

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 418

[CMS-1714-F]

RIN 0938-AT71

Medicare Program; FY 2020 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 updates the hospice wage index, payment rates, and cap amount for fiscal year 2020. This rule also rebases the continuous home care, general inpatient care, and the inpatient respite care per diem payment rates in a budget-neutral manner to more accurately align Medicare payments with the costs of providing care. In addition, this rule modifies the election statement by requiring an addendum that includes information aimed at increasing coverage transparency for patient under a hospice election. Finally, this rule includes changes to the Hospice Quality Reporting Program.

DATES: These regulations are effective on October 1, 2019.

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

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.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose

This final rule makes updates to the hospice wage index, payment rates, and cap amount for fiscal year (FY) 2020, as required under section 1814(i) of the Social Security Act (the Act). This rule also rebases the continuous home care (CHC), general inpatient care (GIP), and inpatient respite care (IRC) per diem payment rates in a budget neutral manner to more accurately align payments with the costs of providing care, using the hospice payment reform authority under section 1814(i)(6) of the Act. This rule changes the hospice wage index to remove the 1-year lag in data

by using the current year's hospital wage data to establish the hospice wage index. In addition, this rule modifies the hospice election statement by requiring an addendum that includes information aimed at increasing coverage transparency for patients under a hospice election. Finally, this rule includes changes to the Hospice Quality Reporting Program.

B. Summary of the Major Provisions

Section III.A.2 of this final rule describes the FY 2020 hospice per diem payment rebasing methodology, cost reports and calculations. Using the hospice payment reform authority under section 1814(i)(6) of the Act, section III.A.3 of this final rule rebases the FY 2020 per diem payment rates for CHC, IRC, and GIP levels of care. As required in section 1814(i)(6)(D)(ii) of the Act, any changes to hospice payment rates must be done in a budget neutral manner. As such, section III.A.3 also finalizes a reduction to the routine home care (RHC) payment amounts for FY 2020 in order to maintain overall budget neutrality. Section III.B.1 of this rule eliminates the 1-year lag of the pre-floor, pre-reclassified hospital wage index that is used in calculating the hospice wage index. Section III.B.2 updates the hospice wage index and makes the application of the updated wage data budget neutral for all four levels of hospice care. In section III.B.3 of this rule, we discuss the FY 2020 hospice payment update percentage of 2.6 percent. Section III.B.4 outlines the final FY 2020 hospice payment rates. Section III.B.5 of this final rule updates the hospice cap amount for FY 2020 by the hospice payment update percentage discussed in section III.B.3 of this rule. Section III.C modifies the hospice election statement content requirements at § 418.24(b) to increase coverage transparency for patients under a hospice election by notifying beneficiaries if there are services that will not be covered by the hospice.

Finally, in section III.E of this rule, we discuss updates to the Hospice Quality Reporting Program (HQRP), including: The development of claims-based and outcome measures, measure concepts, and the hospice assessment tool. We also provide updates on the public reporting change for the "Hospice Visits When Death is Imminent" measure pair, the posting of publicly available government data to the CMS Hospice Compare website, and the CAHPS® Hospice Survey.

C. Summary of Impacts

The overall economic impact of this final rule is estimated to be \$520 million

in increased payments to hospices for FY 2020.

II. Background

A. Hospice Care

Hospice care is a comprehensive, holistic approach to treatment that recognizes the impending death of a terminally ill individual and warrants a change in the focus from curative care to palliative care for relief of pain and for symptom management. 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.

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.

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.

Under the Medicare hospice benefit, the election of hospice care is a patient choice and once a terminally ill patient elects to receive hospice care, a hospice interdisciplinary group is essential in the seamless provision of services. These hospice services are provided primarily in the individual's home. 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.

If, in the judgment of the hospice interdisciplinary team, which includes the hospice physician, the patient's symptoms cannot be effectively managed at home, then the patient is eligible for general inpatient care (GIP), a more medically intense level of care. GIP must be provided in a Medicare-certified hospice freestanding facility, skilled nursing facility, or hospital. GIP is provided to ensure that any new or worsening symptoms are intensively addressed so that the beneficiary can return to his or her home and continue to receive routine home care. 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. CHC 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 must comply with applicable civil rights laws,¹ including section 504 of the Rehabilitation Act of 1973 and the Americans with Disabilities Act, under which covered entities must take appropriate steps to ensure effective communication with patients and patient care representatives with disabilities, including the provisions of auxiliary aids and services. Additionally, they must take reasonable steps to ensure meaningful access for individuals with limited 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. Services Covered by the Medicare Hospice Benefit

Coverage under the Medicare Hospice benefit requires 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 also 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 FY 1983 Hospice Wage Index and Rate Update proposed rule (48 FR 38149), the hospice interdisciplinary group should comprise paid hospice employees as well as hospice volunteers, and that "the hospice benefit and the resulting Medicare reimbursement is not intended to diminish the voluntary

spirit of hospices." This expectation supports the hospice philosophy of community based, holistic, comprehensive, and compassionate end-of-life care.

C. 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 42 CFR 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), CHC, IRC, and 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 changes in the methodology concerning updating the daily payment rates based on the hospital market basket percentage increase applied to the payment rates in effect during the previous federal fiscal year.

2. Balanced Budget Act of 1997

Section 4441(a) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33) established that updates to the hospice payment rates beginning FY 2002 and subsequent FYs be the hospital market basket percentage increase for the FY.

3. FY 1998 Hospice Wage Index Final Rule

The FY 1998 Hospice Wage Index final rule (62 FR 42860), implemented a new methodology for calculating the hospice wage index and instituted an annual Budget Neutrality Adjustment Factor (BNAF) so aggregate Medicare payments to hospices would remain budget neutral to payments calculated using the 1983 wage index.

¹ Hospices are also subject to additional Federal civil rights laws, including the Age Discrimination Act, Section 1557 of the Affordable Care Act, and conscience and religious freedom laws.

4. FY 2010 Hospice Wage Index Final Rule

The FY 2010 Hospice Wage Index and Rate Update final rule (74 FR 39384) instituted an incremental 7-year phase-out of the BNAF beginning in FY 2010 through FY 2016. The BNAF phase-out reduced the amount of the BNAF increase applied to the hospice wage index value, but 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 addition, sections 1814(i)(5)(A) through (C) of the Act, as added by section 3132(a) of the Patient Protection and Affordable Care Act (PPACA) (Pub. L. 111–148), required hospices to begin submitting quality data, based on measures 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 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 PPACA, required, 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 FY 2011 Hospice Wage Index 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 PPACA, authorized 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 PPACA 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

In the FY 2012 Hospice Wage Index final rule (76 FR 47308 through 47314) we announced that beginning in 2012, 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 through 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. 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

The FY 2015 Hospice Wage Index and Rate Update final rule (79 FR 50452) finalized a requirement that 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 within 5 calendar days after the effective date of the discharge or revocation (unless the hospice has already filed a final claim) through the submission of a final claim or a Notice of Termination or Revocation (NOTR).

The FY 2015 Hospice Wage Index and Rate Update final rule (79 FR 50479) also 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.

In addition, the FY 2015 Hospice Wage Index and Rate Update final rule (79 FR 50496) provided background, eligibility criteria, survey respondents,

and implementation of the Hospice Experience of Care Survey for informal caregivers. Hospice providers were required to begin using this survey for hospice patients as of 2015.

Finally, the FY 2015 Hospice Wage Index and 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 failed to timely submit their aggregate cap determinations had their payments suspended until the determination is completed and received by the Medicare contractor (79 FR 50503).

8. IMPACT Act of 2014

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185) 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 of 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 Rate Update final rule (80 FR 47172), 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. 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 Rate Update final rule (80 FR 47186) 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 thereafter. Finally, the FY 2016 Hospice Wage Index and Rate Update final rule (80 FR 47144) 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.

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

In the FY 2017 Hospice Wage Index and Rate Update final rule (81 FR 52160), we finalized several new policies and requirements related to the HQR. First, we codified our policy that if the National Quality Forum (NQF) made non-substantive changes to specifications for HQR measures as part of the NQF's re-endorsement process, we would continue to utilize the measure in its new endorsed status, without going through new notice-and-comment rulemaking. We would 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 would 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 were 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 Consumer Assessment of Healthcare Providers and Systems (CAHPS®) requirements due to newness (81 FR 52182). The exemption is determined by CMS and is for 1 year only.

D. Trends in Medicare Hospice Utilization

Since the implementation of the hospice benefit in 1983, there has been

substantial growth in hospice utilization. The number of Medicare beneficiaries receiving hospice services has grown from 513,000 in FY 2000 to over 1.5 million in FY 2018. Medicare hospice expenditures have risen from \$2.8 billion in FY 2000 to approximately \$18.7 billion in FY 2018. CMS' Office of the Actuary (OACT) projects that hospice expenditures are expected to continue to increase, by approximately 8.5 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.

As a part of our ongoing analysis of hospice utilization trends, we examined the distribution of total hospice days by level of care. A review of claims over the last 10 years shows that RHC remains the highest utilized level of care, accounting for an average of 97.6 percent of total hospice days; GIP accounting for 1.7 percent of total hospice days; CHC accounting for 0.4 percent of total hospice days; and, IRC accounting for 0.3 percent of total hospice days.

There have also been notable changes in the diagnosis patterns among Medicare hospice enrollees. At the time of the implementation of the Medicare hospice benefit, cancer diagnoses were the most frequently reported diagnoses. However, there has been a significant increase in the reporting of neurologically-based diagnoses, including Alzheimer's disease, which has been the top-reported diagnosis on hospice claims since 2014. In the FY 2014 hospice final rule (78 FR 48242), we clarified that "Debility" or "adult failure to thrive" should not be used as a principal hospice diagnosis on the Hospice claim form per ICD-9-CM Coding Guidelines. Since this clarification, there has been an increase in the reporting of neurological conditions as the principal diagnosis on hospice claims. Our ongoing analysis of diagnosis reporting trends finds that neurological and organ-based failure conditions remain top-reported principal diagnoses.

In the FY 2016 Hospice Wage Index and Rate Update final rule (80 FR 47201), we clarified that hospices are to 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 2018 hospice claims show that 100 percent of claims included at least one diagnosis, 90.3 percent of claims included at least two

diagnoses, and 82.1 percent of claims included at least three diagnoses.

III. Provisions of the Final Rule

A. Rebasing of the Continuous Home Care, Inpatient Respite Care, and General Inpatient Care Payment Rates for FY 2020

1. Background

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 (RHC, CHC, IRC, and GIP), based on each day a qualified Medicare beneficiary is under a hospice election. These per diem payments include reimbursement for 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.

We originally set the base payment rates for each level of care in 1983 using information from a relatively small set (n=26) of hospices that were participating in a CMS hospice demonstration. As a result of technological changes to providing hospice care that have occurred since the early 1980's, as well as changes in the patient population that uses the hospice benefit, it is possible that the current per diem payment rates for the Medicare hospice benefit do not align accurately with the costs of providing care. Since the establishment of the hospice benefit, the base payment rates have been updated through the years to primarily account for inflation, but we have not implemented any large scale changes to reflect non-inflationary changes in costs over time, with the exception of the bifurcation of the RHC payment rate and the creation of the SIA payment finalized in the FY 2016 Hospice Wage Index and Payment Rate Update final rule implemented on January 1, 2016 (80 FR 47142). For over a decade, MedPAC and other organizations reported findings that suggested that the hospice benefit's fixed per-diem payment system was inconsistent with the true variance of service costs over the course of an episode.

In the FY 2020 proposed rule (84 FR 17577) we described the information that was collected on hospice claims effective April 1, 2014 and additional changes in reporting requirements over the following years.² The revised cost report expands data collection requirements to supply greater detail related to hospice costs by level of care. Hospices are required to report all direct patient care costs by multiple cost categories into the respective level of care. MedPAC, the Government Accountability Office (GAO), and the Office of the Inspector General (OIG) have all recommended that CMS collect more comprehensive data to better evaluate trends in utilization of the Medicare hospice benefit.

Effective for cost reporting periods beginning on or after October 1, 2014, freestanding hospices are required to file the revised hospice cost report (Form CMS–1984–14). Provider-based hospices began using the revised cost report form for cost reporting periods beginning on or after October 1, 2015. The revised cost report expands data collection requirements to supply greater detail related to hospice costs by level of care. Hospices are required to report all direct patient care costs by multiple cost categories into the respective level of care. Within the revised cost report changes in 2014, there were modifications in the manner in which general service costs and statistical information is accumulated by the hospice and an expansion of the general service cost centers. Instructions for completing the freestanding hospice cost report (Form CMS–1984–14) are found in the Medicare Provider Reimbursement Manual—Part 2, Chapter 43.³

In its March 2018 Report to the Congress, MedPAC stated Medicare's payment rates for the CHC, IRC and GIP levels of care appear to be lower than the average and median costs per day for freestanding providers and suggested that rebalancing the payment rates may be warranted.⁴ Additionally, we received public comments on past rules that indicated the payment rates for CHC, IRC and GIP are much different

from the average costs of providing those levels of care.

2. Methodology and Analysis of Costs per Day for Continuous Home Care, Inpatient Respite Care, and General Inpatient Care

a. Hospice Cost Report Data

Using information collected from the revised hospice cost report, for the first time, we are able to estimate hospices' average costs per day by level of care. As required by section 1814(i)(1)(A) of the Act, payment for hospice services must be an amount equal to the costs which are reasonable and related to providing hospice care, or which are based on such other tests of reasonableness as the Secretary may prescribe in regulations. Therefore, given that we now have several years' worth of cost report data from the revised hospice cost report, we calculated the average costs per day by level of care and compared such costs to the per diem payment rates by level of care to determine if there is a misalignment between payment and costs and whether the per diem payment rates for CHC, IRC, and GIP should be rebased. To conduct this analysis, we used a variety of different data sources, including cost reports and hospice claims data. In the FY 2020 proposed rule, we provided a walkthrough of the methodology and analysis of costs per day for continuous home care, inpatient respite care, and general inpatient care (84 FR 17578). For this final rule, although we used more recent cost report and claims data (still covering FY 2017), the methodology to calculate such costs remains the same as in the FY 2020 proposed rule.

Our analysis was based on information obtained from the Healthcare Cost Report Information System (HCRIS). The hospice cost report data contains cost and statistical data for freestanding and provider-based hospice providers. To determine the average per-day costs of providing hospice services, we conducted initial analysis of both freestanding and provider-based hospice cost reports.⁵

As mentioned in the FY 2020 proposed rule (84 FR 17578), to create the initial analytic file, we took a number of data cleaning steps to exclude certain hospices such as excluding a small number of hospices (as represented by CCN) that had multiple FY 2017 cost reports in the HCRIS cost report data file (exclusion 1). For those hospices, we kept the cost

report that covered the greatest length of time in FY 2017.⁶ We eliminated SNF, HHA, and hospital cost reports that did not contain a hospice CCN (exclusion 2); and we eliminated cost reports (as represented by CCN) due to the same CCN listed multiple times (that is, there might be two separate reports of RHC costs for the same CCN within a provider-based cost report, or a CCN appeared in a freestanding cost report as well as appeared in a provider based cost report)(exclusion 3). In order to limit each hospice to one single cost report, we selected the cost report with the highest RHC cost.⁷

Next, we constructed a series of flags to identify hospice cost reports that did not fill out fields that we would expect hospices to report (for example, nursing services). We identified those cost report fields using information from the Provider Reimbursement Manual—Part 2, Provider Cost Reporting Forms and Instructions, Chapter 43, Form CMS–1984–14, Transmittal 3, dated April 13, 2018, that updated cost reporting instructions for freestanding hospice cost reports.⁸ These instructions describe a number of new Level I edit conditions that required freestanding hospices to fill out certain parts of their cost reports effective for freestanding hospice cost reports with a reporting period that ended on or after December 31, 2017.

Finally, to remove outliers from this analysis, we applied another set of exclusions as described in the FY 2019 Hospice Wage Index and Payment Rate Update proposed rule (83 FR 20948). For each calculated outcome (for example, average RHC costs per day), we excluded those values that are above the 99th percentile and those values that are below the 1st percentile. We refer to this trim as the “1% Trim”. After applying the trimming exclusions, including the Level I edits, 1,232 freestanding hospice cost reports remained as noted in Table 1 below:

² CMS Transmittal 2864. Additional Data Reporting Requirements for Hospice Claims. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2864CP.pdf>.

³ The Provider Reimbursement Manual—Part 2. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935.html>.

⁴ Medicare Payment Advisory Commission (MedPAC). “Hospice Services.” *Report to the Congress: Medicare Payment Policy*. Washington, DC. March 2018. P. 341. http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch12_sec.pdf?sfvrsn=0.

⁶ We determined the length of the cost report by subtracting the cost reports fiscal year begin date from the cost reports fiscal year end date.

⁷ For example, in one home health agency-based cost report, the home health agency reported costs for the same hospice CCN three different times on the same cost report.

⁸ Medicare Provider Reimbursement Manual—Part 2, Provider Cost Reporting Forms and Instructions, Chapter 43, Form CMS–1984–14. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R3P243.pdf>.

⁵ Cost reports from FY 2017 had a start date on or after October 1, 2016 and before October 1, 2017.

TABLE 1—NUMBER OF FY 2017 FREESTANDING HOSPICE COST REPORTS AFTER THE LEVEL I EDITS EXCLUSION AND 1% TRIM

Level of care	Number of cost reports after exclusions	Number of days by level of care (FY2017)
RHC	1,109	43,255,420
GIP	817	790,195
CHC	440	187,554
IRC	915	135,384

Note: We begin with the 3,223 freestanding cost reports that remained after applying exclusions in 1–3. After applying the Level I edits, 1,232 freestanding cost reports remained. Not all cost reports contain information on each level of care. Numbers noted above indicate the number of cost reports available for analysis for each level of care after all exclusions, including the 1% trim are applied.

b. Hospice Claims Data

We created an analytic data set based on Medicare hospice claims downloaded from the Chronic Condition Data Warehouse—Virtual Research Data Center (CCW VRDC) to examine hospice utilization on specific days during FY 2017. We assigned a wage index (using the FY 2017 hospice wage indices) to each day of hospice service based on the core-based statistical area (CBSA) where a particular day's hospice services took place.⁹ We merged information from the June 2018 release of the CMS Provider of Services (POS) file to identify characteristics of each hospice including: Ownership type, census division (based on the hospice's state), and whether the hospice's main office was located either in an urban or rural

location. This data was used in the subsequent section in calculating costs per day by level of care.

c. Calculating Costs per Day by Level of Care

In order to compute the average cost per day for each level of care using information from the freestanding hospice cost reports, after applying the exclusions, we made several adjustments to the average cost calculations, as described in the FY 2020 proposed rule (84 FR 17580).

It is important to calculate average costs after removing any regional differences that may be driven by wages, otherwise we would over-adjust for wage differences across regions. For example, we remove the wage differences in RHC costs by calculating the following value for each hospice:

Adjusted RHC cost per day = (RHC cost per day from 2017 cost reports) * (0.6871) / (Hospice's average wage index for all RHC days in FY 2017) + (RHC cost per day from 2017 cost reports) * (1 – 0.6871)

Note: 0.6871 is the labor share used to wage index adjust RHC payments.

We perform a similar calculation for the other levels of care using the corresponding cost per day from FY 2017 cost reports and the appropriate labor share for CHC, IRC, and GIP. For example, the adjusted GIP cost per day uses the same formula, but instead includes GIP cost per day from FY 2017 cost reports, the hospice's average wage index for all GIP days in the formula, and the GIP labor share of 64.01 percent.

Due to exclusions mentioned previously, not all hospices that submitted claims during FY 2017 have a corresponding cost report in our final sample. As a result, the characteristics of the sample of cost reports used to calculate average cost per day for each level of care do not necessarily match up with the characteristics of all

hospices that submitted claims during FY 2017. If not accounted for, our sample of cost reports may over represent certain types of hospices. To correct for this, we categorize each hospice in our sample by facility type,¹⁰ ownership type,¹¹ urban/rural status,¹² and size.¹³

For each category of hospices and the calculations for each level of care, we use the following steps:

1. Using claims, we compute the total number of days provided in FY 2017 by all hospices within a particular category;

2. We compute the total number of days, as reported on the claims provided in FY 2017, using only the hospices in our trimmed sample of cost reports within a particular category; and

3. For each level of care and each category of hospices, we construct a ratio using the value in Step 1 over the value in Step 2.

For each cost report in our sample, we multiply each provider's days (as reported on claims) by level of care by the ratio in order to make the sample cost reports more representative of the overall population of hospices. We then multiply the provider's average per diem cost as reported on the cost report times the number of adjusted days from the prior step to yield total costs by level of care for that provider. We then compute the weighted average for each level of care by summing across hospices the total costs by level of care divided by the sum of the adjusted days across the cost reports in our sample.¹⁴

$$\text{Weighted Average IRC Cost Per Day} = \frac{\sum_{i=1}^n \text{Cost}_i * \text{Number of Days}_i}{\sum_{i=1}^n \text{Number of Days}_i}$$

Medicare pays for the CHC level of care using a per hour rate instead of a per day rate. We calculated each hospice's hourly cost of CHC by taking their CHC cost per day from the hospice

cost report and dividing it by their average number of hours of CHC provided on CHC days occurring in FY 2017 as reported on each hospice's claims. Each hospice's CHC cost per

hour (adjusted by average number of hours of CHC) is then averaged (using the weighted average formula discussed above) across all hospices in our sample to create the overall average of CHC cost

⁹ FY 2017 Final Hospice Wage Index. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Hospice-Wage-Index/FY-2017-Final-Hospice-Wage-Index.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending>.

¹⁰ Freestanding versus provider-based.

¹¹ We only divide the freestanding cost reports into ownership type categories. We use the ownership type categories from the POS: For-profit, government, non-profit, and other. Due to limited sample size we do not break out the provider-based hospices into ownership type.

¹² Urban/rural status is reported on the POS and corresponds to the mailing address of the hospice.

¹³ We divide hospices into three categories based on their number of RHC days in FY 2017: Large (>=20,000 RHC days), medium (3,500–19,999 RHC days), and small (0–3,499 RHC days).

¹⁴ The formula describes the average cost per day calculation for IRC, however, the same formula can be adapted for each level of care.

per hour. To convert the CHC cost per hour into a CHC cost per day we multiply the average CHC cost per hour by 24 hours. It is important to note that each hospice's hourly CHC cost is based on their average number of CHC minutes per day, which is less than 24 hours. That means a full CHC per day payment (which covers 24 hours) will be larger than the average CHC cost per day (which covers a time period less than 24 hours). Applying all of the steps as described above and in the FY 2020 proposed rule, average costs per day by level of care in FY 2017 are listed in Table 2 below:

TABLE 2—AVERAGE COST PER DAY BY LEVEL OF CARE, FY 2017

Level of care	Average cost per day
RHC	\$130.85
CHC (24 Hours)	1,307.76
CHC (Per Hour)	54.49
IRC	441.03

TABLE 2—AVERAGE COST PER DAY BY LEVEL OF CARE, FY 2017—Continued

Level of care	Average cost per day
GIP	952.56

The current payment system pays hospices a two-tiered rate for RHC. RHC days during the first 60 days are paid a higher per diem rate compared to any RHC days after day 60. Hospice do not report RHC costs separately for the first 60 days versus RHC days after day 60. However, we can estimate the RHC costs in the first 60 days versus after 60 days by making the same assumption that was made to calculate the two-tiered payment. That is, in the FY 2016 hospice final rule (80 FR 47166), we calculated resource use ratios to determine the differences in resource utilization for the first 60 days and any RHC days after day 60. For the creation of the two-tiered RHC rate (80 FR 47166), the following ratios were used:

- *Days 1 through 60:* The ratio of average resource use for RHC days in days 1 through 60 to average resource use across all RHC days was 1.2603 to 1.

- *Days 61 and beyond:* The ratio of average resource use for RHC days after day 60 to the average resource use across all RHC days was 0.8722 to 1.

We multiplied the labor share component of the average cost per day for RHC in FY 2017 by the corresponding resource use ratio to calculate the average cost per day for the first 60 days and any RHC days after 60 days. We only applied the resource ratio to the labor share component because the resource ratio is calculated using minutes of direct patient care as reported on the claims. This approach is consistent with what was done in the FY 2016 hospice final rule (80 FR 47166) to construct the two-tiered payment. The resulting average cost per day for RHC is shown in Table 3.

TABLE 3—AVERAGE RHC COSTS
[FY 2017 per day for days 1 through 60 and days 61+]

RHC level of care	Average cost per day	Resource use ratio (only applied to the labor share, which is 68.71% of the RHC payment rate)	Average cost per day in FY2017 (based on days of RHC)
Days 1–60	\$130.85	1.2603	\$154.25
Days 61+	130.85	0.8722	119.36

To determine if there is any misalignment between the average costs of providing CHC, IRC and GIP and the per diem payment rates for these levels of care, we inflated the average costs in FY 2017 to FY 2019 dollars. We did this

by multiplying the average FY 2017 costs by level of care by the hospice market basket update for FY 2018 (82 FR 36649) and FY 2019 (83 FR 38630) less the multifactor productivity (MFP) adjustments corresponding to each year.

The estimated average costs for FY 2019 (that is, taking the average FY 2017 cost per day by each level of care inflated to FY 2019 dollars) is detailed in Table 4.

TABLE 4—ESTIMATED AVERAGE COSTS (FY 2019) FOR CHC, IRC, AND GIP

Level of care	FY 2017 average costs	FY 2018 hospice market basket update less productivity adjustment	FY 2019 hospice market basket update less productivity adjustment	FY 2019 estimated average costs
CHC (per Hour)	\$54.49	x1.021	x1.021	\$56.80
IRC	441.03	x1.021	x1.021	459.75
GIP	952.56	x1.021	x1.021	992.99

We also analyzed the average costs of RHC for the first 60 days and any RHC days after day 60 inflated from FY 2017 dollars to FY 2019 dollars by applying

the hospice market basket update for FY 2018 and FY 2019 less the MFP adjustments corresponding to each year. The estimated average costs for RHC by

days for FY 2019 is shown in Table 5 below.

TABLE 5—ESTIMATED AVERAGE COSTS FOR RHC (FY 2019) DAYS 1 THROUGH 60 AND DAYS 61+

Level of care	FY 2017 average costs	FY 2018 hospice market basket update less productivity adjustment	FY 2019 hospice market basket update less productivity adjustment	FY 2019 estimated average costs
RHC Days 1–60	\$154.25	x1.021	x1.021	\$160.80
RHC Days 61+	119.36	x1.021	x1.021	124.43

We then compared the FY 2019 average costs for CHC, IRC and GIP to the FY 2019 payment rates for these three levels of care. Our analysis shows that there is a misalignment between average costs and payment for these

three levels of care. Table 6 below shows the percent of total hospice days by level of care; the estimated average FY 2019 costs by level of care; the current FY 2019 per diem payment rates; and the estimated percent increase

to the payment rates to more accurately align the per diem payments for CHC, IRC and GIP with the costs of providing these levels of care.

TABLE 6—COMPARISON OF FY 2019 AVERAGE COSTS TO PAYMENTS FOR CHC, IRC, AND GIP

Level of care	Percent of days by level of care in FY 2018 *	Estimated FY 2019 average costs per day	FY 2019 per diem payment rates	Estimated percent payment increase needed to align with costs
CHC	0.2	\$1,363.26/\$56.80 (per hour).	\$997.38/\$41.56	+36.6
IRC	0.3	\$459.75	176.01	+161.2
GIP	1.3	\$992.99	758.07	+31.0

* **Note:** We used the FY 2018 percent of days by level of care as this is the most current data available.

We also compared the FY 2019 average costs for RHC for the first 60 days and for any RHC days after day 60 to the FY 2019 payment rates for RHC and the percentage difference between payment and average costs. The percent

difference between costs and payment represents how much we would need to reduce the RHC payments in order to align payments with costs. The results are shown in Table 7 below. However, we did not propose to rebase the RHC

payment rates as any changes to the CHC, IRC, and GIP payment rates must be done in a budget-neutral manner as required by law.

TABLE 7—COMPARISON OF FY 2019 AVERAGE COSTS TO PAYMENT FOR RHC

Level of care	Estimated FY 2019 average costs per day	FY 2019 payment rates	Percent difference between costs and payment
RHC Days 1–60	\$160.80	\$196.25	– 18.1
RHC Days 61+	124.43	154.21	– 19.3

3. Rebasing of the CHC, IRC, and GIP Payment Rates for FY 2020

As described in the proposed rule (84 FR 17582) and in this final rule, the average costs of providing CHC, IRC and GIP are significantly higher than the payment amounts for these three levels of care. Using the hospice payment reform authority under section 1814(i)(6) of the Act, in the FY 2020 proposed rule., we proposed to rebase the payment rates for CHC, IRC, and GIP by setting these payment amounts equal to the FY 2019 estimated average costs per day, as described in the methodology above, before application of the hospice payment update percentage outlined in section III.B.3 of

this final rule. Using the updated cost report and claims data as shown previously in this final rule, the rebased payment rates for CHC, IRC, and GIP are as follows:

TABLE 8—REBASED PAYMENT RATES FOR CHC, IRC, AND GIP *

Level of care	Rebased payment rates *
Continuous Home Care (CHC).	\$56.80 per hour/ \$1,363.26 (per day).**
Inpatient Respite Care (IRC).	\$437.86.***
General Inpatient Care (GIP).	\$992.99.

* Prior to application of the hospice payment update of 2.6 percent outlined in section III.B.3 of this final rule.

** Based on a full CHC per day payment (which covers 24 hours).

*** IRC payment rate accounts for 5 percent coinsurance (\$459.75/1.05 = \$437.86).

Section 1813(a)(4)(A)(ii) of the Act states that the amount payable for hospice care shall be reduced in the case of respite care provided by (or under arrangements made by) the hospice program, by a coinsurance amount equal to 5 percent of the amount estimated by the hospice program (in accordance with regulations of the Secretary) to be equal to the amount of payment under section 1814(i) to that program for respite care. To ensure payments (both paid by Medicare and collected from the beneficiary via coinsurance) under a rebased IRC rate

equal the average per-diem cost of IRC, we set the rebased IRC payment rate equal to the average per-diem cost of IRC divided by 1.05. The amount of the individual's coinsurance liability for respite care during a hospice coinsurance period may not exceed the inpatient hospital deductible applicable for the year in which the hospice coinsurance period began. The individual hospice coinsurance period begins on the first day an election is in effect for the beneficiary and ends with the close of the first period of 14 consecutive days on each of which an election is not in effect for the beneficiary.

Section 1814(i)(6)(D)(ii) of the Act requires that any revisions to the methodology for determining the payment rates for other services included in hospice care to be done in a budget-neutral manner in the fiscal year in which such revisions in payment are implemented as would have been made for care in the fiscal year if such revisions had not been implemented. The results of the calculations demonstrated in the FY 2020 proposed rule (84 FR 17583) show that in order to rebase the payment rates for the CHC, IRC, and GIP levels of care in a budget-neutral manner, the RHC payment rates would need to be reduced by 2.71 percent. The 2.71 percent reduction would be applied to the RHC payment rates for the first 60 days and RHC days after day 60. However, using more recent claims data for this final rule, these same calculations show that the actual reduction to the RHC payment rate would need to be 2.72 percent. To calculate the 2.72 percent reduction to the RHC payment rates, we first calculated two sets of payments using different payment parameters.

1. Total payments for hospice days provided during FY 2018 under the existing FY 2019 payment rates and FY 2019 wage indices.

2. Total payments for hospice days provided during FY 2018 under a new RHC payment rate and the rebased payment rates for CHC, IRC, and GIP.

We set the RHC payment rate in step (2) equal to the value that makes total payments between step (1) and step (2) equivalent. We calculate that rate using the following steps:

1. We calculate the difference in Medicare payments when using the rebased CHC, IRC, and GIP payment rates instead of the payment rates in place during FY 2019.

2. We calculate one minus the value from Step (1) over the RHC payments

made under the payment rates in place during FY 2019.¹⁵

3. We multiply the value in Step (2) by each RHC payment rate (the first 60 days and any RHC days after day 60) in place during FY 2019 to establish the budget-neutral RHC payment rates (the first 60 days and any RHC days after day 60).

