proposed rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This final rule does not impose substantial direct costs on state or local governments or preempt state law.

I. Regulatory Reform Analysis Under Executive Order 13771

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 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.'' Though this final rule may contribute to the generation of $132.45 million in annualized cost savings (that is, $176.8 million as calculated in section VII.C.6 above, discounted at 7 percent relative to year 2016), this cost savings was accounted for in Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (CoPs) (83 FR 47686) and was associated with the special requirements for psychiatric hospitals in the April 6, 2020 IFC. As a result, it has been determined that this final rule is an action that primarily results in transfers and does not impose more than *de minimis* costs as described above and thus is not a regulatory or deregulatory action for the purposes of Executive Order 13771.

For the reasons set forth in the preamble, this rule is adopted as final and the amendment to § 482.61 (amendatory instruction number 48) in the interim final rule published on April 6, 2020 (85 FR 19292) is adopted as final without change.

Dated: July 23, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: July 29, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–16990 Filed 7–31–20; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 418

[CMS–1733–F]

RIN 0938–AU09

Medicare Program; FY 2021 Hospice Wage Index and Payment Rate Update

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 (FY) 2021. This rule also revises the hospice wage index to reflect the current Office of Management and Budget area delineations, with a 5 percent cap on wage index decreases. In addition, this rule responds to comments on the modified election statement and the addendum examples that were posted on the Hospice Center web page to assist hospices in understanding the content requirements finalized in the FY 2020 Hospice Wage Index and Payment Rate Update final rule, effective for hospice elections beginning on and after October 1, 2020.

DATES: These regulations are effective on October 1, 2020.

FOR FURTHER INFORMATION CONTACT:

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

SUPPLEMENTARY INFORMATION:

I. 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. Continuous home care may be covered for as much as 24 hours a day, and these periods must be predominantly nursing care, in accordance with our regulations at § 418.204. A minimum of 8 hours of nursing care, or nursing and aide care, must be furnished on a particular day to qualify for the continuous home care rate (§ 418.302(e)(4)).

Hospices 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 (here 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.

While payment is made to hospices is to cover all items, services, and drugs for the palliation and management of the terminal illness and related conditions, federal funds cannot be used for prohibited activities, even in the context of a per diem payment. Recent news reports [2] have brought to light the potential role hospices could play in medical aid in dying (MAID) where such practices have been legalized in certain states. We wish to remind hospices that The Assisted Suicide Funding Restriction Act of 1997 (ASFRA) (Pub. L. 105–12) prohibits the use of federal funds to provide or pay for any health care item or service or health benefit coverage for the purpose of causing, or assisting to cause, the death of any individual including mercy killing, euthanasia, or assisted suicide. However, pursuant to section 3(b)(4) of ASFRA, the prohibition does not apply to the provision of an item or service for the purpose of alleviating pain or discomfort, even if such use may increase the risk of death, so long as the item or service is not furnished for the specific purpose of causing or accelerating death.

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 FY.

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.

[2] Nelson, R., Should Medical Aid in Dying Be Part of Hospice Care? Medscape Nurses. February 26, 2020. *https://www.medscape.com/viewarticle/925769#vp_1.*

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. 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.

8. 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/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 fail to submit their aggregate cap determinations on a timely basis will have their payments suspended until the determination is completed and received by the Medicare contractor (79 FR 50503).

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 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 47185) 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 would be 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 would have to 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 Hospice Quality Reporting Program (HQRP). First, we codified our policy that if the National Quality Forum (NQF) made non-substantive changes to specifications for HQRP 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 HQRP; 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 HQRP 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.

11. FY 2020 Hospice Wage Index and Payment Rate Update Final Rule

In the FY 2020 Hospice Wage Index and Rate Update final rule (84 FR 38487), we rebased the payment rates for CHC and GIP and set those rates equal to their average estimated FY 2019 costs per day. We also rebased IRC per diem rates 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. We finalized the FY 2020 proposal to reduce the RHC payment rates by 2.72 percent 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 (84 FR 38496). We also finalized a policy 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. Finally, in the FY 2020 Hospice Wage Index and Rate Update final rule (84 FR 38505) we finalized modifications to the hospice election statement content requirements at § 418.24(b) by requiring hospices, upon request, to furnish an election statement addendum effective beginning in FY 2021. The addendum must list those items, services, and drugs the hospice has determined to be unrelated to the terminal illness and related conditions, increasing coverage transparency for beneficiaries under a hospice election.

II. Provisions of the Final Rule

A. Hospice Wage Index Changes

1. Implementation of New Labor Market Delineations

In general, the Office of Management and Budget (OMB) issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. On April 10, 2018, OMB issued OMB Bulletin No. 18–03 which superseded the August 15, 2017 OMB Bulletin No. 17–01. On September 14, 2018, OMB issued OMB Bulletin No. 18–04, which superseded the April 10, 2018 OMB Bulletin No. 18–03. These bulletins made revisions to the delineations of Metropolitan Statistical Areas (MSAs), Micropolitan Statistical Areas, and Combined Statistical Areas, and guidance on uses of the delineation in these areas. A copy of the September 14, 2018 bulletin is available online at: *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf.* This bulletin states it ''provides the delineations of all MSAs, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010, in the **Federal Register** (75 FR 37246 through 37252), and Census Bureau data.'' On March 6, 2020 OMB issued Bulletin No. 20–01 (available at: *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf*), and, as discussed below, was not issued in time for development of the FY 2021 Hospice Wage Index and Rate Update proposed rule.

While the revisions OMB published on September 14, 2018, are not as sweeping as the changes made when we adopted the Core-Based Statistical Area (CBSA) geographic designations for FY 2006, the September 14, 2018 bulletin does contain a number of significant changes. For example, there are new CBSAs, urban counties that have become rural, rural counties that have become urban, and existing CBSAs that have been split apart. We believe it is important for the hospice wage index to use the latest OMB delineations available in order to maintain an accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. Using the most current OMB delineations creates a more accurate representation of geographic variation in wage levels. In the FY 2021 Hospice Wage Index and Payment Rate Update proposed rule (85 FR 20953), we proposed to implement the new OMB delineations as described in the September 14, 2018 OMB Bulletin No. 18–04 for the hospice wage index effective beginning in FY 2021. As noted above, the March 6, 2020 OMB Bulletin No. 20–01 was not issued in time for development of the proposed rule. As we stated in the proposed rule, we do not believe that the minor updates included in OMB Bulletin No. 20–01 would impact our proposed updates to the CBSA-based labor market area delineations. However, if needed, we would include any updates from this bulletin in future rulemaking.

i. Micropolitan Statistical Areas

As discussed in the FY 2006 Hospice Wage Index and Payment Rate Update proposed rule (70 FR 22397) and final rule (70 FR 45132), CMS considered how to use the Micropolitan Statistical Area definitions in the calculation of the wage index. OMB defines a ''Micropolitan Statistical Area'' as a ''CBSA'' associated with at least one

urban cluster that has a population of at least 10,000, but less than 50,000 (75 FR 37252). We refer to these as Micropolitan Areas. After extensive impact analysis, consistent with the treatment of these areas under the IPPS as discussed in the FY 2005 IPPS final rule (69 FR 49029 through 49032), CMS determined the best course of action would be to treat Micropolitan Areas as ''rural'' and include them in the calculation of each state's Hospice rural wage index (70 FR 22397 and 70 FR 45132). Thus, the hospice statewide rural wage index is determined using IPPS hospital data from hospitals located in non-MSAs.

Based upon the 2010 Decennial Census data, a number of urban counties have switched status and have joined or became Micropolitan Areas, and some counties that once were part of a Micropolitan Area, have become urban. Overall, there are fewer Micropolitan Areas (542) under the new OMB delineations based on the 2010 Census than existed under the latest data from the 2000 Census (581). We believe that the best course of action would be to continue the policy established in the FY 2006 Hospice Wage Index and Payment Rate Update final rule and include Micropolitan Areas in each state's rural wage index. These areas continue to be defined as having relatively small urban cores (populations of 10,000 to 49,999). Therefore, in conjunction with our proposal to implement the new OMB labor market delineations beginning in FY 2021 and consistent with the treatment of Micropolitan Areas under the IPPS, we proposed to continue to treat Micropolitan Areas as ''rural'' and to include Micropolitan Areas in the calculation of each state's rural wage index.

ii. Urban Counties Becoming Rural

Under the new OMB delineations (based upon the 2010 decennial Census data), a total of 34 counties (and county equivalents) that are currently considered urban would be considered rural beginning in FY 2021. Table 1 lists the 34 counties that would change to rural status with the implementation of the new OMB delineations.

TABLE 1: Counties that Would Change to Rural Status

County Name	State	CBSA	CBSA Name
BAKER	GA	10500	Albany, GA
NEWTON	TX	13140	Beaumont-Port Arthur, TX
GOLDEN VALLEY	MT	13740	Billings, MT
WALKER	AL	13820	Birmingham-Hoover, AL
SIOUX	ND	13900	Bismarck, ND
FLOYD	VA	13980	Blacksburg-Christiansburg-Radford, VA
DE WITT	IL	14010	Bloomington, IL
FORD	IL	16580	Champaign-Urbana, IL
BUCKINGHAM	VA	16820	Charlottesville, VA
ARANSAS	TX	18580	Corpus Christi, TX
MC DONALD	MO	22220	Fayetteville-Springdale-Rogers, AR-MO
LE FLORE	OK	22900	Fort Smith, AR-OK
WELLS	IN	23060	Fort Wayne, IN
HOOD	TX	23104	Fort Worth-Arlington, TX
SOMERVELL	TX	23104	Fort Worth-Arlington, TX
HAMILTON	NE	24260	Grand Island, NE
BARRY	MI	24340	Grand Rapids-Wyoming, MI
KALAWAO	HI	27980	Kahului-Wailuku-Lahaina, HI
VAN BUREN	MI	28020	Kalamazoo-Portage, MI
SCOTT	IN	31140	Louisville/Jefferson County, KY-IN
TRIMBLE	KY	31140	Louisville/Jefferson County, KY-IN
BENTON	MS	32820	Memphis, TN-MS-AR
SIBLEY	MN	33460	Minneapolis-St. Paul-Bloomington, MN-WI
HICKMAN	TN	34980	Nashville-Davidson--Murfreesboro--Franklin, TN
GULF	FL	37460	Panama City, FL
CUSTER	SD	39660	Rapid City, SD
CAROLINE	VA	40060	Richmond, VA
WEBSTER	LA	43340	Shreveport-Bossier City, LA
PLYMOUTH	IA	43580	Sioux City, IA-NE-SD
UNION	SC	43900	Spartanburg, SC
PEND OREILLE	WA	44060	Spokane-Spokane Valley, WA
COLUMBIA	WA	47460	Walla Walla, WA
PULASKI	GA	47580	Warner Robins, GA
KINGMAN	KS	48620	Wichita, KS

iii. Rural Counties Becoming Urban

Under the new OMB delineations (based upon the 2010 decennial Census data), a total of 47 counties (and county equivalents) that are currently designated rural would be considered urban beginning in FY 2021. Table 2 lists the 47 counties that would change to urban status.

