Medicare Program; FY 2016 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements

[CMS-1629-P]

Summary of Proposed Rule

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I. Introduction and Background (pages 25832-25840)

On April 30, 2015, the Centers for Medicare & Medicaid Services (CMS) placed on public display a proposed rule updating the Medicare hospice payment rates and wage index for FY 2016, including implementing the last year of the phase out of the wage index budget neutrality adjustment factor (BNAF). The proposed rule was subsequently published in the May 5, 2015 issue of the *Federal Register* (80 FR 25832-25886). Page references given in this summary are to this published document. ***Comments on the proposed rule are due by June 29, 2015.***

CMS estimates that the overall impact of the proposed rule will be an increase of $200 million (1.3 percent) in Medicare payments to hospices during FY 2016.

This proposed rule provides an update on hospice payment reform analyses, and proposes to differentiate payments for routine home care (RHC) based on the beneficiary's length of stay and to implement a service intensity add-on (SIA) payment for services provided in the last 7 days of a beneficiary's life, if certain criteria are met. In addition, this rule proposes changes to the aggregate cap calculation mandated by the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act), to align the cap accounting year for both the inpatient cap and the hospice aggregate cap with the federal fiscal year starting in FY 2017. In addition, the rule proposes changes to the hospice quality reporting program, and includes a clarification on diagnosis reporting on the hospice claim. It also addresses several other matters.

CMS notes that wage index addenda will be available only through the internet at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/index.html.

The proposed rule reviews the history of the Medicare hospice benefit, including the adoption of a new methodology for calculating the hospice wage index (for FY 1998). CMS notes that the number of Medicare beneficiaries receiving hospice services has grown from 513,000 in FY 2000 to over 1.3 million in FY 2013. Similarly, Medicare hospice expenditures have risen from $2.8 billion in FY 2000 to an estimated $15.3 billion in FY 2013. And the average lifetime length of stay for hospice beneficiaries has increased from 54 days in 2000 to 98.5 days in 2013. Almost one-third of the hospice claims in FY 2014 had one of these principal diagnoses: Alzheimer's disease, Congestive Heart Failure, Lung Cancer, Chronic Airway Obstruction and Senile Dementia.

II. Provisions of the Proposed Rule (pages 25840-25881)

A. Hospice Payment Reform: Research and Analyses (pages 25840-25850)

CMS reports that since the implementation of the Medicare hospice benefit, the principal diagnosis for patients electing the hospice benefit has changed from primarily cancer diagnoses in 1983 to primarily non-cancer diagnoses in FY 2014. The most common principal diagnoses reported were Alzheimer's disease and Congestive Heart Failure, comprising 17 percent of all diagnoses reported. CMS provides data on pre-hospice spending for those beneficiaries who used hospice and died in FY 2013. CMS finds that median Medicare spending for a beneficiary with a diagnosis of Alzheimer's disease, non-Alzheimer's dementia, or Parkinson's was significantly lower than the FY 2013 RHC rate 180 days ($66.84 compared to $153.45) and even 30 days prior ($105.24 compared to $153.45) to a hospice election. CMS notes at this time it does not have the necessary data on the hospice claim form to conduct more thorough research to determine whether a case-mix system is appropriate that would differentiate hospice payments according to patient characteristics. CMS notes that analyzing pre-hospice spending was undertaken as an initial step in examining this issue.

CMS also provides data regarding non-hospice spending for hospice beneficiaries during an election. In FY 2013, the agency found that Medicare paid $694.1 million for Part A and Part B items or services while a beneficiary was receiving hospice care. In addition, total drug spending by Medicare, states, beneficiaries, and other payers in FY 2013 under Part D was $439.5 million for hospice beneficiaries during a hospice election (of which $347.1 million was paid by Medicare). Thus, in FY 2013, non-hospice Medicare expenditures occurring during a hospice election were $694.1 million for Parts A and B spending, plus $347.1 million for Part D spending, or about $1 billion. Further, hospice beneficiaries had $132.5 million in cost-sharing for items and services that were billed to Medicare Parts A and B, and $50.9 million in cost-sharing for drugs that were billed to Medicare Part D, while they were in a hospice election.

CMS also notes concern based on a recent OIG report and its own case studies that have identified instances in which drugs, supplies, and durable medical equipment (DME) were provided to hospice patients and appeared to be related to the principal diagnosis reported on the

hospice claim, but were billed separately to the Medicare program.[1] This is in violation of requirements regarding the Medicare hospice benefit. Based on its analyses, CMS estimates the amount that should have been covered under the hospice benefit (instead of being billed separately to Medicare Part B, D, or DME) for four of the most common principal diagnoses on hospice claims: $11.2 million for cerebral degeneration; $10.4 million for chronic airway obstruction; $5.8 million for congestive heart failure; and $3.4 million for lung cancer.

CMS also notes that starting July 1, 2012, the discharge information collected on the Medicare hospice claim was expanded to capture the reason for all types of discharges. In order to better understand the characteristics of hospices with high live discharge rates, CMS examined the aggregate cap status, skilled visit intensity; average lengths of stay; and non-hospice spending rates per beneficiary. Overall, CMS found that between 2000 and 2013, the overall rate of live discharges increased from 13.2 percent in 2000 to 18.3 percent in 2013. CMS reports that hospices with higher live discharge rates are also above the aggregate cap status, provide fewer visits per week, and had higher non-hospice Medicare spending. CMS suggests based on these findings that the benefit is being used as long-term custodial benefit rather than an end of life benefit, and CMS continues to be concerned, as is MedPAC and the OIG, that hospices may be admitting patients who do not meet eligibility criteria.

B. Proposed Routine Home Care Rates and Service Intensity Add-On Payment
(pages 25850-25859)

CMS notes that MedPAC and other organizations have reported findings suggesting that the hospice benefit's fixed per-diem payment system does not accurately reflect the true variance of costs over the course of a hospice episode of care.[2] These analyses suggest that the intensity of services over the duration of a hospice stay results in a "U-Shaped" pattern; that is, the intensity of services is both higher at both admission and near death, and relatively lower during the middle period of the hospice episode. CMS expresses concern that this financial incentive appears to have resulted in hospices enrolling beneficiaries that are truly not eligible for the benefit, and thus results in the benefit becoming a "long-term custodial care" benefit rather than the end-of-life care for which the benefit was originally designed. At the same time, CMS expresses concern about the possibility that some Medicare beneficiaries and their families are not receiving hospice care and support at the very end of life. In particular, CMS cites analyses that beneficiaries are not receiving skilled visits during the last few days of life, even though patient needs typically surge and more intensive services are warranted (See table 14 in the proposed rule, page 25853).

