hospice wage index utilizes the wage adjustment

factors used by the Secretary for purposes of section 1886(d)(3)(E) of the Act for hospital wage adjustments. 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 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 2018, the hospice wage index will be based on the FY 2017 hospital pre-floor, pre-reclassified 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 IRC.

There exist 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 2008 Hospice Wage Index final rule (72 FR 50214), we implemented a methodology to update the hospice wage index for such areas. In cases where there was a rural area without rural hospital wage data, we use the average pre-floor, pre-reclassified hospital wage index data from all contiguous Core-Based Statistical Areas (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, for rural Puerto Rico, we would not apply this methodology due to the distinct economic circumstances that exist there (for example, due to the close proximity to one another of almost all of Puerto Rico's various urban and non-urban areas, this methodology would produce a wage index for rural Puerto Rico that is higher than that in half of its urban areas); instead, we would continue to use the most recent wage index previously available for that area. For FY 2018, we will continue to use the most recent pre-floor, pre-reclassified hospital wage index value available for Puerto Rico, which is 0.4047.

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. For FY 2018, the only CBSA without a hospital from which hospital wage data can be derived is 25980, Hinesville-Fort Stewart, Georgia.

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 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.

On February 28, 2013, OMB issued OMB Bulletin No. 13-01, announcing revisions to the delineation of MSAs, Micropolitan Statistical Areas, and Combines Statistical Areas, and guidance on uses of the delineation in these areas. In the FY 2016 Hospice Wage Index and Payment Rate Update final rule (80 FR 47178), we adopted the OMB's new area delineations using a 1-year transition. Also, in the FY 2016 Hospice Wage Index and Payment Rate Update final rule, we stated that beginning October 1, 2016, the wage index for all hospice payments would be fully based on the new OMB delineations. The most recent bulletin (No. 15-01) concerning the revised delineations was published by the OMB on July 15, 2015.

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

Comment: Several commenters expressed concern that hospices in Montgomery County and Frederick County, Maryland, which are included

in CBSA 43524 (Silver Spring-Frederick-Rockville, MD), are reimbursed at a lower rate than hospices in the greater Washington DC area that are included in CBSA 47894 (Washington-Arlington-Alexandria, DC-VA-MD-WV). The commenters request that CMS reconsider CBSA 43524 (Silver Spring-Frederick-Rockville, MD).

Response: We refer readers of this final rule to the FY 2016 Hospice Wage Index and Payment Rate Update (80 FR 47179 through 47180) wherein we provided a detailed response to this comment.

Comment: A commenter stated that another complicating factor related to the wage index value for CBSA 43524 (Silver Spring-Frederick-Rockville, MD) is the Maryland Federal Waiver and global budget. In all other states, cost reports drive reimbursement for hospitals and accurate reporting of wages is key to reimbursement rates. The commenter believes that since the data on cost reports does not relate to their reimbursement, hospitals in Maryland have no incentive to report their wages accurately. The commenter asserts that there are two hospitals in CBSA 43524 that have not reported their nursing wages accurately. The cost report data drives the rates for post-acute Medicare services such as hospice; this difference should be taken into consideration.

Response: We would like to thank the commenter for her comment. We disagree with the commenter's statement that hospitals in Maryland have no incentives for ensuring the accuracy of their cost reports and that the cost report data are inaccurate and not representative of the costs that the hospitals actually incur. Hospitals' cost reports, including those of hospitals in Maryland, are required to be certified by the Officer or Administrator of the hospital. The hospital Medicare Cost Report (MCR) Form (CMS-2552-10) states the following:

"I HEREBY CERTIFY that I have read the above statement and that I have examined the accompanying cost report and the Balance Sheet and Statement of Revenue and Expenses prepared by _____ (provider name(s) and number(s)) for the cost report beginning _____ a and ending _____ a and to the best of my knowledge and belief, this report and statement are true, correct, complete and prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this

cost report were provided in compliance with such laws and regulations."

We also note that the hospital Medicare cost report referenced statement above includes the following:

"Misrepresentation or falsification of any information contained in this cost report may be punishable by criminal, civil and administrative action, fine and/or imprisonment under federal law. Furthermore, if services identified in this report were provided or procured through the payment directly or indirectly of a kickback or were otherwise illegal, criminal, civil and administrative action, fines and/or imprisonment may result."

As always, we encourage providers to fill out the Medicare cost reports as accurately as possible.

Comment: A commenter stated that no hospice should receive a wage index below the hospital rural floor. The commenter stated that in some small CBSAs, hospices receive a wage index that is below the rural floor which severely impacts their ability to deliver high-quality hospice care. CMS should mandate that no hospice receive a wage index below the rural floor.

Response: The hospice wage index does not contain a rural floor provision. 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 (for example, SNF PPS, IRF PPS, and HH PPS). The hospice floor is applicable to all CBSAs, both rural and urban. 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.

Comment: A commenter requested that CMS make adjustments to the methodology used to calculate the wage index for rural Puerto Rico. The commenter stated that the proposed ruling for the FY 2018 Hospice Wage Index Update states that "in cases where there was a rural area without rural hospital wage data, we use the average pre-floor, pre-reclassified hospital wage index data from all contiguous Core-Based Statistical Areas (CBSAs), to represent a reasonable proxy for the

rural area.” Currently, the only rural area without a hospital from which hospital wage data could be derived is Puerto Rico. The commenter notes that CMS chose not to use this proxy for Puerto Rico and continued using the most recent wage index previously available for that rural area. The commenter does not believe that this represents a “reasonable proxy for the rural area” in comparison with other jurisdictions, and it still does not justify applying lower wage indices to urban areas in Puerto Rico.

The commenter proposes that CMS should use the wage index defined for the neighboring U.S. Virgin Islands for CY 2018, as this would be in harmony with the policy defined for Part B GPCIs, by providing more consistency across the payment policies among neighboring Territories. Alternatively, the commenter proposes that Puerto Rico wage indices in Hospice care should not be lower than the average ratio of Puerto Rico wages to U.S. wages, using the data from the OES. The Puerto Rico average wage is at 58 percent of the national average, the commenter considers that the Hospice wage index should be at least equal to that ratio.

Response: We will take these comments under consideration for any future policy changes that may be considered for Puerto Rico. The wage index value for rural Puerto Rico is increased by 15 percent in accordance with the hospice floor provision. There was an error in the Proposed FY 2018 Hospice Wage Index file. The value for rural Puerto Rico was listed as 0.4047. The correct value is 0.4654.

Comment: A commenter expressed dissatisfaction with the wage index value for Madera County, California in relation to the wage index value for Fresno County, which is adjacent to Madera County.

Response: As stated earlier in this final rule, we use OMB’s geographic area delineations to differentiate between labor markets. Based on the most recent list of MSA definitions contained in OMB Bulletin No. 15–01, published on July 15, 2015 and available at <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2015/15-01.pdf>, Madera County is associated with a different MSA than Fresno County. Therefore, for payment purposes we calculate these two counties wage indices separately, based on data gathered from the cost reports of the Inpatient Prospective Payment System (IPPS) hospitals in those counties.

Comment: One commenter expressed concern that the proposed FY 2018

hospice wage index will be fully based on the new OMB geographic area wage delineations. The commenter was particularly concerned with the New York City CBSA and the fact that the CBSA contains counties from New Jersey where labor costs are lower.

Response: We responded to this comment in the FY 2017 Hospice Wage Index and Payment Rate Update final rule (81 FR 52154). We continue to believe that the OMB’s geographic area delineations are a reasonable and appropriate method of defining geographic areas for the purposes of wage adjusting the hospice payment rates.

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

Response: We addressed this comment in the FY 2017 Hospice Wage Index and Payment Rate Update final rule (81 FR 52154). We continue to believe that the annual changes in the wage index reflect real variations in costs of providing care in various geographic locations. 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. 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 our policy of utilizing a hospice wage index standardization factor, which was proposed and finalized in FY 2017 rulemaking, provides 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: We responded to this comment in the FY 2017 Hospice Wage Index and Payment Rate Update final rule (81 FR 52154) and believe that it is important to reiterate that the regulations and statutes that govern hospice payments do not provide 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 in 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 they may or may not apply to a given hospice in a given instance. In addition, several post-acute care payment systems utilize the pre-floor, pre-reclassified hospital wage index as the basis for their wage indices (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)).

Final Decision: 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 2018, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2012 and before October 1, 2013 (FY 2013 cost report data).

The wage index applicable for FY 2018 is available on our Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/index.html>. The hospice wage index for FY 2018 will be effective October 1, 2017 through September 30, 2018.

2. FY 2018 Hospice Payment Update Percentage

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 to be updated by a factor equal to the inpatient hospital market basket percentage increase 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 increase for that FY. The Act historically required us to use the inpatient hospital market basket as the basis for the hospice payment rate update.

Section 3401(g) of the Affordable Care Act mandated that, starting with FY 2013 (and in subsequent FYs), the hospice payment update percentage would 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). In addition to the MFP adjustment, section 3401(g) of the Affordable Care Act also mandated that in FY 2013 through FY 2019, the hospice payment update percentage would 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).

Prior to the enactment of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted April 16, 2015), which amended section 1814(i)(1)(C) of the Act, the proposed hospice update percentage for FY 2018 would have been based on the estimated inpatient hospital market basket update of 2.7 percent (based on IHS Global Inc.'s second quarter 2017 forecast with historical data through the first quarter of 2017 of the 2014-based IPPS market basket). Due to the requirements at section 1886(b)(3)(B)(xi)(II) of the Act prior to enactment of the MACRA, the estimated FY 2018 inpatient hospital market basket update of 2.7 percent would have been reduced by a MFP adjustment as mandated by Affordable Care Act (currently estimated to be 0.6 percentage point for FY 2018) and a 0.3 percentage point reduction as mandated by section 1814(i)(1)(C)(v) of the Act. In effect, the hospice payment update percentage for FY 2018 would be 1.8 percent. However, section 411(d) of the MACRA amended section 1814(i)(1)(C) of the Act, such that for hospice payments for FY 2018, the market

basket percentage increase is required to be 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. Beginning with cost reporting periods starting on or after October 1, 2014, freestanding hospice providers are required to submit cost data using CMS Form 1984–14 (<https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/Hospice-2014.html>). We are currently analyzing this data for possible use in updating the labor portion of the hospice payment rates. Any changes to the labor portions will be proposed in future rulemaking and will be subject to public comments.

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

Comment: Several commenters stated that the FY 2018 payment update of 1 percent is inadequate. One of the commenters stated that the update does not appropriately keep pace with the cost of providing hospice care to beneficiaries and does not match the increasing costs associated with data collection requirements and reporting, technology, workforce and training.

Response: We appreciate the commenter's concerns; however, the 1 percent payment update for FY 2018 is mandated by section 411(d) of the MACRA.

Comment: A commenter noted that in MedPAC's March 2017 Report to Congress, MedPAC concluded that indicators of payment adequacy for hospice providers are generally positive. In 2015, the number of hospices increased about 2.6 percent because of continued entry of for-profit providers. The aggregate Medicare margin was 8.2 percent in 2014 and MedPAC projected a 2017 aggregate Medicare margin of 7.7 percent. Based on their assessment of these and other payment adequacy indicators, MedPAC concluded that hospices should be able to accommodate cost changes in 2018 without an update to the 2017 base payment rate. The commenter also acknowledged that CMS is required by statute to update the FY 2018 hospice payment rates by 1 percent.

Response: We thank the commenter for noting that hospices' Medicare margins appear to be adequate and no update to the per diem amounts is needed for FY 2018. We further thank the commenter for acknowledging that we do not have the authority to eliminate the payment update for FY 2018.

3. FY 2018 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 CHC, IRC, or GIP. CHC is provided during a period of patient crisis to maintain the patient at home; IRC is short-term care to allow the usual caregiver to rest and be relieved from caregiving; and 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 for RHC for 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, if certain criteria are met. 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 2018, we calculated the SBNF using FY 2016 utilization data. We examined skilled nursing and social work visit data for the last 7 days of life where RHC was billed and found that, from January 1

through September 30, 2016, approximately 86 percent of nursing visits were identified as RN visits (using G0299) and 14 percent of nursing visits were identified as Licensed Practical Nurse (LPN) visits (using G0300). Because the differentiated nursing visit G-codes were not implemented until January 1, 2016, for skilled nursing visits during the last 7 days of life where RHC was billed and that occurred between October 1 and December 31, 2015, we estimated that 86 percent of the line item visits reported using G0154 were RN and 14 percent were LPN using statistics generated for the 2016 time period where data were available. For FY 2018, the budget

neutrality adjustment that would apply to days 1 through 60 is calculated to be 1.0017. The budget neutrality adjustment that would apply to days 61 and beyond is calculated to be 1.0005.

In the FY 2017 Hospice Wage Index and Payment Rate Update final rule (81 FR 52156), we initiated a policy of applying a wage index standardization factor to hospice payments in order to eliminate the aggregate effect of annual variations in hospital wage data. In order to calculate the wage index standardization factor, we simulate total payments using the FY 2018 hospice wage index and compare it to our simulation of total payments using the FY 2017 hospice wage index. By dividing payments for each level of care

using the FY 2018 wage index by payments for each level of care using the FY 2017 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). The wage index standardization factors for each level of care are shown in the tables below.

Lastly, the hospice payment rates for hospices that submit the required quality data would be increased by the FY 2018 hospice payment update percentage of 1.0 percent as discussed in section III.B.2 of this final rule. The FY 2018 RHC rates are shown in Table 12. The FY 2018 payment rates for CHC, IRC, and GIP are shown in Table 13.

TABLE 12—FY 2018 HOSPICE RHC PAYMENT RATES

| Code | Description | FY 2017 payment rates | SIA budget neutrality factor | Wage index standardization factor | FY 2018 hospice payment update | FY 2018 payment rates |
|-----------|-------------------------------------|-----------------------|------------------------------|-----------------------------------|--------------------------------|-----------------------|
| 651 | Routine Home Care (days 1–60) | \$190.55 | × 1.0017 | × 1.0000 | × 1.01 | \$192.78 |
| 651 | Routine Home Care (days 61+) | 149.82 | × 1.0005 | × 1.0001 | × 1.01 | 151.41 |

TABLE 13—FY 2018 HOSPICE CHC, IRC, AND GIP PAYMENT RATES

| Code | Description | FY 2017 payment rates | Wage index standardization factor | FY 2018 hospice payment update | FY 2018 payment rates |
|-----------|--|-----------------------|-----------------------------------|--------------------------------|-----------------------|
| 652 | Continuous Home Care; Full Rate = 24 hours of care; \$40.68 = FY 2018 hourly rate. | \$964.63 | × 1.0022 | × 1.01 | \$976.42 |
| 655 | Inpatient Respite Care | 170.97 | × 1.0006 | × 1.01 | 172.78 |
| 656 | General Inpatient Care | 734.94 | × 1.0017 | × 1.01 | 743.55 |

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

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

data submission requirements with respect to that FY. The FY 2018 rates for hospices that do not submit the required quality data would be updated by the FY 2018 hospice payment update percentage of 1 percent minus 2 percentage points. These rates are shown in Tables 14 and 15.

TABLE 14—FY 2018 HOSPICE RHC PAYMENT RATES FOR HOSPICES THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

| Code | Description | FY 2017 payment rates | SIA budget neutrality factor | Wage index standardization factor | FY 2018 hospice payment update of 1% minus 2 percentage points = -1.0% | FY 2018 payment rates |
|-----------|-------------------------------------|-----------------------|------------------------------|-----------------------------------|--|-----------------------|
| 651 | Routine Home Care (days 1–60) | \$190.55 | × 1.0017 | × 1.0000 | × 0.99 | \$188.97 |
| 651 | Routine Home Care (days 61+) | 149.82 | × 1.0005 | × 1.0001 | × 0.99 | 148.41 |

TABLE 15—FY 2018 HOSPICE CHC, IRC, AND GIP PAYMENT RATES FOR HOSPICES THAT *DO NOT* SUBMIT THE REQUIRED QUALITY DATA

| Code | Description | FY 2017 payment rates | Wage index standardization factor | FY 2018 hospice payment update of 1% minus 2 percentage points = -1.0% | FY 2018 payment rates |
|-----------|--|-----------------------|-----------------------------------|--|-----------------------|
| 652 | Continuous Home Care; Full Rate = 24 hours of care; \$39.88 = FY 2018 hourly rate. | \$964.63 | × 1.0022 | × 0.99 | \$957.08 |
| 655 | Inpatient Respite Care | 170.97 | × 1.0006 | × 0.99 | 169.36 |
| 656 | General Inpatient Care | 734.94 | × 1.0017 | × 0.99 | 728.83 |

4. Hospice Cap Amount for FY 2018

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). The hospice cap amount for the 2018 cap year will be \$28,689.04, which is equal to the 2017 cap amount (\$28,404.99) updated by the FY 2018 hospice payment update percentage of 1.0 percent.

A summary of the comments we received regarding the hospice cap amount and our responses to those comments appears below.

Comment: One commenter noted that the hospice cap is a uniform amount meaning that each CBSA has the same cap amount. The commenter ascertains that in certain CBSAs, the hospice per diem rate is significantly higher than the national average. The commenter believes that since the cap amount does not adjust relative to CBSA, Medicare beneficiaries in CBSAs with higher wage indices have significantly fewer potential days of hospice care available to them relative to beneficiaries who reside in CBSAs with a lower wage indices. Accordingly, the commenter recommends that, in fairness to providers located in CBSAs with higher than average wage indices, CMS adjust the hospice cap amount by CBSA.

Response: We appreciate the commenter's suggestion that CMS wage-adjust the annual cap amount. However, the restriction set forth in section 1814(i)(2)(B), as amended by section 3(d) of the IMPACT Act, does not give us discretion to adjust the cap amount.

C. Discussion Regarding Sources of Clinical Information for Certifying Terminal Illness

In accordance with the regulations at § 418.20, a patient must be certified as terminally ill in order to be eligible to elect the Medicare Hospice benefit. Furthermore, hospice admission is predicated on the certification of terminal illness that determines eligibility. In reaching a decision to certify, § 418.25 requires a hospice medical director to consider the diagnosis of the terminal condition of the patient, other health conditions (whether related or unrelated to the terminal condition), and current clinically relevant information supporting all diagnoses. In the FY 2018 Hospice Wage Index and Payment Rate Update proposed rule, we discussed a potential proposal for a regulatory text change at § 418.25, clarifying that the documentation used for the initial certification must come from the referring physician's or acute/post-acute care facility's medical records (84 FR 20771). We also discussed the potential benefit of an initial face-to-face visit by the hospice medical director or physician designee, if needed, to support the clinical documentation required to accompany the certification of terminal illness. Although we did not propose this regulatory change, we requested public input on the possible amendment. We solicited comments on current processes used by hospices to ensure comprehensive clinical review to support certification, and encouraged submission of any alternate suggestions for supporting clinical documentation sources that ensure appropriate hospice admission.

Comment: A few commenters expressed support for the potential regulations text change, and stated that they consider "obtaining and analyzing medical records from the referring provider" to be "best practice." Additionally, commenters indicated that their processes for certification

already include review of the referring source's clinical documentation, which one commenter noted includes review of "pathology reports, blood work reports, x-rays, kidney function, heart function, PPS assessment, mental assessment, medications, goals of care, diagnosis, nutritional assessment, weight loss, BMI and any other hospital report available that would indicate the patient has 6 months or less to live." A few commenters specifically noted that the regulations at § 418.22(b) specify that clinical information and other documentation that supports the patient's prognosis must accompany the certification and that hospices receive clinical information from a variety of sources; therefore, a change in the regulations at § 418.25 is not needed.

Response: We thank commenters for their support. We understand from commenters that hospices already obtain and analyze clinical information from a variety of sources, including referring providers, and we agree that the regulations at § 418.22(b) require such information to accompany the certification of terminal illness. While we are not proposing a change in the regulations at this time, we plan to work with our Medicare Administrative Contractors (MACs) to confirm whether they are requesting such information when claims are selected for medical review and, if not, whether such information should be included in any additional documentation requests. We continue to encourage providers to use the full range of clinical documentation when certifying terminal illness in order to ensure physician engagement and accountability.

Comment: The majority of commenters expressed concerns that obtaining clinical documentation from outside physicians or facilities would delay hospice admission and services. In addition, commenters expressed concern that CMS was considering requiring hospice physicians to perform a face-to-face visit within the 2 day

certification time frame in order to certify terminal illness.

Response: The discussion in the FY 2018 Hospice Wage Index and Payment Rate Update proposed rule was meant only to solicit comments on clarifying the source of the clinical information already required to be reviewed by the hospice medical director upon the initial certification. Therefore, this clinical information can be obtained orally from the referring entity and documented in the patient's chart within the 2 day time-frame needed for certification. We stated in the November 22, 2005 Hospice Care Amendments final rule that the clinical information may initially arrive verbally and is documented in the patient's medical record as part of the hospice's assessment of eligibility for hospice. The referring entity's clinical documentation may arrive later for retention in the patient's medical record (70 FR 70539). We believe that clinical information and documentation are critical to the certification decision and this information is needed for the hospice's interdisciplinary group (IDG) to develop the initial plan of care for the new patient and, therefore we would expect the information to accompany, in some fashion, the certification. Likewise, the requirement that the medical documentation that accompanies the initial written certification be obtained prior to submitting a claim remains unchanged and should not impede services. The hospice admission assessment can also accompany the initial written certification; however, this information should further substantiate rather than provide the basis for certification.