TABLE 2: Counties that Would Change to Urban Status

County Name	State	CBSA	CBSA Name
GREENE	AL	46220	Tuscaloosa, AL
WASHINGTON	AL	33660	Mobile, AL
FRANKLIN	AR	22900	Fort Smith, AR-OK
LEVY	FL	23540	Gainesville, FL
STEWART	GA	17980	Columbus, GA-AL
TALBOT	GA	17980	Columbus, GA-AL
POWER	ID	38540	Pocatello, ID
FULTON	IL	37900	Peoria, IL
JOHNSON	IL	16060	Carbondale-Marion, IL
FRANKLIN	IN	17140	Cincinnati, OH-KY-IN
PARKE	IN	45460	Terre Haute, IN
WARREN	IN	29200	Lafayette-West Lafayette, IN
BOONE	IA	11180	Ames, IA
JASPER	IA	19780	Des Moines-West Des Moines, IA
GEARY	KS	31740	Manhattan, KS
CARTER	KY	26580	Huntington-Ashland, WV-KY-OH

ASSUMPTION	LA	12940	Baton Rouge, LA
MOREHOUSE	LA	33740	Monroe, LA
FRANKLIN	MA	44140	Springfield, MA
IONIA	MI	24340	Grand Rapids-Kentwood, MI
SHIAWASSEE	MI	29620	Lansing-East Lansing, MI
LAKE	MN	20260	Duluth, MN-WI
COVINGTON	MS	25620	Hattiesburg, MS
HOLMES	MS	27140	Jackson, MS
STONE	MS	25060	Gulfport-Biloxi, MS
COOPER	MO	17860	Columbia, MO
HOWARD	MO	17860	Columbia, MO
STILLWATER	MT	13740	Billings, MT
ANSON	NC	16740	Charlotte-Concord-Gastonia, NC-SC
CAMDEN	NC	47260	Virginia Beach-Norfolk-Newport News, VA-NC
GRANVILLE	NC	20500	Durham-Chapel Hill, NC
HARNETT	NC	22180	Fayetteville, NC
OTTAWA	OH	45780	Toledo, OH
CLARENDON	SC	44940	Sumter, SC
GIBSON	TN	27180	Jackson, TN
STEWART	TN	17300	Clarksville, TN-KY
HARRISON	TX	30980	Longview, TX
STERLING	TX	41660	San Angelo, TX
KING AND QUEEN	VA	40060	Richmond, VA
MADISON	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV
SOUTHAMPTON	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC
FRANKLIN CITY	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC
JACKSON	WV	16620	Charleston, WV
MORGAN	WV	25180	Hagerstown-Martinsburg, MD-WV
LINCOLN	WI	48140	Wausau-Weston, WI
ADJUNTAS	PR	38660	Ponce, PR
LAS MARIAS	PR	32420	Mayagüez, PR

iv. Urban Counties Moving to a Different Urban CBSA

In addition to rural counties becoming urban and urban counties becoming rural, several urban counties would shift from one urban CBSA to another urban CBSA under the new OMB delineations. In other cases, applying the new OMB delineations would involve a change only in CBSA name or number, while the CBSA continues to encompass the same constituent counties. For example, CBSA 19380 (Dayton, OH) would experience both a change to its number and its name, and become CBSA 19430 (Dayton-Kettering, OH), while all of its three constituent counties would remain the same. In other cases, only the name of the CBSA would be modified, and none of the currently assigned counties would be reassigned to a different urban CBSA. Table 3 lists CBSAs that would change the name and/or CBSA number only.

TABLE 3: Counties that Would Change Name and/or CBSA Number

Proposed CBSA Code	Proposed CBSA Title	Current CBSA Code	Current CBSA Title
10540	Albany-Lebanon, OR	10540	Albany, OR
11500	Anniston-Oxford, AL	11500	Anniston-Oxford-Jacksonville, AL
12060	Atlanta-Sandy Springs-Alpharetta, GA	12060	Atlanta-Sandy Springs-Roswell, GA
12420	Austin-Round Rock-Georgetown, TX	12420	Austin-Round Rock, TX
13460	Bend, OR	13460	Bend-Redmond, OR
13980	Blacksburg-Christiansburg, VA	13980	Blacksburg-Christiansburg-Radford, VA
14740	Bremerton-Silverdale-Port Orchard, WA	14740	Bremerton-Silverdale, WA
15380	Buffalo-Cheektowaga, NY	15380	Buffalo-Cheektowaga-Niagara Falls, NY
19430	Dayton-Kettering, OH	19380	Dayton, OH
24340	Grand Rapids-Kentwood, MI	24340	Grand Rapids-Wyoming, MI
24860	Greenville-Anderson, SC	24860	Greenville-Anderson-Mauldin, SC
25060	Gulfport-Biloxi, MS	25060	Gulfport-Biloxi-Pascagoula, MS
25540	Hartford-East Hartford-Middletown, CT	25540	Hartford-West Hartford-East Hartford, CT
25940	Hilton Head Island-Bluffton, SC	25940	Hilton Head Island-Bluffton-Beaufort, SC
28700	Kingsport-Bristol, TN-VA	28700	Kingsport-Bristol-Bristol, TN-VA
31860	Mankato, MN	31860	Mankato-North Mankato, MN
33340	Milwaukee-Waukesha, WI	33340	Milwaukee-Waukesha-West Allis, WI
34940	Naples-Marco Island, FL	34940	Naples-Immokalee-Marco Island, FL
35660	Niles, MI	35660	Niles-Benton Harbor, MI
36084	Oakland-Berkeley-Livermore, CA	36084	Oakland-Hayward-Berkeley, CA
36500	Olympia-Lacey-Tumwater, WA	36500	Olympia-Tumwater, WA
38060	Phoenix-Mesa-Chandler, AZ	38060	Phoenix-Mesa-Scottsdale, AZ
39150	Prescott Valley-Prescott, AZ	39140	Prescott, AZ
23224	Frederick-Gaithersburg-Rockville, MD	43524	Silver Spring-Frederick-Rockville, MD
44420	Staunton, VA	44420	Staunton-Waynesboro, VA
44700	Stockton, CA	44700	Stockton-Lodi, CA
45940	Trenton-Princeton, NJ	45940	Trenton, NJ
46700	Vallejo, CA	46700	Vallejo-Fairfield, CA
47300	Visalia, CA	47300	Visalia-Porterville, CA
48140	Wausau-Weston, WI	48140	Wausau, WI
48424	West Palm Beach-Boca Raton-Boynton Beach, FL	48424	West Palm Beach-Boca Raton-Delray Beach, FL

Upon adoption of the new OMB delineations, counties would shift between existing and new CBSAs, changing the constituent makeup of the CBSAs. In another type of change, some CBSAs have counties that would split

off to become part of or to form entirely new labor market areas. Finally, in some cases, a CBSA would lose counties to another existing CBSA. Table 4 lists the urban counties that would move from one urban CBSA to a newly or modified CBSA under the new OMB delineations.

TABLE 4: Counties that Would Change to a Different CBSA

Previous CBSA	New CBSA	County	State
16974	16984	COOK	IL
16974	16984	DU PAGE	IL
16974	16984	GRUNDY	IL
16974	20994	KENDALL	IL
16974	16984	MC HENRY	IL
16974	16984	WILL	IL
20524	39100	DUTCHESS	NY
20524	35614	PUTNAM	NY
26580	16620	LINCOLN	WV
28940	34100	GRAINGER	TN
35084	35154	SOMERSET	NJ
35614	35154	MIDDLESEX	NJ
35614	35154	MONMOUTH	NJ
35614	35154	OCEAN	NJ
35614	39100	ORANGE	NY
38660	49500	GUANICA	PR
38660	49500	GUAYANILLA	PR
38660	49500	PENUELAS	PR
38660	49500	YAUCO	PR

2. Transition Period

As discussed previously, overall, we believe that our proposal to adopt the revised OMB delineations for FY 2021 would result in hospice wage index values being more representative of the actual costs of labor in a given area. However, we also recognize that some hospices would experience decreases in their area wage index values as a result of our proposal. We also realize that many hospices would have higher area wage index values under our proposal.

To mitigate the potential impacts of adopting new OMB delineations on hospices, we have in the past provided for transition periods when adopting changes that have significant payment implications, particularly large negative impacts. For example, we have proposed and finalized budget-neutral transition policies to help mitigate negative impacts on hospices following the adoption of the new CBSA delineations based on the 2010 decennial census data in the FY 2016 Hospice Wage Index and Payment Rate Update final rule (80 FR 47142). Specifically, we applied a blended wage index for 1 year (FY 2016) for all geographic areas that would consist of a 50/50 blend of the wage index values using OMB's old area delineations and the wage index values using OMB's new area delineations. That is, for each county, a blended wage index was calculated equal to 50 percent of the FY 2016 wage index using the old labor market area delineation and 50 percent of the FY 2016 wage index using the new labor market area delineation, which resulted in an average of the two values. While we believed that using the new OMB delineations would create a more accurate payment adjustment for differences in area wage levels, we also recognized that adopting such changes may cause some short-term instability in hospice payments, in particular for hospices that would be negatively impacted by the proposed adoption of the updates to the OMB delineations. Therefore, we also proposed a transition policy to help mitigate any significant negative impacts that hospices may experience due to our proposal to adopt the revised OMB delineations. For FY 2021 as a transition, we proposed to apply a 5 percent cap on any decrease in a geographic area's wage index value from the wage index value from the prior FY. This transition would allow the effects of our proposed adoption of the revised CBSA delineations to be phased in over 2 years, where the estimated reduction in a geographic area's wage index would be capped at 5 percent in FY 2021 (that is, no cap would be applied to the reduction in the wage index for the second year (FY 2022)). We believe a 5 percent cap on the overall decrease in a geographic area's wage index value would be appropriate for FY 2021, as it provides predictability in payment levels from FY 2020 to the upcoming FY 2021 and additional transparency because it is administratively simpler than our prior 1-year 50/50 blended wage index approach. We believe 5 percent is a reasonable level for the cap because it would effectively mitigate any significant decreases in a geographic area's wage index value for FY 2021.

Because we believe that using the new OMB delineations would create a more accurate payment adjustment for differences in area wage levels we proposed to include a cap on the overall decrease in a geographic area's wage index value.

Overall, the impact between the FY 2021 wage index using the old OMB delineations and the proposed FY 2021 wage index using the new OMB delineations would be 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. We solicited comments on this proposed transition methodology.

We received approximately 12 comments on the FY 2021 hospice wage 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: Nearly all commenters stated that they support the adoption of the revised OMB delineations from the September 14, 2018 Bulletin No. 18–04 and the proposed transition methodology that would apply a 5 percent cap on decreases to a geographic area's wage index value relative to the wage index value from the prior fiscal year.

Response: We appreciate the commenters' support of the adoption of the new OMB delineations and a 5 percent cap on wage index decreases for FY 2021 as an appropriate transition policy.

Comment: A few commenters stated that the adoption of the New Brunswick-Lakewood, NJ CBSA would result in a reduction in reimbursement for the four New Jersey counties that would make up the new CBSA. One commenter recommended that CMS delay finalizing the proposal to implement the new OMB delineations. While another commenter suggested that the transition policy is critical to offset economic losses for hospices like those in the impacted New Jersey counties throughout the country.

Response: We appreciate the concerns sent in by the commenters regarding the impact of implementing the New Brunswick-Lakewood, NJ CBSA designation on their specific counties. While, we understand the commenters' concern regarding the potential financial impact, we believe that implementing the revised OMB delineations will create more accurate representations of labor market areas nationally and result in hospice wage index values being more representative of the actual costs of labor in a given area. Although this comment only addressed the negative impact on the commenter's geographic area, we believe it is important to note that there are many geographic locations and hospice providers that will experience positive impacts upon implementation of the revised CBSA designations. We believe that the OMB delineations for Metropolitan and Micropolitan Statistical Areas are appropriate for use in accounting for wage area differences and that the values computed under the revised delineations will result in more appropriate payments to providers by more accurately accounting for and reflecting the differences in area wage levels.