The calculated payment rates in Step (3) will make the total payments made under the rebased FY 2019 payment rates equal to the total payments made under the existing FY 2019 payment rates. Essentially, the reduction is the weighted difference between non-RHC costs and payments divided by the weighted RHC payments, where the weights are the percent of days by level of care.

The results of this calculation demonstrate that in order to rebase the payment rates for the CHC, IRC, and GIP levels of care in a budget neutral manner, the RHC payment rates would need to be reduced by 2.72 percent. The 2.72 percent reduction would be applied to the RHC payment rates for the first 60 days and RHC days after day 60 (that is, we would take each of the RHC payment rates and multiply by the 0.9728 to determine the FY 2019 RHC payment rates).

Therefore, in order to offset the increases in payment rates to the CHC, IRC, and GIP levels of care, we would reduce the RHC payment rates by 2.72 percent in order to implement rebasing in a budget-neutral manner in FY 2020. However, reducing the RHC payment rate to a level equal to the estimated RHC costs would require a reduction in the RHC payment rate that exceeds the 2.72 percent. Therefore, while we are rebasing the per diem payment rates for CHC, GIP, and IRC to more accurately align the payment with costs, the reduction to the RHC payment rates is not considered rebasing as the 2.72 percent reduction does not bring the RHC payment in alignment with the costs of providing this level of care. The purpose of the 2.72 percent reduction to the RHC payment rates is to ensure that the revisions to the payment rates for CHC, GIP and IRC are made in a budget-neutral manner, in accordance with the law.

We received 113 unique comments regarding the rebasing methodology and

analysis, as well as the rebased payment rates for CHC, IRC, and GIP. Most of these comments were from hospices, industry associations and other relevant stakeholders, including comments from the Medicare Payment Advisory Commission (MedPAC). These comments are summarized below along with our responses:

Comment: Several commenters were supportive of CMS' proposal to rebase the per diem payment amounts for CHC, GIP and IRC in order to ensure that payments are closer to the estimated cost of providing each level of care. Commenters stated that rebasing the rates for these three levels of care addresses concerns that hospices lose money on the increased costs of providing more complex medical management. These commenters stated that hospices often have to pay contractors and the facilities providing this increased level of care more than the payment rates the hospices are currently receiving. Further, commenters suggested that, were CMS to finalize this proposal, the potential increase in availability of hospices to provide these levels of care would benefit patients and their caregivers. A few commenters stated that rebasing the CHC, GIP, and IRC rates would benefit rural hospices who have fewer facilities and contractors with which to provide this care.

Response: We thank commenters for their thoughtful review and support of our efforts to better align hospice costs of providing care for patients receiving CHC, GIP, and IRC and to support hospices working with outside contractors and facilities. We agree that rebasing these rates would adequately cover the costs of providing these higher intensity levels of care, could ensure that hospices have access to the providers needed to comply with the hospice Conditions of Participation (CoPs), and promote patient access to all levels of care.

Comment: CMS received several comments about the large number of cost reports eliminated with exclusion 2 (that is, we eliminated SNF, HHA and hospital cost reports that did not contain a hospice CCN) and as reported in Table 2 of the proposed rule (84 FR 17578). Many commenters also mentioned that CMS used cost reports for FY 2017 and applied Level I edits; however, the edits went into effect for cost reporting periods that ended on or after December 31, 2017. These commenters expressed concern that CMS applied the Level I edits to freestanding and provider-based cost reports even though the edits were not applicable to provider-based cost

¹⁵ Using the average per-diem costs generated from our sample of freestanding hospice cost reports, rebasing CHC, IRC, and GIP results in extra payments of \$468,223,480.70 for those levels of care. The RHC payments that were made under the payment rates in place during FY 2019 were \$17,238,380,386.58. One minus the value of the extra payments over the RHC payments equals 0.9728.

reports for 2017 or subsequent cost reports thus stating we shouldn't use them in our analysis. Several commenters recommended that CMS include provider-based cost reports as the sample size used for the analysis and methodology is relatively small. These commenters suggested that using larger sample of cost reports by incorporating cost reports from provider-based hospices when rebasing CHC, IRC and GIP per diem rates would provide more robust and accurate information.

Response: For the FY 2020 final rule, CMS updated the FY 2017 cost reports using the hospice cost report file <http://downloads.cms.gov/Files/hcris/HOSPC14-ALL-YEARS.zip> from the proposed rule (84 FR 17578). There are 4,195 hospice cost reports as of June 21, 2019 versus 4,125 from the proposed rule. We describe, in detail, in this final rule and in the FY 2020 hospice proposed rule (84 FR 17570), all of the exclusions applied to hospice cost reports to estimate the average cost per day by level of care. And in this final rule, we remind commenters that the final sample of cost reports is higher than described in the proposed rule (1,232 cost reports for this final rule compared to 1,120 in the proposed rule). We note that most SNFs do not have a hospice CCN associated with it, so most of the SNF cost reports were dropped. We believe that eliminating these SNF cost reports with no associated hospice CCN would more accurately filter out those costs not related to the cost of providing hospice care and where much of the reported costs may be for the provision of SNF services. Additionally, we considered proposing to use freestanding and provider-based cost reports to rebase CHC, IRC, and GIP payment rates, rather than just using freestanding cost reports. However, when we analyzed both freestanding and provider-based cost reports, the results tend to be similar. On average, incorporating provider-based cost reports results in higher costs than the cost reports for freestanding hospices only, as shown in Table 27 of the FY 2020 hospice proposed rule (84 FR 17616).

Similarly, when we rebased the national, standardized 60-day episode payment rate for home health agencies beginning in CY 2014, we estimated costs using only freestanding HHA cost reports for the same reasons detailed in the FY 2020 hospice proposed rule (that is, freestanding cost reports reflect actual hospice costs and not those additional costs borne from the parent entity). Therefore, it is not unprecedented in Medicare payment

systems to use only freestanding cost reports, rather than including provider-based cost reports for rebasing purposes.

Additionally, in MedPAC's March 2018 report to Congress, MedPAC stated that overhead costs allocated from the parent provider are included in the costs for provider-based hospices, which contributes to provider-based hospices having higher costs than freestanding hospices. If freestanding hospices are able to provide high-quality care at a lower cost than provider-based hospices, payment rates should be set accordingly, and the higher costs of provider-based hospices should not be a reason for increasing Medicare payment rates. Ultimately, we used freestanding cost reports to estimate the average cost per day by level of care.

As detailed in the FY 2020 proposed rule, we also applied Level I edits (and removed certain reports with missing data from our sample) manually because not all FY 2017 freestanding cost reports had a reporting period that ended on or after December 31, 2017. We decided to apply Level I edits based on suggestions by industry representatives to apply certain edits to force adherence to certain cost-reporting principles that could lead to the reporting of higher-quality cost data. Therefore, we believe it is most technically appropriate to apply the Level I edits. Furthermore, we show in Table 26 of the proposed rule (84 FR 17616) that the differences in costs between including and not including exclusions based on the Level I edits were minimal for RHC, CHC, and GIP. The difference between applying Level I edits versus not applying the edits is less than one dollar for RHC, CHC, and GIP. However, the IRC cost per day between the two trimming methodologies was more pronounced, but still not significantly so. In looking at FY 2017 estimated average per day costs using all of the trimming exclusions, and as shown in Table 26 in the proposed rule, the cost for IRC was \$438.97; applying all of the trimming exclusions, excluding the Level I edits, the cost for IRC was \$467.78 (a 6.6% increase). Therefore, for purposes of estimating the costs by level of care, we believe that applying the Level I edits is appropriate given these edits are now applied for hospice cost reports and there was minimal effect on the average costs per day.

Comment: Several commenters stated that many hospices do not accurately or consistently complete cost reports, thus rendering the data inaccurate. These commenters stated that because of the inaccuracies in the cost reports, CMS should not use hospice cost reports as

the source of data to estimate costs. Several commenters mentioned concerns about the accuracy of the cost report data in the FY 2017 cost reports that CMS used for their analysis and methodology. A few commenters stated that CMS did not provide additional information about which provider's data was used.

Response: We remind hospices that each hospice cost report is required to be certified by the medical officer or hospice administrator. The hospice Medicare Cost Report (MCR) form (CMS-1984-14) includes a dated and signed statement indicating that all information is true, correct, and prepared from the books and records of the provider in accordance with applicable instructions, except as noted. Additionally, as required by section § 413.24(f)(4)(iv)(A) the cost report must be signed by either the Chief Financial Officer or the Administrator. If there are errors within a cost report, they must be filed on time and if there is any type of problem with it that cannot be addressed timely, the MAC may withhold Medicare payments. Therefore, we expect and it is required that hospice cost reports contain accurate and complete data on which to base our analyses.

As always, we encourage providers to fill out the Medicare cost reports as accurately as possible. The Provider Reimbursement Manual¹⁵ provides detailed instructions on filling out the cost reports. CMS further encourages hospice providers to contact the appropriate Medicare Administrative Contractor (MAC) if additional instruction or assistance is needed. Furthermore, as the cost reports are to reflect all of the costs associated with providing hospice care by level of care, we believe that it is the most appropriate mechanism in which to estimate costs for rebasing payment rates.

Our cost report analysis was based on information obtained from the Healthcare Cost Report Information System (HCRIS). As mentioned in the proposed rule (84 FR 17578), the hospice cost report data contains cost and statistical data for freestanding and provider-based hospice providers. For the proposed rule, we used HCRIS data files from December 31, 2018. For this final rule we used more up to date cost report data from March 31, 2019. The updated data contains 4,195 hospice cost reports versus 4,125 from the

¹⁵ The Provider Reimbursement Manual—Part 2. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935.html>.

proposed rule. In our analysis, we used Worksheet S–2 to determine if the provider-based cost reports had a hospice CCN. Information regarding costs per day by level of care came from worksheet O8 for provider-based cost reports and worksheet C for freestanding cost reports. Information needed to construct the level I edits came from worksheet A for freestanding cost reports and worksheet O and O5 for provider-based cost reports. We feel confident that the cost reports that the hospice providers submit are accurate and that the signatures obtained by the administrator and or Officer are true, correct, complete, and prepared from the books and records of the provider in accordance with applicable instructions.

Comment: Several commenters disagreed with the proposal to rebase the CHC, IRC, and GIP payment rates stating that the reduction in the RHC payment rate in order to maintain budget neutrality effectively turns the rebasing proposal into a rate cut even after the proposed payment update. These commenters stated that this would create financial and staffing hardships for hospices, especially smaller rural hospices. Some commenters stated that payment adjustments that more accurately capture and compensate for differences in costs of providing hospice services in rural versus urban communities may first be necessary before CMS rebases payment rates. A few commenters stated that the effect of rebasing will be felt unevenly across providers, depending on the amount of GIP, CHC and IRC being provided by an individual hospice and that CMS should ensure that payment adjustments adequately account for differences in costs based on geography.

Response: Section 1814(i)(6)(D)(ii) of the Act requires that any revisions to the hospice payment rates be done in a budget neutral manner. Meaning the revisions in payment for GIP, IRC and CHC must result in the same estimated aggregate expenditures had the revisions not been implemented. After applying the FY 2020 hospice payment update of 2.6 percent and accounting for the rebasing of the GIP, IRC and CHC payment rates (which requires a 2.72 percent reduction to the RHC payment rate) the net result would only be a reduction of 0.19 percent to the RHC payment rate. That reduction equates to approximately 37 cents on RHC days 1 through 60 and 29 cents on days 61 plus (compared to the FY 2019 RHC payment rates). Given that MedPAC in their recent March 2019 Report recommended a 2 percent reduction to the hospice base payment rates and

projects Medicare hospice margins to be 10.1 percent for 2019, we feel the reduction to the RHC payment rate would not create financial hardships for hospices. Furthermore, in their March 2019 report, and their comments on the proposed rule, MedPAC reported that the aggregate 2016 Medicare margin, which is an indicator of the adequacy of Medicare payments relative to providers' costs, was 10.9 percent, up from 9.9 percent in 2015. They stated that hospice costs per day vary substantially by type of provider, which is one reason for differences in hospice margins across provider types. In 2016, hospice costs per day across all hospice providers were about \$149 on average, a slight decrease from \$150 in the previous year. Some of the decline in cost per day is accounted for by a shift in the mix of hospice days, with the share of days accounted for by routine home care (the lowest cost level of care) increasing in 2016. Freestanding hospices had lower costs per day than provider-based hospices (that is, home health-based hospices and hospital based hospices). For-profit, above-cap, and rural hospices also had lower average costs per day than their respective counterparts.

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. The appropriate wage index value is applied to the labor portion of the hospice 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. Overall, rural hospices would have a slight decrease (estimated to be less than 1 percent) in payments as a result of the rebased payment rates for CHC, GIP, and IRC. However, rural, non-profit HHAs will see an increase in payments, compared to rural for-profit HHAs who will see a slight decrease in payments as a result of the rebased rates.

Comment: Several commenters, including a national industry group, agreed that while the CHC, IRC, and GIP payment rates need to be increased, they expressed concern that CMS needs to examine any negative impact on access to care.

Response: We disagree that increasing the rates for CHC, IRC, and GIP would have a negative impact on access to care. Conversely, we believe that

aligning the payment with the cost of providing care should have a positive effect on access to needed levels of care. We believe that hospices who currently cannot provide adequate CHC will now have the resources to hire adequate staff to ensure patients needing CHC level of care will have the needed nursing support during a time of symptom crisis. Likewise, for those hospices who do not have their own freestanding, inpatient unit, we believe the higher payment rates for IRC and GIP will afford them more latitude when negotiating contracts with skilled nursing facilities and hospitals to best meet the needs of their patients requiring inpatient levels of care. However, we will continue to monitor the effects of these rebased rates to determine if there are any notable shifts in the provision of care or any other perverse utilization patterns that would warrant any program integrity or survey actions.

Comment: Many commenters suggested to postpone any rebasing for 2 years so that CMS has enough time to validate cost reports and accuracy of data to support the changes, or at the very least, implement a phased-in approach to increasing the payment rates for CHC, IRC, and GIP payment rates and reducing the RHC payment rates.

Response: While we understand why some hospices would prefer to postpone or phase-in rebasing of the CHC, IRC, and GIP payments and the corresponding reduction to RHC payments to maintain budget neutrality, we disagree with either of these approaches as this would not align payment with the costs of providing the higher intensity levels of care.

We will continue to monitor utilization with implementation of these rebased rates to see if there are any trends that may warrant other appropriate actions, including program integrity measures. Furthermore, a phased-in approach would require a recalculation of the RHC amount each year based on the most recent utilization of CHC, IRC and GIP. If there was an increase in utilization of those levels (CHC, IRC, GIP) we would then have to further adjust the RHC rate to account for the increase in utilization, which could further reduce the RHC rate. Likewise, even with the 2.72 percent reduction to the RHC rates, the payment for both days 1–60 and days 61+ still exceeds the cost of providing this level of care, as shown in Table 7 in this final rule.

Comment: Several commenters noted that the changes to the IRC per diem payments would make it easier to

provide respite care to patients and their families needing such support. One commenter noted that the rebasing of GIP would have a positive impact on those hospices that provide GIP in their own freestanding facilities. Hospice providers stated that this change would allow their freestanding facility to operate with positive margins for the first time. Other commenters remarked that the increased IRC rates will enable them to find nursing facilities willing to contract with them for respite stays. A large number of commenters stated that upward adjustment for CHC, GIP, and IRC is warranted given the misalignment between payment and costs.

Response: We appreciate these comments and agree that rebasing the IRC payment rate may result in greater access to inpatient respite care for terminally ill patients and their families. Likewise, the rebasing proposals help to align payment with the cost of providing care and we believe that this proposal is responsive to industry concerns and challenges related to providing these higher intensity levels of care.

Comment: Many hospices, along with MedPAC, noted concerns about creating incentives for hospices to improperly expand the use of inpatient levels of care as a result of rebasing. They suggested considering a prospective payment adjustment to GIP to maintain budget neutrality if aggregate payments increase as a result of these payment changes. MedPAC also expressed concern about the proposed increase in the GIP payment rate provided in a skilled nursing facility (SNF) and urged CMS to maintain the current payment rate of GIP provided in SNFs. MedPAC cited reports from hospice providers that it costs less to contract for GIP in a SNF than with a hospital. A few other commenters suggested that CMS reconsider increasing the GIP per diem payment rate in skilled nursing facilities (SNFs). They suggested that an increase in the payment rate for GIP would likely make providing GIP in SNFs quite profitable and could create incentives for more hospice providers to furnish GIP in SNFs. They further note that GIP care in the SNF setting tends to be less resource intensive and less costly than in a hospital or hospice facility.

Response: We believe that the rebased rates will help appropriately increase access to care but we are aware of the perverse incentives that could occur with increases in payment rates. We recognize that there may be an increase in utilization of these higher intensity levels of care but we believe that this may be appropriate to meet patient care

needs. We remind stakeholders that there are criteria for receiving these higher levels of care which may potentially buffer any inappropriate increases in utilization. Continuous home care may be provided only during a period of crisis as necessary to maintain an individual at home. Either homemaker or home health aide (hospice aide) services or both may be covered on a 24-hour continuous basis during periods of crisis but care during these periods must be predominantly nursing care. A period of crisis is a period in which a patient requires continuous care to achieve palliation or management of acute medical symptoms. The hospice must provide a minimum of 8 hours of care during a 24-hour day, which begins and ends at midnight. This care need not be continuous; for example, 4 hours could be provided in the morning and another 4 hours in the evening. In addition to the 8 hour minimum, the services provided must be predominantly nursing care, provided by either an RN, an LPN, or an LVN. Respite care is short-term inpatient care provided to the individual only when necessary to relieve the family members or other persons who normally care for the individual at home. Respite care may be provided only on an occasional basis and may not be reimbursed for more than 5 consecutive days at a time. Payment for the sixth and any subsequent day of respite care is made at the routine home care rate, and the patient would be liable for room and board. Respite care cannot be provided to hospice patients who reside in a facility (such as a long term care nursing facility). Provision of respite care depends upon the needs of the patient and of the patient's caregiver (and is subject to the regulatory limitations set out at § 418.302(e)(5)). And finally, GIP is allowed when the patient's medical condition warrants a short term inpatient stay for pain control or acute or chronic symptom management that cannot feasibly be provided in other settings.

To address MedPAC and other stakeholder comments regarding the difference in the provision of GIP in a SNF compared to an inpatient hospital, we note the current cost report does not allocate costs for GIP by site of service. Additionally, our analysis has shown that very few GIP days are provided in a SNF compared to other freestanding facilities and inpatient hospitals. Likewise, the types of hospices providing GIP in a SNF may be different in other ways compared to hospices that do not provide GIP in a SNF. It is

possible those differences are correlated with the costs.

Additionally, we continue to expect hospices to provide care in accordance with the individualized plan of care as required by the hospice CoPs at § 418.56. This means that we do not expect that hospices would move patients into higher intensity levels of care solely to receive higher payments. As mentioned in the proposed rule, we believe that rebasing the per diem payment amounts for CHC, GIP, and IRC is appropriate in order to align payments with cost of providing care. Likewise, potential, subsequent increases in utilization would not necessarily be inappropriate. Hospice providers still need to meet the necessary requirements stated in section 1861(dd) of the Act and the hospice CoPs, which require that hospice agencies regardless of size, location or other organizational or market characteristics must be able to provide all four levels of hospice care. As part of our routine monitoring of hospice utilization, we will continue to closely analyze any changes in the patterns of care in response to these rebased payment rates to determine if any additional actions are warranted.

Comment: Several commenters suggested that CMS should increase its oversight of hospice providers not delivering the services required under the hospice CoPs and exhibiting inappropriate practices highlighted by the OIG and the MedPAC.

Response: We note that compliance with the hospice CoPs is monitored through the survey process. The IMPACT Act of 2014 currently requires hospice survey/recertifications every 3 years. Survey protocols and Interpretive Guidelines are established to provide guidance to personnel conducting surveys of hospices. They serve to clarify and/or explain the intent of the regulations. All surveyors are required to use them in assessing compliance with federal requirements.¹⁶ There are different types of surveys including survey for initial certification for participation in Medicare; a recertification survey which are unannounced and must verify compliance with all the regulatory requirements contained at §§ 418.52 thru 418.116; a post-survey onsite revisit is to reevaluate the specific care and services that were cited during a previous survey that cannot be adequately assessed by mail, telephone

¹⁶ State Operations Manual Appendix M—Guidance to Surveyors: Hospice. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_m_hospice.pdf.

or electronic contact, or; a complaint investigation in which a survey is conducted to investigate and resolve a complaint against a hospice. We believe that there are already systems in place to ensure compliance with the hospice CoPs and we will continue to coordinate with the State Agencies to identify any ongoing concerns as they relate to the CoPs and to determine whether any additional oversight mechanisms need to be in place. We are committed to encouraging providers to supply the best quality care in the most appropriate ways, and we will continue to work to incentivize and monitor for the most appropriate practices in the hospice provider community.

Comment: Several commenters expressed concern that increasing the rates for IRC and GIP will result in contracted facilities raising the rates they charge hospices to provide these levels of care. Stakeholders remarked that these are essentially “pass-through payments” to contracted providers and would require hospice providers to bear the cost of providing these services while taking a large reduction to the RHC reimbursements. Some commenters stated that IRC and GIP can be supplied by hospice in various ways resulting in wide differences in costs for providing these levels of care. Commenters asserted that a small proportion of hospices operate hospice inpatient units directly, while some others are system or SNF-based and secure inpatient care through a parent entity. They suggested that the vast majority of hospice providers, more than 75 percent, enter into contracts with local hospitals or other facilities and therefore costs for inpatient days vary significantly. One commenter suggested that the estimated cost of IRC reported in the proposed rule does not accurately reflect the average cost of providing this level of care as it is being affected by high cost outliers and therefore the rebased payment rate may be inaccurate.

Response: We remind stakeholders that CMS does not have the authority to mandate specific contractual agreements between hospices and other entities which have entered into an agreement to provide arranged hospice services. Hospices are required, in accordance with the CoPs at §§ 418.100 and 418.108, to be able to provide all levels of hospice care. This means it is the responsibility of hospices to secure the necessary contracts to provide inpatient

levels of care if the hospice does not provide them in their own freestanding facility. As such, hospices would have to negotiate appropriate rates with the contracted providers to ensure that the hospice has sufficient resources to provide the necessary care.

To address the comment about IRC cost outliers, in the proposed rule, we trimmed the top and bottom 1 percent of cost reports, which excluded some outliers and have done so for the final rule. We recognize that IRC does have a wide distribution with outliers (even after taking out the top and bottom 1 percent). While there may be some high-cost outliers that affect the estimated, average cost of IRC, we remind stakeholders that utilization of IRC is low, accounting for 0.3 percent of total hospice days and it would not take many outliers to impact the estimated costs of providing this level of care. As such, we would not want to make any further exclusions to only one particular level of care. Additionally, we note that the rebased payment rate for IRC excludes the 5 percent coinsurance for each day of respite care. However, commenters on the proposed rule stated that most hospices do not collect this coinsurance from beneficiaries. Therefore, overall payment to hospices for IRC is even further reduced in those circumstances when hospices do not collect this coinsurance.

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 rebase the payment rates for CHC and GIP and set these rates equal to their average FY 2019 costs per day as shown in Table 8 of this final rule. We are finalizing rebasing of IRC payment rates and setting this rate equal to the estimated FY 2019 average costs per day, with a reduction of 5 percent to the FY 2019 average cost per day to account for coinsurance, also as shown in Table 8 of this final rule. Lastly, we are finalizing a 2.72 percent reduction to the RHC payment rates to offset the increases to CHC, IRC, and GIP payment rates to implement this policy in a budget-neutral manner in accordance with section 1814(i)(6) of the Act.

B. FY 2020 Hospice Wage Index and Rate Update

1. Wage Index Lag Elimination

Historically, we have calculated the hospice wage index values by using the

prior fiscal year's pre-floor, pre-reclassified hospital wage index. In an effort to align with the Inpatient Prospective Payment System (IPPS) and other payment systems, in the FY 2020 hospice proposed rule (84 FR 17584), we proposed to change the hospice wage index methodology. Specifically, we proposed to change from our established policy of using the pre-floor, pre-reclassified acute care hospital wage index from the prior fiscal year as the basis for the hospice wage index, and instead to align with the same timeframe used by the IPPS and other payment systems. In other words, we proposed to use the pre-floor, pre-reclassified hospital wage index from the current fiscal year as the basis for the hospice wage index. Under this proposal, the FY 2020 hospice wage index would be based on the FY 2020 pre-floor, pre-reclassified IPPS hospital wage index rather than on the FY 2019 pre-floor, pre-reclassified IPPS hospital wage index.

Using the concurrent pre-floor, pre-reclassified hospital wage index would result in the most up-to-date wage data being the basis for the hospice wage index, increasing payment accuracy. It would also result in more consistency and parity in the wage index methodology used by Medicare. Medicare's skilled nursing facility (SNF), home health and inpatient hospital prospective payment systems already use the most current wage index data as the basis for their wage indices. Thus, the wage-adjusted Medicare payments of various provider types would be based upon wage index data from the same timeframe. We are considering similar policies to use the concurrent pre-floor, pre-reclassified hospital wage index data in other Medicare payment systems, such as inpatient psychiatric facilities and inpatient rehabilitation facilities.

Overall, the impact between the FY 2020 wage index with the 1-year lag and the proposed FY 2020 wage index removing the 1-year lag is 0.0 percent due to the wage index standardization factor, which ensures that wage index updates and revisions are implemented in a budget-neutral manner. The anticipated impact on Medicare hospice payments due to the change in the wage index methodology can be found in Table 9 below.

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Table 9: Impact on Medicare Hospice Payments, FY 2020 Hospice Wage Index With and Without 1 year Lag

Hospice Subgroup	Hospices	FY 2020 Wage Index with 1-year Lag Minus FY 2019 Wage Index (Percentage Change)	FY 2020 Wage Index without 1-Year Lag Minus FY 2020 Wage Index with 1-Year Lag (Percentage Change)
All Hospices	4,599	0.0%	0.0%
Facility Type and Control			
Freestanding/Non-Profit	602	-0.1%	0.0%
Freestanding/For-Profit	2,843	0.1%	0.0%
Freestanding/Government	39	0.1%	-0.3%
Freestanding/Other	325	-0.2%	0.1%
Facility/HHA Based/Non-Profit	396	-0.3%	-0.1%
Facility/HHA Based/For-Profit	196	-0.2%	-0.1%
Facility/HHA Based/Government	101	-0.3%	-0.1%
Facility/HHA Based/Other	97	0.0%	0.1%
Subtotal: Freestanding Facility Type	3,809	0.0%	0.0%
Subtotal: Facility/HHA Based Facility Type	790	-0.2%	-0.1%
Subtotal: Non-Profit	998	-0.1%	0.0%
Subtotal: For Profit	3,039	0.1%	0.0%
Subtotal: Government	140	-0.1%	-0.2%
Subtotal: Other	422	-0.2%	0.1%
Facility Type and Control: Rural			
Freestanding/Non-Profit	154	0.0%	0.2%
Freestanding/For-Profit	329	0.1%	-0.1%
Freestanding/Government	20	-0.3%	-0.3%
Freestanding/Other	45	-0.2%	0.0%
Facility/HHA Based/Non-Profit	157	-0.4%	-0.2%
Facility/HHA Based/For-Profit	47	0.0%	-0.2%
Facility/HHA Based/Government	74	0.0%	0.0%
Facility/HHA Based/Other	54	-0.8%	0.3%
Facility Type and Control: Urban			
Freestanding/Non-Profit	448	-0.1%	0.0%
Freestanding/For-Profit	2,514	0.1%	0.0%
Freestanding/Government	19	0.2%	-0.3%
Freestanding/Other	280	-0.2%	0.1%
Facility/HHA Based/Non-Profit	239	-0.3%	0.0%
Facility/HHA Based/For-Profit	149	-0.3%	-0.1%

Facility/HHA Based/Government	27	-0.5%	-0.2%
Facility/HHA Based/Other	43	0.2%	0.0%
Facility Location: Urban or Rural			
Rural	880	-0.1%	0.0%
Urban	3,719	0.0%	0.0%
Facility Location: Region of the Country (Census Division)			
New England	158	-0.5%	-0.7%
Middle Atlantic	282	-0.2%	-0.2%
South Atlantic	558	-0.1%	-0.1%
East North Central	546	-0.4%	-0.1%
East South Central	264	-0.2%	-0.2%
West North Central	406	-0.3%	0.3%
West South Central	887	0.3%	-0.1%
Mountain	462	-0.5%	0.1%
Pacific	990	0.9%	0.6%
Outlying	46	-1.3%	-0.2%
Facility Size			
0 - 3,499 RHC Days (Small)	1,004	0.4%	0.2%
3,500-19,999 RHC Days (Medium)	2,131	0.1%	0.0%
20,000+ RHC Days (Large)	1,464	0.0%	0.0%

Note: 6 hospices with claims in FY 2018 were dropped from the analysis because they had no information on their location, facility type, or ownership status in the December 2018 POS file.

Source: FY 2018 hospice claims data from the CCW Research Identifiable Files (RIFs), accessed May 2019.

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2. FY 2020 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.

In the FY 2020 proposed rule (84 FR 17586), we proposed to use the current FY's hospital wage index data to calculate the hospice wage index values. For FY 2020, the proposed hospice wage index would be based on the FY 2020 hospital pre-floor, pre-reclassified wage index. This means that the hospital wage data used for the hospice wage index are 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 hospice 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.

In the FY 2006 Hospice Wage Index final rule (70 FR 45135), we adopted the policy that, for urban labor markets without a hospital from which hospital wage index data could be derived, all of the Core-Based Statistical Areas (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 2020, the only CBSA without a hospital from which hospital wage data can be derived is 25980, Hinesville-Fort Stewart, Georgia. The FY 2020 wage index value Hinesville-Fort Stewart, Georgia is 0.8322. Please note that CBSA 16180 Carson City, NV had no provider wage

data for the FY 2020 proposed hospice rule (84 FR 17586). However, this CBSA now has provider wage data for the updated final wage index file. The new wage index value for CBSA 16180 is 1.0070.

There exist some geographic areas where there were no hospitals, and thus, no hospital wage data on which to base the calculation of the hospice wage index. In the FY 2008 Hospice Wage Index final rule (72 FR 50217 through 50218), we implemented a methodology to update the hospice wage index for rural areas without hospital wage data. 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 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 2020, we propose to continue to use the most recent pre-floor, pre-reclassified hospital wage index value available for Puerto Rico, which is 0.4047, subsequently adjusted by the hospice floor.

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.

We identified a slight error in the proposed rule wage index values after the FY 2020 Hospice Wage Index and Payment Rate Update proposed rule was published. A programming error caused the data for all providers in a single county to be included twice, which affected the national average hourly rate, and therefore affected nearly all wage index values. We have changed the programming logic so this error cannot occur again. In addition, we corrected the classification of one provider in North Carolina that was erroneously identified as being in an urban CBSA. We also standardized our procedures for rounding, to ensure consistency. The correction to the proposed rule wage index data was not completed until after the comment period closed June 18, 2019. This final rule reflects the corrected and updated wage index data. The final hospice wage index applicable for FY 2020 (October 1, 2019 through September 30, 2020) is available on our website at: <https://www.cms.gov/Medicare/Medicare-Fee->

[for-Service-Payment/Hospice/Hospice-Wage-Index.html](#).

We received approximately 22 comments on the FY 2020 hospice index proposals from various stakeholders including hospices, national industry associations and MedPAC. A summary of these comments and our responses to those comments appear below:

Comment: Several commenters expressed support for the wage index lag elimination. Several commenters stated that changing the lag with the Hospital Wage Index will help hospices be more competitive in the labor market, allow wages to track closer to market shifts, and allow hospices to compete in tight labor markets. One commenter expressed support for CMS' efforts to eliminate differences between provider types by removing the time lag. A few commenters suggested the proposed changes to the wage index calculations would provide consistency with the other Medicare payment systems. One commenter suggested that the existing lag makes it difficult for agencies and companies operating in multiple states. One commenter stated that there is value in consistency across provider types so that all providers can compete in same labor pool. The commenter further asserted that hospices may be able to provide input to hospitals on proposed wage index values. One commenter expressed support for eliminating the lag year and recognizes the value in having wage index consistency across provider types to enhance the ability of all employers in a given area to compete for staff from the same labor pool. The commenter further asserted that elimination of the lag year also provides some potential for hospices to provide input to local hospitals when proposed wage index values appear to undervalue the cost of labor in a geographic area.