We would also like to clarify that the hospice medical director or physician designee would not be required to perform a face-to-face visit before the third benefit period recertification, as currently required by the regulations at § 418.22(a)(4). Rather, the intent of the discussion and solicitation of comments in the FY 2018 Hospice Wage Index and Payment Rate Update proposed rule was to determine whether such optional visits could be useful to augment the referral source's clinical documentation to support a medical prognosis of 6 months or less.

We appreciate and thank all commenters for providing feedback on this discussion. We will carefully consider all comments for any future rulemaking proposals, if needed, regarding the sources of clinical information to support the certification of terminal illness.

D. 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 year 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 a 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 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/reports/annual-reports/nqs2015annlrpt.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) (<http://www.nationalconsensusproject.org/Default.aspx>), recommended by multi-stakeholder organizations, and developed with the input of providers, purchasers/payers, and other stakeholders.

In the FY 2018 Hospice proposed rule (82 FR 20773 through 20774), we discussed accounting for social risk factors in the HQRP. We stated that we consider related factors that may affect measures in the HQRP. We understand that social risk factors such as income, education, race and ethnicity, employment, disability, community resources, and social support (certain factors of which are also sometimes referred to as socioeconomic status (SES) factors or socio-demographic status (SDS) factors) play a major role in health. One of our core objectives is to improve beneficiary outcomes including reducing health disparities, and we want to ensure that all beneficiaries, including those with social risk factors, receive high quality care. In addition, we seek to ensure that the quality of care furnished by providers and suppliers is assessed as fairly as possible under our programs while ensuring that beneficiaries have adequate access to excellent care.

We have been reviewing reports prepared by the Office of the Assistant Secretary for Planning and Evaluation (ASPE)⁴ and the National Academies of Sciences, Engineering, and Medicine on the issue of measuring and accounting for social risk factors in CMS' quality measurement and payment programs, and considering options on how to address the issue in these programs. On December 21, 2016, ASPE submitted a Report to Congress on a study they were required to conduct under section 2(d) of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. The study analyzed the effects of certain social risk factors of Medicare beneficiaries on quality measures and measures of resource use used in one or more of nine Medicare value-based purchasing programs.⁵ The report also included considerations for strategies to account for social risk factors in these programs. In a January 10, 2017, report released by The National Academies of Sciences, Engineering, and Medicine, that body provided various potential methods for measuring and accounting for social risk factors, including stratified public reporting.⁶ In addition, the NQF undertook a 2-year trial period in which new measures, measures undergoing maintenance review, and measures endorsed with the condition that they enter the trial period were assessed to determine whether risk adjustment for selected social risk factors was appropriate for these measures. This trial entailed temporarily allowing inclusion of social risk factors in the risk-adjustment approach for these measures. The trial has concluded and NQF will issue recommendations on the future inclusion of social risk factors in risk adjustment for quality measures.

As we continue to consider the analyses and recommendations from these reports and await the recommendations of the NQF trial on risk adjustment for quality measures, we are continuing to work with stakeholders in this process. As we have previously communicated, we are concerned about holding providers to different standards for the outcomes of their patients with social risk factors because we do not want to mask potential disparities or minimize

incentives to improve the outcomes for disadvantaged populations. Keeping this concern in mind, while we sought input on this topic previously, we continue to seek public comment on whether we should account for social risk factors in measures in the HQR, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors. Examples of methods include: Confidential reporting to providers of measure rates stratified by social risk factors, public reporting of stratified measure rates, and potential risk adjustment of a particular measure as appropriate based on data and evidence.

In addition, in the proposed rule, we sought public comment on which social risk factors might be most appropriate for reporting stratified measure scores and/or potential risk adjustment of a particular measure. Examples of social risk factors include, but are not limited to, dual eligibility/low-income subsidy, race and ethnicity, and geographic area of residence. We also sought comments on which of these factors, including current data sources where this information would be available, could be used alone or in combination, and whether other data should be collected to better capture the effects of social risk. We will take commenters' input into consideration as we continue to assess the appropriateness and feasibility of accounting for social risk factors in the HQR. We note that any such changes would be proposed through future notice and comment rulemaking.

We look forward to working with stakeholders as we consider the issue of accounting for social risk factors and reducing health disparities in CMS programs. Of note, implementing any of the above methods would be taken into consideration in the context of how this and other CMS programs operate (for example, data submission methods, availability of data, statistical considerations relating to reliability of data calculations, among others), so we sought comment on operational considerations. We are committed to ensuring that its beneficiaries have access to and receive excellent care, and that the quality of care furnished by providers and suppliers is assessed fairly in our programs.

We received many comments in response to our request for public comment on whether we should account for social risk factors in the Hospice Quality Reporting Program.

Comment: Commenters were supportive of CMS accounting for social risk factors however, the majority of the commenters cautioned that social risk

factors should be used to inform only outcome quality measures. Specifically, they were not supportive of identifying social risk factors for process measures or direct impacts of care under the hospice's control. Several commenters were concerned about quality measures for items that a hospice has minimal control over and many of these items are under discussion for risk adjustment.

Regarding methodology for adjustment, overall, commenters were supportive of risk adjustment in general, but a few commenters indicated preference for stratification or peer grouping, due to the minimal measure-level research required and low impact on provider incentives to improve care when their adjusted performance is transparent. One commenter suggested using standard statistical methodology and adopting the approach used for adjusting CAHPS® data. Prior to conducting social risk factor stratification, however, a few commenters noted that they would like for CMS to evaluate and disseminate the testing results from the NQF and solicit provider comment on the results. Several commenters encouraged CMS to determine the feasibility and appropriateness of identifying social risk factors, and a couple commenters recommended involving hospice providers in determining appropriate social risk factors and associated outcome measures. One commenter recommended piloting the outcome measures with social risk factors in advanced care planning pilot instead of incorporating them with current hospice measures. However, several commenters expressed concern that risk adjusting may lead to the unintended consequences of discouraging providers from admitting patients with identified social risk factors, and enabling providers to deliver sub-optimal care to disadvantaged populations. One commenter noted providers wishing to maintain or improve scores on quality measures may consider exclusively admitting patients who will demonstrate positive care outcomes. Another commenter emphasized that patients impacted by many social risk factors require intensified, complex care at end of life, so CMS should not unfairly penalize providers when taking these patient needs and challenges into account in the quality measurement process. Additionally, commenters offered specific suggestions for types of social risk factors to identify and recommended ways CMS could manage the testing, data collection, and reporting. In commenters' discussion of suggested social risk factors, a few

⁴ <https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicare-value-based-purchasing-programs>.

⁵ <https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicare-value-based-purchasing-programs>.

⁶ National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

commenters drew attention to how adjustment should be conducted on a measure-specific basis, as different social risk factors affect different outcomes such as caregiver satisfaction and care delivery. In addition to support for CMS's suggested categories of race and ethnicity, dual eligibility status, and geographical location, many commenters emphasized adjusting for family dynamics, such as the patient's relationship with the family, accessibility/availability of an adequate caregiver, history of substance abuse in the family, and psychosocial acuity. Other commenters promoted education level, literacy and health literacy levels, mental health, rurality and English as a second language. A few commenters highlighted adjusting for Medicaid-covered services in the area and income-subsidy levels. Some emphasized that core-based statistical area (CBSAs), geographical location of patient residence, and driving distance to home locations are important because they impact timeliness of care delivery. One commenter noted adequate and safe housing impacts the hospice's ability to deliver care. A few commenters suggested adjusting for length of stay, as patient needs will require differing acuities of care for short and long stays. One commenter requested that extraction of social risk factors pose low burden for providers. A few commenters discussed public display of data adjusted for social risk factors. One commenter suggested displaying both unadjusted and adjusted data in confidential feedback reports as a means of provider performance improvement before publicly reporting adjusted data to be used for determining reimbursement.

Response: As we have previously stated, we are concerned about holding providers to different standards for the outcomes of their patients with social risk factors, because we do not want to mask potential disparities. We believe that the path forward should incentivize improvements in health outcomes for disadvantaged populations while ensuring that beneficiaries have adequate access to excellent care. We will consider all suggestions as we continue to assess each measure and the overall program. We intend to explore options including but not limited to measure stratification by social risk factors in a consistent manner across programs, informed by considerations of stratification methods described in the upcoming FY 2018 Inpatient Prospective Payment System/Long-Term Care Hospital Prospective Payment System (IPPS/LTCH PPS) final rule,

which is expected to publish in the **Federal Register** shortly after this final rule. We thank commenters for this important feedback and will continue to consider options to account for social risk factors that would allow us to view disparities and potentially incentivize improvement in care for patients and beneficiaries. We will also consider providing feedback to providers on outcomes for individuals with social risk factors in confidential reports.

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 us for reasons including, but not limited to the following:

- 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 unavailable.
- A measure that was more proximal in time to desired patient outcomes for the particular topic was not available.
- A measure that was more strongly associated with desired patient outcomes for the particular topic was not available.
- 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 was reason to believe continued inclusion of a measure in the HQRP would encourage delivery of care that 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 CMS HQRP Web site, listserv messages via the Post-Acute Care Quality Reporting Program listserv,⁷ Medicare Learning Network (MLN) Connects® National Provider Calls & Events, MLN Connects® Provider eNews. Following immediate removal of the measures, we would also notify the public of any such removal in the next annual rulemaking cycle. CMS expects immediate removal of a measure due to safety concerns to be an unlikely event, given the rigorous testing and analysis all measures undergo prior to adoption in the HQRP.

4. Policy for Adopting Changes to Previously Adopted Measures

To further streamline the rulemaking process, we finalized in the FY 2017 Hospice Wage Index final rule (81 FR 52159) that if measures in the HQRP undergo non-substantive changes in specifications as part of their NQF re-endorsement process, we would subsequently utilize the measure with their new endorsed status in the HQRP without going through new notice-and-comment rulemaking. 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 or the measure steward's measure maintenance process, measures are sometimes updated to incorporate changes that we believe do not substantively change the intent of the measure. Examples of such changes may include updated diagnosis or procedure codes or changes to

⁷ CMS, Post-Acute Care QRP listserv, available at: https://public-dc2.govdelivery.com/accounts/USCMS/subscriber/new?topic_id=USCMS_12265.

exclusions to the patient population or definitions. While we address such changes on a case-by case basis, we generally believe these types of maintenance changes are distinct from substantive changes to measures that result in what are considered new or different 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,⁸ we believe that the NQF measure endorsement and maintenance process itself is transparent, scientifically rigorous, and provides opportunity for public input. Thus, we finalized our proposal 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 (81 FR 52159 through 52160). If NQF-endorsed specifications change and we do not adopt those changes, then we would propose the measure as a modification. A modification of a NQF-endorsed quality measure is utilized in instances when we have 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, "[i]n 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 the prior 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 CMS HQRP Web site, listserv messages on the Post-Acute Care QRP listserv, MLN Connects® National Provider Calls & Events, MLN Connects® Provider eNews and announcements on Open Door Forums and Special Open Door Forums.

5. Previously Adopted Quality Measures for FY 2018 Payment Determination and Future Years

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 7 NQF-endorsed measures 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).⁶

We finalized the following two additional measures in the FY 2017 Hospice Wage Index final rule effective April 1, 2017. Data collected will, if not reported, affect payments for FY 2019 and subsequent years. (81 FR 52163 through 52173):

- Hospice Visits when Death is Imminent
- Hospice and Palliative Care Composite Process Measure—Comprehensive Assessment at Admission

We finalized the HIS effective July 1, 2014 (78 FR 48258). The HIS is the data collection mechanism for all of the aforementioned measures. 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). For the two measures finalized in the FY 2017 Hospice Wage Index final rule, we require regular and ongoing electronic submission for each patient admission to hospice after April 1, 2017. 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. Table 16 provides a summary of measures previously finalized affecting the FY 2019 APU, data collection mechanism, and data submission deadline.

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 2017 will have their market basket update reduced by 2 percentage points in FY 2019 (beginning in October 1, 2018). 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 entitled "Hospice Item Set (HIS) System," SOR number 09-70-0548, was published in the **Federal Register** on April 8, 2014 (79 FR 19341).

The 7 NQF endorsed HIS measures adopted in FY 2014 Hospice Wage Index final rule successfully underwent NQF Endorsement Maintenance in 2016.⁹ We recognize that the NQF endorsement process is an important part of measure development and plan to submit the two measures finalized in the FY 2017 Hospice Wage Index final rule for NQF endorsement once sufficient measure data are available and we conduct the analyses necessary to support NQF submission for endorsement (for example, reliability and validity analyses). Typically, we need at least 4 quarters worth of data to conduct the necessary analyses and establish measure reliability and validity. Because the Hospice and Palliative Care Composite Process Measure—Comprehensive Assessment at Admission did not require any new data collection and can be calculated using existing data, CMS's measure development contractor, RTI

⁸ "NQF: How Endorsement Happens—National Quality Forum." 2010. 26 Jan. 2016 http://www.qualityforum.org/Measuring_Performance/ABCs/How_Endorsement_Happens.aspx.

⁹ National Quality Forum, *NQF Palliative and End-of-Life Care 2015–2016 Report*, available at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdIdentifier=id&ItemID=84242>.

International, has already conducted the analyses necessary to support submission of the measure for NQF endorsement. We have already submitted the Hospice and Palliative Care Composite Process Measure for consideration for endorsement at NQF (NQF #3235); the measure is currently under review. Data for the Hospice Visits when Death is Imminent measure pair will be collected using new items added to the HIS V2.00.0, effective April 1, 2017. Once data collection for the

measure pair begins, we will need at least 4 quarters of reliable data to conduct the necessary analyses to support submission to NQF. We will also need to assess the quality of data submitted in the first quarter of item implementation to determine whether they can be used in the analyses. Pending analysis, we will submit the Hospice Visits when Death is Imminent measure pair to NQF for endorsement review in accordance with NQF project timelines and call for measures. In the

FY 2015 Hospice Wage Index final rule (79 FR 50491 through 50496), we also finalized the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Hospice Survey to support quality measures based on patient and family experience of care. We refer readers to section III.D.11 of the May 3, 2017 proposed rule (82 FR 20750 through 20792) for details regarding the CAHPS® Hospice Survey, including public reporting of selected survey measures.

TABLE 16—PREVIOUSLY FINALIZED QUALITY MEASURES AFFECTING THE FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

| NQF No. | Hospice item set quality measure | Year the measure was first adopted for use in APU determination |
|------------|---|---|
| 1641 | Treatment Preferences | FY 2016 |
| 1647 | Beliefs/Values Addressed (if desired by the patient) | FY 2016 |
| 1634 | Pain Screening | FY 2016 |
| 1637 | Pain Assessment | FY 2016 |
| 1639 | Dyspnea Screening | FY 2016 |
| 1638 | Dyspnea Treatment | FY 2016 |
| 1617 | Patients Treated with an Opioid Who Are Given a Bowel Regimen | FY 2016 |
| N/A | Hospice and Palliative Care Composite Process Measure—Comprehensive Assessment at Admission | FY 2019 |
| N/A | Hospice Visits When Death is Imminent Measure Pair | FY 2019 |

The comment and our response are set forth below.

Comment: We received several comments on previously adopted quality measures, including measure refinement suggestions for the Hospice Visits when Death is Imminent Measure Pair. One commenter suggested that CMS include a way to capture whether visits were offered but declined. Another commenter noted that frequent visits by hospice staff may not be necessary or desired by all patients and encouraged CMS to include evidence of a need or desire for these visits in the measure specifications. We received one comment recommending risk adjustment for the Visits Measure Pair.

Response: The Visits when Death is Imminent Measure Pair is a measure that was previously proposed and finalized in the HQRP. We refer readers to the FY 2017 Hospice Wage Index final rule (81 FR 52162 through 52169) for a detailed discussion of measure specifications for this measure pair, including discussion of why refused visits were not included in measure specifications, as well as discussion on risk adjustment. We invite the public to submit questions or suggestions about previously finalized and currently implemented proposals through sub-regulatory communication channels, including the Hospice Quality Help Desk at [HospiceQualityQuestions@](mailto:HospiceQualityQuestions@cms.hhs.gov)

cms.hhs.gov, and through other communication channels such as Open Door Forums and Special Open Door Forums.

6. Removal of Previously Adopted Measures

We did not propose to remove any of the current HQRP measures at this time. Any future proposals regarding removal, suspension, or replacement of measures will be proposed here in this preamble of future rules. As stated in section III.D.3 of the FY 2018 Hospice Wage Index proposed rule (82 FR 20750), a quality measure that is adopted and implemented in the HQRP will be retained for all subsequent years, unless the measure is proposed for removal, suspension, or replacement by CMS. Policies and criteria for removing a measure were also discussed.

7. Measure Concepts Under Consideration for Future Years

Although we did not propose any HIS-based measures, we have measure concepts under consideration for future years. Our paramount concern is to develop quality measures that promote care that is person-centered, high quality, and safe. We continue to work with our measure development contractor, RTI International, to identify measure concepts for future implementation in the HQRP. In

identifying priority areas for future measure enhancement and development, we take into consideration input from numerous stakeholders, including the MAP, the MedPAC, Technical Expert Panels (TEP), and national priorities, such as those established by the Department of Health and Human Services (HHS) Strategic Plan, the National Strategy for Quality Improvement in Healthcare, and the CMS Quality Strategy. In addition, we take into consideration vital feedback and input from research published by our payment reform contractor. 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, including current HIS measures and CAHPS® Hospice Survey measures, without creating unnecessary burden or redundant reporting. Based on input from stakeholders, we identified two high priority areas that will be addressed by claims-based measure development. Developing quality measures using claims does not require new data collection, thus minimizing provider burden and expediting implementation.

Priority Area 1: Potentially Avoidable Hospice Care Transitions

The concept of a claims-based measure focusing on transitions of care was first introduced in the FY 2016 Hospice Wage Index final rule (80 FR 47188 through 47189). Comments received during this rule were overall supportive of our efforts to develop more robust quality measures that capture hospice performance and show links to patient and family outcomes. We refer readers to the FY 2016 Hospice Wage Index final rule (80 FR 47188 through 47189) and for additional details: <https://www.gpo.gov/fdsys/pkg/FR-2015-08-06/pdf/2015-19033.pdf>.

Potentially avoidable hospice care transitions at end of life are burdensome to patients, families, and the health care system at large, because they are associated with adverse health outcomes, lower patient and family satisfaction, higher health care costs, and fragmentation of care delivery.^{10 11 12 13 14} By encouraging hospice providers to assess and manage patients' risk of care transitions, this measure concept has the potential to improve quality care at the end of life by reducing potentially avoidable hospice care transitions.

Priority Area 2: Access to Levels of Hospice Care

The Medicare Hospice Benefit covers four levels of care to meet patients' and families' clinical needs: Routine home care (RHC), continuous home care (CHC), general inpatient care (GIP), and inpatient respite care. The goal of this measure concept is to assess the rates at which hospices provide different levels of hospice care. The measure has the potential to improve access to various levels of care for patients and caregivers. Appropriate use of CHC and GIP increases the likelihood of a hospice

patient dying in his or her location of choice, decreases health resource utilization resulting in potential cost savings, and increases patient and caregiver satisfaction.^{15 16} Measuring use of levels of care will encourage hospice providers to continuously assess patient and caregiver needs and provide the appropriate level of care to meet these needs. These two measure concepts are under development, and details regarding measure definitions, specifications and timeline for implementation will be communicated in future rulemaking.

We solicited comments regarding high priority measure areas for future measure development including two specific measures under consideration related to: (1) Potentially avoidable hospice care transitions, and (2) access to levels of hospice care.

The comments and our responses have been grouped below: (1) Comments applying to both high priority measure areas, (2) comments specific to the potentially avoidable hospice care transitions measure area, (3) comments specific to the access to levels of hospice care measure area, and (4) other comments and suggestions regarding future HQRPs measure development.

Comment: Many commenters agreed that these measure areas were important.

Response: We appreciate the commenters' support of these measure areas as high priority areas for future HQRPs measure development.

Comment: Many commenters expressed concerns with the limitations of using claims data for quality measure development. Specifically, commenters were concerned with the limited range of data elements available in claims data. Many commenters stated that claims data do not capture sufficient information about the clinical condition of patients, the preferences and needs of patients and families, or various other factors that influence care planning and decision-making. Several commenters believed that claims do not provide sufficient information to adequately reflect hospice practice. In general, commenters were concerned that, in the absence of these data elements, providers would be unfairly penalized should these measures be implemented.

Response: We recognize that administrative data are not collected for the purpose of quality measure

development and thus, claims data lack certain data elements that might be important to consider in constructing quality measures. For example, we agree that patient and family preferences and clinical needs are important factors in determining whether a specific care transition or use of certain level of hospice are appropriate in a specific scenario. We acknowledge the limitations of claims data in capturing this information. However, we would like to clarify that quality measures are not intended to determine whether each individual experience of a care transition or use of a certain level of hospice care, is clinically appropriate. Instead, the measures will present provider-level rates of the process and outcome in the two proposed measure areas, comparing providers to their peers with relevant and available patient-level and hospice-level factors taken into account. Despite the inability to control for certain relevant factors such as patient and family preferences, these factors tend to distribute evenly across hospices. In other words, each hospice may serve patients and families with varying levels of preference for care. As such, the inability to control for these factors does not necessarily disadvantage certain hospices.