We recognize that there are areas which will experience a decrease in their wage index. As such, it is our longstanding policy to provide temporary adjustments to mitigate negative impacts from the adoption of new policies or procedures. In the FY 2021 Hospice Wage Index and Payment Rate Update proposed rule, we proposed a transition in order to mitigate the resulting short-term instability and negative impacts on certain providers and to provide time for providers to adjust to their new labor market delineations. We continue to believe that the 1-year 5 percent cap transitional policy provides an adequate safeguard against any significant payment reductions, allows for sufficient time to make operational changes for future fiscal years, and provides a reasonable balance between mitigating some short-term instability in hospice payments and improving the accuracy of the payment adjustment for differences in area wage levels. Therefore, we believe that it is appropriate to implement the new OMB delineations without delay.

Comment: A few commenters including MedPAC suggested alternatives to the 5 percent cap transition policy. MedPAC suggested that the 5 percent cap limit should apply to both increases and decreases in the wage index so that no provider would have its wage index value increase or decrease by more than 5 percent for FY 2021. One commenter suggested that wage index decreases should be capped at 3 percent instead of 5 percent. Finally, several commenters recommended that CMS consider implementing a 5 percent cap, similar to that which we proposed for FY 2021, for years beyond the implementation of the revised OMB delineations.

Response: We appreciate MedPAC's suggestion that the cap on wage index movements of more than 5 percent should also be applied to increases in the wage index. However, as we discussed in the proposed rule, the purpose of the proposed transition policy is to help mitigate the significant negative impacts of certain wage index changes. Additionally, we believe that the 5 percent cap on wage index decreases is an adequate safeguard against any significant payment reductions and do not believe that capping wage index decreases at 3 percent instead of 5 percent is appropriate. We believe that 5 percent is a reasonable level for the cap rather than 3 percent because it would more effectively mitigate any significant decreases in a hospice's wage index for FY 2021, while still balancing the importance of ensuring that area wage index values accurately reflect relative differences in area wage levels. Furthermore, a 5 percent cap on wage index decreases in FY 2021 provides a degree of predictability in payment changes for providers and allows providers time to adjust to any significant decreases they may face in FY 2022, after the transition period has ended. Finally, with regards to the comments recommending that CMS consider implementing this type of transition in future years, we believe that this would be counter to the purpose of the wage index, which is used to adjust payments to account for local differences in area wage levels. While we believe that a transition is necessary to help mitigate the negative impact from the revised OMB delineations in the first year of implementation, this transition must be balanced against the importance of ensuring accurate payments.

Final Decision: We are finalizing our proposal to adopt the revised OMB delineations from the September 14, 2018 OMB Bulletin 18–04 and apply a 1-year 5 percent cap on wage index decreases as proposed, meaning the counties impacted will receive a 5 percent cap on any decrease in a geographic area's wage index value from the wage index value from the prior fiscal year for FY 2021 effective October 1, 2020.

The final wage index applicable to FY 2021 can be found on our website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice.* The final hospice wage index for FY 2021 is effective October 1, 2020 through September 30, 2021.

The wage index file also provides a crosswalk between the FY 2021 wage index using the current OMB delineations and the FY 2021 wage index using the revised OMB

delineations that will be in effect in FY 2021. This file shows each state and county and its corresponding wage index along with the previous CBSA number, the new CBSA number or alternate identification number, and the new CBSA name.

B. FY 2021 Hospice Wage Index and Rate Update

1. FY 2021 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 OMB to the MSAs.

In the FY 2020 Hospice Wage Index and Payment Rate Update final rule (84 FR 38484), we finalized the proposal to use the current FY's hospital wage index data to calculate the hospice wage index values. In the FY 2021 Hospice Wage Index and Payment Rate Update proposed rule (85 FR 20957) we discussed our proposal to use the FY 2021 pre-floor, pre-reclassified hospital wage index data to calculate the hospice wage index values with a 5 percent cap on wage index decreases. This means that the hospital wage data used for the hospice wage index would reflect the new OMB delineations but would not 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 and Payment Rate Update 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 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 2021, the only CBSA without a hospital from which hospital wage data can be derived is 25980, Hinesville-Fort Stewart, Georgia. The FY 2021 adjusted wage index value for Hinesville-Fort Stewart, Georgia is 0.8527.

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 and Payment Rate Update 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 2021, we will 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. As discussed above the pre-floor, pre-reclassified hospital wage index values below 0.8 will be 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.

The final hospice wage index applicable for FY 2021 (October 1, 2020 through September 30, 2021) is available on our website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Hospice-Wage-Index* .

A summary of the general comments on the hospice wage index and our responses to those comments appear below:

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 CBSAs. This commenter suggested that since CMS began using CBSAs to determine payment, hospices in Montgomery County have received lower payments than hospices in adjacent counties due to Montgomery County being carved out of Washington DC. The commenter recommended two options to resolve this issue: allow hospices serving patients in MSAs that are large enough to be subdivided into metropolitan divisions to opt for the higher wage index valuation within the MSA's respective CBSAs or assigning the highest wage index valuation from among the MSA's metropolitan divisions for the purpose of hospice Medicare reimbursement.

Response: We thank the commenter for the recommendation. However, 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. The general concept of the CBSAs is that of an area containing a recognized population nucleus and adjacent communities that have a high degree of integration with that nucleus. The purpose of the standards is to provide nationally consistent definitions for collecting, tabulating, and publishing federal statistics for a set of geographic areas. CBSAs include adjacent counties that have a minimum of 25 percent commuting to the central counties of the area. This is an increase over the minimum commuting threshold for outlying counties applied in the previous definition of MSAs of 15 percent. Based on the OMB's current delineations, Montgomery County belongs in a separate CBSA from the areas defined in the Washington-Arlington-Alexandria, DCVA CBSA. Unlike inpatient prospective payment system (IPPS) hospitals, inpatient rehabilitation facilities (IRFs), and

skilled nursing facilities (SNFs), where each provider uses a single CBSA, hospice agencies may be reimbursed based on more than one wage index. Payments are based upon the location of the beneficiary for routine and continuous home care or the location of the facility for respite and general inpatient care. Hospices in Montgomery County, Maryland may provide RHC and CHC to patients in the ''Washington Arlington-Alexandria, DC–VA'' CBSA and to patients in the ''Baltimore-Columbia-Towson, Maryland'' CBSA. We have used CBSAs for determining hospice payments since FY 2006. Additionally, other provider types, such as IPPS hospitals, home health agencies (HHAs), SNFs, IRFs, and the dialysis facilities all used CBSAs to define their labor market areas. We believe that using the most current OMB delineations provides a more accurate representation of geographic variation in wage levels and do not believe it would be appropriate to allow hospices to opt for or be assigned a higher CBSA designation.

Comment: Many commenters recommended more far-reaching revisions and reforms to the wage index methodology used under Medicare fee-for-service. MedPAC recommended that Congress repeal the existing hospital wage index and instead implement a market-level wage index for use across other prospective payment systems that would use wage data from all employers and industry-specific occupational weights, and adjust for geographic differences in the ratio of benefits to wages. Additionally, many commenters recommended that CMS develop and implement a wage index model that is consistent across all provider types, incorporates some means by which providers are protected against substantial payment reductions due to dramatic reductions in wage index values from one year to the next, allows hospices and other post-acute providers to utilize a reclassification board and guarantees that wage index values do not drop below the rural wage index value applicable in the state of operation. Finally, one commenter recommended that CMS implement a policy similar to that of the FY 2020 IPPS final rule which increased the wage index for hospitals with a wage index value below the 25th percentile in order to address the discrepancies between counties whose wage index falls below the statewide rural wage index.

Response: We appreciate the commenters' recommendations; however, these comments are outside the scope of the proposed rule. Any changes to the way we adjust hospice payments to account for geographic wage differences, beyond the wage index proposals discussed in the FY 2021 Hospice Wage Index and Rate Update proposed rule, would have to go through notice and comment rulemaking. While CMS and other stakeholders have explored potential alternatives to the current CBSA-based labor market system, no consensus has been achieved regarding how best to implement a replacement system. We believe that in the absence of hospice specific wage data, using the pre-floor, pre-reclassified hospital wage data is appropriate and reasonable for hospice payments.

Additionally, the regulations that govern hospice reimbursement do not provide a mechanism for allowing hospices to seek geographic reclassification or to utilize the rural floor provisions that exist for IPPS hospitals. The reclassification provision found in section 1886(d)(10) of the Act is specific to hospitals. 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 also specific to hospitals. Because the reclassification provision and 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). However, the hospice wage index does include the hospice floor which 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. Finally, with regards to the wage index changes detailed in the FY 2020 IPPS final rule, we would like to note that the hospice wage index is derived from hospital wage data. As such, any changes in the wage data of hospitals extend to the hospice setting, as hospital data is used to establish the wage index for hospices.

Final Decision: After considering the comments received in response to the proposed rule and for the reasons discussed previously, we are finalizing our proposal to use the FY 2021 pre-floor, pre-reclassified hospital wage index data as the basis for the FY 2021 hospice wage index. The wage index applicable for FY 2021 is available on our website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Hospice-Wage-Index.* The hospice wage index for FY 2021 is effective October 1, 2020 through September 30, 2021.

2. FY 2021 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.

In the FY 2021 Hospice Wage Index and Payment Rate Update proposed rule (85 FR 20958), we proposed the market basket percentage increase of 3.0 percent for FY 2021 using the most current estimate of the inpatient hospital market basket (based on IHS Global Inc.'s fourth-quarter 2019 forecast with historical data through the third quarter 2019). We also stated if more recent data became available after the publication of the proposed rule and before the publication of the final rule (for example, more recent estimates of the inpatient hospital market basket update and/or multifactor productivity (MFP) adjustment), we would use such data to determine the hospice payment update percentage for FY 2021 in the final rule. For this final rule, based on IHS Global Inc.'s (IGIs) second-quarter 2020 forecast with historical data through the first quarter 2020 of the inpatient hospital market basket update, the market basket percentage increase for FY 2021 is 2.4 percent. We note that the fourth quarter 2019 forecast used for the proposed market basket update was developed prior to the economic impacts of the COVID–19 pandemic. This lower update (2.4 percent) for FY 2021, relative to the proposed rule (3.0 percent), is primarily driven by slower anticipated compensation growth for both health-related and other occupations as labor markets are expected to be significantly impacted during the recession that started in February 2020 and throughout the anticipated recovery.

Section 1814(i)(1)(C)(iv)(I), as added by section 3401(g) of the Act, requires, starting with FY 2013 (and in subsequent FYs), that the market basket percentage increase be annually reduced by changes in economy-wide productivity specified in section 1886(b)(3)(B)(xi)(II) of the Act. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business MFP.