Response: While we appreciate the commenters' careful review of the proposal and the support for the removal of the wage index lag elimination, we reiterate that using the most current year's data will most accurately adjust payment to account for geographic wage differences.

Comment: Several commenters suggested utilizing a transitional year wage index value that is a 50–50 blend of the lag year value and FY 2020 wage index value. One commenter suggested that a transitional wage index would provide some relief from substantial negative impact that many providers would experience by going directly to the FY 2020 wage index. The commenter further asserted that wage index values for the other regions under

a blend would still exceed the values they would have been assigned in FY 2019. One commenter recommended a phase-in to the removal over multiple years to minimize the disruption of the impact on the industry. The commenter further asserted that a phase-in is appropriate given the significant redistribution created by the proposed change. One commenter stated that while not opposed to removing the 1-year lag as other types use the most current wage index in calculating their indices, the commenter is concerned that the proposed rule does not provide additional adjustments.

Response: While we appreciate commenters' suggestion to create a transitional wage index that is a 50–50 blend of FY 2019 and FY 2020 wage index values, we believe that it is important to use the most recent data to increase payment accuracy. We also believe it is important to stay in alignment with other CMS payment systems so that there is parity and consistency in the wage index methodology.

Comment: A few commenters expressed concern that removing the 1-year lag would have a negative impact on hospices. One commenter suggested that removing the lag would have a negative short-term impact on hospices due to a shorter time period for providers to plan in cases where the wage index drops substantially. One commenter stated that the current 1-year lag allows hospices to plan for wage index changes which would be far more difficult if changes were based on the current year's wage index. One commenter stated that the proposal disadvantages providers because they would no longer have advance warning of wage index changes. The commenter further asserted that providers will be unable to plan for any significant shifts (particularly negative shifts). One commenter stated that elimination of the lag year allows hospices a much shorter period of time to adapt or adjust their financial expectations and absorb the impact of negative wage index swings, particularly swings under which the wage index value for an area drops precipitously.

Response: We disagree that removing the 1-year lag would have a negative impact on hospices and we refer commenters to Table 9 of this final rule to see the impact with and without the 1 year wage index lag. We continue to believe that using the most current year's wage index would improve overall payment accuracy.

Final Decision: After considering the comments we received on the elimination of the wage index lag, we

are finalizing the removal of the 1 year wage index lag. We are finalizing that we will use the current year's wage index to geographically wage adjust hospice payments, so for the FY 2020 hospice per diem payment rates, these will be geographically wage-adjusted using the FY 2020 wage index. Using the most current up to date information will increase payment accuracy and result in more consistency and parity in the wage index methodology used by Medicare.

We also received comments on the hospice wage index in general and these are summarized below, along with our responses.

Comment: Several commenters suggested that providers be guaranteed a wage index value that does not drop below the rural wage index applicable in their state of operation.

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 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: One commenter expressed concern that hospitals currently receive special consideration in a number of ways, but hospices and other small provider types are not granted the same considerations. The commenter suggested that creating value that is consistent across provider types will ensure that providers can compete in same labor pool. One commenter expressed concern that the current wage index system does not provide parity to all providers competing for the same professionals from the same labor pool. One commenter expressed concern that hospitals are allowed to reclassify and post-acute care facilities are at a disadvantage when competing for employees. The commenter suggested that until CMS can create a hospice

specific wage index methodology, CMS should equalize rates between hospitals and post-acute care. One commenter expressed concern that while the same data are used to establish the basic wage index values applicable to most provider types, hospitals are permitted to seek geographic reclassification from their assigned geographic area (thereby receiving higher wage adjustments to their payments).

Response: The current statute and regulations that govern the hospice payment system do not currently provide a mechanism for allowing hospices to seek geographic reclassification. The reclassification provision is found in section 1886(d)(10)(C)(i) of the Act, which 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.

Comment: One commenter expressed concern that wage index values, at some times and in some localities, are subject to significant year-to-year swings. This volatility has a disproportionate impact on not-for-profit hospice programs that have smaller operating margins and therefore less ability to absorb large cost swings. One commenter expressed appreciation for adjustments in wages that recognize the need to recruit and contain a stable workforce for hospice. However, the commenter also expressed concern that for programs with tight margins, the continued compression of rates will result in more limited choices of hospice providers, particularly in rural areas and non profit hospices. One commenter expressed concern that hospice payment rules adopt the hospital wage index (HWI) of the Medicare Inpatient Hospital Prospective Payment Systems (IPPS) which can make Medicare payments to Hospices volatile when there are changes in the hospital wage costs, particularly in rural communities. The commenter further asserted that the HWI is threatening the financial stability of several hospices in Washington State and potentially across the country, including precipitous reductions in Medicare reimbursement having nothing to do with local factors, but triggered instead by organizational changes at nearby hospitals. The commenter suggested that the wage index should be based on wages and hours of labor directly tied to Medicare

Part A services. One commenter stated that the wage index varies for their southern service areas, with significant year to year swings. One commenter expressed concern that providers experience swings in wage index values from year to year, and they are often surprised by the variation in their rates.

Response: 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 Inpatient Prospective Payment System (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. Our review processes result in an accurate reflection of the applicable wages for the areas given. In addition, we finalized a hospice wage index standardization factor in FY 2017 (81 FR 52156) to ensure overall budget neutrality when updating the hospice wage index with more recent hospital wage data. Applying a wage index standardization factor to hospice payments will eliminate the aggregate effect of annual variations in hospital wage data. Our policy of utilizing a hospice wage index standardization factor 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: One commenter expressed concern that hospices in Montgomery County, Maryland are at a long-term competitive disadvantage due to a Medicare hospice federal payment inequity involving core-based statistical areas (CBSAs). The commenter suggested that the out migration adjustment referenced in section 505 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 be applied to the hospice wage index. Section 505 introduced a hospital wage index adjustment that is based on commuting patterns. One commenter stated that CMS’s and OMB’s decision to view the current CBSA area designation in the “aggregate” for a

large geographic region like NYC (making it a NY and New Jersey area) fails to account for the higher costs faced by New York providers. The commenter also disagreed with CMS's assertion that OMB's CBSA designations are reasonable and appropriate, reflecting the most recent available geographic classifications, and suggested wholesale revisions and reform of the hospice and home health wage index to more accurately reflect local market conditions.

Response: We further believe that using the most current OMB delineations will increase the integrity of the hospice wage index by creating a more accurate representation of geographic variation in wage levels. We recognize that the OMB cautions that the delineations should not be used to develop and implement federal, state, and local nonstatistical programs and policies without full consideration of the effects of using these delineations for such purposes. As discussed in the OMB Bulletin No. 03–04 (June 6, 2003), the OMB stated that, “In cases where there is no statutory requirement and an agency elects to use the Metropolitan, Micropolitan, or Combined Statistical Area definitions in nonstatistical programs, it is the sponsoring agency's responsibility to ensure that the definitions are appropriate for such use. When an agency is publishing for comment a proposed regulation that would use the definitions for a nonstatistical purpose, the agency should seek public comment on the proposed use.”¹⁷ While we recognize that OMB's geographic area delineations are not designed specifically for use in nonstatistical programs or for program purposes, including the allocation of federal funds, we continue to believe that the OMB's geographic area delineations represent a useful proxy for differentiating between labor markets and that the geographic area delineations are appropriate for use in determining Medicare hospice payments. In implementing the use of CBSAs for hospice payment purposes in our FY 2006 final rule (70 FR 45130), we considered the effects of using these delineations. We have used CBSAs for determining hospice payments for 13 years (since FY 2006). In addition, other provider types, such as IPPS hospital, home health, SNF, IRF), and the ESRD program, have used CBSAs to define

their labor market areas for the last decade.

Comment: MedPAC recommended that the Congress repeal the existing hospital wage index and instead implement a market-level wage index for use across other prospective payment systems, including certain post-acute care providers. MedPAC suggested that their recommended wage index would: Use wage data from all employers and industry-specific occupational weights, adjust for geographic differences in the ratio of benefits to wages, adjust at the county level and smooth large differences between counties, and include a transition period to mitigate large changes in wage index values. Several commenters recommended that CMS should develop a wage index model in line with the system recommended by MedPAC. One commenter questioned whether the hospital wage index sufficiently takes into account the labor costs associated with the extensive travel routinely required in the delivery of hospice care. The commenter further asserted that the travel costs are even higher on a per-patient per-day basis for hospices that serve rural populations with large catchment areas, where patients may be located in remote and geographically isolated areas. The commenter suggested that CMS should analyze cost data to determine the extent to which costs vary based on geographic setting and should incorporate findings from its analysis into payment through appropriate payment adjustments, in order to protect and promote access to hospice care for rural beneficiaries with terminal illness.

Response: We appreciate MedPAC's recommendations; however, we do not have the authority to repeal the existing hospital wage index absent Congressional action. We note that our regulations at § 418.306(c) require that each hospice's labor market is determined based on definitions of Metropolitan Statistical Areas (MSAs) issued by OMB. We will issue annually, in the **Federal Register**, a hospice wage index based on the most current available CMS hospital wage data, including changes to the definition of MSAs. The urban and rural area geographic classifications are defined in § 412.64(b)(1)(ii)(A) through (C). The payment rates established by us are adjusted by the Medicare contractor to reflect local differences in wages according to the revised wage data. Any changes to the way we adjust hospice payments to account for geographic wage differences would have to go through the rulemaking with comment

process. We note that in the proposed rule, we did solicit requests for information to explore alternate ways to wage-adjust payments. We will review all comments for any consideration in future rulemaking.

To address the comment whether the hospital wage index sufficiently takes into account the labor costs associated with, the extensive travel routinely required in the delivery of hospice care, we note that the hospital wage index reflects the area wages and does not factor in any travel expenses. We recognize that hospices do incur travel expenses and with the rebasing of the CHC, IRC, and GIP payment rates finalized in this rule, such expenses were captured to more accurately align payment with the cost of providing care.

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 current year's pre-floor, pre-reclassified hospital inpatient wage index as the wage adjustment to the labor portion of the hospice rates. For FY 2020, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2014 and before October 1, 2015 (FY 2015 cost report data). The wage index applicable for FY 2020 is available on our website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Hospice-Wage-Index.html>. The hospice wage index for FY 2020 will be effective October 1, 2019 through September 30, 2020.

3. FY 2020 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.

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

¹⁷ Bulletin 05–02, Update of Statistical Area Definitions and Guidance on Their Uses. February 2005. https://www.whitehouse.gov/wp-content/uploads/2017/11/bulletins_fy05_b05-02.pdf.

the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP).

The hospice payment update percentage for FY 2020 is based on the estimated inpatient hospital market basket update of 3.0 percent (based on IHS Global Inc.'s second-quarter 2019 forecast with historical data through the first quarter 2019). Due to the requirements at sections 1886(b)(3)(B)(xi)(II) and 1814(i)(1)(C)(v) of the Act, the estimated inpatient hospital market basket update for FY 2020 of 3.0 percent must be reduced by a MFP adjustment as mandated by Affordable Care Act (currently estimated to be 0.4 percentage point for FY 2020). In effect, the hospice payment update percentage for FY 2020 is 2.6 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 continue to analyze this data for possible use in updating the labor portion of the hospice payment rates. Any changes to the labor portions would be proposed in future rulemaking and would be subject to public comments.

While a majority of the comments received were about the rebasing methodology and analysis, we did receive a few comments regarding the hospice payment update percentage. Our responses to those comments are below:

Comment: MedPAC recognizes that CMS is required by statute to propose an increase to the FY 2020 base rates of 2.7 percent, however they noted that in their 2019 report to Congress, they recommended that Congress reduce the aggregate level of payment to hospices for FY 2020 by 2 percent.

Response: We appreciate the comment, however, we do not have the statutory authority to use an alternate methodology to determine the amount

of the annual payment updates to hospice payment rates.

Comment: One commenter stated that for organizations that rely on contractual arrangements to meet their inpatient care requirements, the budget neutrality component that lowers the RHC payment rates effectively turns the rebasing proposal into a rate cut even after the proposed 2.7 percent payment update.

Response: We note that we are statutorily required, as set forth in section 1814(i)(1)(C)(ii)(VII) of the Act, to update the hospice rates annually by the inpatient market basket percentage increase for that FY.

Final Decision: We are finalizing the hospice payment update percentage for FY 2020 as proposed. Based on IHS Global, Inc.'s updated forecast of the inpatient hospital market basket update and the multifactor productivity adjustment, the hospice payment update percentage for FY 2020 is equal to 2.6 percent for hospices that submit the required quality data and 0.6 percent (FY 2020 hospice payment update of 2.6 percent minus 2 percentage points) for hospices that do not submit the required data.

4. FY 2020 Rebased Hospice Payment Rates

There are four hospice payment categories, all of which 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 provided to treat symptoms that cannot be managed in another setting.

As discussed in the FY 2016 Hospice Wage Index and 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 that final rule, we implemented a Service Intensity Add-on (SIA) payment for RHC 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 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 utilization data available at the time of rulemaking. For FY 2020, this calculation reflects the proposed increase in the hourly rate for CHC as a result of rebasing, discussed in section III.A.3 of this final rule.

In the FY 2017 Hospice Wage Index and 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 proposed FY 2020 hospice wage index (no lag) and compare it to our simulation of total payments using the FY 2019 hospice wage index. By dividing payments for each level of care using the FY 2020 wage index (no lag) by payments for each level of care using the FY 2019 wage index, we obtain a wage index standardization factor for each level of care (the first 60 RHC days and RHC days after day 60 and, CHC, IRC, and GIP). The wage index standardization factors for each level of care are shown in the Tables 10 and 12 below.

As discussed in section III.A.3, we are finalizing rebasing of the per diem payment rates for CHC, IRC, and GIP levels of care. As mentioned above and outlined in the Affordable Care Act, hospice payment reform must be done in a budget-neutral manner. In order to rebase the per diem payment amounts for CHC, IRC, and GIP in a budget-neutral manner, as described in section III.A.3, increases to the CHC, IRC, and GIP per diem payment amounts will be offset by corresponding decreases to the RHC per diem payment amounts to maintain overall budget neutrality.

The FY 2020 RHC per diem payment rates are the FY 2019 rebased payment rates, reduced by a budget neutrality factor as a result of rebasing of the CHC, IRC, and GIP payment amounts, adjusted by the SIA budget neutrality factor, adjusted by the wage index standardization factor, and increased by

the 2.6 percent hospice payment update percentage as shown in Table 10. The FY 2020 rebased CHC, IRC, and GIP per diem payment rates are equal to the FY

2019 rebased payment rates, adjusted by the wage index standardization factor and increased by the hospice payment

update percentage (2.6 percent) as shown in Table 11.
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Table 10: FY 2020 Hospice RHC Payment Rates

Code	Description	FY 2019 Rebased Payment Rates*	SIA Budget Neutrality Factor	Wage Index Standardization Factor**	FY 2020 Hospice Payment Update	FY 2020 Payment Rates
651	Routine Home Care (days 1-60)	\$190.91	X 0.9924	X 1.0006	X 1.026	\$194.50
651	Routine Home Care (days 61+)	\$150.02	X 0.9982	X 1.0005	X 1.026	\$153.72

* FY 2019 RHC rate for days 1-60 = \$196.25 * 0.9728 = \$190.91. FY 2019 RHC rate for days 61+ = \$154.21 * 0.9728 = \$150.02.

**Transition from FY 2019 Wage Index to FY 2020 Wage Index without 1-Year Lag.

Table 11: FY 2020 Hospice CHC, IRC, and GIP Payment Rates

Code	Description	FY 2019 Rebased Payment Rates	Wage Index Standardization Factor*	FY 2020 Hospice Payment Update	FY 2020 Payment Rates
652	Continuous Home Care Full Rate = 24 hours of care	\$1,363.26 (\$56.80/hourly rate)	X .9978	X 1.026	\$1,395.63 (\$58.15/hourly rate)
655	Inpatient Respite Care	\$437.86	X 1.0019	X 1.026	\$450.10
656	General Inpatient Care	\$992.99	X 1.0024	X 1.026	\$1,021.25

*Transition from FY 2019 Wage Index to FY 2020 Wage Index without 1-Year Lag.

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 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 2020 rates for hospices that do not submit the required quality data is updated by the FY 2020 hospice payment update percentage of 2.6 percent minus 2 percentage points. These rates are shown in Tables 12 and 13.

Table 12: FY 2020 Hospice RHC Payment Rates for Hospices That DO NOT Submit the Required Quality Data

Code	Description	FY 2019 Rebased Payment Rates*	SIA Budget Neutrality Factor	Wage Index Standardization Factor**	FY 2020 Hospice Payment Update of 2.6% minus 2 percentage points = +0.6%	FY 2020 Payment Rates
651	Routine Home Care (days 1-60)	\$190.91	X 0.9924	X 1.0006	X 1.006	\$190.71
651	Routine Home Care (days 61+)	\$150.02	X 0.9982	X 1.0005	X 1.006	\$150.72

* FY 2019 RHC payment rates adjusted to rebase CHC, IRC, and GIP in the following manner: FY 2019 RHC rate for days 1-60 = \$196.25 * 0.9728 = \$190.91. FY 2019 RHC rate for days 61+ = \$154.21 * 0.9728 = \$150.02.

**Transition from FY 2019 Wage Index to FY 2020 Wage Index without 1-Year Lag.

Table 13: FY 2020 Hospice CHC, IRC, and GIP Payment Rates for Hospices That DO NOT Submit the Required Quality Data

Code	Description	FY 2019 Rebased Payment Rates	Wage Index Standardization Factor*	FY 2020 Hospice Payment Update of 2.6% minus 2 percentage points = +0.6%	FY 2020 Payment Rates
652	Continuous Home Care Full Rate = 24 hours of care	\$1,363.26 (\$56.80=hourly rate)	X .9978	X 1.006	\$1,368.42 (\$57.02= hourly rate)
655	Inpatient Respite Care	\$437.86	X 1.0019	X 1.006	\$441.32
656	General Inpatient Care	\$992.99	X 1.0024	X 1.006	\$1,001.35

*Transition from FY 2019 Wage Index to FY 2020 Wage Index without 1-Year Lag.

Final Decision: We are finalizing the FY 2020 payment rates in accordance with statutorily mandated requirements.

5. Hospice Cap Amount for FY 2020

As discussed in the FY 2016 Hospice Wage Index and Rate Update final rule (80 FR 47183), we implemented changes mandated by the IMPACT Act of 2014 (Pub. L. 113–185). 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 CPI–U. The hospice cap amount for the FY 2020 cap year will be \$29,964.78, which is equal to the FY 2019 cap amount (\$29,205.44) updated by the FY 2020 hospice payment update percentage of 2.6 percent. A summary of the comments we received regarding the hospice cap amount and our responses to those comments appear below:

Comment: A few commenters suggested that geographical differences should be considered when calculating the annual cap amounts. One commenter stated that the cap discriminates against providers with higher daily reimbursement rates because the cap is applied on a national basis, without regard to the geographical location of the patient. Another commenter suggested adjusting the hospice cap amounts for wage index in the same manner that the per diem payments are adjusted. This commenter further asserted that wage adjusting the payments and not the cap has the effect of reversing the wage index, since the caps will be reached (and exceeded) more quickly in high wage labor markets than in low wage labor markets. The commenter suggested that this creates an unintended penalty or benefit to a hospice based on where it is located, not on the quality or efficiency of the care provided.

Response: We appreciate the commenters' suggestion that we consider geographical differences when calculating the annual cap amount. However, the restriction set forth in section 1814(i)(2)(B) of the Act, as amended by section 3(d) of the IMPACT Act, does not give us discretion to adjust the cap amount.

Comment: One commenter recommended that funds allocated for the cap amount increase instead be applied to reducing the cut to the RHC. The commenter suggested that holding the cap at its current level would also likely hold down margins from high-margin hospices. A few commenters also suggested that lowering the aggregate cap amount for all hospices by at least 10 percent from the FY 2019

amount would be a better way to control hospice spending.

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

Comment: One commenter suggested the cap amount be used to explore questionable practices by hospices. Specifically, this commenter was referring to hospices that come up to the cap limit, but do not exceed it, because they are deliberately discharging beneficiaries solely to avoid any overpayments. This commenter also stated that CMS should further investigate those hospices that routinely exceed the cap limit to see if there is any aberrant patterns of care that may warrant targeted program integrity efforts. The commenter stated that CMS could use its program integrity authority using claims and quality data to address this issue with little additional burden to hospice agencies.

Response: We appreciate the commenter's suggestion to consider looking into the practices of hospices that regularly reach or exceed the annual aggregate cap amount to target further program integrity investigations. We remind stakeholders that under the Medicare hospice benefit, § 418.26(a)(1), (2), and (3), there are limited reasons why a hospice can discharge a beneficiary alive: The beneficiary decides to revoke the hospice benefit; the beneficiary transfers to another hospice; or, the beneficiary is no longer terminally ill. Hospice care is provided to beneficiaries who are nearing the end of life and provides comfort for the dying, neither hastening death nor prolonging life by attempting to cure the terminal illness. Discharging a beneficiary solely to avoid exceeding the cap limit is in violation of the regulations at § 418.26 and may cause undue distress and potential harm to terminally ill patients who would have to seek care outside of the hospice benefit. We will closely monitor this issue and address any identified concerns, if necessary.

Final Decision: We are finalizing the update to the hospice cap in accordance with statutorily mandated requirements.

C. Election Statement Content Modifications and Addendum To Provide Greater Coverage Transparency and Safeguard Patient Rights

1. Background

In the FY 2020 hospice proposed rule (84 FR 17589), we provided background on the holistic nature of the services provided under the Medicare hospice benefit, as well as the current statutory and regulatory requirements for care planning and patient rights. We stated that in order to make an informed choice about whether to receive hospice care, the patient, family, and caregiver must have an understanding of what services are going to be provided by the hospice and that, because there is no longer a reasonable expectation for a cure, care should now focus on comfort and quality of life. The services covered under the Medicare hospice benefit are comprehensive such that, upon election, the individual waives all rights to Medicare payment for services related to the treatment of the individual's condition with respect to which a diagnosis of terminal illness has been made, except when provided by the designated hospice or attending physician. Because of the significance of this decision, the terminally ill individual must elect hospice care in order to receive services under the Medicare hospice benefit. Since we first implemented the Medicare hospice benefit in 1983, it has been our general view that the waiver required by law requires hospices to provide virtually all the care that is needed by terminally ill patients (48 FR 56010).

Additionally, in the FY 2015 proposed rule (79 FR 26555), we described the eligibility, certification, and election requirements for receipt of hospice services as set forth at 42 CFR 418.20, 418.22 and 418.24. We also emphasized that in reaching a decision to certify that the patient is terminally ill, the hospice medical director must consider the principal diagnosis of the patient, all other health conditions, whether related or unrelated to the terminal condition, and all clinically relevant information supporting all diagnoses. The clinical information and other documentation that support the medical prognosis must accompany the written certification and must be filed in the individuals' hospice medical record in accordance with the regulations at § 418.22(b)(2) and the hospice CoPs at § 418.102(b). Once a beneficiary is certified as terminally ill, he or she becomes eligible to elect hospice care under the Medicare hospice benefit.

Because the receipt of hospice services under the Medicare hospice

benefit is dependent upon the eligible beneficiary electing to receive hospice care, the regulations at § 418.24 provide the requirements of the hospice election statement. The election statement must include the identification of the designated hospice and attending physician (if any); the individual's or representative's acknowledgement that he or she has been given a full understanding of the palliative rather than curative nature of hospice care; and the individual's or representative's acknowledgement that the individual waives the right to Medicare payment for services related to the terminal illness and related conditions, except when provided by the designated hospice or attending physician. Services unrelated to the terminal illness and related conditions remain eligible for Medicare coverage and payment outside of the hospice benefit.

Once the beneficiary has elected hospice care, the hospice conducts an initial assessment visit in advance of furnishing care. During this visit, the hospice must provide the patient or representative with a spoken and written notice of the patient's rights and responsibilities as required by the CoPs at § 418.52. Our rules state that the beneficiary has the right to be involved in developing his or her hospice plan of care; receive information about the services covered under the hospice benefit; and receive information about the scope of services that the hospice will provide and specific limitations on those services. The hospice program must assure the patient that its staff will protect patients' rights and will involve patients in decisions about their care, treatment and services.¹⁸ Likewise, the regulations at § 476.78(b)(3) state that providers must inform Medicare beneficiaries at the time of admission, in writing, that the care for which Medicare payment is sought will be subject to Quality Improvement Organization (QIO) review.

Additionally, the hospice CoPs at § 418.54(c) provide the content requirements for the initial and comprehensive assessments used to identify patient, family, and caregiver needs for physical, emotional, psychosocial, and spiritual care. As part of the comprehensive assessment, the hospice is required to assess the patient for complications and risk factors, which can affect care planning. The needs identified in these assessments drive the development and revisions of

an individualized written plan of care for each patient as required by the CoPs at § 418.56. Collectively, the interdisciplinary team (IDG), in consultation with the patient's attending physician (if any), makes care plan decisions for each patient to ensure that each care plan is individualized to meet the unique needs of each hospice beneficiary. The plan of care also must reflect patient, family, and caregiver preferences, goals, and interventions based on the problems identified in the initial, comprehensive, and updated comprehensive assessments. The plan of care must include all services necessary for the palliation and management of the terminal illness and related conditions and the CoPs at § 418.56(c) detail the plan of care content requirements. However, though hospices are responsible for providing all services needed for palliation and management of the terminal illness and related conditions, the 2008 Hospice Conditions of Participation final rule (73 FR 32088, June 5, 2008) states that while needs unrelated to the terminal illness and related conditions are not the responsibility of the hospice, the hospice may choose to furnish services for those needs regardless of responsibility (73 FR 32114). If a hospice does not choose to furnish services for those needs unrelated to the terminal illness and related conditions, the hospice is to document such needs and communicate and coordinate with those health care providers who are identified as caring for the unrelated needs, as set out at § 418.56(e)(5). To ensure comprehensive and coordinated care, at § 418.56(e) we require hospices to have a communication system that allows for the exchange of information with other non-hospice health care providers who are furnishing care unrelated to the terminal illness and related conditions.

We also require hospices to designate a registered nurse (RN) who is a member of the IDG to coordinate implementation of the comprehensive plan of care. The designated RN must assure that coordination of care and continuous assessment of patient, family, and caregiver needs occur among staff providing services to the patient, family, and caregiver so that all IDG members are kept informed of the patient/family's status.¹⁹ The goal of a coordinated communication process and a designated nurse coordinator is to

adequately ensure that each patient's hospice care is coordinated both within the hospice and with other health care providers.

2. Services Unrelated to the Terminal Illness and Related Conditions

In the FY 2020 hospice proposed rule, we reiterated our long-standing position that services unrelated to the terminal illness and related conditions should be exceptional, unusual and rare given the comprehensive nature of the services covered under the Medicare hospice benefit as articulated upon the implementation of the benefit (48 FR 56008, 56010, December 16, 1983). To the extent that individuals receive services outside of the Medicare hospice benefit during a hospice election, Medicare coverage is determined by whether or not the services are for the treatment of a condition completely unrelated to the individual's terminal illness and related conditions (48 FR 38146, 38148, August 22, 1983). In the FY 2020 hospice proposed rule, we detailed numerous anecdotal reports from beneficiaries, families, the Medicare Ombudsman's office, and non-hospice providers where hospice patients were obtaining needed items, services, and drugs outside of the hospice benefit because they had been told that hospice would not cover these items, services, and drugs, as the hospice had determined that they were unrelated to the terminal illness and related conditions. Many of these anecdotal reports state that the beneficiaries and families believed that these items, services, and drugs were related to the terminal illness and related conditions and thought that they should have been provided by the hospice. The beneficiaries and/or the families stated that they did not know they would have to seek care outside of the hospice benefit for these conditions because the hospice did not tell them these items, services, and drugs would not be furnished by the hospice until the patient needed them. We remind stakeholders that the Medicare Beneficiary Ombudsman (MBO) is charged with supporting CMS' customer service and administration efforts by receiving and responding to beneficiary and other stakeholder inquiries and complaints, working with partners to provide outreach and education to beneficiaries, and providing recommendations for improving the administration of Medicare. The MBO also provides an annual report to

¹⁸ State Operations Manual Appendix M—Guidance to Surveyors: Hospice. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_m_hospice.pdf.

¹⁹ State Operations Manual Appendix M—Guidance to Surveyors: Hospice. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_m_hospice.pdf.

Congress that are posted on the MBO website.²⁰

In accordance with the hospice CoPs at § 418.56(e)(5), and in alignment with continuity of care principles,²¹ the ongoing sharing of information with other non-hospice healthcare providers and suppliers furnishing services unrelated to the terminal illness and related conditions is necessary to ensure coordination of services and to meet the patient, family, and caregiver needs. The coordination requirements include that the hospice must develop and maintain a system of communication and integration amongst all providers furnishing care to the terminally ill patient. This communication helps to minimize fragmented care and to improve quality of life. Part of that communication process is the clear identification of what the related and unrelated conditions are and who is responsible for providing reasonable and necessary services for those conditions. As is the preferred practice for care coordination and communication,²² both hospice and non-hospice providers typically document these discussions, which then becomes part of the patient's medical record with each provider. Accordingly, all Medicare providers and suppliers must be able to provide medical documentation to support payment for services billed (sections 1815(a) and 1833(e) of the Act). For non-hospice providers or suppliers billing Medicare for services received by hospice beneficiaries unrelated to their terminal illness and related conditions, this includes being able to provide documentation from the hospice listing the conditions (and thus items, drugs, and services) the hospice determined to be unrelated and documented as such on the hospice plan of care.

While hospices are required by the CoPs to have a system of communication with non-hospice providers to furnish such information, we have heard anecdotally from non-hospice providers stating that they are unable to reach or do not receive return

calls from the hospice to discuss the hospice beneficiary's coordination of services that the hospice has determined unrelated to his or her terminal illness and related condition(s). Likewise, we have also received anecdotal reports from hospices who state they were unaware that patients had received care from non-hospice providers. In these reports, the hospice would first learn of this outside care when non-hospice providers would contact the hospice seeking reimbursement. If this care was related to the terminal illness and related conditions and the hospice did not make arrangements for such care, the beneficiary would be liable for the costs of receiving that care. Additionally, if non-hospice providers bill Medicare for services that potentially should have been the coverage responsibility of hospice, Medicare could be making duplicative payments for care related to the terminal illness and related conditions, as described in the June, 2012 OIG report²³ identifying situations where Medicare may have been paying twice for prescription drugs for hospice beneficiaries.

In previous years' hospice proposed rules, we have included data on non-hospice expenditures for beneficiaries under a hospice election. These total non-hospice expenditures include beneficiary cost-sharing amounts. For Parts A and B, the beneficiary cost-sharing amounts in FY 2017 totaled approximately \$138 million and for Part D, the beneficiary cost-sharing totaled approximately \$68.6 million (83 FR 20946 through 20947). We believe that this is a substantial financial burden being placed on terminally ill individuals for services that potentially should have been covered by hospice. This suggests that hospice beneficiaries may be incurring unnecessary financial burden as they are having to seek out and pay for items and services for pain and symptom relief—services that hospice should be furnishing and covering.

However, in spite of the data provided and reiteration of longstanding policy regarding the comprehensive nature of hospice services covered under Medicare, we continue to have concerns that these decisions as to what hospices will cover and not cover are based on a more narrow view of the overall condition of the individual, as is evidenced by the non-trivial amount of items, services, and drugs for potentially

related conditions provided by non-hospice providers to beneficiaries under a hospice election.

