After consideration of the public comments we received, we are finalizing our proposals relating to the process for requesting and obtaining the low-volume hospital payment adjustment as described above, without modification.

E. Indirect Medical Education (IME) Payment Adjustment Factor (§ 412.105)

1. IME Payment Adjustment Factor for FY 2019

Under the IPPS, an additional payment amount is made to hospitals with residents in an approved graduate medical education (GME) program in order to reflect the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The payment amount is determined by use of a statutorily specified adjustment factor. The regulations regarding the calculation of this additional payment, known as the IME adjustment, are located at § 412.105. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51680) for a full discussion of the IME adjustment and IME adjustment factor. Section 1886(d)(5)(B)(ii)(XII) of the Act provides that, for discharges occurring during FY 2008 and fiscal years thereafter, the IME formula multiplier is 1.35. Accordingly, for discharges occurring during FY 2019, the formula multiplier is 1.35. We estimate that application of this formula multiplier for the FY 2019 IME adjustment will result in an increase in IPPS payment of 5.5 percent for every approximately 10 percent increase in the hospital's resident-to-bed ratio.

We did not receive any comments regarding the IME adjustment factor, which, as noted earlier, is statutorily required. Accordingly, for discharges occurring during FY 2019, the IME formula multiplier is 1.35.

2. Technical Correction to Regulations at 42 CFR 412.105(f)(1)(vii)

As discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20386), in the regulation governing the IME payment adjustment at § 412.105(f)(1)(vii), we identified an inadvertent omission of a cross-reference relating to an adjustment to a hospital's full-time equivalent cap for a new medical residency training program. Section 412.105(f)(1)(vii) states that if a hospital establishes a new medical residency training program, as defined in § 413.79(l), the hospital's full-time equivalent cap may be adjusted in accordance with the provisions of § 413.79(e)(1) through (e)(4). However, there is a paragraph (e)(5) under § 413.79 that we have inadvertently omitted that applies to the regulation at § 412.105(f)(1)(vii). In the proposed regulation (83 FR 20567), we proposed to correct this omission by amending § 412.105 to remove the reference to ''§§ 413.79(e)(1) through (e)(4)'' and add in its place the reference ''§ 413.79(e)'' to make clear that the provisions of § 413.79(e)(1) through (e)(5) apply. This proposed revision was intended to correct the omission and was not intended to substantially change the underlying regulation.

We did not receive any public comments on this proposed technical correction to § 412.105, and therefore are finalizing it as was proposed in the proposed regulation.

F. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2019 (§ 412.106)

1. General Discussion

Section 1886(d)(5)(F) of the Act provides for additional Medicare payments to subsection (d) hospitals that serve a significantly disproportionate number of low-income patients. The Act specifies two methods by which a hospital may qualify for the Medicare disproportionate share hospital (DSH) adjustment. Under the first method, hospitals that are located in an urban area and have 100 or more beds may receive a Medicare DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to needy patients with low incomes. This method is commonly referred to as the ''Pickle method.'' The second method for qualifying for the DSH payment adjustment, which is the most common, is based on a complex statutory formula under which the DSH payment adjustment is based on the hospital's geographic designation, the number of beds in the hospital, and the level of the hospital's disproportionate patient percentage (DPP). A hospital's DPP is the sum of two fractions: the ''Medicare fraction'' and the ''Medicaid fraction.'' The Medicare fraction (also known as the ''SSI fraction'' or ''SSI ratio'') is computed by dividing the number of the hospital's inpatient days that are furnished to patients who were entitled to both Medicare Part A and Supplemental Security Income (SSI) benefits by the hospital's total number of patient days furnished to patients entitled to benefits under Medicare Part A. The Medicaid fraction is computed by dividing the hospital's number of inpatient days furnished to patients who, for such days, were eligible for Medicaid, but were not entitled to benefits under Medicare Part A, by the hospital's total number of inpatient days in the same period.

Because the DSH payment adjustment is part of the IPPS, the statutory references to ''days'' in section 1886(d)(5)(F) of the Act have been interpreted to apply only to hospital acute care inpatient days. Regulations located at 42 CFR 412.106 govern the Medicare DSH payment adjustment and specify how the DPP is calculated as well as how beds and patient days are counted in determining the Medicare DSH payment adjustment. Under § 412.106(a)(1)(i), the number of beds for the Medicare DSH payment adjustment is determined in accordance with bed counting rules for the IME adjustment under § 412.105(b).

Section 3133 of the Patient Protection and Affordable Care Act, as amended by section 10316 of the same Act and section 1104 of the Health Care and Education Reconciliation Act (Pub. L. 111–152), added a section 1886(r) to the Act that modifies the methodology for computing the Medicare DSH payment adjustment. (For purposes of this final rule, we refer to these provisions collectively as section 3133 of the Affordable Care Act.) Beginning with discharges in FY 2014, hospitals that qualify for Medicare DSH payments under section 1886(d)(5)(F) of the Act receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments. This provision applies equally to hospitals that qualify for DSH payments under section 1886(d)(5)(F)(i)(I) of the Act and those hospitals that qualify under the Pickle method under section 1886(d)(5)(F)(i)(II) of the Act.

The remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured, is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The payments to each hospital for a fiscal year are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all hospitals that receive Medicare DSH payments for that fiscal year.

As provided by section 3133 of the Affordable Care Act, section 1886(r) of the Act requires that, for FY 2014 and each subsequent fiscal year, a subsection (d) hospital that would

otherwise receive DSH payments made under section 1886(d)(5)(F) of the Act receives two separately calculated payments. Specifically, section 1886(r)(1) of the Act provides that the Secretary shall pay to such subsection (d) hospital (including a Pickle hospital) 25 percent of the amount the hospital would have received under section 1886(d)(5)(F) of the Act for DSH payments, which represents the empirically justified amount for such payment, as determined by the MedPAC in its March 2007 Report to Congress. We refer to this payment as the ''empirically justified Medicare DSH payment.''

In addition to this empirically justified Medicare DSH payment, section 1886(r)(2) of the Act provides that, for FY 2014 and each subsequent fiscal year, the Secretary shall pay to such subsection (d) hospital an additional amount equal to the product of three factors. The first factor is the difference between the aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if subsection (r) did not apply and the aggregate amount of payments that are made to subsection (d) hospitals under section 1886(r)(1) of the Act for such fiscal year. Therefore, this factor amounts to 75 percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act.

The second factor is, for FY 2018 and subsequent fiscal years, 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who were uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS), and the percent of individuals who were uninsured in the most recent period for which data are available (as so estimated and certified), minus 0.2 percentage point for FYs 2018 and 2019.

The third factor is a percent that, for each subsection (d) hospital, represents the quotient of the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data), including the use of alternative data where the Secretary determines that alternative data are available which are a better proxy for the costs of subsection (d) hospitals for treating the uninsured, and the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act. Therefore, this third factor represents a hospital's uncompensated care amount for a given time period relative to the uncompensated care amount for that same time period for all hospitals that receive Medicare DSH payments in the applicable fiscal year, expressed as a percent.

For each hospital, the product of these three factors represents its additional payment for uncompensated care for the applicable fiscal year. We refer to the additional payment determined by these factors as the ''uncompensated care payment.''

Section 1886(r) of the Act applies to FY 2014 and each subsequent fiscal year. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50620 through 50647) and the FY 2014 IPPS interim final rule with comment period (78 FR 61191 through 61197), we set forth our policies for implementing the required changes to the Medicare DSH payment methodology made by section 3133 of the Affordable Care Act for FY 2014. In those rules, we noted that, because section 1886(r) of the Act modifies the payment required under section 1886(d)(5)(F) of the Act, it affects only the DSH payment under the operating IPPS. It does not revise or replace the capital IPPS DSH payment provided under the regulations at 42 CFR part 412, subpart M, which were established through the exercise of the Secretary's discretion in implementing the capital IPPS under section 1886(g)(1)(A) of the Act.

Finally, section 1886(r)(3) of the Act provides that there shall be no administrative or judicial review under section 1869, section 1878, or otherwise of any estimate of the Secretary for purposes of determining the factors described in section 1886(r)(2) of the Act or of any period selected by the Secretary for the purpose of determining those factors. Therefore, there is no administrative or judicial review of the estimates developed for purposes of applying the three factors used to determine uncompensated care payments, or the periods selected in order to develop such estimates.

2. Eligibility for Empirically Justified Medicare DSH Payments and Uncompensated Care Payments

As explained earlier, the payment methodology under section 3133 of the Affordable Care Act applies to ''subsection (d) hospitals'' that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act. Therefore, hospitals must receive empirically justified Medicare DSH payments in a fiscal year in order to receive an additional Medicare uncompensated care payment for that year. Specifically, section 1886(r)(2) of the Act states that, in addition to the payment made to a subsection (d) hospital under section 1886(r)(1) of the Act, the Secretary shall pay to such subsection (d) hospitals an additional amount. Because section 1886(r)(1) of the Act refers to empirically justified Medicare DSH payments, the additional payment under section 1886(r)(2) of the Act is limited to hospitals that receive empirically justified Medicare DSH payments in accordance with section 1886(r)(1) of the Act for the applicable fiscal year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and the FY 2014 IPPS interim final rule with comment period (78 FR 61193), we provided that hospitals that are not eligible to receive empirically justified Medicare DSH payments in a fiscal year will not receive uncompensated care payments for that year. We also specified that we would make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status for the applicable fiscal year (using the most recent data that are available). We indicated that our final determination on the hospital's eligibility for uncompensated care payments will be based on the hospital's actual DSH status at cost report settlement for that payment year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and in the rulemaking for subsequent fiscal years, we have specified our policies for several specific classes of hospitals within the scope of section 1886(r) of the Act. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20388 and 20389), we discussed our specific policies with respect to the following hospitals:

- *Subsection (d) Puerto Rico hospitals* that are eligible for DSH payments also are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the new payment methodology (78 FR 50623 and 79 FR 50006).
- *Maryland hospitals* are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the payment methodology of section 1886(r) of the Act because they are not paid under the IPPS. As discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50007), effective January 1, 2014, the State of Maryland elected to no longer have Medicare pay Maryland hospitals in accordance with section 1814(b)(3) of the Act and entered into an agreement with CMS that Maryland hospitals would be paid under the Maryland All-Payer Model. As discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83

FR 20388), the performance period of the Maryland All-Payer Model is scheduled to end on December 31, 2018. However, since the proposed rule was issued, CMS and the State have entered into an agreement to govern payments to Maryland hospitals under a new payment model, the Maryland Total Cost of Care (TCOC) Model, which begins on January 1, 2019. Under both the Maryland All-Payer Model and the new Maryland TCOC Model, Maryland hospitals will not be paid under the IPPS in FY 2019, and will remain ineligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act.

• Sole community hospitals (*SCHs) that are paid under their hospital-specific rate* are not eligible for Medicare DSH payments. SCHs that are paid under the IPPS Federal rate receive interim payments based on what we estimate and project their DSH status to be prior to the beginning of the Federal fiscal year (based on the best available data at that time) subject to settlement through the cost report, and if they receive interim empirically justified Medicare DSH payments in a fiscal year, they also will receive interim uncompensated care payments for that fiscal year on a per discharge basis, subject as well to settlement through the cost report. Final eligibility determinations will be made at the end of the cost reporting period at settlement, and both interim empirically justified Medicare DSH payments and uncompensated care payments will be adjusted accordingly (78 FR 50624 and 79 FR 50007).

• *Medicare-dependent, small rural hospitals (MDHs)* are paid based on the IPPS Federal rate or, if higher, the IPPS Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate from certain specified base years (76 FR 51684). The IPPS Federal rate that is used in the MDH payment methodology is the same IPPS Federal rate that is used in the SCH payment methodology. Section 50205 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), enacted on February 9, 2018, extended the MDH program for discharges on or after October 1, 2017, through September 30, 2022. Because MDHs are paid based on the IPPS Federal rate, they continue to be eligible to receive empirically justified Medicare DSH payments and uncompensated care payments if their DPP is at least 15 percent, and we apply the same process to determine MDHs' eligibility for empirically justified Medicare DSH and uncompensated care payments as we do for all other IPPS hospitals. Due to the extension of the MDH program, MDHs will continue to be paid based on the IPPS Federal rate or, if higher, the IPPS Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate from certain specified base years. Accordingly, we will continue to make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status for the applicable fiscal year (using the most recent data that are available). Our final determination on the hospital's eligibility for uncompensated care payments will be based on the hospital's actual DSH status at cost report settlement for that payment year. In addition, as we do for all IPPS hospitals, we will calculate a numerator for Factor 3 for all MDHs, regardless of whether they are projected to be eligible for Medicare DSH payments during the fiscal year, but the denominator for Factor 3 will be based on the uncompensated care data from the hospitals that we have projected to be eligible for Medicare DSH payments during the fiscal year.

• *IPPS hospitals that elect to participate in the Bundled Payments for Care Improvement Advanced Initiative (BPCI Advanced) model starting October 1, 2018,* will continue to be paid under the IPPS and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments. For further information regarding the BPCI Advanced model, we refer readers to the CMS website at: *https://innovation.cms.gov/initiatives/bpci-advanced/*.

• *IPPS hospitals that are participating in the Comprehensive Care for Joint Replacement Model* (80 FR 73300) continue to be paid under the IPPS and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments.

• *Hospitals participating in the Rural Community Hospital Demonstration Program* are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act because they are not paid under the IPPS (78 FR 50625 and 79 FR 50008). The Rural Community Hospital Demonstration Program was originally authorized for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), and extended for another 5-year period by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 114–255). The period of performance for this 5-year extension period ended December 31, 2016. Section 15003 of the 21st Century Cures Act (Pub. L. 114–255), enacted December 13, 2016, again amended section 410A of Public Law 108–173 to require a 10-year extension period (in place of the 5-year extension required by the Affordable Care Act), therefore requiring an additional 5-year participation period for the demonstration program. Section 15003 of Public Law 114–255 also required a solicitation for applications for additional hospitals to participate in the demonstration program. At the time of issuance of the proposed rule, there were 30 hospitals participating in the demonstration program (83 FR 20389). Since issuance of the proposed rule, one hospital has withdrawn from the demonstration program. Under the payment methodology that applies during the second 5 years of the extension period under the demonstration program, participating hospitals do not receive empirically justified Medicare DSH payments, and they are also excluded from receiving interim and final uncompensated care payments.

3. Empirically Justified Medicare DSH Payments

As we have discussed earlier, section 1886(r)(1) of the Act requires the Secretary to pay 25 percent of the amount of the Medicare DSH payment that would otherwise be made under section 1886(d)(5)(F) of the Act to a subsection (d) hospital. Because section 1886(r)(1) of the Act merely requires the program to pay a designated percentage of these payments, without revising the criteria governing eligibility for DSH payments or the underlying payment methodology, we stated in the FY 2014 IPPS/LTCH PPS final rule that we did not believe that it was necessary to develop any new operational mechanisms for making such payments. Therefore, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50626), we implemented this provision by advising MACs to simply adjust the interim claim payments to the requisite 25 percent of what would have otherwise been paid. We also made corresponding changes to the hospital cost report so that these empirically justified Medicare DSH payments can be settled at the appropriate level at the time of cost report settlement. We provided more detailed operational instructions and cost report instructions following issuance of the FY 2014 IPPS/LTCH PPS final rule that are available on the CMS website at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/*

Transmittals/2014-Transmittals-Items/R5P240.html.