In the FY 2021 Hospice Wage Index and Payment Rate Update proposed rule (85 FR 20958), we proposed a MFP adjustment of 0.4 percentage point based on IGIs fourth quarter 2019 forecast. Based on the more recent data available for this final rule, the current estimate of the MFP adjustment for FY 2021 is projected to be –0.1 percentage point. This MFP adjustment is based on the most recent macroeconomic outlook from IGI at the time of rulemaking (released June 2020) in order to reflect more current historical economic data. IGI produces monthly macroeconomic forecasts, which include projections of all of the economic series used to derive MFP. In contrast, IGI only produces forecasts of the more detailed price proxies used in the inpatient hospital market basket on a quarterly basis. Therefore, IGI's second quarter 2020 forecast is the most recent forecast of the inpatient hospital market basket update.

We note that it has typically been our practice to base the projection of the market basket price proxies and MFP in the final rule on the second quarter IGI forecast. For the FY 2021 Hospice Wage Index and Payment Rate Update final rule, we are using the IGI June macroeconomic forecast for MFP because it is a more recent forecast, and it is important to use more recent data during this period when economic trends, particularly employment and labor productivity, are notably uncertain because of the COVID–19 pandemic. Historically, the MFP adjustment based on the second quarter IGI forecast has been very similar to the MFP adjustment derived with IGI's June macroeconomic forecast. Substantial changes in the macroeconomic indicators in between monthly forecasts are atypical.

Given the unprecedented economic uncertainty as a result of the COVID–19 pandemic, the changes in the IGI macroeconomic series used to derive MFP between the second quarter 2020 IGI forecast and the IGI June 2020 macroeconomic forecast is significant. Therefore, we believe it is technically appropriate to use IGI's more recent June 2020 macroeconomic forecast to determine the MFP adjustment for the final rule as it reflects more current historical data. For comparison purposes, the 10-year moving average growth of MFP for FY 2021 is projected to be –0.1 percentage point based on IGI's June 2020 macroeconomic forecast compared to a FY 2021 projected 10-year moving average growth of MFP of 0.7 percentage point based on IGI's second quarter 2020 forecast. Mechanically subtracting the negative 10-year moving average growth of MFP from the market basket percentage increase using the data from the IGI June, 2020 macroeconomic forecast of the FY 2021 MFP adjustment would have resulted in a 0.1 percentage point increase in the FY 2021 hospice payment update percentage. However, under sections 1886(b)(3)(B)(xi)(I) and 1814(i)(1)(C)(v) of the Act, the Secretary is required to reduce (not increase) the hospice market basket percentage increase by changes in economy-wide productivity. Accordingly, we will be applying a 0.0 percentage point MFP adjustment to the market basket percentage increase. Therefore, the hospice payment update percentage for FY 2021 is 2.4 percent.

The labor portion of the hospice payment rates are as follows: For RHC, 68.71 percent; for CHC, 68.71 percent; for GIP, 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 are as follows: For RHC, 31.29 percent; for CHC, 31.29 percent; for GIP, 35.99 percent; and for Respite Care, 45.87 percent.

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

Comment: Nearly all commenters noted their support of the proposed hospice payment update percentage.

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

Comment: MedPAC recognizes that CMS is required by statute to update the hospice payments rates for FY 2021 (an increase of 2.4 percent as outlined in this final rule), however, they noted that in their March 2020 report to Congress, they recommended that Congress eliminate the payment update for FY 2021 (that is, hold the payment rates for FY 2021 at the FY 2020 levels).

Response: We appreciate the comment, however, we do not have the statutory authority to eliminate the annual payment updates to the hospice payment rates for FY 2021.

Final Decision: We are finalizing the 2.4 percent hospice payment update percentage for FY 2021. Based on IHS Global, Inc.'s updated forecast of the inpatient hospital market basket update and the MFP adjustment, the hospice payment update percentage for FY 2021 will be 2.4 percent for hospices that submit the required quality data and 0.4 percent (FY 2021 hospice payment update of 2.4 percent minus 2.0 percentage points) for hospices that do not submit the required data.

3. FY 2021 Hospice Payment Rates

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

Additionally, in the FY 2016 Hospice Wage Index and Payment Rate Update final rule (80 FR 47172), we implemented two different RHC payment rates, one RHC rate for the first 60 days and a second RHC rate for days 61 and beyond. In that final rule we also implemented a 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 on the day of service (up to 4 hours), if certain criteria are met. In order to maintain budget neutrality in the first year of implementation, as required under section 1814(i)(6)(D)(ii) of the Act, the new RHC rates were adjusted by a service intensity add-on budget neutrality factor (SBNF). The SBNF is used to reduce the overall RHC rate in order to ensure that SIA payments are budget-neutral. At the beginning of every fiscal year, SIA utilization is compared to the prior year in order calculate a budget neutrality adjustment. For FY 2021, we calculated the SBNF using FY 2019 utilization data. For FY 2021, the SBNF that would apply to days 1 through 60 is calculated to be 1.0002 and the SBNF that would apply to days 61 and beyond is calculated to be 1.0001.

As discussed in the FY 2021 Hospice Wage Index and Payment Rate Update

proposed rule (85 FR 20958), there have been very minor SBNF adjustments over the past several years suggesting that the utilization of the SIA from one year to the next remains relatively constant. Because the SBNF remains stable, we proposed to remove the factor to simplify the RHC payment rate updates.

In the FY 2017 Hospice Wage Index and Payment Rate Update final rule (81 FR 52156), we initiated a policy of applying a wage index standardization factor to hospice payments in order to eliminate the aggregate effect of annual variations in hospital wage data. In order to calculate the wage index standardization factor, we simulate total payments using the FY 2020 hospice wage index and FY 2020 payment rates and compare it to our simulation of total payments using the FY 2021 wage index with a 5 percent cap on wage index decreases and FY 2020 payment rates. By dividing payments for each level of care (RHC days 1 through 60, RHC days 61+, CHC, IRC, and GIP) using the FY 2020 wage index and payment rates by payments for each level of care using the FY 2021 wage index and FY 2020 payment rates, we obtain a wage index standardization factor for each level of care. The wage index standardization factors for each level of care are shown in the tables 5 and 6.

The FY 2021 RHC payment rates are shown in Table 5. The FY 2021 payment rates for CHC, IRC, and GIP are shown in Table 6.

TABLE 5: FY 2021 Hospice RHC Payment Rates

Code	Description	FY 2020 Payment Rates	SIA Budget Neutrality Factor	Wage Index Standardization Factor	FY 2021 Hospice Payment Update	FY 2021 Payment Rates
651	Routine Home Care (days 1-60)	$194.50	1.0002	1.0002	X 1.024	$199.25
651	Routine Home Care (days 61+)	$153.72	1.0001	1.0004	X 1.024	$157.49

TABLE 6: FY 2021 Hospice CHC, IRC, and GIP Payment Rates

Code	Description	FY 2020 Payment Rates	Wage Index Standardization Factor	FY 2021 Hospice Payment Update	FY 2021 Payment Rates
652	Continuous Home Care Full Rate = 24 hours of care	$1,395.63 ($58.15/hourly rate)	1.0023	X 1.024	$1,432.41 ($59.68/hourly rate)
655	Inpatient Respite Care	$450.10	1.0004	X 1.024	$461.09
656	General Inpatient Care	$1,021.25	0.9999	X 1.024	$1,045.66

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 and Payment Rate Update final rule (76 FR 47320 through 47324), we implemented a HQRP as required by section 3004 of the Affordable Care Act. Hospices were required to begin collecting quality data in October 2012, and submit that quality data in 2013. Section 1814(i)(5)(A)(i) of the Act requires that beginning with FY 2014 and each subsequent FY, the Secretary shall reduce the market basket update by 2 percentage points for any hospice that does not comply with the quality data submission requirements with respect to that FY. The FY 2021 payment rates for hospices that do not submit the required quality data would be updated by the FY 2021 hospice payment update percentage of 2.4 percent minus 2 percentage points. These rates are shown in Tables 7 and 8.

TABLE 7: FY 2021 Hospice RHC Payment Rates for Hospices That DO NOT Submit the Required Quality Data

Code	Description	FY 2020 Payment Rates	SIA Budget Neutrality Factor	Wage Index Standardization Factor	FY 2021 Hospice Payment Update of 2.4% minus 2 percentage points = +0.4%	FY 2021 Payment Rates
651	Routine Home Care (days 1-60)	$194.50	1.0002	1.0002	X 1.004	$195.36
651	Routine Home Care (days 61+)	$153.72	1.0001	1.0004	X 1.004	$154.42

TABLE 8: FY 2021 Hospice CHC, IRC, and GIP Payment Rates for Hospices That DO NOT Submit the Required Quality Data

Code	Description	FY 2020 Payment Rates	Wage Index Standardization Factor	FY 2021 Hospice Payment Update of 2.4% minus 2 percentage points = +0.4%	FY 2021 Payment Rates
652	Continuous Home Care Full Rate= 24 hours of care	$1,395.63 ($58.15/hourly rate)	1.0023	X 1.004	$1,404.44 ($58.52/ hourly rate)
655	Inpatient Respite Care	$450.10	1.0004	X 1.004	$452.08
656	General Inpatient Care	$1,021.25	0.9999	X 1.004	$1025.23

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

Comment: Several commenters did not support CMS's proposal to sunset the SBNF and believes the SBNF recalibration should continue on an annual basis. They suggested that the SBNF serves an important purpose to retain budget neutrality going forward if visits in the last seven days of life increase. They stated that the SIA payments have served to align payment with costs of care and that the SIA payments help balance the cost of short-length-of stay patients for whom hospices receive very little reimbursement, but may provide many hours of intense care by professional staff. A few commenters stated that the FY 2020 payment rule's recalibration of the payment rates has resulted in a considerable increase in the hourly rate for CHC, and could have an impact on SIA utilization going forward; that is, the significant increase in the CHC rate may incentivize an increase in visits made during the last 7 days of life. On the other hand, several commenters were supportive of CMS' efforts to simplify Medicare payment calculations where warranted, and understands CMS' rationale for eliminating the SBNF. They stated that the removal of the SBNF from RHC payment updates would result in a more administratively simple application of the RHC payment rate updates. One commenter recommended that CMS wait to implement this change. Many commenters requested that CMS continue to monitor visits in the last 7 days of life to ensure that current trends do not change in light of the increased payment amount associated with the CHC rate.

Response: After considering the comments received in response to the proposed removal of the SBNF, we are not finalizing the removal of the SBNF for FY 2021. As noted by commenters, we rebased the CHC payment amount in FY 2020. Given the increase to the CHC hourly rate in FY 2020, we agree that it is prudent to evaluate FY 2020 utilization data prior to eliminating the SBNF. We will continue to analyze data on visits in the last 7 days of life and whether there are changes in utilization that could affect overall budget neutrality. If there continues to be very minor SBNF adjustments in the future, suggesting that the utilization of the SIA from one year to the next remains relatively constant, we may propose to remove the factor to simplify the RHC payment rate updates in future rulemaking.

Comment: While outside the scope of the proposed rule, two commenters noted their support of the suspension of the sequestration reduction due to the public health emergency (PHE) in response to the COVID–19 pandemic. One commenter recommended that quality reporting be suspended for the duration of CY 2020 and that hospices be held harmless from a negative payment adjustment for the remainder of the 2020 performance period.