To address these concerns, CMS proposes changes to its RHC rates and adding a SIA payment.

1. <u>Proposed Routine Home Care Rates</u>

CMS proposes two different RHC rates that would result in a higher base payment rate for the first 60 days of hospice care and a reduced base payment rate for days 61 or over of hospice care.

[1] https://oig.hhs.gov/oas/reports/region6/61000059.asp "Medicare Could Be Paying Twice for Prescriptions For Beneficiaries in Hospice

[2] Medicare Payment Advisory Commission (MedPAC). "Reforming Medicare's Hospice Benefit." *Report to the Congress: Medicare Payment Policy*. March, 2009. Web. 18 Feb. 2015.

CMS believes that this will help ensure that hospices are paid adequately for providing care to patients regardless of their needs, while also encouraging hospices to more carefully determine patient eligibility for hospice care. In particular, CMS notes that the daily cost of care, as measured in wage-weighted minutes, declines quickly for individual patients during their hospice episodes, and for long-episode periods remain low (See figures 5 and 6 in proposed rule, page 25855). As a result, CMS points out that long-episode patients are potentially more profitable than shorter-episode patients under the current payment structure where the payment rate is the same for the entire episode.

CMS calculates the RHC payment rate in a multi-step process by first calculating the revised labor portion of the RHC rate, adjusting the rate to maintain budget neutrality, and adding in the non-labor portion. Table 17 in the proposed rule (reproduced below) shows the steps required to calculate the revised labor portion of the RHC rate. To calculate the labor portion of the RHC payment rate for days 1 through 60, CMS first compares the average wage weighted minutes per day for days 1 through 60 to the overall average wage-weighted minutes per day ($21.69/$17.21)=1.2603. CMS then multiplies this ratio by the labor portion of the FY 2015 RHC rate which equals 1.2603*$109.48 = $137.98 (calculations reproduced from Table 17 in proposed rule). A similar calculation is performed for days 61+ payment category.

Table 17: FY 2015 RHC Rate Revised Labor Portion Calculation

(1)	(2)	(3)	(4)	(5)	(6)
	FY 2015 RHC Payment Rate	RHC Labor Related Share	FY 2015 RHC Payment Rate - Labor Portion	Average wage weighted minutes for RHC differential rate/Overall RHC Average wage weighted minutes	Revised FY 2015 Labor Portion
Days 1-60	$159.34	X 0.6871	$109.48	X 1.2603 ($21.69/$17.21)	$137.98
Days 61+	$159.34	X 0.6871	$109.48	X 0.8722 ($15.01/$17.21)	$95.48

CMS then adjusts the revised 2015 labor portion for budget neutrality, as required by statute, and adds in the FY 2015 non-labor portion. Table 18 in the proposed rule (reproduced below) shows the steps required to calculate the FY 2015 revised RHC payment rates. To adjust for budget neutrality, the proposed RHC rates are adjusted by a ratio of the total labor payments for RHC under using the current single rate for RHC to the estimated total labor payments for RHC using the two proposed rates for RHC. This ratio results in a budget neutrality adjustment of 0.9985. Then, CMS adds in the FY 2015 non-labor portion. For example, to calculate the revised RHC payment rate for days 1-60, CMS multiples the revised 2015 labor portion by the budget neutrality adjustment factor ($137.98*0.9985=$137.77) and then adds in the FY 2015 non-labor portion ($137.77+$49.86=$187.63). This rate is then adjusted by the market basket update factor and other adjustments to determine the 2016 RHC payment rate (see page 9 of this summary). A similar calculation is performed for days 61+ payment category.

Table 18: RHC Budget Neutrality Adjustment for RHC Rates

(1)	(2)	(3)	(4)	(5)	(6)
	Revised FY 2015 Labor Portion	Budget Neutrality Factor[1]	Revised FY 2015 Labor Portion with Budget Neutrality	FY 2015 Non-Labor Portion	FY 2015 Revised RHC Payment Rates
Days 1-60	$137.98	X 0.9985	$137.77	$49.86	$187.63
Days 61+	$95.49	X 0.9985	$95.35	$49.86	$145.21

[1]The budget neutrality adjustment is required due to differences in the average wage index for days 1-60 compared to days 61 and over.

CMS also proposes that the count of days follow the patient to mitigate potential high rates of discharge and readmissions. For hospice patients who are discharged and readmitted to hospice within 60 days of that discharge, his or her prior hospice days will continue to follow the patient and count toward his or her patient days for the receiving hospice upon hospice election. This is solely to determine whether the receiving hospice may bill at the 1 through 60 or 61+ RHC rate. CMS further clarifies that the proposed policy does not preclude the receiving hospice (same or different hospice) from billing for a per diem payment for each hospice day. CMS notes that program integrity and oversight efforts including but not limited to medical review, MAC audits, Zone Program Integrity Contractor actions, Recovery Auditor activities, or suspension of provider billing privileges, are being considered to address fraud and abuse.

CMS solicits public comments on all aspects of the proposed RHC payment rates as well as this policy in conjunction with the proposed SIA payment (described below).

2. Proposed Service Intensity Add-on Payment

CMS proposes to implement a SIA payment for FY 2016 and subsequent fiscal years. This proposed payment is a payment that would be made for the last seven days of life in addition to the per-diem rate for the RHC level of care, if certain criteria are met. This is intended to address MedPAC and industry concerns regarding the visit intensity at the end of life and the concerns associated with the profitability of hospice short stays. CMS had considered other options, including a tiered payment model, but believed a SIA payment would best address the requirements of reasonable costs (as required by Section 1814(i)(1)(A) of the Social Security Act, or the Act) and could be implemented with minimal processing system changes.