3. Election Statement Content Modifications and Addendum To Provide Greater Coverage Transparency and Safeguard Patient Rights

The regulations, as described previously, require the hospice to include all services needed for the palliation and management of the terminal illness and related conditions on the individualized hospice plan of care, and the plan of care should also identify the conditions or symptoms that the hospice determines to be "unrelated" so hospices can provide ongoing sharing of information with other non-hospice healthcare providers who may be furnishing services unrelated to the terminal illness and related conditions.²⁴ Although hospices are required to educate each patient and the primary caregiver(s) on the services identified on the plan of care and document the patient's or representative's level of understanding, involvement, and agreement with the plan of care, the incidence of anecdotal reports and the amount and nature of the non-hospice services being billed to Medicare outside of the hospice benefit suggests that hospice beneficiaries may not be fully informed, at the time of admission or throughout the hospice election, of the items, services, and drugs the hospice has determined to be unrelated to their terminal illness and related conditions. We believe this is necessary information for patients and their families to make informed care decisions and to anticipate any financial liability associated with needed items, services, and drugs not provided under the Medicare hospice benefit. Not having this information may result in a lack of coverage transparency and where beneficiaries are unaware of their financial liability while under a hospice election for those items, services, and drugs the hospice has determined to be unrelated to their terminal prognosis.

Therefore, in the FY 2020 hospice proposed rule (84 FR 17570), we proposed to modify the hospice election statement content requirements at § 418.24(b) to increase coverage transparency for patients under a hospice election. In addition to the existing election statement content requirements at § 418.24(b), we proposed that hospices also would be

²⁰ Medicare Beneficiary Ombudsman (MBO). <https://www.cms.gov/Center/Special-Topic/Ombudsman/Medicare-Beneficiary-Ombudsman-Home.html>.

²¹ Uijena, A., Schersa, H., Schellevis, F., van den Bosch, W. How unique is continuity of care? A review of continuity and related concepts. *Family Practice* 2012; 29:264–271 doi:10.1093/fampra/cmr104.

²² National Quality Forum (NQF), Preferred Practices and Performance Measures for Measuring and Reporting Care Coordination: A Consensus Report, Washington, DC: NQF; 2010. https://www.qualityforum.org/Publications/2010/10/Preferred_Practices_and_Performance_Measures_for_Measuring_and_Reporting_Care_Coordination.aspx.

²³ Medicare Could Be Paying Twice for Prescription Drugs for Beneficiaries in Hospice (A-06-10-00059). June 28, 2012. <https://oig.hhs.gov/oas/reports/region6/61000059.pdf>.

²⁴ State Operations Manual Appendix M—Guidance to Surveyors: Hospice https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_m_hospice.pdf. (L-Tag 538)

required to include the following on the election statement:

- Information about the holistic, comprehensive nature of the Medicare hospice benefit.

- A statement that, although it would be rare, there could be some necessary items, drugs, or services that will not be covered by the hospice because the hospice has determined that these items, drugs, or services are to treat a condition that is unrelated to the terminal illness and related conditions.

- Information about beneficiary cost-sharing for hospice services.

- Notification of the beneficiary's (or representative's) right to request an election statement addendum that includes a written list and a rationale for the conditions, items, drugs, or services that the hospice has determined to be unrelated to the terminal illness and related conditions and that immediate advocacy is available through the BFCC-QIO if the beneficiary (or representative) disagrees with the hospice's determination.

Likewise, we proposed to make the corresponding regulations text changes at § 418.24(b).

Additionally, we proposed a new requirement where hospices would be required, but only upon request, to provide to the beneficiary (or representative) an election statement addendum (hereafter called "the addendum") with a list and rationale for the conditions items, services, and drugs that the hospice has determined as unrelated to the terminal illness and related conditions. Similarly, we proposed that hospices would be required to provide the addendum, upon request, to other non-hospice providers that are treating such conditions, and Medicare contractors who request such information. We proposed that if the addendum is requested at the time of hospice election, the hospice must provide this information, in writing, to the individual (or representative) within 48 hours of the request. Furthermore, we proposed that if this addendum is requested during the course of hospice care, the hospice must provide this information, in writing, immediately to the requesting individual (or representative), non-hospice provider, or Medicare contractor, as this information should be readily available in the beneficiary's hospice medical record. During the course of hospice care, if there are changes to the plan of care that result in a determination that a new illness or condition has arisen, we proposed that hospices would be required to issue an updated addendum to the patient (or representative)

reflecting whether or not items, services and supplies related to the new illness or condition will be provided by the hospice. We also proposed that hospices would be exempt from completing this addendum if the beneficiary died within 48 hours of the election date of hospice care.

The purpose of the proposed addendum is to inform beneficiaries and their families of hospice-determined non-covered conditions, items, services, and drugs to provide full coverage transparency to hospice patients and their families to assist in making treatment decisions. Likewise, the addendum would help facilitate communication and benefit coordination between hospices and non-hospice providers.

We proposed that hospices would develop and design the addendum to meet their needs, similar to how hospices develop their own hospice election statement. We proposed the addendum would be titled "Patient Notification of Hospice Non-Covered Items, Services, and Drugs." We proposed that the addendum would include the following information:

1. Name of the hospice;
2. Beneficiary's name and hospice medical record identifier;
3. Identification of the beneficiary's terminal illness and related conditions;
4. A list of the beneficiary's current diagnoses/conditions present on hospice admission (or upon plan of care update, as applicable) and the associated items, services, and drugs, not covered by the hospice because they have been determined by the hospice to be unrelated to the terminal illness and related conditions;
5. A written clinical explanation, in language the beneficiary and his or her representative can understand, as to why the identified conditions, items, services, and drugs are considered unrelated to the terminal illness and related conditions and not needed for pain or symptom management. This clinical explanation would be accompanied by a general statement that the decision as to whether or not conditions, items, services, and drugs is related is made for each patient and that the beneficiary should share this clinical explanation with other health care providers from which they seek services unrelated to their terminal illness and related conditions;

6. References to any relevant clinical practice, policy, or coverage guidelines.

7. Information on the following domains:

- a. Purpose of Addendum.
- b. Right to Immediate Advocacy.

8. Name and signature of Medicare hospice beneficiary (or representative) and date signed, along with a statement that signing this addendum (or its updates) is only acknowledgement of receipt of the addendum (or its updates) and not necessarily the beneficiary's agreement with the hospice's determinations.

We proposed to add the election statement modifications and the election statement addendum content requirements to the regulations at § 418.24.

Finally, we proposed that the signed addendum (and any signed updates) would be a new condition for payment. We also stated that this would not mean that in order to meet this condition for payment that the beneficiary (or representative), or non-hospice provider must agree with the hospice's determination. For purposes of this condition for payment, we proposed that the signed addendum is only acknowledgement of the beneficiary's (or representative's) receipt of the addendum (or its updates) and this payment requirement would be met if there was a signed addendum (and any signed updates) in the requesting beneficiary's medical record with the hospice. This addendum would not be required to be submitted with any hospice claims. Likewise, the hospice beneficiary (or representative) would not have to separately consent to the release of this information to non-hospice providers furnishing services for unrelated conditions as the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule allows those doctors, nurses, hospitals, laboratory technicians, and other health care providers that are covered entities to use or disclose protected health information, such as X-rays, laboratory and pathology reports, diagnoses, and other medical information for treatment purposes without the patient's express authorization. This includes sharing the information to consult with other providers, including providers who are not covered entities, to treat a different patient, or to refer the patient (45 CFR 164.506).

Ninety-two unique stakeholders submitted their comments on the proposed modifications to the election statement content requirements and the proposed election statement addendum. These stakeholders included hospices, national and state industry associations, individual commenters, as well as the Medicare Payment Advisory Commission (MedPAC).

Election Statement Modifications

While many commenters supported the modifications to the election statement content requirements, several had concerns regarding these changes. These comments, along with our responses, are summarized below.

Comment: Several commenters, including MedPAC, supported the proposal to modify the hospice election statement content requirements to increase coverage transparency for patients under a hospice election. Commenters agreed with CMS' efforts to educate and empower patients to make informed decisions. They reiterated the importance of beneficiaries and their families understanding what is covered by the hospice benefit and being informed of the resources available to appeal decisions by hospice providers if they have concerns or disagree with coverage determinations made by their hospice provider.

Response: We appreciate these comments and thank commenters for their thoughtful review and support of our efforts to provide patients with complete information regarding payment and cost-sharing obligations as well as implications for other providers.

Comment: One commenter disagreed with the proposal that the election statement include information on individual cost-sharing for hospice services. This commenter stated that hospices are permitted, but not required, to impose small coinsurance payments for hospice drugs and inpatient respite care, and that most hospices do not charge patients for this coinsurance. This commenter remarked that including this information on the election statement would be confusing for patients and burdensome for hospices to have to explain. Other commenters suggested that additional language should be added to the election statement to indicate that Medicare continues to pay for any such unrelated items under traditional Medicare benefits.

Response: To provide full transparency regarding hospice coverage under the Medicare hospice benefit, we believe that the election statement should include information that there may be individual cost-sharing for certain hospice services while under a hospice election. We did not propose specific language requirements for communicating information on cost-sharing for hospice services and we believe this information can be communicated simply and in a straightforward fashion to beneficiaries. For example, a general statement saying that while under a hospice election

there may be cost-sharing for hospice medications and inpatient respite allows beneficiaries to ask the hospice for more information on such cost-sharing, if needed. Likewise, if a hospice does not charge any coinsurance for hospice drugs of inpatient respite care, it could include such a statement on their election statements.

As for the suggestion that CMS should require hospices to indicate that there is coverage for unrelated items, services, and drugs on the election statement itself, hospices can add whatever language they feel best communicates information to the beneficiary about coverage under the Medicare hospice benefit as long as such information is in accordance with the hospice regulations. This could include a disclaimer statement that unrelated items, services, and drugs may be covered through other Medicare benefits. We note that in 2016, we provided a model election statement as part of a MLN Matters® article (SE1631)²⁵ in which there is a statement that reads: "I understand that services not related to my terminal illness or related conditions will continue to be eligible for coverage by Medicare." Hospices could adopt such language on the election statement to best meet their needs and to adequately communicate this information to beneficiaries and their families at the time of hospice election. One industry commenter stated that many hospices already use this model election statement and simple modifications to this election statement could be easily achieved to satisfy the proposed changes to the election statement content requirements.

Election Statement Addendum

Comment: Several commenters stated that the time of hospice election is an overwhelming and confusing time for individuals and their families. Commenters remarked that the addendum might have the unintended consequence of further overwhelming and frightening patients and their families, giving the impression that patients would not be given the symptom-controlling medications that they need. Some commenters believe that the addendum may delay access to needed services because of the time it would take to make these determinations and consult with the

IDG and could potentially deter individuals from electing the benefit.

Response: The services covered under the Medicare hospice benefit are comprehensive such that, upon election, the individual waives all rights to Medicare payment for services related to the treatment of the individual's condition with respect to which a diagnosis of terminal illness has been made, except when provided by the designated hospice or attending physician. Since we first implemented the Medicare hospice benefit in 1983, it has been our general view that the waiver required by law requires hospices to provide virtually all the care that is needed for terminally ill patients (48 FR 56010). As such, we understand that the decision to elect hospice is not one that is taken lightly and it is because of the significance of this decision that we believe individuals and their families need to have full disclosure and coverage transparency regarding the services provided and not provided by the hospice as they approach the end of life.

The hospice CoPs at § 418.52(a) require that during the initial assessment visit, in advance of furnishing care, the hospice must provide the patient or representative with verbal (meaning spoken) and written notice of the patient's rights and responsibilities in a language and manner that the patient understands. Furthermore, hospices are to inform the beneficiary of the services covered under the Medicare hospice benefit, as well as the scope of such services. The intent of this standard was to ensure that patients were aware of their potential out-of-pocket costs for hospice care, such as co-payments, so that they would not be surprised by financial concerns at this stressful time (73 FR 32097). Therefore, hospices are already tasked with providing detailed information on hospice services and limitations to those services to the patient upon election of the benefit. We believe that the addendum further complements these requirements by ensuring that the hospice informs them of any items, services, or drugs which the terminally ill individual would have to seek outside of the benefit.

Because of the longstanding requirements to communicate the breadth of the Medicare hospice benefit to individuals and their families prior to the provision of any hospice services, we do not believe that providing full coverage transparency at the time of hospice election would generally deter or unnecessarily overwhelm individuals from electing hospice, thereby limiting access to such services. Terminally ill

²⁵ Sample Hospice Election Statement. MLN Matters® Number: SE1631 Revised. December 2016. <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1631.pdf>.

individuals and their families are making decisions for how the individual chooses to live out their remaining days at the end of life.

As the hospice model of care is for palliation and comfort, rather than for a cure, the Medicare hospice benefit must be elected by the terminally ill individual who is agreeing to this model of care, as well as waiving the right to Medicare payment for items, services and drugs for the treatment of the terminal illness and related conditions. The purpose of the addendum as noted in the proposed and this final rule is to provide for coverage transparency to help ensure individuals are fully informed when making such a decision. If, after receiving information about all of the items, services, and drugs the hospice will and will not cover, the individual chooses not to elect the benefit (or to discontinue the benefit), then the individual has made an informed choice based on his or her goals and preferences of care. Hospices should be able to communicate this information in a clear, thoughtful, and compassionate manner in accordance with the spirit of hospice philosophy where the individual and the family are the center of the care team. In doing so, the hospice will have made every effort to ensure patients are aware of all services covered and not covered by the hospice. We believe that an informed beneficiary will make the most appropriate choice to meet his or her needs and it is the hospice's responsibility to provide this information to support and promote beneficiary choice and access to needed services.

Comment: A few commenters disagreed with providing a written clinical reason for why certain diagnoses/conditions, items, services, and drugs are not covered to beneficiaries (or their representatives) and non-hospice providers. These commenters stated that hospices may be inconsistent with using evidence-based rationale or may use different sources to support their determinations. Others voiced concerns over disagreements between non-hospice providers and hospice providers on the unrelated determinations and stated this may result in debate regarding the hospice physician's reasoning. Commenters stated that varying clinical opinions between hospice and non-hospice providers may delay the provision of items, services, and drugs.

Response: We believe it is not only important to inform beneficiaries of what items, services, and drugs the hospice will not be covering because they have determined these items,

services, and drugs to be unrelated to the terminal illness and related conditions, but why the hospice has made this determination. As noted previously, beneficiaries are making a choice to elect hospice care and we believe it to be of utmost importance to promote transparency, autonomy, and patient choice, and patients need to understand the rationale for decisions being made that affect their care. While we proposed that hospices would provide a clinical rationale as part of the proposed addendum, we did not propose requirements as to specific sources of such information as we believe that hospices would use evidence-based information to communicate the rationale to patients in a manner in which they understand. There is a large quantity of available information and hospices can choose to use supporting materials to best communicate the clinical rationale to their patients. We do not expect that this would mean hospices would have to provide complex or technical supporting information to patients to rationalize their determinations. However, similar to hospices explaining what items, services, and drugs are related to the palliation and management of the terminal illness and related conditions, we also believe that they have the expertise to explain to patients why certain items, services and drugs are not related. Furthermore, while there may be debate between hospices and non-hospice providers regarding whether or not certain items, services, or drugs are unrelated, we believe that the addendum provides a tool to steer the debate and prompt meaningful communication and care coordination between all providers rendering care to terminally ill beneficiaries.

We agree with the hospice industry's views that hospice care is "the nation's first coordinated care model" and should show how the health care system can work at its best for patients at the end of life.²⁶ We think that an important part of this care coordination is communication with non-hospice providers who are also providing care to the patient, in order to ensure that continuity of care and access to needed services is part of the decision-making process and we do not anticipate any delay in the furnishing of items, services, and drugs due to the provision of this information to the patient.

²⁶ NHPCO Op-ed: "Coordinated Care Is More Than a Buzzword for Hospice Providers", April 24, 2018. <https://morningconsult.com/opinions/coordinated-care-more-than-buzzword-for-hospice-providers/>

Similarly, the hospice CoPs at 418.56(e)(5) require that hospices provide for an ongoing sharing of information with other non-hospice healthcare providers furnishing services unrelated to the terminal illness and related conditions.

Comment: Overall, while commenters did not disagree in general with the proposal of the election statement addendum, the majority of commenters stated concern with the proposed timeframe with which the hospice would be required to provide the patient and caregiver such information. Commenters indicated that 48 hours after the time of hospice election is insufficient considering that the hospice has 5 days to complete the comprehensive assessment. Commenters noted that prior to the comprehensive assessment, hospices may not have a complete patient profile, including the services or medications a patient is currently utilizing. These commenters stated that this may require hospices to anticipate covered and non-covered services, which would lead to an inaccurate election statement addendum. Commenters stated that this fails to provide patients with the information the election statement addendum is intended to convey. A few commenters stated that the 48 hour timeframe would not allow adequate time to consult with the patient's certifying physician and/or the medical director regarding medications and treatments, or to provide a written clinical explanation of why the medications or services are unrelated. Other commenters noted that nurses may be required to complete and print the election statement addendum in the patient's home, where clinical practice and policy guidelines may not be readily accessible, and would necessitate the hospice providing nurses with printers. Similarly, commenters stated that this timeframe may pose problems meeting signature requirements if the patient or representative does not return the signed election statement addendum within the required timeframe. Another commenter suggested that this may require a costly electronic solution or modifications to the existing electronic medical record (EMR).

Response: We understand the concern regarding the proposed 48 hour timeframe for providing the addendum if requested at the time of a hospice election. We recognize that in order to provide the patient or representative with the most accurate information, and ensure the usefulness of the proposed addendum, it would be beneficial to align the timeframe of the completion of

the addendum with the timeframe requirement of the completion of the comprehensive assessment, that is, if an addendum is requested at the time of a hospice election, the hospice would have 5 calendar days to provide the addendum to the requesting beneficiary (or representative). This would allow hospices sufficient time to assess all of the patient and family needs, establish the individualized plan of care, and make decisions about any items, services, or drugs they will not be covering, as they have determined them to be unrelated to the terminal illness and related conditions. Furthermore, if a beneficiary requests the addendum at the time of hospice election and dies within 5 days from the start of the hospice election, the hospice would not be required to furnish such addendum as this requirement would be deemed as being met in this circumstance.

We also understand that if the beneficiary, representative, non-hospice provider, or Medicare contractor requests an addendum at any time during the course of hospice care (that is, after the election of hospice), the hospice would need sufficient time for the IDG to adequately review the patient's plan of care and review any decisions on those items, services, or drugs they have determined to be unrelated to the individual's terminal illness and related conditions. As such, we believe that the hospice should have additional time to complete the addendum, rather than the proposal to require the hospice to provide it immediately upon request during the course of hospice care. Because the hospice has already completed the comprehensive assessment and has begun providing care, we believe 72 hours after a patient, representative, non-hospice provider or Medicare contractor request for such information represents a sufficient timeframe for reviewing the patient record and completing the addendum if this information is requested during the course of hospice care. As the plan of care should identify the conditions or symptoms that the hospice determines to be "unrelated," this information should be readily accessible to the hospice in order to allow for the timely completion of the addendum. Expanding the timeframe for completion would ensure that the hospice has adequate time to determine those items, services, and drugs that are unrelated, complete the written addendum, and provide this information to the patient (or his or her representative).

As detailed in the FY 2020 hospice proposed rule, we proposed that each individual hospice develop and

incorporate the addendum into their current admissions process in a way that best meets the hospices' needs, as well as providing this information as quickly as possible considering the potential for beneficiary cost-sharing. Likewise, non-hospice providers should have timely access to this information in order to promote continuity of care and communication amongst all patient providers and to ensure appropriate claims submission.

Comment: Many commenters suggested modifying the current Advance Beneficiary Notice of Non-coverage (ABN) (Form CMS-R-131) or the Home Health Change of Care Notice (HHCCN) (Form CMS-10280) to be hospice-specific to communicate unrelated information regarding items, services, and drugs, rather than requiring hospices to develop a new form. One industry association suggested a "Hospice Change of Care Notice" be developed and provided to patients and representatives upon request to meet the requirements for communication about items and services determined to be unrelated to the terminal prognosis. This commenter suggested providing this form after the initial and comprehensive assessment has been completed, the plan of care has been established, and members of the IDG have agreed upon the unrelated items and services.

Others suggested offering patients (and their representatives), upon request, a list of known diagnoses unrelated to the terminal illness and related conditions with the recommendation that this list could be updated through the course of care if any new unrelated diagnoses/conditions became known. These commenters stated that this would improve transparency and hold hospices more accountable for documenting and communicating these unrelated diagnoses to the patient and representative. A few commenters suggested the need for a patient/representative statement acknowledging that the patient or patient representative has reviewed the items, services, and medications with the hospice representative in order to protect the hospice from inadvertently excluding any medications or treatments the patient is receiving at the time of admission, but that may not be revealed. Commenters also suggested that the patient be required to acknowledge that a new election statement addendum would be signed if additional non-covered items, services, or medications were identified during the course of treatment.

Additionally, commenters noted that the addendum should address items, services and drugs that may be related, but that the hospice is not covering, for example a generic drug over a brand name drug due to patient preference or if a patient requests to continue using a specific drug that the hospice determines is no longer providing medical benefit to the patient. A few commenters recommended using the Medicare form, Hospice Information for Medicare Part D (OMB Form 0938-1269) stating that most hospices already use this form and that requiring a separate addendum is redundant and not necessary. Conversely, a few commenters stated that the aforementioned Part D form is fraught with issues and there is inconsistency with its use amongst hospices and Part D plan sponsors. A few commenters stated that this proposal is unreasonable because no other healthcare provider is required to furnish references for any decision that the provider makes regarding services not provided nor requires a patient to sign a detailed document listing what will not be provided.

Response: We agree with commenters that the list of items, services, and drugs not covered by the hospice because they have determined them to be unrelated to the terminal illness and related conditions should be in a format that communicates this information to patients and their representatives in the most clear and unobtrusive way possible. As stated earlier, we believe that hospices should develop this addendum, with the required content elements, to best meet their patients' needs and to align with their current admission processes and other business procedures. We disagree with commenters about using a modified ABN to communicate information about hospice non-covered items, services and drugs determined to be unrelated to the terminal illness and related conditions. The ABN, Form CMS-R-131, is issued by providers (including independent laboratories, home health agencies, and hospices), physicians, practitioners, and suppliers to Original Medicare (fee for service—FFS) beneficiaries in situations where Medicare payment is expected to be denied. The ABN is issued in order to transfer potential financial liability to the Medicare beneficiary in certain instances. Guidelines for issuing the ABN are published in the Medicare Claims Processing Manual, Chapter 30, Section 50.²⁷ As such, the purpose of

²⁷ Medicare Claims Processing Manual Chapter 30—Financial Liability Protections. <https://www.cms.gov/medicare/claims/processingmanual>

the ABN is to inform beneficiaries of the listed items and services that Medicare is not expected to approve, and the specific denial reason (that is, not medically reasonable and necessary), whereas, the proposed hospice addendum is intended to inform beneficiaries of items and services that the hospice will not cover as the hospice has determined them to be unrelated to the terminal illness and related conditions, and therefore, subject to coverage under other Medicare benefits. Similarly, mandatory use of the ABN is very limited for hospices. The three situations that would require issuance of the ABN by a hospice are:

- Ineligibility because the beneficiary is not determined to be “terminally ill” as defined in § 1879(g)(2) of the Act;
- Specific items or services that are billed separately from the hospice payment, such as physician services, are not reasonable and necessary as defined in either § 1862(a)(1)(A) or § 1862(a)(1)(C); or
- The level of hospice care is determined to be not reasonable or medically necessary as defined in § 1862(a)(1)(A) or § 1862(a)(1)(C), specifically for the management of the terminal illness and/or related conditions.

An ABN is not required to be given to a beneficiary for items and services unrelated to the terminal illness and related conditions. Additionally, an ABN cannot be issued to transfer liability to the beneficiary when Medicare would otherwise pay for items and services. Because the purpose of the ABN is to notify beneficiaries of Medicare non-coverage and shift financial liability for payment of such services to the beneficiary, we believe that modifying the ABN for purposes of notifying the beneficiary of items, services, and drugs not covered by the hospice as unrelated, may be more confusing for patients in understanding exactly what the hospice is communicating and how to seek coverage from other benefits.

The Home Health Change of Care Notice (HHCCN) is provided to beneficiaries to notify them of home health plan of care changes. That is, the HHCCN is given to a beneficiary where there is a reduction or termination of services listed on the home health plan of care due to physician/provider orders or limitations of the HHA providing the specific service. While we agree that the HHCCN has some similar components of the proposed addendum (for

example, the addendum would inform beneficiaries of changes to non-covered items and services and the reason for the change), there are also inherent differences between the HHCCN and the proposed addendum. As stated in the FY 2020 hospice proposed rule (84 FR 17594), the purpose of the proposed addendum is to inform beneficiaries and their families of those items, services, and drugs determined by the hospice to be unrelated to the terminal illness and related conditions, and therefore, not covered by hospice. In other words, these are determined not to be hospice items, services or drugs related to the terminal illness, and therefore, would not be considered the hospice’s responsibility to provide. We believe that the addendum should clearly state that these are items, services, and drugs that the hospice has determined to be unrelated and therefore, not covered by the hospice. However, as we are proposing that hospices develop their own addendum, there is nothing prohibiting them from mirroring forms such as the HHCCN to facilitate clear communication between the hospice beneficiary and their representative, as long as the addendum includes the required elements.

The suggested “Hospice Change of Care Notice” sounds very much like the proposed addendum given the purpose of this suggested change of care notice is to communicate similar information as the addendum. However, the timeframes accompanying the suggested “Hospice Change of Care Notice” allow more time to complete the initial and comprehensive assessment, establish the plan of care with IDG input and secure agreement of those items unrelated to the terminal illness and related conditions. As described above, we agree that the timeframe for completion of the requested addendum should more accurately align with already existing requirements. However, as stated above, we believe that the addendum should be clear in its purpose that these are items, services, and drugs the hospice has determined to be unrelated to the terminal illness and therefore not the hospice’s coverage responsibility, but may be covered under other Medicare benefits.

We believe that 5 days to complete the addendum, if requested at the time of a hospice election, should provide adequate time for all of these activities to occur and is in alignment with the timeframe requirements at § 418.54(b) for completion of the comprehensive assessment. We remind hospices that the hospice CoPs at § 418.54(b) require that the RN, in consultation with the other members of the IDG, considers the

information gathered from the initial assessment as they develop the plan of care and the group determines who should visit the patient/family during the first 5 days of hospice care in accordance with patient/family needs and desires, and the hospice’s own policies and procedures. A hospice does not have to wait 5 days to complete the comprehensive assessment as hospices may choose to complete the comprehensive assessment earlier than 5 days after the effective date of the election (for example, the hospice may complete the comprehensive assessment at the same time as the initial assessment). Care planning begins as soon as the individual elects hospice care and much of the care planning and the decision-making occurs throughout this period of time, so we believe that completing the addendum within 5 days of the hospice election (or within 72 hours if the addendum is requested during the course of hospice care) is not unreasonable.

While some commenters suggested adding statements to the addendum to acknowledge that the patient or patient representative has reviewed the items, services, and medications with the hospice representative in order to protect the hospice from inadvertently excluding any medications or treatments the patient is receiving at the time of admission, and to acknowledge that a new addendum would be signed if additional non-covered items, services, or medications are identified during the course of treatment, we proposed that the addendum would include a statement that the addendum is subject to review and shall be updated, as applicable, in writing, to the beneficiary (or representative). Additionally, we proposed that the addendum would include a statement that signing the addendum (and any updates) is only an acknowledgement of receipt of the addendum and not necessarily the beneficiary’s agreement with the hospice’s determinations (84 FR 17595). If the beneficiary (or representative) requests the addendum at the time of the hospice election (that is, at the time of admission to hospice), hospices could include language on the addendum that those unrelated conditions, items, services, and drugs are those the hospice has identified as present on admission and that any changes to this list (due to new, changing, or inadvertently excluded conditions, items, services, and drugs) would be reflected in written updates to the addendum. While we expect hospices to be as thorough as possible when completing the election statement

addendum, we recognize that there may be times when they are not aware of all of the individual's conditions/diagnoses at the time of the hospice election, which could result in information inadvertently excluded on the addendum. Consequently, hospices have the option to make updates to the addendum, if necessary, to include such conditions, items, services and drugs they determine to be unrelated throughout the course of a hospice election. We believe that the requirements proposed and these suggestions would mitigate hospices' concerns regarding any items, services, or drugs that may have been inadvertently excluded when completing the addendum.

Given that hospices would develop their own addendum, hospices may add additional language to inform beneficiaries that the addendum reflects the most accurate information that they have at the time the addendum is completed and that updates would be provided, in writing, if there are any changes that would need to be included based on any new information.

While some commenters stated that addendum should also address those items, services, and drugs that may be related, but that the hospice is not covering, for example a brand name drug as opposed to a hospice formulary drug, or if a patient requests to continue using a specific drug that the hospice determines is no longer providing medical benefit to the patient, we do not think the addendum is the appropriate mechanism to communicate this information. The individualized hospice plan of care is developed in accordance with patient preferences and goals in mind, including those related to drugs. Decisions about those items, services, and drugs should be made based on collaboration between members of the interdisciplinary group (IDG), the patient's attending physician (if any), as well as the patient and their family. This decision-making would include determinations of what is reasonable and necessary to meet the care plan goals. We remind stakeholders that when a beneficiary elects the hospice benefit, he or she agrees to forego the right to Medicare payment for services related to the terminal illness and related conditions unless provided by the hospice. This would mean that if a beneficiary wants to use a brand name drug instead of its' generic equivalent, or wants to continue a drug that the hospice has determined to no longer be reasonable and necessary, the beneficiary is liable for payment for the drug. The purpose of the addendum is to inform the beneficiary of those items,

services and drugs the hospice has determined to be unrelated to the terminal illness and related conditions. The scenario described by these commenters reflects a situation in which the drug would be related to the terminal illness and related conditions but is not on the hospice formulary. Therefore, we believe it would be confusing to provide beneficiaries information on related items, services, and drugs on the addendum meant to document unrelated items, services, and drugs not covered by the hospice. While we do not routinely receive reports of beneficiaries preferring to use a brand name drug instead of a generic equivalent drug on a hospice's formulary, we are aware of a few instances in which that to be the case. Therefore, we will continue to monitor reports of these types of situations to consider whether the use of the addendum could be expanded and we would make such proposals in future rulemaking if warranted.

However, if there is a situation in which the patient wants to continue with related items, services, and drugs that the hospice has previously been providing, but that the hospice determines are no longer reasonable and necessary, or the patient decides to switch to a brand name drug rather than the generic equivalent on the hospice formulary, and the hospice provides the item, service, or drug, the hospice would provide the beneficiary with an ABN to notify the beneficiary that he or she would be financially liable. If the hospice does not continue to provide the item, service, or drug, no ABN is required to be given to the beneficiary.

If the beneficiary desires to continue taking drugs that are not covered by Medicare Part A (hospice) or Part D, then the hospice must fully inform the beneficiary of his or her financial liability. Beneficiaries may also submit quality of care complaints to a Quality Improvement Organization (QIO) when the beneficiary prefers a non-formulary drug because, for example, it's believed to be more efficacious than the formulary drug prescribed by the hospice.

Beneficiaries who disagree with such determinations may continue raising these issues through the Medicare fee-for-service appeals process if the determination relates to Part A or B coverage and the Part D appeals process if the determination relates to Part D coverage. Whether or not the hospice furnishes the drug, if the beneficiary feels that the Medicare hospice should cover the cost of the drug, the beneficiary may submit a claim for the medication directly to Medicare on

Form CMS-1490S. If the claim is denied, the beneficiary may file an appeal of that determination under the appeals process set forth in part 405, subpart I.

We note that the hospice CoPs at § 418.56 require a review of the hospice plan of care at least every 15 days, or more often as the patient conditions requires. This ensures that there are ongoing discussions with the beneficiary so that all hospice care is provided in accordance with patient needs. Similarly, the IDG should be proactive in developing each patient's plan of care by planning ahead for anticipated patient changes and needs. Decisions should reflect patient/family preferences and should not solely be a response to a crisis.²⁸ We believe that the addendum is to be used as a tool to have these discussions both at the time of hospice election, when care planning begins, and throughout the course of a hospice election, as care planning changes to meet the needs of hospice patients and their families.