Response: While the HQRP is statutorily mandated under section 1814(i)(5)(A)(i) of the Act, we provided an exemption under its extraordinary and extenuating circumstances policy for the COVID–19 pandemic as discussed in the FY 2016 Final Rule (80 FR 47194). We may grant exemptions or

extensions to hospices without a request if it determines that an extraordinary circumstances exemption (ECE), such as an act of nature including a pandemic, affects an entire region or locale. Accordingly, to allow all Medicare-certified hospices to focus on patient care during the start of the COVID–19 pandemic, we granted such an exemption that ended on June 30, 2020. This limited timeframe allowed hospices time to address issues and continue with submitting quality data for public reporting starting on July 1, 2020. Further, in coordination with other provider-types who have also been given blanket waivers, CMS expects to suspend penalties for Quarter 1 (Q1) and Q2 of 2020 (January 1 through June 30, 2020). Therefore, the calendar year 2020 data used for meeting the HQRP requirements include July 1 through December 31, 2020. This means that even if hospice providers submit the Hospice Item Set and CAHPS® Hospice Survey data for Q1 and Q2 2020, we will not include any of that data for purposes of calculating whether a hospice meets the HQRP requirements impacting FY 2022 payments. We provided a tip sheet to assist providers with this issue that can be accessed at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/HQRP-Requirements-and-Best-Practices.*

Final Decision: We are finalizing the FY 2021 payment rates in accordance with statutorily-mandated requirements. We are not finalizing the removal of the SBNF at this time; the SBNF will be applied to the payment rates as shown in Tables 6 and 8.

4. Hospice Cap Amount for FY 2021

As discussed in the FY 2016 Hospice Wage Index and Payment 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 2021 cap year will be $30,683.93, which is equal to the FY 2020 cap amount ($29,964.78) updated by the FY 2021 hospice payment update percentage of 2.4 percent.

A summary of the two comments we received regarding the hospice cap amount and our responses to those comments appear below:

Comment: MedPAC recommended reducing the hospice aggregate cap by 20 percent and wage adjusting the hospice aggregate cap.

Response: We appreciate the commission's recommendation, however, we do not have the statutory authority to wage adjust or reduce the hospice cap amount.

Comment: Another commenter suggested that the cap amount is an area that CMS could explore under its program integrity authority using available claims and quality data to target enforcement activities to hospices that regularly come close to or go over their aggregate cap amount.

Response: We appreciate the commenter's suggestion to consider looking into the practices of hospices that regularly come close to or exceed their aggregate cap to target further program integrity efforts. We will continue to 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

In the FY 2020 Hospice Wage Index and Payment Rate Update final rule (84 FR 38484), we finalized modifications to 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 finalized that hospices also would be 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 Beneficiary and Family Centered Care Quality Improvement Organization (BFCC–QIO) if the beneficiary (or representative) disagrees with the hospice's determination.

Also in the FY 2020 Hospice Wage Index and Payment Rate Update final rule, we finalized the requirements as set forth at § 418.24(c) for the hospice election statement addendum titled, ''Patient Notification of Hospice Non-Covered Items, Services, and Drugs'' to 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:
a. The purpose of addendum; and
b. the patient's 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.

While we finalized that the election statement modifications apply to all hospice elections, the addendum is only required to be furnished to beneficiaries, their representatives, non-hospice providers, or Medicare contractors who requested such information. Additionally, we finalized a policy that if the beneficiary (or representative) requested an addendum at the time of hospice election, the hospice has 5 days from the start of hospice care to furnish this information in writing.

Furthermore, if the beneficiary requested the election statement at the time of hospice election, but died within 5 days, the hospice is not required to furnish the addendum as the requirement would be deemed to have been met in this circumstance. If the addendum was requested during the course of hospice care (that is, after the date of the hospice election), we finalized a policy that the hospice has 72 hours from the date of the request to provide the written addendum. The election statement modifications and the election statement addendum requirements will be effective for hospice elections beginning on and after October 1, 2020 (that is, FY 2021).

While we finalized the content requirements for the election statement addendum, we did not mandate that hospices use a specific form. Hospices are to develop and design the addendum to meet their needs, similar to how hospices develop their own hospice election statement (84 FR 38507). Additionally, we finalized a policy that the signed addendum (and any signed updates) are a new condition for payment. However, this does not mean in order to meet this condition for payment that the beneficiary (or representative), or non-hospice provider needs to agree with the hospice's determination. For purposes of this condition for payment, we finalized the policy that the signed addendum is only an acknowledgement of the beneficiary's (or representative's) receipt of the addendum (or its updates) and this payment requirement is met if there is a signed addendum (and any signed updates) in the requesting beneficiary's medical record with the hospice. This addendum is not required to be submitted routinely with each hospice claim. Likewise, the hospice beneficiary (or representative) does not have to separately consent to the release of this information to non-hospice providers furnishing services for unrelated conditions, because 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).

We delayed the effective date of the election statement content modifications and the hospice election statement addendum until FY 2021 to allow hospices adequate time to make the necessary modifications to their current election statements, develop their own election statement addendum, and make any changes to their current software and business processes to accommodate the requirements. Additionally, with publication of the FY 2021 Hospice Wage Index and Payment Rate Update proposed rule, we posted a modified model election statement and addendum on the Hospice Center web page to give hospices an illustrative example as they modify and develop own forms to meet the content requirements and best meet their respective needs.

While we did not make any proposals in the FY 2021 Hospice Wage Index and Payment Rate Update proposed rule to the finalized election statement and election statement addendum content requirements at § 418.24, or the October 1, 2020 effective date, we solicited comments on both of these model examples to see if they are helpful in educating hospices in how to meet these requirements effective for hospice elections beginning in FY 2021. We received 45 comments from primarily hospices and industry associations. Below is a summary of those comments and our responses.

Comment: In general, commenters had many suggested revisions for the modified election statement and the election statement addendum. Comments on the modifications to the model election statement and the addendum included formatting changes and reordering the required items for ease of use and readability. Some commenters suggested language revisions to make some of the content requirements more clear. Other suggestions included the removal of certain statements because they are not content requirements, outlined in regulation, and a few commenters suggested adding additional language to further explain the purpose of the addendum.

Several commenters questioned what recourse the hospice has if the patient/representative refuses to sign the addendum, given the beneficiary signature is a content requirement. These commenters suggested a process similar to the Notices of Medicare Non-Coverage (NOMNC) where CMS has stated that ''[i]f the beneficiary refuses to sign the NOMNC the provider should annotate the notice to that effect and indicate the date of refusal on the notice.'' And finally, one commenter requested an example of a completed addendum as they stated that it would be helpful for hospices to understand what CMS expects in terms of the way to write the rationale for an unrelated condition, item, service, or drug that is considered to be communicated in a language the beneficiary can understand.

Response: We appreciate commenters taking the time and thoroughly reviewing the model examples of the modifications to the election statement and the election statement addendum posted on the Hospice Center web page. As noted in the proposed rule and in this final rule, these examples are only meant to be illustrative and are not required to be in the exact format as provided. We have accepted the majority of commenters' suggestions and have incorporated them into the model examples, which we will post on the Hospice Center web page with this final rule. We removed language and checkboxes that are not content requirements at § 418.24(b) or (c) for the election statement or the addendum. We did not accept those recommendations to add language that are not regulatory requirements. The model examples of the election statement and the addendum posted with this final rule include only those content requirements set forth at § 418.24(b) and (c). However, as we noted in the proposed rule, hospices can develop their election statement and election statement addendum in any format that best suits their needs as long as the content requirements at § 418.24(b) and (c) are met. The examples were intended to assist hospices in understanding how they could format their election statement and addendum to meet the content requirements.

To address the comment of beneficiary (or representative) refusal to sign the addendum, we again point to the statement that must be included on the addendum that the signature is only acknowledgement of receipt and not a tacit agreement to its contents. Additionally, if the beneficiary (or representative) requests the addendum, we believe that hospices would conduct due diligence that the beneficiary (or representative) has been informed about the purpose of the addendum and the rationale for the signature. However, we recognize that there may be those rare instances in which the beneficiary (or representative) may refuse to sign the addendum, even though he or she has requested the form. We did not make any proposals addressing situations in which the beneficiary (or representative)

refuses to sign a requested addendum. While we believe that this would be a rare occurrence given this is primarily a beneficiary (or representative) request to receive such form, we will consider whether this issue needs to be addressed in future rulemaking.

We do not believe that providing an example of a completed addendum would be particularly helpful because of the unique clinical conditions of hospice beneficiaries and given that determinations regarding what is related versus unrelated to a patient's terminal illness and related conditions are made on a case-by-case basis.

As mentioned previously in this final rule, we did not propose any new policies as they relate to the modifications to the hospice election statement or the addendum requirements. These policies were finalized in the FY 2020 Hospice Wage Index and Payment Rate Update final rule with a delayed effective date of October 1, 2020. However, we still received comments on various aspects of the finalized policy and we have summarized these and responded below.

Comment: One commenter questioned if there is any impact on the election statement if non-covered items, services, or drugs are requested after the initial admission to hospice. That is, whether there are any additional documentation requirements to note that the addendum was requested. Another questioned whether there is a different form to sign, other than the election statement, if the patient requests the addendum after the effective date of the election acknowledging that the addendum was requested.

Response: If a beneficiary (or representative) requests the addendum after the effective date of the election, there is no impact on the election statement. Similarly, there is no separate form or additional documentation required if the beneficiary does request the addendum after the effective date of the election. As we stated in the FY 2020 Hospice Wage Index and Payment Rate Update final rule, we would expect hospices to document that the addendum was discussed with the patient (or representative) similar to how other patient and family discussions are documented. 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. This could be done however the hospice determines best meets its' needs.

Comment: A commenter stated that the regulations for the election statement addendum do not include language addressing the issuance of a requested addendum at the time of hospice election but where the beneficiary dies within the first 5 days of hospice care. This commenter stated that the preamble of the FY 2020 Hospice Wage Index and Payment Rate Update final rule addressed this particular issue. Specifically, CMS stated that if a beneficiary requests the addendum at the time of hospice election and dies within 5 days from the start of the hospice election and before the hospice can furnish the addendum, the hospice would not be required to furnish such addendum after the patient has died, as this requirement would be deemed as being met in this circumstance.

Response: Commenters are correct that, in the FY 2020 Hospice Wage Index and Payment Rate Update final rule (84 FR 38511), we stated that if the addendum is requested on the effective date of the hospice election (that is, the start of care date) and the beneficiary dies within the first 5 days from the start of hospice care and before the hospice is able to furnish the addendum, the addendum would not be required to be furnished after the patient has died, and this condition for payment would be considered met. While this was not codified in the regulations, we will issue sub-regulatory guidance to this effect and we will consider including this in the regulations in future rulemaking.

Comment: Several commenters remarked that there is conflicting language in § 418.24(c) as to who can request the addendum. Specifically, commenters referenced § 418.24(c)(6), which states that the beneficiary or representative should request the addendum and share the information with other health care providers. However, commenters stated that § 418.24(c) requires that the hospice provide the addendum to not only the requesting individual (or representative), but also to requesting non-hospice providers or Medicare contractors. One commenter expressed concern that the regulatory language at § 418.24(c) allows non-hospice providers and Medicare contractors to request the addendum absent the beneficiary (or representative) requesting such information from the hospice and this violates the rights of the patient to have control over their protected health information. A few commenters expressed concern that any lack of clarity regarding the addendum requirements could result in non-payment for hospice services given the addendum is a condition for payment.

Response: The regulations at § 418.24(c) reference who can request the addendum, that is the beneficiary (or representative), non-hospice provider, or Medicare contractor. Whereas, the regulations at § 418.24(c)(6) refer to one of the specific content items required on the addendum form, along with the statement 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.