To qualify for the SIA payment, CMS proposes that the following criteria must be met:

(1) the day is billed as an RHC level of care day;

(2) the day occurs during the last 7 days of life (and the beneficiary is discharged dead);

(3) direct patient care is provided by an RN or a social worker that day; and

(4) the service is not provided in a skilled nursing facility/nursing facility (SNF/NF).

The proposed SIA payment would be equal to the CHC hourly payment rate (the current FY 2015 CHC rate is $38.75 per hour), multiplied by the amount of direct patient care provided by

an RN or social worker for up to 4 hours total, per day, as long as the four criteria listed above are met. The proposed SIA payment would be paid in addition to the current per diem rate for the RHC level of care. CMS says that it would create two separate G-codes for use when billing skilled nursing visits (revenue center 055x), one for an RN and one for a Licensed Practical Nurse (LPN). CMS also proposes that it will only pay an SIA for social work visits that are provided in-person.

CMS states, as required by statute, that any changes to the hospice payment system must be made in a budget neutral manner in the first year of implementation. CMS proposes to make the SIA payments budget neutral through a reduction to the overall RHC rate. In addition, CMS proposes to continue budget neutrality through an annual determination of the SIA payment budget neutrality factor (SBNF), which will then be applied to the RHC payment rate. CMS also proposes wording changes in the regulation text; proposing to change the word "Intermediary" to "Medicare Administrative Contractor" in the regulations text at §418.302 and proposing technical regulations text changes to §418.306. ***CMS solicits public comment on all aspects of the proposed SIA payment.***

C. FY 2016 Hospice Wage Index and Rates Update (pages 25859-25867)

A summary of key data for the proposed hospice payment rates for FY 2016 is presented below with additional details in the subsequent sections.

Summary of Key Data for Proposed Hospice Payment Rates for FY 2016			
Market basket update factor			
Market basket increase			+2.7%
Required multi-factor productivity (MFP) adjustment			-0.6%
ACA mandated reduction			-0.3%
Net MFP-adjusted update reporting quality data			**+1.8%**
Net MFP-adjusted update not reporting quality data			**-0.2%**
Hospice aggregate cap amount			$27,624.41
Hospice Payment Rate Care Categories	**Labor Share**	**FY 2015 Federal Rates Per Diem**	**FY 2016 Federal Rates Per Diem**
Routine Home Care (days 1-60)	68.71%	$159.34**	$188.20
Routine Home Care (days 61+)	68.71%	$159.34**	$147.34
Continuous Home Care, Full Rate = 24 hours of care, $39.44 hourly rate	68.71%	$929.91	$946.65
Inpatient Respite Care	64.01%	$164.81	$167.78
General Inpatient Care	54.13%	$708.77	$721.53
Proposed Service Intensity Add-on (SIA) payment, up to 4 hours			$39.44 per hour
** Note, only one payment category exists for Routine Home Care in FY 2015, CMS proposes to split this care category into two levels in FY 2016.			

1. <u>FY 2016 Hospice Wage Index</u>

For FY 2016, CMS proposes to use the 2015 pre-floor, pre-reclassified hospital wage index to derive the applicable wage index values for the hospice program, and to continue its policy of

not taking into account geographic reclassifications under the inpatient prospective payment system in determining payments for hospices. CMS also proposes to continue to apply current policies for handling geographic areas where there are no hospitals. For urban areas of this kind, all of the core-based statistical areas (CBSAs) within the state would be used to calculate a statewide urban average pre-floor, pre-reclassified hospital wage index value for use as a reasonable proxy for these areas. In FY 2016, the only CBSA without a hospital from which hospital wage data could be derived in 25980, Hinesville-Fort Stewart, Georgia. For rural areas without hospital wage data, CMS has used the average pre-floor, pre-reclassified hospital wage index data from all contiguous CBSAs to represent a reasonable proxy for the rural area. However, the only rural area currently without a hospital is on the island of Puerto Rico, which does not lend itself to this "contiguous" approach. Because CMS has not identified an alternative methodology, the agency proposes to continue to use the most recent pre-floor, pre-reclassified hospital wage index value available for Puerto Rico, which is 0.4047.

2. Elimination of the Wage Index Budget Neutrality Adjustment Factor (BNAF)

As described in the 1997 Hospice Wage Index final rule, inpatient hospital pre-floor and pre-classified wage index values are subject to either a budget neutrality adjustment or application of the hospice floor to compute the hospice wage index. Pre-floor, pre-reclassified hospital wage index values below 0.8 are adjusted by either: (1) the hospice budget neutrality adjustment factor (BNAF); or (2) the hospice floor subject to a maximum wage index value of 0.8; whichever results in the greater value. Wage index values of 0.8 or greater are adjusted by the BNAF. The BNAF is an adjustment which increases the hospice wage index value. Therefore the BNAF reduction is a reduction in the amount of the BNAF increase applied to the hospice wage index value. It is not a reduction in the hospice wage index value or in the hospice payment rate.

Starting in FY 2010, a seven-year phase out of the BNAF began with a 10 percent reduction in FY 2010, and additional 15 percent reductions in FY 2011 through FY 2015. For FY 2016, the BNAF is reduced by an additional and final 15 percent for a cumulative reduction of 100 percent. Thus, for FY 2016, the BNAF is completely phased-out and eliminated.

3. Proposed Implementation of New Labor Market Delineations

CMS proposes to implement the new Office of Management and Budget (OMB) delineations as described in the February 28, 2013 OMB Bulletin No. 13-01 for the hospice wage index effective beginning in FY 2016. CMS' proposed adoption for hospice lags a year because the hospice payment system uses the previous year's hospital wage index data to calculate the hospice wage index values. CMS has already implemented for the 2015 payment year the new OMB delineations in the Inpatient Prospective Payment System (IPPS), Home Health (HH), and SNF payment systems.

In summary, CMS establishes labor market areas for purposes of applying the wage index based on Core-Based Statistical Areas (CBSAs) established by OMB. On February 28, 2013, OMB announced in OMB Bulletin No. 13-01 revisions to its delineation of Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, based on the 2010 Census data and standards it had announced in 2010. Similar to its policy in IPPS, CMS proposes to

continue its policy of treating Micropolitan areas as rural and to include them in the calculation of a state's rural wage index. There are 541 such areas under the new OMB definitions.