Regardless, given the limitations of claims data noted above, we are placing careful emphasis on how we construct the specifications of the measure and are using claims data to examine the patient factors that are available and related to the hospice's performance in these measure areas. In addition, we believe that the advantages of using claims data, including minimized burden to providers and expedited implementation, outweigh the limitations of this data source. We will continue to consider the limitations of claims data as we develop specifications for these measure areas. We continue to engage stakeholders in developing measures that provide meaningful information about hospice quality. We will also continue to engage stakeholders and conduct analyses to inform the specifications of these measures.

Comment: Several commenters expressed concerns with the public's ability to understand these measure areas and easily discern their connection to quality. Commenters recommended CMS to ensure that claims-based measures are understandable to the public prior to public reporting.

Response: We appreciate the commenters' concerns regarding public reporting of measures that use claims as a data source. We agree that it is critical

¹⁰ Aldridge MDP, MBA; Epstein, Andrew J. Ph.D.; Brody, Abraham A. RN, Ph.D.; Lee, Eric J. MPH; Cherlin, Emily Ph.D., MSW; Bradley, Elizabeth H. Ph.D. The Impact of Reported Hospice Preferred Practices on Hospital Utilization at the End of Life Medical Care. 2016;54(7):657-663.

¹¹ Wang S-Y, Aldridge MD, Gross CP, et al. Transitions Between Healthcare Settings of Hospice Enrollees at the End of Life. Journal of the American Geriatrics Society. 2016;64(2):314-322.

¹² Carlson MDA, Herrin J, Du Q, et al. Impact of Hospice Disenrollment on Health Care Use and Medicare Expenditures for Patients With Cancer. Journal of Clinical Oncology. 2010;28(28):4371-4375.

¹³ Teno JM, Bowman J, Plotzke M, et al. Characteristics of Hospice Programs With Problematic Live Discharges. Journal of Pain and Symptom Management. 2015;50(4):548-552.

¹⁴ Prsic E, Plotzke M, Christian TJ, Gozalo P, Teno JM. A National Study of Live Hospice Discharges between 2000 and 2012. Journal of Palliative Medicine. 2016;19(9):987-990.

¹⁵ Barclay, J, et al., Association of hospice patients' income and care level with place of death. JAMA Internal Medicine, 2013. 173(6): p. 450-456.

¹⁶ Casarett, D., et al., Does Continuous Hospice Care Help Patients Remain at Home? Journal of Pain and Symptom Management, 2015. 50(3): p. 297-304.

to ensure that quality measures are understandable to the public, especially prior to public reporting of measures. As such, all measures developed and implemented in the HQRP, including claims-based measures, undergo rigorous user testing to ensure that they are understandable to providers and patients and families. For both high priority measure areas, we continue to engage stakeholders including a technical expert panel, caregiver workgroup and clinical users in measure development to ensure that these measures are both meaningful and understandable to the public. In addition, prior to public reporting of these measures, we will provide resources through the Hospice Compare Web site to aid the public in interpreting publicly displayed quality data.

Comment: We received several comments focused on the burden associated with future implementation of the two high priority measure areas. Although most of these commenters applauded CMS for developing measures based on claims data because of the minimal burden for providers associated with their data collection and submission and measure calculation and reporting, one commenter encouraged CMS to carefully consider the burden associated with other aspects of implementing these measure concept areas.

Response: We appreciate the comments regarding the burden associated with the two high priority measure areas. It is our goal to minimize burden for providers when considering any new measure for implementation in the HQRP. Claims-based measures require no additional data collection and submission and thus, minimize burden for providers. We recognize that the implementation of these measures may compel some providers to establish internal systems for monitoring care patterns captured by these measure concepts and are aware that some providers are already doing so. We will consider these internal monitoring and performance improvement efforts within the scope of Quality Assessment and Performance Improvement (QAPI) requirements and other current hospice conditions of participation. We believe such systems may facilitate the appropriate provision of care and prevent unnecessary transitions, thus improving quality of care provided by the hospice. However, we would like to remind providers that no new measures are being proposed in this year's rule, so there will be no additional burden placed on providers.

Comment: Several commenters noted that only a small proportion of hospice patients are discharged alive from hospice. Similarly, they noted that only 2 to 3 percent of billed days in hospice are for levels of care other than Routine Home Care.

Response: We recognize that the two high priority measure areas will capture lower-frequency events. However, studies have demonstrated considerable variation across hospice providers in both measures areas, indicating that some hospices are having a substantially higher rate of live discharges¹⁷ or provide very little or no GIP or CHC care to their patients compared to other providers.^{18 19} This signals performance gaps and, by developing and implementing these measures, we hope to capture these important quality issues. Additionally, low-frequency events can still reveal important quality issues and gaps in care that hospices should address and consumers should be aware of. Thus, measurement of low-frequency events is still important. Hospice patients are likely to need these services as their care needs change, especially as they approach the end of life, so monitoring access to these services will help encourage providers to continually assess patient need.

Moreover, both measure concepts show relationship with patient and family outcomes. Care transitions from hospice including live discharge can result in adverse health outcomes, lower patient and family satisfaction, higher health care costs, and fragmentation of care delivery.^{20 21 22 23 24} In regards to the

¹⁷ Wang S-Y, Aldridge MD, Gross CP, et al. Transitions Between Healthcare Settings of Hospice Enrollees at the End of Life. *Journal of the American Geriatrics Society*. 2016;64(2):314-322.

¹⁸ Stevenson DG, Grabowski DC, Keating NL, et al. Effect of ownership on hospice service use: 2005-2011. *J Am Geriatr Soc*. 2016 May;64(5):1024-31. doi: 10.1111/jgs.14093. PMID: 27131344.

¹⁹ Teno JM, Gozalo PL, Bynum JP, et al. Change in end-of-life care for Medicare beneficiaries: site of death, place of care, and health care transitions in 2000, 2005, and 2009. *JAMA*. 2013 Feb 6;309(5):470-7. doi: 10.1001/jama.2012.207624. PMID: 23385273.

²⁰ Aldridge MDP, MBA; Epstein, Andrew J, Ph.D.; Brody, Abraham A, RN, Ph.D.; Lee, Eric J, MPH; Cherlin, Emily Ph.D., MSW; Bradley, Elizabeth H, Ph.D. The Impact of Reported Hospice Preferred Practices on Hospital Utilization at the End of Life *Medical Care*. 2016;54(7):657-663.

²¹ Wang S-Y, Aldridge MD, Gross CP, et al. Transitions Between Healthcare Settings of Hospice Enrollees at the End of Life. *Journal of the American Geriatrics Society*. 2016;64(2):314-322.

²² Carlson MDA, Herrin J, Du Q, et al. Impact of Hospice Disenrollment on Health Care Use and Medicare Expenditures for Patients With Cancer. *Journal of Clinical Oncology*. 2010;28(28):4371-4375.

²³ Teno JM, Bowman J, Plotzke M, et al. Characteristics of Hospice Programs With Problematic Live Discharges. *Journal of Pain and Symptom Management*. 2015;50(4):548-552.

access to levels of hospice care measure, though only about 2 percent of days are billed as higher intensity levels of care (for example, CHC and GIP), a higher proportion of patients use at least one of these higher intensity levels of care at some point during their stay.

Appropriate use of CHC and GIP increases the likelihood of a hospice patient dying in his or her location of choice, decreases health resource utilization resulting in potential cost savings, and increases patient and caregiver satisfaction.^{25 26 27} Given the potentially severe consequences of receiving suboptimal care in these areas, we believe that it is appropriate to develop these measures even though they capture relatively lower frequency, but important events. It is our goal to ensure that all hospice patients and families are receiving high quality of care and having their needs met.

Comment: In the context of both high priority measure areas, several commenters expressed concerns that these measure areas are more suitable as utilization measures rather than quality measures. For example, several commenters stated that performance measures should not be implemented as a means to discourage or correct undesirable organizational practices. Several commenters noted that information about these two measure areas is available via Program for Evaluating Payment Patterns Electronic Report (PEPPER) reports. While some believed Hospice PEPPER reports, alone, were sufficient to monitor access to levels of hospice care and potentially avoidable hospice care transitions, others felt that information from the PEPPER report is distinct from information provided by the quality measurement areas, and that the two quality measure areas thus represent value-added for the HQRP and providers.

Response: We appreciate commenters' comments regarding the distinction between utilization indicators and quality measures and similarities between the two high priority measure

²⁴ Prsic E, Plotzke M, Christian TJ, Gozalo P, Teno JM. A National Study of Live Hospice Discharges between 2000 and 2012. *Journal of Palliative Medicine*. 2016;19(9):987-990.

²⁵ Barclay, J., et al., Association of hospice patients' income and care level with place of death. *JAMA Internal Medicine*, 2013. 173(6): p. 450-456.

²⁶ Casarett, D., et al., Does Continuous Hospice Care Help Patients Remain at Home? *Journal of Pain and Symptom Management*, 2015. 50(3): p. 297-304.

²⁷ Holland JM, Keene JR, Kirkendall A, et al. Family evaluation of hospice care: examining direct and indirect associations with overall satisfaction and caregiver confidence. *Palliat Support Care*. 2015 Aug;13(4):901-8. doi: 10.1017/S1478951514000595. PMID: 24992378.

areas and PEPPER measures. We would like to clarify that quality measures are distinct from utilization indicators, such as those included in the PEPPER reports. Utilization measures report statistics on services provided and billed to Medicare, and have a primary goal of protecting the Medicare program. That said, certain practice areas may be related to the integrity of the Medicare program and have significant implications on patient and family care outcomes and experience. Developing quality measures around those areas is a more effective strategy to ultimately promote quality improvement. The two high priority measure areas described in this rule measure areas that have been shown in the literature to impact quality of care through some structure, process, or outcome of care.^{28 29 30 31 32 33 34 35} As such, these 2 measure concept areas have a direct link to quality of care. Each measure concept's relationship to quality of care is addressed in greater detail in section 7. Measure Concepts Under Consideration for Future Years of this final rule, on comments specific to the potentially avoidable hospice care transitions measure area, and the section on comments specific to the access to levels of hospice care measure area. We continue to solicit input from stakeholders, including a TEP, a hospice caregiver workgroup, and a clinical user's panel to supplement evidence of this link in the literature.

Comment: Regarding measurement priority area 1 (Potentially Avoidable Hospice Care Transitions), many commenters agreed that care transitions at the end of life can be burdensome for patients and families. They noted that transitions out of hospice can often be prevented through diligent symptom management, patient and family education, and other aspects of care delivered by the hospice during the patient's stay. Thus, many of these commenters supported the importance of this measure area and its relationship to quality of care. Several commenters, including MedPAC, supported a measure related to potentially avoidable hospice care transitions. Others expressed concerns regarding potential measure specifications but were generally supportive of the concept. A few commenters recommended that CMS not pursue the development of this measure and shared their concerns.

Response: We thank the commenters for their support of a future HQR measure related to potentially avoidable hospice care transitions. We also appreciate comments offering conditional support of the measure, with suggestions for how to define and specify this measure such that it meaningfully reflects hospice quality. These suggestions, in addition to the concerns of those who did not support continued development of this measure, are addressed in detail in the paragraph below.

Comment: In addition to the general comments regarding the limitations of claims data detailed earlier in the preamble, we also received comments expressing concerns about using claims as a data source for this measure area, specifically. Many commenters were concerned that patient and family needs and preferences are not captured in claims data and thus, the measure might penalize providers whose patients choose to disenroll from hospice. For example, commenters stated that patients may revoke the hospice benefit because they decide to pursue aggressive treatment for their terminal condition or to seek care from a hospital that is not contracted with the hospice. Several commenters noted that, even if a hospice provided adequate education to patients and families, they would still want to seek acute care for various reasons unrelated to the quality of care provided by the hospice. Several commenters emphasized that patients have the right to revoke the hospice benefit at any time and that these decisions are sometimes outside of the hospice's control. Commenters described other scenarios in which they believed that discharges from hospice

and subsequent care transitions were outside the control of the hospice. For example, a few commenters mentioned payment and policy factors or local market-level factors that may trigger transitions from hospice to acute care. A few described instances in which a nearby hospital refuses to contract with them for providing GIP care, forcing them to discharge patients should they need GIP care. Several commenters believed that claims did not provide sufficient information to adequately reflect hospice practice. Specifically, commenters were concerned with using claims data to identify potentially avoidable hospice care transitions or distinguish between appropriate and inappropriate live discharges. Commenters discussed the situation in which a patient's clinical condition improved as an example of an appropriate live discharge. Several commenters requested that CMS provide examples of potentially avoidable hospice care transitions. Lastly, commenters suggested that claims data be supplemented with other data sources, such as the HEART tool in the future, in order to provide that contextual information necessary to determine whether a transition was appropriate or indicative of poor quality provided by a hospice.

Response: As previously stated, we acknowledge the limitations of claims data in capturing this information and would also like to clarify that this measure is not intended to determine whether each individual care transition or live discharge is appropriate. Instead, the measures will present provider-level rates of the process and outcome in the two proposed measure areas, comparing providers to their peers with relevant and available patient-level and hospice-level factors taken into account. Given the limitations of claims data to measure this area, we are examining information about care patterns and subsequent outcomes that are available in claims data to identify transitions that might be reflective of suboptimal quality provided by a hospice during a patient's stay (that is, failure to meet the needs of patients and their families). These transitions represent disruptions in continuity of care at a time when patients and families are extremely vulnerable. We agree that patient and family needs and preferences are an important factor in determining whether a hospice provider should be held accountable for a care transition and the related outcomes and that this information is not fully captured in claims data. However, research has demonstrated provider- and state-level

²⁸ Aldridge MDP, MBA; Epstein, Andrew J. Ph.D.; Brody, Abraham A. RN, Ph.D.; Lee, Eric J. MPH; Cherlin, Emily Ph.D., MSW; Bradley, Elizabeth H. Ph.D. The Impact of Reported Hospice Preferred Practices on Hospital Utilization at the End of Life Medical Care. 2016;54(7):657–663.

²⁹ Wang S–Y, Aldridge MD, Gross CP, et al. Transitions Between Healthcare Settings of Hospice Enrollees at the End of Life. Journal of the American Geriatrics Society. 2016;64(2):314–322.

³⁰ Carlson MDA, Herrin J, Du Q, et al. Impact of Hospice Disenrollment on Health Care Use and Medicare Expenditures for Patients With Cancer. Journal of Clinical Oncology. 2010;28(28):4371–4375.

³¹ Teno JM, Bowman J, Plotzke M, et al. Characteristics of Hospice Programs With Problematic Live Discharges. Journal of Pain and Symptom Management. 2015;50(4):548–552.

³² Prsic E, Plotzke M, Christian TJ, Gozalo P, Teno JM. A National Study of Live Hospice Discharges between 2000 and 2012. Journal of Palliative Medicine. 2016;19(9):987–990.

³³ Barclay, J., et al., Association of hospice patients' income and care level with place of death. JAMA Internal Medicine. 2013. 173(6): p. 450–456.

³⁴ Casarett, D., et al., Does Continuous Hospice Care Help Patients Remain at Home? Journal of Pain and Symptom Management, 2015. 50(3): p. 297–304.

³⁵ Holland JM, Keene JR, Kirkendall A, et al. Family evaluation of hospice care: examining direct and indirect associations with overall satisfaction and caregiver confidence. Palliat Support Care. 2015 Aug;13(4):901–8. doi: 10.1017/S1478951514000595. PMID: 24992378.

variation in proportion of hospice users experiencing care transitions, which signifies that market factors and hospice characteristics (that is, factors other than patient/family needs and preferences) influence transitions. We also agree that there are situations in which live discharges may be appropriate—for example, when a patient's clinical condition improves and they are no longer deemed to have a prognosis of 6 months or less. This measure area is not intended to suggest that live discharge is inappropriate for any individual patient but rather, to identify hospices with substantially higher rates of live discharges followed by either death or acute care use during a short period of time. Substantially higher rates of live discharge with these subsequent outcomes may indicate that providers are not meeting patient needs, signaling poor quality.³⁶

In response to commenters' requests that we provide examples of potentially avoidable hospice care transitions, we would like to reiterate that this measure is currently in development and thus, its specifications have not yet been finalized. As previously stated, this measure is intended to address lack of continuity of care during a vulnerable time for patients and families. Thus, measure specifications will focus on live discharges from hospice followed by either death or acute care use during a short period of time. We will continue to carefully examine patterns of care for live discharge and consider them in measure development. We will continue to solicit and consider stakeholder input before finalizing measure definitions and specifications. The public will have the opportunity to comment on proposed measures and their specifications if and when these measure concepts are proposed in future rulemaking cycles.

Comment: Commenters offered suggestions for how to specify a measure examining potentially avoidable hospice care transitions. Several commenters recommended that CMS to look at live discharge followed by readmission to hospice, hospitalization, or death within a short time frame. One commenter suggested incorporating data elements from providers transferring patients to hospice. Several commenters cautioned against setting a benchmark for acceptable rates of live discharge.

Response: This measure is currently under development so its specifications

have not yet been finalized. We appreciate the commenters' suggestions and will continue to take stakeholder input into consideration before finalizing measure specifications. This measure is intended to address lack of continuity of care by assessing transitions that may reflect poor quality on the part of the hospice. Thus, in line with the suggestions of commenters, measure specifications will focus on live discharges from hospice followed by either death or acute care use during a short period of time. We will carefully examine patterns of care for live discharge and consider them in measure development. We also appreciate commenters' concerns regarding the identification of a threshold or benchmark for this measure area. We acknowledge that some live discharges and care transitions are to be expected and appropriate, and agree that a threshold should not be set initially without careful analysis of national data and measure trends. We will also continue to engage stakeholders and conduct analyses to inform the specifications of this measure.

Comment: Several commenters questioned the relationship between this high priority measure and quality.

Response: We appreciate the commenters' concerns regarding this measure area's relationship to quality of care. The linkage between potentially avoidable hospice care transitions and outcomes for patients and families is demonstrated in the literature^{37 38 39 40 41} with evidence suggesting that substantially higher rates of live discharge may signal poor quality.⁴² For example, failures on the part of the hospice in advanced care planning, symptom management, responsiveness,

and family education could drive patients and families to seek acute care. Furthermore, stakeholders support the importance of this measure and its relationship to quality. Overall, TEP members agreed on the importance of this measure concept and supported its continued development and future implementation. In addition, input solicited from hospice patients and caregivers suggests that this measure concept is important and meaningful to patients and families.

Comment: In addition to the general concerns regarding public reporting of the two high priority measure areas, we received a few comments specific to public reporting of the potentially avoidable hospice care transitions measure area. One commenter expressed concerns regarding hospice provider access to information that would enable them to internally monitor their performance on this measure (that is, claims for acute care stays occurring after hospice live discharge; information allowing them to compare their performance on this measure to the performance of other hospices). They recommended CMS to refrain from public reporting until hospice providers have access to this information.

Response: We appreciate the commenter's concerns regarding the ability of hospice providers to internally monitor their performance in this measure area. Though this measure would consider patient care transitions after hospice discharge, the intention is to capture performance gaps during the hospice stay that leads to the risk of transition. Thus, hospice's provision of high quality care during a patient's hospice stay should minimize the risk of those transitions. For example, adequate symptom management and responsiveness on the part of the hospice might prevent unnecessary transitions from occurring. Though hospice providers might not have access to claims from acute care stays occurring after they discharge a patient alive, this should not affect their ability to take steps to ensure the provision of high quality care to prevent these transitions and thus, should not affect their ability to perform well on this measure. Before the onset of any public reporting for any new quality measure, we provide confidential feedback reports (that is, Certification and Survey Provider Enhanced Reports (CASPER) Quality Measure (QM) reports, confidential to the extent permissible by federal law) to providers that allow them to compare their performance to national averages.

³⁶ MedPAC, Report to the Congress: Medicare Payment Policy. March 2017. http://www.medpac.gov/docs/defaultsource/reports/mar17_medpac_ch12.pdf?sfvrsn=0.

³⁷ Aldridge MDP, MBA; Epstein, Andrew J. Ph.D.; Brody, Abraham A. RN, Ph.D.; Lee, Eric J. MPH; Cherlin, Emily Ph.D., MSW; Bradley, Elizabeth H. Ph.D. The Impact of Reported Hospice Preferred Practices on Hospital Utilization at the End of Life Medical Care. 2016;54(7):657–663.

³⁸ Wang S–Y, Aldridge MD, Gross CP, et al. Transitions Between Healthcare Settings of Hospice Enrollees at the End of Life. Journal of the American Geriatrics Society. 2016;64(2):314–322.

³⁹ Carlson MDA, Herrin J, Du Q, et al. Impact of Hospice Disenrollment on Health Care Use and Medicare Expenditures for Patients With Cancer. Journal of Clinical Oncology. 2010;28(28):4371–4375.

⁴⁰ Teno JM, Bowman J, Plotzke M, et al. Characteristics of Hospice Programs With Problematic Live Discharges. Journal of Pain and Symptom Management. 2015;50(4):548–552.

⁴¹ Prsic E, Plotzke M, Christian TJ, Gozalo P, Teno JM. A National Study of Live Hospice Discharges between 2000 and 2012. Journal of Palliative Medicine. 2016;19(9):987–990.

⁴² MedPAC, Report to the Congress: Medicare Payment Policy. March 2017. http://www.medpac.gov/docs/defaultsource/reports/mar17_medpac_ch12.pdf?sfvrsn=0.

Comment: Several commenters were concerned that this measure may result in unintended consequences for patients and families. For example, a few commenters worried that it may encourage providers to approach care decisions with less attention towards patient and family wishes.