4. Uncompensated Care Payments

As we discussed earlier, section 1886(r)(2) of the Act provides that, for each eligible hospital in FY 2014 and subsequent years, the uncompensated care payment is the product of three factors. These three factors represent our estimate of 75 percent of the amount of Medicare DSH payments that would otherwise have been paid, an adjustment to this amount for the percent change in the national rate of uninsurance compared to the rate of uninsurance in 2013, and each eligible hospital's estimated uncompensated care amount relative to the estimated uncompensated care amount for all eligible hospitals. Below we discuss the data sources and methodologies for computing each of these factors, our final policies for FYs 2014 through 2018, and our proposed and final policies for FY 2019.

a. Calculation of Factor 1 for FY 2019

Section 1886(r)(2)(A) of the Act establishes Factor 1 in the calculation of the uncompensated care payment. Section 1886(r)(2)(A) of the Act states that this factor is equal to the difference between: (1) The aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if section 1886(r) of the Act did not apply for such fiscal year (as estimated by the Secretary); and (2) the aggregate amount of payments that are made to subsection (d) hospitals under section 1886(r)(1) of the Act for such fiscal year (as so estimated). Therefore, section 1886(r)(2)(A)(i) of the Act represents the estimated Medicare DSH payments that would have been made under section 1886(d)(5)(F) of the Act if section 1886(r) of the Act did not apply for such fiscal year. Under a prospective payment system, we would not know the precise aggregate Medicare DSH payment amount that would be paid for a Federal fiscal year until cost report settlement for all IPPS hospitals is completed, which occurs several years after the end of the Federal fiscal year. Therefore, section 1886(r)(2)(A)(i) of the Act provides authority to estimate this amount, by specifying that, for each fiscal year to which the provision applies, such amount is to be estimated by the Secretary. Similarly, section 1886(r)(2)(A)(ii) of the Act represents the estimated empirically justified Medicare DSH payments to be made in a fiscal year, as prescribed under section 1886(r)(1) of the Act. Again, section 1886(r)(2)(A)(ii) of the Act provides authority to estimate this amount.

Therefore, Factor 1 is the difference between our estimates of: (1) The amount that would have been paid in Medicare DSH payments for the fiscal year, in the absence of the new payment provision; and (2) the amount of empirically justified Medicare DSH payments that are made for the fiscal year, which takes into account the requirement to pay 25 percent of what would have otherwise been paid under section 1886(d)(5)(F) of the Act. In other words, this factor represents our estimate of 75 percent (100 percent minus 25 percent) of our estimate of Medicare DSH payments that would otherwise be made, in the absence of section 1886(r) of the Act, for the fiscal year.

As we did for FY 2018, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20389), in order to determine Factor 1 in the uncompensated care payment formula for FY 2019, we proposed to continue the policy established in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50628 through 50630) and in the FY 2014 IPPS interim final rule with comment period (78 FR 61194) of determining Factor 1 by developing estimates of both the aggregate amount of Medicare DSH payments that would be made in the absence of section 1886(r)(1) of the Act and the aggregate amount of empirically justified Medicare DSH payments to hospitals under 1886(r)(1) of the Act. These estimates will not be revised or updated after we know the final Medicare DSH payments for FY 2019.

Therefore, in order to determine the two elements of proposed Factor 1 for FY 2019 (Medicare DSH payments *prior* to the application of section 1886(r)(1) of the Act, and empirically justified Medicare DSH payments *after* application of section 1886(r)(1) of the Act), for the proposed rule, we used the most recently available projections of Medicare DSH payments for the fiscal year, as calculated by CMS' Office of the Actuary using the most recently filed Medicare hospital cost reports with Medicare DSH payment information and the most recent Medicare DSH patient percentages and Medicare DSH payment adjustments provided in the IPPS Impact File. The determination of the amount of DSH payments is partially based on the Office of the Actuary's Part A benefits projection model. One of the results of this model is inpatient hospital spending. Projections of DSH payments require projections for expected increases in utilization and case-mix. The assumptions that were used in making these projections and the resulting estimates of DSH payments for FY 2016 through FY 2019 are discussed in the table titled ''Factors Applied for FY 2016 through FY 2019 to Estimate Medicare DSH Expenditures Using FY 2015 Baseline.''

For purposes of calculating Factor 1 and modeling the impact of the FY 2019 IPPS/LTCH PPS proposed rule, we used the Office of the Actuary's December 2017 Medicare DSH estimates, which were based on data from the September 2017 update of the Medicare Hospital Cost Report Information System (HCRIS) and the FY 2018 IPPS/LTCH PPS final rule IPPS Impact file, published in conjunction with the publication of the FY 2018 IPPS/LTCH PPS final rule. (We note that the proposed rule included an inadvertent reference to the HCRIS December 2017 update, which we have corrected in this final rule to reflect the September 2017 update of HCRIS, which was used by OACT in developing the December 2017 estimates. The cost report data from the December quarterly update were not available to be used in OACT's December 2017 estimates of Medicare DSH payments.) Because SCHs that are projected to be paid under their hospital-specific rate are excluded from the application of section 1886(r) of the Act, these hospitals also were excluded from the December 2017 Medicare DSH estimates. Furthermore, because section 1886(r) of the Act specifies that the uncompensated care payment is in addition to the empirically justified Medicare DSH payment (25 percent of DSH payments that would be made without regard to section 1886(r) of the Act), Maryland hospitals, which are not eligible to receive DSH payments, were also excluded from the Office of the Actuary's December 2017 Medicare DSH estimates. The 30 hospitals that were then participating in the Rural Community Hospital Demonstration Program were also excluded from these estimates because, under the payment methodology that applies during the second 5 years of the extension period, these hospitals are not eligible to receive empirically justified Medicare DSH payments or interim and final uncompensated care payments.

For the proposed rule, using the data sources discussed above, the Office of the Actuary's December 2017 estimate for Medicare DSH payments for FY 2019, without regard to the application of section 1886(r)(1) of the Act, was approximately $16.295 billion. Therefore, also based on the December 2017 estimate, the estimate of empirically justified Medicare DSH payments for FY 2019, with the application of section 1886(r)(1) of the

Act, was approximately $4.074 billion (or 25 percent of the total amount of estimated Medicare DSH payments for FY 2019). Under § 412.106(g)(1)(i) of the regulations, Factor 1 is the difference between these two estimates of the Office of the Actuary. Therefore, in the proposed rule, we proposed that Factor 1 for FY 2019 would be $12,221,027,954.62, which is equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2019 ($16,294,703,939.49 minus $4,073,675,984.87).

Comment: Some commenters requested greater transparency in the methodology used by CMS and the OACT, particularly with respect to the calculation of estimated DSH payments for purposes of determining Factor 1, and the ''Other'' factors that are used to estimate Medicare DSH expenditures. A number of commenters urged CMS to provide a detailed explanation, including calculations, of the assumptions used to make these projections. Some commenters believed that the lack of opportunity afforded to hospitals to review the data used in rulemaking is in violation of the Administrative Procedure Act. Specifically, the commenters noted that the update factors used to derive the estimated DSH payment for FY 2019 were different from the factors used in previous years, but the changes were not addressed by CMS in the proposed rule. The commenters also noted that they have not had the opportunity to comment on the extrapolation of the 2015 DSH data and the way in which Medicaid expansion was accounted for in the DSH payment impact, or on any adjustments made to the data.

Some commenters expressed concern about whether underreporting of Medicaid coverage was factored into the calculation of Factor 1, as it was for Factor 2. The commenters noted that, in the proposed rule, CMS did not explain why OACT assumed that there is an underreporting of Medicaid coverage due to ''a perceived stigma associated with being enrolled in the Medicaid program or confusion about the source of health insurance.'' The commenters further stated that the proposed rule did not indicate that the same presumption was also applied to the calculation of Factor 1. Many commenters provided examples of other assumptions made by OACT for which CMS did not provide information in rulemaking to explain the basis for or the data used to make the assumptions. The commenters believed that, given the information available to CMS, such as enrollment and utilization information from States that have expanded Medicaid and recently released reports that concluded that the Affordable Care Act had insured fewer individuals than previously estimated (CBO September 2017 report; President's 2018 Economic Report), coverage levels were lower than estimated by CMS; and therefore, DSH payments to hospitals were suppressed. The commenters requested that CMS implement a system to reconcile uncompensated care payments once later data on Medicare DSH payments are available. One commenter thanked CMS for providing a table listing hospital-specific estimated uncompensated care payments and other DSH-related information for FY 2019. Another commenter suggested that, as CMS is permitting revisions to Factor 3, the agency consider completing reconciliation for Factor 1 and Factor 2. The commenter recognized that there are issues pertaining to completing reconciliation for all three factors, such as the determination of when to finalize all cost reports, but suggested using a methodology similar to the one used to determine the wage index by using prior years' data for settlement of a future year and developing time tables for submissions and revisions to the data.

Response: We thank the commenters for their input. For the reasons discussed below, we have been and continue to be transparent with respect to the methodology and data used to estimate Factor 1 and we disagree with commenters who assert otherwise. Regarding the commenters who reference the Administrative Procedure Act, we note that under the Administrative Procedure Act, a proposed rule is required to include either the terms or substance of the proposed rule or a description of the subjects and issues involved. In this case, the FY 2019 IPPS/LTCH PPS proposed rule did include a detailed discussion of our proposed Factor 1 methodology and the data sources that would be used in making our estimate.

To provide context, we first note that Factor 1 is not estimated in isolation from other OACT projections. The Factor 1 estimates for proposed rules are generally consistent with the economic assumptions and actuarial analysis used to develop the President's Budget estimates under current law, and the Factor 1 estimates for the final rule are generally consistent with those used for the Midsession Review of the President's Budget. As we have in the past, for additional information on the development of the President's Budget, we refer readers to the Office of Management and Budget website at: *https://www.whitehouse.gov/omb/budget.* For additional information on the specific economic assumptions used in the Midsession Review of the President's FY 2019 Budget, we refer readers to the ''Midsession Review of the President's FY 2019 Budget'' available on the Office of Management and Budget website at: *https://www.whitehouse.gov/omb/budget.* We recognize that our reliance on the economic assumptions and actuarial analysis used to develop the President's Budget and the Midsession Review of the President's Budget in estimating Factor 1 has an impact on stakeholders who wish to replicate the Factor 1 calculation, such as modelling the relevant Medicare Part A portion of the budget, but we believe commenters are able to meaningfully comment on our proposed estimate of Factor 1 without replicating the budget.

For a general overview of the principal steps involved in projecting future inpatient costs and utilization, we refer readers to the ''2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds'' available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/index.html?redirect=/reportstrustfunds/* under ''Downloads.'' We note that the annual reports of the Medicare Boards of Trustees to Congress represent the Federal Government's official evaluation of the financial status of the Medicare Program. The actuarial projections contained in these reports are based on numerous assumptions regarding future trends in program enrollment, utilization and costs of health care services covered by Medicare, as well as other factors affecting program expenditures. In addition, although the methods used to estimate future costs based on these assumptions are complex, they are subject to periodic review by independent experts to ensure their validity and reasonableness.

We also refer the public to the Actuarial Report on the Financial Outlook for Medicaid for a discussion of general issues regarding Medicaid projections.

Second, as described in more detail later in this section, in the FY 2019 IPPS/LTCH PPS proposed rule, we included information regarding the data sources, methods, and assumptions employed by the actuaries in determining the OACT's estimate of Factor 1. In summary, we indicated the historical HCRIS data update OACT used to identify Medicare DSH

payments, we explained that the most recent Medicare DSH payment adjustments provided in the IPPS Impact File were used, and we provided the components of all the update factors that were applied to the historical data to estimate the Medicare DSH payments for the upcoming fiscal year, along with the associated rationale and assumptions. This discussion also included a description of the ''Other'' and ''Discharges'' assumptions, and also provided additional information regarding how we address the Medicaid and CHIP expansion. Thus, for example, in response to the commenters' assertion that Medicaid expansion is not adequately accounted for in the ''Other'' column, we note that the discussion in the proposed rule made clear that, based on data from the Midsession Review of the President's Budget, the OACT assumed per capita spending for Medicaid beneficiaries who enrolled due to the expansion to be 50 percent of the average per capita expenditures for a preexpansion Medicaid beneficiary due to the better health of these beneficiaries. Taken as a whole, this description of our proposed methodology for estimating Factor 1 and the data sources used in making this estimate was entirely consistent with the requirements of the Administrative Procedure Act, and gave stakeholders adequate notice of and a meaningful opportunity to comment on the proposed estimate of Factor 1.

Regarding the commenters' assertion that, similar to the adjustment for Medicaid underreporting on survey data in the estimation of Factor 2, we should also account for this underreporting in our estimate of Factor 1, we note that the Factor 1 calculation uses Medicaid enrollment data and estimates and does not require the adjustment because it does not use survey data.

Lastly, regarding the commenters' suggestion that CMS consider reconciling the estimates of Factors 1, 2, and 3, we continue to believe that applying our best estimates prospectively is most conducive to administrative efficiency, finality, and predictability in payments (78 FR 50628; 79 FR 50010; 80 FR 49518; 81 FR 56949; and 82 FR 38195). We believe that, in affording the Secretary the discretion to estimate the three factors used to determine uncompensated care payments and by including a prohibition against administrative and judicial review of those estimates in section 1886(r)(3) of the Act, Congress recognized the importance of finality and predictability under a prospective payment system. As a result, we do not agree with the commenters' suggestion that we should establish a process for reconciling our estimates of the three factors, which would be contrary to the notion of prospectivity. We also address comments specifically requesting that we establish procedures for reconciling Factor 3 later in this section, as part of the discussion of the comments received on the proposed methodology for Facto 3.

After consideration of the public comments we received, we are finalizing, as proposed, the methodology for calculating Factor 1 for FY 2019. We discuss the resulting Factor 1 amount for FY 2019 below.

For this final rule, the OACT used the most recently submitted Medicare cost report data from the March 2018 update of HCIRS to identify Medicare DSH payments and the most recent Medicare DSH payment adjustments provided in the Impact File published in conjunction with the publication of the FY 2018 IPPS/LTCH PPS final rule and applied update factors and assumptions for future changes in utilization and case-mix to estimate Medicare DSH payments for the upcoming fiscal year. The June 2018 OACT estimate for Medicare DSH payments for FY 2019, without regard to the application of section 1886(r)(1) of the Act, was approximately $16.339 billion. This estimate excluded Maryland hospitals participating in the Maryland All-Payer Model, hospitals participating in the Rural Community Hospital Demonstration, and SCHs paid under their hospital-specific payment rate. Therefore, based on the June 2018 estimate, the estimate of empirically justified Medicare DSH payments for FY 2019, with the application of section 1886(r)(1) of the Act, was approximately $4.085 billion (or 25 percent of the total amount of estimated Medicare DSH payments for FY 2019). Under § 412.106(g)(1)(i) of the regulations, Factor 1 is the difference between these two estimates of the OACT. Therefore, in this final rule, Factor 1 for FY 2019 is $12,254,291,878.57, which is equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2019 ($16,339,055,838.09 minus $4,084,763,959.52).