CMS notes a number of changes in geographic classification under proposed new labor market delineations. The changes, and references to county-specific tables, are presented below.

Changes	Reference
37 counties would shift from urban to rural	CMS Table 19, page 25861
105 counties would shift from rural to urban	CMS Table 20, page 25861
46 urban counties would change to a different CBSA	CMS Table 21, page 25863

CMS finds that implementation of the new OMB delineations would yield:

- no change in wage index values for 88.6 percent of providers;
- a higher wage index value for 4.0 percent of providers; and
- a lower wage index value for 7.4 percent of providers.

CMS proposes a one-year transition, under which it would establish the wage index for 2016 using a 50/50 weighting: 50 percent based on the wage index computed under the new OMB delineations and 50 percent based on the prior OMB delineations. CMS refers to this blended wage index as the FY 2016 hospice transition wage index and states its transition policy is consistent with its approach for the SNF and HH payment systems. ***CMS invites comments on its proposed transition methodology***.

The proposed wage index applicable to FY 2016 is set forth in Addendum A available on the CMS Web site at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/index.html.

4. Proposed Hospice Payment Update Percentage

For FY 2016, the estimated inpatient hospital market basket update of 2.7 percent (the inpatient hospital market basket is used in determining the hospice update factor) must be reduced by a productivity adjustment as mandated by the ACA (currently estimated to be 0.6 percentage point) and further reduced by 0.3 percentage point as also mandated by the ACA. This results in a proposed hospice payment update percentage for FY 2015 of 1.8 percent; CMS proposes to revise this amount in the final rule if more recent data become available.

CMS notes that the labor portion of the hospice payment rates is currently as follows: for Routine Home Care, 68.71 percent; for Continuous Home Care, 68.71 percent; for General Inpatient Care, 64.01 percent; and for Respite Care, 54.13 percent.

5. Proposed FY 2016 Hospice Payment Rates

CMS notes beginning in FY 2014 and for subsequent fiscal years, it uses rulemaking as the means to update payment rates (prior to FY 2014 CMS had used a separate administrative instruction), consistent with the rate update process for other Medicare payment systems. In the

hospice payment system, there are four payment categories that are distinguished by the location and intensity of the services provided: RHC or routine home care, IRC or short-term care to allow the usual caregiver to rest, CHC or care provided in a period of patient crisis to maintain the patient at home, and GIP or general inpatient care to treat symptoms that cannot be managed in another setting. The applicable base payment is then 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.

For the RHC payment category, CMS is proposing two different RHC payment rates: one for the RHC rate for the first 60 days and a second RHC rate for days 60 and beyond. In addition, CMS is also proposing to make a SIA payment, in addition to the daily RHC payment, when direct patient care is provided by an RN or social worker during the last 7 days of the patient's life. CMS notes that the proposed SIA payment would also be adjusted by the appropriate wage index, and for budget neutrality, as required by statute, through an adjustment to the proposed RHC rates. The budget neutrality factor for days 1 through 60 is 0.9853, and for days 61 and beyond the factor is 0.9967.[3] Lastly, the RHC rates would be increased by the proposed FY 2016 hospice payment update percentage of 1.8 percent. The proposed FY 2016 payment rates for CHC, IRC, and GIP would be the FY 2015 payment rates increased by 1.8 percent.

Tables 22 and 23 of the proposed rule (reproduced below) list the preliminary FY 2016 hospice payment rates by care category.

Table 22: Proposed FY 2016 Hospice Payment Rates for RHC

Code	Description	Proposed Rates	Proposed SIA budget neutrality factor adjustment	Proposed FY 2016 hospice payment update percentage	Proposed FY 2016 Payment Rates
651	Routine Home Care (days 1-60)	$187.63	x 0.9853	x 1.018	$188.20
651	Routine Home Care (days 61+)	$145.21	x 0.9967	x 1.018	$147.34

Table 23: Proposed FY 2016 Hospice Payment Rates for CHC, IRC, and GIP

Code	Description	FY 2015 Payment Rate	Multiply by the FY 2015 proposed hospice payment update of 1.8 percent	Proposed FY 2016 Payment Rate
652	Continuous Home Care Full Rate = 24 hours of care, $39.44 hourly rate	$929.91	x 1.018	$946.65

[3] The budget neutrality adjustment calculation that would apply to days 1 through 60 is equal to 1 minus the ratio of SIA payments for days 1 through 60 to the total payments. Similarly, the budget neutrality adjustment for days 61 and beyond is equal to 1 minus the ratio of SIA payments for days 61 and beyond to the total payments for days 61 and beyond.

655	Inpatient Respite Care	$164.81	x 1.018	$167.78
656	General Inpatient Care	$708.77	x 1.018	$721.53

Tables 24 and 25 of the proposed rule list the comparable FY 2016 preliminary payment rates for hospices that do not submit the required quality data under the Hospice Quality Reporting Program as follows: Routine Home Care (days 1-60), $184.50; Routine Home Care (days 61+), $144.44; Continuous Home Care, $928.05; Inpatient Respite Care, $164.48; and General Inpatient Care, $707.35.

6. Hospice Aggregate Cap and the IMPACT Act of 2014

CMS notes that when the Medicare hospice benefit was implemented, Congress included 2 limits on payments to hospices: an aggregate cap and an inpatient cap. The intent of the hospice aggregate cap was to protect Medicare from spending more for hospice care than it would for conventional care at the end-of-life, and the intent of the inpatient cap was to ensure that hospice remained a home-based benefit.[4] The aggregate cap amount was set at $6,500 per beneficiary when first enacted in 1983, and since then this amount has been adjusted annually by the change in the medical care expenditure category of the consumer price index for urban consumers (CPI-U).

As required by the Impact Act, effective for the 2016 cap year (November 1, 2015 through October 31, 2016) and through September 30, 2025, the cap amount for the previous year will be updated by the hospice payment update percentage, rather than by the CPI-U for medical care, This provision will sunset for cap years ending after September 30, 2025, and revert back to the original methodology. This provision is estimated to result in $540 million in savings over 10 years starting in 2017.