Response: We appreciate commenters' concerns regarding potential unintended consequences of a measure examining potentially avoidable hospice care transitions. With the development of any new quality measures, it is a priority of CMS to minimize any potential unintended consequences. Thus, we will work closely with the hospice industry and other stakeholder groups to ensure that this measure does not inadvertently impede a patients' choice to make a desired transition or have any other unintended consequence.

Comment: Regarding measure development priority area 2 (Access to Levels of Hospice Care), most commenters, including MedPAC, supported the "access to levels of hospice care" measure area. Several commented on its potential to encourage providers to better meet the needs of patients and families as well as its potential usefulness for Medicare beneficiaries and their families. Some commenters, though they had concerns with potential specifications for this measure, generally agreed that access to levels of hospice care is an important aspect of hospice care for patients and families.

Response: We thank the commenters for their support of a future HQRP measure related to access to levels of hospice care. We also appreciate comments offering conditional support of the measure, with suggestions for how to define and specify this measure such that it meaningfully reflects hospice quality. These suggestions are addressed in detail in the paragraph below.

Comment: In addition to the general comments regarding the limitations of claims data detailed above, we also received comments expressing concerns about using claims as a data source for this measure area, specifically, commenters noted that claims data would not provide information about when higher intensity levels of hospice care were needed, such as information about patient acuity. One commenter stated that claims data would not reflect situations in which GIP or CHC were offered but refused by patients and families. Several commenters were concerned that claims data would not reflect instances in which a patient didn't receive a higher intensity level of

care because the hospice was able to get their symptoms under control without escalating the patient to GIP or CHC. A few commenters worried that their performance on this measure might be lower because their hospices focused on preemptively mitigating the need for higher intensity levels of care through diligent symptom management and patient and family education. Some commenters cautioned against judging access to and availability of GIP and CHC by delivery of such care. Several commenters suggested linking claims data with survey data that demonstrates a hospice's ability to provide higher intensity levels of care (for example, contracts with inpatient facilities).

Response: We agree that patient and caregiver needs and preferences for certain levels of care can impact the use of more intensive levels of hospice care and recognize that claims only provide information about what level of care was provided, not what level of care was needed or desired. However, research has demonstrated provider- and state-level variation in proportion of hospice users receiving higher intensity levels of hospice care, which signifies that market factors and hospice characteristics (that is, factors other than patient/family needs and preferences) influence GIP and CHC provision. This measure concept is not intended to suggest that a higher intensity level of care is appropriate or needed for any given individual; the purpose of this measure concept is to ensure that patients and families have access to these higher intensity levels of care if needed. Furthermore, there will be risk adjustment for this measure, which will statistically account for patient case-mix differences across hospices so that the outcome rates can be more accurately compared despite the differences in patient case-mix. We acknowledge the limitations of claims data and thus, the inability to control for certain relevant factors such as patient and family preferences and refusal of care. However, these factors tend to distribute evenly across hospices. In other words, each hospice may serve patients and families with varying level of preference for higher intensity levels of hospice care. As such, the inability to control for these factors does not necessarily disadvantage certain hospices. We encourage hospice providers to take measures to preemptively meet the symptom management and other needs of patients and applaud those who are doing so. However, we also recognize that there will be instances in which, despite a hospice's best efforts, certain patients will require higher intensity

levels of hospice care. The focus of this measure area is to ensure that these patients have access to the care that they need, and to encourage hospices to continually assess patients and provide different levels of care as needed. We also thank commenters for their suggestions regarding supplementing claims data with other data sources. We will consider the benefit of doing such in the context of the potential burden associated with data collection and measure calculation and reporting. We will also consider opportunities to incorporate other data sources into future HQRP measure development efforts.

Comment: Several commenters cautioned against setting a threshold or benchmark for GIP and CHC provision in the absence of evidence regarding where this threshold should lie.

Response: We appreciate the commenters' concerns regarding the identification of a threshold or benchmark for this measure area. We agree that thresholds should not be set arbitrarily, without rigorous information gathering and measure testing. We will continue to engage stakeholders and conduct claims data analyses to inform the specifications of this measure.

Comment: Several commenters questioned the relationship between this high priority measure area and quality.

Response: This measure area's relationship with quality of care is supported by the literature. Appropriate use of CHC and GIP increases the likelihood of a hospice patient dying in his or her location of choice, decreases health resource utilization resulting in potential cost savings, and increases patient and caregiver satisfaction.^{43 44 45} This linkage between appropriate use of higher intensity levels of hospice care and outcomes for patients and families is further supported by a technical expert panel and other stakeholder groups thus far engaged in the development of this measure. Overall, TEP members agreed on the importance of this measure concept and supported its relationship to quality. Additionally, input solicited from hospice caregivers has suggested that this measure concept

⁴³ Barclay, J., et al., Association of hospice patients' income and care level with place of death. *JAMA Internal Medicine*, 2013. 173(6): p. 450–456.

⁴⁴ Casarett, D., et al., Does Continuous Hospice Care Help Patients Remain at Home? *Journal of Pain and Symptom Management*, 2015. 50(3): p. 297–304.

⁴⁵ Holland JM, Keene JR, Kirkendall A, et al. Family evaluation of hospice care: examining direct and indirect associations with overall satisfaction and caregiver confidence. *Palliat Support Care*. 2015 Aug;13(4):901–8. doi: 10.1017/S1478951514000595. PMID: 24992378.

is important and meaningful to patients and families.

Comment: Several commenters expressed concern with the feasibility of certain hospices providing all four levels of care and described factors that may lower their performance on a measure examining access to higher intensity levels of hospice care. For example, some commenters discussed staffing challenges associated with providing CHC and GIP, particularly for smaller hospices. Several commenters noted challenges related to the CHC billing requirement that at least 8 hours of continuous care be provided within one calendar day. They described situations in which the continuous care they are providing is not reflected as CHC in claims data because it did not meet the 8 hour threshold within 1 calendar day. Others described market factors influencing a hospice's ability to provide GIP, including issues with contracting with nearby hospitals.

Response: While we acknowledge that some hospice providers may face unexpected challenges in providing higher intensity levels of hospice care, according to the Hospice Conditions of Participation (CoPs) all hospice agencies regardless of size, location or other organizational or market characteristics must be able to provide all four levels of hospice care. We will continue to discuss these issues with a technical expert panel and other stakeholder groups and conduct analyses to better understand sources of variation in GIP and CHC provision across hospices. These discussions and analyses will inform the specifications for this measure. Though we do acknowledge the challenges that commenters raised, it is our expectation that all hospices meet the requirements set forth in the Hospice (CoPs) and demonstrate the capacity to meet the needs of patients and families.

Comment: A few commenters expressed concerns with the access to levels of hospice care measure promoting overutilization of GIP and CHC. They added that the intent of this quality measure conflicts with efforts to discourage overutilization of these higher intensity, more costly levels of hospice care.

Response: We appreciate these commenters raising one potential unintended consequence of this measure area. It is our goal to minimize the unintended consequences of any new quality measure. The purpose of this measure area is not to encourage GIP or CHC for any individual patient or to encourage very high rates of GIP or CHC use within hospices. Rather, the focus of this measure area is to assess

whether patients have access to these levels of care if they need it, and to encourage hospices to continually assess patients and provide different levels of care as needed. With that said, we will provide educational opportunities for providers and the public to clearly explain the intent of this measure and its relationship to quality of care. Provider education will emphasize that the purpose of this measure is to promote access, not to encourage increased use of GIP or CHC for any given patient. We will also coordinate this measure and relevant utilization measures reported under the PEPPER to design a balanced incentive for hospices to provide the level of GIP and CHC care to meet patient and family needs.

Comment: In addition to offering comments about the two high priority measure development areas, several commenters stated their general support for future HQRP measure development efforts. Commenters noted the importance of developing quality measures that reflect the holistic and comprehensive care provided by hospice and measures that recognize that the unit of hospice care is composed of both the patient and their family. Several commenters recommended CMS to turn attention towards the development of outcome measures for the HQRP to supplement current measures, many of which are process measures. Additionally, several commenters recommended CMS to ensure that all future measures are clearly defined and undergo rigorous testing prior to implementation in the HQRP. Commenters emphasized the importance of stakeholder engagement in all measure development efforts. Several commenters specifically noted the importance of patient and family engagement to develop new HQRP measures, including measures that capture patient experience. Several commenters suggested that CMS engage with NQF and the MAP in determining priority areas for future measurement. One commenter pointed specifically to the PEACE Project, a CMS project that developed a set of quality measures, with complete specifications, and data collection tools for use by hospice and palliative care providers in quality improvement, and the 2012 MAP Performance Measurement Coordination Strategy for Hospice and Palliative Care as resources from which to pull measures and measure concepts.

Response: We thank the commenters for their support and suggestions for future quality measurement efforts as part of the HQRP. We agree that quality measures should capture the aspects of

care that set hospice apart from many other types of care, including the provision of holistic interdisciplinary care and the recognition of both the patient and their family as the unit of care. Further, we agree with commenters that the development of outcome measures should be prioritized in future HQRP measure development. It is our goal to supplement existing HIS and CAHPS® measures to develop a more comprehensive measure set that captures key domains of hospice care. With the development of any new QRP measure, we follow a rigorous process for measure development which includes measure conceptualization, measure specification, and measure testing prior to measure implementation. Each of these stages of development incorporates ample opportunity for stakeholder engagement. We consider the perspective of clinicians, patients and caregivers, and other stakeholder groups integral to the development process. We will continue to engage with the NQF and the MAP to identify priority measure concepts. We would like to note that all measures undergo review by the MAP prior to implementation in the HQRP. Further, where possible, CMS seeks NQF endorsement for any new HQRP measures that are not already endorsed by NQF. For more details regarding our measure development process, please refer to the Blueprint for CMS Measures Management System Version 13: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MMS-Blueprint.html>.

Comment: Commenters offered suggestions for future measure concepts to consider for implementation in the HQRP including:

- Congruence of place of death and patient wishes;
- Psychological, psychiatric, and psychosocial aspects of care;
- Spiritual well-being;
- Bereavement services offered by a hospice;
- Volunteer services offered by a hospice;
- Occupational therapy outcomes;
- Provider commitment to credentialing their staff;
- Care planning (for example, regular review of patient and family goals; shared decision making);
- Timely communication of patient's goals across all providers;
- Cost of care; and
- Care coordination among providers.

In addition, commenters suggested measures specific to certain subpopulations of hospice patients including:

- Pediatric patients;

- Patients with a diagnosis of Alzheimer's or Dementia;
- Patients with a short length of stay; and
- Patients receiving hospice care in a nursing facility or assisted living facility.

Response: We thank the commenters for their suggestions regarding potential future quality measures. We agree that these are important areas of hospice and will consider these suggestions in future HQRP measure development efforts.

8. 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. 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, 2017, that provider will begin submitting HIS data for patient admissions occurring after November 5, 2017. 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 2019 APU, which is associated with patient admissions occurring January 1, 2017 through December 31, 2017).

This policy allows us 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, we finalized that new hospices begin collecting HIS quality data beginning on the date noted on the CCN notification letter. We believe this policy provides 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 our policy requirements for new providers with the functionality of the HIS data submission system (QIES ASAP).

c. Previously Finalized Data Submission Mechanisms, Timelines, and Deadlines

In the FY 2015 Hospice Wage Index final rule (79 FR 50486), we finalized our policy requiring that hospices 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.9.b through III.C.9.c of the FY 2015 Hospice final rule (79 FR 50486) 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 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. 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-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.

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 us 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), we 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), we 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 after the Event Date for HIS Admission records and 7 days after 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, we will continue 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 CMS HQRP Web site, listserv messages via the Post-Acute Care QRP listserv, MLN Connects® National Provider Calls & Events, MLN Connects® Provider eNews and announcements on Open Door Forums and Special Open Door Forums.

The comment and our response are below.

Comment: We received a few comments on the previously finalized data submission mechanism, the HIS. One commenter offered several suggestions for potential revisions to the HIS V2.00.0, including suggested edits to items in Section A and Section J of the HIS-Admission record. The commenter offered suggestions for response options or items that could be potentially eliminated, and offered suggestions for refinements to coding guidance provided in the HIS Manual for these items. Another commenter requested CMS include additional examples in the HIS Manual; specifically, examples that had greater clinical relevance for a broader range of hospice providers.

Response: The HIS V2.00.0 was previously proposed and finalized as a data collection mechanism for the HQRP. We refer readers to the FY 2017 Hospice Wage Index final rule (81 FR 52167 through 52192) for a detailed discussion of the HIS V2.00.0. We invite the public to submit questions or suggestions about previously finalized and currently implemented proposals through sub-regulatory communication channels, including the Hospice Quality Help Desk at HospiceQualityQuestions@cms.hhs.gov, and through other communication channels such as Open Door Forums and Special Open Door Forums. These can be found at the CMS Web site: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Spotlight.html>. Requests such as including additional examples in the HIS Manual can be addressed at the Hospice Quality Help Desk. We are always seeking ways to make the HIS Manual more user-friendly and will consider adding examples that provide more clinical relevance for a broader range of hospice providers. By writing to the Hospice Quality Help Desk, we can communicate to be sure we understand the issue to most appropriately address it.

d. New Data Collection and Submission Mechanisms Under Consideration: Hospice Evaluation & Assessment Reporting Tool (HEART)

We have 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, we have established the HQRP, which includes clinical quality measures from the HIS and patient experience of care measures from the CAHPS® Hospice Survey. We have also 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 discussed in the FY 2017 Hospice Wage Index final rule (81 FR 52177), to facilitate continued progress towards the requirements set forth in section 3004 of the Affordable Care Act, we are in the early stages of the development of a new data collection mechanism for use by hospices. This new data collection mechanism would be a hospice patient assessment tool, which would serve two 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. In the FY 2017 Hospice Wage Index final rule (81 FR 52143), we solicited input from the public on the development of a hospice patient assessment tool that would collect quality, clinical, and other data with the ability to be used to inform future payment refinement efforts. Overall, feedback from the public was supportive of the move towards a standardized patient assessment instrument, and commenters offered some guiding principles for CMS to keep in mind in the development of a patient assessment tool, given the unique nature of hospice care. For a detailed discussion of the public comments and responses, as well as our guiding principles and motivation behind the development of a hospice patient assessment tool, we refer readers to the FY 2017 (81 FR 52143). As noted in the FY 2017 Hospice Wage Index final rule, we envision 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 also 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 and comprehensive assessment), but would be designed to complement data that are collected as part of high-quality clinical care. The new data collection effort would replace the current HIS, but would not replace other HQRP data collection efforts (that is, the CAHPS® Hospice Survey), nor would it replace regular submission of claims data. We envision 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.

We did not propose a hospice patient assessment tool at this time; we are still in the early stages of development of an assessment tool to determine the appropriate content and feasibility of such a tool. As such, we have made progress over the past year in the development of a hospice patient assessment tool, preliminarily called the Hospice Evaluation & Assessment Reporting Tool (HEART). CMS's measure development contractor, RTI International, has begun preliminary HEART development activities, including: Conducting environmental scans and engaging clinical experts to determine which domains of care are

important to capture in a hospice patient assessment; posting a national provider call and forming a Clinical Committee comprised of hospice organizations from across the United States to participate in the early development of an assessment; and collaborating within CMS to assess various stakeholder needs and encourage collaboration within CMS and across other HHS agencies. As we move forward with the development of the HEART patient assessment tool, we will continue to keep the public informed of our progress and solicit input as we establish and finalize domains of care to include in the assessment, and as we move towards specific item wording and development. Once we move past the preliminary phases of development and conceptualization, we will communicate a timeline for the HEART development, testing, and proposed implementation in future rulemaking cycles.

As mentioned in the FY 2017 Hospice Wage Index final rule (81 FR 52143), it is important for CMS to develop a hospice patient assessment tool that is scientifically rigorous and clinically appropriate for the hospice population, thus we believe that continued and transparent involvement of stakeholders is critical. We will continue to receive stakeholder input from MedPAC and ongoing input from the provider community, Medicare beneficiaries, and technical experts. Additionally, it is important for CMS to minimize data collection burden on providers in the development of HEART. We will ensure that hospice patient assessment data items are not duplicative or overly burdensome to providers, patients, caregivers, or their families. We will also work with the public and other stakeholders to ensure that HEART takes into account the unique aspects of hospice care delivery including symptom burden and psychosocial needs, patient and family preferences, care of imminently dying patients, and the complexity of providing hospice care in multiple settings and at multiple intensity levels.

The comments and our responses are set forth below.

Comment: Many commenters were supportive of the continued development of a patient assessment tool, HEART. Commenters believed that—beyond currently available CMS data sources—a tool such as HEART would enable a broader picture of the quality of care provided by hospice agencies, as well as a more comprehensive picture of patient need and service delivery. Commenters also

agreed with CMS that this enhanced patient assessment tool could be useful for quality purposes and potential payment purposes. MedPAC supported HEART, noting that a patient assessment instrument would gather more detailed clinical information on hospice patients (for example, patients' symptom burden), facilitate the development of more meaningful quality measures, and be helpful for payment policy purposes. Many commenters offered their support to CMS in the development of HEART, noting that transparent involvement of stakeholders would be crucial for ensuring HEART is scientifically rigorous, clinically appropriate, addresses the needs of individual patients, and sets the foundation for data collection that more accurately reflects the needs of patients served. In addition to voicing general support for HEART, commenters also offered several suggestions and considerations for CMS to keep in mind as we move forward with the development of HEART. Suggestions focused on the following themes: Intended use of HEART, Content of HEART, Processes for HEART development, HEART Policies and Procedures, and Burden. Beyond these major themes, commenters also offered suggestions for HEART's relationship to quality and payment and cross-setting considerations.

Response: First, we thank commenters for their support of the development of a patient assessment tool, HEART. We agree that enhanced data collection would further the goals of the HQRP and the Medicare Hospice Benefit by providing data that could be useful for development of future quality measures and potential future payment refinements. Second, we appreciate the input and recommendations from the hospice community. The input received from commenters are invaluable as we move forward with the development of HEART; we look forward to continued collaboration with our stakeholders and the hospice community. We address specific comments received in greater detail in paragraph below.

Comment: CMS received a few comments regarding the utility of HEART and CMS's vision for how HEART would be used for quality and payment purposes. A couple of commenters recommend CMS to "move cautiously", particularly in the area of payment refinement. One commenter suggested that CMS make a concerted effort to—in future rulemaking cycles—separate payment refinements from the expanded quality data that HEART would offer.

Response: We would like to take this opportunity to further clarify our vision for HEART and HEART's ultimate utility. At this time, we envision HEART as a patient assessment tool that would replace the HIS. HEART would provide richer data to offer a broader, more comprehensive picture of quality of care received by hospice patients and their families. We believe HEART may provide data that could inform future payment refinements, we would like to clarify that HEART's role in future payment refinements is not definite. We realize that before a patient assessment can be used for payment purposes, it must undergo rigorous testing to investigate whether data items are reliable and valid predictors of resource utilization. We acknowledge and appreciate that extensive testing of HEART data items will need to occur before we can make a final determination about whether HEART will prove useful in informing future payment refinements. This analysis would be in addition to the analyses that will be conducted to determine the scientific soundness of the data items themselves, as well as in addition to analyses conducted to inform the development of future quality measures. Thus, at this time, we cannot say definitively whether HEART will be used for payment refinements. Furthermore, any changes to the hospice payment methodology would be subject to the rulemaking process, which allows for public comment on any payment proposal. Although this is a potential use of the data, until extensive analysis and testing is conducted, we cannot make a final determination on the role HEART may play in future payment refinements. We would also like to take this opportunity to reassure the public of our timeline for development and testing of HEART. We appreciate the need to use a rigorous process in the development of testing and HEART; we assure the public that we will work on a timeline that allows for iterative testing and refinements, and provides ample opportunity to solicit the feedback of technical experts and the hospice community. Further details on our timeline and processes for development and testing of HEART are discussed further on in the preamble.

Comment: Many commenters offered recommendations on the content of HEART. Many commenters noted the unique nature of hospice care and offered considerations for designing HEART to ensure it would reflect the comprehensive and holistic aspects of hospice care. Specifically, commenters recommended that CMS ensure HEART:

(1) Reflects the holistic and comprehensive nature of hospice care, including physical, psychosocial, and spiritual components; (2) recognizes the importance of an individualized approach to care; (3) includes the patient and family's right to refuse or defer offered services; (4) accommodates the delivery of care in various settings, including nursing homes, assisted living facilities, hospitals, hospice facilities, and the patient's home; and (5) recognizes that the assessment must be interdisciplinary. These commenters also encouraged CMS to ensure that data gathered through HEART is easily and readily usable for development of and updates to the plan of care. In addition to accommodating the facets of care noted above, a few commenters discussed the importance of ensuring flexibility in HEART to accommodate care of the imminently dying patient. Commenters noted that patients who are imminently dying at the time of admission to hospice need the hospice to immediately address high priority patient and family needs; completing assessment forms such as HEART could interfere with providing immediate clinical and psychosocial support for vulnerable patients and families who are facing imminent death. One commenter believed that requiring completion of all HEART data elements, regardless of patient status, would obligate hospices to complete regulatory requirements at the expense of addressing urgent patient and family needs for patients who are close to death upon admission to hospice. This commenter believed hospices should have the discretion to complete only those aspects of assessment that are most critical to the needs of the patient and family, and that to promote this discretion, CMS should allow flexibility in completing HEART items for these patients. CMS received a couple of comments regarding the inclusion of standardized tools in HEART. One commenter was supportive of including validated, standardized instruments in HEART (for example, standardized pain scales, symptom management assessment tools). This commenter believed that the inclusion of standardized tools would reduce duplication with assessments that hospices already complete as part of usual care. On the other hand, another commenter cautioned against prescribing the use of specific validated, standardized tools. This commenter believed that it would be important for CMS to preserve the integrity of the hospice philosophy by allowing hospice clinicians to individualize assessments

and care based on clinical judgment, and that prescribing specific standardized tools may restrict clinical judgment and practice. One commenter recommended including HEART data elements that would capture social risk factors. Another commenter suggested CMS to include patient preferences in HEART data elements.