We note that it is not a violation of patient rights to have control over their health information in the scenario where a non-hospice provider or Medicare contractor requests the addendum absent the beneficiary (or representative) requesting such information. As discussed previously in this final rule, the hospice beneficiary (or representative) does not have to separately consent to the release of this information to non-hospice providers furnishing services for unrelated conditions, because 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 (45 CFR 164.506).

Though non-hospice providers and Medicare contractors can request the addendum even in the event that the beneficiary (or representative) did not request this information, we remind commenters that this condition for payment is met only in those circumstances in which the beneficiary (or representative) has requested the addendum and there is a signed form in the hospice's medical record. In the event that a non-hospice provider or Medicare contractor requests the addendum, but the beneficiary (or representative) did not already request and sign the addendum, this would not be a violation of the condition for payment as described previously. Hospices can develop processes (including how to document such requests from non-hospice providers and Medicare contractors) to address circumstances in which the addendum was requested by a non-hospice provider or Medicare contractor but where there was no previous beneficiary

(or representative) request to receive the addendum.

Comment: One commenter requested that CMS clearly delineate in the final rule the differences between the election statement addendum and the Advance Beneficiary Notice (ABN) and provide guidance on when each document should be used as there are concerns that hospices may be confused as to each documents' purpose.

Response: We agree that it is important to ensure that hospices do not conflate these two documents and their respective purposes. We note that we provided detailed information on the purpose and use of the ABN in the FY 2020 Hospice Wage Index and Payment Rate Update final rule (84 FR 38512).

The ABN, Form CMS–R–131,[3] is issued by providers (including independent laboratories, home health agencies, and hospices), physicians, practitioners, and suppliers to Original Medicare (Fee-for-Service) 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, and its use 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 section 1879(g)(2) of the Act;
- Specific items or services that are billed separately from the hospice per diem payment, such as physician services, that are not reasonable and necessary as defined in either sections 1862(a)(1)(A) or 1862(a)(1)(C) of the Act; or
- The level of hospice care is determined to be not reasonable or medically necessary as defined in sections 1862(a)(1)(A) or 1862(a)(1)(C) of the Act.

Guidelines for issuing the ABN are published in the Medicare Claims Processing Manual, chapter 30, section 50. An ABN is not required to be given to a beneficiary for those items and services the hospice has determined to be unrelated to the terminal illness and related conditions, as these still may be covered under other Medicare benefits. Additionally, an ABN cannot be issued to transfer liability to the beneficiary when Medicare would otherwise pay for items and services. The purpose of the ABN is to inform beneficiaries of the listed items and services that Medicare in general, is not expected to approve, and the specific denial reason (that is, not medically reasonable and necessary). The hospice election statement addendum is intended to inform beneficiaries of items and services that the hospice benefit will not cover as the hospice has determined them to be unrelated to the terminal illness and related conditions. However, these items, services, and drugs may be covered under other Medicare benefits it eligibility and coverage conditions are met. Table 9 provides a quick reference as to the type of document that can be issued to Medicare hospice beneficiaries, the purpose of each document, the timing of when the document must be provided to the beneficiary, and when hospices would use the respective documents.

[3] CMS R–131. Advance Beneficiary Notice. *https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-Items/CMS012932.*

TABLE 9: Differences between the Advance Beneficiary Notice (ABN) and the Hospice Election Statement Addendum

Type of Document	Purpose of Document	Timing to Provide to Beneficiary	When it is Used by Hospices
Advance Beneficiary Notice (ABN)	To transfer potential financial liability to the Medicare beneficiary in certain instances.	Prior to delivery of the item or service in question. The hospice must provide enough time for the beneficiary to make an informed decision on whether or not to receive the service or item in question and accept potential financial liability	If there is an item or service that is usually paid for by Medicare Part A but may not be paid for in this particular case because it is not considered medically reasonable and necessary. If a patient is not terminally ill If the level of hospice care is determined to be not reasonable or medically necessary.
Hospice Election Statement Addendum	To inform the beneficiary (or representative) upon request, of any items, services, or drugs the hospice will not be providing because the hospice has determined them to be unrelated to the terminal illness and related conditions.	If the addendum is requested at the time of hospice election, the hospice has 5 days from the effective date of the election to furnish this information in writing. If the addendum is requested during the course of hospice care (that is, after the effective date of the election), the hospice has 72 hours (or 3 days) from the date of the request to furnish this information in writing.	Upon beneficiary request, if the hospice has determined that certain items, services, and drugs are unrelated to the terminal illness and related conditions and not covered by hospice. However, these items, services, and drugs may be covered under other Medicare benefits if coverage and eligibility requirements are met.

Comment: A few commenters urged CMS to encourage the use of an electronic format for both the hospice election statement and the addendum given the shift of most hospice providers to electronic platforms. Several other commenters questioned whether the addendum could be provided via an electronic patient portal and whether there could be an electronic version for potential use in communicating with other non-hospice providers. Another commenter recommended that CMS provide additional guidance for the hospice community and Medicare contractors on patient/representative electronic signatures and include in such guidance the ability to print an electronically signed document to provide a hard copy to a patient or representative. Other commenters stated that they are hopeful that if the election statement is in an electronic format then the electronic exchange of same data elements can be used to provide hospice election information to Part D plans more timely.

Response: We agree with these commenters that the use of electronic platforms can help facilitate more timely notification of hospice elections and can be expanded to increase interoperability. As noted in the FY 2020 Hospice Wage Index and Payment Rate Update final rule (84 FR 38511), hospices are free to develop their modified election statement and addendum to best meet their needs. This includes those hospices who develop these forms in an electronic format. As long as the content requirements at § 418.24(b) and (c) are met, there is nothing precluding a hospice from having an election statement and addendum in an electronic format.

While we did not specifically address the provision of the addendum via electronic patient portals or whether the addendum could be developed as an electronic version, we note that the requirement is that the information must be provided to the beneficiary (or representative), in writing. While we envisioned a hard copy document for ease of use and sharing with non-hospice providers, we note that we did not explicitly prohibit the use of an electronic patient portal or provision of the addendum as an electronic version, as we recognize information can be provided in a written, electronic format. We want hospices to be able to furnish

such information in the least burdensome way to facilitate the communication of this information to hospice patients and their families, and even potentially for communicating with non-hospice providers as suggested by the commenters. We also recognize that hospices may already have their existing election statements in an electronic format and hospices may prefer to have the addendum incorporated into their Electronic Medical Records (EMRs) as well. As long as the content requirements at § 418.24 (b) and (c) are met, including securing the beneficiary's (or representative's) signature acknowledging receipt of the addendum, there is nothing precluding a hospice from leveraging such technology. However, we require that the information be provided in a language and format that the beneficiary (or representative) understands. Therefore, if the beneficiary (or representative) receives the addendum in an electronic format but requests to have a hard copy version for their records, we expect that the hospice would accommodate such request.

The commenter is correct that there is no specific guidance addressing beneficiary (or representative) electronic signatures on the hospice election statement. Generally, it is at the contractor's discretion as to how they address patient (or representative) electronic signatures in their review of medical records. However, we will consider future guidance, if warranted, to address any issues as they relate to electronic signatures.

Finally, we are aware of some of the issues where Part D Plans are not aware of a beneficiary's hospice election in a timely fashion. We understand that delayed notifications of a hospice election prevent the Part D plan from placing patient-specific prior authorization on the drugs in the four classes commonly paid by the hospice providers; analgesics, anti-nauseants (antiemetics), laxatives, and antianxiety drugs (anxiolytics). Currently, hospices are encouraged to use an OMB approved form entitled ''Hospice Information for Medicare Part D Plans'' (OMB NO 0938–1269) to communicate hospice election and drug use to Part D plans.[4] However, since OMB form NO 0938–1269 was first approved, hospices have begun to use electronic health records (EHRs) in growing numbers. This development has opened the door to electronic transactions from the hospice to part D plans. The National Council for Prescription Drug Plans (NCPDP) convened a diverse task group which included payers, hospice organizations and processors to see if they could leverage hospice EHR capabilities to produce standard electronic transactions that can be used by Part D plans. CMS was pleased to learn that the NCPDP hospice task group is embarking upon a pilot project which extract data from a hospice's EHR and route that information to the correct Part D plan in real-time, thereby minimizing delays in the prior authorization process. We encourage hospices, their software vendors and Part D plans to participate in the pilot project and we await its outcome.

Comment: Most commenters still disagree with CMS's decision to make the election statement addendum a condition for payment. One commenter stated the addendum is redundant to existing obligations and that there is no basis for the addendum to be treated as a condition for payment for hospice services. This commenter added that the Social Security Act only authorizes the condition for hospice payment based on a patient's having made an election to receive hospice care and that an addendum, provided after the election, cannot and should not legally alter the election or make the election retroactively invalid for purposes of payment. Concerns about any errors to the addendum or an unreturned addendum could give rise to non-payment of hospice services for what CMS implies could be the patient's entire election period.

Response: We disagree with commenters that the election statement addendum should not be a condition for payment given the enormity of the decision of a Medicare beneficiary electing to receive hospice services. In fact, the content requirements for the hospice election statement at § 418.24 specifically state that there must be 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, as well as beneficiary acknowledgement that certain Medicare services are waived by the election. Moreover, section 1812(d)(2)(A) of the Act makes it clear that ''except in such exceptional and unusual circumstances as the Secretary may provide . . . if an individual makes such an election for a period with respect to a particular hospice program, the individual shall be deemed to have waived all rights to have payment made by Medicare'' for services that are related to the treatment of the individual's condition for which a diagnosis of terminal illness has been made. The Secretary has not provided for any ''unusual and exceptional circumstances'' and in the 1983 hospice final rule (48 FR 56010) we stated that hospices are required to provide virtually all the care needed by terminally ill patients. Our position remains the same today.

We do not believe that the decision to elect hospice services can be made without full information and disclosure as to what items, services, and drugs the hospice will and will not be covering based on their determinations of what is and what is not related to the terminal illness and related conditions. As detailed in the FY 2020 Hospice Wage Index and Payment Rate Update final rule (84 FR 38518), we believe making the hospice election statement addendum a condition for payment is necessary to ensure that hospices are diligent in providing this information to Medicare hospice beneficiaries on request. We regard this addendum as a means of accountability for hospices to provide coverage information to beneficiaries electing the hospice benefit.

In the FY 2020 Hospice Wage Index and Payment Rate Update proposed and final rules (84 FR 17570 and 84 FR 38484), we provided examples from OIG reports[5] [6] that highlight the issues with a patient's lack of knowledge regarding hospices' limitation on their coverage, and the potential for hospice non-coverage of certain expected items, services, and drugs. Also, as described in the preamble of the FY 2020 Hospice Wage Index and Payment Rate Update proposed rule, the impetus for this policy was not only from these various OIG reports, but from numerous anecdotal reports received by CMS describing situations in which hospice beneficiaries and their families had to continually seek items, services, and drugs outside of the hospice benefit to receive needed care that they expected the hospice would cover and provide.

One commenter remarked that requiring an addendum is redundant, implying that because hospices are already making determinations of relatedness, the beneficiary (or representative) is already being

[4] Medicare Part D Hospice Care Hospice Information for Medicare Part D Plans. *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Downloads/Instruction-and-Form-for-Hospice-and-Medicare-Part-D.pdf.*

[5] 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.*

[6] 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.*

informed of these determinations in order to allow them to make treatment decisions that best align with their preferences and goals of care. While we are encouraged that many hospices are already providing this important coverage information to hospice beneficiaries, both the OIG reports and anecdotal reports, as mentioned previously in this final rule, indicate that a lack of coverage transparency continues to be an issue for hospice beneficiaries.