As a result, CMS proposes to update §418.309 to reflect the new language added to section 1814(i)(2)(B) of the Act. CMS notes that a Change Request with the finalized hospice payment rates, a finalized hospice wage index, the Pricer for FY 2016, and the hospice cap amount for the cap year ending October 31, 2015 will be issued in the summer. CMS adds that the hospice aggregate cap amount for the 2016 cap year will be $27,624.41 per beneficiary or the 2015 cap amount updated by the FY 2016 hospice payment update percentage ($27,135.96 * 1.018).

D. Proposed Alignment of the Inpatient and Aggregate Cap Accounting Year with the Federal Fiscal Year (pages 25867-25869)

The aggregate cap amount for any given hospice is established by multiplying the cap amount by the number of Medicare beneficiaries who received hospice services during the year. CMS uses two different approaches for counting beneficiaries to determine each hospice's aggregate cap amount: the streamlined method and the patient-by-patient proportional method. The

[4] If a hospice's inpatient days (GIP and respite) exceed 20 percent of all hospice days then for inpatient care the hospice is paid: (1) the sum of the total reimbursement for inpatient care multiplied by the ratio of the maximum number of allowable inpatient days to actual number of all inpatient days; and (2) the sum of the actual number of inpatient days in excess of the limitation by the routine home care rate.

aggregate cap amount for each hospice is now primarily calculated using the patient-by-patient proportional method; only 486 hospices used the streamline method for the 2013 cap year.

Under the streamlined method, a different timeframe from the cap year is used to count the number of Medicare beneficiaries; the cap year period begins on September 28th (34 days before the beginning of the cap year) and ending on September 27th (35 days before the end of the cap year). The patient-by-patient proportional methodology timeframe for counting the number of Medicare beneficiaries is the same as the cap accounting year (November 1 through October 31).

CMS believes there is no longer an advantage to defining the cap accounting year differently from the hospice rate update year and maintaining a cap accounting year that is different from the federal fiscal year. Thus, CMS proposes to align the cap accounting year for both the inpatient cap and the hospice aggregate cap with the federal fiscal year for FYs 2017 and later. Under this proposal, in addition to aligning the cap accounting year with the federal fiscal year, CMS would also align the timeframe for counting the number of beneficiaries with the federal fiscal year. CMS says that this proposal would eliminate timeframe complexities associated with counting payments and beneficiaries differently from the federal fiscal year and would help hospices avoid mistakes in calculating their aggregate cap determinations. CMS also notes that the IMPACT Act requires the cap amount for 2016 through 2025 to be updated by the hospice payment update percentage in effect "during the FY beginning on the October 1 preceding the beginning of the accounting year''. CMS interprets this to mean that the most current hospice payment update percentage (for 2016 this would be the FY 2016 hospice update percentage) would be used.[5]

CMS proposes specific timeframes in which beneficiaries and payments are counted for the purposes of determining each individual hospice's aggregate cap amount (see table 26 below reproduced from the proposed rule) as well as the timeframes in which days of hospice care are counted for the purposes of determining whether a given hospice exceeded the inpatient cap. In the year of transition (2017 cap year), for the inpatient cap, CMS proposes to calculate the percentage of all hospice days of care that were provided as inpatient days (GIP care and respite care) from November 1, 2016 through September 30, 2017 (11 months). For those hospices using the patient-by-patient proportional method for their aggregate cap determinations, for the 2017 cap year, CMS would count beneficiaries from November 1, 2016 to September 30, 2017. For those hospices using the streamlined method for their aggregate cap determinations, CMS proposes to allow 3 extra days to count beneficiaries in the year of transition. CMS notes that because of the non-discretionary language used by Congress in determining the cap for a year, the actual cap amount for the adjustment year would not be prorated for a shorter time frame.

CMS is soliciting public comment on all aspects of the proposed alignment of the cap accounting year with the federal fiscal year.

[5] Based on the requirements of the IMPACT Act, CMS will use the CPI-U for February instead of March for the 2026 cap year and beyond.

Table 26: Hospice Aggregate Cap Timeframes for Counting Beneficiaries and Payments for the Proposed Alignment of the Cap Accounting Year with the Federal Fiscal Year

Cap Year	Beneficiaries		Payments	
	Streamlined Method	Patient-by-Patient Proportional Method	Streamlined Method	Patient-by-Patient Proportional Method
2016	9/28/15 – 9/27/16	11/1/15-10/31/16	11/1/15-10/31/16	11/1/15-10/31/16
Proposed 2017 (Transition Year)	9/28/16 – 9/30/17	11/1/16 – 9/30/17	11/1/16 – 9/30/17	11/1/16 – 9/30/17
Proposed 2018	10/1/17– 9/30/18	10/1/17– 9/30/18	10/1/17– 9/30/18	10/1/17– 9/30/18

E. Proposed Updates to the Hospice Quality Reporting Program (HQRP) (pages 25869-25877)

Hospices that fail to meet quality data submission requirements will receive a two percentage point reduction to the market basket update beginning in FY 2014. Any measure selected by the Secretary must have been endorsed by the consensus-based entity holding a contract for performance measures (currently held by the National Quality Forum (NQF). However, the Secretary may specify measures that are not so endorsed as long as a feasible and practical measure has not yet been endorsed by the consensus-based entity and consideration is given to measures that have been endorsed by the consensus-based organization.

1. <u>Proposed Policy for Retention of HQRP Measures Adopted for Previous Payment Determinations</u>

CMS proposes that measures adopted for the HQRP, beginning with a payment determination year, will be automatically adopted for all subsequent years unless CMS proposes to remove, suspend, or replace the measure.

CMS may propose removal of a quality measure for several reasons including:

- The measure performance is so high and unvarying that meaningful distinctions in improvement can no longer be made;
- Performance or improvement on a measure does not result in better patient outcomes;
- A measure does not align with current clinical guidelines or practice;
- A more broadly available measure (across settings, populations, or conditions) is available;
- Another measure is more strongly associated with desired outcomes; or
- Collection or public reporting of a measure leads to negative unintended consequences.

CMS will propose removal of measures through the annual rulemaking process. CMS notes however, that if they believe continued collection of a measure raises potential safety concerns, they will promptly remove the measure form the HQRP and notify hospices through the various HQRP communication channels (i.e. email notification and Web postings).