Response: We appreciate commenters' considerations on what should be included in the content of HEART. We wholeheartedly agree with commenters regarding the unique nature of hospice care, and we will continue to keep the hospice philosophy as the foundation of the HEART patient assessment. We seek to develop an assessment that reflects the distinctive aspects of hospice care, including the team-based, multi-disciplinary approach that is essential to hospice. We agree with the points raised by commenters about the overall focus of HEART and aims to develop a tool that addresses the holistic nature of hospice, incorporating medical, psychosocial, spiritual, and other aspects of care that are important for patients and their caregivers. We also appreciate commenters' specific suggestions regarding 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 patients who are imminently dying, patients' and caregivers' right to decline services or treatment, and the fact that hospice is delivered in multiple settings. We appreciate commenters' suggestions about including items to capture other important facets of care, including suggestions about the inclusion of standardized tools, the suggestion to incorporate patient preference into HEART, and the suggestion to consider data collection on social risk factors. We will keep these considerations in mind as we move forward with HEART development.

Comment: CMS received many suggestions from commenters regarding the process for continued development of HEART. All of these commenters encouraged CMS to engage stakeholders and the hospice community in the development process, and appreciated CMS's commitment to a transparent and collaborative development process. Commenters believed that extensive stakeholder engagement would lead to meaningful data that is truly reflective of quality of care delivered by hospices. Due to the magnitude, complexity, and importance of HEART, one commenter encouraged CMS to go beyond traditional opportunities for input (for example, TEPs) and employ widespread

processes for gathering provider input. Another commenter encouraged CMS to broaden the definition of relevant stakeholders and include EMR vendors as a stakeholder in the HEART development process. This commenter believed that many of the difficulties encountered in implementation of new requirements stem from the complexity of integrating data collection into EMR systems, and that inclusion of EMR vendors in the development process may result in a smoother implementation of HEART. In addition to offering suggestions for stakeholder engagement, many commenters offered suggestions for testing and refinement of HEART. Several commenters encouraged CMS to use an iterative testing approach; commenters encouraged CMS to conduct several phased pilot tests, which would allow for the iterative and ongoing refinement of HEART. A few commenters recommended CMS include a range of hospice agencies in pilot tests, including hospices of varying sizes, locations, and organizational structure. One commenter asked if CMS could share any progress or materials on the development of HEART, such as the structure of the assessment. Finally, many commenters offered their support to CMS throughout the development process, volunteering to provide feedback and participate in pilot initiatives.

Response: We are appreciative commenters continued support and engagement throughout the development process; and we look forward to opportunities for continued collaboration and input. We have already begun to engage the public and other stakeholders in our development process. We have formed a Clinical Committee comprised of hospice organizations from across the United States, and we have begun conversations with hospice clinical experts and other stakeholders with CMS and across HHS. We look forward to continuing these discussions and engaging in additional opportunities for stakeholder input. We agree that input from the hospice industry will be invaluable and assure commenters that our process for development and testing of HEART will allow ample opportunity to refine and improve HEART based on stakeholder input. We plan to hold TEPs to inform the development, testing, and refinement of the patient assessment. We also plan to provide other opportunities for stakeholders to provide input through venues such as Special Open Door Forums and other regular HQRPs communication channels.

We will also consider additional mechanisms for soliciting input from the public to further enhance opportunities for input.

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. As with the development of patient assessment instruments in other care settings, tentative development processes may include holding TEPs to gather input from hospice clinicians and researchers, conducting small-scale pilot tests to determine feasibility of a patient assessment instrument for hospice, conducting a larger, national test to establish reliability and validity of items and determine appropriate use of each item, providing ongoing opportunities for input and engagement from the hospice community. Only after completion of a thorough development process over the next several years would CMS consider proposing HEART through rulemaking for implementation in the HQRPs. We believe our tentative development process to be aligned with commenters' recommendations for a thorough and iterative testing approach, allowing ample opportunity for the refinement of HEART prior to implementation. Further details on HEART development and testing will be communicated in future rulemaking cycles and through sub-regulatory communication channels. We will also announce opportunities for stakeholder input and participation regularly through sub-regulatory communication channels (for example, MLN eNews ListServes, ODFs, SODFs). Regarding the commenter's request for information on the current draft version of HEART, we are still in the early, initial phases of HEART development; we look forward to sharing our progress with the provider community as developments become available.

Comment: Several commenters offered suggestions to CMS regarding policies and procedures for HEART data collection and submission, including feedback on data collection intervals, modes and timing for data collection and submission, and implementation of HEART. Commenters had differing opinions as to whether HEART data should be collected at admission and discharge only, or if data should be collected at additional interim time points beyond admission and discharge. Commenters who supported interim data collection efforts noted the importance of measuring care throughout a patient's stay to fully

understand quality of care delivered to patients over the course of their length of stay. Commenters who supported admission and discharge data collection believed interim data collection efforts only would prove overly burdensome for providers. Regarding data completion and submission, one commenter encouraged CMS to implement data collection and submission timeframes that are reasonable and clear.

Several commenters offered suggestions regarding the implementation of HEART. Commenters encouraged CMS to provide advanced notice prior to any final implementation date in order to allow ample time for infrastructure and IT system development, as well as clinician training. Several commenters recommended CMS use a phased implementation or dry run approach, which would ensure adequate time (that is, at least 1 year) for EMR vendors to incorporate HEART into their software; for hospices to initiate and thoroughly test HEART data collection processes; and, to train staff and ensure competency in use. One commenter noted that issues experienced with the implementation of prior HQRPs data collection efforts (for example, NQF #0209 measure) might have been alleviated with longer implementation and dry run periods. Several commenters underscored the importance of adequately training clinicians and other staff on HEART data collection, coding rules, and definitions to ensure accurate data collection. These commenters recommended CMS to provide ample and ongoing educational opportunities to support HEART implementation. Commenters encouraged CMS to include clear definitions for each data element included in HEART. These commenters believed that clear definitions that are readily understood are imperative to the success of any patient assessment data collection effort. One commenter noted that although CMS training materials for the HIS are thorough and comprehensive, proving useful for staff responsible for HIS data submission, the level of detail included in CMS materials is often too great for clinical staff. This commenter recommended that, in addition to providing traditional educational and training materials, CMS consider developing streamlined educational materials geared towards clinical staff. Finally, a few commenters touched on the information technology (IT) burden related to potential implementation of HEART. These commenters noted the

time and effort associated with upgrading EMR vendor systems and training staff on functionality of updated systems. One commenter recommended CMS to “include sufficient protections for small hospices” and keep in mind how IT burden affects these organizations. This commenter also suggested that CMS ensure new quality reporting requirements are tenable for small hospice programs, given their limited health IT resources.

Response: We appreciate commenters’ input on processes and policies for HEART data collection and submission. We appreciate commenters’ feedback on intervals for HEART data collection, as well as commenters’ recommendations regarding data collection and submission timeframes, systems for data submission, and timeline for implementation of HEART. We agree that having data submission timeframes and policies that align with clinical workflow and are clear to providers is very important. We also agree that a longer or phased implementation approach could help facilitate a smooth transition to HEART and minimize burden, allowing ample time for upgrading IT and EMR systems, with minimal disruption of provider workflow and increased quality of data submitted. We also agree that educational materials and ample opportunity for training—including clear and understandable definitions for each data element—will be critical to the success of HEART. Finally, we understand and appreciate commenters’ concerns about the complexity of upgrading EMR and IT systems to accommodate new data collection efforts. With respect to commenters’ suggestions about clear and understandable definitions for each data element, our hope is that our phased, iterative pilot testing approach will offer rich information on how hospices interpret HEART data elements, yielding definitions that are reflective of the reality of hospice care and are readily understood by providers. Regarding commenters’ concerns about health IT and the complexity of upgrading EMR systems, we understand the concerns about the time required for vendors to upgrade EMR systems and for hospices to be trained. In addition, we would like to note that we anticipate making data completion and submission software available to providers at no cost so that providers can complete and submit HEART data free of charge, without the need to purchase an EMR or vendor software. This would be analogous to the HART and QIES ASAP

systems currently used for HIS data completion and submission.

Comment: Although commenters were generally supportive of HEART, many commenters cautioned CMS against the creation of a patient assessment that would be overly burdensome. Commenters applauded CMS’s commitment to the development of a tool that is minimally burdensome and not duplicative. In their comments related to burden, commenters discussed the consideration of burden to the hospice provider, as well as potential burden to the patient and family. Commenters encouraged CMS to be cognizant of potential burden that additional data collection could place on patients and families. Commenters stated that the initial portion of a patient’s stay in hospice is a time when clinicians and staff are developing a relationship with the patient and family and noted that in usual practice, hospices must balance the collection of important data necessary to deliver care with the need to not overwhelm the patient and family unit during this time. One commenter noted that this consideration is even more critical when caring for an imminently dying patient. This commenter believed that standardized data collection has the potential to be burdensome to the patient and family and delay initiation of timely care to address high priority needs. Commenters encouraged CMS to keep this balance in mind when developing HEART.

Regarding burden to the provider, commenters cautioned CMS against designing an assessment that would be overly burdensome for providers, noting that the move to a more comprehensive patient assessment would require investments in chart review and other data completion activities. One commenter recommended CMS to accurately account for any potential increases in burden and cost in calculations of burden and costs of regulatory impacts. Commenters mentioned collaboration with the provider community and efficiencies from EMR software as potential ways to reduce burden. One commenter raised the relationship between HEART and existing CoP requirements and questioned how CMS envisioned this tool being minimally burdensome when CMS stated in the proposed rule that HEART would not replace initial or comprehensive assessment requirements.

Finally, several commenters noted the tradeoff between time spent on assessment tools and regulatory requirements and time spent delivering care and addressing patient and family

needs. Commenters recommended CMS to ensure that HEART data elements are overall meaningful and contribute to care planning, and cautioned CMS against the creation of a patient assessment tool that would simply be an exercise in “filling out forms” and “checking off boxes”. Commenters noted that time spent completing HEART would be time spent away from providing direct care and implored CMS to keep this tradeoff in mind in the development of HEART.

Response: We appreciate commenters’ concerns about burden of data collection efforts for both hospice providers and for hospice patients and their families. Regarding burden to patients and families, we agree with commenters that HEART should not impose burden on patients and families, especially during this early time in hospice care, and in instances where hospice patients are admitted close to death. It is our objective to ensure that HEART aligns with clinical practices so that collection of data for HEART poses no additional burden on patients and families beyond what hospices collect as part of usual care delivery. To ensure this objective is met, we will solicit clinician and patient and family caregiver input as part of HEART development process. Finally, we recognize the potential tradeoff between data collection and reporting requirements and time spent with the patient and family delivering care. CMS will keep this tradeoff at the forefront of HEART development to ensure that HEART does not detract from the primary mission of hospice care.

Regarding burden to hospice providers, we are not including HEART in this rule, so there is no additional burden associated with this rule. Once the HEART assessment has been tested and is proposed in rulemaking, CMS will provide a PRA package and burden estimates. As noted in this rule, the HEART assessment would replace the current HIS reporting requirement, meaning HEART would not represent an additional reporting requirement for hospices. Although HEART would not replace current CoP requirements for the initial and comprehensive assessment, CMS’s intent is to design HEART in a way that is complementary to the initial and comprehensive assessment to minimize burden on providers. Similar to how CoP requirements for the initial and comprehensive assessment do not require hospices to use specific formats, we envision HEART having similar levels of flexibility for providers. We believe that a flexible patient assessment tool that allows for clinician judgment will help minimize burden

and duplication of existing requirements. Moreover, any patient assessment tool proposed through rulemaking would undergo OMB and PRA review and approval, the purpose of which is to ensure required data collection efforts do not impose undue burden on the public.

We will continue to collaborate with stakeholders and will ensure that any patient assessment is minimally burdensome and not duplicative. We consider the perspective of clinicians and patients, and caregivers integral to the development process and will provide ample opportunity for stakeholder input to ensure any assessment tool is clinically appropriate and minimally burdensome. Moreover, burden will be a focus of the pilot data collection efforts in order to ensure we are appropriately assessing burden of data collection.

Comment: CMS received a few comments about HEART's relationship to quality and payment, and what providers should or should not be held accountable for. With respect to HEART's relationship to quality and the development of future quality measures using HEART data, one commenter stated that CMS should not hold providers accountable for outcomes of care that are not feasible for all hospice patients. For example, the commenter felt that providers should not be held accountable or penalized for occurrence of skin wounds at the end of life because organ failure and skin breakdown is a normal part of the dying process. Similarly, the commenter also suggested CMS not hold providers accountable for decreases in function and activities of daily living since this is an expected trajectory among hospice patients. Finally, the commenter requested that CMS not hold providers to achieving complete symptom control because this is not feasible in all patients. Another commenter encouraged CMS to appropriately risk adjust any outcomes generated from HEART data to appropriately reflect patients' right to refuse services, short lengths of stay in hospice, and instances where attending physicians refuse to sign orders that align with the patient preferences. This commenter also encouraged CMS to capture preference-concordant care as an outcome measure in HEART.

Several commenters addressed HEART's relationship to resource utilization and payment, offering suggestions to CMS as to how assessment data might be useful for future payment refinements. One commenter discussed data that HEART would need to capture if CMS moved to

a case-mix payment methodology. The commenter noted that hospices should be paid higher rates for patients needing higher levels of services, including patients who have pain or other symptoms that are difficult to manage, and patients with wounds who need higher levels of skilled care. The commenter suggested that CMS not set a payment rate lower than the rate hospices receive under current payment policy. MedPAC recommended CMS to ensure that elements of HEART were not unduly subject to provider manipulation if HEART data was to be used for payment purposes.

Response: We appreciate commenters' feedback and suggestions about HEART's relationship to quality. We will take these suggestions into consideration for future rulemaking and the continued development of HEART and any associated quality measures. We recognize and agree with the commenter that some outcomes of care are not achievable for dying patients and will work to ensure that any future outcome measures are appropriate for the hospice population. We also appreciate the commenter's suggestion to consider preference-concordant care as a future quality domain in HEART, as well as the suggestion to appropriately risk-adjust any future outcome measures generated from HEART data.

We also thank commenters for their suggestions regarding HEART's relationship to resource utilization and payment. As noted earlier in the preamble, we will need to complete extensive analysis before we determine what—if any—utility HEART will have for future payment refinements. That said, we recognize that resource utilization in hospice is unique and is most often linked to patient symptomology and service needs rather than diagnosis. As such, it is our paramount concern to develop a patient assessment tool that appropriately reflects the needs of patients and services provided by hospices to meet those needs. We will continue to involve stakeholders, including hospice organizations and clinicians, in the development process to ensure this objective is met. We also recognize the importance of developing patient assessment data elements that are scientifically rigorous and are not easily manipulated by providers. We will ensure that any data elements included in HEART undergo rigorous testing and validation prior to implementation.

Comment: Several commenters also discussed cross-setting issues with respect to HEART. Commenters suggested that CMS consider how HEART would fit in with efforts to

develop other patient assessment instruments for other post-acute care settings (for example, IRFs, SNFs, home health, and LTCHs). Commenters encouraged CMS to balance the need between developing uniform and consistent post-acute care assessment tools that would include post-acute settings and hospice, with the need to ensure HEART is reflective of the unique aspects of hospice care. Although commenters recognized cross-setting standardization and coordination as an opportunity to develop cohesive patient assessments that enable better longitudinal plans of care and integration across the care continuum, commenters also stressed the importance of ensuring that HEART reflect the interdisciplinary and unique aspects of hospice care. One commenter also encouraged CMS to incorporate HEART into the CMS Data Element Library (DEL).

Response: We appreciate the commenters' suggestions on cross-setting issues. We 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 used in other quality reporting programs for different patient populations. 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. At the same time, we also agree that HEART is an opportunity to coordinate and harmonize with measure and data elements from other care settings, where applicable. Although hospice was not a care setting included in the IMPACT Act, we are coordinating within CMS to ensure HEART promotes continuity of care across the post-acute care continuum where feasible and appropriate.

9. Previously Adopted APU Determination and Compliance Criteria for the HQRP

a. Background

The HQRP is currently designed as a "pay-for-reporting" system, meaning that it is the act of submitting data that determines compliance with HQRP requirements. Performance level is not a consideration when determining market basket updates/APU. Reporting compliance is determined by successfully fulfilling both the Hospice CAHPS® Survey requirements and the HIS data submission requirements.

b. Previously Finalized HIS Data Submission Timelines and Compliance Thresholds for 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), we finalized the timeliness criteria for submission of HIS-Admission and HIS-Discharge records. The finalized timeliness criteria were 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.

As stated in that rule, 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 the timeliness criteria for submission of HIS-Admission and HIS-Discharge records, in the FY 2016 Hospice Wage Index final rule (80 FR 47192) we also finalized a policy 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 HIS-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 and thereafter, 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.

In July of 2016, we released the Hospice Timeliness Compliance Threshold Report in the Certification and Survey Provider Enhanced Reports (CASPER) system. This report allows providers with a QIES ASAP User ID to check their preliminary compliance with the 70/80/90 timeliness compliance threshold described above. For more information on the Hospice Timeliness Compliance Threshold Report, we refer readers to the Timeliness Compliance Threshold Fact Sheet, 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> and Chapter 3 of the CASPER User's Manual, available on the QTSO Web site: <https://www.qtso.com/hospicetrain.html>.

In the FY 2016 Hospice Wage Index final rule (80 FR 47192 through 47193), we 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), we also stated that 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 HIS Web page 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 CMS HQRP Web site, listserv messages via the Post-Acute Care QRP listserv, MLN Connects® National Provider Calls & Events, MLN Connects® Provider eNews and announcements on Open Door Forums and Special Open Door Forums.

c. CAHPS® Participation Requirements for FY 2018 APU Determination and Determinations for Subsequent 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 FY APU years (79 FR 50491).

In the FY 2017 Hospice Wage Index final rule, we finalized that to meet the HQRP requirements for the FY 2018, FY 2019 and FY 2020 APU payment determinations, 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 FY 2018 APU; 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 FY 2019 APU, and hospices would collect survey data on a monthly basis for the months of January 1, 2018 through December 31, 2018 for the full FY 2020 APU (81 FR 25529 through 25530). In the May 2017 proposed rule we proposed that in order to meet the HQRP requirements for the FY 2021 APU payment determination, hospices would collect survey data on a monthly basis for the months of January 1, 2019 through December 31, 2019 to qualify for the FY 2021 APU. In addition, we proposed that in order to meet the HQRP requirements for the FY 2022 APU payment determination, hospices would collect survey data on a monthly basis for the months of January 1, 2020 through December 31, 2020 to qualify for the FY 2022 APU.

10. HQRP Submission Exemption and Extension Requirements for the FY 2019 Payment Determination and Subsequent Years

a. Extraordinary Circumstances Exemption and Extension

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. Such extraordinary circumstances may include, but are not limited to, acts of nature or other systemic issues with our data systems. We further finalized that hospices must request such an exemption or extension within 30 days of the date that the extraordinary circumstances occurred. In certain instances, however, it may be difficult for hospices to timely evaluate the impact of extraordinary circumstances within 30 calendar days. For other quality reporting programs such as the Hospital Inpatient Quality Reporting (81 FR 57182), Inpatient Rehabilitation Facility Quality Reporting Program (81 FR 52125) and the Long term Care Hospital Quality Reporting Program (81 FR 25205), we have reevaluated our policy and subsequently finalized through rulemaking an extension of that period of time to 90 calendar days. Therefore, we proposed to extend the deadline for submitting an exemption or extension request to 90 calendar days from the qualifying event which is preventing a hospice from submitting their quality data for the HQRP. We believe that extending the deadline to 90 calendar days would allow hospices more time to determine whether it is necessary and appropriate to submit an exemption or extension request and to provide a more comprehensive account of the qualifying event in their request form to CMS. For example, if a hospice has suffered damage due to a hurricane on January 1st, it would have until March 31st to submit a request form to CMS via email to the HQRP mailbox at HospiceQRPreconsiderations@cms.hhs.gov.

Further, while we finalized our policy in the past for exception/extension for the submission of the HIS data, we proposed to extend this policy beyond the submission of the HIS date to submission of the CAHPS® Hospice Survey data, given that multiple data submission processes could be impacted by the same qualifying event. Therefore, we proposed for FY 2019 payment determination and subsequent payment determinations to extend the period of

time a hospice may have to submit a request for an extension or exception for quality reporting purposes from 30 calendar days to 90 calendar days after the date that the extraordinary circumstances occurred, by submitting a request to CMS via email to the HQRP mailbox at HospiceQRPreconsiderations@cms.hhs.gov. Exemption or extension requests sent to us 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 HIS and/or CAHPS® Hospice Survey 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 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 the various means, including the CMS HQRP Web site, listserv messages via the Post-Acute Care QRP listserv, MLN Connects® National Provider Calls & Events, MLN Connects® Provider eNews and announcements on Open Door Forums and Special Open Door Forums.