The Office of the Actuary's final estimates for FY 2019 began with a baseline of $13.230 billion in Medicare DSH expenditures for FY 2015. The following table shows the factors applied to update this baseline through the current estimate for FY 2019:

FACTORS APPLIED FOR FY 2016 THROUGH FY 2019 TO ESTIMATE MEDICARE DSH EXPENDITURES USING FY 2015 BASELINE

FY	Update	Discharges	Case-mix	Other	Total	Estimated DSH payment (in billions) *
2016	1.009	0.9864	1.031	1.0443	1.071589	14.177
2017	1.0015	0.9931	1.004	1.0662	1.064673	15.094
2018	1.018088	0.9892	1.02	1.0277	1.055689	15.935
2019	1.0185	1.0014	1.005	1.00035	1.025384	16.339

* Rounded.

In this table, the discharges column shows the increase in the number of Medicare fee-for-service (FFS) inpatient hospital discharges. The figures for FY 2016 and FY 2017 are based on Medicare claims data that have been adjusted by a completion factor. The discharge figure for FY 2018 is based on preliminary data for 2018. The discharge figure for FY 2019 is an assumption based on recent trends recovering back to the long-term trend and assumptions related to how many beneficiaries will be enrolled in Medicare Advantage (MA) plans. The case-mix column shows the increase in case-mix for IPPS hospitals. The case-mix figures for FY 2016 and FY 2017 are based on actual data adjusted by a completion factor. The FY 2018 increase is based on preliminary data. The FY 2019 increase is an estimate based on the recommendation of the 2010–2011 Medicare Technical Review Panel. The ''Other'' column shows the increase in other factors that contribute to the Medicare DSH estimates. These factors

include the difference between the total inpatient hospital discharges and the IPPS discharges, and various adjustments to the payment rates that have been included over the years but are not reflected in the other columns (such as the change in rates for the 2-midnight stay policy). In addition, the ''Other'' column includes a factor for the Medicaid expansion due to the Affordable Care Act. The factor for Medicaid expansion was developed using public information and statements for each State regarding its intent to implement the expansion. Based on this information, it is assumed that 50 percent of all individuals who were potentially newly eligible Medicaid enrollees in 2016 resided in States that had elected to expand Medicaid eligibility and, for 2017 and thereafter, that 55 percent of such individuals would reside in expansion States. In the future, these assumptions may change based on actual participation by States. For a discussion of general issues regarding Medicaid projections, we refer readers to the 2016~~7~~ Actuarial Report on the Financial Outlook for Medicaid, which is available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/MedicaidReport2016.pdf*. We note that, in developing their estimates of the effect of Medicaid expansion on Medicare DSH expenditures, our actuaries have assumed that the new Medicaid enrollees are healthier than the average Medicaid recipient and, therefore, use fewer hospital services. Specifically, based on data from the Mid-Session Review of the President's Budget, the OACT assumed per capita spending for Medicaid beneficiaries who enrolled due to the expansion to be 50 percent of the average per capita expenditures for a pre-expansion Medicaid beneficiary due to the better health of these beneficiaries. This assumption is consistent with recent internal estimates of Medicaid per capita spending pre-expansion and post-expansion.

The table below shows the factors that are included in the ''Update'' column of the above table:

FY	Market basket percentage	Affordable Care Act payment reductions	Multifactor productivity adjustment	Documentation and coding	Total update percentage
2016	2.4	−0.2	−0.5	−0.8	0.9
2017	2.7	−0.75	−0.3	−1.5	0.15
2018	2.7	−0.75	−0.6	0.4588	1.8088
2019	2.9	−0.75	−0.8	0.5	1.85

Note: All numbers are based on the Midsession Review of FY 2019 President's Budget projections.

b. Calculation of Factor 2 for FY 2019

(1) Background

Section 1886(r)(2)(B) of the Act establishes Factor 2 in the calculation of the uncompensated care payment. Specifically, section 1886(r)(2)(B)(i) of the Act provides that, for each of FYs 2014, 2015, 2016, and 2017, a factor equal to 1 minus the percent change in the percent of individuals under the age of 65 who are uninsured, as determined by comparing the percent of such individuals (1) who were uninsured in 2013, the last year before coverage expansion under the Affordable Care Act (as calculated by the Secretary based on the most recent estimates available from the Director of the Congressional Budget Office before a vote in either House on the Health Care and Education Reconciliation Act of 2010 that, if determined in the affirmative, would clear such Act for enrollment); and (2) who are uninsured in the most recent period for which data are available (as so calculated), minus 0.1 percentage point for FY 2014 and minus 0.2 percentage point for each of FYs 2015, 2016, and 2017.

Section 1886(r)(2)(B)(ii) of the Act permits the use of a data source other than the CBO estimates to determine the percent change in the rate of uninsurance beginning in FY 2018. In addition, for FY 2018 and subsequent years, the statute does not require that the estimate of the percent of individuals who are uninsured be limited to individuals who are under 65. Specifically, the statute states that, for FY 2018 and subsequent fiscal years, the second factor is 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who were uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS) and the percent of individuals who were uninsured in the most recent period for which data are available (as so estimated and certified), minus 0.2 percentage point for FYs 2018 and 2019.

(2) Methodology for Calculation of Factor 2 for FY 2019

As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38197), in our analysis of a potential data source for the rate of uninsurance for purposes of computing Factor 2 in FY 2018, we considered the following: (a) The extent to which the source accounted for the full U.S. population; (b) the extent to which the source comprehensively accounted for both public and private health insurance coverage in deriving its estimates of the number of uninsured; (c) the extent to which the source utilized data from the Census Bureau; (d) the timeliness of the estimates; (e) the continuity of the estimates over time; (f) the accuracy of the estimates; and (g) the availability of projections (including the availability of projections using an established estimation methodology that would allow for calculation of the rate of uninsurance for the applicable Federal fiscal year). As we explained in the FY 2018 IPPS/LTCH PPS final rule, these considerations are consistent with the statutory requirement that this estimate be based on data from the Census Bureau or other sources the Secretary determines appropriate and help to ensure the data source will provide reasonable estimates for the rate of uninsurance that are available in conjunction with the IPPS rulemaking cycle. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20391), we proposed to use the same methodology as was used in FY 2018 to determine Factor 2 for FY 2019.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38197 and 38198), we explained that we determined the source that, on balance, best meets all of these considerations is the uninsured estimates produced by CMS' Office of the Actuary (OACT) as part of the development of the National Health Expenditure Accounts (NHEA). The NHEA represents the government's official estimates of economic activity (spending) within the health sector. The information contained in the NHEA has

been used to study numerous topics related to the health care sector, including, but not limited to, changes in the amount and cost of health services purchased and the payers or programs that provide or purchase these services; the economic causal factors at work in the health sector; the impact of policy changes, including major health reform; and comparisons to other countries' health spending. Of relevance to the determination of Factor 2 is that the comprehensive and integrated structure of the NHEA creates an ideal tool for evaluating changes to the health care system, such as the mix of the insured and uninsured because this mix is integral to the well-established NHEA methodology. Below we describe some aspects of the methodology used to develop the NHEA that were particularly relevant in estimating the percent change in the rate of uninsurance for FY 2018 and that we believe continue to be relevant in developing the estimate for FY 2019. A full description of the methodology used to develop the NHEA is available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/DSM-15.pdf*.

The NHEA estimates of U.S. population reflect the Census Bureau's definition of the resident-based population, which includes all people who usually reside in the 50 States or the District of Columbia, but excludes residents living in Puerto Rico and areas under U.S. sovereignty, members of the U.S. Armed Forces overseas, and U.S. citizens whose usual place of residence is outside of the United States, plus a small (typically less than 0.2 percent of population) adjustment to reflect Census undercounts. In past years, the estimates for Factor 2 were made using the CBO's uninsured population estimates for the under 65 population. For FY 2018 and subsequent years, the statute does not restrict the estimate to the measurement of the percent of individuals under the age of 65 who are uninsured. Accordingly, as we explained in the FY 2018 IPPS/LTCH PPS proposed and final rules, we believe it is appropriate to use an estimate that reflects the rate of uninsurance in the United States across all age groups. In addition, we continue to believe that a resident-based population estimate more fully reflects the levels of uninsurance in the United States that influence uncompensated care for hospitals than an estimate that reflects only legal residents. The NHEA estimates of uninsurance are for the total U.S. population (all ages) and not by specific age cohort, such as the population under the age of 65.

The NHEA includes comprehensive enrollment estimates for total private health insurance (PHI) (including direct and employer-sponsored plans), Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and other public programs, and estimates of the number of individuals who are uninsured. Estimates of total PHI enrollment are available for 1960 through 2016, estimates of Medicaid, Medicare, and CHIP enrollment are available for the length of the respective programs, and all other estimates (including the more detailed estimates of direct-purchased and employer-sponsored insurance) are available for 1987 through 2016. The NHEA data are publicly available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/index.html*.

In order to compute Factor 2, the first metric that is needed is the proportion of the total U.S. population that was uninsured in 2013. In developing the estimates for the NHEA, OACT's methodology included using the number of uninsured individuals for 1987 through 2009 based on the enhanced Current Population Survey (CPS) from the State Health Access Data Assistance Center (SHADAC). The CPS, sponsored jointly by the U.S. Census Bureau and the U.S. Bureau of Labor Statistics (BLS), is the primary source of labor force statistics for the population of the United States. (We refer readers to the website at: *http://www.census.gov/programs-surveys/cps.html*.) The enhanced CPS, available from SHADAC (available at *http://datacenter.shadac.org*) accounts for changes in the CPS methodology over time. OACT further adjusts the enhanced CPS for an estimated undercount of Medicaid enrollees (a population that is often not fully captured in surveys that include Medicaid enrollees due to a perceived stigma associated with being enrolled in the Medicaid program or confusion about the source of their health insurance).

To estimate the number of uninsured individuals for 2010 through 2014, the OACT extrapolates from the 2009 CPS data using data from the National Health Interview Survey (NHIS). For both 2015 and 2016, OACT's estimates of the rate of uninsurance are derived by applying the NHIS data on the proportion of uninsured individuals to the total U.S. population as described above. The NHIS is one of the major data collection programs of the National Center for Health Statistics (NCHS), which is part of the Centers for Disease Control and Prevention (CDC). The U.S. Census Bureau is the data collection agent for the NHIS. The NHIS results have been instrumental over the years in providing data to track health status, health care access, and progress toward achieving national health objectives. For further information regarding the NHIS, we refer readers to the CDC website at: *https://www.cdc.gov/nchs/nhis/index.htm*.

The next metrics needed to compute Factor 2 are projections of the rate of uninsurance in both calendar years 2018 and 2019. On an annual basis, OACT projects enrollment and spending trends for the coming 10-year period. Those projections (currently for years 2017 through 2026) use the latest NHEA historical data, which presently run through 2016. The NHEA projection methodology accounts for expected changes in enrollment across all of the categories of insurance coverage previously listed. The sources for projected growth rates in enrollment for Medicare, Medicaid, and CHIP include the latest Medicare Trustees Report, the Medicaid Actuarial Report, or other updated estimates as produced by OACT. Projected rates of growth in enrollment for private health insurance and the uninsured are based largely on OACT's econometric models, which rely on the set of macroeconomic assumptions underlying the latest Medicare Trustees Report. Greater detail can be found in OACT's report titled ''Projections of National Health Expenditure: Methodology and Model Specification,'' which is available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology.pdf*.

As discussed in the FY 2018 IPPS/LTCH PPS final rule, the use of data from the NHEA to estimate the rate of uninsurance is consistent with the statute and meets the criteria we have identified for determining the appropriate data source. Section 1886(r)(2)(B)(ii) of the Act instructs the Secretary to estimate the rate of uninsurance for purposes of Factor 2 based on data from the Census Bureau or other sources the Secretary determines appropriate. The NHEA utilizes data from the Census Bureau; the estimates are available in time for the IPPS rulemaking cycle; the estimates are produced by OACT on an annual basis and are expected to continue to be produced for the foreseeable future; and projections are available for calendar year time periods that span the

upcoming fiscal year. Timeliness and continuity are important considerations because of our need to be able to update this estimate annually. Accuracy is also a very important consideration and, all things being equal, we would choose the most accurate data source that sufficiently meets our other criteria.

Using these data sources and the methodologies described above, the OACT estimates that the uninsured rate for the historical, baseline year of 2013 was 14 percent and for CYs 2018 and 2019 is 9.1 percent and 9.6 percent, respectively.[229] As required by section 1886(r)(2)(B)(ii) of the Act, the Chief Actuary of CMS has certified these estimates.

As with the CBO estimates on which we based Factor 2 in prior fiscal years, the NHEA estimates are for a calendar year. In the rulemaking for FY 2014, many commenters noted that the uncompensated care payments are made for the fiscal year and not on a calendar year basis and requested that CMS normalize the CBO estimate to reflect a fiscal year basis. Specifically, commenters requested that CMS calculate a weighted average of the CBO estimate for October through December 2013 and the CBO estimate for January through September 2014 when determining Factor 2 for FY 2014. We agreed with the commenters that normalizing the estimate to cover FY 2014 rather than CY 2014 would more accurately reflect the rate of uninsurance that hospitals would experience during the FY 2014 payment year. Accordingly, we estimated the rate of uninsurance for FY 2014 by calculating a weighted average of the CBO estimates for CY 2013 and CY 2014 (78 FR 50633). We have continued this weighted average approach in each fiscal year since FY 2014.

We continue to believe that, in order to estimate the rate of uninsurance during a fiscal year more accurately, Factor 2 should reflect the estimated rate of uninsurance that hospitals will experience during the fiscal year, rather than the rate of uninsurance during only one of the calendar years that the fiscal year spans. Accordingly, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20393), we proposed to continue to apply the weighted average approach used in past fiscal years in order to estimate the rate of uninsurance for FY 2019. The OACT has certified this estimate of the fiscal year rate of uninsurance to be reasonable and appropriate for purposes of section 1886(r)(2)(B)(ii) of the Act.

The calculation of the proposed Factor 2 for FY 2019 using a weighted average of the OACT's projections for CY 2018 and CY 2019 was as follows:

- Percent of individuals without insurance for CY 2013: 14 percent.
- Percent of individuals without insurance for CY 2018: 9.1 percent.
- Percent of individuals without insurance for CY 2019: 9.6 percent.
- Percent of individuals without insurance for FY 2019 $(0.25 \times 0.091) + (0.75 \times 0.096)$: 9.48 percent.

$1 - |((0.0948 - 0.14)/0.14)| = 1 - 0.3229 = 0.6771$ (67.71 percent)

0.6771 (67.71 percent) − .002 (0.2 percentage points for FY 2019 under section 1886(r)(2)(B)(ii) of the Act) = 0.6751 or 67.51 percent

0.6751 = Factor 2

Therefore, we proposed that Factor 2 for FY 2019 would be 67.51 percent.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20393), we stated that the proposed FY 2019 uncompensated care amount was: $\$12,221,027,954.62 \times 0.6751 = \$8,250,415,972.16$.

We invited public comments on our proposed methodology for calculation of Factor 2 for FY 2019.

Comment: A number of commenters expressed appreciation for CMS' recognition that the aggregate amount available to be distributed to hospitals for uncompensated care costs will increase by approximately $1.5 billion based on the most recently available projections of Medicare DSH payments for FY 2019 by CMS' Office of the Actuary. Other commenters stated the increase in the estimated amount available to make uncompensated care payments in FY 2019 was not enough to address the underpayments to hospitals that occurred as a result of using CBO data since FY 2014 to estimate the change in the rate of uninsurance. Several commenters supported CMS' continued use of the uninsured estimates produced by the OACT as part of the development of the National Health Expenditure Accounts in estimating the percent change in the rate of uninsured for FY 2019. Some of these commenters stated that, in their view, the estimates produced by the OACT are more complete and more accurately capture the change in the rate at which uninsured individuals have obtained health insurance. A few commenters noted that the data source added greater transparency to the process as the NHEA estimates are publicly available, while other commenters urged CMS to ensure that all data are provided with complete transparency with respect to the type of data and data collection methods that are used.