CMS does not propose removing any HQRP measures for the FY 2017 reporting cycle. ***CMS invites public comment on their proposal for retaining measures.***

2. Previously Adopted Quality Measures for FY 2016 and FY 2017 Payment Determination and Concepts Under Consideration for Future Years

In the FY 2014 Hospice Wage Index and Payment Rate Update final rule, CMS finalized the specific collection of data items under a Hospice Item Set (HIS) that support the following six NQF-endorsed measures and one modified measure:

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

CMS also finalized that the HIS will be implemented in July 2014; CMS will require regular and ongoing electronic submission of the HIS data for each patient admission to hospice on or after July 1, 2014, regardless of payer or patient age. Hospices failing to report quality data via the HIS in 2014 will have their market basket update reduced by 2 percentage points in FY 2016.

Hospices are required to complete and submit an HIS-Admission and an HIS-Discharge record for each patient admission. Hospices failing to report quality data via the HIS in FY 2015 will have their market basket update reduced by 2 percentage points in FY 2017, beginning in October 1, 2016.

CMS is not proposing any new measures for FY 2017. Based on input from stakeholders, CMS has identified four high priority areas for future measure development: patient reported pain outcome measures that incorporate patient and/or proxy report regarding pain management; claims-based measures focused on care practice patterns such as skilled visits in the last days of life; responsiveness of hospice to patient and family care needs; and hospice team communication and care coordination. ***CMS welcomes comments about these four high priority areas for future measure development.***

3. Quality Data Submission

a. Proposed Policy for New Facilities to Begin Submitting Quality Data

In FY 2015, CMS finalized that newly certified hospices that receive notice of their CMS certification number on or after November 1, 2014 for payments to be made in FY 2016 would be excluded from the quality reporting requirements for the FY 2016 payment determination. Similarly, CMS finalized that in future years, hospices that receive notification of certification on or after November 1 of the preceding year involved would continue to be excluded from any payment penalty for quality reporting purposes for the following FY.

CMS proposes that beginning with the FY 2018 payment determination and for each subsequent payment determination, a new hospice will be responsible for HQRP quality data reporting beginning on the date they receive their Certification Number (CCN) notification letter. CMS notes that new hospices may experience a lag between Medicare certification and receipt of their CCN number which is required for submitting data to the Quality Improvement and Evaluation System (QIES) Assessment Submission and Processing (ASAP) system and that their proposal allows new hospices sufficient time to establish procedures to submit quality data to CMS. ***CMS invites comment on this proposal.***

b. Proposed HQRP Data Submission Timelines and Compliance Threshold Requirements for FY 2018 Payment Determination and Subsequent Years

The submission date for any given HIS record is defined as the date on which a completed record is submitted and accepted by the QIES ASAP system. Electronic data submission via the QIES ASAP system is required for all HIS submissions; there are no other data submission methods available. Hospices have 30 days from a patient admission or discharge to submit the appropriate HIS record through the QIES ASAP system.

CMS proposes that beginning with the FY 2018 payment determination, hospices must submit all HIS records within 30 days of the Event Date defined as the patient's admission or discharge date:

- The HIS-Admission record within 30 days of the admission (the submission date would be no later than the admission date plus 30 calendar days) and
- The HIS-Discharge records within 30 days of the discharge (the submission date would be no later than the discharge date plus 30 calendar days).

The QIES ASAP validation edits are designed to monitor the timeliness of HIS submissions and the system will issue a warning on the Final Validation Report if the submission date is late. CMS states that timely submission of data is essential to ensure the reliability of the data.

CMS also proposes establishing an incremental threshold for compliance with the timeliness requirement that would be implemented over a 3 year period with the following schedule:

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

CMS invites comment on their proposal to implement the data submission and compliance threshold requirement.

4. HQRP Submission Exception and Extension Requirements for the FY 2017 Payment Determination and Subsequent Years

In the FY 2015 Hospice Wage Index and Payment Rate Update final rule (79 *FR* 50488), CMS finalized their proposal to allow hospices to request and for CMS to grant exemptions/extensions with respect to the reporting of required quality data when there are extraordinary circumstances beyond the control of the provider. When an extension/exception is granted, a hospice will not incur payment reduction penalties for failure to comply with the requirements. CMS proposes to codify the HQRP Submission Exception and Extension Requirements at §418.312.

CMS notes that a request must contain all of the requirements as outlined on their Web site at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/index.html. CMS can also grant extensions/exceptions to hospices that have not requested them when it determines that an extraordinary circumstance, such as an act of nature, affects an entire region or locale or if they determine that a systemic problem with the agency's data collection systems directly affected the ability of a hospice to submit data. CMS notes, however, that exceptions and extensions will generally not be granted for hospice vendor issues, fatal error messages preventing record submission, or staff error.

5. Adoption of the CAHPS® Hospice Survey for the FY 2017 Payment Determination

In the FY 2015 Hospice Wage Index and Payment Rate Update final rule (79 *FR* 50452) , CMS stated that it would start national implementation of the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Hospice Survey as of January 1, 2015. (Table 27 in the proposed rule lists the measurements in the CAHPS® Hospice Survey.) CMS refers readers to the extensive discussion of the Hospice Experience of Care Survey in that final rule (79 *FR* 50450 and 78 *FR* 48261-48266) for a description of the measurements involved and their relationship to the statutory requirement for hospice quality reporting. CMS notes that the CAHPS® Hospice Survey seeks information from the informal caregivers of patients who died while enrolled in hospices. Survey fielding timelines give the grieving respondent some recovery time (two to three months), while simultaneously not delaying so long that the respondent forgets details of the hospice experience. CMS adds that hospices are required to conduct the survey to meet the hospice quality reporting requirements, but individual caregivers will respond only if they voluntarily choose to do so. CMS notes that the survey web site is the primary information resource for hospices and vendors (www.hospicecahpssurvey.org). A list of approved vendors is also available at this web site.

Participation Requirements to Meet Quality Reporting Requirements for the FY 2018 and FY 2019 Annual Payment Update (APU)

In the FY 2015 Hospice Wage Index, CMS added the CAHPS® Hospice Survey to the HQRP reporting requirements for the FY 2017 and subsequent years payment determinations.