Regarding the use of the current Hospice Information for Medicare Part D (OMB Form 0938-1269), we note that Part D plan sponsors currently have a prior authorization process in place for their member enrolled in hospice for the four categories of drugs (analgesics, anti-nausea, anti-anxiety, and laxatives). A voluntary, standardized prior authorization (PA) form was developed with industry input for hospices to submit to Part D plans in order to assist in:

- (1) Proactively avoiding a drug claim from rejecting at point-of-sale;
- (2) Overriding reject edit at point-of-sale; and
- (3) Communicating a change in the patient's hospice status.²⁹

Hospices currently can use the standardized PA form as a means of notifying a Part D plan that their member has elected hospice care, as well as to document specific drugs that are or are not being covered by the hospice. We don't agree that use of the Hospice Information for Medicare Part D (OMB Form 0938-1269) meets the purpose of the addendum as the Hospice Information for Medicare Part D (OMB Form 0938-1269) is exclusively for use for the identified four classes of

²⁸ State Operations Manual Appendix M—Guidance to Surveyors: Hospice. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_m_hospice.pdf.

²⁹ Hospice Information for Medicare Part D Plans, OMB-approved form (No. 0938-1269). <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Downloads/Instruction-and-Form-for-Hospice-and-Medicare-Part-D.pdf>.

drugs (analgesics, anti-nausea, anti-anxiety, and laxatives) for hospice beneficiaries who are seeking to receive these drugs through their Part D prescription coverage. Unfortunately, this particular form is not comprehensive enough to communicate those items, services, and drugs (not just the four classes) the hospice has determined to be unrelated to the terminal illness and related conditions.

However, as mentioned in the FY 2020 hospice proposed rule (84 FR 17596), we intend to work with hospices and Part D plans to develop a process in which the addendum potentially could be used at the point-of-service when hospice beneficiaries are filling drug prescriptions to ensure timely access to needed drugs. Complete documentation on the part of the hospice, coupled with timely notification of Part D sponsors, mitigates the risk for possible double payment by the Medicare program for drugs, and is anticipated to prevent Part D enrollees in hospice from having a hospice related medication billed by a pharmacy to their Part D plan, potentially subjecting the beneficiary to out-of-pocket expenses.

Comment: Several commenters report that obtaining signatures on the addendum statement would be prohibitively challenging. These commenters cited instances where it is extremely difficult obtaining the patient/representative signature for the hospice election statement and expressed concerns about having a requirement to obtain a signature again on the addendum. Reasons for these challenges included having representatives who live in a different state from the hospice beneficiary who may be unable to make healthcare decisions on his or her own, lack of readily available technology such as patients or representatives not having email accounts or access to a fax machine in order to return signed documents. Other commenters asked specific questions regarding the frequency of providing the addendum and whether the signature would be required on each version of the addendum. Another commenter remarked that other providers, such as home health agencies, are not required to obtain patient/representative signature for changes to the plan of care and stated that as the addendum would be similar to a change in the home health plan of care, requirements for the hospice addendum should be a similar process. A few commenters requested further guidance regarding the acceptance of an electronic patient signature for the addendum.

Response: We note that the hospice regulations at § 418.24(b) require that the patient or representative sign the election statement. We appreciate the challenges that commenters have identified in obtaining a signature on the election statement, however, we note that obtaining the required signatures on the election statement has been a longstanding regulatory requirement. We expect that hospices already have processes and procedures in place to ensure that required signatures are obtained, either from the beneficiary or his or her representative in the event that the beneficiary is unable to sign and we expect that the same procedures may be used for obtaining signatures on the addendum. Likewise, the hospice CoPs at § 418.52(a)(3) require that the hospice obtain the patient's or representative's signature confirming that he or she has received a copy of the notice of rights and responsibilities. Therefore, we believe that it is not unreasonable to require that the addendum also be signed to ensure that the patient is aware of the important information about hospice non-covered items, services, and drugs. As noted previously in this rule and in the proposed rule (84 FR 17608), the addendum would be signed by the beneficiary as an acknowledgement that he or she has received this information, but signing it does not mean the beneficiary agrees with the determination.

Contrary to commenters' statements that beneficiaries receiving home health services are not required to sign when there are changes to the home health plan of care, the HHCCN form (CMS Form 10280) is completed when there are changes to the home health plan of care due to a reduction or termination of home health services, and the beneficiary or representative is required to sign and date the HHCCN confirming his or her review and understanding of the notice.^{30 31} Additionally, the home health CoPs at § 484.60(c)(3)(ii) require that any revisions related to plans for the patient's discharge must be communicated to the patient, representative, caregiver, all physicians issuing orders for the HHA plan of care, and the patient's primary care practitioner or other health care professional who will be responsible for

providing care and services to the patient after discharge from the HHA (if any). We also remind stakeholders that the HHCCN references services that are or were provided under the home health plan of care. Conversely, the addendum is used to communicate items, services, and drugs that would not be on the initial (or subsequent) hospice plan of care to ensure coverage transparency where the hospice has determined that certain items, services, or drugs would not be covered (that is, furnished and paid for by the hospice) because they are unrelated to the terminal illness and related conditions.

In summary, we continue to believe that because of the significance of the decision to elect hospice care and waive the right to Medicare payment for care related to terminal illness and related conditions, the terminally ill individual (and his or her representative) must have information related to all aspects of their care, including what the hospice has determined to be "unrelated". Requiring the patient to sign the written addendum memorializes that this important information has been provided by the hospice to the beneficiary.

Comment: Several stakeholders strongly urged CMS to examine non-hospice expenditures to determine what proportion is actually the responsibility of, and within the control of, the hospice before implementing a mandatory process for hospices. Commenters noted that there are frequent instances when care is provided to hospice patients without the hospice's knowledge and the hospice discovers that the item, service, or drug has been provided only after the fact. An industry association stated that the language in the proposed rule presupposes that it is only the hospice's responsibility to communicate with other providers and offered ideas for improving the flow of communication between hospice and non-hospice providers. Commenters noted that other providers may be unaware that a patient has elected hospice and that they need to coordinate with the patient's hospice to determine whether the services are unrelated to the terminal prognosis and that these non-hospice providers must treat claims for hospice beneficiaries differently with the use of modifiers or a condition code. These commenters recommended that CMS and Medicare Administrative Contractors (MACs) provide clear guidance to physicians on billing requirements for using the GV and GW modifiers and to circulate this guidance widely in a variety of publications to promote awareness of these billing requirements as they

³⁰ Form Instructions for the Home Health Change of Care Notice (HHCCN) CMS-10280. <https://www.cms.gov/Medicare/Medicare-General-Information/BNI/Downloads/HHCCN-Form-Instructions.pdf>.

³¹ Medicare Claims Processing Manual Chapter 30—Financial Liability Protections. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c30.pdf>.

related to non-hospice care for hospice beneficiaries. Some suggested that non-hospice providers should share in the responsibility of identifying their patients who are under a hospice election. These suggestions included making Medicare system changes to allow for a shortened process that would expedite the notification of election in the Common Working File (CWF), implementing flags in the Medicare claims processing systems to notify other provider types of the hospice election and requiring these other providers to communicate and coordinate with the hospice, as well as asking beneficiaries and/or their representative if they are a hospice patient.

Response: While we agree that all participating Medicare providers should actively engage in ongoing communication and care coordination to ensure that Medicare beneficiaries receive appropriate care, the proposed rule primarily focused on the hospice's responsibility in these activities. The hospice CoPs at § 418.56(e) detail the requirements of hospice care coordination. Specifically, the hospice CoPs require that the hospice provide for an ongoing sharing of information with other non-hospice healthcare providers furnishing services unrelated to the terminal illness and related conditions. Furthermore, hospices are required to have systems in place to facilitate the exchange of information and coordination of services among staff and with other non-hospice healthcare providers. Likewise, hospices are required to have documentation in the clinical record of the sharing of information between all disciplines providing care and with other healthcare providers furnishing services to the patient.³² The goal of this coordination is to ensure that the patient's hospice plan of care is implemented, and that the hospice care is furnished in concert with other care sources to ensure that all patient needs are met (73 FR 32099). We expect the hospice plan of care to address all patient goals in some way. If a patient has a goal that is not related to the terminal illness and related conditions, and if the hospice does not intend to address this goal, then the hospice plan of care should identify the party that is responsible for meeting the unrelated goal. Furthermore, § 418.56(e) requires the hospice to actively communicate

with the outside party to ensure that the goal is addressed. Therefore, given the comprehensive nature of the Medicare hospice benefit and the CoPs regarding the pivotal role hospices are required to play in care coordination, we believe hospices are primarily responsible for communication and care coordination with non-hospice providers while a beneficiary is under a hospice election. Likewise, the requirement that care is provided under the direction of an IDG means that the approach to patient care under hospice is holistic and requires the hospice to be primarily responsible for the medical, emotional, and spiritual care of the individual.

To address comments regarding physician education on the appropriate use of the GW and GV modifiers, we remind stakeholders that CMS does routinely provide information on various aspects of the Medicare program include educational materials on Medicare benefits and claims processing. There is a MLN Matters® article, "Hospice Related Services—Part B", intended for physicians submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries who are in a hospice period of coverage.³³ Likewise, the Medicare claims processing manual, chapter 11, "Processing Hospice Claims" includes detailed information on the appropriate use of the GW and GV modifiers. We believe these are the most appropriate CMS mechanisms for providing such information to physicians and other providers of services.

To address comments regarding making changes to the Medicare systems to allow for a shortened process to update the CWF, we note that CWF processing time still varies because of whether an NOE must go through the one-time out of service area (OSA) process. OSA processing occurs when a beneficiary's master record is not found on the local CWF host site for the MAC and several nightly batch cycles are required to query each of the other host sites to find it. This process is standard for all claims and cannot be revised just for hospice without creating risk for all other Medicare payments. While Electronic Data Interchange (EDI) submission of NOEs does not affect the processing time in CWF, it reduces delays caused by keying errors. Once the NOE is accepted at CWF, the hospice record is available for all providers on the HIPAA (Health

Insurance Portability and Accountability Act) Eligibility Transaction System (HETS) inquiries. The HETS allows providers to check Medicare beneficiary eligibility data in real-time. Providers are encouraged to use HETS to prepare accurate Medicare claims, determine beneficiary liability, or check eligibility for specific services.

Comment: A few commenters expressed concern over the role of the QIO when beneficiaries disagree with the hospice determination as to those items, services, and drugs. These commenters disagreed with having to include QIO information on the election statement given hospices are already required to provide information to beneficiaries regarding QIOs at hospice admission. Other commenters expressed concerns over how QIO determinations would be made, given that these determinations are within the scope of a hospice physician who has medical information in the clinical record with which to base such a determination. These commenters stated that unless the QIO reviewer is a physician with experience/training in end-of-life care and has sufficient information, the QIO reviewer could not make a determination as to whether the hospice's determination of unrelatedness is correct and appropriate. Commenters request additional clarity about the BFCC–QIO findings and how the hospice is to implement them so there is no confusion regarding the authority of the BFCC–QIO, the hospice medical director, and the MACs when determining relatedness, eligibility, and continued coverage of hospice services.

A few commenters remarked that the crux of the issue is the lack of guidelines provided by CMS as to how determinations of relatedness are made, other than it is the responsibility of the hospice physician. One commenter stated that relatedness is vague. One industry association reiterated that there is a lack of clarity around what "relatedness" means and that guidance should be updated and be more specific. This commenter stated that the repeated requests for clarification underscores the reality of how decisions are being made. This commenter went on to state that there are those hospices that have a broad, holistic view and philosophy of care that is in alignment with CMS' intent and is aligned with their organizational mission and values, though this commenter remarked that there are those hospices that take advantage of the "gray space" and manipulate the system to avoid payment of items, services, and drugs that should be the hospices' responsibility. Finally,

³² State Operations Manual Appendix M—Guidance to Surveyors: Hospice. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_m_hospice.pdf.

³³ MLN Matters® Number: SE1321, Hospice Related Services—Part B. November 2014. <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1321.pdf>.

this commenter recommended that CMS work with stakeholders to develop more standardized definitions of related and unrelated in order to promote consistency of delivery across the benefit and where the need for an addendum would be unnecessary as a result.

Response: We remind stakeholders that Immediate Advocacy with the Beneficiary and Family Centered Care Quality Improvement Organization (BFCC-QIO) is an informal alternative dispute resolution process used to quickly resolve a Medicare beneficiary's (or his or her representative's) verbal complaint regarding the quality of Medicare-covered health care received or services that accompany medical care (for example, medical equipment). This process involves the BFCC-QIO directly contacting the beneficiary's practitioner or provider, usually by telephone. The process is voluntary for both the beneficiary and the provider or practitioner. The purpose of Immediate Advocacy is to provide a flexible, dialogue-based resolution process between the beneficiary and the provider.

There are specific criteria for eligibility for Immediate Advocacy. A QIO may offer Immediate Advocacy to the beneficiary prior to obtaining a written beneficiary complaint when the following criteria are met:

1. After initially screening the complaint, the QIO determines the complaint was received within 6 months from the date of service on which the care occurred concerning the complaints and:

- a. The beneficiary complains about a matter that is unrelated to the clinical quality of health care itself but that relates to items or services that accompany or are incidental to the medical care and are provided by a practitioner and/or provider (for example, beneficiary in search of or needing an intervention for resources and/or services covered by Medicare, such as a wheelchair that was not delivered, a beneficiary concerned about the quality of communication with their practitioner and/or provider); or

- b. The beneficiary complains about a matter that, while related to the clinical quality of health care the beneficiary received, does not rise to the level of being a "gross and flagrant," "substantial," or "serious or urgent" quality of care concern. This may include situations where the QIO determines that the medical information will most likely not contain evidence related to the complaint.

2. The beneficiary agrees to the disclosure of his or her name. (42 CFR 476.110(a)(3)).

3. All parties orally consent to the use of Immediate Advocacy. (42 CFR 476.110(a)(4)).

4. All parties agree to the limitations on redisclosure; namely, all communications, written and oral, exchanged during the Immediate Advocacy process must not be redisclosed without the written consent of all parties (42 CFR 476.110(c) and 480.107).

If the practitioner/provider opts NOT to participate in the Immediate Advocacy process, the QIO must immediately contact the beneficiary and give him or her the opportunity to file his or her complaint in writing.³⁴

As noted previously, the regulations at § 476.110 set forth the requirements as they relate to the Immediate Advocacy process which is meant to be an informal alternative dispute resolution process used to quickly resolve an oral complaint a Medicare beneficiary or his or her representation has regarding the quality of Medicare covered health care received. This process involves a QIO representative's direct contact with the provider and/or practitioner. When a quality of care complaint is handled through the Immediate Advocacy process, the QIO does not make clinical determinations based on whether or not it agrees with the hospice's determination about whether or not the disputed items, services, or drugs are unrelated to the terminal illness and related conditions, but rather facilitates discussion between the beneficiary and the hospice to see if the two parties can come to a satisfactory resolution. While it cannot require services be covered, provided, or be paid for by Medicare, the BFCC-QIO addresses quality of care issues for Medicare beneficiaries. Additionally, with the agreement to use Immediate Advocacy, a Peer Review is not performed. A Peer Review is a review by health care practitioners of services ordered or furnished by other practitioners in the same professional field and is generally part of the written complaint process through the QIO. If the QIO receives a written complaint, Immediate Advocacy may not be offered; rather the written complaint would be subject to the Beneficiary Complaint Review Peer Review process.³⁵ Furthermore, medical

information should not be requested from the practitioner or provider for this Immediate Advocacy process. While the goal of Immediate Advocacy is to informally and quickly resolve the beneficiary's complaint, in certain instances the beneficiary might remain dissatisfied after completion of Immediate Advocacy. Should this occur, the QIO must advise the beneficiary of his or her right to file a written complaint. Therefore, we reiterate to commenters that the role and scope of the BFCC-QIO's Immediate Advocacy authority is limited, as described in regulation.

We also remind commenters that the hospice medical director must consider all health conditions, whether related or unrelated to the terminal condition, as well as current clinically relevant information supporting all diagnoses when making the decision to admit a patient into hospice (42 CFR 418.25). Additionally, all hospice care and services furnished to patients and their families must follow the individualized written plan of care established by the hospice interdisciplinary group in collaboration with the attending physician (if any), the patient or representative, and the primary caregiver in accordance with the patient's needs if any of them so desire (42 CFR 418.56). The hospice must ensure that each patient and the primary care giver(s) receive education and training provided by the hospice as appropriate to their responsibilities for the care and services identified in the plan of care. The plan of care must specify the hospice care and services necessary to meet the patient and family-specific needs identified in the comprehensive assessment as such needs relate to the terminal illness and related conditions (42 CFR 418.56). Based on this information, each hospice makes the determination as to what items, services, or drugs are considered related to the terminal illness and related conditions, and belong on the plan of care. However, that is not to say that these determinations cannot be questioned by the beneficiary, or his or her representative. Therefore, the addendum is to provide the information on hospice determinations as to what unrelated items, services, and drugs it will not be covering to spur conversations with the patient about these determinations and the impact on the patient. In addition, Immediate Advocacy is a process in which the beneficiary can question such determinations.

³⁴ Quality Improvement Organization Manual Chapter 5—Quality of Care Review. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/qio110c05.pdf>.

³⁵ Quality Improvement Organization Manual Chapter 5—Quality of Care Review. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/qio110c05.pdf>.

www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/qio110c05.pdf.

In response to comments regarding concerns about the vagueness of “relatedness” and requests for additional CMS guidance as to what is “related” and “unrelated”, we remind commenters that since the implementation of the Medicare hospice benefit, it has been our position that virtually all of the care needed by terminally ill individuals should be provided by the hospice (48 FR 56010). As such, there should not be a voluminous list of unrelated items, services, and drugs given the comprehensive nature of hospice services under the Medicare hospice benefit and the requirement that the hospice provide care addressing the physical, medical, psychosocial, emotional, and spiritual needs of hospice patients and families facing terminal illness and bereavement. We note that in the FY 2015 hospice proposed rule (79 FR 26538) we solicited comments on definitions of “terminal illness and related conditions.” We received a significant number of comments on these definitions, with most commenters opposing CMS proposing these definitions. Commenters stated that hospices were the experts at making such clinical determinations and that the statute and hospice regulations allow for hospices to make such determinations. Commenters noted that the hospice should be the entity that establishes a process to make determinations as to what is related and unrelated to the terminal illness and related conditions on a patient-by-patient basis. Due to this feedback, we have not proposed definitions for “terminal illness or related conditions”.

We understand that national industry associations have subsequently engaged in activities with hospices to communicate a process for helping hospices make these relatedness determinations in the form of clinical decision-making process workflows.³⁶ We appreciate these efforts and ongoing dialogue amongst the hospice industry in addressing best practices in making clinical decisions to provide comprehensive and holistic care to hospice beneficiaries and their families.

Comment: Some commenters suggested that rather than implement sweeping regulations required of all hospices, CMS should implement a more targeted approach by analyzing data to identify hospices that are out of compliance with the coverage of DME

and disease-specific drugs and penalizing them directly for failure to provide such services. One commenter remarked that most hospices provide all items, services, and drugs in good faith and in accordance with Medicare regulations and therefore should not be subject to unnecessary requirements. Another commenter recommended that CMS take additional steps to identify the breadth of the issues contributing to non-hospice spending and address inappropriate spending outside of the hospice benefit accordingly. Specifically, this commenter suggested that CMS determine what proportion of hospice spending is occurring within the first few weeks of hospice care when the CMS systems have not been updated with Medicare notice of election information and where the hospice is informing non-hospice providers that the item, service, or drug is unrelated. One commenter stated that a simple solution would be to block all Medicare services without hospice approval. One commenter wrote that the addendum proposal would make hospices look like “the bad guy” in communicating those items, services, and drugs they have determined to be unrelated even if the hospice is providing this information in good faith.

Response: For those providers who do furnish all items, services and drugs for hospice patients, this requirement would be met in that there would be no request for an addendum as the hospice would be furnishing all of the patient's care needs. We remind stakeholders that the hospice regulations are applicable to all Medicare-participating hospice providers. Program integrity audits and survey actions are appropriate mechanisms to enforce the payment regulations and the CoPs. If there are identified program integrity concerns or CoP violations, the appropriate targeted actions can then be taken for those who do not meet the requirements.

To reduce the incidence of inappropriate payments for beneficiaries under a hospice election, hospices are required to submit a Notice of Election (NOE with its Medicare contractor within 5 calendar days after the effective date of the election statement. The purpose of a timely-filed the NOE is to alert the Medicare claims processing system that a beneficiary is under a hospice election to avoid inappropriate or duplicative payments to other Part A, Part B, or Part D providers, and to safeguard beneficiaries from inappropriate liability for copayments or deductibles.

We have been analyzing non-hospice spending for a number of years and have been presenting information on the

breadth of this issue in proposed and final rules (for instance, our FY 2016 hospice wage index proposed rule at 80 FR 25849, and our FY 2019 hospice wage index proposed rule at 83 FR 20946). We also note that in examining non-hospice spending, we have excluded admission and discharge dates as part of our analysis. In the future, we will consider examining other time points of non-hospice spending, including the proportion of spending that is occurring in the first 5 days of a hospice election where the claims processing system may not yet be aware of the hospice election.

We oppose blocking all beneficiary access to services ordinarily covered by Medicare without hospice approval because the complexity of instituting such a process would potentially delay access to needed items, services, and drugs.

Non-hospice providers are already required to submit claims with the appropriate modifier when furnishing services to beneficiaries under a hospice election. Non-hospice providers are required to report the GW modifier (or condition code 07 for institutional providers) to identify that services were unrelated to the terminal illness and related conditions or the GV modifier to identify that services were related to the terminal illness and related conditions. For beneficiaries enrolled in hospice, A/B MACs (B) shall deny any services on professional claims that are submitted without either the GV or GW modifier. Therefore, there is already a mechanism in place to prevent inappropriate payments during a hospice election. As we stated in the FY 2020 proposed rule (84 FR 17597), we also believe that the addendum may allow the non-hospice provider to be “without fault” if there is any question regarding an overpayment. In accordance with section 1870 of the Act, a provider is responsible for an overpayment if the provider knew or had reason to know that service(s) were not reasonable and necessary, and/or the provider did not follow correct procedures or use care in billing or receiving payment. If non-hospice providers were given access to a patient's addendum, this potentially could provide evidence under section 1870 of the Act in demonstrating that the non-hospice provider did or did not have reason to know that the services provided by the non-hospice provider were duplicative, or otherwise not reasonable and necessary (considering the service itself was otherwise reasonable and necessary and satisfied all other requirements for payment). Moreover, if a non-hospice provider submitted a claim to Medicare for

³⁶ Determining Relatedness to the Terminal Prognosis Process Flow, National Hospice and Palliative Care Organization. December 2014. https://wshpco.org/media/Relatedness_Process_Flow_FINAL_2.14.pdf.

services provided to a beneficiary that were unrelated to the terminal illness and related conditions but did not have the supporting documentation demonstrating that the services were unrelated, this could, among other things, delay payment. Having the addendum identifying the unrelated conditions, items, services, and drugs may provide the necessary documentation support that the non-hospice provider was rendering services unrelated to the terminal illness and related conditions. Therefore, the addendum could assist in more accurate claims submission, mitigate potential duplicative payments, and provide non-hospice providers with documentation to support a “without fault” determination.

Finally, we disagree that the purpose of furnishing an addendum to communicate hospice non-covered, unrelated items, services, and drugs is to make the hospice look like “the bad guy”. Again, hospices are already required to inform beneficiaries of coverage under the Medicare hospice benefit. As such, providing this information supports the philosophy of care of putting patients first, promoting patient choice, and advocating for patient autonomy.

Comment: A majority of commenters opposed the proposal that the addendum be a condition for payment. Many commenters suggested that instead of a condition for payment, the proposed addendum should be a CoP, as they believe that protection of patient rights is more appropriately reviewed under the survey oversight process. Commenters stated that in order for the proposed addendum to be a condition for payment, there would need to be a standardized process of recording any unrelated items, services, and drugs and documenting whether or not the addendum was requested in the patient’s medical record. Several commenters questioned how an addendum that is mandatory, but only upon request, could be appropriately used as a condition for payment. Many commenters expressed concern over the implications for auditing under medical review. Specifically, commenters asked how to protect themselves from claims denials if there is no addendum (or addendum updates) present in the medical record because there was no patient (or representative) or provider request. Others question whether the MACs would use the addendum for claims denials if the MAC disagrees with the hospice’s determinations. A national industry association stated that the process to determine whether the addendum was requested, when it was

requested, whether it is present, and whether the condition for payment requirement has been met, is fraught with issues. Several commenters requested that CMS develop specific protections to prevent claims denials solely because an addendum is not in the medical record and to state that the addendum would not be used to dispute determinations of relatedness which could result in claims denials. A few commenters thought that the addendum should be provided to every hospice beneficiary, whether requested or not, to protect the hospice from claims denials resulting from missing addendums in patients’ medical records. A few commenters stated that the vast majority of patients have no unrelated conditions and therefore it seems unnecessary to require such a form. Another commenter believed that the addendum would have a chilling effect at the time of hospice election and may deter admissions, especially for those patients who are reluctant to discontinue certain services and drugs, like maintenance medications.

Response: While we understand stakeholder concerns about including an addendum statement as a condition for payment, we believe this is necessary to ensure that hospices are diligent in providing this information to Medicare hospice beneficiaries on request. We regard this addendum as an important mechanism of accountability for hospices to provide coverage information to beneficiaries electing the hospice benefit. We also believe that the various reports by the OIG (for example; OEI-02-16-00570, July, 2018, “Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program Integrity: An OIG Portfolio,”³⁷ and A-06-10-00059, June 2012, “Medicare Could Be Paying Twice For Prescription Drugs For Beneficiaries In Hospice”)³⁸ highlight the issues with a patient’s lack of knowledge of hospices’ limitation on their coverage, and the possibility of hospices potentially not covering items, services, and drugs that should be hospices’ responsibility. We reiterate that the election statement addendum, as a condition for payment, would achieve the goal of increasing comprehensive patient education, awareness, empowerment, and coverage transparency. As stated in the FY 2020

hospice proposed rule, this does not mean that in order to meet this condition for payment that the beneficiary (or representative), or non-hospice provider must agree with the hospice’s determination. For purposes of this condition for payment, the signed addendum is only acknowledgement of the beneficiary’s (or representative’s) receipt of the addendum (or its updates) and this payment requirement would be met if there was a signed addendum (and any signed updates) in the requesting beneficiary’s medical record with the hospice. Likewise, this addendum would not be required to be submitted with any hospice claims. While we agree that this could be a CoP as opposed to a condition for payment, we continue to believe that as a condition for payment, this would ensure a more comprehensive and thoughtful approach by hospices in communicating important coverage information to beneficiaries.

We agree that it would be helpful for hospices to have a standardized documentation process for recording any unrelated items, services, and drugs and expect that many hospices may already have a documentation process in place, given the existing requirements for admission to hospice and development of the individualized plan of care. We would expect hospices to document, in some fashion, that the addendum was discussed with the patient (or representative) at the time of admission, similar to how other patient and family discussions are documented. Likewise, hospices can develop a way to document whether or not the addendum was requested at the time of hospice election (or at any time throughout the course of hospice care). This could be done in checklist format or as anecdotal notes by the nurse. However, we did not propose a specific format in which to document such conversations and hospices can develop their own processes to incorporate into their workflow. We believe that careful documentation that the addendum was discussed and whether or not it was requested would be an essential step hospices could take to protect themselves from claims denials related to any absence of an addendum (or addendum update) in the medical record.

We are aware of commenter concerns about the potential for this addendum to be used for medical review auditing purposes if it is a condition for payment. We note that there is no current process for the MACs to make determinations of “relatedness”. We remind commenters that the regulations

³⁷ Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program Integrity: An OIG Portfolio. July 2018. <https://oig.hhs.gov/oei/reports/oei-02-16-00570.pdf>.

³⁸ Medicare Could Be Paying Twice for Prescription Drugs for Beneficiaries in Hospice (A-06-10-00059). June 2012. <https://oig.hhs.gov/oas/reports/region6/61000059.pdf>.

afford hospices this responsibility in accordance with the CoPs at § 418.56. Therefore, the hospices' determination of those unrelated items, services, or drugs reported on the addendum could not be used solely to deny hospice claims. Nonetheless, to assuage commenter concerns about increased claims denials and documentation requests, we will collaborate with the MACs to establish clear guidelines on the use of the addendum as a condition for payment and we will propose any requirements in future rulemaking, as necessary. We do not want hospices to perceive that the purpose of this addendum is punitive against hospices, nor that it is a mechanism to deny claims; rather we want hospices to understand that the intent of this addendum is to keep patients at the forefront of their decision-making equipped with adequate information to make care choices as they approach the end of life.

While hospices can choose to provide the addendum to every electing beneficiary, we are not requiring that it is mandatory, unless the patient (or representative) requests the addendum. We encourage hospices to review their current admission processes to see how the addendum could assimilate into their procedures to help ameliorate any issues upon implementation. We believe that because hospices already should have processes in place to make determinations about those items, services, and drugs that they will not cover because they are unrelated to the terminal illness and related conditions, hospices will be able to adapt the addendum into their current processes.

Finally, we disagree that the provision of the addendum would have a "chilling effect" on hospice admissions. Generally, beneficiaries make decisions that are based on information furnished by providers rendering care. We continue to assert that the information provided in the addendum will allow beneficiaries to make those decisions to best meet their preferences and goals of care and will mitigate any unexpected need to seek services outside of the hospice and assume the associated cost-sharing. We believe beneficiaries and their families would appreciate full disclosure from the hospice as to what to expect when electing the Medicare hospice benefit.

Comment: The majority of commenters agreed that if the addendum is finalized, the effective date should be delayed until FY 2021, at minimum, in order to ensure that hospices and software vendors have adequate time to develop the addendum, modify the existing election

statement to include the new content requirements, and develop and educate on the protocols and procedural changes necessary to incorporate the addendum into hospice work flow processes, as well as work with non-hospice providers to ensure compliance.

Response: We understand that making modifications to the election statement and developing an addendum to accompany the election statement will take time for hospices to create, educate staff, and incorporate into current admission processes. Likewise, we recognize that there are some additional logistical and operation considerations (see response below) that we will need to consider and communicate to the hospice industry to help ensure a more seamless implementation. Therefore, we will finalize an effective date of FY 2021 for the election statement modifications and the addendum. This delayed effective date will allow sufficient time for us to develop a model election statement addendum to provide the industry as they move forward making the changes to their own election statements and as they develop an addendum to communicate those items, services, and drugs they will not be covering because they have determined them to be unrelated to the terminal illness and related conditions. This additional year will allow hospices to make any current process and software changes to incorporate the addendum into their workflow.

Comment: Many commenters stated that CMS underestimated the amount of time it would take for the nurse to complete the addendum stating that 10 minutes is an insufficient amount of time to extrapolate this information from the existing documentation. A few commenters stated that this would take between 20 and 30 minutes to complete. Others stated that this is not just a process of extrapolating the information, but that this is often a process of information gathering as not all relevant information is readily available at the time of the initial assessment. However, a few commenters believed that even though the timeframe to complete the addendum would be longer than 10 minutes, they suggested that the addendum should not be optional but patients (or their representatives) should be provided this detailed list as this is critical to the care process, patient empowerment, quality of care, and transparency. One commenter stated that the addendum proposal would be improved by adding appropriate reimbursement for the time and process redesign needed to make this a successful addition to hospice practice.

Additionally, the majority of commenters stated that this would significantly increase burden for hospices, as well as for patients and their families and could potentially impede access to care stating that this conflicts with CMS' Patients over Paperwork initiative. Commenters cited such concerns as the increase in time spent gathering, documenting, and communicating this information, as well as providing copies of such information, in writing, to patients, their representatives, non-hospice providers, and Medicare contractors.

Response: While we understand commenter concerns over the time it takes to complete the addendum, we remind hospices that the addendum is not a requirement for every electing beneficiary. Several commenters stated that because they do provide such a comprehensive range of services most beneficiaries would not need an addendum. We continue to believe that once a beneficiary elects the hospice benefit, most items, services, and drugs would be for the palliation and management of the terminal illness and related conditions and that there would be few things that would be unrelated.