Comment: A few commenters requested clarity regarding transfer situations; when to update the addendum; situations where a beneficiary requests the addendum but where the hospice has determined that there are no unrelated conditions, items, services, or drugs; whether specific QIO language must be used; the timeframe for providing the addendum if requested after the effective date of the election but within the first 5 days of hospice care; handling situations in which the beneficiary elects hospice care but with a future hospice date; the timing to obtain a signature on the addendum; and whether the addendum must be provided to all individuals receiving hospice care, including non-Medicare patients.

Response: Regarding the timeframe for providing the addendum to a requesting beneficiary who has transferred from one hospice to another, we remind commenters that a transfer does not change the effective date of hospice election. That means, if the beneficiary (or representative) requests the addendum from the receiving hospice, the hospice would have 72 hours (or 3 days) to furnish this information in writing. As to when hospices should update the addendum, in the FY 2020 Hospice Wage Index and Payment Rate Update final rule, we stated that 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. This could also include updating the addendum in situation where a condition, item, service or drug was previously considered unrelated, and therefore included on the addendum, is now considered related, and therefore would be covered by the hospice and removed from the addendum. Given that hospices develop their own addendum, hospices may add additional language to inform beneficiaries that the addendum reflects the most accurate information that the hospice has 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. Additionally, if the beneficiary (or representative) requested the addendum but the hospice has determined that all conditions, items, services, and drugs were related, and thereby covered by the hospice, the hospice could explain to the beneficiary (or beneficiary) that it is furnishing all care or the hospice can provide the addendum noting that at the time of the request, the hospice has determined that there were no unrelated conditions, items, services, and drugs. Hospices are free to develop any process for addendum updates to distinguish whether any updates are additions, deletions, or modifications, similar to processes hospices have in place for updates to the hospice plan of care.

As for the comment regarding specific BFCC–QIO language, we note that we did include specific BFCC–QIO language in the FY 2020 Hospice Wage Index and Payment Rate Update proposed rule. We finalized a requirement that the election statement itself must include information on the BFCC–QIO (including the BFCC–QIO contact information), and both the election statement and the addendum must include a statement about the beneficiary's right to Immediate Advocacy. Hospices can use whatever language they choose as long as this information is included in accordance with the requirements at § 418.24.

If the beneficiary does not request the addendum on the effective date of the election (that it, the start of care date), but within the 5-day timeframe after the effective date, the hospice would have 72 hours (or 3 days) from the date of the request to furnish the addendum as the regulations are clear that the 5-day timeframe relates to whether the beneficiary (or representative) requested the addendum on the effective date of the election (that is, the start date of hospice care). Regarding those situations in which the beneficiary elects hospice care, but with a future effective date, we remind commenters that the addendum would be furnished to the beneficiary (or representative) within 5 days of the effective date of the election. For example, if the beneficiary elects hospice on May 1st with an effective date of May 7th, the addendum, if requested, would be provided within 5 days of May 7th. And because the beneficiary signature is an acknowledgement of receipt of the addendum, this means that the beneficiary would sign the addendum when the hospice provides it, in writing, to the beneficiary (or representative). We note that these finalized policies relating to the election statement modifications and the addendum are for beneficiaries receiving services under the Medicare hospice benefit. While the addendum is not required to be provided to non-Medicare patients, hospices can choose to do so.

Comment: One commenter recommended that to effectively address inappropriate spending outside of the Medicare hospice benefit, CMS must take steps in addition to the addendum policy, to identify the breadth of issues that are contributing to the problem. The commenter suggested analysis of the spending data to determine what proportion of this spending is occurring within the first weeks of hospice care when CMS systems have not been updated with Medicare election information and what proportion of this spending is a result a hospice informing the provider that the item, service, or drug is unrelated. Finally, this commenter stated that CMS must look at any additional systems issues, as well as any other delays that slow the posting of new beneficiary status information. This commenter also stated that a large proportion of non-hospice spending is a result of related items, services, or drugs but which are not reasonable and necessary under a hospice plan of care.

Response: We appreciate the suggestions made by this commenter and we note that we continue to analyze hospice utilization data, including analyzing data on live discharges, lengths of stay, pre-hospice spending, and non-hospice spending. We have previously shared these results through rulemaking and other mechanisms of communication. We also note that we have made every effort to enhance the processing time of the hospice NOE to ensure that Medicare systems are updated in a timelier fashion. Specifically, effective January 1, 2018, hospices can submit the NOE via Electronic Data Interchange (EDI). EDI transmission and receipt of NOEs would reduce, and potentially eliminate, problems with NOEs that result from Direct Data Entry (DDE) keying errors. Hospices could export data from their electronic medical record or other software system into the EDI format without human intervention. We continually look at ways to further streamline these processes and appreciate commenter suggestions. We will consider the commenter's recommendations moving forward as we continue to analyze the effects of current hospice policies and for any future rulemaking and other efforts.

Comment: Most commenters recommended that CMS delay the

October 1, 2020 effective date because of the public health emergency declared by the Secretary in response to the COVID–19 pandemic. Specifically, commenters recommended a delay of at least one full year beyond the end date of the COVID–19 public health emergency because of concerns that hospices have shifted their operational priorities to address the pandemic and have not had time to complete the modifications to the election statement, develop the addendum, or establish new processes and train new staff on the new content requirements. Commenters also expressed concerns over EMR software readiness citing that EMR vendors have not provided any deliverables related to the modifications to the election statement and the addendum, and that hospices need delivery of software modifications in order to test the software, as well as develop processes and prepare for implementation.

Commenters also stated that, based on their research and inquiries to the Medicare contractors and the BFCC–QIOs, there has been no communication from CMS to the contractors related to the addendum as a condition for payment, or to the BFCC–QIOs related to a patient/representative request for Immediate Advocacy if the beneficiary (or representative) disagrees with the hospices determinations as to those items, services, and drugs the hospice has determined to be unrelated to the terminal illness and related conditions. These commenters cited the delayed implementation of OASIS–E as a result of the public health emergency as precedent and requested a similar delay for the addendum requirements as this would allow for adequate time for hospices, EMR vendors, Medicare contractors, and BFCC–QIOs to be fully prepared for these changes.

Response: We appreciate the magnitude of efforts undertaken by hospice providers as our country responds to the public health emergency for the COVID–19 pandemic. The effective date for the election statement modifications and the addendum implementation are effective for hospice elections on and after October 1, 2020 and this finalized policy already reflects a delayed effective date of 1 year. We note that there were no proposed changes to the election statement modifications or the addendum in the FY 2021 Hospice Wage Index and Payment Rate Update proposed rule, therefore, all of the content requirements were finalized in the FY 2020 Hospice Wage Index and Payment Rate Update final rule. We expect that hospices have already begun making the modifications to their election statements and developing their addendums in anticipation of a FY 2021 effective date and well before the start of the public health emergency. We also anticipate that hospices already have engaged with their EMR vendors to start making the necessary changes resulting from a policy that was finalized in the FY 2020 Hospice Wage Index and Payment Rate Update final rule but with a delayed effective date. The expectation was that hospices would start making these modifications when these requirements were finalized in the FY 2020 Hospice Wage Index and Payment Rate Update final rule (published on August 6, 2019). The public health emergency underscores the importance of providing the ''Patient Notification of Hospice Non-Covered Items, Services, and Drugs'' to requesting hospice beneficiaries to ensure they are able to make treatment decisions to best meet their needs during this time.

We continue to have ongoing discussions with the MACs and BFCC–QIOs and will continue to provide education throughout the upcoming months leading up to the effective date of this policy. This will include the release of sub-regulatory guidance, and MLN® articles to ensure education is furnished to all relevant stakeholders. We assure hospices that all parties will be aware of the policies and their respective roles. And with any new policy, we will continue to monitor and communicate with stakeholders to determine if any future changes are warranted. The goal is to ensure the least amount of burden to providers while also ensuring beneficiary protection and engagement.

In summary, the hospice election statement modifications and the hospice election statement addendum requirements at 42 CFR 418.24(b) and (c) will be effective for hospice elections beginning on and after October 1, 2020 as finalized in the FY 2020 Hospice Wage Index and Payment Rate Update final rule (84 FR 38520). The hospice election statement addendum will remain a condition for payment and as finalized, this condition for payment would be met if there is a signed addendum (and its updates) in the requesting beneficiary's hospice medical record. The signed addendum is only acknowledgement of the beneficiary's (or representative's) receipt of the addendum and not agreement with the hospice's determination. To assist hospices in understanding these content requirements and based on comments received, we have posted with this final rule, the modified model examples of the hospice election statement and hospice election statement addendum on the Hospice Center web page as illustrative examples. As finalized in the FY 2020 Hospice Wage Index and Payment Rate Update final rule, hospices will make the election statement modifications and develop the addendum to best suit their needs as long as the content requirements are met.

D. Hospice Quality Reporting Program (HQRP)

Although CMS did not propose any changes to the HQRP for FY 2021, some therapy associations commented and encouraged the agency to continue to provide adequate provider training to ensure accuracy and consistency in linking care planning and services with data collection to allow the data to effectively promote improved care planning and service implementation. Another commenter stated that CMS should require quality performance be factored into payment and determinations of any performance-based incentives for hospice providers. We thank commenters for their suggestions. While these comments are outside the scope of this rule, we assure commenters that we continue to consider ways to inform and educate hospices regarding quality reporting, data collection, and processes to ensure that hospice beneficiaries continue to receive high quality hospice care. We agree that quality performance should factor into performance-based incentives for hospice providers and the HQRP is one mechanism to promote such performance.

III. Collection of Information Requirements

This final rule does not impose any new or revised ''collection of information'' requirements or burden. For the purpose of this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of OMB's Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*) implementing regulations. Since this rule does not impose any new or revised collection of information requirements or burden, the rule is not subject to the requirements of the PRA.

IV. 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 CBSAs or previously used 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 HQRP 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 rule will result in an increase of $540 million in payments to hospices, resulting from the hospice payment update percentage of 2.4 percent for FY 2021. The impact analysis of this rule represents the projected effects of the changes in hospice payments from FY 2020 to FY 2021. Using the most recent data available at the time of rulemaking, in this case FY 2019 hospice claims data as of May 12, 2020, we apply the current FY 2020 wage index. Then, using the same FY 2019 data, we apply the FY 2021 wage index to simulate FY 2021 payments. Finally, we apply a budget neutrality adjustment so that the aggregate simulated payments do not increase or decrease due to changes in the wage index.

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 hospices and most other hospice-related 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 2021 hospice payment update percentage results in an overall increase of hospice payments of 2.4 percent, or $540 million. The distributional effects of the final FY 2021 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. 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 MSA 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. In 2020, that threshold is approximately $156 million. This final rule is not anticipated to have an effect on state, local, or tribal governments, in the aggregate, or on the private sector of $156 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 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 last year's proposed rule

will be the number of reviewers of this rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we believe that the number of past commenters would be a fair estimate of the number of reviewers of this final rule. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of the proposed rule, and therefore, for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule.