- To meet the HQRP requirement for the FY 2018 payment determination, hospices need to collect survey data on a monthly basis for the months of January 1, 2016 through December 31, 2016 to qualify for the full APU.
- To meet the HQRP requirement for the FY 2019 payment determination, hospices need to collect survey data on a monthly basis for the months of January 1, 2017 through December 31, 2017 to qualify for the full APU.

For purposes of the CAHPS® Hospice Survey, Medicare-certified hospices will need to contract with a third-party vendor that is CMS-trained and approved to administer the survey on their behalf. For compliance with the FY 2018 APU, ongoing monthly participation in the survey is required January 1, 2016 through December 31, 2016. The deadlines for data submission occur quarterly and are shown in Table 28 in the proposed rule which is reproduced below.

Table 28: CAHPS® Hospice Survey Data Submission Dates for 2017-2019 APUs

Sample Month[1]	Quarterly Data Submission Deadlines[2]
FY 2017 APU	
Dry Run January-March 2015 (Q1)	August 12, 2015
Monthly data collection April-June 2015 (Q2)	November 1, 2015[3]
Monthly data collection July-September 2015 (Q3)	February 10, 2016
Monthly data collection October-December 2015 (Q4)	May 11, 2016
FY 2018 APU	
Dry Run January-March 2016 (Q1)	August 10, 2016
Monthly data collection April-June 2016 (Q2)	November 9, 2016
Monthly data collection July-September 2016 (Q3)	February 8, 2017
Monthly data collection October-December 2016 (Q4)	May 10, 2017
FY 2019 APU	
Dry Run January-March 2017 (Q1)	August 9, 2017
Monthly data collection April-June 2017 (Q2)	November 8, 2017
Monthly data collection July-September 2017 (Q3)	February 14, 2018
Monthly data collection October-December 2017 (Q4)	May 9, 2018

[1]Data collection for each sample month initiates two months following the month of patient death (for example, in April for deaths occurring in January).
[2]Data submission deadlines are the second Wednesday of the submission month.
[3]Corrected from the Final Rule published August 22, 2014, 79 *FR* 50493.

CMS proposes to continue the CAHPS® Hospice Survey exemption for both the FY 2018 and FY2019 APU. For the 2018 APU, CMS proposes an exemption for hospices with fewer than 50 survey-eligible decedents/caregivers in the period from January 1, 2015 through December 31, 2015 from the CAHPS® Hospice Survey data collection and reporting requirements To qualify for this exemption, hospices must submit an exemption request form by August 10, 2016 (the form will be available at http://www.hospicecahpssurvey.org.). For the 2019 APU, CMS proposes an exemption for hospices with fewer than 50 survey-eligible decedents/caregivers in the period from January 1, 2016 through December 31, 2016 from the CAHPS® Hospice Survey data collection and reporting requirements. CMS will announce the date submission deadline for the 2019 APU in future rulemaking. (CMS notes the form will be available in the first quarter of 2017 at http://www.hospicecahpssurvey.org.).

CMS proposes to continue the requirement that vendors and hospice providers participate in CAHPS® Hospice Survey oversight activities to ensure compliance with Hospice CAHPS® technical specifications and survey requirements.

6. HQRP Reconsideration and Appeals Procedures for the FY 2016 Payment Determination and Subsequent Years

In the FY Hospice final rule (79 *FR* 50496), CMS notified hospice providers on the process for seeking reconsideration if they received a noncompliance decision for the FY 2016 payment determination and subsequent years. CMS determines reporting compliance by successfully fulfilling both the CAHPS® Hospice Survey requirements and the HIS data submission requirements.

In the proposed rule, CMS clarifies that any hospice submitting a **reconsideration request must do so by submitting an email to CMS**, sent to HQRPReconsiderations@cms.hhs.gov, containing all of the requirements listed on the HQRP web site. (http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Reconsideration-Requests.html.) Any reconsideration requests received through any other mechanism, including US postal service or phone, will not be considered as valid reconsideration requests.

CMS notifies hospices that are non-compliant with reporting requirements and provides instructions for requesting reconsideration. In addition to their current practice of sending the hospice provider a certified US Postal service letter, CMS proposes to have providers access electronic letters using the Certification and Survey Provider Enhanced Reports (CASPER) reporting application, beginning with the FY 2017 payment determination. CMS also intends to disseminate communications about the availability of hospice compliance reports in CASFER through normal channels they use to communicate to hospices and vendors.

CMS also proposes to publish a list of hospices who successfully meet the reporting requirements for the applicable payment determination of the HQRP website. They plan to update the list after reconsideration requests are processed on an annual basis.

CMS invites comments on these proposals.

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

CMS discusses their plans to publicly report quality measures; decisions about whether to report some or all of the quality measures publicly will be based on their analysis of the data from quarter 4 of CY 2014 and Quarter 1, 2 and 3 for CY 2015. CMS also plans to make available provider-level feedback reports in the CASPER system; these reports will be intended to provide feedback to providers about quality reporting measures, as well as benchmarks and thresholds. CMS anticipates that these provider reports will be available sometime in CY 2015.

CMS is developing the infrastructure for public reporting which includes providing hospices an opportunity to review their data prior to public reporting. CMS notes the HQRP is prepared to post hospice data on the public data set, the Medicare Provider Utilization and Payment Data: Physician and Other Supplier Public Use File located at https://data.cms.hhs.gov. CMS has not yet developed a timeline for posting hospice data publicly; if a timeline becomes available prior to the next annual rulemaking cycle, CMS plans to make announcements about the timeline through regular HQRP communication channels.

CMS also discusses their plans to develop a Compare Web site for hospice, which will list hospice providers geographically and allow searches for all Medicare approved hospice providers, including information about their quality measures and CAHPS® Hospice Survey results. Similar to other Compare Web sites, CMS plans to have a quality rating system that gives each hospice a rating of between one and five stars. As information about the Hospice Compare Web site become available, CMS will share updates through ongoing communications.