Furthermore, because hospices should already be considering those items, services, and drugs they have determined to be unrelated as part of the admission and care planning process, we believe that providing such information, in writing, to the beneficiary (or representative) should not take a significant amount of time. Additionally, hospices would develop their own addendums, in a format that suits them to best meet the requirements and patient needs while minimizing operational burden. We also stated in the proposed rule that we would develop a model addendum to help hospices in developing their own. Several commenters stated that most hospices use the current model election statement so we trust that hospices would take advantage of the model addendum to help mitigate any burden in developing their own addendum to meet this requirement.

Additionally, we are finalizing expansion of the time to complete the addendum to 5 days in accordance with the timeframe to complete the comprehensive assessment. This means that if a requesting beneficiary dies within the first 5 days of the hospice election, hospices would not be required to complete any requested addendum as this requirement would be deemed as being met in this circumstance. Given that almost 28 percent of beneficiaries die within the first 5 days of hospice care, this would

further reduce hospice burden. We have recalculated the burden estimate in section IV. of this final rule to account for the expanded timeframe to complete the addendum where there would be fewer eligible elections subject to this requirement and thus, less burden on hospices.

We agree with those commenters who stated that the addendum would be critical in the care process and would promote patient empowerment, quality of care, and transparency. However, we are not making this a mandatory requirement for all hospice elections; we reiterate that the requirement is that the addendum would be provided only upon request as we believe this would best achieve coverage transparency without imposing undue burden on hospices. Likewise, because we believe that hospices should already have processes in place to make determinations of unrelatedness, additional payment should not be made for completion of the addendum.

Finally, while we recognize that the addendum, may result in a small increase in operational burden for some hospices, we believe this burden is outweighed by our initiative to put patients first. We believe that if a requirement results in promoting patient choice, autonomy, and coverage transparency then it is within the framework of this initiative.

Comment: In addition to the comments summarized above, we received numerous comments from hospices, industry associations, and other stakeholders who stated concerns with operational and logistical aspects of the addendum policy. Furthermore, commenters wrote that CMS drastically underestimated the operational complexity and the impact this particular requirement would have on hospice providers and patients.

Generally, commenters had questions on the logistics of delivering the addendum to the patient and family within 48 hours, the clinician who would be responsible for delivering the addendum, and whether this would require the nurse to have a mobile printer to deliver such information. Others asked what the expectations would be when there are changes to the plan of care after admission; whether the timeframe is based on when CMS accepts the election or when the provider submits the NOE; what provisions would be made for weekends and holidays; what education would be provided to MACs and the BFCC-QIOs regarding their role in this process; how CMS would expect evidence that the unrelated items, services, and drugs were discussed at admission or at other

time points during a hospice election; documentation requirements in the medical record referencing the addendum, including who requested such information and when; what CMS means when we state that the clinical rationale should be provided in “language a beneficiary can understand”; how CMS would determine whether the clinical rationale is adequately supported; and how differences between clinical opinion between the hospice physician and non-hospice providers would be handled.

Response: We realize that commenters have concerns over some of the operational and logistical details of developing and implementing an addendum to communicate, in writing, those items, services, and drugs the hospice will not cover as they have been determined by the hospice to be unrelated to the terminal illness and related conditions. As mentioned previously, hospices have asked for additional guidance and details on some of these issues including the submission of handwritten versus electronic signatures, expectations of the type of documentation expected in the medical record regarding whether or not the addendum was requested; what documentation would be requested by the MACs when an Additional Documentation Request (ADR) is made; whether the addendum could be provided in an electronic format; the provision of MAC and BFCC-QIO education, among others. Some of these issues have been addressed in previous responses in this final rule.

Because of some of the issues brought to light by commenters, we will delay the effective date for implementation of the election statement modifications and the addendum until FY 2021 to allow additional consideration of these operational and logistical issues. This will allow CMS more time to fully investigate the details brought up by commenters specifically regarding operational and auditing processes, training and education, and we will engage in rulemaking for FY 2021 as necessary to seek any additional comments on any operational or logistical proposals.

Final Decision: We are finalizing the election statement modifications as proposed. We are also finalizing our proposal that the addendum be titled “Patient Notification of Hospice Non-Covered Items, Services, and Drugs” and would include the following content requirements:

1. Name of the hospice;
2. Beneficiary’s name and hospice medical record identifier;

3. Identification of the beneficiary’s terminal illness and related conditions;

4. A list of the beneficiary’s current diagnoses/conditions present on hospice admission (or upon plan of care update, as applicable) and the associated items, services, and drugs, not covered by the hospice because they have been determined by the hospice to be unrelated to the terminal illness and related conditions;

5. A written clinical explanation, in language the beneficiary and his or her representative can understand, as to why the identified conditions, items, services, and drugs are considered unrelated to the terminal illness and related conditions and not needed for pain or symptom management. This clinical explanation would be accompanied by a general statement that the decision as to whether or not conditions, items, services, and drugs is related is made for each patient and that the beneficiary should share this clinical explanation with other health care providers from which they seek services unrelated to their terminal illness and related conditions;

6. References to any relevant clinical practice, policy, or coverage guidelines.

7. Information on the following domains:

a. *Purpose of Addendum*

b. *Right to Immediate Advocacy*

8. Name and signature of Medicare hospice beneficiary (or representative) and date signed, along with a statement that signing this addendum (or its updates) is only acknowledgement of receipt of the addendum (or its updates) and not necessarily the beneficiary’s agreement with the hospice’s determinations.

We are finalizing that the election statement modifications apply to all hospice elections but the addendum only would be furnished to beneficiaries, their representatives, non-hospice providers, or Medicare contractors who request such information. Additionally, we are finalizing our policy that if the beneficiary (or representative) requests an addendum at the time of hospice election, the hospice would have 5 days from the start of hospice care to furnish this information in writing. We are finalizing our proposal that if the beneficiary requests the election statement at the time of hospice election but dies within 5 days, the hospice would not be required to furnish the addendum as the requirement would be deemed as being met in this circumstance. If the addendum is requested during the course of hospice care (that is, after the date of the hospice election), we are finalizing that the

hospice would have 72 hours from the date of the request to provide the written addendum. We are finalizing our proposal that the election statement modifications and the addendum be effective for hospice elections beginning on and after October 1, 2020 (that is, FY 2021). As noted previously, we will continue to examine some of the operational and logistical issues highlighted by commenters to determine if any additional proposals are required for FY 2021 rulemaking.

At § 418.24(b), we are finalizing the provisions regarding the election statement modifications and the election statement addendum. In addition, we made several revisions to § 418.24. Specifically, we redesignated paragraphs (c) through (f) as paragraphs (d) through (g). This redesignation would affect two cross-references in § 418.26(c)(2) and § 418.28(c)(2). As a result, we made conforming changes to accompany the redesignations in § 418.24. Likewise, at § 418.3, we define the term BFCC-QIO as the Beneficiary and Family Centered Care Quality Improvement Organization. Because these conforming changes were not proposed in the proposed rule, we are adopting them here under a “good cause” waiver of proposed rulemaking. The specific changes we are making in the regulations simply codify the final policies we described in the proposed rule and do not reflect any additional substantive changes.

D. Request for Information Regarding the Role of Hospice and Coordination of Care at End-of-Life

In the FY 2020 Hospice Wage Index and Rate Update proposed rule (84 FR 17598), we solicited public comments on the interaction of the Medicare hospice benefit and various alternative care delivery models, including Medicare Advantage (MA), Accountable Care Organizations (ACOs), and other future models designed to change the incentives in providing care under traditional FFS Medicare. We specifically sought public comments on how hospice under Medicare FFS relates to other treatment options, how it impacts the provision of a spectrum of care for those that need supportive and palliative care before becoming hospice eligible and after, and whether rates of live discharge are a reflection of the current structure of Medicare FFS. We further solicited comments on any care coordination differences for hospice patients that received Medicare through traditional FFS prior to a hospice election, were enrolled in an MA plan prior to hospice election, or received care from providers that

participate in an ACO prior to a hospice election.

We appreciate the thoughtful input and suggestions provided by commenters in response to this request for information (RFI). We generally do not summarize or respond to comments in the final rule for requests for information as the purpose of such requests is to help CMS for future rulemaking or the development of models through CMS' Innovation Center. However, as we continue to review the comments received, we believe that the information gathered under this RFI will help inform: (1) Future CMS payment models; (2) the role of hospice with respect to ACOs; and (3) our general understanding of the traditional FFS hospice environment in relation to the increasing penetration of managed care through the MA program.

E. Updates to the Hospice Quality Reporting Program (HQRP)

1. Background and Statutory Authority

The Hospice Quality Reporting Program includes meeting the reporting requirements for both the Hospice Item Set (HIS) and Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Hospice Survey. 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 nor 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. Update to Quality Measure Development for Future Years

As stated in the FY 2019 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements (83 FR 38622), we launched the Meaningful Measures initiative (which identifies high priority areas for quality measurement and improvement) to improve outcomes for patients, their families, and providers while also reducing burden on clinicians and providers. The Meaningful Measures initiative is not intended to replace any existing programs, but will help programs identify and select individual measures. The Meaningful Measure Initiative areas are intended to increase measure alignment across our programs and other public and private initiatives. Additionally, it will point to high priority areas where there may be gaps in available quality measures while helping to guide our efforts to develop and implement quality measures to fill those gaps. More information about the Meaningful Measures initiative can be found at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html>.

The Meaningful Measures initiative fits well with the HQRP since it has changed little since we began with FY 2014 Hospice Wage Index and Payment Rate Update final rule (76 FR 26806). The Meaningful Measures initiative enables us to review the HQRP in order to close the gaps in quality measures to reflect the hospice industry as it has progressed to meet hospice care, including symptom management for its patients regardless of where hospice care is provided.

In the FY 2014 Hospice Wage Index and Payment Rate Update 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 National Quality Forum (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 and Payment Rate Update 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.

The Hospice and Palliative Care Composite Process Measure—Comprehensive Assessment at Admission measure (hereafter referred to as “the Hospice Comprehensive Assessment Measure”) underwent an off-cycle review by the NQF Palliative and End-of-Life Standing Committee and successfully received NQF endorsement in July 2017. Data for the “Hospice Visits when Death is Imminent” measure pair is being collected using new items added to the HIS V2.00.0, effective April 1, 2017.

Our goal is to identify measures that provide a window into hospice care throughout the dying process, fit well with the hospice business model, and meet the objectives of the Meaningful Measures initiative. Quality measures should provide timely, understandable, comprehensive, clinically valid, and meaningful feedback to hospice leadership, all of its staff, and their different teams regardless of the hospice setting where care is provided. We solicited public input on measure concepts and actual quality measures, along with public comment on the discussions presented below.

a. Claims-Based and Outcome Quality Measure Development for Future Years

As part of Meaningful Measures initiative, we seek to develop claims-based and outcome measures as part of the future for the HQRP. While we acknowledge that there are limitations of using claims data as a source for measure development, there are several advantages to using claims data as part of a robust hospice quality reporting program. Claims-based measures place minimal burden on providers, as they do not require additional data collection and data submission. Furthermore, in contrast to self-reported data that are dependent on hospice, patient, or caregiver participation, claims data has the benefit of following a relatively consistent format and of using a standard set of pre-established codes that describe specific diagnoses, procedures, and drugs. Additionally, nearly every encounter that a patient has with the healthcare system leads to the generation of a claim, creating an abundant and standardized source of patient information. This makes claims

data widely available, relatively inexpensive, and amenable to analysis because they are readily available in an electronic format.

Medicare is the largest payer of hospice services and Medicare-certified providers predominate in hospice so it makes good sense to use claims data to reflect hospice care. Further, other settings’ quality reporting programs, such as the Inpatient Quality Reporting Program (QRP) and the post-acute care (PAC) QRPs, have adopted claims-based measures. The NQF has endorsed claims-based measures and believes they can capture quality even when not directly assessing clinical care. Although claims data have some limitations, such as incomplete reflection of care processes and patient outcomes, they will continue to be a valuable and important source of data for quality reporting for a selected set of metrics and as part of a hospice quality reporting program that includes other measures, such as HIS and CAHPS® Hospice Survey.

While not mutually exclusive of claims-based measures, we also seek to develop outcome measures as part of the Meaningful Measures initiative. Outcome measures could help with improving pain management and symptom management, which are core to hospice care. They could also help identify the value of different staff providing care at different times in hospice. For these reasons, we plan to explore the development of other claims-based and outcome measures for the HQRP to work toward the high priority areas of reducing regulatory burden and identifying gaps in care. In identifying high priority areas for future measure enhancement and development, CMS takes into consideration input from all stakeholders including: Measures Application Partnership (MAP); the Office of the Inspector General (OIG); the Medicare Payment Advisory Commission (MedPAC); Technical Expert Panels (TEP); issues raised through the Beneficiary and Family-Centered Care Quality Improvement Organization; and national priorities, such as those established by the National Priorities Partnership, the HHS Strategic Plan, the National Strategy for Quality Improvement in Healthcare, the CMS Quality Strategy, the Meaningful Measures initiative and the general public, such as through rulemaking. In addition, CMS considers feedback and input from published research and reports. We did not propose any new claims-based or outcome measures at this time. However, we solicited public comments and suggestions related to

ideas for future claims-based and outcome measure concepts and quality measures in the HQRP that could also be tied to the goals of the Meaningful Measures initiative.

A summary of the comments received regarding the future claims-based and outcome measure concepts and our responses to those comments appear below:

Comment: Several commenters support CMS efforts to develop outcome measures for hospice care. Additionally, many commenters support using claims data to develop new measures and cited the importance of a balanced measure portfolio comprising different measure types and data sources. We also received many comments in support of using data from the hospice assessment tool under development to create new patient and family outcome measures. Several commenters noted concerns about using claims data for quality measurement. Specifically the commenters noted that claims data only capture processes and not outcomes of patient care, and some commenters stated that the number of visits was not a good indicator of care quality. Commenters also stated that claims do not reflect the full scope of hospice experience because not all disciplines of the hospice team, such as volunteers or spiritual staff, are captured on a claim. Several commenters stated that claims data do not provide sufficient information to adequately represent hospice practice. Additionally, some commenters recommended that CMS modify hospice claims to capture information on all hospice disciplines such as chaplain visits.

Response: We appreciate the commenters’ support for outcome measure development and reiterate our commitment to measuring outcomes as part of the Meaningful Measures Initiative. We also appreciate the support for using a future hospice assessment tool to develop additional quality measures. We will take these recommendations under consideration as we pursue new measure development.

Regarding the limited focus of claims data, we refer readers to our discussion in the FY 2016 Hospice Wage Index and Payment Rate Update final rule (80 FR 47189) where we address those concerns regarding claims-based measures. As previously noted, claims-based measures place minimal burden on providers, as they do not require additional data collection and data submission, and follow a relatively consistent format, using standardized and established coding. Claims-based measures would be only one type of

quality measure in the QRP. This is in line with our efforts to create a broader set of quality measurement that include outcome and claims-based measures, since currently we report measures based on HIS and CAHPS® Hospice data that are process and outcome measures. We will take these comments into consideration as we continue to address the high priority areas of identifying gaps in care and reducing regulatory burden as we explore the development of other claims-based and outcome measures for the HQR.

b. Update on Claims-Based Measure Development

The FY 2018 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements, (82 FR 36638), noted that, based on input from stakeholders, CMS has identified two “high priority” areas that will be addressed by claims-based measure development: Potentially avoidable hospice care transitions and access to levels of hospice care. The potentially avoidable hospice care transitions concept was developed as a measure under consideration called “Transitions from Hospice Care, Followed by Death or Acute Care.” The goal of this measure is to identify hospices that have notably higher rates of live discharges followed shortly by death or acute care utilization, when compared to their peers. Details about this measure can be found in the FY 2017 Hospice Wage Index and Payment Rate Update and the NQF website, <http://www.qualityforum.org/map/>, where it went on the measures under consideration (MUC) list in July 2018 and was reviewed by the MAP in December 2018. At this time, we are revisiting the subject of potentially avoidable hospice care transitions. While the MAP did not support the measure as specified, MAP recognized the impact that care transitions at the end of life can have on patients and suggested a number of ways the MAP’s concerns with the measure could be mitigated. Areas that the MAP recommended included reconsidering the exclusion criteria for the measure. Specifically, they recommended that we review the exclusion for Medicare Advantage patients, as this may be excluding too many patients. Additionally, the MAP suggested adding an exclusion to allow for patient choice, as there are a number of reasons a patient may choose to transition from hospice. For example, a patient may choose to pursue additional curative treatment, have cultural beliefs that influence the definition of a good death, have limited access to primary care, or

may need to revoke the hospice benefit to avoid a financial penalty for seeking more acute care. MAP also noted that the measure may provide more useful information if it separates out the concepts addressed in the measure, as the measure may be trying to address different concepts by including both death within 30 days and admission to an acute care use within 7 days. The MAP also requested that we consider shortening the timeframe for the measure (MAP 2019, “Considerations for Implementing Measures in Federal Programs: Post-Acute Care and Long-Term Care, Final Report” February 15, 2019, <https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=89400>). The access to levels of hospice care measure concept is also detailed in the FY 2018 Hospice Wage Index and Payment Rate Update. After further analyses, it was determined that this measure concept as currently specified could result in hospices providing higher levels of care when it is not required by the plan of care or expected by CMS. We remain committed to developing claims-based measures that meet high priority areas and are rethinking both measures based on feedback from the MAP and our analyses. We solicited public comments on ways to further develop these two measure concepts and different measure concepts that fall under these high priority areas. A summary of those comments and our responses to the comments appear below:

While commenters supported measuring potentially-avoidable transitions and access to levels of care and agreed that these are high priority areas, they had several concerns and suggested modifying the measures, requested more detail and encouraged CMS to consider the feedback and recommendations from the National Quality Forum’s MAP in 2018 for modifying the measure specifications. They also recommended more measure testing in the measure development to help gain further support for these measures.

Comment: Several commenters noted concerns about how a hospice transitions measure would capture patient and family choices to revoke hospice in favor of other types of treatment or access to additional services. They recommended excluding from the measure live discharges when the patient elects a different hospice provider or is discharged for cause, and noted that patients’ decisions to seek acute care is outside of a hospice provider’s control. Some commenters recommended that claims data capture the reasons for a live discharge, noting

there could be many different ones. Several commenters recommended the measure be simplified by separating into two separate measures, as it is addressing different concepts by including both death within 30 days and admission to an acute care use within 7 days. They also recommended shortening the measurement period to create a stronger nexus between the hospice stay and the adverse event.

Comment: Several commenters noted that claims data do not sufficiently reflect the factors that determine appropriate provision of the various levels of hospice care and that patient and caregiver needs vary greatly. They noted that claims only indicate if the hospice has billed one of the four levels of care. They further noted that patient needs vary and the acuity information need to evaluate appropriate GIP and CHC utilization is not available in claims data. Commenters recommended looking at interdependent patterns of care and monitoring for unintended consequences, such as providing higher levels of care than needed.

Response: CMS appreciates the comments and the support for continuing to refine efforts to measure these two high priority concepts identified by the OIG in its 2018 report, entitled “Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program Integrity: An OIG Portfolio” and available at <https://oig.hhs.gov/oei/reports/oei-02-16-00570.asp>. We will take these comments under advisement as we continue exploring options for measuring these constructs and reiterate our commitment to working with NQF and the MAP. With respect to potentially-avoidable transitions, we are carefully considering stakeholder and MAP feedback, and are looking at multiple ways to measure this construct, including separating out the components to reduce the measure’s complexity. In our ongoing development efforts we are examining the potential impact of these measures, including any unintended consequences.

c. Update on the Hospice Assessment Tool

We discussed the plan to develop a hospice assessment tool in the FY 2018 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements, (82 FR 36638). A technical expert panel on development of such an assessment tool was held in October 2017 followed by a pilot study that began with training 9 hospice sites in December 2017. We are sincerely thankful for and appreciative of the 9

Medicare hospices that participated in the pilot study. We learned much from them during the pilot study and afterwards in lessons learned interviews. Information from that pilot study, referred to as Pilot A, can be found on the HQRP website at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/HEART.html>. We also discussed Pilot A findings, lessons learned, and goals of a hospice assessment tool at the September 2018 special open door forum (SODF). The transcript for that SODF can be found at <https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/PodcastAndTranscripts.html>. Key concepts in developing a hospice assessment tool include understanding the care needs of people through the dying process and ensuring the safety and comfort of individuals enrolled in hospice institutions nationwide. Currently, admission and discharge data from HIS are used to calculate measures in the HQRP. We would like to replace HIS and capture data with a hospice assessment instrument in order to develop quality measures and any possible future payment considerations to include bridging the gap to achieve a fuller understanding of patient care needs. While it must be recognized that hospice care differs from other PAC settings, there is a need to create a comprehensive assessment instrument for hospice care to align with other PAC settings, where feasible and practical. As such, objectives of a comprehensive assessment instrument must include the ability to establish goals of care that embrace the individual's values and preferences, and are consistent with a person-centered approach that values the person and caregiver in the care continuum with an emphasis on physical, psychosocial, spiritual, and emotional support. We continue our commitment to engaging stakeholders at regular SODF meetings and other means like the HQRP website, open door forums (ODF), webinars, and other sub-regulatory means.

One of the requests raised at the September 2018 SODF was to change the name of the hospice assessment tool from Hospice Evaluation Assessment Reporting Tool (HEART) to a name that is not as easily confused with other HQRP related tools like the Hospice Abstraction Reporting Tool (HART). We agree with this feedback since people refer to both by their same sounding acronyms and solicited public comments on the name for the hospice assessment tool.

We will keep providers informed about future measure and assessment tool development efforts and solicit key stakeholder input through regular sub-regulatory channels. Additionally, future measure concepts under development, including details regarding measure definitions, data sources, data collection approaches, and timeline for implementation will be communicated in future rulemaking.

Comment: We received several comments expressing strong support for the development of a new assessment tool for use in conducting patient assessments in real-time to assist in the plan of care and also for developing future measures to benefit hospice providers and consumers. These commenters also appreciated our ongoing and regular engagement of stakeholders via sub-regulatory means in the development process.

Commenters also expressed support for changing the name and acronym of an assessment tool, to avoid confusion. Commenters offered the following suggestions: Hospice Comprehensive Assessment Tool or the Comprehensive Assessment Tool for Hospice; Hospice Outcomes & Patient Evaluation (HOPE); Hospice Care Assessment Tool; Hospice Assessment Tool (HAT); and Evaluation and Assessment Reporting Tool for Hospice (EARTH). One commenter recommended rather than renaming the HEART (Hospice Evaluation Assessment Reporting Tool), CMS rename the Hospice Abstraction Reporting Tool (HART) to the Hospice Assessment Software Tool (HAST).

Response: We appreciate the support for and feedback on developing a new hospice assessment. We are continuing the process of developing a new hospice assessment that meets the objectives of patient-centered care. This process includes additional information gathering, including review of feedback on the HEART tool, and stakeholder engagement to develop a draft instrument for alpha testing that will ultimately support a national beta test. We intend to use rule-making to propose a timeline and process for implementing the final, tested assessment tool. We appreciate the support for wanting to use a new assessment to development outcome measures and reiterate our commitment to providing updates and engaging stakeholders through sub-regulatory means.

While HIS is a standardized mechanism for extracting medical record data, it is not a patient assessment instrument that can capture patient data in real time for use in care planning. Our goal for a hospice

assessment tool is to be more comprehensive than the HIS by capturing care needs in real-time and throughout the end of life; not just at admission and discharge. This includes flexibility to accommodate patients with varying lengths of stay. In addition, a comprehensive assessment tool will provide standardized data as all Medicare-certified hospices will be collecting the same data in standardized manner. By aligning the assessment with regular patient care, we intend to capture baseline data to support care planning and to inform quality measurement for the Hospice QRP, including outcome measures, and to support providers' quality improvement efforts. A new hospice assessment tool is intended to support quality measure development and care planning. We intend to offer training and other supports as the new tool is being prepared for implementation; the timeline for roll-out will be established through rule-making.

We also appreciate commenter's support for changing the name of the assessment under development. After reviewing the many great suggestions, we like the name, Hospice Outcomes & Patient Evaluation (HOPE). Both the full name and acronym, HOPE, captures our goals for this assessment tool. It is a patient evaluation for use by hospices and enables CMS to develop outcome measures that will help consumers in selecting hospices when publicly reported. The acronym, HOPE, also provides the sentiment of hope for patients achieving the quality of life per their goals and wishes and supported by the hospice.

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 call the hospice assessment tool the Hospice Outcomes & Patient Evaluation (HOPE).

3. 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. Update on the CMS System for Reporting Quality Measures and Standardized Patient Assessment Data and Associated Procedural Issues

Hospices are currently required to submit HIS data to CMS using the Quality Improvement and Evaluation System (QIES) Assessment and the Submission Processing (ASAP) system. We will be migrating to a new internet Quality Improvement and Evaluation System (iQIES) as soon as FY 2020 that will enable us to make real-time upgrades, and we are designating that system as the data submission system for the Hospice QRP. Effective October 1, 2019, we will notify the public of any changes to the CMS-designated system in the future using sub-regulatory mechanisms such as web page postings, listserv messaging, and webinars. We solicited public comment on the iQIES and received no comments.

Final Decision: For the reasons discussed in the above paragraph, we will be migrating to the iQIES system as soon as FY 2020 and will provide further information regarding the migration and any future system of record changes via sub-regulatory mechanisms to make this transition as smooth as possible.

4. CAHPS® Hospice Survey Participation Requirements for the FY 2023 APU and Subsequent Years

a. Background and Description of the CAHPS® Hospice Survey

The CAHPS® Hospice Survey is a component of the CMS HQRP which 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 about the development of the survey, originally called the Hospice Experience of Care Survey, may refer to 79 FR 50452 and 78 FR 48261. 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).

b. Overview of the CAHPS® Hospice Survey Measures

The CAHPS® Hospice Survey measures received NQF endorsement on October 26th, 2016 (NQF #2651). We adopted these 8 survey based measures for the CY 2018 data collection period and for subsequent years. These 8 measures are publicly reported on a designated CMS website that is currently Hospice Compare.

c. Data Sources

We previously finalized the participation requirements for the FY 2020, FY 2021, and FY 2022 APUs (see 82 FR 36673). We proposed to extend the same participation requirements for the HQRP for FY 2023 and all future years. As part of the Patients Over Paperwork initiative, we solicited comments about the CAHPS® Hospice Survey questionnaire. We solicited comments regarding suggested changes, additions or deletions to the instrument that would improve its value to hospices for quality improvement and consumers for selecting a hospice.

A summary of those comments and our responses to them appear below:

Comment: Some commenters suggested that the survey was too long, too complex and duplicative. Other commenters stated that the language could be “friendlier,” that the setting of the patient’s death should determine the survey questions asked, and that the survey should be offered in a web-based version.

Response: We are currently exploring ways to simplify and shorten the survey and we are examining the feasibility of using web-based data collection in conjunction with traditional survey methods. In addition, we had a literacy-level review of the questionnaire and are reviewing what changes may be feasible to make. When we designed the survey, we considered allowing the setting of the patient’s death to determine the questions. However, the results from testing showed this would be burdensome to patients, hospices and vendors and determined a single survey would be easier to administer.

Comment: Some commenters requested changes to the timing of data collection. Most of the commenters suggested that we should start data collection sooner after the death, 45 days instead of a lag of 2 months.

Response: In the initial development of the survey, the original timeframe for sending out the survey was trying to balance respecting the difficult time the loved one was going through following the death and not waiting too long after the hospice services were provided. We will take this into consideration as we consider potential changes to the survey.

Comment: Some commenters stated that patients’ families do not make a distinction between the hospice staff and nursing home/assistance living facility staff when responding to the questionnaire.

Response: To help the respondent make these distinctions, we include specific references to the hospice

involved as part of the mail questionnaire and the telephone questionnaire script.

Comment: Several commenters requested a variety of different wording changes to the questionnaire, including changes to the response options and the addition of “not applicable” as a response. Some commenters stated that the hospice logo should be included in mailing packages.

Response: During survey development we conducted extensive cognitive interviews with potential respondents to see if they could understand the response scales. The respondents had no problems understanding or using our response options. We do not need to include “not applicable” as a response option because we provide instructions for skipping inapplicable items. We do allow hospice logos to be placed on the questionnaire for mail surveys. Please refer to the Quality Assurance Guidelines Manual on the survey website (www.hospicecahpsurvey.org).

Comment: Some commenters suggested changes to the survey exclusions, in particular the exclusion of patients who have been in hospice less than 48 hours when they died. In addition, several commenters stated that we should “give credit” for the response of “usually,” as there may be persons who are uncomfortable with absolutes such as “always.” A few commenters suggested the inclusion of questions specifically about veterans and to use ethnicity as a case-mix adjustment factor.

Response: The reason we excluded patients who die within 48 hours is because we were concerned that caregivers did not have enough experience with the hospice to provide informed responses to the survey. We do publicly report the results including responses of “usually.” We determined that we would not require the inclusion of questions specifically about veterans because it would make the survey even longer. We also note that among our case-mix adjustments are variables for the language in which the survey was administered, along with the language the caregiver reports speaking at home. The goal of case-mix adjustment is to adjust for differences in patient or caregiver characteristics that impact response tendencies. We generally do not adjust for race and ethnicity in order to not mask true differences in the quality of care across racial and ethnic groups.

Comment: Several commenters stated that we should take into consideration hospice characteristics, including rural versus urban, and hospice size.

Response: We publicly report hospice size. We consider a variety of variables, including urban and rural characteristics, when looking at quality measures. Internal analysis of our data shows that approximately eight in ten hospices that report CAHPS data are urban and about two in ten are rural. Please note that rural hospices may be more likely to qualify for size exemptions and therefore may not participate in the CAHPS® Hospice Survey.

Final Decision: We appreciate the feedback on potential changes to the CAHPS® Hospice Survey and will take these comments into consideration as we consider changes. Any potential changes will be proposed through future rulemaking.

d. Public Reporting of CAHPS® Hospice Survey Results

We began public reporting of the results of the CAHPS® Hospice Survey on Hospice Compare as of February 2018. We report the most recent 8 quarters of data on the basis of a rolling average, with the most recent quarter of data being added and the oldest quarter of data removed from the averages for each data refresh. We refresh the data 4 times a year in the months of February, May, August, and November.

e. 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 Hospice Wage Index and Payment Rate Update final rule (82 FR 36671). We proposed to continue our policy for a volume-based exemption for CAHPS® Hospice Survey Data Collection for FY 2021 and every year thereafter. For example, for the FY 2021 APU, hospices that have fewer than 50 survey-eligible decedents or caregivers in the period from January 1, 2018 through December 31, 2018 (reference year) are eligible to apply for an exemption from CAHPS® Hospice Survey data collection and reporting requirements (corresponds to the CY 2019 data collection period). To qualify, hospices must submit an exemption request form for the FY 2021 APU. The exemption request form is available on the official CAHPS® Hospice Survey website: <http://www.hospiceCAHPSsurvey.org>. Hospices that intend to claim the size exemption are required to submit to CMS their completed exemption request form covering their total unique patient count for the reference year (for the CY 2019 data collection period the reference year is 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. 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 by the final day of the calendar year. Subsequent periods will follow the

same pattern of using the year before the data collection year as the reference year for determining eligibility.

Starting with FY 2022, we proposed to provide an automatic exemption to any hospice that (1) is an active agency and (2) according to CMS data sources has served less than a total of 50 unique decedents in the reference year. The automatic exemption is good for 1 year and will be reassessed in subsequent years. Hospices with fewer than 50 unique decedents in the reference year would not be required to submit an exemption request form.

Hospices that have a total patient count of more than 50 unique decedents in the reference year, but that have a total of fewer than 50 survey-eligible decedent/caregiver pairs, will not be granted an automatic exemption. However, hospices may qualify to apply for a size exemption if they have fewer than 50 survey-eligible decedent/caregiver pairs (for example, if a patient dies in hospice care less than 48 hours after admission, they and their caregiver is not considered to be survey-eligible). Similarly, if a caregiver has an address outside the United States (U.S.) and its possessions, then that decedent/caregiver pair is not survey-eligible. Hospices may apply for a size exemption by submitting the size exemption request form as outlined above. This exemption is valid for 1 year only. If the hospice remains eligible for the size exemption, it must request the exemption annually for every applicable FY APU period. We solicited feedback on these proposals.