We solicited comments on these proposals. The comments and our responses are set forth below.

Comment: Commenters were unanimously supportive of CMS's proposal to extend the deadline for submitting an exemption or extension request to 90 calendar days from the qualifying event which is preventing a hospice from submitting their quality data for the HQRP. One commenter believed the change in policy will

enable hospice agencies to have more time to determine whether an emergency may warrant an extension or exemption request. Another commenter believed the change in policy will enhance fairness where acts of nature or a systemic problem on part of CMS's data collection system prevents compliance. One commenter requested clarification about form for submitting requests for exemption and extensions; specifically, what the appropriate mode of submission of exemption and extension requests is.

Response: We appreciate the commenters' support for the proposal to extend the submission deadline from 30 to 90 days. We agree that the change will be helpful for providers and maximize compliance and participation in the HQRP. Regarding the commenter's request for clarification on our policies for exemption and extension, including mode of submission of these requests, as noted in this rule, we accept requests for exemption and extension via email to the HQRP Reconsiderations mailbox at HospiceQRPreconsiderations@cms.hhs.gov. Procedures for exemptions and extensions are further outlined on the CMS HQRP Web site here: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Extensions-and-Exemption-Requests.html>.

Final Action: We are finalizing our proposal to implement the change in deadline from 30 to 90 days for hospices requesting an exemption or extension for the FY 2019 payment determination and subsequent payment determinations.

b. Volume-Based Exemption for CAHPS® Hospice Survey Data Collection and Reporting Requirements

We previously finalized a volume-based exemption for CAHPS® Hospice Survey Data Collection and Reporting requirements in the FY 2017 Final Rule (81 FR 52143). Hospices that have fewer than 50 survey eligible decedents/caregivers in the period from January 1, 2017 through December 31, 2017 are eligible to apply for an exemption from CAHPS® Hospice Survey data collection and reporting requirements for the FY 2020 payment determination (corresponds to the CY 2018 data collection period). To qualify, hospices must submit an exemption request form for the FY 2020 APU. The exemption request form is available on the official CAHPS® Hospice Survey Web site <http://www.hospiceCAHPSsurvey.org>. Hospices that intend 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 December 31, 2018. Small hospices that meet the exemption for size criteria for FY 2020 must complete an exemption form for FY 2020. Exemptions for size are active for 1 year only. If a hospice continues to meet the eligibility requirements for this exemption in future FY APU periods, the organization needs to request the exemption annually for every applicable FY APU period.

Hospices that have fewer than 50 survey eligible decedents/caregivers in the period from January 1, 2018 through December 31, 2018 are eligible to apply for an exemption from CAHPS® Hospice Survey data collection and reporting requirements for the FY 2021 payment determination. Hospices that intend to claim the size exemption are required to submit to CMS their total unique patient count for the period of January 1, 2018 through December 31, 2018. The due date for submitting the exemption request form for the FY 2021 APU is December 31, 2019. Small hospices that meet the exemption for size criteria for FY 2021 must complete an exemption form for FY 2021.

Hospices that have fewer than 50 survey eligible decedents/caregivers in the period from January 1, 2019 through December 31, 2019 are eligible to apply for an exemption from CAHPS® Hospice Survey data collection and reporting requirements for the FY 2022 payment determination. Hospices that intend to claim the size exemption are required to submit to CMS their total unique patient count for the period of January 1, 2019 through December 31, 2019. The due date for submitting the exemption request form for the FY 2022 APU is December 31, 2020. If a hospice continues to meet the eligibility requirements for this exemption in future FY APU periods, the organization should request the exemption annually for every applicable FY APU period.

c. Newness Exemption for CAHPS® Hospice Survey Data Collection and Reporting Requirements

We previously finalized a one-time newness exemption for hospices that meet the criteria (81 FR 52181). Accordingly, hospices that are notified about their Medicare CCN after January 1, 2018 are exempted from the FY 2020 APU CAHPS® Hospice Survey requirements due to newness. No action is required on the part of the hospice to receive this exemption. The newness exemption is a one-time exemption from the survey. Likewise, hospices notified

about their Medicare CCN after January 1, 2019, are exempted from the FY 2021 APU CAHPS® Hospice Survey and hospices notified about their Medicare CCN after January 1, 2020, are exempted from the FY 2022 APU CAHPS® Hospice Survey requirements.

11. CAHPS® Hospice Survey Participation Requirements for the FY 2020 APU and Subsequent Years

The CAHPS® Hospice Survey of CMS' Hospice Quality Reporting Program is used to collect data on the experiences of hospice patients and the primary caregivers listed in their hospice records. Readers who want more information are referred to our extensive discussion of the Hospice Experience of Care prior to our proposal for the public reporting of measures should refer to 79 FR 50452 and 78 FR 48261.

a. Background and Description of the CAHPS® Hospice Survey

The CAHPS® Hospice Survey is the first standardized national survey available to collect information on patients' and informal caregivers' experience of hospice care. Patient-centered experience measures are a key component of the CMS Quality Strategy, emphasizing patient-centered care by rating experience as a means to empower patients and their caregivers and improving the quality of their care.⁴⁶ In addition, the survey introduces standard survey administration protocols that allow for fair comparisons across hospices.

Details regarding CAHPS® Hospice Survey national implementation, survey administration, participation requirements, exemptions from the survey's requirements, hospice patient and caregiver eligibility criteria, fielding schedules, sampling requirements, survey instruments, and the languages that are available for the survey, are all available on the official CAHPS® Hospice Survey Web site, www.HospiceCAHPSsurvey.org and in the CAHPS® Hospice Survey Quality Assurance Guidelines (QAG), which is posted on the Web site.

b. Overview of Proposed Measures

The CAHPS® Hospice Survey was developed in line with the U.S. Department of Health and Human Services' Transparency Initiative to measure patient experience. Unlike the Hospital CAHPS® Survey deployed in 2006 (71 FR 48037 through 48039) and

other subsequent CAHPS® surveys, the CAHPS® Hospice Survey is administered after the patient is deceased and queries the decedent's primary caregiver regarding the patient and family experience of care. National implementation of the CAHPS® Hospice Survey commenced January 1, 2015 as stated in the FY 2015 Hospice Wage Index and Payment Rate Update final rule (79 FR 50452).

The survey consists of 47 questions and is available (using the mailed version) in English, Spanish, Chinese, Russian, Portuguese, Vietnamese, Polish, and Korean. It covers topics such as access to care, communications, getting help for symptoms, and interactions with hospice staff. The survey also contains two global rating questions and asks for self-reported demographic information (race/ethnicity, educational attainment level, languages spoken at home, among others). The CAHPS® Hospice Survey measures received NQF endorsement on October 26th, 2016 (NQF number 2651). Measures derived from the CAHPS® Hospice Survey include six multi-item (composite) measures and two global ratings measures under NQF 2651. We proposed to adopt these eight survey-based measures for the CY 2018 data collection period and for subsequent years. We believe these survey-based measures will be useful in assessing aspects of hospice care where the family/primary caregiver is the most useful or only source of information, and to allow meaningful and objective comparisons between hospice providers. The six CAHPS® Hospice Survey composite survey-based measures are:

- Hospice Team Communication;
- Getting Timely Care;
- Treating Family Member with Respect;
- Getting Emotional and Religious Support;
- Getting Help for Symptoms; and
- Getting Hospice Care Training.

Each of the six composite survey-based measures consists of two or more questions. The two global survey-based measures are:

- Rating of Hospice; and
- Willingness to Recommend Hospice.

The two global survey-based measures comprise a single question each and ask the primary caregiver of the decedent to rate the care provided by the hospice facility and his or her willingness to recommend the hospice to family and friends. More information about these measures can be found on the official CAHPS® Hospice Survey Web site, www.HospiceCAHPSsurvey.org and in

⁴⁶ CMS National Quality Strategy 2016. Available at: <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/qualityinitiativesgeninfo/downloads/cms-quality-strategy.pdf>.

the CAHPS® Hospice Survey Quality Assurance Guidelines (QAG), which is posted on the Web site.

The eight survey-based measures we proposed were included on the CY 2016 MUC⁴⁷ list, and reviewed by the MAP.⁴⁸ They are as follows:

- CAHPS® Hospice Survey: Rating of Hospice (MUC ID: MUC16–31).
- CAHPS® Hospice Survey: Hospice Team Communications (MUC16–32).
- CAHPS® Hospice Survey: Willingness to Recommend (MUC16–33).
- CAHPS® Hospice Survey: Getting Hospice Care Training (MUC16–35).
- CAHPS® Hospice Survey: Getting Timely Care (MUC16–36).
- CAHPS® Hospice Survey: Getting Emotional and Religious Support (MUC16–37).
- CAHPS® Hospice Survey: Getting Help for Symptoms (MUC16–39)
- CAHPS® Hospice Survey: Treating Family Member with Respect (MUC16–40)

The MAP supported rulemaking for all eight “patient-reported” measures derived from the CAHPS® Hospice Survey. We received no comments about these items and therefore, we are adopting these measures as final for CY 2018.

c. Data Sources

As discussed in the CAHPS® Hospice Survey Quality Assurance Guidelines V3.0 (QAG V3.0) (<http://www.hospicecahpsurvey.org/en/quality-assurance-guidelines/>), the survey has three administration methods: Mail-only, telephone only, and mixed mode (mail with telephone follow-up of non-respondents). We previously finalized the participation requirements for the FY 2018 and FY 2019 Annual Payment Updates (80 FR 47194). To summarize, to meet the CAHPS® Hospice Survey requirements for the HQRP, we proposed that hospice facilities must contract with a CMS-approved vendor to collect survey data for eligible patients on a monthly basis and report that data to CMS on the hospice’s behalf by the quarterly deadlines established for each data collection period. The list of approved vendors is available at: <http://www.hospicecahpsurvey.org/en/approved-vendor-list>.

Hospices are required to provide lists of the patients who died under their care, along with the associated primary caregiver information, to their respective survey vendors to form the samples for the CAHPS® Hospice Survey. We emphasize the importance

of hospices providing complete and accurate information to their respective survey vendors in a timely manner. Hospices must contract with an approved CAHPS® Hospice Survey vendor to conduct the survey on their behalf. Hospices are responsible for making sure their respective survey vendors meet all data submission deadlines. Vendor failures to submit data on time are the responsibility of the hospices.

i. Requirements for the FY 2020 Annual Payment Update

To meet participation requirements for the FY 2020 annual payment update (APU), Medicare-certified hospices must collect CAHPS® Hospice Survey data on an ongoing monthly basis from January 2018 through December 2018 (all 12 months) in order to receive their full payment for the FY 2020 APU. All data submission deadlines for the FY 2020 APU are in Table 17. CAHPS® Hospice Survey vendors must submit data by the deadlines listed in Table 17 for all APU periods listed in the table and moving forward. There are no late submissions permitted after the deadlines, except for extraordinary circumstances beyond the control of the provider as discussed above.

TABLE 17—CAHPS® HOSPICE SURVEY DATA SUBMISSION DATES FOR THE APU IN FY 2020, FY 2021, AND FY 2022

| Sample months (that is, month of death ¹) | Quarterly data submission deadlines ² |
|--|--|
| FY 2020 APU | |
| January–March 2018 (Q1) | August 8, 2018. |
| April–June 2018 (Q2) | November 14, 2018. |
| July–September 2018 (Q3) | February 13, 2019. |
| October–December 2018 (Q4) | May 8, 2019. |
| FY 2021 APU | |
| January–March 2019 (Q1) | August 14, 2019. |
| April–June 2019 (Q2) | November 13, 2019. |
| July–September 2019 (Q3) | February 12, 2020. |
| October–December 2019 (Q4) | May 13, 2020. |
| FY 2022 APU | |
| January–March 2020 (Q1) | August 12, 2020. |
| April–June 2020 (Q2) | November 12, 2020 ³ . |
| July–September 2020 (Q3) | February 10, 2021. |
| October–December 2020 (Q4) | May 12, 2021. |

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 the months August, November, February, and May.

³ Second Wednesday is Veterans Day Holiday.

ii. Requirements for the FY 2021 Annual Payment Update

To meet participation requirements for the FY 2021 APU, Medicare-certified hospices must collect CAHPS® Hospice

Survey data on an ongoing monthly basis from January 2019 through December 2019 (all 12 months) in order to receive their full payment for the FY 2021 APU. All data submission

deadlines for the FY 2021 APU are in Table 17. CAHPS® Hospice Survey vendors must submit data by the deadlines listed in Table 17 for all APU periods listed in the table and moving

⁴⁷ CMS, *List of Measures Under Consideration for December 1, 2016*. Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/>

Downloads/Measures-under-Consideration-List-for-2016.pdf.

⁴⁸ The National Quality Forum. *MAP 2016–2017 Preliminary Recommendations*. National Quality

Forum, 2016 Recommendations for Measures Under Consideration, Jan. 2017. Available at: <http://www.qualityforum.org/map/>.

forward. There are no late submissions permitted after the deadlines, except for extraordinary circumstances beyond the control of the provider as discussed above.

iii. Requirements for the FY 2022 Annual Payment Update

To meet participation requirements for the FY 2022 APU, Medicare-certified hospices must collect CAHPS® Hospice Survey data on an ongoing monthly basis from January 2020 through December 2020 (all 12 months) in order to receive their full payment for the FY 2022 APU. All data submission deadlines for the FY 2022 APU are in Table 17. CAHPS® Hospice Survey vendors must submit data by the deadlines listed in Table 17 for all APU periods listed in the table and moving forward. There are no late submissions permitted after the deadlines, except for extraordinary circumstances beyond the control of the provider as discussed above.

d. Measure Calculations

As noted above, we proposed to adopt six composite CAHPS® Hospice Survey-based measures and two global survey-based measures. As with other measures adopted for HQR, a hospice's performance for a given payment determination year will be based upon the successful submission of data required in accordance with the administrative, form, manner and timing requirements established for the program. Therefore, hospices' substantive scores on the CAHPS® Hospice Survey-based measures will not affect whether they are subject to the 2.0 percentage point payment reduction for hospices that fail to report data required to be submitted. Rather, the 2.0 percentage point reduction will be applied based on whether the data were submitted in accordance with our requirements.

We proposed that CAHPS® Hospice Survey scores for a given hospice be displayed as "top box" scores, with the national average top-box score for participating hospices provided for comparison. Top-box scores reflect the proportion of caregiver respondents that endorse the most positive response(s) to a given measure, such as the proportion that rate the hospice a 9 or 10 out of 10 on a 0 to 10 scale, or the proportion that report that they "always" received timely care. The top-box numerator for each question within a measure is the number of respondents that endorse the most positive response(s) to the question. The denominator includes all respondents eligible to respond to the question, with one exception. The

exception is the Getting Hospice Care Training measure; for this measure, the measure score is calculated only among those respondents who indicated that their family member received hospice care at home or in an assisted living facility.

For additional information on the specifications of these measures, including details regarding top-box scoring methodology and mode and case-mix adjustment, please refer to the CAHPS® Hospice Survey Web page at <http://www.hospicecahpsurvey.org/en/>.

i. Composite Survey-Based Measures

Unadjusted hospice scores on each composite CAHPS® Hospice Survey-based measure would be calculated by determining the proportion of "top-box" responses for each question within the composite and averaging these proportions over all the questions in the composite measure. For example, to assess hospice performance on the composite measure CAHPS® Hospice Survey—Hospice Team Communication, we would calculate the proportion of top-box responses for each of the measure's six questions, add those proportions together, and divide by the number of questions in the composite measure (in this case, six).

As a specific example, we take a theoretical hospice facility that had 50 surveys completed and received the proportions of "top-box" responses through sample calculations:

- 25 "top-box" responses out of 50 total responses on Question One
- 40 "top-box" responses out of 50 total responses on Question Two
- 50 "top-box" responses out of 50 total responses on Question Three
- 35 "top-box" responses out of 50 total responses on Question Four
- 45 "top-box" responses out of 50 total responses on Question Five
- 40 "top-box" responses out of 50 total responses on Question Six

Based on the above responses, we would calculate that hospice's unadjusted measure score for public reporting as follows:

$$\text{Publicly Reported Score} = ((0.5 + 0.8 + 1 + 0.7 + 0.9 + 0.8)/6)$$

This calculation would give this example hospice an unadjusted score of 0.78 or 78 percent for the Hospice Team Communication measure for purposes of public reporting. We note that an adjusted hospice score would be calculated by adjusting the score for each question for differences in the characteristics of decedents and caregivers across hospices and for mode, and then averaging across questions within the measure as described here.

Further detailed information regarding scoring and risk adjustment can be found at the CAHPS® Hospice Survey Web site (<http://www.hospicecahpsurvey.org/en/technical-specifications/>).

ii. Global Survey-Based Measures

We proposed to adopt two global CAHPS® Hospice Survey measures. CAHPS® Hospice Survey—Rating of Hospice asks the primary caregiver of the decedent to rate the care provided by the hospice on a scale of 0 to 10, and CAHPS® Hospice Survey—Willingness to Recommend asks about the caregiver's willingness to recommend the hospice to family and friends on a scale of "Definitely No" to "Definitely Yes". Unadjusted hospice performance on each of the two global CAHPS® Hospice Survey-based measures would be calculated by the proportion of respondents providing high-value responses (that is, a 9 to 10 rating or "Definitely Yes") to the survey questions over the total number of respondents. For example, if a hospice received 45 ratings of 9 or 10 points out of 50 responses, this hospital would receive a 0.9 or 90 percent unadjusted score, which would then be adjusted for differences in the characteristics of decedents and caregivers across hospices and modes.

iii. Cohort

The CAHPS® Hospice Survey is administered to all eligible patients/caregivers—or a random sample thereof—who meet the eligibility criteria. Eligible patients, regardless of insurance or payment, can participate.

For purposes of each survey-based measure captured in the CAHPS® Hospice Survey, an "eligible patient" is a decedent 18 years or older:

- With death at least 48 hours following last admission to hospice care.
- for whom there is a caregiver of record.
- whose caregiver is someone other than a non-familial legal guardian.
- for whom the caregiver has a United States or United States Territory home address.

Patients who are still alive or whose admission to the hospice resulted in a live discharge, are not eligible to participate in the survey. In addition, decedents/caregivers who initiate or voluntarily request that the hospice not reveal the patient's identity; and/or not survey the patient/caregiver ("no publicity patients/caregivers") are excluded from the sample.

e. Risk Adjustment

The CAHPS® Hospice Survey measures assess activities that are fully under the control of hospice care professionals and/or hospice organizations. In order to ensure fair comparisons in public reporting, we believe it is necessary and appropriate to adjust for factors that are not directly related to hospice performance, such as patient mix, for these CAHPS® Hospice Survey measures. The survey based measures are adjusted for decedent and caregiver characteristics (including the lag time between patient death and survey response; decedent's age, payer for hospice care, decedent's primary diagnosis, decedent's length of final episode of hospice care, caregiver's education, decedent's relationship to caregiver, caregiver's preferred language and language in which the survey was completed, and caregiver's age) known to be associated with systematic difference in survey responses.

i. Patient-Mix Adjustment

Previous research, on both CAHPS® surveys and other types of surveys, has identified respondent characteristics that are not under the control of the entities being assessed but tend to be related to survey responses. Hence, variations in the proportion of respondents with such characteristics will be associated with variations in survey responses that are unrelated to the actual quality of hospice care. To ensure that comparisons between hospices reflect differences in performance rather than differences in patient and/or caregiver characteristics, publicly reported hospice scores will be adjusted for variations of such characteristics across hospices. This adjustment is performed using a linear regression model applied to all data within a quarter, with indicator variables for each hospice and each characteristic as an independent variable in the model.

ii. Mode Adjustment

We conducted an experiment to determine whether survey mode adjustments were needed to fairly compare CAHPS® Hospice Survey scores. The experiment found that mode adjustments are needed. Publicly reported CAHPS® Hospice Survey scores will be adjusted for the mode of survey administration, which affects scores but is not related to quality of hospice care (Authorized survey modes are: mail-only, telephone-only, and mail with telephone follow up, also called mixed mode.). Mode adjustment is performed prior to patient-mix

adjustment; a mode adjustment value is added/subtracted (depending on the mode) to each response to the survey by mail-only mode or mixed mode. Responses obtained using telephone-only mode are not adjusted since this is the reference mode. As a result of the risk adjustment methodologies proposed here, the final percentages may vary from the unadjusted percentage as calculated in the examples provided above.

f. For Further Information About the CAHPS® Hospice Survey

We encourage hospices and other entities to learn more about the survey on www.hospicecahpsurvey.org. For direct questions, please contact the CAHPS® Hospice Survey Team at hospicecahpsurvey@HCQIS.org or telephone 1-844-472-4621.

The comments and our responses are set forth below.

Comment: One commenter stated that: "typically anything that is impacted significantly by patient perception—subjective measures regarding quality of an end of life process are probably not going to be meaningful. Combined with low health literacy surrounding dying/end of life and then tying these measures to the hospice payment structure is probably damaging. Patients and their families probably receive all of their knowledge about the dying process from hospices themselves, and since that topic is quite deep to begin with, and the emotional state of many families and patients is not one that is prepared to learn in their circumstances, their responses to their surroundings/the proceedings of hospice probably do not reflect the actual care they are receiving."