F. Clarification Regarding Diagnosis Reporting on Hospice Claims (pages 25877-25881)

In the proposed rule, CMS discusses their concerns that there are varying interpretations as to what constitutes "terminal illness" and "related conditions" and consequently what services should be provided and covered by hospices. CMS notes that based on numerous comments received in previous rulemaking and anecdotal reports from providers and beneficiaries, they are concerned that some hospices are not conducting a comprehensive assessment nor updating the plan of care as stated in the Conditions of Participation to recognize the conditions that affect an individual's terminal illness.

Because of these concerns, CMS is clarifying that **hospices are required to report all diagnoses, including mental health disorders and conditions, identified in the initial and comprehensive assessments on hospice claims, whether related or unrelated to the terminal prognosis of the individual**. CMS notes this is in keeping with the requirements of determining whether an individual is terminally ill. CMS plans to monitor compliance with required coding practices and work with all relevant CMS components to determine whether further policy changes, including additional program oversight activities, are needed.

III. Collection of Information Requirements (page 25881)

CMS states that this proposed rule does not impose any information collection requirements that require review by OMB under the authority of the Paperwork Reduction Act of 1995.

IV. Regulatory Impact Analysis (pages 25881-25885)

CMS states that the overall impact of this proposed rule is an estimated net increase in Federal Medicare payments to hospices of $200 million or 1.3 percent, for FY 2016. The $200 million increase in estimated payments for FY 2016 reflects 3 factors: (1) the proposed hospice update percentage of 1.8 percent ($290 million increase); (2) the use of updated wage index data and the phase-out of the BNAF (-0.7 percent or $120 million decrease); and (3) the proposed implementation of the new OMB CBSA delineations for the FY 2016 hospice wage index with a

1-year transition (0.2 percent/$30 million increase). CMS notes that the proposed RHC rates and the proposed SIA payment would be implemented in a budget neutral manner, as required by statute.

Table 29 in the proposed rule shows the detailed estimated hospice impacts by facility type and area of country. The table below reproduces this data for the selected categories of hospice. In brief, these provisions are anticipated to increase payments to small hospices by 4.5 percent compared with a 1.2 percent increase for large hospices. Proprietary (for-profit) hospices (60 percent of all hospices) are expected have a small increase in hospice payments of 0.3 percent compared with payment increases of 2.7 percent, and 2.2 percent for non-profit and government hospices, respectively. The small overall increase in payments for proprietary hospices is due in large part to the CMS proposal to create two different payment rates for RHC proposed routines home care rates (days 1 thru 60 and days 61+). This policy is projected to reduce hospice payments to proprietary hospices by 1 percent.

TABLE 29: Estimated Hospice Impacts by Facility Type and Area of the Country, FY 2016

	Providers	Updated FY 2016 Wage Index Data and Phase-Out of BNAF (% change)	Proposed 50/50 Blend of FY 2016 Wage Index Values Under Old and New CBSA Delineations (% change)	Proposed Routine Home Care Rates (days 1 thru 60 and days 61+)	Proposed FY 2016 SIA Payment (% change)	Proposed FY 2016 Hospice Payment Update Percentage(% Change)	Total FY 2016 proposed policies (% change)
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
All Hospices	4,010	-0.7%	0.2%	0.0%	0.0%	1.8%	1.3%
Urban	3,015	-0.7%	0.3%	0.0%	0.0%	1.8%	1.4%
Rural	995	-0.3%	-0.2%	0.4%	0.0%	1.8%	1.7%
Size/Days							
0 - 3,499 RHC Days (Small)	840	-0.5%	0.1%	3.0%	0.1%	1.8%	4.5%
3,500-19,999 RHC Days (Medium)	1,924	-0.6%	0.2%	0.6%	0.0%	1.8%	2.0%
20,000+ RHC Days (Large)	1,246	-0.7%	0.3%	-0.2%	0.0%	1.8%	1.2%
Type of Ownership							
Non-Profit	1,070	-0.6%	0.2%	1.2%	0.1%	1.8%	2.7%
For Profit	2,398	-0.7%	0.3%	-1.0%	-0.1%	1.8%	0.3%
Govt/Other	542	-0.6%	0.3%	0.6%	0.1%	1.8%	2.2%
Hospice Base:							
Freestanding	3,016	-0.7%	0.3%	-0.4%	0.0%	1.8%	1.0%
HHA/Facility-Based	994	-0.4%	0.2%	1.8%	0.2%	1.8%	3.6%

Rate of RHC/SNF Days							
Lowest Quartile (Less than or equal to 3.1%)	1,002	-0.5%	0.1%	0.7%	0.0%	1.8%	2.1%
2nd Quartile (Greater than 3.1% and Less than or equal to 16.7%)	1,003	-0.6%	0.1%	0.4%	0.2%	1.8%	1.9%
3rd Quartile (Greater than 16.7% and less than or equal to 35.5%)	1,003	-0.7%	0.3%	-0.1%	0.0%	1.8%	1.3%
Highest Quartile (Greater than 35.5%)	1,002	-0.7%	0.4%	-0.6%	-0.2%	1.8%	0.7%

CMS also considered several alternatives to the proposals discussed above. CMS considered proposing that the higher rate of the RHC payment be applied to the first 30 days of hospice rather than the 60 days proposed. Because the decline in marginal costs was small, between days 15-30 and days 31-60, CMS decided against this option. In addition, CMS also considered a longer (90 days instead of 60) window of time between a discharge and a subsequent hospice election as a basis for determining which RHC payment rates would be applied. CMS also considered not applying the higher initial RHC rate (1 through 60 days) to beneficiaries in nursing homes. Finally, CMS considered proposing to allow the SIA payment to apply to the first two days of a new hospice election (in addition to the last seven days of life), but found that doing so would result in a larger decrease to the RHC rates for all hospice providers (due to budget neutrality).

CMS considers the proposed rule economically significant and a major rule under the Congressional Review Act; it has been reviewed by OMB. CMS states that the Secretary has determined that the proposed rule will not create a significant economic impact on a substantial number of small entities or have a significant impact on the operation of a substantial number of small hospitals. It is also not anticipated to have an effect on State, local, or tribal governments, in the aggregate, or on the private sector of $141 million or more, the current threshold under the Unfunded Mandates Reform Act. CMS has also determined that the proposed rule will not have substantial direct effects on the rights, roles, and responsibilities of States, or of local or tribal governments.