TABLE 14—SIZE EXEMPTION KEY DATES FY 2021 THROUGH FY 2025

Fiscal year	Data collection year	Reference year	Size exemption form submission deadline
FY 2021	2019	2018	December 31, 2019.
FY 2022	2020	2019	December 31, 2020.
FY 2023	2021	2020	December 31, 2021.
FY 2024	2022	2021	December 31, 2022.
FY 2025	2023	2022	December 31, 2023.

f. 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 as stated in the FY 2017 Hospice Wage Index and Payment Rate Update final rule (81 FR 52181). In the FY 2019 Hospice Wage Index and Payment Rate Update final rule (83 FR

38642), we continued the newness exemption for FY 2023, FY 2024, FY 2025, and all future years. We encourage hospices to keep the letter they receive providing them with their CCN. The letter can be used to show when you received your number.

g. Survey Participation Requirements

We previously finalized survey participation requirements for FY 2022

through FY 2025 as stated in the FY 2018 and FY 2019 Hospice Wage Index and Payment Rate Update final rules (82 FR 36670 and 83 FR 38642 through 38643). We proposed to continue those requirements in all subsequent years. Below we reprint the Hospice Survey data submission dates finalized in the FY 2019 Hospice Wage Index and Payment Rate Update final rule (83 FR 38643).

TABLE 15—CAHPS® HOSPICE SURVEY DATA SUBMISSION DATES FOR THE APU IN FY 2023, FY 2024, AND FY 2025

Sample months (month of death)*	CAHPS® quarterly data submission deadlines**
FY 2023 APU	
CY January–March 2021 (Quarter 1)	August 11, 2021.
CY April–June 2021 (Quarter 2)	November 10, 2021.
CY July–September 2021 (Quarter 3)	February 9, 2022.
CY October–December 2021 (Quarter 4)	May 11, 2022.
FY 2024 APU	
CY January–March 2022 (Quarter 1)	August 10, 2022.
CY April–June 2022 (Quarter 2)	November 9, 2022.
CY July–September 2022 (Quarter 3)	February 8, 2023.
CY October–December 2022 (Quarter 4)	May 10, 2023.
FY 2025 APU	
CY January–March 2023 (Quarter 1)	August 9, 2023.
CY April–June 2023 (Quarter 2)	November 8, 2023.
CY July–September 2023 (Quarter 3)	February 14, 2024.
CY October–December 2023 (Quarter 4)	May 80, 2024.

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

** Data submission deadlines are the second Wednesday of the submission months, which are the months August, November, February, and May.

For further information about the CAHPS® Hospice Survey, we encourage hospices and other entities to visit: <https://www.hospiceCAHPSsurvey.org>. For direct questions, contact the CAHPS® Hospice Survey Team at hospiceCAHPSsurvey@HCQIS.org or call 1 (844) 472-4621.

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

a. Background

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 prior to such data being made public; the data will be available on our public website. To meet the Act's requirement for making quality measure data public, we launched the Hospice Compare website in August 2017. This website allows consumers, providers, and other stakeholders to search for all Medicare-certified hospice providers and view their information and quality measure scores. Since its release, the CMS Hospice Compare website has reported 7 HIS Measures (NQF #1641, NQF #1647, NQF #1634, NQF #1637, NQF #1639, NQF #1638, and NQF #1617). In February 2018, CAHPS® Hospice Survey measures (NQF #2651) were added to the website, and in November 2018, the Hospice and Palliative Care Composite Process Measure—Comprehensive Assessment at

Admission (NQF #3235) was added to the website; please see the following rules where these topics were discussed, FY 2016 Hospice Wage Index and Payment Rate Update (80 FR 47199); FY 2017 Hospice Wage Index and Payment Rate Update (81 FR 52184); FY 2018 Hospice Wage Index and Payment Rate Update (82 FR 36675); and FY 2019 Hospice Wage Index and Payment Rate Update (83 FR 38640).

b. Update to “Hospice Visits when Death is Imminent” Measure To Be Publicly Displayed in August 2019

1. Background and Description of “Hospice Visits when Death is Imminent” Measure Pair

In the FY 2017 Hospice Wage Index and Payment Rate Update (81 FR 52163 to 52169, August 6, 2016), we finalized the “Hospice Visits when Death is Imminent” measure pair for implementation April 1, 2017. This measure pair assesses whether the needs of hospice patients and their caregivers were addressed by the hospice staff during the last days of life. The “Hospice Visits when Death is Imminent” measure pair is made up of two measures, Measure 1 and Measure 2. Measure 1 of the pair assesses the percentage of patients receiving at least 1 visit from a registered nurse, physician, nurse practitioner, or physician assistant in the last 3 days of life. Measure 2 assesses the percentage of patients receiving at least 2 visits from social workers, chaplains or

spiritual counselors, licensed practical nurses, or aides in the last 7 days of life.

2. Update to Public Reporting of the “Hospice Visits when Death is Imminent” Measure Pair

As stated in the FY 2019 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements (83 FR 38643 through 38645, August 6, 2018), quality measures are publicly reported on Hospice Compare or other CMS websites once they meet the readiness standards for public reporting, which is determined through rigorous testing for reliability, validity, and reportability. Since the proposal of the “Hospice Visits when Death is Imminent” measure pair, we have conducted further measure testing activities according to NQF guidelines and the Blueprint for the CMS Measures Management System Version 14.0 available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/BlueprintVer14.pdf>. This testing is conducted to ensure that measures demonstrate scientific acceptability (including reliability and validity) and meet the goals of the HQRP, which include distinguishing performance among hospices and contributing to better patient outcomes.

As we assessed the scientific acceptability of “Hospice Visits when Death is Imminent” measure pair, we determined that Measure 1 meets established standards for reliability,

validity, and reportability. Therefore, the measure is being publicly reported as stated in the FY 2019 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements (83 FR 38645 through 38648). Our testing of Measure 2 of the “Hospice Visits when Death is Imminent” measure pair (referred to as Measure 2) revealed that the measure did not meet readiness standards for public reporting and additional testing was needed before we could make a decision on the public reporting of Measure 2. Therefore, we decided not to publish Measure 2 of the “Hospice Visits when Death is Imminent” measure pair. See our discussion on our website: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Public-Reporting-Background-and-Announcements.html> for more information.

Although Measure 2 will not be publicly reported, we believe that Measure 2 focuses on an important aspect of quality care for imminently dying patients. Therefore, we will include quality performance data on the measure in each hospice’s confidential Quality Measure Reports and the Review and Correct Report available on the Certification and Survey Provider Enhanced Reporting (CASPER) system. Hospices will also still receive credit for reporting on Measure 2 as part of the HQRP requirements. Furthermore, Measure 2 aligns with our Meaningful Measures initiative and its quality priorities, particularly “Strengthen Person and Family Engagement as Partners in Their Care—End of Life Care according to Preferences.” While Measure 1 of the “Hospice Visits when Death is Imminent” measure pair (referred to as Measure 1) addresses case management and clinical care, Measure 2, which includes visits from social workers, chaplains or spiritual counselors, licensed practical nurses, and aides, recognizes providers’ flexibility to provide individualized care from a variety of disciplines that is in line with the patient, family, and caregiver’s preferences and goals for care and contributes to the overall well-being of the individual and others important to them at the end of life. As such, we believe that Measure 2 addresses a high-priority measure area where there is significant opportunity for improvement, as well as is meaningful to patients, clinicians, and providers alike.

We will conduct additional testing on Measure 2 to determine if and how the measure specifications may be modified or re-specified, and if the method for

displaying the measure may be adjusted, so that this measure meets the highest standards of scientific acceptability and reportability. Additional testing will also ensure that Measure 2 is thoroughly evaluated to determine that it meets the criteria for public reporting.

The results of the additional testing will inform the next steps regarding the public reporting of Measure 2 of “Hospice Visits when Death is Imminent” measure pair. As stated in the FY 2019 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements (83 FR 38643), we will inform providers of updates to testing and public reporting of quality measures, including Measure 2 of the “Hospice Visits when Death is Imminent” measure pair, through sub-regulatory channels and regular HQRP communication strategies, such as Open Door Forums, Medicare Learning Network, CMS.gov website announcements, listserv messaging, and other opportunities. We will announce any policy changes through the notice and comment rulemaking process.

Our decision not to publicly report Measure 2 of the “Hospice Visits when Death is Imminent” measure pair at this time is distinct from our interest in continuing collecting these data. Specifically, these data are needed to determine whether a measure meets all the criteria for public reporting. Continued data collection will enable us to test and modify or re-specify a measure so that these criteria are satisfied. We seek to balance these data collection effort with the section 1814(i)(5)(E) of the Act, which states, “The Secretary shall report quality measures that relate to hospice care provided by hospice programs on the internet website of the Centers for Medicare & Medicaid Services.” We believe that information required for the robust analyses to further develop this measure, modify or re-specify it to allow for public reporting justifies continuing data collection.

The data collection and submission requirements for the “Hospice Visits When Death is Imminent” measure pair will not change in order to collect the data for measure 1, which will be publicly reported beginning with FY 2019. Measure 2, which will not be publicly reported at this time, needs to be further evaluated for modification or re-specification. Measure 2 of “Hospice Visits when Death is Imminent” measure pair is calculated using items O5010, O5020 and O5030 from the HIS V2.00.0. These items collect data on hospice visits in the final 3 days of life, level of care in the final 7 days of life, and hospice visits in the three to six

days prior to death. Because the measure is not being removed from the HQRP, providers should continue to complete these items accurately and completely and submit HIS records to us in a timely manner. We require data from Section O to calculate Hospice Visits when Death is Imminent Measure 1, which will be publicly reported beginning in August 2019. Therefore, we proposed continued collection of this data to complete additional testing and to make a determination about the public reporting of Measure 2 of the “Hospice Visits when Death is Imminent” measure pair. We expect to complete our analysis by the end of FY 2020, and determine next steps for public reporting based on meeting established standards for reliability, validity, and reportability.

We are cognizant and respectful of the time and effort that hospices take to complete the HIS V2.00.0 items used to calculate and test Measure 2. We will continually evaluate the volume and robustness of the resulting data to determine when data collection is no longer required.

Comments: We received support from several commenters for our proposal to continue data collection of relevant data to support testing through September 30, 2020. We also received support for continued testing of Measure 2 of the “Hospice Visits when Death is Imminent” measure pair to evaluate if it should be publicly-reported.

Some commenters also confirmed the value of visit information for quality purposes. In addition, commenters provided suggestions for modifying Measure 2. These included addressing higher levels of care and short lengths of stay, including RN visits in the definition, and capturing whether patients and their families declined a visit during the last days of life, potentially through skip logic. Some commenters stated that Measure 1 and Measure 2 were paired metrics that should be reported together. A few commenters noted location of care and rural versus urban settings as factors that could affect measure results.

Response: We appreciate the commenters’ feedback and support for our plans to continue data collection and testing to assess options for assuring this measure meets the highest standards of scientific acceptability and reportability for public reporting. We intend to consider commenters’ specific suggestions during our testing process for this quality measure. We note that we do include urban and rural issues and location of care as we develop, modify, or re-specify this and other measures. Overall, we have found that

there is no statistical difference between the visits in urban versus rural locations and this is further supported by the literature³⁹ that supports this position.

The two visit measures are referred to as paired because they relate to the same topic of measuring visits in the last days of life by hospice disciplines. However, the measures are independent constructs and can be reported separately. The measures are each developed using different number of visits and different hospice disciplines. They are unique measures that each provide useful and distinct information for separate public reporting.

Final Decision: After considering the comments received in response to the proposed rule and for the reasons discussed in the above paragraph, we are finalizing our proposal to continue collection of this data to complete additional testing and to make a determination about the public reporting of Measure 2 of the “Hospice Visits when Death is Imminent”

measure pair. We expect to complete our analysis by the end of FY 2020, and determine next steps for public reporting based on meeting established standards for reliability, validity, and reportability. We will continue to use a variety of sub-regulatory channels and regular HQRP communication strategies, such as Open Door Forums, Medicare Learning Network, CMS.gov website announcements, listserv messaging, and other opportunities, to provide ongoing updates of testing results and our plans for modifying and reporting this measure.

c. Display of Publicly Available Government Data Along With CMS and Medicare Hospice Related Data as Information for Public Reporting

1. Update To Posting of Public Use File (PUF) Data as Information for Public Reporting

In the FY 2019 Hospice Wage Index and Payment Rate Update and Hospice

Quality Reporting Requirements (83 FR 38649), we finalized plans to publicly post information from the Medicare Provider Utilization and Payment Data: Physician and Other Supplier Public Use File (PUF) and other publicly available CMS data to the Hospice Compare or other CMS website. This PUF data, along with clear text explaining the purpose and uses of this information and suggesting consumers discuss this information with their healthcare provider, displayed under a new section on Hospice Compare in May 2019. This new section precede the existing “Family Experience of Care” section on the Hospice Compare website. Tables 16 through 18 show how these data displayed on Hospice Compare.

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Table 16: Mock-up of Level of Care Provided Information on Hospice Compare

Level of care provided in calendar years 2014, 2015, and 2016	Hospice A Average Daily Census: 345 Date Certified: 04/01/1995	Hospice B Average Daily Census: 67 Date Certified: 04/01/2002	Hospice C Average Daily Census: Not available Date Certified: 04/01/2017	National Average Average Daily Census: 74
Provided Routine Home Care <u>only</u>	✓		Not Available	3.1%
Provided Routine Home Care <u>and</u> other levels of care		✓	Not Available	96.9%

Note: Information is “Not Available” for Hospice C because the hospice was Medicare-certified in 2017. PUF data currently are only available through 2016.

³⁹ Teno JM, Plotzke M, Christian T, Gozalo P. Examining Variation in Hospice Visits by

Professional Staff in the Last 2 Days of Life. JAMA

Intern Med. 2016;176(3):364–370. doi:10.1001/jamainternmed.2015.7479

Table 17: Mock-up of Primary Diagnosis Information on Hospice Compare

Medical Conditions	Hospice A Average Daily Census: 345 Date Certified: 04/01/1995	Hospice B Average Daily Census: 67 Date Certified: 04/01/2002	Hospice C Average Daily Census: Not available Date Certified: 04/01/2017	National Average Average Daily Census: 74
Cancer	18.3%	45.6%	Not Available	27.3%
Dementia	45.5%	20.7%	Not Available	21.1%
Stroke	Less than 11 patients	18.9%	Not Available	9.4%
Heart Disease	17.8%		Not Available	20.8%
Respiratory Disease		17.0%	Not Available	11.9%
Other	Less than 11 patients	Less than 11 patients	Not Available	16.1%

Note: Information is “Not Available” for Hospice C because the hospice was Medicare-certified in 2017. PUF data currently are only available through 2016. “Less than 11 patients” indicates the hospice served less than 11 patients with the indicated condition in 2016. Data for hospice providers who served between 0 and 11 patients with a particular condition is not reported in the PUF to protect personal health information and ensure publicly reported data is a reliable indication of services provided by the hospice.

Table 18: Mock-up of Location of Care Information on Hospice Compare

Location	Hospice A Average Daily Census: 345 Date Certified: 04/01/1995	Hospice B Average Daily Census: 67 Date Certified: 04/01/2002	Hospice C Average Daily Census: Not available Date Certified: 04/01/2017	National Average Average Daily Census: 74
Home	✓	✓	Not Available	99.8%
Assisted Living Facility	✓	✓	Not Available	76.1%
Nursing Facility	✓	Less than 11 patients	Not Available	60.8%
Skilled Nursing Facility	Less than 11 patients	✓	Not Available	52.5%
Inpatient Hospital Facility	✓		Not Available	31.5%
Inpatient Hospice Facility		Less than 11 patients	Not Available	17.0%
All other locations	Less than 11 patients	✓	Not Available	17.6%

Note: Information is “Not Available” for Hospice C because the hospice was Medicare-certified in 2017. PUF data currently are only available through 2016. “Less than 11 patients” indicates the hospice served less than 11 patients in the indicated location in 2016. Data for hospice providers who served between 0 and 11 patients in a particular location is not reported in the PUF to protect personal health information and ensure publicly reported data is a reliable indication of services provided by the hospice.

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2. Posting Information From Government Data Sources as Information for Public Reporting

As part of our ongoing efforts to make public reporting more meaningful and informative to our beneficiaries, their caregivers, and families, we propose to publicly post information that utilizes publicly available government data from other agencies, in addition to the data from the PUF or other CMS or Medicare sources, at some time in the future. We propose to use comparative and complementary data from other government sources as part of public reporting on Hospice Compare or other CMS websites in the future and as soon as FY 2020. Examples include information compiled by the U.S. Census Bureau, Centers for Disease Control and Prevention, Bureau of Labor

Statistics, and National Institutes of Health.

We may use information available in these public government files to augment the section described above. This section including PUF data and information from other public government data will provide additional information along with the HQRP measures currently from the HIS and CAHPS® quality measures that are already displayed.

Any future reporting of public government data as information for public reporting will be displayed in a consumer-friendly format on Hospice Compare or other CMS website. This means we may display the data as shown in these publicly available government files or present the data after additional calculations. For example, the data could be averaged over multiple years, displayed as a

percentage rather than the raw number, or other calculations could be based on a given year or over multiple years, so the data has meaning to end-users. Furthermore, by performing these calculations, we can make the data apply to hospices broadly regardless of size, location, or other factors.

Also, we would like to note that data used from these publicly available sources are not quality measures. Rather, they present supplementary information that many consumers seek during the provider selection process and, therefore, will help them to make an informed decision. This is similar to other useful information we already publicly display under the Spotlight, Tools and Tips, and Additional Information sections on the Hospice Compare homepage. Data from publicly available data sources can serve as one more piece of information, along with

quality of care metrics from the HIS and CAHPS® Hospice Survey and other useful information, to help consumers effectively and efficiently compare hospice providers and make an informed decision about their care in a stressful time. We also believe such information may be useful to providers. For example, adding data as information from the U.S. Census Bureau in coordination with this service area from Medicare claims data may help consumers better understand the service area in which they are looking for services (for example, if there is a large population of people from a similar race or ethnicity in the area). This information may also help providers better understand their service area to see if there are any business development opportunities (for example, if there is a large population of a similar race or ethnicity, the provider may consider investing resources in better serving patients from this background).

To ensure that end-users understand that these data provide information about hospice characteristics and are not a reflection of the quality of care a hospice provides, we will, with consultation from key stakeholders, carefully craft explanatory language to ensure that consumers understand the information and how the data are meant for informational purposes only.

As we determine which publicly available government data sources we will use and how we will be using and presenting information from these sources, we will inform the public and engage with stakeholders via sub-regulatory processes, including regular HQRP communication strategies such as Open Door Forums, Medicare Learning Network, Spotlight Announcements, and other opportunities.

We solicited public comment on our proposal to post information from publicly available government sources for public reporting in the future.

A summary of those comments and our responses to them appear below:

Comment: Overall commenters supported publicly posting contextual government information to supplement the already posted CMS and Medicare public data, but several requested more detail on the specific information for posting data from other U.S. government websites and how it would be used. Some commenters recommended that there be a correlation between any other U.S. government data and the quality of hospice care or meaningful context of hospice and questioned the sources noted. They also recommended seeking stakeholder input prior to adding information for public reporting and

making sure any posted information was clearly explained.

Response: We appreciate the commenters' support and request for more detail about any additional data from public other U.S. government websites under consideration for posting publicly. We confirm our commitment to using sub-regulatory processes for soliciting and receiving ongoing stakeholder information and feedback as we develop these data. As part of this effort, we will provide mock-ups of the data for stakeholder feedback and show the relationship between the data from other U.S. government websites and hospice related data. The goal is for the information to help consumers in comparing providers. We reiterate our intent to conduct plain language testing, including distinguishing this information from quality data.

Final Decision: After considering the comments received in response to the proposed rule and for the reasons discussed in the above paragraph, we are finalizing our proposal to post information from other publicly-available U.S. government sources to publicly report in the future and as soon as FY 2020 on Hospice Compare or other CMS website.

IV. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment before the provisions of a rule take effect in accordance with section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). However, we can waive this notice and comment procedure if the Secretary finds, for good cause, that the notice and comment process is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons therefore in the rule. This hospice proposed rule has previously been subjected to notice and comment procedures. These corrections do not make substantive changes to this policy. Specifically, we redesignated paragraphs (c) through (f) as paragraphs (d) through (g). This redesignation would affect two cross-references in § 418.26(c) (2) and § 418.28(c) (2). As a result, we made conforming changes to accompany the redesignations in § 418.24. Likewise, at § 418.3, we define the term BFCC-QIO as the Beneficiary and Family Centered Care Quality Improvement Organization. Because these conforming changes were not proposed in the proposed rule, we are adopting them here under a "good cause" waiver of proposed rulemaking. The specific changes we are making in

the regulations simply codify the final policies we described in the proposed rule and do not reflect any additional substantive changes. Therefore, we find that undertaking further notice and comment procedures to incorporate these corrections into the final rule is unnecessary and contrary to the public interest.

V. Collection of Information Requirements

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

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

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 on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. Election Statement Addendum: "Patient Notification of Hospice Non-Covered Items, Services, and Drugs"

To calculate this burden estimate, we use salary information from the Bureau of Labor Statistics (BLS) website at <https://www.bls.gov/> and include a fringe benefits package worth 100 percent of the base salary. The mean hourly wage rates are based on May, 2018 BLS data for each discipline. Table 19 contains our burden estimate assumptions for the proposed Election Statement Addendum: "Patient Notification of Hospice Non-Covered Items, Services, and Drugs" discussed in section III.C. of this final rule. The required addendum would not be required until FY 2021; that is, the addendum would be required, upon

request, for those hospice elections beginning on or after October 1, 2020. This burden estimate represents what the estimated costs would be if implemented in FY 2020. We will re-

estimate this burden in the FY 2021 proposed rule using more recent claims data to more accurately reflect costs for FY 2021 implementation. For the purposes of this estimate, we are

assuming that all beneficiaries electing the hospice benefit, and who do not die within the first 5 days of care, would request the addendum.

TABLE 19—ELECTION STATEMENT ADDENDUM: “PATIENT NOTIFICATION OF HOSPICE NON-COVERED ITEMS, SERVICES, AND DRUGS” BURDEN ESTIMATE ASSUMPTIONS

Number of Medicare-billing hospices, from FY 2017 Medicare Enrollment Database, Provider of Service files.	4,465.
Number of hospice elections in FY 2017	(1,268,497 × 0.72) = 913,318.
Hourly rate of an office employee (Executive Secretaries and Executive Administrative Assistants, 43–6011).	\$59.18 (\$29.59 × 2.00).
Hourly rate of an administrator (General and Operations Managers, 11–1021)	\$119.12 (\$59.56 × 2.00).
Hourly rate of registered nurses (Registered Nurses, 29–1141)	\$72.60 (\$36.30 × 2.00).
Hourly rate of pharmacy technicians (Pharmacy Technicians, 29–2052)	\$32.70 (\$16.35 × 2.00).

Source: FY 2017 hospice claims data. 28 percent of beneficiaries die within the first 5 days of hospice care. Hospices are exempt from completing addendum if beneficiary dies within first the first 5 days of care.

Section 1814(a) (7) of the Act requires for the first 90-day period of a hospice election the individual's attending physician (as defined in section 1861(dd)(3)(B) of the Act) (which for purposes of this subparagraph does not include a nurse practitioner), and the medical director (or physician member of the interdisciplinary group described in section 1861(dd)(2)(B) of the Act) of the hospice program providing (or arranging for) the care, each certify in writing, at the beginning of the period, that the individual is terminally ill (as defined in section 1861(dd)(3)(A) of the Act). The regulations codified at § 418.22 and § 418.25 provide the requirements regarding the certification of terminal illness and admission to hospice care. The hospice medical director must specify that the individual's prognosis is for a life expectancy of 6 months or less if the terminal illness runs its normal course. Additionally, clinical information and other documentation that support the medical prognosis must accompany the certification and must be filed in the medical record with the written certification. The physician must include a brief narrative explanation of the clinical findings that supports a life expectancy of 6 months or less as part of the certification. The aforementioned regulations also require that the hospice medical director must consider both related and unrelated conditions and current clinically relevant information when making the decision to certify the individual as terminally ill. Likewise, the hospice CoPs at § 418.102(b) provide the requirements regarding the certification responsibility of the hospice medical director or hospice physician designee which includes a review of the clinical information, including both related and unrelated conditions, for each hospice patient.

In order to receive hospice services under the Medicare hospice benefit, eligible beneficiaries must elect to receive hospice care by completing an election statement. By signing this election statement, the individual acknowledges that he or she waives all rights to Medicare payments for treatment related to the terminal illness and related conditions. The content requirements for the hospice election statement are listed at § 418.24(b) and each hospice election statement must include the following information:

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

(2) The individual's or representative's acknowledgement that he or she has been given a full understanding of the palliative rather than curative nature of hospice care, as it relates to the individual's terminal illness.

(3) Acknowledgement that certain Medicare services, as set forth in § 418.24(d) of this section, are waived by the election.

(4) The effective date of the election, which may be the first day of hospice care or a later date, but may be no earlier than the date of the election statement.

(5) The signature of the individual or representative.

Once a beneficiary is certified as terminally ill and elects the Medicare hospice benefit, the hospice conducts an initial assessment visit in advance of furnishing care. During this visit, the hospice must provide the patient or representative with verbal and written notice of the patient's rights and responsibilities as required by the CoPs

at § 418.52. Likewise, the regulations at § 476.78 state that providers must inform Medicare beneficiaries at the time of admission, in writing, that the care for which Medicare payment is sought will be subject to Quality Improvement Organization (QIO) review.

The beneficiary needs identified in the initial and comprehensive assessments drive the development and revisions of an individualized written plan of care for each patient as required by the hospice CoPs at § 418.56. The hospice plan of care is established, reviewed and updated by the hospice IDG and must include all services necessary for the palliation and management of the terminal illness and related conditions. While needs unrelated to the terminal illness and related conditions are not the responsibility of the hospice, the hospice may choose to furnish services for those needs regardless of responsibility. However, if a hospice does not choose to furnish services for those needs unrelated to the terminal illness and related conditions, the hospice is to communicate and coordinate with those health care providers who are caring for the unrelated needs, as described in § 418.56(e). In accordance with the CoPs, the hospice must document the services and treatments that address how they will meet the patient and family-specific needs related to the terminal illness and related conditions in the plan of care, and those needs unrelated to the terminal illness and related conditions that are present when the patient elects hospice should also be documented. This documentation ensures that the hospice is aware of those unrelated needs and who is addressing them. This documentation provides the support for the hospices'

financial responsibility for the hospice services they will be providing. There is limited beneficiary financial liability for hospice services upon election of the Medicare hospice benefit. However, for any services received that are unrelated to the terminal illness and related conditions, the beneficiary would incur any associated copayments and coinsurance.

Hospices already are required to review, determine, and document information on unrelated conditions in accordance with the hospice regulations and CoPs. However, to ensure Medicare beneficiaries are provided disclosure of those conditions, items, services, and drugs the hospice has determined to be unrelated to the terminal illness and related conditions at the time of admission, we are finalizing additions to the regulations at § 418.24(b) and (c) for FY 2021, which will require an election statement addendum titled "Patient Notification of Hospice Non-Covered Items, Services, and Drugs" that must be issued, on request, to the patient (or representative) within 5 days of the hospice election date to ensure that Medicare beneficiaries are fully informed whether or not all items, services, and drugs identified on the hospice plan of care will be furnished by the hospice. The addendum statement would not be required if the beneficiary died within 5 days of the hospice election date. This addendum would accompany the hospice election statement and each hospice would use the required proposed elements to develop and design their own addendum to best meet their needs and the requirement. This requirement for payment would be added to the regulations at § 418.24(b) and (c) effective for hospice elections beginning on and after October 1, 2020.

The burden associated with the documentation requirement for the addendum includes the time for each hospice to develop the addendum that the hospice provides to the beneficiary (or their representative) within 5 days of election of the Medicare hospice benefit. The addendum must include the name of the issuing hospice, beneficiary's name, and hospice medical record identifier. The addendum must also allow the hospice registered nurse to document a list of non-covered conditions and associated items, services, and drugs, as well as provide a clinical explanation as to why these conditions and associated items, services, and drugs have been determined to be unrelated to the

terminal illness and related conditions. This documentation would include references to any relevant clinical practice, policy, or coverage guidelines. The addendum must include statements informing the patient as to the purpose of the addendum and information on BFCC-QIO Immediate Advocacy rights and contact information. The addendum would be signed by the beneficiary as an acknowledgement that he or she has received this information, but signing it does not mean the beneficiary agrees with the determination. We believe that the burden for the hospice associated with the election statements addendum would be the cost of developing the form and the cost of filling out the form. There is no associated burden for hospices to communicate/coordinate with non-hospice providers regarding the content of the addendum statement because the hospice CoPs, as described above, have always required hospices to have a system of communication with non-hospice providers in place. However, we believe that the election statement addendum would reduce burden for non-hospice providers through a consistent and streamlined process by which non-hospice providers can make informed treatment decisions and accurately submit claims with the appropriate condition code or modifier.

1. Estimated Hospice Burden With Election Statement Addendum

a. Estimated One-Time Form Development

We estimate a one-time burden for the development of a template election statement addendum. We estimate that it would take a hospice administrative assistant 15 minutes ($15/60 = 0.25$ hours) to develop the addendum with the required elements, and the hospice administrator 15 minutes ($15/60 = 0.25$ hours) to review the addendum. The clerical time plus administrator time equals a one-time burden of 30 minutes or ($30/60 = 0.50$ hours) per hospice. For all 4,465 hospices, the total time required would be ($0.50 \times 4,465$) = 2,232.5 hours. At \$59.18 per hour for an executive administrative assistant, the cost per hospice would be ($0.25 \times \$59.18$) = \$14.80. At \$119.12 per hour for the administrator's time, the cost per hospice would be ($0.25 \times \$119.12$) = \$29.78. Therefore, the one-time cost, per hospice, for the development of the template would be ($\$14.80 + \29.78) = \$44.58, and the total one-time cost for all hospices would be ($\$44.58 \times 4,465$) = \$199,050.

b. Estimated Time for Hospice To Complete Addendum

Per the hospice CoPs at § 418.56(a), the hospice must designate a registered nurse that is a member of the interdisciplinary group to provide coordination of care and to ensure continuous assessment of each patient's and family's needs and implementation of the interdisciplinary plan of care. The hospice CoPs at § 418.54 require that a registered nurse conduct the initial assessment, therefore, the registered nurse would be responsible for completing the addendum for each hospice election as part of the routine admission paperwork. We estimate that there would be 1,268,497 hospice elections in a year based on FY 2017 claims data. Approximately 28 percent of hospice beneficiaries die within the first 5 days after the hospice election date. Hospices would not be required to complete the election statement addendum for those hospice beneficiaries that die within 5 days of hospice election. Therefore, the estimated total number of hospice elections in FY 2020 that would require the hospice election statement addendum would be ($1,268,497 \times 0.72$) = 913,318. There are 4,465 Medicare-certified hospices, so on average there would be ($913,318/4,465$) = 205 hospice elections per hospice. The estimated burden for the hospice registered nurse to extrapolate this information from the existing documentation in the patient's hospice medical record and complete this addendum would be 10 minutes ($10/60 = 0.1667$). At \$72.60 per hour for a registered nurse over 10 minutes ($0.1667 \times \$72.60 = \12.10), we estimate the total cost of RN time to complete the addendum per hospice in FY 2020 to be ($\$12.10 \times 205$) = \$2,481, and the total cost of RN time to complete the addendum for all hospices in FY 2020 would be ($\$2,481 \times 4,465$) = \$11,077,665. The estimated total per hospice and total annual hospice cost associated with the proposed addendum (including one-time form development and total RN costs) in FY 2020 are shown in Table 20 below. These total costs would include the one-time development of the addendum, so subsequent years' costs would only include the cost for the RN to complete the addendum statement. Providing this information to the beneficiary would be part of the routine admissions process and, as such, incurs no additional burden to that process.