Response: We believe that patient experience surveys constitute a useful element in quality reporting programs. Our Hospice CAHPS® survey was designed using interviews with caregivers, providers and other interested professionals to include questions that address the domains of interest to the caregiving public. Survey results, combined with other measures such as the HIS, can provide a more rounded view of hospice quality. Hospices can, and we believe do, use CAHPS® results to help them with quality improvement.

Comment: Several commenters expressed reservations about the timeframe for reporting CAHPS® Hospice Survey results publicly on Hospice Compare. Commenters thought the data would be too outdated and that it would not reflect adjustments and quality improvement efforts by the hospices.

Response: We are currently planning on reporting scores using a rolling average over the most recent eight quarters. We are trying to balance two competing goals. First, we want to present reliable data. Second, we want to include as large a proportion of hospices as possible on the Hospice Compare site. Small sample sizes tend to be less reliable than larger ones. This means that displaying data for hospices with only a few completed surveys results in providing less reliable data. On the other hand, if we only report results with large numbers of completes, a great many hospices will not appear on the Compare site at all. We tried to avoid both problems by elongating the amount of time we are using to report the data. We hoped this would produce larger numbers of completed surveys for the smaller hospices, thus allowing them to be reported with more reliable data. We are willing to consider other options and would welcome more input from hospices.

Comment: One commenter suggested that CMS look at ways to ameliorate the age of the publicly reported data by "appropriately weighting the current data and separately weight the older data or not include it at all. Further exploration is needed to include patient/respondent characteristics that may have an impact on the CAHPS® survey responses, including issues that are not currently specified for use in the risk adjustment of CAHPS® responses."

Response: We will explore options, if any, offered by weighting schemes for the publicly reported data. We assume the commenter would want the newest data weighted more heavily than older data. We are also willing to continue to examine patient and respondent characteristics that may be suitable for case mix adjustment. Remember that case mix variables must be variables that are beyond the control of the hospice.

Comment: Another commenter suggested that CMS consider using a six month analysis with the most current data for the reporting of CAHPS® results. The commenter was concerned that the eight-quarter rolling reporting period for CAHPS® results could be misleading to the public as organization improvement would not be seen for an extended period and not reflect current performance.

Response: We will continue to review the decision to use an eight-quarter average. We are aware that there are several potential pitfalls with survey data. One of the characteristics of small samples is that the results may shift greatly month to month because of one or a few outliers among respondents. As

a result, including small hospices with small sample sizes on the Compare site also creates the risk of misleading the public. On the other hand, we are reluctant to restrict the Hospice Compare site to large hospices. We welcome more input from hospices on this issue.

Comment: One commenter suggested that CMS consider displaying two sets of data on Hospice Compare, one for eight quarters of data and one for four quarters of data, which would address concerns about the age of the data.

Response: We thank the commenter for this suggestion. We are aware of the concerns about the age of the data. We believe displaying two sets of CAHPS® data would make the CAHPS® pages on Hospice Compare more complex and might confuse members of the public.

Comment: One commenter stated that analysis of missing data for the CAHPS® Hospice Survey is needed to determine how well the survey results represent the totality of hospice care quality and assist hospices with the interpretation of survey results for quality improvement programs.

Response: Our analysis of CAHPS® Hospice Survey data suggest that adjustment for differences in case mix, as is done when calculating CAHPS® Hospice Survey measure scores, adequately addresses nonresponse bias associated with these case mix characteristics.

Comment: CMS should conduct ongoing analysis of the demographics and other characteristics (for example, age, gender, diagnosis, geographic area, care setting, etc.) for those patients whose caregivers (a) are not included in Hospice CAHPS® administration; or (b) do not complete a survey. This information at a minimum should be shared with hospice providers so it can be used to inform their quality improvement efforts and development of strategies to improve survey response rates. CMS should also consider including these results in Hospice Compare to provide consumers with an idea of the degree that Hospice CAHPS® survey respondents may differ from themselves.

Response: We are conducting ongoing analyses of the characteristics of decedents for whom CAHPS® Hospice Surveys are completed, and is considering a variety of means for sharing this information with hospices.

Comment: One commenter said that caregiver involvement in care should be included in case mix adjustment of the CAHPS® Hospice Survey measures.

Response: Case-mix adjustment addresses factors that are systematically associated with differences in how

caregivers respond to the CAHPS® Hospice Survey, and that are not in the control of the hospice. Hospice activities may influence the degree of caregiver involvement.

Comment: One commenter noted that the 47 CAHPS® hospice survey questions do not address the care planning and/or patient and family/family caregiver shared decision making. The commenter also noted that the CAHPS® survey does ask related questions, but only after the death of the patient.

Response: We chose to make Hospice CAHPS® a survey of caregivers that occurs after the death of the patient, in order to obtain information about the entire trajectory of hospice care, not just the care upon which the patient was themselves able to respond. As the commenter noted, the survey does ask questions related to care planning and shared-decision making. When developing the questions for the survey we focused on domains that caregivers told us were important to them. We are willing to consider other questions for inclusion in the survey and will think further about care planning and shared decision making in the future.

Comment: One commenter mentioned that there are no questions about the “extent to which the family was able to satisfactorily or confidently engage in the care or support of their terminally ill family member.”

Response: We are willing to consider items for inclusion in the survey. We think the subject raised by the comment would be related to how often hospice training resulted in the caregiver being confident in caring for or support of a terminally ill patient.

Comment: One commenter supported “that CAHPS® Hospice Survey scores for a given hospice be displayed as “top-box” scores, with the national average top-box score for participating hospices provided for comparison. This will allow hospice providers to understand their measures and identify areas for improvement.”

Response: We are planning to include national average top box scores for CAHPS® on Hospice Compare.

Comment: One commenter suggested that CMS incorporate additional information into the Hospice Compare Web site. Specifically, they recommended helping the users understand what the hospice benefit entails. They also suggested that the site provide advice on how to use quality reports to choose hospices.

Response: We are designing the Hospice Compare site to provide users with information about the hospice benefit. We are also testing the site to

make sure it is understandable to the public. We will provide information about how the data are calculated and what it includes when the hospice data is published on Hospice Compare. We anticipate this occurring in the Winter of 2018.

Comment: One commenter said, “It would be wonderful if there were comments and explanations that tell the story of what the HIS and data elements were saying. A summary of sorts?”

Response: We appreciate the commenter’s suggestion and will consider for the future, including a guide or legend that describes the measures. We agree that stakeholders would find this useful.

Comment: One commenter raised a concern about some of the national benchmarking scores for CAHPS®, asking if it is a valid measure when the national benchmark scores are all low in one area. The commenter also asked if anyone is evaluating these survey items.

Response: We are not certain what the commenter means by “benchmark scores are all low in one area.” It is unclear if the commenter means a geographic area or a topic area. Hospice usage and quality can and does vary by geographic region. The questions included in the Hospice CAHPS® survey are thoroughly reviewed by the Agency for Healthcare Research and Quality (AHRQ) and other healthcare and research professionals. The CAHPS Hospice Survey was awarded use of the CAHPS trademark after extensive review by AHRQ’s CAHPS® Consortium. Measures from the survey were reviewed and endorsed by the National Quality Forum (NQF #2651). The questions were also reviewed by the multi-stakeholder MAP, which guides the selection of measures for HHS.

Comment: One commenter raised the issue of fairness regarding hospices that are not included in Hospice Compare due to their small volume of patients served and their length of service.

Response: We are aware of the issue as it impacts inclusion in Hospice Compare. This is the major rationale for showing eight quarters of data—it allows us to display more reliable data for more hospices. We welcome further advice on how best to handle the fairness issue while at the same time providing accurate information to the public. We also welcome alternative suggestions for a solution to this issue.

Comment: One commenter noted, “Families often tell hospice providers they do not understand why they were sent a second CAHPS® survey. They state that they either complete the second survey or assume we sent it by mistake. Many question the program’s

organizational skills. The instructions/process sent with the surveys needs to be clearer for bereaved family members.”

Response: We will work with vendors to make sure that caregivers know why they received a second survey. Much of the time the reason is that the caregiver's completed survey is sent late enough that we are into a second wave of mailings to “non-respondents.” The questionnaires cross in the mail.

12. HQRP Reconsideration and Appeals Procedures for the FY 2018 Payment Determination and Subsequent Years

In the FY 2015 Hospice 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 HQRP 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: <https://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 (USPS) or phone will not be considered as a valid reconsideration request. In the FY 2017 final rule (81 FR 52143) we further clarified that providers should submit reconsideration requests of decision by CMS that the hospice has not met the CAHPS® Hospice Survey requirements using the same process (81 FR 52181). (Details about the reports and emails received after data submission are in the CAHPS® Hospice Quality Assurance Guidelines, which is available on the official CAHPS® Hospice Survey Web site, www.hospicecahpsurvey.org). 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 of this final rule. 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/2017-Transmittals.html>.

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 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 have implemented this additional communication mechanism via the CASPER Hospice Timeliness Compliance Threshold Report previously discussed in the FY 2017 Hospice Wage Index proposed rule at 81 FR 25527 and 25528. We will continue to send notification of noncompliance via delivery of a letter via the USPS. We previously finalized our proposal (80 FR 47198) to publish a list of hospices who successfully meet the reporting requirements for the applicable payment determination on the CMS HQRP Web site. The list of providers found to be compliant with the FY 2017 APU requirements can be found on the CMS HQRP Web site here: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/HQRP-Requirements-and-Best-Practices.html>.

13. Confidential Feedback Reports

As part of our effort to promote use of standardized quality data to improve quality of care, in December 2016, we made available two new provider feedback reports: The Hospice-Level Quality Measure Report and the Patient Stay-Level Quality Measure Report. These confidential feedback reports are available to each hospice using the CASPER system, and are part of the class of CASPER reports known as Quality Measure (QM) Reports. These reports are separate from public reporting and are for provider viewing only (to the extent permissible under federal law), for the purposes of internal provider quality improvement. These reports are on-demand and thus enable hospice providers to view and compare their performance to the national average for a reporting period of their choice.

Hospices are able to view their data and information at both the hospice and patient stay levels for their HIS-based quality measures. The CASPER hospice-level QM Reports contain information such as the numerator, denominator, hospice-level QM score, and national average. The CASPER patient stay-level QM Reports show whether each patient stay is counted toward each quality measure. The HIS based QMs reported in both reports include:

- NQF #1641 Treatment Preferences
- NQF #1647 Beliefs/Values
- NQF #1634 Pain Screening
- NQF #1637 Pain Assessment
- NQF #1639 Dyspnea Screening
- NQF #1638 Dyspnea Treatment
- NQF #1617 Bowel Regimen

For more information on the CASPER QM Reports, we refer readers to the CASPER QM Factsheet on the HQRP Web site at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/HQRP-Requirements-and-Best-Practices.html>. This fact sheet contains detailed information about each CASPER QM report currently available, the data included in the reports, and how providers can use the reports as part of their Quality Assessment and Performance Improvement (QAPI) efforts. For technical information on the reports and how to access the CASPER QM Reports, we refer readers to: <https://www.qtso.com/hospicetrain.html>.

As new HIS measures are implemented in the HQRP, we will continue to expand the functionality of the QM reports to allow providers to view data on additional HIS measures. We will announce refinements and additions to the QM reports through sub-regulatory communication channels and in future rulemaking cycles.

We also proposed to provide hospices with preview reports of their data prior to the quarterly publication of CAHPS® Hospice Survey data on the Compare site. The reports will be provided through the CASPER reporting system. Each hospice will receive only its own, individual reports.

14. 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. These procedures shall ensure that a hospice has the opportunity to review the data that is to be made public for the hospice prior to such data being made public. The Secretary shall report quality measures that relate to hospice

care provided by hospice programs on a publicly available CMS Web site.

In the FY 2017 Hospice final rule, we discussed our analysis of HIS data to inform which measures were eligible for public reporting and reportability analysis to determine data selection period and minimum denominator size for measures to be publicly reported. Based on analysis results, we determined that all 7 HIS quality measures adopted for the FY 2016 and beyond (NQF #1634, NQF #1637, NQF #1639, NQF #1638, NQF #1641, NQF #1647, NQF #1617), calculated based on a rolling 12-month data selection period, to be eligible for public reporting with a minimum denominator size of 20 patient stays. For additional details on these analyses, we refer readers to the FY 2017 Hospice final rule (81 FR 52183 through 52184).

In the FY 2017 Hospice final rule, we also clarified policies for reportability analyses for new measures. As stated in the FY 2017 Hospice final rule, new measures will undergo reportability analysis to determine (1) appropriateness for public reporting and (2) appropriate data selection period. In accordance with discussion in the prior year's rule, we will use the same analytic approach used in previous reportability analyses to determine data selection period and minimum denominator size for the Hospice and Palliative Care Composite Process Measure—Comprehensive Assessment at Admission. We will begin reportability analyses for the Hospice Visits When Death is Imminent Measure Pair once data for the measure are available. Results of reportability analyses conducted for these new measures will be communicated through future rulemaking.

To meet the Affordable Care Act's requirement for making quality measure data public, we are developing a CMS Hospice Compare Web site, which will allow consumers, providers and stakeholders to search for all Medicare-certified hospice providers and view their information and quality measure scores. We anticipate that public reporting of HQRP data on the CMS Compare Web site will begin August 2017. To help providers prepare for public reporting, we will offer opportunities for stakeholder engagement and education prior to the rollout of a CMS Hospice Compare site. We will offer outreach opportunities for providers through CMS HQRP Public reporting Web page: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Hospice-Quality-Public-Reporting.html>,

listserv messages via the Post-Acute Care QRP listserv, MLN Connects® National Provider Calls & Events, MLN Connects® Provider eNews and announcements on Open Door Forums and Special Open Door Forums. Finally, we will offer educational support and outreach to all hospice providers on the systems and processes for reviewing their data prior to public reporting; availability of educational support and outreach opportunities will be communicated through the listed channels above.

We will provide hospices an opportunity to preview their quality measure data prior to publicly reporting information. 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 preview their quality measure data prior to public reporting on the CMS Hospice Compare Web site. We will provide hospices 30 days to review the preview report beginning from the date on which they can access the report. Hospices will have an opportunity to request review of their data by CMS during the 30 day preview period if they believe that errors in data submitted to CMS may have resulted in incorrect measure scores and can submit proof along with a plan describing how the errors will be corrected. We will review these requests and if we confirm that the errors have affected the measures and agree to correct the measure, we will suppress the measure on the Hospice Compare Web site for one time only and display the corrected measure during the subsequent quarterly refresh of the Compare Web site. When the preview reports are ready for providers to access, anticipated August 2017 prior to the release of Hospice Compare, we will post the policies and procedures for providers to submit requests for reviewing of their data by CMS on the CMS HQRP Web site: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Hospice-Quality-Public-Reporting.html>. CMS encourages hospices to use CASPER QM Reports (see section III.D.14 of the FY 2018 proposed rule) to review their HIS quality measures after they submit the HIS data to CMS. If hospices determine that erroneous data have been submitted, they should submit either of these two types of HIS records: Modify existing record or inactivate existing record to correct their data. HIS data corrected before the data are frozen for the creation of the

preview reports will be reflected in the preview reports.

We proposed to begin public reporting of CAHPS® Hospice Survey measures in 2018. Specifically, we proposed to publicly report data in winter CY 2018 on all eight CAHPS® Hospice Survey measures. Scores would be displayed based on eight rolling quarters of data and would initially use CAHPS® Hospice Survey data collected from caregivers of patients who died while receiving hospice care between April 1, 2015 and March 31, 2017. We proposed that the display of these scores be updated quarterly, and that scores be displayed only for those hospices for which there are 30 or more completed questionnaires during the reporting period. Scores will not be displayed for hospices with fewer than 30 completed questionnaires during the reporting period.

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 the CMS HQRP Web page, listserv messages via the Post-Acute Care QRP listserv, MLN Connects® National Provider Calls & Events, MLN Connects® Provider eNews 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, we have posted a hospice directory and quality data on a public data set located at <https://data.medicare.gov>. 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 have initially posted demographic data of hospice agencies that have been registered with Medicare. This list includes high-level demographic data for each agency, including provider name, address, phone numbers, ownership type, CCN, profit status, and date of original CMS certification. The posting of this hospice data directory

occurred on June 14, 2016, and will be refreshed quarterly. Information can be located at <https://data.medicare.gov/data/hospice-directory>. Additionally, we have posted two hospice data files containing national level aggregate quality data regarding seven HIS quality measures and CAHPS® Hospice Survey measures in December 2016. These data files are a one-time release with a goal to make quality data available prior to the release of the Hospice Compare in August 2017. Additional details regarding hospice datasets will be announced via the CMS HQRP Web page, listserv messages via the Post-Acute Care QRP listserv, MLN Connects® National Provider Calls & Events, MLN Connects® Provider eNews and announcements on Open Door Forums and Special Open Door Forums. In addition, we have provided the list of CASPER/ASPEN contacts, Regional Office and State coordinators in the event that a 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. Once the Hospice Compare Web site is released in August 2017, <https://data.medicare.gov> will post the official datasets used on the Medicare.gov Compare Web sites provided by CM.

The comments and our responses are set forth below.

Comment: CMS received several comments that were supportive of public reporting of hospice quality measures. Commenters noted that they were in favor of CMS' efforts to publicly report hospice quality data to support the timely and transparent reporting of HQRP data to hospice beneficiaries, their families and caregivers, providers, and other stakeholders. One commenter shared that the public reporting of hospice quality data was essential to achieving industry goals of delivering the right care, to the right patient, at the right time. Several commenters had suggestions, recommendations, and concerns about specific aspects of the public display of HIS 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 the public display of quality measures in our responses below.

Comment: One commenter expressed concern that hospices not included in public reporting due to not meeting the minimum denominator size for public reporting, may be disadvantaged. This commenter believed that the lack of data on the Hospice Compare Web site may disadvantage these smaller providers as consumers may unfairly assume that the lack of publicly displayed data indicates lower quality providers. The commenter believed that this may raise an issue of fairness, whereby those hospices without publicly displayed quality data may be negatively impacted by consumers who misinterpret missing data as an indicator of quality in and of itself and choose not to receive services from these providers. To mitigate this issue, the commenter suggested that CMS develop a means to counterbalance the potential negative consequences for these hospices for which quality information is not publicly displayed.

Response: We appreciate the commenter sharing concerns regarding the possible negative impact of the minimum denominator size on small hospices. The minimum denominator size of 20 patient stays for HIS data was established through extensive data analysis to ensure that QM scores were statistically meaningful and reliable. The determination of the minimum denominator size balanced the necessity of yielding statistically meaningful QM scores and the goal of allowing as many hospices as possible to have their QM scores publicly displayed. Analysis conducted by RTI International shows that only about 10 percent of hospices would not have accumulated enough patient stays to have their HIS quality measures publicly displayed. The results of this data analysis are summarized in the Measure Testing Executive Summary document 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>. In order to counterbalance any potential negative impact of some hospices not having their measure data publicly displayed, we plan to clearly indicate on the Hospice Compare Web site instances where data is not displayed due to a small denominator size. We believe that this will signal to consumers that, in such instances, the lack of data is not an indication of poor quality but rather a result of the hospice having too few admissions to allow for reporting of a

reliable QM. This approach is consistent with other quality reporting programs. We will also consider future education and outreach activities to educate consumers about the minimum denominator size for public reporting to inform the public that a lack of publicly displayed data does not necessarily indicate of poor quality.

Comment: One commenter noted that many providers have high scores on the current HIS-based QMs and that the limited range of scores could make it difficult for consumers to differentiate between high and low quality providers. The commenter suggested that publicly displayed data be presented as a rating or in another similar format.

Response: We agree that many hospice providers are performing well on the HIS-based QMs. The overall distribution and variability of the scores of the seven HIS QMs that will be publicly displayed initially indicate that most hospices are completing the important care processes for most hospice patients around hospice admission. However, there is still noticeable room for improvement. Analysis completed by RTI International shows that a low percentage of hospices have perfect scores for most measures and a small percentage of hospices have very low scores. To view the results of these analyses please see the Measure Testing Executive Summary document posted on the "Current Measures" portion of the CMS HQRP Web site at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Current-Measures.html>. In preparation for public reporting, CMS's measure development contractor, RTI International, interviewed hospice caregivers. Interviews with these caregivers found that public display of these measures would be useful in avoiding low-performing providers. Additionally, publicly reporting these measures inform consumers the important care processes that they should expect upon hospice admission.

Finally, the Hospice Compare Web site will likely feature a quality rating system that gives each hospice a rating such as between 1 and 5 stars. This will help supplement the measure scores by presenting the data as a rating. We will announce the timeline for the development and implementation of the star rating system in future rulemaking.

Comment: CMS received a few comments raising concerns about consumers' understanding of quality measure data reported on the Hospice Compare Web site. They recommended that CMS ensure that all information posted to the Web site is meaningful

and easily understandable to the general public. Commenters suggested that supplemental information, including general descriptions of the Medicare hospice benefit and consumer-friendly explanations of the HIS data be included on the Hospice Compare Web site to provide context for interpretation of publicly reported quality data. Furthermore, one commenter suggested CMS engage patients, caregivers, providers, and other stakeholders in the development process for the Hospice Compare Web site to ensure that the data presented are meaningful and actionable.