Response: We appreciate the support for our proposal to continue using the uninsured estimates produced by OACT in the computation of Factor 2 for FY 2019. Section 1886(r)(2)(B)(ii) of the Act permits us to use a data source other than CBO estimates to determine the percent change in the rate of uninsurance beginning in FY 2018. We believe that the NHEA data, on balance, best meet all of our considerations to ensure that the data source meets the statutory requirement that the estimate be based on data from the Census Bureau or other sources the Secretary determines appropriate and will provide reasonable estimates for the rate of uninsurance that are available in conjunction with the IPPS rulemaking cycle.

In response to commenters who stated the increase in the estimated amount available to make uncompensated care payments in FY 2019 was not enough to address the underpayments to hospitals that occurred as a result of using CBO data in the past to estimate the change in the rate of uninsurance, we do not agree that addressing any difference between the prospectively determined estimates using the CBO data and later retrospective estimates would be appropriate for reasons we have articulated in past rulemaking and earlier in this section. We continue to believe that applying our best estimates prospectively is most conducive to administrative efficiency, finality, and predictability in payments (78 FR 50628; 79 FR 50010; 80 FR 49518; 81 FR 56949; and 82 FR 38195). We believe that, in affording the Secretary the discretion to estimate the three factors used to determine uncompensated care payments and by including a prohibition against administrative and judicial review of those estimates in section 1886(r)(3) of the Act, Congress recognized the importance of finality and predictability under a prospective payment system. As a result, we do not agree with the commenters' suggestion that we should establish a process for reconciling our estimate of Factor 2 for any given year using later estimates.

After consideration of the public comments we received, we are finalizing the calculation of Factor 2 for FY 2019 as proposed. The estimates of the percent of uninsured individuals have been certified by the Chief Actuary of CMS, as discussed in the proposed rule. The calculation of the final Factor 2 for FY 2019 using a weighted average of OACT's projections for CY 2018 and CY 2019 is as follows:

[229] Certification of Rates of Uninsured. March 22, 2018. Available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/FY2019-CMS-1694-P-OACT.pdf.*

- Percent of individuals without insurance for CY 2013: 14 percent.
- Percent of individuals without insurance for CY 2018: 9.1 percent.
- Percent of individuals without insurance for CY 2019: 9.6 percent.
- Percent of individuals without insurance for FY 2019 (0.25 times 0.091) + (0.75 times 0.096): 9.48 percent.

1 − |((0.0948 − 0.14)/0.14)| = 1 − 0.3229 = 0.6771 (67.71 percent)

0.6771 (67.71 percent) − .002 (0.2 percentage points for FY 2019 under section 1886(r)(2)(B)(ii) of the Act) = 0.6751 or 67.51 percent

0.6751 = Factor 2

Therefore, the final Factor 2 for FY 2019 is 67.51 percent.

The final FY 2019 uncompensated care amount is: $12,254,291,878.57 × 0.6751 = $8,272,872,447.22.

Final FY 2019 Uncompensated Care Amount	$8,272,872,447.22

c. Calculation of Factor 3 for FY 2019

(1) Background

Section 1886(r)(2)(C) of the Act defines Factor 3 in the calculation of the uncompensated care payment. As we have discussed earlier, section 1886(r)(2)(C) of the Act states that Factor 3 is equal to the percent, for each subsection (d) hospital, that represents the quotient of: (1) The amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data (including, in the case where the Secretary determines alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating the uninsured, the use of such alternative data)); and (2) the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act for such period (as so estimated, based on such data).

Therefore, Factor 3 is a hospital-specific value that expresses the proportion of the estimated uncompensated care amount for each subsection (d) hospital and each subsection (d) Puerto Rico hospital with the potential to receive Medicare DSH payments relative to the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the fiscal year for which the uncompensated care payment is to be made. Factor 3 is applied to the product of Factor 1 and Factor 2 to determine the amount of the uncompensated care payment that each eligible hospital will receive for FY 2014 and subsequent fiscal years. In order to implement the statutory requirements for this factor of the uncompensated care payment formula, it was necessary to determine: (1) The definition of uncompensated care or, in other words, the specific items that are to be included in the numerator (that is, the estimated uncompensated care amount for an individual hospital) and the denominator (that is, the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the applicable fiscal year); (2) the data source(s) for the estimated uncompensated care amount; and (3) the timing and manner of computing the quotient for each hospital estimated to receive Medicare DSH payments. The statute instructs the Secretary to estimate the amounts of uncompensated care for a period based on appropriate data. In addition, we note that the statute permits the Secretary to use alternative data in the case where the Secretary determines that such alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured.

In the course of considering how to determine Factor 3 during the rulemaking process for FY 2014, the first year this provision was in effect, we considered defining the amount of uncompensated care for a hospital as the uncompensated care costs of that hospital and determined that Worksheet S–10 of the Medicare cost report potentially provides the most complete data regarding uncompensated care costs for Medicare hospitals. However, because of concerns regarding variations in the data reported on Worksheet S–10 and the completeness of these data, we did not use Worksheet S–10 data to determine Factor 3 for FY 2014, or for FYs 2015, 2016, or 2017. Instead, we believed that the utilization of insured low-income patients, as measured by patient days, would be a better proxy for the costs of hospitals in treating the uninsured and therefore appropriate to use in calculating Factor 3 for these years. Of particular importance in our decision making was the relative newness of Worksheet S–10, which went into effect on May 1, 2010. At the time of the rulemaking for FY 2014, the most recent available cost reports would have been from FYs 2010 and 2011, which were submitted on or after May 1, 2010, when the new Worksheet S–10 went into effect. We believed that concerns about the standardization and completeness of the Worksheet S–10 data could be more acute for data collected in the first year of the Worksheet's use (78 FR 50635). In addition, we believed that it would be most appropriate to use data elements that have been historically publicly available, subject to audit, and used for payment purposes (or that the public understands will be used for payment purposes) to determine the amount of uncompensated care for purposes of Factor 3 (78 FR 50635). At the time we issued the FY 2014 IPPS/LTCH PPS final rule, we did not believe that the available data regarding uncompensated care from Worksheet S–10 met these criteria and, therefore, we believed they were not reliable enough to use for determining FY 2014 uncompensated care payments. For FYs 2015, 2016, and 2017, the cost reports used for calculating uncompensated care payments (that is, FYs 2011, 2012, and 2013) were also submitted prior to the time that hospitals were on notice that Worksheet S–10 could be the data source for calculating uncompensated care payments. Therefore, we believed it was also appropriate to use proxy data to calculate Factor 3 for these years. We indicated our belief that Worksheet S–10 could ultimately serve as an appropriate source of more direct data regarding uncompensated care costs for purposes of determining Factor 3 once hospitals were submitting more accurate and consistent data through this reporting mechanism.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38202), we stated that we can no longer conclude that alternative data to the Worksheet S–10 are available for FY 2014 that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. Hospitals were on notice as of FY 2014 that Worksheet S–10 could eventually become the data source for CMS to calculate uncompensated care payments. Furthermore, hospitals' cost reports from FY 2014 had been publicly available for some time, and CMS had analyses of Worksheet S–10, conducted both internally and by stakeholders, demonstrating that Worksheet S–10 accuracy had improved over time. Analyses performed by MedPAC had already shown that the correlation between audited uncompensated care data from 2009 and the data from the FY 2011 Worksheet S–10 was over 0.80, as compared to a correlation of approximately 0.50 between the audited uncompensated care data and 2011 Medicare SSI and Medicaid days. Based on this analysis, MedPAC concluded that use of Worksheet S–10 data was already better than using Medicare SSI and Medicaid days as a proxy for uncompensated care costs, and that the

data on Worksheet S–10 would improve over time as the data are actually used to make payments (81 FR 25090). In addition, a 2007 MedPAC analysis of data from the Government Accountability Office (GAO) and the American Hospital Association (AHA) had suggested that Medicaid days and low-income Medicare days are not an accurate proxy for uncompensated care costs (80 FR 49525).

Subsequent analyses from Dobson/DaVanzo, originally commissioned by CMS for the FY 2014 rulemaking and updated in later years, compared Worksheet S–10 and IRS Form 990 data and assessed the correlation in Factor 3s derived from each of the data sources. The most recent update of this analysis, which used IRS Form 990 data for tax years 2011, 2012, and 2013 (the latest available years) as a benchmark, found that the amounts for Factor 3 derived using the IRS Form 990 and Worksheet S–10 data continue to be highly correlated and that this correlation continues to increase over time, from 0.80 in 2011 to 0.85 in 2013.

This empirical evidence led us to believe that we had reached a tipping point in FY 2018 with respect to the use of the Worksheet S–10 data. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38201 through 38203) for a complete discussion of these analyses.

We found further evidence for this tipping point when we examined changes to the FY 2014 Worksheet S–10 data submitted by hospitals following the publication of the FY 2017 IPPS/LTCH PPS final rule. In the FY 2017 IPPS/LTCH PPS final rule, as part of our ongoing quality control and data improvement measures for the Worksheet S–10, we referred readers to Change Request 9648, Transmittal 1681, titled ''The Supplemental Security Income (SSI)/Medicare Beneficiary Data for Fiscal Year 2014 for Inpatient Prospective Payment System (IPPS) Hospitals, Inpatient Rehabilitation Facilities (IRFs), and Long Term Care Hospitals (LTCHs),'' issued on July 15, 2016 (available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1681OTN.pdf*). In this transmittal, as part of the process for ensuring complete submission of Worksheet S–10 by all eligible DSH hospitals, we instructed MACs to accept amended Worksheets S–10 for FY 2014 cost reports submitted by hospitals (or initial submissions of Worksheet S–10 if none had been submitted previously) and to upload them to the Health Care Provider Cost Report Information System (HCRIS) in a timely manner. The transmittal stated that, for revisions to be considered, hospitals were required to submit their amended FY 2014 cost report containing the revised Worksheet S–10 (or a completed Worksheet S–10 if no data were included on the previously submitted cost report) to the MAC no later than September 30, 2016. For the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19949 through 19950), we examined hospitals' FY 2014 cost reports to see if the Worksheet S–10 data on those cost reports had changed as a result of the opportunity for hospitals to submit revised Worksheet S–10 data for FY 2014. Specifically, we compared hospitals' FY 2014 Worksheet S–10 data as they existed in the first quarter of CY 2016 with data from the fourth quarter of CY 2016. We found that the FY 2014 Worksheet S–10 data had changed over that time period for approximately one quarter of hospitals that receive uncompensated care payments. The fact that the Worksheet S–10 data changed for such a significant number of hospitals following a review of the cost report data they originally submitted and that the revised Worksheet S–10 information is available to be used in determining uncompensated care costs contributed to our belief that we could no longer conclude that alternative data are available that are a better proxy than the Worksheet S–10 data for the costs of subsection (d) hospitals for treating individuals who are uninsured.

We also recognized commenters' concerns that, in using Medicaid days as part of the proxy for uncompensated care, it would be possible for hospitals in States that choose to expand Medicaid to receive higher uncompensated care payments because they may have more Medicaid patient days than hospitals in a State that does not choose to expand Medicaid. Because the earliest Medicaid expansions under the Affordable Care Act began in 2014, the 2011, 2012, and 2013 Medicaid days used to calculate uncompensated care payments in FYs 2015, 2016, and 2017 are the latest available data on Medicaid utilization that do not reflect the effects of these Medicaid expansions. Accordingly, if we had used only low-income insured days to estimate uncompensated care in FY 2018, we would have needed to hold the time period of these data constant and use data on Medicaid days from 2011, 2012, and 2013 in order to avoid the risk of any redistributive effects arising from the decision to expand Medicaid in certain States. As a result, we would have been using older data that may provide a less accurate proxy for the level of uncompensated care being furnished by hospitals, contributing to our growing concerns regarding the continued use of low-income insured days as a proxy for uncompensated care costs in FY 2018.

In summary, as we stated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38203), when weighing the new information regarding the growing correlation between the Worksheet S–10 data and IRS 990 data that became available to us after the FY 2017 rulemaking in conjunction with the information regarding Worksheet S–10 data and the low-income days proxy that we analyzed as part of our consideration of this issue in prior rulemaking, we determined that we could no longer conclude that alternative data to the Worksheet S–10 are available for FY 2014 that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. We also stated that we believe that continued use of Worksheet S–10 will improve the accuracy and consistency of the reported data, especially in light of CMS' concerted efforts to allow hospitals to review and resubmit their Worksheet S–10 data for past years and the use of select audit protocols to trim aberrant data and replace them with more reasonable amounts. We also committed to continue to work with stakeholders to address their concerns regarding the accuracy of the reporting of uncompensated care costs through provider education and refinement of the instructions to Worksheet S–10.

(2) Methodology Used To Calculate Factor 3 in Prior Fiscal Years

Section 1886(r)(2)(C) of the Act governs both the selection of the data to be used in calculating Factor 3, and also allows the Secretary the discretion to determine the time periods from which we will derive the data to estimate the numerator and the denominator of the Factor 3 quotient. Specifically, section 1886(r)(2)(C)(i) of the Act defines the numerator of the quotient as the amount of uncompensated care for such hospital for a period selected by the Secretary. Section 1886(r)(2)(C)(ii) of the Act defines the denominator as the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act for such period. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50638), we adopted a process of making interim payments with final cost report settlement for both the empirically justified Medicare DSH payments and the uncompensated care payments required by section 3133 of the

Affordable Care Act. Consistent with that process, we also determined the time period from which to calculate the numerator and denominator of the Factor 3 quotient in a way that would be consistent with making interim and final payments. Specifically, we must have Factor 3 values available for hospitals that we estimate will qualify for Medicare DSH payments and for those hospitals that we do not estimate will qualify for Medicare DSH payments but that may ultimately qualify for Medicare DSH payments at the time of cost report settlement.

In the FY 2017 IPPS/LTCH PPS final rule, in order to mitigate undue fluctuations in the amount of uncompensated care payments to hospitals from year to year and smooth over anomalies between cost reporting periods, we finalized a policy of calculating a hospital's share of uncompensated care based on an average of data derived from three cost reporting periods instead of one cost reporting period. As explained in the preamble to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56957 through 56959), instead of determining Factor 3 using data from a single cost reporting period as we did in FY 2014, FY 2015, and FY 2016, we used data from three cost reporting periods (Medicaid data for FYs 2011, 2012, and 2013 and SSI days from the three most recent available years of SSI utilization data (FYs 2012, 2013, and 2014)) to compute Factor 3 for FY 2017. Furthermore, instead of determining a single Factor 3 as we had done since the first year of the uncompensated care payment in FY 2014, we calculated an individual Factor 3 for each of the three cost reporting periods, which we then averaged by the number of cost reporting years with data to compute the final Factor 3 for a hospital. Under this policy, if a hospital had merged, we would combine data from both hospitals for the cost reporting periods in which the merger was not reflected in the surviving hospital's cost report data to compute Factor 3 for the surviving hospital. Moreover, to further reduce undue fluctuations in a hospital's uncompensated care payments, if a hospital filed multiple cost reports beginning in the same fiscal year, we combined data from the multiple cost reports so that a hospital could have a Factor 3 calculated using more than one cost report within a cost reporting period. We codified these changes for FY 2017 by amending the regulations at § 412.106(g)(1)(iii)(C).