Using the wage information from the May 2019 Bureau of Labor Statistics (BLS) for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $110.74 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes_nat.htm*). This rule consists of approximately 23,000 words. Assuming an average reading speed of 250 words per minute, it would take approximately 0.77 hours for the staff to review half of it. For each hospice that reviews the rule, the estimated cost is $85.27 (0.77 hour × $110.74). Therefore, we estimate that the total cost of reviewing this regulation is $4,519.31 ($85.27 × 53 reviewers).

D. Detailed Economic Analysis

1. Hospice Payment Update for FY 2021

The FY 2021 hospice payment impacts appear in Table 10. 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 effect of using the FY 2021 updated wage data. This represents the effect of moving from the FY 2020 hospice wage index to the FY 2021 unadjusted hospice wage index with the old OMB delineations. The fourth column shows the effect of moving from the old OMB delineations to the new OMB delineations with a 5 percent cap on wage index decreases. The aggregate impact of the changes in columns three and four is zero percent, due to the hospice wage index standardization factor. However, there are distributional effects of the FY 2021 hospice wage index. The fifth column shows the FY 2021 hospice payment update percentage of 2.4 percent as mandated by section 1814(i)(1)(C) of the Act, and is consistent for all providers. The 2.4 percent hospice payment update percentage is based on an estimated 2.4 percent inpatient hospital market basket update, reduced by a 0 percentage point productivity adjustment. It is projected that aggregate payments would increase by 2.4 percent, assuming hospices do not change their service and billing practices. The sixth column shows the estimated total impact for FY 2021.

We note that simulated payments are based on utilization in FY 2019 as seen on Medicare hospice claims (accessed from the CCW in May of 2020) 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 10, the combined effects of all the proposals vary by specific types of providers and by location.

TABLE 10: Impact to Hospices for FY 2021

Hospice Subgroup	Hospices	FY 21 Updated Wage Data	New OMB Delineations (5% Cap)	Market Basket	Overall Total Impact (Adding Individual Percentage Changes)
All Hospices	4,760	0.0%	0.0%	2.4%	2.4%
Hospice Type and Control					
Freestanding/Non-Profit	594	0.0%	0.1%	2.4%	2.5%
Freestanding/For-Profit	3,002	0.0%	0.0%	2.4%	2.4%
Freestanding/Government	39	0.3%	0.0%	2.4%	2.7%

Freestanding/Other	362	0.1%	-0.1%	2.4%	2.4%
Facility/HHA Based/Non-Profit	381	-0.1%	0.0%	2.4%	2.3%
Facility/HHA Based/For-Profit	204	0.1%	0.0%	2.4%	2.5%
Facility/HHA Based/Government	94	0.0%	0.1%	2.4%	2.5%
Facility/HHA Based/Other	84	0.3%	0.2%	2.4%	2.9%
Subtotal: Freestanding Facility Type	3,997	0.0%	0.0%	2.4%	2.4%
Subtotal: Facility/HHA Based Facility Type	763	0.0%	0.0%	2.4%	2.4%
Subtotal: Non-Profit	975	0.0%	0.0%	2.4%	2.4%
Subtotal: For Profit	3,206	0.0%	0.0%	2.4%	2.4%
Subtotal: Government	133	0.2%	0.0%	2.4%	2.6%
Subtotal: Other	446	0.1%	-0.1%	2.4%	2.4%
Hospice Type and Control: Rural					
Freestanding/Non-Profit	147	0.3%	0.0%	2.4%	2.7%
Freestanding/For-Profit	335	0.2%	0.0%	2.4%	2.6%
Freestanding/Government	21	0.3%	0.0%	2.4%	2.7%
Freestanding/Other	48	0.2%	0.0%	2.4%	2.6%
Facility/HHA Based/Non-Profit	151	0.2%	0.0%	2.4%	2.6%
Facility/HHA Based/For-Profit	47	0.5%	0.0%	2.4%	2.9%
Facility/HHA Based/Government	68	0.1%	0.0%	2.4%	2.5%
Facility/HHA Based/Other	51	0.1%	0.0%	2.4%	2.5%
Facility Type and Control: Urban					
Freestanding/Non-Profit	447	0.0%	0.1%	2.4%	2.5%
Freestanding/For-Profit	2,667	0.0%	0.0%	2.4%	2.4%
Freestanding/Government	18	0.3%	0.0%	2.4%	2.7%
Freestanding/Other	314	0.1%	-0.1%	2.4%	2.4%
Facility/HHA Based/Non-Profit	230	-0.2%	0.0%	2.4%	2.2%
Facility/HHA Based/For-Profit	157	0.0%	0.0%	2.4%	2.4%
Facility/HHA Based/Government	26	0.0%	0.1%	2.4%	2.5%
Facility/HHA Based/Other	33	0.3%	0.3%	2.4%	3.0%
Hospice Location: Urban or Rural					
Rural	868	0.2%	0.0%	2.4%	2.6%
Urban	3,892	0.0%	0.0%	2.4%	2.4%

Hospice Location: Region of the Country (Census Division)					
New England	155	-0.7%	0.0%	2.4%	1.7%
Middle Atlantic	279	0.5%	0.0%	2.4%	2.9%
South Atlantic	562	0.0%	0.0%	2.4%	2.4%
East North Central	548	0.3%	0.0%	2.4%	2.7%
East South Central	261	0.1%	0.0%	2.4%	2.5%
West North Central	407	-0.6%	0.0%	2.4%	1.8%
West South Central	924	0.2%	0.0%	2.4%	2.6%
Mountain	484	-0.5%	0.0%	2.4%	1.9%
Pacific	1,094	0.0%	0.1%	2.4%	2.5%
Outlying	46	-0.7%	-0.1%	2.4%	1.6%
Hospice Size					
0 - 3,499 RHC Days (Small)	1,066	0.0%	0.0%	2.4%	2.4%
3,500-19,999 RHC Days (Medium)	2,142	0.0%	0.0%	2.4%	2.4%
20,000+ RHC Days (Large)	1,552	0.0%	0.0%	2.4%	2.4%

Source: FY 2019 hospice claims data from CCW accessed on May 12, 2020.

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 P**acific**= Alaska, California, Hawaii, Oregon, Washington
Outlying=Guam, Puerto Rico, Virgin Islands

2. Hospice Election Statement Addendum

In the FY 2020 Hospice Wage Index and Payment Rate Update final rule (84 FR 38553), we finalized modifications to the election statement content requirements at § 418.24(b) and (c) to include a hospice election statement addendum, effective for hospice elections beginning on and after October 1, 2020. This effective date reflects a 1-year delay to allow hospices to make the necessary modifications to their existing election statement, develop their own addendum to best meet their needs, and establish processes for incorporating the addendum into their work flow.

In the FY 2020 Hospice Wage Index and Payment Rate Update final rule (84 FR 38532), we estimated that the addendum requirement would generate an annualized net reduction in burden of approximately $5.2 million, 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.

While we did not re-estimate this burden in the regulatory impact analysis in the FY 2021 Hospice Wage Index and Payment Rate Update proposed rule, we received the following comment regarding the hospice election statement burden estimate as described and calculated in the FY 2020 Hospice Wage Index and Payment Rate Update final rule.

Comment: One commenter noted that there was no updated burden estimate in the FY 2021 Hospice Wage Index and Payment Rate Update proposed rule even though we stated in the FY 2020 Hospice Wage Index and Payment Rate Update final rule (84 FR 38533) that we would re-estimate the burden estimate using more current data for 2021 rulemaking. The commenter stated that the previous burden estimate underestimates the amount of time it takes to complete the addendum and requested an updated estimate in the FY 2021 Hospice Wage Index and Payment Rate Update final rule with an opportunity for stakeholder comment.

Response: We apologize for any oversight in providing an updated burden estimate in the FY 2021 Hospice Wage Index and Payment Rate Update proposed rule. The calculated burden for completion of the hospice addendum is only an estimate using the most current data at the time of rulemaking. Hospices are already required to make determinations as to the items, services, and drugs that are to be included in the individualized hospice plan of care; therefore, this means they are also making decisions as what items, services, and drugs it will not be covering as the hospice has determined them to be unrelated to the terminal illness and related conditions.

We do not believe that a hospice can make a determination of what is related to the terminal illness and related conditions without also determining what is unrelated. Therefore, this decision making process is already occurring; the addendum is only requiring to furnish this information, in writing, to the beneficiary (or representative). We believe that hospices are developing their respective addendums to incorporate into their work flow processes in the most efficient way possible to ensure that the communication of these determinations is done in the most unobtrusive and least burdensome way possible.

We recalculated the overall burden using the May, 2019 BLS wage data and 2019 hospice claims data for this final rule. To calculate this burden estimate, we used the same methodology described in the FY 2020 Hospice Wage Index and Payment Rate Update final rule (84 FR 38532). We calculated this updated estimate based on 1,387,331 hospice elections in FY 2019. Of these hospice elections, 27 percent of beneficiaries died within the first 5 days of hospice care, leaving 1,012,752 eligible hospice elections for this burden estimate (1,387,331 x 0.73). We remind commenters that the addendum would not need to be furnished if the beneficiary dies within 5 days of the hospice effective date. For FY 2021, we estimate the annualized net burden for hospice providers with the one-time form development and completion of election statement addendum to be $12.8 million. This is slightly higher than the estimated $11.3 million in the FY 2020 Hospice Wage Index and Payment Rate Update final rule primarily because there were more eligible hospice elections using FY 2019 hospice claims data compared to the FY 2017 hospice claims data used in the previous calculation. We estimate the annualized monetized net reduction in burden for non-hospice providers with the regulations change at § 418.24, Election Statement Addendum, to be $19.3 million. This would result in a total annualized net reduction in burden with the election statement addendum in FY 2021 to be $6.5 million. Because we included these burden estimates in the accounting statement in the FY 2020 Hospice Wage Index and Payment Rate Update final rule (84 FR 38543), this updated estimate is not included in accounting statement in this FY 2021 Hospice Wage Index and Payment Rate Update final rule.

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 11, 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 $540 million in transfers to hospices in FY 2021. All expenditures are classified as transfers to hospices. The costs for the hospice election statement addendum were accounted for in the FY 2020 Hospice Wage Index and Payment Rate final rule (84 FR 38543) and therefore these are not accounted for in this FY 2021 final rule accounting statement.

TABLE 11: Accounting Statement: Classification of Estimated Transfers and Costs, From FY 2020 to FY 2021

Category	Transfers
Annualized Monetized Transfers	$ 540 million*
From Whom to Whom?	Federal Government to Medicare Hospices

*The net increase of $540 million in transfer payments is a result of the 2.4 percent hospice payment update compared to payments in FY 2020.

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.'' It has been determined that this rule is an action that primarily results in transfers and does not impose more than *de minimis* costs as described above and thus is not a regulatory or deregulatory action for the purposes of Executive Order 13771.

G. Conclusion

We estimate that aggregate payments to hospices in FY 2021 will increase by $540 million, or 2.4 percent, compared to payments in FY 2020. We estimate that in FY 2021, hospices in urban areas will experience, on average, 2.4 percent increase in estimated payments compared to FY 2020, while hospices in rural areas will experience, on average, 2.6 percent increase in estimated payments compared to FY 2020. Hospices providing services in the Middle Atlantic region would experience the largest estimated increases in payments of 2.9 percent. Hospices serving patients in areas in the New England and Outlying regions would experience, on average, the lowest estimated increase of 1.7 percent and 1.6 percent, respectively in FY 2021 payments.

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

Dated: July 23, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: July 29, 2020

Alex M. Azar II,

Secretary, Department of Health and Human Services.

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