Response: We appreciate commenters' suggestions on information to include on the Hospice Compare Web site. We will take these into consideration as we continue to develop the Web site. We are committed to ensuring that all publicly reported data is presented in an appropriate and meaningful manner to the public. As such, we are working with our Web site development contractor to ensure that the Hospice Compare Web site will be tested for usability, readability, and navigation before its launch in August 2017. Consumers and stakeholders are continuously involved and are having opportunities for input throughout the development process. Text on the Hospice Compare Web site will comply with the Plain Writing Act of 2010. In addition to complying with the Plain Language Act, we are also taking into account variations in health and general literacy, and are soliciting input from key stakeholders and technical experts in the development and presentation of publicly available data.

Comment: A commenter raised concerns that public reporting of quality measures could lead to negative unintended consequences for hospice providers, such as reduced referrals.

Response: We appreciate the commenter's concerns about potential negative implications of public reporting of quality data. It is our hope that the public display of hospice-level data will provide an incentive to providers to identify areas of improvement and develop performance improvement plans to improve the quality of care delivered to their patients and their performance on quality measures. By developing performance improvement plans around areas for improvement, hospices can help minimize negative impacts on referrals. We will continue to carefully consider any potential unintended consequences of public reporting as we develop and report future HIS-based measures.

Comment: A few commenters expressed concerns that data reported in the inaugural release of the Hospice Compare Web site would be incorrect, and cited two main reasons for potential inaccuracies in data. One commenter believed that provider knowledge gaps about measure specifications could lead to errors in coding of HIS items and, subsequently, errors in measure scores and the display of incorrect measure data. The commenter encouraged CMS to identify knowledge gaps and quickly provide education to correct these misunderstandings so that inaccurate data (that is, data that is not reflective of actual care processes taking place but rather of inaccurate coding of HIS items) is not reported on Hospice Compare. A second reason that commenters provided was that there was insufficient time to preview HIS data submissions prior to public reporting. These commenters believed that hospices did not have sufficient time to correct data during the 30-day preview period.

Response: We appreciate commenters taking time to express their concerns about the accuracy of publicly reported data. We agree that it is of the utmost importance that data presented on the Web site is accurate and that providers have all the information and training necessary to accurately report HIS-based quality measure scores. We encourage providers to submit questions about measure specifications, coding guidance for HIS items, public reporting, and the preview period to the Hospice Quality Help Desk at HospiceQualityQuestions@cms.hhs.gov. We monitor common types of questions submitted to the Help Desk and use this information to determine potential knowledge gaps that should be the focus of regular outreach and education efforts. Such regular education efforts and clarifications in coding guidance for the HIS are communicated to providers on a regular basis through quarterly Question & Answer documents, Help Desk guidance, spotlights and announcements, and MLN eNews Listservs. We encourage providers to regularly check the CMS HQRP Web page for these educational materials. We routinely communicate updates about measure specifications and/or HIS items through these educational and communication outlets.

To prevent the public display of incorrect HIS measure data, we encourage hospices to use their CASPER QM reports (see section III.D.13 of the FY 2018 Hospice proposed rule) to regularly review their HIS quality measure scores. If hospices determine that erroneous data have been submitted, providers should use the HIS

record modification and inactivation processes, as outlined in the HIS Manual available on the "Hospice Item Set (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>. Hospice providers can submit modification and inactivation requests up to 36 months from the target date of any given HIS record. Regular monitoring of CASPER QM reports will help ensure that erroneous data are identified early and errors can be corrected in a timely manner. In addition to using QM reports as a mechanism for identifying errors, we also encourages hospices to proactively prevent errors in submitted data by ensuring that staff and clinicians are trained on the latest coding guidance, and that quality assurance and monitoring processes are in place to prevent the submission of incorrect data. We would like to note that HIS data corrected after the data are frozen for the creation of the Provider Preview Reports will not be reflected in the upcoming Hospice Compare Web site update, but will be displayed in the subsequent quarterly update. Because of this, we encourage providers to implement quality assurance and monitoring processes and check CASPER QM reports frequently.

Once the preview reports are generated, the underlying data cannot be corrected. If a hospice disagrees with the QM scores presented in their preview report, the hospice will have the opportunity to request review of their data by CMS during the 30-calendar day preview period. We will review these requests and if CMS agrees that the data is incorrect, the data will be suppressed for one quarter and the corrected data will be posted during the subsequent quarterly refresh of the Compare site. The process for CMS review of data is posted on the "Hospice Quality Public Reporting" portion of the CMS HQRP Web site: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Hospice-Quality-Public-Reporting.html>. The 30-calendar day preview period for Hospice Compare is consistent with preview periods in other quality reporting programs and has been sufficient in other settings. We encourage providers to sign up for the Post-Acute Care QRP listserv for more information about preview report roll-out and the preview period. We will take concerns about the length of the preview period into consideration for

future updates to public reporting of quality data.

Comment: CMS received several comments in support of the future development of a star rating system for the Hospice Compare Web site. Commenters provided several suggestions on creating a star rating system that would be useful to consumers and providers. A majority of commenters were opposed to a normative approach to calculating star ratings where ratings are placed on a bell curve. They believed that this approach would be confusing to consumers and not truly indicative of hospice performance. Commenters preferred a criterion approach for star ratings where CMS would establish benchmarks and calculate ratings based on hospice performance in relation to the established quality benchmark. Other commenters suggested that the star ratings include criteria beyond measure scores, such as patient/family satisfaction, financial performance, geographic indicators, and specialized services provided by the hospice.

Response: We appreciate commenters' detailed input on the development of a star rating methodology for hospice. While we have not set a date for implementing such a system, it is of paramount concern to us to develop a star rating methodology that is valid, reliable, and meaningful to consumers. We will alert our stakeholders once we are closer to entering that phase. We will provide continued opportunities for the provider community and other stakeholders to comment on and provide input to development of a star proposed rating system. In addition to regular HQRP communication channels, we expect to solicit input from the public regarding star rating methodology through communication channels which may include special listening sessions, Open Door Forums, a TEP, and other opportunities. Additionally, we will benefit from lessons learned from the development and implementation of the star ratings in other quality reporting programs to help guide development of star ratings for hospice. Finally, we will announce the timeline for development and implementation of Hospice star ratings in future rulemaking, which will provide additional opportunity for stakeholders to provide public feedback on any proposed star rating methodology.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and

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

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

Unless noted otherwise, all salary information is from the Bureau of Labor Statistics (BLS) Web site at <http://www.bls.gov/oes> and includes a fringe benefits package worth 100 percent of the base salary. The mean hourly wage rates are based on May, 2015 BLS data for each discipline.

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

We solicited public comment and received no comments on each of these issues for the following sections of this document that contain information collection requirements (ICRs) and are finalizing them.

A. Hospice Item Set (OMB Control Number 0938–1153)

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 7 NQF endorsed measures 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).

We finalized the following two additional measures in the FY 2017 Hospice Wage Index final rule affecting FY 2019 payment determinations (81 FR 52163 through 52173):

- Hospice Visits when Death is Imminent

- Hospice and Palliative Care Composite Process Measure—Comprehensive Assessment at Admission

Data for the aforementioned 9 measures is collected via the HIS as discussed in the FY 2017 Hospice Wage Index final rule (81 FR 52189) and covered under OMB control number 0938–1153. The HIS V2.00.0 was approved by the Office of Management and Budget on April 17, 2017 under control number 0938–1153. We are not making any new updates or additional collections of information in this rule in regards to the Hospice Item Set or its constituent quality measures.

B. Summary of CAHPS® Hospice Survey Information Collection Requirements (OMB Control Number 0938–1257)

National Implementation of the Hospice Experience of Care Survey (CAHPs Hospice Survey) data measures are covered under OMB control number 0938–1257 and is summarized here for convenience. We have implemented patient experience surveys in a number of settings including Medicare, Medicare Advantage, and Part D Prescription Drug Plans, hospitals, and home health agencies. Other CAHPS® surveys exist for hemodialysis facilities, nursing homes, and physician practices. The hospice survey differs from most other CMS patient experience surveys because its target population is bereaved family members or close friends of patients who died in hospice care. Family members and friends are the best source of information regarding the entire trajectory of hospice care. In addition, many hospice patients are very ill and unable to answer survey questions.

Surveys are administered by CMS-approved survey vendors hired by hospice providers to conduct the survey on their behalf. The survey vendor may collect data in one of three modes: Mail-only, telephone-only, or mixed mode (mail with telephone follow-up). The sample consists of bereaved family members or close friends of patients who died while receiving hospice care (1) at home, (2) in a nursing home, or (3) an inpatient setting (that is, freestanding inpatient unit or acute care hospital). The questionnaire is composed of 47 items.

The estimated annualized burden hours and costs to respondents for the national implementation of the CAHPS® Hospice Survey are shown in Tables 18 and 19. Based on participation in national implementation in the CAHPS® Hospice Survey from Quarter 2 2015 through Quarter 1 2016, we assume that

3,414 hospices will administer the survey to an average of 278.7 cases. Thus, we estimate that the CAHPS® Hospice Survey will be administered to a maximum of 951,482 individuals each year for the duration of the collection period covered by this application for the purposes of national implementation. As not all sampled cases will complete the survey, this estimate reflects the maximum burden possible. The estimated number of responses is based on actual hospice

participation in national implementation of the CAHPS® Hospice Survey. Table 18 shows the estimated annualized burden for the respondents' time to participate in the national implementation data collection. The survey contains 47 items and is estimated to require an average administration time of 10.4 minutes in English (at a pace of 4.5 items per minute) and 12.5 minutes in Spanish (assuming 20 percent more words in the Spanish translation), for an average

response time of 10.47 minutes or 0.174 hours (assuming that 1 percent of survey respondents complete the survey in Spanish). These burden and pace estimates are based on CMS' experience with the CAHPS® Hospice Survey and surveys of similar length that were fielded with Medicare beneficiaries. As indicated below, the annual total burden hours for survey participants are estimated to be 165,959.57 for the continued national implementation of the survey.

TABLE 18—ESTIMATED ANNUALIZED BURDEN HOURS FOR RESPONDENTS: NATIONAL IMPLEMENTATION OF THE CAHPS® HOSPICE SURVEY

| Survey version | Number of respondents | Number of responses per respondent | Hours per response | Total burden hours |
|-----------------------------|-----------------------|------------------------------------|--------------------|--------------------|
| CAHPS® Hospice Survey | 951,482 | 1 | 0.174 | 165,959.57 |
| Total | 951,482 | 1 | 0.174 | 165,959.57 |

Table 19 shows the cost burden to respondents associated with their time to complete a survey as part of national implementation. The annual total cost

burden is estimated to be \$7,710,481.60. This estimate is higher than the \$3,034,789.70 estimated in the prior OMB filing, due to the increased

number of hospices participating (and correspondingly, the increased number of respondents), as well as an increase in the average hourly rate.

TABLE 19—ESTIMATED ANNUALIZED COST BURDEN FOR RESPONDENTS: NATIONAL IMPLEMENTATION

| Form name | Number of respondents | Total burden hours | Average hourly wage rate * | Total cost burden |
|-----------------------------|-----------------------|--------------------|----------------------------|-------------------|
| CAHPS® Hospice Survey | 951,482 | 165,959.57 | * \$46.46 | \$7,710,481.60 |
| Total | 951,482 | 165,959.57 | * 46.46 | 7,710,481.60 |

* Source: Data from the U.S. Bureau of Labor Statistics' May 2015 National Occupational Employment and Wage Estimates for all salary estimates (<http://www.bls.gov/oes>). This figure includes a 100% fringe benefit on an average wage of \$23.23. Retrieved April 10, 2017.

V. Regulatory Impact Analysis

A. 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 2018 as required under section 1814(i)(1)(C)(ii)(VII) of the Act. Section 411(d) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) amended section 1814(i)(1)(C) of the Act such that for hospice payments for FY 2018, the market basket percentage increase shall be 1 percent. Finally, section 3004 of the Affordable Care Act amended the Act to authorize a quality reporting program

for hospices and this rule discusses changes in the requirements for the hospice quality reporting program in accordance with section 1814(i)(5) of the Act.

B. Overall Impacts

We estimate that the aggregate impact of the payment provisions in this final rule will result in an increase of \$180 million in payments to hospices, resulting from the hospice payment update percentage of 1.0 percent. The impact analysis of this final rule represents the projected effects of the changes in hospice payments from FY 2017 to FY 2018. Using the most recent data available at the time of rulemaking, in this case FY 2016 hospice claims data, we apply the current FY 2017 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 2017 payments. Then, using the same FY 2016 data, we apply the FY 2018 wage

index and labor-related share values to simulate FY 2018 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.

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4,

1999), the Congressional Review Act (5 U.S.C. 804(2) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017)).

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). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) Having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We estimate that this rulemaking is “economically significant” as measured by the \$100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that, to the best of our ability presents the costs and benefits of the rulemaking.

C. Anticipated Effects

The Regulatory Flexibility Act (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 greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. The effect of the FY 2018 hospice payment update percentage results in an overall increase in estimated hospice payments of 1.0 percent, or \$180 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.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) 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 2017, that threshold is approximately \$148 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 \$148 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. We have reviewed this final rule under these criteria of Executive Order 13132, and have determined that it will not impose substantial direct costs on state or local governments.

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on the published proposed rule will be the number of reviewers of this final rule. We acknowledge that this

assumption may understate or overstate the costs of reviewing this final rule. It is possible that not all commenters reviewed the proposed rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of comments received on the proposed rule would be a fair estimate of the number of reviewers of this final rule. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is \$105.16 per hour, including overhead and fringe benefits (https://www.bls.gov/oes/current/oes_nat.htm). Assuming an average reading speed, we estimate that it would take approximately 1.6 hours for the staff to review half of this rule. For each hospice that reviews the rule, the estimated cost is \$168.26 (1.6 hours × \$105.16). Therefore, we estimate that the total cost of reviewing this regulation is \$15,143.40 (\$168.26 × 90 reviewers).

A summary of the comments we received on the RIA and our responses to those comments are set forth below.

Comment: A commenter disagreed with CMS’ assertion the proposed rule will not create a significant economic impact on a substantial number of small entities. The commenter believes that the impact of the overall increase will not be felt proportionally across hospices. Small hospices will face significant financial hardships, especially those with fewer data collection resources, who would be subject to the 2 percent penalty for inadequate quality data submission. The commenter encouraged CMS to provide a more detailed analysis of the impact on hospices, especially small and rural hospices.

Response: Hospices are estimated to receive a 1 percent increase in payments in FY 2018. Based on our analysis, we concluded that the policies in the proposed rule would not result in an estimated total adverse impact of 3 to 5 percent or more on Medicare revenue for greater than 5 percent of hospices. The 1 percent payment update is statutorily-mandated by MACRA (Pub. L. 114–10, enacted April 16, 2015). Furthermore, we believe that Table 20 sufficiently describes the impact on rural hospices as well as small hospices (as measured by the number of RHC days).

Comment: A commenter agreed that if regulations impose administrative costs on private entities, such as the time needed to read and interpret the proposed rule, CMS should estimate the cost associated with regulatory review. The commenter stated that CMS should not assume that the number of commenters equates to the number of reviewers. Many individual hospices, especially smaller hospices, may not submit an individual comment but instead will collaborate with their professional associations to provide comments. However, each hospice still thoroughly reviews, engages in background research, interprets and assesses the impact of proposals on current practice, as well as how practices may need to shift if proposals are finalized, in order to engage in those collective processes to prepare a comment letter.

Response: We thank the commenter for providing feedback on the methodology used to determine the costs associated with regulatory review. We will take the comment under

consideration for any future refinements to the methodology used to determine the costs of regulatory review. As noted previously, we already take many of these costs into account.

D. Detailed Economic Analysis

The FY 2018 hospice payment impacts appear in Table 20. We tabulate the resulting payments according to the classifications in Table 20 (for example, facility type, geographic region, facility ownership), and compare the difference between current and future 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 2018 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 2018 hospice wage index.

The fourth column shows the effect of the hospice payment update percentage for FY 2018. The FY 2018 hospice payment update percentage of 1 percent is mandated by section 1814(i)(1)(C) of the Act, as amended by section 411(d) of the MACRA.

The fifth column shows the effect of all the changes on FY 2018 hospice payments. It is projected that aggregate payments will increase by 1.0 percent, assuming hospices do not change their service and billing practices.

As illustrated in Table 20, 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 2018 payments range from a 0.9 percent decrease for hospices providing care in the rural outlying region to a 1.7 percent increase for hospices providing care in the urban Pacific region.

TABLE 20—PROJECTED IMPACT TO HOSPICES FOR FY 2018

| (1) | (2) | (3) | (4) | (5) |
|---|---------------------|-----------------------|------------------------------------|--------------------------|
| | Number of providers | Updated wage data (%) | FY 2018 hospice payment update (%) | FY 2018 total change (%) |
| All Hospices | 4,355 | 0.0 | 1.0 | 1.0 |
| Urban Hospices | 3,381 | 0.0 | 1.0 | 1.0 |
| Rural Hospices | 974 | 0.1 | 1.0 | 1.1 |
| Urban Hospices—New England | 134 | −0.7 | 1.0 | 0.3 |
| Urban Hospices—Middle Atlantic | 252 | 0.1 | 1.0 | 1.1 |
| Urban Hospices—South Atlantic | 430 | −0.3 | 1.0 | 0.7 |
| Urban Hospices—East North Central | 407 | −0.1 | 1.0 | 0.9 |
| Urban Hospices—East South Central | 159 | 0.0 | 1.0 | 1.0 |
| Urban Hospices—West North Central | 233 | −0.2 | 1.0 | 0.8 |
| Urban Hospices—West South Central | 662 | 0.0 | 1.0 | 1.0 |
| Urban Hospices—Mountain | 327 | −0.1 | 1.0 | 0.9 |
| Urban Hospices—Pacific | 736 | 0.7 | 1.0 | 1.7 |
| Urban Hospices—Outlying | 41 | −0.6 | 1.0 | 0.4 |
| Rural Hospices—New England | 23 | 0.0 | 1.0 | 1.0 |
| Rural Hospices—Middle Atlantic | 40 | 0.6 | 1.0 | 1.6 |
| Rural Hospices—South Atlantic | 135 | 0.1 | 1.0 | 1.1 |
| Rural Hospices—East North Central | 141 | 0.2 | 1.0 | 1.2 |
| Rural Hospices—East South Central | 124 | −0.1 | 1.0 | 0.9 |
| Rural Hospices—West North Central | 181 | 0.2 | 1.0 | 1.2 |
| Rural Hospices—West South Central | 180 | 0.1 | 1.0 | 1.1 |
| Rural Hospices—Mountain | 101 | 0.2 | 1.0 | 1.2 |
| Rural Hospices—Pacific | 46 | 0.3 | 1.0 | 1.3 |
| Rural Hospices—Outlying | 3 | −1.9 | 1.0 | −0.9 |
| 0–3,499 RHC Days (Small) | 1,004 | 0.2 | 1.0 | 1.2 |
| 3,500–19,999 RHC Days (Medium) | 2,017 | 0.1 | 1.0 | 1.1 |
| 20,000+ RHC Days (Large) | 1,334 | 0.0 | 1.0 | 1.0 |
| Non-Profit Ownership | 1,059 | 0.0 | 1.0 | 1.0 |
| For Profit Ownership | 2,735 | 0.1 | 1.0 | 1.1 |
| Government Ownership | 155 | −0.3 | 1.0 | 0.7 |
| Other Ownership | 406 | −0.2 | 1.0 | 0.8 |
| Freestanding Facility Type | 3,379 | 0.0 | 1.0 | 1.0 |
| HHA/Facility-Based Facility Type | 976 | 0.0 | 1.0 | 1.0 |

Source: FY 2016 hospice claims from the Chronic Condition Data Warehouse (CCW) Research Identifiable File (RIF) in June 2017.
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.

E. Accounting Statement

As required by OMB Circular A-4 (available at <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>), in Table 21, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule. Table 21 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 4,355 hospices in our impact analysis file, which was constructed using FY 2016 claims available in June 2017. All expenditures are classified as transfers to hospices.

TABLE 21—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS, FROM FY 2017 TO FY 2018

| Category | Transfers |
|---|--|
| Annualized Monetized Transfers. From Whom to Whom?. | \$180 million* Federal Government to Medicare Hospices. |

* The net increase of \$180 million in transfer payments is a result of the 1.0 percent hospice payment update compared to payments in FY 2017.

F. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, entitled “Reducing Regulation and Controlling Regulatory Costs,” was issued on January 30, 2017 (82 FR 9339, February 3, 2017). It has been determined that this final rule is a transfer rule that does not impose more than de minimis costs as described above and thus is not a regulatory or deregulatory action for the purposes of Executive Order 13771.

G. Conclusion

We estimate that aggregate payments to hospices in FY 2018 will increase by

\$180 million, or 1.0 percent, compared to payments in FY 2017. We estimate that in FY 2018, hospices in urban and rural areas will experience, on average, 1.0 percent and 1.1 percent increases, respectively, in estimated payments compared to FY 2017. Hospices providing services in the urban Pacific and rural Middle Atlantic regions will experience the largest estimated increases in payments of 1.7 percent and 1.6 percent, respectively. Hospices serving patients in urban areas in the New England region will experience, on average, the lowest estimated increase of 0.3 percent in FY 2018 payments.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Dated: July 25, 2017.

Seema Verma,
Administrator, Centers for Medicare & Medicaid Services.

Dated: July 27, 2017

Thomas E. Price,
Secretary, Department of Health and Human Services.

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