For FY 2018, consistent with the methodology used to calculate Factor 3 for FY 2017, we advanced the time period of the data used in the calculation of Factor 3 forward by one year and used data from FY 2012, FY 2013, and FY 2014 cost reports. We believed it would not be appropriate to use Worksheet S–10 data for periods prior to FY 2014, as hospitals did not have notice that the Worksheet S–10 data from these years might be used for purposes of computing uncompensated care payments and, as a result, may not have fully appreciated the importance of reporting their uncompensated care costs as completely and accurately as possible. Rather, for cost reporting periods prior to FY 2014, we believed it would be appropriate to continue to use low-income insured days. Accordingly, for the time period consisting of three cost reporting years, including FY 2014, FY 2013, and FY 2012, we used Worksheet S–10 data for the FY 2014 cost reporting period and the low-income insured days proxy data for the two earlier cost reporting periods. In order to perform this calculation, we drew three sets of data (2 years of Medicaid utilization data and 1 year of Worksheet S–10 data) from the most recent available HCRIS extract. Accordingly, for FY 2018, in addition to the Worksheet S–10 data for FY 2014, we used Medicaid days from FY 2012 and FY 2013 cost reports and FY 2014 and FY 2015 SSI ratios. We also continued to use FY 2012 cost report data submitted to CMS by IHS and Tribal hospitals to determine FY 2012 Medicaid days for those hospitals. (Cost report data from IHS and Tribal hospitals are included in HCRIS beginning in FY 2013 and are no longer submitted separately.) We continued the policies that were finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50020) to address several specific issues concerning the process and data to be employed in determining Factor 3 in the case of hospital mergers as well as the policies finalized in the FY 2017 IPPS/LTCH PPS final rule concerning multiple cost reports beginning in the same fiscal year (81 FR 56957).

To limit the effect of aberrant reporting of Worksheet S–10 data, we identified those hospitals that had high levels of reported uncompensated care relative to the total operating costs reported on the cost report. Specifically, for those hospitals where the ratio of uncompensated care costs relative to total operating costs for the hospital's 2014 cost report exceeded 50 percent, we determined the ratio of uncompensated care costs relative to total operating costs from the hospital's 2015 cost report and applied that ratio to the hospital's total operating costs from the 2014 cost report to determine an adjusted amount of uncompensated care costs for FY 2014. We then substituted this amount for the FY 2014 Worksheet S–10 data when determining Factor 3 for FY 2018. We believed that this approach, which affected the data for three hospitals in FY 2018, balanced our desire to exclude potentially aberrant data from a small number of hospitals in the determination of Factor 3 with our concern regarding inappropriately reducing FY 2018 uncompensated care payments to a hospital that may have a legitimately high ratio. We stated our intent to consider in future rulemaking whether continued use of this adjustment or an alternative adjustment is necessary for subsequent years.

Due to concerns that the uncompensated care data reported by Puerto Rico hospitals and Indian Health Service and Tribal hospitals need to be examined further, we concluded that the Worksheet S–10 data for these hospitals should not be used to determine Factor 3 for FY 2018 (82 FR 38209). We also determined that Worksheet S–10 data should not be used to determine Factor 3 for all-inclusive rate providers, whose CCRs were deemed to be potentially erroneous and in need of further examination (82 FR 38212). For the reasons described earlier related to the impact of the Medicaid expansion beginning in FY 2014, we did not believe it was appropriate to calculate a Factor 3 for these hospitals using FY 2014 low-income insured days. Because we did not believe it was appropriate to use the FY 2014 uncompensated care data for these hospitals and we also did not believe it was appropriate to use the FY 2014 low-income insured days, we concluded that the best proxy for the costs of Puerto Rico, Indian Health Service and Tribal hospitals, and all-inclusive rate providers for treating the uninsured was the low-income insured days data for FY 2012 and FY 2013. Accordingly, in order to determine the Factor 3 for FY 2018 for these hospitals, we calculated an average of three individual Factor 3s using the Factor 3 calculated using FY 2013 cost report data twice and the Factor 3 calculated using FY 2012 cost report data once. We believed it was appropriate to double-weight the Factor 3 calculated using FY 2013 data as it reflects the most recent available information regarding the hospital's low-income insured days before any expansion of Medicaid. We stated that we would reexamine the use of the Worksheet S–10 data for Puerto Rico, Indian Health Service and Tribal

hospitals, and all-inclusive rate providers as part of the FY 2019 rulemaking. In addition, for Puerto Rico hospitals, we continued to use a proxy for SSI days consisting of 14 percent of a hospital's Medicaid days, as was first applied in FY 2017 (82 FR 38209).

Therefore, for FY 2018, we computed a Factor 3 for each hospital by—

- Step 1: Calculating Factor 3 using the low-income insured days proxy based on FY 2012 cost report data and the FY 2014 SSI ratio;
- Step 2: Calculating Factor 3 using the insured low-income days proxy based on FY 2013 cost report data and the FY 2015 SSI ratio;
- Step 3: Calculating Factor 3 based on the FY 2014 Worksheet S–10 data (or using the Factor 3 calculated in Step 2 for Puerto Rico, IHS/Tribal hospitals, and all-inclusive rate providers); and
- Step 4: Averaging the Factor 3 values from Steps 1, 2, and 3; that is, adding the Factor 3 values from FY 2012, FY 2013, and FY 2014 for each hospital, and dividing that amount by the number of cost reporting periods with data to compute an average Factor 3.

We stated our belief that if we were to propose to continue this methodology for FY 2019 and FY 2020, this approach would have the effect of transitioning the incorporation of data from Worksheet S–10 into the calculation of Factor 3 because an additional year of Worksheet S–10 data would be incorporated into the calculation of Factor 3 in FY 2019, and the use of low-income insured days would be phased out by FY 2020.

(3) Methodology for Calculating Factor 3 for FY 2019

As discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20396), since the publication of the FY 2018 IPPS/LTCH PPS final rule, we have continued to monitor the reporting of Worksheet S–10 data in anticipation of using Worksheet S–10 data from hospitals' FY 2014 and FY 2015 cost reports in the calculation of Factor 3. We acknowledge the concerns that have been raised regarding the instructions for Worksheet S–10. In particular, commenters have expressed concerns that the lack of clear and concise line level instructions prevents accurate and consistent data from being reported on Worksheet S–10. We note that, in November 2016, CMS issued Transmittal 10, which clarified and revised the instructions for the Worksheet S–10, including the instructions regarding the reporting of charity care charges. Transmittal 10 is available for download on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R10P240.pdf*. In Transmittal 10, we clarified that hospitals may include discounts given to uninsured patients who meet the hospital's charity care criteria in effect for that cost reporting period. This clarification applied to cost reporting periods beginning prior to October 1, 2016, as well as cost reporting periods beginning on or after October 1, 2016. As a result, nothing prohibits a hospital from considering a patient's insurance status as a criterion in its charity care policy. A hospital determines its own financial criteria as part of its charity care policy. The instructions for the Worksheet S–10 set forth that hospitals may include discounts given to uninsured patients, including patients with coverage from an entity that does not have a contractual relationship with the provider, who meet the hospital's charity care criteria in effect for that cost reporting period. In addition, we revised the instructions for the Worksheet S–10 for cost reporting periods beginning on or after October 1, 2016, to provide that charity care charges must be determined in accordance with the hospital's charity care criteria/policy and written off in the cost reporting period, regardless of the date of service.

During the FY 2018 rulemaking, commenters pointed out that, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56963), CMS agreed to institute certain additional quality control and data improvement measures prior to moving forward with incorporating Worksheet S–10 data into the calculation of Factor 3. However, the commenters indicated that, aside from a brief window in 2016 for hospitals to submit corrected data on their FY 2014 Worksheet S–10 by September 30, 2016, and the issuance of revised instructions (Transmittal 10) in November 2016 that are applicable to cost reports beginning on or after October 1, 2016, CMS had not implemented any additional quality control and data improvement measures. We stated in the FY 2018 IPPS/LTCH PPS final rule that we would continue to work with stakeholders to address their concerns regarding the reporting of uncompensated care through provider education and refinement of the instructions to the Worksheet S–10 (82 FR 38206).

On September 29, 2017, we issued Transmittal 11, which clarified the definitions and instructions for uncompensated care, non-Medicare bad debt, non-reimbursed Medicare bad debt, and charity care, as well as modified the calculations relative to uncompensated care costs and added edits to ensure the integrity of the data reported on Worksheet S–10. Transmittal 11 is available for download on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R11p240.pdf*. We further clarified that full or partial discounts given to uninsured patients who meet the hospital's charity care policy or financial assistance policy/uninsured discount policy (hereinafter referred to as Financial Assistance Policy or FAP) may be included on Line 20, Column 1 of Worksheet S–10. These clarifications apply to cost reporting periods beginning on or after October 1, 2013. We also modified the application of the CCR. We specified that the CCR will not be applied to the deductible and coinsurance amounts for insured patients approved for charity care and non-reimbursed Medicare bad debt. The CCR will be applied to the charges for uninsured patients approved for charity care or an uninsured discount, non-Medicare bad debt, and charges for noncovered days exceeding a length of stay limit imposed on patients covered by Medicaid or other indigent care programs.

We also provided another opportunity for hospitals to submit revisions to their Worksheet S–10 data for FY 2014 and FY 2015 cost reports. We refer readers to Change Request 10378, Transmittal 1981, titled ''Fiscal Year (FY) 2014 and 2015 Worksheet S 10 Revisions: Further Extension for All Inpatient Prospective Payment System (IPPS) Hospitals,'' issued on December 1, 2017 (available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R1981OTN.pdf*). In this transmittal, we instructed MACs to accept amended Worksheets S–10 for FY 2014 and FY 2015 cost reports submitted by hospitals (or initial submissions of Worksheet S–10 if none had been submitted previously) and to upload them to the Health Care Provider Cost Report Information System (HCRIS) in a timely manner. The transmittal states that hospitals must submit their amended FY 2014 and FY 2015 cost reports containing the revised Worksheet S–10 (or a completed Worksheet S–10 if no data were included on the previously submitted cost report) to the MAC no later than January 2, 2018. We note that this transmittal supersedes the previous deadline in Change Request 10026, which was issued on June 30, 2017, with respect to the dates by which hospitals must submit their revised or newly submitted Worksheet S–10 in

order to be considered for purposes of this rulemaking, as well as the dates by which MACs must accept these data and upload a revised cost report to HCRIS. Under the deadlines established in Change Request 10378, in order for revisions to be guaranteed consideration for the FY 2019 proposed rule, hospitals had to submit their amended FY 2014 and FY 2015 cost reports containing the revised Worksheet S–10 (or a completed Worksheet S–10 if no data were included on the previously submitted cost report) to the MAC no later than December 1, 2017. We also indicated that, all revised data received by December 1, 2017, would be considered for purposes of the FY 2019 IPPS/LTCH PPS proposed rule, and all revised data received by the January 2, 2018 deadline would be available to be considered for purposes of the FY 2019 IPPS/LTCH PPS final rule.

However, for the FY 2019 IPPS/LTCH PPS proposed rule, we were able to include data updated in HCRIS through February 15, 2018. Specifically, in light of the impact of the hurricanes in 2017 (Harvey, Irma, Maria, and Nate) and the extension of the deadline for resubmitting Worksheets S–10 for FY 2014 and FY 2015 through January 2, 2018, we believed it was appropriate to use data updated through February 15, 2018, rather than the December 2017 HCRIS update, which we typically use for the annual proposed rule. We believe that providing the additional time to allow cost reports that may have been delayed due to these unique circumstances to be included in our calculations for purposes of the FY 2019 proposed rule, enabled us to use more accurate uncompensated care cost data in calculating the proposed Factor 3 values.

We examined hospitals' FY 2014 and FY 2015 cost reports to determine if the Worksheet S–10 data on those cost reports had changed as a result of the additional opportunity for hospitals to submit revised Worksheet S–10 data for FY 2014 and FY 2015. Specifically, we compared hospitals' FY 2014 and FY 2015 Worksheet S–10 data as reported in the fourth quarter of CY 2016 update of HCRIS to the February 15, 2018 update of HCRIS. We examined hospitals' cost report data to determine if the Worksheet S 10 data had changed for any of the following lines: Total bad debt from Line 26, charity care for uninsured patients from Line 20, Column 1, or charity care for insured patients from Line 20, Column 2. Based on our review, we found that Worksheet S–10 data for both FY 2014 and FY 2015 had changed over that time period for approximately one-half of the hospitals that were eligible to receive Medicare DSH payments in FY 2018. The fact that the Worksheet S–10 data changed for such a significant number of hospitals following the opportunity to review their previously submitted cost report data and submit a revised Worksheet S–10, and that this revised Worksheet S–10 information is available to be used in determining uncompensated care costs, contributes to our determination that it is appropriate to continue to incorporate Worksheet S–10 data into the calculation of Factor 3 values for hospitals that are eligible to receive Medicare DSH payments.

As we stated in the FY 2019 IPPS/LTCH PPS proposed rule, with the additional steps we have taken to ensure the accuracy and consistency of the data reported on Worksheet S–10 since the publication of the FY 2018 IPPS/LTCH PPS final rule, we continue to believe that we can no longer conclude that alternative data to the Worksheet S–10 are currently available for FY 2014 that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. Similarly, the actions that we have taken to improve the accuracy and consistency of the Worksheet S–10 data, including the opportunity for hospitals to resubmit Worksheet S–10 data for FY 2015, lead us to conclude that there are no alternative data to the Worksheet S–10 data currently available for FY 2015 that are a better proxy for the costs of subsection (d) hospitals for treating uninsured individuals. As such, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20400), we proposed to advance the time period of the data used in the calculation of Factor 3 forward by 1 year and to use data from FY 2013, FY 2014, and FY 2015 cost reports to determine Factor 3 for FY 2019. For the reasons we described earlier, we stated that we continue to believe it is inappropriate to use Worksheet S–10 data for periods prior to FY 2014. Rather, for cost reporting periods prior to FY 2014, we believe it is appropriate to continue to use low-income insured days. Accordingly, with a time period that includes 3 cost reporting years consisting of FY 2015, FY 2014, and FY 2013, we proposed to use Worksheet S–10 data for the FY 2014 and FY 2015 cost reporting periods and the low-income insured days proxy data for the earliest cost reporting period. As in previous years, in order to perform this calculation, we drew three sets of data (1 year of Medicaid utilization data and 2 years of Worksheet S–10 data) from the most recent available HCRIS extract, which, for purposes of the FY 2019 proposed rule, was the HCRIS data updated through February 15, 2018. In the FY 2019 IPPS/LTCH PPS proposed rule, we stated that we expected to use the March 2018 update of HCRIS for the final rule. However, due to unique circumstances regarding the impact of the hurricanes in 2017 (Harvey, Irma, Maria, and Nate) and the extension of the deadline to resubmit Worksheet S–10 data through January 2, 2018, and the subsequent impact on the MAC review timeline, we indicated that we might consider using data updated through May 31, 2018, in the final rule, if necessary.