Table 20: FY 2020 Estimated Per Hospice and Total Hospice Costs for Election Statement Addendum

	Average # of Elections Per Hospice	Total # of Hospice Elections (based on FY 2017)
Number of Hospice Elections	205	913,318
	Average Cost Per Hospice	Total Annual Costs for All Hospices
Total # of Hospices		4,465
One-time Form Development	\$44.58	\$199,050
RN Form Completion	\$2,481	\$11,077,665
Total Hospice Estimated FY 2020 Costs		\$11,276,715

Source: FY 2017 CWF Claims Data, Medicare Enrollment Database, and Provider of Service (POS). Enrollment data.

2. Estimated Burden Reduction for Non-Hospice Providers

To ensure comprehensive and coordinated care, the CoPs at § 418.56(e) require hospices to have a communication system that allows for the exchange of information with other non-hospice health care providers who are furnishing care unrelated to the terminal illness and related conditions. Therefore, it is our expectation that hospices are already determining what is related and unrelated to the terminal illness and related conditions. The election statement addendum would add no additional burden for communicating with non-hospice providers, as this decision-making process has been a long-standing CoP requirement, as described above and in the preamble of this final rule. However, burden would be reduced for non-hospice providers, including institutional, non-institutional and pharmacy providers because less time would be spent trying to obtain needed information for treatment decisions and accurate claims submissions.

For the calculation of this burden estimate, we did drop those elections where the beneficiary died within the first 5 days. To estimate the cost burden reduction, we first calculated the

estimated current burden, in the absence of the addendum, for communicating and coordinating information regarding unrelated conditions between hospice and non-hospice providers. Next, we calculated the estimated burden, using the addendum for communicating and coordinating information regarding unrelated conditions between hospice and non-hospice providers. Finally, we analyzed the difference between the burden estimates to see if there is any overall reduction. To do this, we analyzed all Medicare Parts A and B non-hospice claims for beneficiaries under a hospice election in FY 2017. We also examined the Part D claims for drugs provided to hospice beneficiaries under a hospice election. Specifically, we analyzed the following:

- The total number of non-hospice, institutional claims with condition code 07 (to indicate the services were unrelated to the terminal illness and related conditions).
- The total number of non-hospice, non-institutional claims with “GW” modifier (to indicate the services were unrelated to the terminal illness and related conditions).
- The total number of Part D claims for beneficiaries under a hospice election.

- The average number of hospice beneficiaries per non-hospice provider with institutional claims with condition code 07.

- The average number of hospice beneficiaries per non-hospice provider with non-institutional claims with “GW” modifier.

- The average number of hospice beneficiaries per non-hospice provider with Part D claims.

To calculate the average number of hospice beneficiaries per non-hospice provider, we count the number of unique beneficiaries associated with each non-hospice provider as beneficiaries may receive services by more than one non-hospice provider. This means that some beneficiaries are double-counted. However, given this estimate is calculated based on the number of expected communication encounters between hospices and non-hospice providers, this is the appropriate approach. Because we double-counted beneficiaries, we expect that average to be larger than the ratio of unique beneficiaries to unique non-hospice providers. Table 21 below summarizes Part A, B and D claims that overlap with hospice episodes in FY 2017.

Table 21: Summary of Part A, B and D Claims that Overlap with Hospice Episodes, FY 2017

Non-Hospice Claim Type	# of Hospice Beneficiaries	# of Non-Hospice Providers	# of Hospice Providers	Average # of Hospice Benes per Non-hospice Provider
Part A & B, Non-Hospice Total	462,308	94,159	4,341	
Institutional Claims w/ 07	171,055	19,226	4,114	11.0
Non-Institutional Lines w/ GW	421,546	74,933	4,322	11.0
Part D	591,543	60,632	4,416	12.0

Source: FY 2017 Parts A, B, and D claims.

3. Burden Estimate Without Election Statement Addendum for Non-Hospice Providers

In order for non-hospice providers to make treatment decisions regarding services, items, and drugs for hospice beneficiaries and to submit the appropriate modifier or condition code on Medicare claims, they need supporting information from the hospice regarding related and unrelated conditions. As such, we first estimate the current burden associated with this communication and coordination in the absence of the election statement addendum. We believe this would require the non-hospice providers to contact the hospice and have a detailed phone call to obtain and document the information on unrelated conditions, items, services, and medications. For non-hospice providers submitting institutional claims (including inpatient acute care hospitals, SNFs, HHAs, and institutional outpatient providers), typically nurse case managers provide coordination of care for those beneficiaries in these settings who are receiving inpatient services or who are preparing to transition to a post-acute care setting or home. The estimated burden for the registered nurse to contact the hospice to obtain the needed information would be 15 minutes (15/60 = 0.25). The average number of hospice beneficiaries receiving services per institutional, non-hospice provider is 11 per year, which would mean each institutional, non-hospice provider would have an average of 11 communication encounters with hospice. The total number of institutional, non-hospice providers servicing hospice beneficiaries in FY 2017 was 19,226. At \$72.60 per hour for a registered nurse ($0.25 \times \$72.60$) = \$18.15, we estimate the total cost per institutional, non-hospice provider furnishing services to hospice beneficiaries in FY 2020 to be $(\$18.15 \times$

11) = \$199.65 and the annual total cost for all institutional, non-hospice providers in FY 2018 would be $(\$199.65 \times 19,226) = \$3,838,471$.

For non-institutional, non-hospice providers (including physicians), we also expect that a nurse would contact the hospice to obtain the needed clinical information on unrelated conditions, items, services and drugs. The estimated burden for the registered nurse to contact the hospice to obtain the needed information would be 15 minutes (15/60 = 0.25). The average number of hospice beneficiaries receiving services per non-institutional, non-hospice provider is 11 per year, which would mean each provider would have an average of 11 communication encounters with a hospice. The total number of non-institutional, non-hospice providers servicing hospice beneficiaries in FY 2017 was 74,933. At \$72.60 per hour for a registered nurse ($0.25 \times \$72.60$) = \$18.15, we estimate the total cost per non-institutional, non-hospice provider furnishing services to hospice beneficiaries in FY 2020 to be $(\$18.15 \times 11) = \199.65 and the annual total cost for all non-institutional, non-hospice providers in FY 2018 would be $(\$199.65 \times 74,933) = \$14,960,373$.

For pharmacies dispensing Part D drugs to hospice beneficiaries, the estimated burden for the pharmacy technician at the point of service to contact the hospice to obtain the needed clinical information regarding the drugs deemed by the hospice as unrelated to the terminal illness and related conditions would be 15 minutes (15/60 = 0.25). The average number of hospice beneficiaries receiving services per pharmacy dispensing Part D maintenance drugs is 12 per year, which would mean each pharmacy would have an average of 12 communication encounters with hospice. The total number of pharmacies dispensing Part D maintenance drugs to hospice

beneficiaries in FY 2017 was 60,632. At \$32.70 per hour for a pharmacy technician ($0.25 \times \$32.70$) = \$8.18, we estimate the total cost per pharmacy dispensing Part D maintenance drugs to be $(\$8.18 \times 12) = \98.16 and the annual total cost for all pharmacies dispensing Part D maintenance drugs to be $(\$98.16 \times 60,632) = \$5,951,637$. The estimated total annual burden for all non-hospice providers furnishing services, items and medications to hospice beneficiaries in FY 2020 without the availability of the hospice election statement addendum identifying unrelated conditions, items, services and drugs would be \$24,750,481 ($\$3,838,471 + \$14,960,373 + \$5,951,637$).

4. Burden Reduction Estimate With Election Statement Addendum for Non-Hospice Providers

However, with the availability of the "Patient Notification of Hospice Covered/Non-Covered Items, Services, and Drugs" election statement addendum, we believe this estimated burden would be reduced for non-hospice providers through a streamlining of the communication and coordination process. For institutional, non-hospice providers (those who would submit claims for unrelated services with condition code 07), the estimated burden for the registered nurse to contact the hospice to obtain the needed information would be reduced from 15 minutes in the absence of the addendum to 5 minutes (5/60 = 0.0833). The average number of hospice beneficiaries receiving services per institutional non-hospice provider is 11 per year. The total number of institutional non-hospice providers servicing hospice beneficiaries in FY 2017 was 19,226. At \$72.60 per hour for a registered nurse ($0.0833 \times \$72.60$) = \$6.05, we estimate the total cost per institutional non-hospice provider in FY 2020 to be $(\$6.05 \times 11) = \66.55 and the

annual total cost for all institutional non-hospice providers in FY 2020 would be $(\$66.55 \times 19,226) = \$1,279,490$ an annual decrease in burden by $(\$3,838,471 - 1,279,490) = \$2,558,981$.

For non-institutional, non-hospice providers (those who would submit claims for unrelated services with modifier GW), the estimated burden for the registered nurse to contact the hospice to obtain the needed information would be reduced to 5 minutes ($5/60 = 0.0833$). The average number of hospice beneficiaries receiving services per non-institutional, non-hospice provider is 11 per year. The total number of non-institutional, non-hospice providers servicing hospice beneficiaries in FY 2017 was 74,933. At \$72.60 per hour for a registered nurse ($0.0833 \times \$72.60$) = \$6.05, we estimate the total cost per non-institutional, non-hospice provider in FY 2020 to be $(\$6.05 \times 11) = \66.55 and the annual

total cost for all non-institutional, non-hospice providers in FY 2020 would be $(\$66.55 \times 74,933) = \$4,986,791$, an annual decrease in burden by $(\$14,960,373 - 4,986,791) = \$9,973,582$.

For pharmacies dispensing Part D drugs to hospice beneficiaries, the estimated burden for the pharmacy technician at the point of service to contact the hospice to obtain the needed clinical information regarding the drugs deemed by the hospice as unrelated to the terminal illness and related conditions would be reduced to 5 minutes ($5/60 = 0.0833$). The average number of hospice beneficiaries receiving services from pharmacies dispensing Part D maintenance drugs is 12 per year. The total number of pharmacies dispensing Part D maintenance drugs to hospice beneficiaries in FY 2017 was 60,632. At \$32.70 per hour for a pharmacy technicians ($0.0833 \times \$32.70$) = \$2.72,

we estimate the total cost per pharmacies dispensing Part D maintenance drugs to be $(\$2.72 \times 12) = \32.64 and the annual total cost for all pharmacies dispensing Part D maintenance drugs to be $(\$32.64 \times 60,632) = \$1,979,028$, an annual decrease in burden by $(\$5,951,637 - \$1,979,028) = \$3,972,609$. The estimated total annual burden for all non-hospice providers furnishing services, items and drugs to hospice beneficiaries in FY 2020 with the availability of the hospice election statement addendum identifying unrelated conditions, items, services and medication would be \$8,245,309 $(\$1,279,490 + \$4,986,791 + \$1,979,028)$ for an overall burden reduction of $(\$24,750,481 - \$8,245,309) = \$16,505,172$. The total reduction in burden for all institutional, non-institutional, and Part D pharmacy non-hospice providers is summarized in Table 22 below.

Table 22: FY 2020 Estimated Total Overall Burden Reduction for Non-Hospice Providers Using Election Statement Addendum

Non-hospice Claims	Burden without Addendum	Burden with Addendum	Estimated Burden Reduction For Non-Hospice Providers with Use of the Addendum*
Institutional Claims with Condition Code 07	\$3,838,471	\$1,279,490	\$2,558,981
Non-institutional Claims with GW Modifier	\$14,960,373	\$4,986,791	\$9,973,582
Part D Maintenance Drugs	\$5,951,637	\$1,979,028	\$3,972,609
Total Burden Reduction for Non-Hospice Providers	\$24,750,481	\$8,245,309	\$ 16,505,172

***Note:** Estimated Burden Reduction for Non-hospice Providers with Use of the Addendum= Burden without Addendum (column 2) minus Burden with Addendum (column 3).

The use of the "Patient Notification of Hospice Non-Covered Items, Services, and Drugs" election statement

addendum would result in an estimated, annual net reduction in burden of \$5,228,457 $(\$11,276,715 - \$16,505,172)$

in FY 2020. Table 23 below summarizes the FY 2020 estimated total burden reduction.

Table 23: FY 2020 Estimated Total Provider Burden Reduction Using Election Statement Addendum

FY 2020 Estimated Hospice Burden for Election Statement Addendum	\$11,276,715
FY 2020 Estimated Non-hospice Provider Burden Reduction	\$16,505,172
FY 2020 Estimated Annual Net Reduction in Burden	\$5,228,457

B. Comments

We note that many commenters stated that CMS underestimated the amount of time it would take for the nurse to complete the addendum stating that 10 minutes is an insufficient amount of time to extrapolate this information from the existing documentation. A few commenters stated that this would take between 20 and 30 minutes to complete. Others stated that this is not just a process of extrapolating the information, but that this is often a process of information gathering as not all relevant information is readily available at the time of the initial assessment. However, a few commenters believed that even though the timeframe to complete the addendum would be longer than 10 minutes, they suggested that the addendum should not be optional but patients (or their representatives) should be provided this detailed list as this is critical to the care process, patient empowerment, quality of care, and transparency. However, we remind hospices that the addendum is only required if the beneficiary (or representative) requests this information, though for purposes of this burden reduction estimate we calculate it as if every eligible beneficiary requests the addendum. Additionally, there are those hospices that will cover all items, services, and drugs, and therefore, this would further reduce the number of hospice elections in which the addendum would be provided. Furthermore, if a beneficiary requests the addendum at the time of hospice election but dies within 5 days, the hospice would not be required to furnish the addendum and the requirement would be deemed as having being met in this circumstance.

C. Submission of PRA-Related Comments

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

To obtain copies of the supporting statement and any related forms for the proposed collections previously discussed, visit our website at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>, or call the Reports Clearance Office at (410) 786-1326.

VI. Regulatory Impact Analysis*A. Statement of Need*

This final rule meets the requirements of our regulations at § 418.306(c) and (d), which require 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), as well as any changes to the methodology for determining the per diem payment rates. This final rule also updates payment rates for each of the categories of hospice care, described in § 418.302(b), for FY 2020 as required under section 1814(i)(1)(C)(ii)(VII) of the Act. The payment rate updates are subject to changes in economy-wide productivity as specified in section 1886(b)(3)(B)(xi)(II) of the Act. Lastly, 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 would result in an estimated increase of \$520 million in payments to hospices, resulting from the hospice payment update percentage of 2.6 percent for FY 2020. Section 1814(i)(6)(D)(ii) of the Act requires the final rebasing of the per diem payment rates for CHC, GIP, and IRC to be done in a budget-neutral manner in the first year of implementation. Therefore, the final rebased rates for CHC, GIP, and IRC would not result in an overall payment impact for the Medicare program as we are finalizing the reduction of the RHC payment rates to ensure that total estimated payments to hospices are budget-neutral given the increases to the CHC, GIP, and IRC payment rates. In addition, the final change in the hospice wage index to use the FY 2020 pre-floor, pre-reclassified hospital wage index (rather than the FY 2019 pre-floor, pre-reclassified hospital wage index) as the basis for the FY 2020 hospice wage index would not result in an overall payment impact for the Medicare program as annual wage index updates are now similarly implemented in a budget-neutral manner. 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 (RFA) (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 2020 hospice payment update percentage results in an overall increase in estimated hospice payments of 2.6 percent, or \$520 million. The distributional effects of the final FY 2020 hospice wage index do not result in a greater than 5 percent of hospices experiencing decreases in payments of 3 percent or more of total revenue. Finally, the distributional effects of the final FY 2020 increases to the CHC, IRC, and GIP per diem payment rates as a result of rebasing, offset by a decrease to the FY 2020 RHC payment rates of less than 3 percent to maintain budget neutrality in the first year of implementation, do not result in a greater than 5 percent of hospices experiencing decreases in payments of 3 percent or more of total revenue. Therefore, the Secretary has determined that this rule will not create a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Social Security 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 rule will only affect hospices. Therefore, the Secretary has determined that this 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. The 2019 UMRA threshold is \$154 million. This rule is not anticipated to have an effect on state, local, or tribal governments, in the aggregate, or on the private sector of \$154 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 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 past commenters would be a fair estimate of the number of reviewers of this final rule.

Using the wage information from the Bureau of Labor Statistics (BLS) for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is \$107.38 per hour, including overhead and fringe benefits (https://www.bls.gov/oes/current/oes_nat.htm). This final rule consists of approximately 57,000 words in its entirety. Assuming an average reading speed of 250 words per minute, it would take approximately 2 hours for the staff to review half of it. For each hospice that reviews the rule, the estimated cost is approximately \$215.00 (2 hours × \$107.38). Therefore, we estimate that the total cost of reviewing this regulation is \$32,250 (\$215.00 × 150 reviewers).

D. Detailed Economic Analysis

1. Hospice Payment Update for FY 2020

The FY 2020 hospice payment impacts appear in Table 24. We tabulate the resulting payments according to the classifications (for example, provider type, geographic region, facility size), and compare the difference between current and future payments to determine the overall impact. The first column shows the breakdown of all hospices by provider type and control (non-profit, for-profit, government, other), facility location, facility size. The

second column shows the number of hospices in each of the categories in the first column. The third column shows the effects of applying the final rebased payment rates of CHC, IRC, and GIP (and the decreased RHC rate used to achieve budget neutrality). The fourth column shows the hospice payments using FY 2018 Hospice Claims, FY 2020 rebased Payments, and FY 2020 Wage Index without the 1-Year lag. The fifth column show the final FY 2020 hospice payment update percentage of 2.6 percent as mandated by section 1814(i)(1)(C) of the Act, and is consistent for all providers. The 2.6 percent hospice payment update percentage is based on an estimated 3.0 percent inpatient hospital market basket

update, reduced by a 0.4 percentage point productivity adjustment. It is projected that aggregate payments would increase by 2.6 percent, assuming hospices do not change their service and billing practices. The sixth column shows the total impact for FY 2020. We have set the rates so the overall impact is zero percent due to the requirement that any revisions in payment are implemented in a budget-neutral manner in accordance with section 1814(i)(6)(D)(ii) of the Act (accomplished by rebasing the CHC, GIP, and IRC payment rates by a corresponding decrease to the RHC payment rates).

In addition, to assist providers in understanding the impacts of the final wage index without the lag and the

rebasings of CHC, IRC, and GIP, we are providing a provider-specific impact analysis file, which is available on our website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Hospice-Regulations-and-Notices.html>. We note that simulated payments are based on utilization in FY 2018 as seen on Medicare hospice claims (accessed from the CCW in May 2019) and only include payments related to the level of care and do not include payments related to the service intensity add-on.

As illustrated in Table 24, the combined effects of all the proposals vary by specific types of providers and by location.

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Table 24: Impact to Hospices for FY 2020

	Hospices	Rebasing of CHC, IRC, and GIP	FY 2020 Updated Wage Data Without the 1 Year Lag	FY 2020 Hospice Payment Update Percentage	Total Impact for FY 2020
All Hospices	4,599	0.0%	0.0%	2.6%	2.6%
Hospice Type and Control					
Freestanding/Non-Profit	602	1.4%	0.0%	2.6%	4.0%
Freestanding/For-Profit	2,843	-0.8%	0.0%	2.6%	1.8%
Freestanding/Government	39	0.0%	-0.3%	2.6%	2.3%
Freestanding/Other	325	0.2%	0.1%	2.6%	2.9%
Provider/HHA-Based/Non-Profit	396	0.7%	-0.1%	2.6%	3.2%
Provider/HHA-Based/For-Profit	196	-1.3%	-0.1%	2.6%	1.2%
Provider/HHA-Based/Government	101	0.4%	-0.1%	2.6%	2.9%
Provider/HHA-Based/Other	97	0.6%	0.1%	2.6%	3.3%
Subtotal: Freestanding Provider Type	3,809	0.0%	0.0%	2.6%	2.6%
Subtotal: Provider/HHA Based Provider Type	790	0.2%	-0.1%	2.6%	2.7%
Subtotal: Non-Profit	998	1.2%	0.0%	2.6%	3.8%
Subtotal: For Profit	3,039	-0.8%	0.0%	2.6%	1.8%
Subtotal: Government	140	0.2%	-0.2%	2.6%	2.6%
Subtotal: Other	422	0.3%	0.1%	2.6%	3.0%
Hospice Type and Control: Rural					
Freestanding/Non-Profit	154	0.4%	0.2%	2.6%	3.2%
Freestanding/For-Profit	329	-1.7%	-0.1%	2.6%	0.8%
Freestanding/Government	20	-0.9%	-0.3%	2.6%	1.4%
Freestanding/Other	45	-1.3%	0.0%	2.6%	1.3%
Provider/HHA-Based/Non-Profit	157	0.6%	-0.2%	2.6%	3.0%
Provider/HHA-Based/For-Profit	47	-1.6%	-0.2%	2.6%	0.8%
Provider/HHA-Based/Government	74	-0.7%	0.0%	2.6%	1.9%
Provider/HHA-Based/Other	54	-0.5%	0.3%	2.6%	2.4%
Hospice Type and Control: Urban					
Freestanding/Non-Profit	448	1.5%	0.0%	2.6%	4.1%
Freestanding/For-Profit	2,514	-0.7%	0.0%	2.6%	1.9%
Freestanding/Government	19	0.2%	-0.3%	2.6%	2.5%
Freestanding/Other	280	0.3%	0.1%	2.6%	3.0%
Provider/HHA-Based/Non-Profit	239	0.7%	0.0%	2.6%	3.3%
Provider/HHA-Based/For-Profit	149	-1.3%	-0.1%	2.6%	1.2%
Provider/HHA-Based/Government	27	1.4%	-0.2%	2.6%	3.8%
Provider/HHA-Based/Other	43	0.9%	0.0%	2.6%	3.5%

Hospice Location: Urban or Rural					
Rural	880	-0.8%	0.0%	2.6%	1.8%
Urban	3,719	0.1%	0.0%	2.6%	2.7%
Hospice Location: Region of the Country (Census Division)					
New England	158	0.0%	-0.7%	2.6%	1.9%
Middle Atlantic	282	0.2%	-0.2%	2.6%	2.6%
South Atlantic	558	2.0%	-0.1%	2.6%	4.5%
East North Central	546	0.1%	-0.1%	2.6%	2.6%
East South Central	264	-0.4%	-0.2%	2.6%	2.0%
West North Central	406	-1.5%	0.3%	2.6%	1.4%
West South Central	887	-0.5%	-0.1%	2.6%	2.0%
Mountain	462	-0.6%	0.1%	2.6%	2.1%
Pacific	990	-1.5%	0.6%	2.6%	1.7%
Outlying	46	-2.7%	-0.2%	2.6%	-0.3%
Hospice Size					
0 - 3,499 RHC Days (Small)	1,004	-1.0%	0.2%	2.6%	1.8%
3,500-19,999 RHC Days (Medium)	2,131	-1.1%	0.0%	2.6%	1.5%
20,000+ RHC Days (Large)	1,464	0.3%	0.0%	2.6%	2.9%

Source: FY 2018 hospice claims data as of May 21, 2019 from the CCW RIFs, accessed May 2019.

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

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2. Hospice Election Statement Addendum

This final rule includes requirements related to the election statement addendum that must be provided, upon request, to hospice beneficiaries (or representative), non-hospice providers, and Medicare contractors. This change is effective for hospice elections on and after October 1, 2020. The burden estimate for hospices to develop and complete the election statement addendum is provided in section V of this final rule. However, the election statement addendum adds no additional burden for communicating with non-hospice providers, as this decision-making process has been a long-standing CoP requirement, as described in the preamble of this rule. Furthermore, burden would be reduced for non-hospice providers, including institutional, non-institutional and

pharmacy providers because less time would be spent trying to obtain needed information for treatment decisions and accurate claims submissions. As a result of this election statement addendum, we estimate that this rule generates \$5.2 million in an annualized net reduction in burden, or \$3.7 million per year on an ongoing basis discounted at 7 percent relative to year 2016, over a perpetual time horizon beginning in FY 2021. The burden reduction estimate for the addendum is detailed in section V of this final rule and the total annual reduction is included in Table 25.

E. Accounting Statement

As required by OMB Circular A-4 (available at: <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>), in table 25, we have prepared an accounting statement showing the classification of the transfers and costs associated with the provisions of this

final rule. This table shows an estimated \$520 million in transfers to hospices in FY 2020. All expenditures are classified as transfers to hospices. Table 25 also reflects the estimated change in costs and burden for hospices and non-hospice providers as a result of the finalized election statement addendum requirements described in section III.C. Table 20 provides our best estimate of a one-time burden for hospices to develop the election statement addendum form of approximately 2,233 hours or \$199,050, as well as our estimate of the annual burden for hospices to complete the election statement addendum of approximately 746 hours or \$11 million for an estimated total burden for hospices of \$11.2 million, as described in section IV of this final rule. Additionally, we estimate a net reduction in burden for non-hospice providers of approximately 25,900 hours or \$16.5 million (see section IV of this final rule) for an

estimated overall, annualized net
reduction in burden with the proposed

election statement addendum of \$5.2
million.

**Table 25 -- Accounting Statement: Classification of Estimated Transfers and Costs,
From FY 2019 to FY 2020**

Category	Transfers
Annualized Monetized Transfers	\$ 520 million*
From Whom to Whom?	Federal Government to Medicare Hospices
Category	Costs
Annualized Monetized Net Reduction in Burden for Non-Hospice Providers with the Proposed Regulations Change at § 418.24, Election Statement Addendum	\$16.5 million
Annualized Net Burden for Hospice Providers with the One-time Form Development and Completion of Election Statement Addendum	\$11.2 million
Total Annualized Net Reduction In Burden with the Proposed Election Statement Addendum	\$5.2 million**

* The net increase of \$520 million in transfer payments is a result of the 2.6 percent hospice payment update compared to payments in FY 2019

**The total net reduction does not equal the sum of rounded components.

F. Regulatory Reform Analysis Under E.O. 13771

Executive Order 13771, entitled “Reducing Regulation and Controlling Regulatory Costs,” was issued on January 30, 2017 (82 FR 9339, February 3, 2017) and requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” This final rule is expected to be an E.O. 13771 deregulatory action with \$5.2 million in an annualized net reduction in burden, or \$3.7 million per year on an ongoing basis discounted at 7 percent relative to year 2016, over a perpetual time horizon beginning in FY 2021. The burden reduction for the addendum is detailed in section V of this final rule and the total annual net reduction in burden is included in Table 25. Details on the estimated net reduction in burden of this rule can be found in the rule’s collection of information and economic analysis.

G. Conclusion

We estimate that aggregate payments to hospices in FY 2020 will increase by \$520 million, or 2.6 percent, compared to payments in FY 2019. We estimate that in FY 2020, hospices in urban and rural areas will experience, on average, 2.7 percent and 1.8 percent increases, respectively, in estimated payments compared to FY 2019. Hospices providing services in the South Atlantic, Middle Atlantic, and East North Central regions would experience the largest estimated increases in payments of 4.5 percent, 2.6 percent, and 2.6 percent, respectively. Hospices serving patients in the West North Central and outlying regions would experience, on average, the lowest estimated increase of 1.4 percent and -0.3 percent, respectively in FY 2020 payments. We are finalizing the modifications to the election statement including the election statement addendum in this final rule with an implementation date of October 1, 2020 to allow hospices additional time to make the necessary changes to meet these requirements. We also estimate an overall net reduction in burden of \$5.2

million beginning in FY 2021 as a result of the finalized election statement addendum. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 418

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

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

PART 418—HOSPICE CARE

■ 1. The authority citation for part 418 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 418.3 is amended by adding the definition of “BFCC–QIO” to read as follows:

§ 418.3 Definitions.

* * * * *

BFCC-QIO means Beneficiary and Family Centered Care Quality Improvement Organization.

* * * * *

- 3. Section 418.24 is amended by —
- a. Revising paragraphs (b)(2) and (3);
- b. Redesignating paragraph (b)(5) as paragraph (b)(8);
- c. Adding new paragraphs (b)(5), (6), and (7);
- d. Redesignating paragraphs (c) through (f) as paragraphs (d) through (g) respectively; and
- e. Adding a new paragraph (c).

The revisions and additions read as follows:

§ 418.24 Election of hospice care.

* * * * *

(b) * * *

(2) The individual's or representative's acknowledgement that he or she has been given a full understanding of the palliative rather than curative nature of hospice care, as it relates to the individual's terminal illness and related conditions.

(3) Acknowledgement that the individual has been provided information on the hospice's coverage responsibility and that certain Medicare services, as set forth in paragraph (e) of this section, are waived by the election. For Hospice elections beginning on or after October 1, 2020, this would include providing the individual with information indicating that services unrelated to the terminal illness and related conditions are exceptional and unusual and hospice should be providing virtually all care needed by the individual who has elected hospice.

* * * * *

(5) For Hospice elections beginning on or after October 1, 2020, the Hospice must provide information on individual cost-sharing for hospice services.

(6) For Hospice elections beginning on or after October 1, 2020, the Hospice must provide notification of the individual's (or representative's) right to receive an election statement addendum, as set forth in paragraph (c) of this section, if there are conditions, items, services, and drugs the hospice has determined to be unrelated to the individual's terminal illness and related conditions and would not be covered by the hospice.

(7) For Hospice elections beginning on or after October 1, 2020, the Hospice must provide information on the Beneficiary and Family Centered Care Quality Improvement Organization

(BFCC-QIO), including the right to immediate advocacy and BFCC-QIO contact information.

* * * * *

(c) *Content of hospice election statement addendum.* For Hospice elections beginning on or after October 1, 2020, in the event that the hospice determines there are conditions, items, services, or drugs that are unrelated to the individual's terminal illness and related conditions, the individual (or representative), non-hospice providers furnishing such items, services, or drugs, or Medicare contractors may request a written list as an addendum to the election statement. If the election statement addendum is requested at the time of initial hospice election (that is, at the time of admission to hospice), the hospice must provide this information, in writing, to the individual (or representative) within 5 days from the date of the election. If this addendum is requested during the course of hospice care (that is, after the hospice election date), the hospice must provide this information, in writing, within 72 hours of the request to the requesting individual (or representative), non-hospice provider, or Medicare contractor. If there are any changes to the content on the addendum during the course of hospice care, the hospice must update the addendum and provide these updates, in writing, to the individual (or representative). The election statement addendum must include the following:

(1) The addendum must be titled "Patient Notification of Hospice Non-Covered Items, Services, and Drugs."

(2) Name of the hospice.

(3) Individual's name and hospice medical record identifier.

(4) Identification of the individual's terminal illness and related conditions.

(5) A list of the individual's conditions present on hospice admission (or upon plan of care update) and the associated items, services, and drugs not covered by the hospice because they have been determined by the hospice to be unrelated to the terminal illness and related conditions.

(6) A written clinical explanation, in language the individual (or representative) can understand, as to why the identified conditions, items, services, and drugs are considered unrelated to the individual's terminal illness and related conditions and not needed for pain or symptom management. This clinical explanation must be accompanied by a general

statement that the decision as to whether or not conditions, items, services, and drugs are related is made for each patient and that the individual should share this clinical explanation with other health care providers from which they seek items, services, or drugs unrelated to their terminal illness and related conditions.

(7) References to any relevant clinical practice, policy, or coverage guidelines.

(8) Information on the following:

(i) *Purpose of Addendum.* The purpose of the addendum is to notify the individual (or representative), in writing, of those conditions, items, services, and drugs the hospice will not be covering because the hospice has determined they are unrelated to the individual's terminal illness and related conditions.

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

(9) Name and signature of the individual (or representative) and date signed, along with a statement that signing this addendum (or its updates) is only acknowledgement of receipt of the addendum (or its updates) and not necessarily the individual's (or representative's) agreement with the hospice's determinations.

* * * * *

§ 418.26 [Amended]

■ 4. Section 418.26 is amended in paragraph (c)(2) by removing the reference "\$ 418.24(d)" and adding in its place the reference "\$ 418.24(e)".

§ 418.28 [Amended]

■ 5. Section 418.28 is amended in paragraph (c)(2) by removing the reference "\$ 418.24(e)(2)" and adding in its place the reference "\$ 418.24(f)(2)".

Dated: July 25, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: July 26, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

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