Accordingly, for FY 2019, in addition to the Worksheet S–10 data for FY 2014 and FY 2015, we proposed to use Medicaid days from FY 2013 cost reports and FY 2016 SSI ratios. We noted that cost report data from Indian Health Service and Tribal hospitals are included in HCRIS beginning in FY 2013 and no longer need to be incorporated from a separate data source. We also proposed to continue the policies that were finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50020) to address several specific issues concerning the process and data to be employed in determining Factor 3 in the case of hospital mergers. In addition, we proposed to continue the policies that were finalized in the FY 2018 IPPS/LTCH PPS final rule to address technical considerations related to the calculation of Factor 3 and the incorporation of Worksheet S–10 data (82 FR 38213 through 38220). In that final rule, we adopted a policy, for purposes of calculating Factor 3, under which we annualize Medicaid days data and uncompensated care cost data reported on the Worksheet S–10 if a hospital's cost report does not equal 12 months of data. As in FY 2018, for FY 2019, we did not propose to annualize SSI days because we do not obtain these data from hospital cost reports in HCRIS. Rather, we obtain these data from the latest available SSI ratios posted on the Medicare DSH homepage (*https://www.cms.gov/Medicare/Medicare-fee-for-service-payment/AcuteInpatientPPS/dsh.html*), which are aggregated at the hospital level and do not include the information needed to determine if the data should be annualized. To address the effects of averaging Factor 3s calculated for 3 separate fiscal years, we proposed to continue to apply a scaling factor to the Factor 3 values of all DSH eligible hospitals such that total uncompensated care payments are consistent with the estimated amount available to make uncompensated care payments for the

applicable fiscal year. With respect to the incorporation of Worksheet S–10, we indicated that we believe that the definition of uncompensated care adopted in FY 2018 is still appropriate because it incorporates the most commonly used factors within uncompensated care as reported by stakeholders, including charity care costs and non-Medicare bad debt costs, and correlates to Line 30 of Worksheet S–10. Therefore, we again proposed that, for purposes of calculating Factor 3 and uncompensated care costs in FY 2019, ''uncompensated care'' would be defined as the amount on Line 30 of Worksheet S–10, which is the cost of charity care (Line 23) and the cost of non-Medicare bad debt and non-reimbursable Medicare bad debt (Line 29).

We noted that we were proposing to discontinue the policy finalized in the FY 2017 IPPS/LTCH PPS final rule concerning multiple cost reports beginning in the same fiscal year (81 FR 56957). Under this policy, we would first combine the data across the multiple cost reports before determining the difference between the start date and the end date to determine if annualization is needed. The policy was developed in response to commenters' concerns regarding the unique circumstances of hospitals that filed cost reports that are shorter or longer than 12 months. As we explained in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56957 through 56959) and in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19953), we believed that, for hospitals that file multiple cost reports beginning in the same year, combining the data from these cost reports had the benefit of supplementing the data of hospitals that filed cost reports that are less than 12 months, such that the basis of their uncompensated care payments and those of hospitals that filed full-year 12-month cost reports would be more equitable. As we stated in the FY 2019 IPPS/LTCH PPS proposed rule, we now believe that concerns about the equitability of the data used as the basis of hospital uncompensated care payments are more thoroughly addressed by the policy finalized in the FY 2018 IPPS/LTCH PPS final rule, under which CMS annualizes the Medicaid days and uncompensated care cost data of hospital cost reports that do not equal 12 months of data. Based on our experience, we stated that we believe that in many cases where a hospital files two cost reports beginning in the same fiscal year, combining the data across multiple cost reports before annualizing would yield a similar result to choosing the longer of the two cost reports and then annualizing the data if the cost report is shorter or longer than 12 months. Furthermore, even in cases where a hospital files more than one cost report beginning in the same fiscal year, it is not uncommon for one of those cost reports to span exactly 12 months. In this case, if Factor 3 is determined using only the full 12-month cost report, annualization would be unnecessary as there would already be 12 months of data. Therefore, for FY 2019, we stated that we believed it was appropriate to propose to eliminate the additional step of combining data across multiple cost reports if a hospital filed more than one cost report beginning in the same fiscal year. Instead, for purposes of calculating Factor 3, we would use data from the cost report that is equivalent to 12 months or, if no such cost report exists, the cost report that is closest to 12 months and annualize the data. Furthermore, we acknowledged that, in rare cases, a hospital may have more than one cost report beginning in one fiscal year, where one report also spans the entirety of the following fiscal year, such that the hospital has no cost report beginning in that fiscal year. For instance, a hospital's cost reporting period may have started towards the end of FY 2012 but cover the duration of FY 2013. In these rare situations, we proposed to use data from the cost report that spans both fiscal years in the Factor 3 calculation for the latter fiscal year as the hospital would already have data from the preceding cost report that could be used to determine Factor 3 for the previous fiscal year.

We also proposed to continue to apply statistical trims to anomalous hospital CCRs using the methodology adopted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38217 through 38219), where we stated our belief that, just as we apply trims to hospitals' CCRs to eliminate anomalies when calculating outlier payments for extraordinarily high cost cases (§ 412.84(h)(3)(ii)), it is appropriate to apply statistical trims to the CCRs on Worksheet S–10, Line 1, that are considered anomalies. Specifically, § 412.84(h)(3)(ii) states that the Medicare contractor may use a statewide CCR for hospitals whose operating or capital CCR is in excess of 3 standard deviations above the corresponding national geometric mean (that is, the CCR ''ceiling''). This mean is recalculated annually by CMS and published in the proposed and final IPPS rules each year.

Similar to the process used in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38217 through 38218) for trimming CCRs, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20398), we proposed the following steps for FY 2019:

Step 1: Remove Maryland hospitals. In addition, we would remove All Inclusive Rate Providers because they have charge structures that differ from other IPPS hospitals. For providers that did not report a CCR on Worksheet S–10, Line 1, we would assign them the statewide average CCR in step 5 below.

Step 2: For each fiscal year (FY 2014 and FY 2015), calculate a CCR ''ceiling'' with the following data: For each IPPS hospital that was not removed in Step 1 (including non-DSH eligible hospitals), we would use cost report data to calculate a CCR by dividing the total costs on Worksheet C, Part I, Line 202, Column 3 by the charges reported on Worksheet C, Part I, Line 202, Column 8. (Combining data from multiple cost reports from the same FY is no longer necessary in this step, as the longer cost report would be selected). The ceiling would be calculated as 3 standard deviations above the national geometric mean CCR for the applicable fiscal year. This approach is consistent with the methodology for calculating the CCR ceiling used for high-cost outliers. Remove all hospitals that exceed the ceiling so that these aberrant CCRs do not skew the calculation of the statewide average CCR. (For this final rule, this trim would remove 5 hospitals that have a CCR above the calculated ceiling of 1.031 for FY 2014 and 9 hospitals that have a CCR above the calculated ceiling of 0.93 for FY 2015.)

Step 3: Using the CCRs for the remaining hospitals in Step 2, determine the urban and rural statewide average CCRs for FY 2014 and for FY 2015 for hospitals within each State (including non-DSH eligible hospitals), weighted by the sum of total inpatient discharges and outpatient visits from Worksheet S–3, Part I, Line 14, Column 14.

Step 4: Assign the appropriate statewide average CCR (urban or rural) calculated in Step 3 to all hospitals with a CCR for the applicable fiscal year greater than 3 standard deviations above the corresponding national geometric mean for that fiscal year (that is, the CCR ''ceiling''). For this final rule, the statewide average CCR would therefore be applied to 14 hospitals, of which 2 hospitals in FY 2014 have Worksheet S–10 data and 5 hospitals in FY 2015 have Worksheet S–10 data.

After applying the applicable trims to a hospital's CCR as appropriate, we proposed that we would calculate a hospital's uncompensated care costs for the applicable fiscal year as being equal

to Line 30, which is the sum of Line 23, Column 3 and Line 29, as follows:

Hospital Uncompensated Care Costs = Line 30 (Line 23, Column 3 + Line 29), which is equal to—

[(Line 1 CCR (as adjusted, if applicable) × Uninsured patient charity care Line 20, Column 1) − (Payments received from uninsured patient charity care Line 22, Column 1)] + [(Insured patient charity care Line 20, Column 2) − Insured patient charges from days beyond length of stay limit * (1 − (Line 1 CCR (as adjusted, if applicable))) − (Payments received from insured patient charity care Line 22, Column 2)] + [(Line 1 CCR (as adjusted, if applicable) × Non-Medicare bad debt Line 28) + (Medicare allowable bad debts Line 27.01 − Medicare reimbursable bad debt Line 27)].

Similar in concept to the policy that we adopted for FY 2018, for FY 2019, we stated in the proposed rule that we continue to believe that uncompensated care costs that represent an extremely high ratio of a hospital's total operating expenses (such as the ratio of 50 percent used in the FY 2018 IPPS/LTCH PPS final rule) may be potentially aberrant, and that using the ratio of uncompensated care costs to total operating costs to identify potentially aberrant data when determining Factor 3 amounts has merit. That is, we stated that we continue to believe that, in the rare situations where a hospital has a ratio of uncompensated care costs to total operating expenditures that is extremely high, the issue is most likely with the hospital's uncompensated care costs and not its total operating costs. We noted that we had instructed the MACs to review situations where a hospital has an extremely high ratio of uncompensated care costs to total operating costs with the hospital, but indicated that we did not intend to make the MACs' review protocols public. As stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56964), for program integrity reasons, CMS desk review and audit protocols are confidential and are for CMS and MAC use only. If the hospital cannot justify its reported uncompensated care amount, we stated that we believed it would be appropriate to utilize data from another fiscal year to address the potentially aberrant Worksheet S–10 data for FY 2014 or FY 2015. As we have previously indicated, we do not believe it would be appropriate to use Worksheet S–10 data from years prior to FY 2014 in the determination of Factor 3. Therefore, the most widely available Worksheet S–10 data available to us if a hospital has an extremely high ratio of uncompensated care costs to total operating expenses based on its FY 2014 or FY 2015 Worksheet S–10 data are the FY 2015 and FY 2016 Worksheet S–10 data. Accordingly, similar in concept to the approach we used in FY 2018, in cases where a hospital's uncompensated care costs for FY 2014 are an extremely high ratio of its total operating costs and the hospital cannot justify the amount it reported, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20399), we proposed to determine the ratio of FY 2015 uncompensated care costs to FY 2015 total operating expenses from the hospital's FY 2015 cost report and apply that ratio to the FY 2014 total operating expenses from the hospital's FY 2014 cost report to determine an adjusted amount of uncompensated care costs for FY 2014. We proposed that we would then use this adjusted amount to determine Factor 3 for FY 2019. Similarly, if a hospital has uncompensated care costs for FY 2015 that are an extremely high ratio of its total operating costs for that year and the hospital cannot justify its reported amount, we proposed to follow the same methodology using data from the hospital's FY 2016 cost report to determine an adjusted amount of uncompensated care costs for FY 2015. That is, we would determine the ratio of FY 2016 uncompensated care costs to FY 2016 total operating expenses from a hospital's FY 2016 cost report and apply that ratio to the FY 2015 total operating expenses from the hospital's FY 2015 cost report to determine an adjusted amount of uncompensated care costs for FY 2015. We proposed that we would then use this adjusted amount when determining Factor 3 for FY 2019. We tentatively included the data for hospitals that had a high ratio of uncompensated care costs to total operating expenses when calculating Factor 3 for the proposed rule. However, we noted in the proposed rule that our calculation of Factor 3 for this final rule would be contingent on the results of the ongoing MAC reviews of these hospitals. In the event those reviews necessitate supplemental data edits, we stated that we would incorporate such edits in the final rule for the purpose of correcting aberrant data.

We also stated in the proposed rule that, for FY 2019, we believe that situations where there were extremely large dollar increases or decreases in a hospital's uncompensated care costs when it resubmitted its FY 2014 Worksheet S–10 or FY 2015 Worksheet S–10 data, or when the data it had previously submitted were reprocessed by the MAC, may reflect potentially aberrant data and warrant further review. For example, although we do not make our actual review protocols public, we indicated that we might conclude that it would be appropriate to review hospitals with increases or decreases in uncompensated care costs in the top 1 percent of such changes. We noted that we had instructed our MACs to review these situations with each hospital. If it is determined after this review that an increase or decrease in uncompensated care costs cannot be justified by the hospital, we proposed to follow the same approach that we proposed to use to address situations when a hospital's ratio of its uncompensated care costs to its operating expenses is extremely high and the hospital cannot justify its reported amount. Specifically, if after review, the increase or decrease in uncompensated care costs for FY 2014 or FY 2015 cannot be justified by the hospital, we proposed that we would determine the ratio of the uncompensated care costs to total operating expenses from the hospital's cost report for the subsequent fiscal year and apply that ratio to the total operating expenses from the hospital's resubmitted cost report with the large increase or decrease in uncompensated care payments to determine an adjusted amount of uncompensated care costs for the applicable fiscal year. We indicated that we had tentatively included the data for hospitals where there was an extremely large increase or decrease in uncompensated care payments when calculating Factor 3 for the proposed rule. However, we noted in the proposed rule that our calculation of Factor 3 for the final rule was contingent on the results of the ongoing MAC reviews of these hospitals. In the event those reviews necessitate supplemental data edits, we stated that we would incorporate such edits in the final rule for the purpose of correcting aberrant data.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20400), for Indian Health Service and Tribal hospitals, subsection (d) Puerto Rico hospitals, and all-inclusive rate providers, we proposed to continue the policy we first adopted for FY 2018 of substituting data regarding FY 2013 low-income insured days for the Worksheet S–10 data when determining Factor 3. As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38209), the use of data from Worksheet S–10 to calculate the uncompensated care amount for Indian Health Service and Tribal hospitals may jeopardize these hospitals' uncompensated care payments due to their unique funding structure. With

respect to Puerto Rico hospitals, we continue to agree with concerns raised by commenters that the uncompensated care data reported by these hospitals need to be further examined before the data are used to determine Factor 3 (82 FR 38209). Finally, the CCRs for all-inclusive rate providers are potentially erroneous and still in need of further examination before they can be used in the determination of uncompensated care amounts for purposes of Factor 3 (82 FR 38212). For the reasons described earlier, related to the impact of the Medicaid expansion beginning in FY 2014, we stated in the proposed rule that we also continue to believe that it is inappropriate to calculate a Factor 3 using FY 2014 and FY 2015 low-income insured days. Because we do not believe it is appropriate to use the FY 2014 or FY 2015 uncompensated care data for these hospitals and we also do not believe it is appropriate to use the FY 2014 or FY 2015 low-income insured days, the best proxy for the costs of Indian Health Service and Tribal hospitals, subsection (d) Puerto Rico hospitals, and all-inclusive rate providers for treating the uninsured continues to be the low-income insured days data for FY 2013. Accordingly, for these hospitals, we proposed to determine Factor 3 only on the basis of low-income insured days for FY 2013. We stated that we believe this approach is appropriate as the FY 2013 data reflect the most recent available information regarding these hospitals' low-income insured days before any expansion of Medicaid. In the proposed rule, we did not make any proposals with respect to the calculation of Factor 3 for FY 2020 and indicated that we will reexamine the use of the Worksheet S–10 data for Indian Health Service and Tribal hospitals, subsection (d) Puerto Rico hospitals, and all-inclusive rate providers as part of the FY 2020 rulemaking. In addition, because we proposed to continue to use 1 year of insured low-income patient days as a proxy for uncompensated care and residents of Puerto Rico are not eligible for SSI benefits, we proposed to continue to use a proxy for SSI days for Puerto Rico hospitals consisting of 14 percent of the hospital's Medicaid days, as finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56953 through 56956).

Therefore, for FY 2019, we proposed to compute Factor 3 for each hospital by—

Step 1: Calculating Factor 3 using the low-income insured days proxy based on FY 2013 cost report data and the FY 2016 SSI ratio (or, for Puerto Rico hospitals, 14 percent of the hospital's FY 2013 Medicaid days);

Step 2: Calculating Factor 3 based on the FY 2014 Worksheet S–10 data;

Step 3: Calculating Factor 3 based on the FY 2015 Worksheet S–10 data; and

Step 4: Averaging the Factor 3 values from Steps 1, 2, and 3; that is, adding the Factor 3 values from FY 2013, FY 2014, and FY 2015 for each hospital, and dividing that amount by the number of cost reporting periods with data to compute an average Factor 3 (or for Puerto Rico hospitals, Indian Health Service and Tribal hospitals, and all-inclusive rate providers using the Factor 3 value from Step 1).

We also proposed to amend the regulations at § 412.106(g)(1)(iii)(C) by adding a new paragraph (5) to reflect this proposed methodology for computing Factor 3 for FY 2019.

In the proposed rule, we noted that if a hospital does not have both Medicaid days for FY 2013 and SSI days for FY 2016 available for use in the calculation of Factor 3 in Step 1, we consider the hospital not to have data available for the fiscal year, and will remove that fiscal year from the calculation and divide by the number of years with data. A hospital will be considered to have both Medicaid days and SSI days data available if it reports zero days for either component of the Factor 3 calculation in Step 1. However, if a hospital is missing data due to not filing a cost report in one of the applicable fiscal years, we will divide by the remaining number of fiscal years.

Although we did not make any proposals with respect to the development of Factor 3 for FY 2020 and subsequent fiscal years, in the proposed rule, we noted that the above methodology would have the effect of fully transitioning the incorporation of data from Worksheet S–10 into the calculation of Factor 3 if used in FY 2020. Starting with 1 year of Worksheet S–10 data in FY 2018, an additional year of Worksheet S–10 data will be incorporated into the calculation of Factor 3 in FY 2019 under the policies included in this final rule, and the use of low-income insured days would be phased out by FY 2020 if the same methodology is proposed and finalized for that year. We also indicated that it is possible that when we examine the FY 2016 Worksheet S–10 data, we may determine that the use of multiple years of Worksheet S–10 data is no longer necessary in calculating Factor 3 for FY 2020. For example, given the efforts hospitals have already undertaken with respect to reporting their Worksheet S–10 data and the subsequent reviews by the MACs that had already been conducted prior to the development of this final rule, along with additional review work that may take place following the issuance of this final rule, we may consider using 1 year of Worksheet S–10 data as the basis for calculating Factor 3 for FY 2020.

For new hospitals that do not have data for any of the three cost reporting periods used in the Factor 3 calculation, we proposed to continue to apply the new hospital policy finalized in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50643). That is, the hospital would not receive either interim empirically justified Medicare DSH payments or interim uncompensated care payments. However, if the hospital is later determined to be eligible to receive empirically justified Medicare DSH payments based on its FY 2019 cost report, the hospital would also receive an uncompensated care payment calculated using a Factor 3, where the numerator is the uncompensated care costs reported on Worksheet S–10 of the hospital's FY 2019 cost report, and the denominator is the sum of uncompensated care costs reported on Worksheet S–10 of all DSH eligible hospitals' FY 2015 cost reports. Due to the uncertainty regarding the completeness and accuracy of the FY 2019 uncompensated care cost data at the time this calculation would need to be performed, we stated that we believe it would be more appropriate to use the sum of the uncompensated care costs reported on Worksheet S–10 of all DSH eligible hospitals' cost reports from FY 2015, the most recent year of the 3-year time period used in the development of Factor 3, to determine the denominator of Factor 3 for new hospitals. We noted that, given the time period of the data used to calculate Factor 3, any hospitals with a CCN established after October 1, 2015 would be considered new and subject to this policy.

As we have done for every proposed and final rule beginning in FY 2014, we stated that, in conjunction with both the FY 2019 IPPS/LTCH PPS proposed rule and this final rule, we would publish on the CMS website a table listing Factor 3 for all hospitals that we estimate would receive empirically justified Medicare DSH payments in FY 2019 (that is, those hospitals that would receive interim uncompensated care payments during the fiscal year), and for the remaining subsection (d) hospitals and subsection (d) Puerto Rico hospitals that have the potential of receiving a Medicare DSH payment in the event that they receive an empirically justified Medicare DSH payment for the fiscal year as determined at cost report settlement. We noted that, at the time of the

development of the proposed rule, the FY 2016 SSI ratios were available. Accordingly, for modeling purposes, we computed the proposed Factor 3 for each hospital using the most recent available data regarding SSI days from the FY 2016 SSI ratios.

In conjunction with the proposed rule, we also published a supplemental data file containing a list of the mergers that we were aware of and the computed uncompensated care payment for each merged hospital. Hospitals had 60 days from the date of public display of the FY 2019 IPPS/LTCH PPS proposed rule to review the table and supplemental data file published on the CMS website in conjunction with the proposed rule and to notify CMS in writing of any inaccuracies. Comments could be submitted to the CMS inbox at *Section3133DSH@cms.hhs.gov*. We stated that we would address these comments as appropriate in the table and the supplemental data file that we will publish on the CMS website in conjunction with the publication of this FY 2019 IPPS/LTCH PPS final rule. After the publication of this FY 2019 IPPS/LTCH PPS final rule, hospitals will have until August 31, 2018, to review and submit comments on the accuracy of the table and supplemental data file published in conjunction with this final rule. Comments may be submitted to the CMS inbox at *Section3133DSH@cms.hhs.gov* through August 31, 2018, and any changes to Factor 3 will be posted on the CMS website prior to October 1, 2018.

Comment: A number of commenters supported CMS' proposal to continue using data from Worksheet S–10 in the calculation of Factor 3 for FY 2019. These commenters stated that using Worksheet S–10 data, in conjunction with select auditing of cost reports, will lead to better estimates of uncompensated care costs than the continued use of the current proxy of Medicaid and SSI days. Other commenters noted that the metrics from Worksheet S–10 appear to provide a better assessment of a hospital's uncompensated care costs than the current proxy data, which assess only low-income insured days and distribute the bulk of Medicare DSH payments based on the amount of inpatient care a hospital delivers to Medicaid patients and recipients of SSI payments. Thus, the commenters stated, using data from Worksheet S–10 will address the inequity across Medicaid expansion/nonexpansion States in distributing disproportionate share hospital dollars. One commenter stated that the use of Worksheet S–10 data in calculating the distribution of uncompensated care payments will continue CMS on a path to improve transparency and accuracy with regard to hospitals' share of uncompensated care costs. Other commenters noted that any negative effects from the transition to using the Worksheet S–10 will be eased due to the $1.5 billion increase in the amount available to make uncompensated care payments relative to FY 2018. In addition, several commenters pointed to the evaluation performed by the consulting firm Dobson DaVanzo, which found a high degree of correlation between data reported on Worksheet S–10 and audited uncompensated care data, as evidence that the information currently reported on Worksheet S–10 is satisfactory for purposes of allocating uncompensated care payments.

Other commenters opposed the use of Worksheet S–10 to compute Factor 3 and allocate uncompensated care costs in FY 2019. Many of these commenters maintained their position from previous years that, while Worksheet S–10 has the potential to serve as a more exact measure of hospital uncompensated care costs, the data reported are not presently a reliable and accurate reflection of these uncompensated care costs. The commenters also noted that the administrative burden for hospitals to complete Worksheet S–10 is high. These commenters asserted that CMS should suspend its use, or not advance its implementation, until the agency can demonstrate that the data being reported are accurate and consistent, or at least until FY 2021. Some commenters pointed to the evaluation performed by Dobson DaVanzo and asserted that, while the analysis demonstrated correlation between Worksheet S–10 and IRS Form 990, it did not address potentially significant differences in the reporting requirements for the forms.

Response: We appreciate the support for our proposal to continue incorporating Worksheet S–10 data into the computation of Factor 3 for FY 2019. We also appreciate the input from those commenters who are opposed to the use of data from Worksheet S–10 in the calculation of Factor 3. We understand the commenters' concerns about the limitations of the IRS 990 correlation analysis and the shortcomings of using the findings from this study to support assertions about the validity of the Worksheet S–10 data. Notwithstanding these limitations, a number of commenters supported the findings of the study and our proposal to use of Worksheet S–10 in FY 2019. Furthermore, as explained in the FY 2019 IPPS/LTCH PPS proposed rule, we did not make the decision to continue Worksheet S–10 implementation in FY 2019 based on the correlation analysis alone. Historical analyses performed by MedPAC also show a high level of correlation between audited uncompensated care data and uncompensated care costs reported on Worksheet S–10 and a lower correlation between the audited uncompensated care data and Medicaid and SSI days. Furthermore, hospitals have expended considerable effort to resubmit their FY 2014 and FY 2015 data and the MACs have dedicated significant resources to conducting the subsequent reviews in the time available for the FY 2019 rulemaking, and we believe that, overall, those efforts have improved the data.

In the FY 2019 IPPS/LTCH PPS proposed rule, we stated that we could no longer conclude that alternative data to the Worksheet S–10 are available for FY 2014 and FY 2015 that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. Our reviews of selected FY 2014 and FY 2015 data and the potential data aberrancies pointed out by commenters have not altered that conclusion. We continue to acknowledge that the Worksheet S–10 data are not perfect, but there are no perfect data sources available to us. We also acknowledge that the approximately $1.5 billion increase in the overall amount available to make uncompensated care payments will help to mitigate the impact of any redistribution of uncompensated care payments due to the continued incorporation of Worksheet S–10 data on hospitals that serve a large number of Medicaid and SSI patients, yet report proportionately lower uncompensated care amounts.

Comment: Most commenters, whether supportive of or opposed to the use of data from Worksheet S–10 to compute Factor 3, believed that it was premature to use Worksheet S–10 data in the calculation of Factor 3 for FY 2019, and expressed concerns about the lack of accurate and consistent data being reported on Worksheet S–10, primarily due to what they perceive as a lack of clear and concise line-level instructions for reporting on the Worksheet S–10. Some commenters acknowledged and appreciated the changes CMS had implemented through the issuance of revised instructions (Transmittal 11) in September 2017, and the opportunity for hospitals to revise their uncompensated care data previously reported on Worksheet S–10 for FY 2014 and FY 2015. These commenters also appreciated CMS' instructions to the MACs to contact hospitals with aberrant data. These commenters noted

that, given all of the steps that CMS has taken to improve the data from Worksheet S–10, it would be reasonable to see large increases or decreases in hospital uncompensated care costs. Other commenters expressed continued concerns with the clarity of the instructions and indicated that even with the revisions implemented under Transmittal 11, a great deal of ambiguity remains in the Worksheet S–10 instructions, leading to inconsistent reporting among hospitals and questionable accuracy of the updated data.

Many commenters recognized the efforts undertaken by CMS in contacting select hospitals to verify reported data, and some commenters noted data improvements since the release of Transmittal 11 and CMS' subsequent contact with individual hospitals. However, a number of commenters provided specific examples of potentially aberrant data that they asserted are a result of the ambiguity of the Worksheet S–10 instructions. These examples of potentially aberrant data related in large part to the reporting of charity care charges and uninsured discounts on Worksheet S–10, Line 20, Columns 1 and 2. For example, commenters noted that some hospitals reported charity care coinsurance and deductibles of more than 25 percent of their total charity care charges; some hospitals reported charity care charges that were, on average, 80 percent of total hospital charges; and some hospitals reported negative charity care charges. Several commenters also noted potentially aberrant data related to bad debt, including, for example, cases in which a hospital reported Medicare allowable bad debt elsewhere on the cost report, but those amounts were not reflected in its Worksheet S–10; hospitals that reported having more Medicare bad debt than total hospital bad debts; and hospitals with significant differences in bad debt charges over time. With respect to uncompensated care costs, commenters noted that, for example, some hospitals reported uncompensated care costs that were 30 to 70 percent of total hospital costs; and some hospitals reported uncompensated care costs that ranged from 0.14 percent to 250 percent of total hospital revenue. Commenters remarked that these results are implausible and indicate that CMS must continue working to improve the reliability of Worksheet S–10. Several commenters observed that the current Worksheet S–10 methodology may provide an incentive to hospitals to overstate charity care, compromising the fidelity of the information collected. Another commenter was concerned that the revisions to the Worksheet S–10 instructions through Transmittal 11 and subsequent opportunity for hospitals to resubmit their cost reports for prior years created an incentive for hospitals to inflate charges for charity care. Finally, some commenters requested that CMS continue to offer hospitals the opportunity to amend, or require them to amend, cost reports for FY 2014, FY 2015, and later years.

Response: We believe that continued use of Worksheet S–10 will improve the accuracy and consistency of the reported data. In addition, we intend to continue with and further refine our efforts to review the Worksheet S–10 data submitted by hospitals based on what we have learned from the review process we conducted for the FY 2019 rulemaking. We also intend to consider the various issues raised by the commenters specifically related to the reporting of charity care and bad debt costs on Worksheet S–10 as we continue to review the Worksheet S–10 data and instructions. In addition, we will continue to work with stakeholders to address their concerns regarding the accuracy and consistency of reporting of uncompensated care costs through provider education and further refinement of the instructions to the Worksheet S–10 as appropriate.

As noted in the FY 2019 IPPS/LTCH PPS proposed rule, (83 FR 20396 and 20397), on September 29, 2017, we issued Transmittal 11, which clarified the definitions and instructions for reporting uncompensated care, non-Medicare bad debt, nonreimbursed Medicare bad debt, and charity care, as well as modified the calculations relative to uncompensated care costs and added edits to improve the integrity of the data reported on Worksheet S–10. We also provided another opportunity for hospitals to submit revisions to their Worksheet S–10 data for FY 2014 and FY 2015 cost reports. We refer readers to Change Request 10378, Transmittal 1981, titled ''Fiscal Year (FY) 2014 and 2015 Worksheet S–10 Revisions: Further Extension for All Inpatient Prospective Payment System (IPPS) Hospitals,'' issued on December 1, 2017 (available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R1981OTN.pdf*). In this transmittal, we instructed MACs to accept amended Worksheets S–10 for FY 2014 and FY 2015 cost reports submitted by hospitals (or initial submissions of Worksheet S–10 if none have been submitted previously) and to upload them to the Health Care Provider Cost Report Information System (HCRIS) in a timely manner. The transmittal stated that hospitals must submit their amended FY 2014 and FY 2015 cost reports containing the revised Worksheet S–10 (or a completed Worksheet S–10 if no data were included on the previously submitted cost report) to the MAC no later than January 2, 2018. Under the deadlines established in Change Request 10378, in order for revisions to be guaranteed consideration for the FY 2019 proposed rule, hospitals had to submit their amended FY 2014 and FY 2015 cost reports containing the revised Worksheet S–10 (or a completed Worksheet S–10 if no data were included on the previously submitted cost report) to the MAC no later than December 1, 2017. We also indicated that all revised data received by December 1, 2017, would be considered for purposes of the FY 2019 IPPS/LTCH PPS proposed rule, and all revised data received by the January 2, 2018 deadline would be available to be considered for purposes of the FY 2019 IPPS/LTCH PPS final rule. However, for the FY 2019 IPPS/LTCH PPS proposed rule, we were able to include data updated in HCRIS through February 15, 2018, and for this FY 2019 IPPS/LTCH PPS final rule, we have been able to include data updated in HCRIS through June 30, 2018. Specifically, in light of the impact of the hurricanes in 2017 (Harvey, Irma, Maria, and Nate), the extension of the deadline for resubmitting Worksheets S–10 for FY 2014 and FY 2015 through January 2, 2018, and our targeted provider outreach, we determined that it would be appropriate to use data updated through June 30, 2018, rather than the March 2018 HCRIS update, which we would typically use for the annual final rule. We believe that providing this additional time to allow data from resubmitted cost reports that may have been delayed due to the unique circumstances during 2017 and 2018 to be included in our calculations for purposes of this FY 2019 final rule, enabled us to use more accurate uncompensated care cost data in calculating the final Factor 3 values.

We believe that the new Worksheet S–10 instructions implemented in Transmittal 11 were sufficiently clear to allow hospitals to accurately complete Worksheet S–10, and that hospitals were provided ample time following the issuance of Transmittal 11 to revise and amend Worksheet S–10 for FY 2014 and FY 2015. Because we recognize that there were delays in processing Worksheet S–10 to reflect the revisions in Transmittal 11 and consistent with our historical practice of using the best data available, we are using the June 30,

2018 HCRIS update to calculate Factor 3 for this FY 2019 IPPS/LTCH PPS final rule. We continue to believe that Worksheet S–10 data are the best data available to use in calculating uncompensated care costs for purposes of determining Factor 3 of the uncompensated care payment methodology. As stated in the FY 2018 IPPS/LTCH PPS final rule, (82 FR 38203), the agency can no longer conclude that alternative data to the Worksheet S–10 are available for FY 2014 that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. Similarly, we believe that the Worksheet S–10 data for FY 2014 are the best available data on the costs of subsection (d) hospitals for treating the uninsured during that fiscal year.

In response to the request by some commenters that CMS continue to offer hospitals the opportunity to amend, or require them to amend, cost reports for FY 2014, FY 2015 and later years, we are using data from a June 30, 2018 HCRIS update to determine Factor 3 for this FY 2019 IPPS/LTCH PPS final rule. We believe this gave hospitals ample time to review the revised instructions in Transmittal 11, and to resubmit Worksheet S–10 for these years. Furthermore, as discussed earlier with respect to our estimates of Factors 1 and 2, we continue to believe that applying our best estimates to determine uncompensated care payment amounts prospectively would be most conducive to administrative efficiency, finality, and predictability in payments. We believe that, in affording the Secretary the discretion to estimate the amount of the three factors used to determine uncompensated care payments and by including a prohibition against administrative and judicial review of those estimates in section 1886(r)(3) of the Act, Congress recognized the importance of finality and predictability under a prospective payment system. As a result, we do not agree that we should continue to offer hospitals the opportunity to amend, or require them to amend their FY 2014 and FY 2015 cost reports for purposes of determining uncompensated care payments for FY 2019, as this would be contrary to the notion of prospectivity. To the extent these commenters were requesting a further opportunity to revise their Worksheet S–10 data for use in future rulemaking for FY 2020 or later years, we are not addressing the issue of future resubmissions in this final rule. Therefore, the normal timelines and procedures apply for a hospital to request to amend a cost report.

Comment: A number of stakeholders commented on Transmittal 10 (issued on November 17, 2016) in which we clarified that hospitals may include discounts given to the uninsured who meet the hospital's charity care criteria in effect for that cost reporting period and Transmittal 11 (issued on September 29, 2017) in which we clarified definitions and instructions for uncompensated care, non-Medicare bad debt, non-reimbursed Medicare bad debt, and charity care; modified the calculations relative to uncompensated care costs; and added edits to ensure the integrity of Worksheet S–10 data. In general, the commenters appreciated the release of these transmittals, particularly the revisions issued in Transmittal 11. Several commenters believed that the release of Transmittal 11 was a step forward to improve the Worksheet S–10 instructions, reporting consistency, and data accuracy and quality, in addition to offering an opportunity for hospitals to revise their FY 2014 and FY 2015 Worksheet S–10 reports and instructing the MACs flag potentially aberrant data.

However, numerous commenters also expressed concerns with the release of the transmittals, noting that between Transmittal 10 and 11, there were significant changes in the instructions and clarifications that resulted in significant modifications to hospitals' reporting. One commenter also pointed out that CMS' requests for data resubmissions in both Transmittal 10 and Transmittal 11 were only 1 year apart, adding to hospitals' administrative burden. One commenter stated that, by the time Transmittal 11 was issued, hospitals had already filed their initial FY 2014 and FY 2015 cost reports, with some hospitals having already updated Worksheet S–10 data through amended cost reports. Several commenters believed that Transmittal 11 added significant strain on and caused confusion for hospitals.

Aside from these concerns about the timing of and differences between Transmittals 10 and 11, numerous commenters pointed out specific reasons as to why the guidelines were confusing and difficult to be carried out, especially with regard to the changes made in Transmittal 11. For example, one commenter pointed out that providers that have already complied with CMS' updated instructions would not have to change submitted data. However, it was not clear from Transmittal 11 how hospitals were supposed to proceed in such a situation or if they simply had to calculate Worksheet S–10 data again and then resubmit.

Among the chief concerns raised by commenters regarding the release of Transmittal 11 was that hospitals did not have enough time or sufficient resources to revise their Worksheet S–10 data. According to commenters, the timeframe afforded by CMS was not long enough, given the administrative burden of complying with all of the changes in Transmittal 11. In addition, a few commenters pointed out that the Electronic Health Record audit by the Office of the Inspector General was earlier than the release of Transmittal 11, contributing to an even shorter timeline for hospitals to respond to changes in cost reporting for Worksheet S–10.

Many commenters also stated that among the factors contributing to restrict hospitals' ability to make timely revisions to their Worksheet S–10 data in response to Transmittal 11 were the limited personnel and financial resources available to make the changes in cost reporting outlined in Transmittal 11. The commenters also indicated that hospitals with inadequate internal financial management tracking systems were at an extreme disadvantage in meeting CMS' timeline.

On a related issue, many commenters stated that the software updates, which were required to accommodate the changes reflected in Transmittal 11, reduced the timeframe hospitals had to amend their cost reports by the deadline for inclusion in the proposed rule. At times, according to one commenter, the changes mandated by Transmittal 11 could not be executed by hospitals' information systems until a software update was possible, which likely did not coincide with the submission timeframe for the revisions.

Some commenters pointed out that the MACs' review of data following the issuance of Transmittal 11 largely focused on FY 2015 data, and perhaps paid much less attention to equally troubling FY 2014 data. Other commenters stated that only limited education efforts accompanied the issuance of Transmittal 11.

Response: We appreciate all of the comments raising concerns regarding Transmittals 10 and 11. However, we believe that hospitals were provided sufficient time to address the changes outlined in Transmittal 11 and to submit an amended Worksheet S–10 in time for it to be considered for the FY 2019 rulemaking, especially given our extension of the deadline to file resubmissions to January 2, 2018, as evidenced by the many hospitals that were able to resubmit their information by this deadline. Specifically, we issued Transmittal 11 on September 29, 2017,

and indicated that all revised data received by December 1, 2017, would be considered for purposes of the FY 2019 IPPS/LTCH PPS proposed rule. In light of the 2017 hurricanes (Harvey, Irma, Maria, Nate), we provided a further opportunity for hospitals to revise their Worksheet S–10 data for both FY 2014 and FY 2015 through Change Request 10378, Transmittal 1981, titled ''Fiscal Year (FY) 2014 and 2015 Worksheet S–10 Revisions: Further Extension for All Inpatient Prospective Payment System (IPPS) Hospitals,'' issued on December 1, 2017. This change request stated that hospitals needed to submit revised data by January 2, 2018. In this transmittal, we instructed MACs to accept amended Worksheets S–10 for FY 2014 and FY 2015 cost reports submitted by hospitals (or initial submissions of Worksheet S–10 if none had been submitted previously) and to upload them to HCRIS in a timely manner. Based on the significant number of resubmissions, we believe that hospitals were given ample time to revise and amend their Worksheets S–10 for FY 2014 and FY 2015 to reflect the instructions in Transmittal 11.

Regarding the confusion Transmittal 11 may have caused among stakeholders, we note Transmittal 11 was designed to be responsive to previous stakeholder concerns regarding Worksheet S–10, such as reporting of uninsured patient discounts and the modification of certain calculations to account for nonreimbursable Medicare bad debt. We also note that some commenters indicated that Worksheet S–10 instructions, consistency, and data accuracy have improved as a result Transmittal 11. However, we recognize that there are continuing opportunities to further improve guidance and education, and we will continue to work with our stakeholders to address their concerns through provider education and further refinement of the instructions.

Comment: Several commenters provided specific merger information and requested that CMS include these mergers in determining Factor 3 for FY 2019 payments. Several commenters noted other inaccuracies in the FY 2019 Proposed Rule Supplemental Data File, such as incorrect merger information errors in claims average calculations.

Response: We thank the commenters for their input. We have updated our list of mergers based on information received by the MACs as of June 2018. In addition, we have reviewed the commenters' submissions regarding mergers not previously identified in the proposed rule and have updated our list accordingly. We note that, under the policy finalized in FY 2015 IPPS/LTCH PPS final rule, a merger is defined as an acquisition where the Medicare provider agreement of one hospital is subsumed into the provider agreement of the surviving provider (79 FR 50020). We have also corrected the other inaccuracies identified by commenters, and will continue to pay diligent attention to data inaccuracies and work internally and with our contractors to resolve these issues in a timely manner.

Comment: Numerous commenters expressed concerns that HCRIS data do not reflect hospital submissions in response to Transmittal 11. For example, one commenter pointed out that the March HCRIS data update still reflects data reported under the Transmittal 10 instructions rather than the Transmittal 11 instructions for a large number of hospitals. Commenters also expressed that, given problems with some amended cost reports not automatically being reprocessed with the Transmittal 11 calculation modification, the May 31, 2018 HCRIS file will provide the best data in determining Factor 3.

Several commenters specifically requested that their cost data in the proposed FY 2019 DSH Supplemental Data File be updated in a timely manner to reflect the latest HCRIS information in order ensure that their Factor 3 for FY 2019 accurately reflects their uncompensated care costs. A few commenters also expressed concerns that many hospitals were still having challenges in resubmitting their corrections to Worksheet S–10 data and having them accepted by the MACs. One commenter urged CMS to validate the information in HCRIS before pulling data for the proposed and final rules. Another commenter suggested that CMS implement an alternative means for hospitals to submit cost report data to alleviate burden on hospitals and improve accuracy.

Response: We appreciate the commenters' diligence in checking that their own reports were properly reprocessed under Transmittal 11. We also understand their concerns regarding the timeliness of updates to the HCRIS data. We recognize that hospitals' data in the March HCRIS update may not have reflected all corrections made to Worksheet S–10 data in response to Transmittal 11. Although we instructed MACs to accept amended Worksheets S–10 for FY 2014 and FY 2015 cost reports submitted by hospitals (or initial submissions of Worksheet S–10 if none had been submitted previously) and to upload them to HCRIS in a timely manner, we recognize that there were unusual delays in processing the amended Worksheets S–10 to reflect the revisions in response to Transmission 11. Consistent with our historical practice of using the best data available, and due to the unique circumstances that affected hospitals' ability to resubmit Worksheet S–10, as discussed in the proposed rule, and the delays in processing by the MACs, we used a June 30, 2018 HCRIS update to calculate Factor 3 for this FY 2019 IPPS/LTH PPS final rule.

We have not previously been able to use such a recent update of HCRIS for purposes of the annual rulemaking, and it was operationally challenging to take the steps necessary to be able to use a June 30, 2018 update to calculate Factor 3 for FY 2019. The time required to complete the public use file process, which involves interactions with the MACs to ensure all reports have been appropriately included, would have exceeded the time we had available. In order to have the data with a bare minimum of time to use it in performing our calculations for the final rule, we needed to use a new expedited ad hoc process outside of the established process normally used to develop the public use file. We were not sure it even would be feasible to develop such an expedited ad hoc process. Ultimately, in order to develop the expedited process that was used, we had to bypass some of the safeguards built into the ordinary process and forgo our opportunity to further review the data. Given the unique circumstances that affected hospitals' ability to resubmit their Worksheet S–10 for FY 2014 and/or FY 2015, and the delays in processing by the MACs, we concluded that the potential to include additional, revised data for the final rule outweighed the risk that we might not include a report that would have been properly included had we been able to follow the usual process for preparing a public use file. Therefore, under ordinary circumstances, we would not even have contemplated this approach because the additional review time afforded by the use of the March extract under the established public use file process is important from an enhanced quality assurance standpoint and the benefits of this enhanced quality assurance were only outweighed by the extenuating circumstances affecting the timeline for both the resubmission of Worksheet S–10 data and the review of these data by the MACs in time to allow the data to be considered in this final rule.

Following the publication of this final rule, hospitals will have until August 31, 2018, to review and submit comments on the accuracy of the table

and supplemental data file published in conjunction with this final rule relative to information they submitted to their MAC by the deadlines prescribed in Transmittal 11 and Change Request 10378.

Comment: Some commenters expressed specific concerns related to possible violations of the Administrative Procedure Act by CMS. These commenters suggested that any final rule issued by CMS that disregards information in the rulemaking record, including copies of revised Worksheets S–10, that are submitted as attachments to comments, would violate the Administrative Procedure Act because it would not be supported by substantial evidence. The commenters urged CMS to calculate Factor 3 with the best possible data. One commenter also asserted that CMS is not upholding its statutory obligation unless it continues to accept updated Worksheets S–10 for the duration of time that the rulemaking period is open. The commenter cited the decision in *Baystate Medical Center* v. *Leavitt,* in which CMS was instructed to use the best data available to determine Medicare DSH payments under section 1886(d)(5)(F) of the Act. Another commenter also noted that, in the FY 2019 IPPS/LTCH PPS proposed rule, CMS proposed to use a May 31, 2018 HCRIS update for Factor 3 calculations in the final rule. The commenter stated that this proposal could lead to a situation where hospitals see their final uncompensated care payment amounts only in the final rule, and thus the hospitals would not have the ability to comment on these amounts, which the commenter suggests is in violation of both the Administrative Procedure Act and the Medicare statute.

One commenter also suggested that CMS allow for administrative or judicial review of its Medicare DSH payment calculations, which would provide an important check if the agency makes errors in the calculations. One commenter also asked CMS to reconsider its decision not to reconcile final payments for uncompensated care with actual data for cost reporting periods during FY 2019. One commenter included a request to reopen its cost reports for FY 2014 and FY 2015 to make corrections.

Response: We appreciate commenters' concerns regarding Factor 3 calculations and the importance of using the best available data. In response to these concerns, and in light of the considerations we have previously discussed, we used a June 30, 2018 HCRIS update to perform the Factor 3 calculations for this FY 2019 IPPS/LTCH PPS final rule, which was the best data available for purposes of this final rule.

Unless the relevant information was also reflected in the June 30, 2018 HCRIS update, we have not considered information from any revised Worksheets S–10 that were submitted as attachments to comments. We do not believe it would be appropriate to allow a hospital to use the rulemaking process to circumvent the requirement that cost report data need to be submitted to the MAC or the requirement that requests to reopen cost reports need to be submitted to the MAC. Otherwise we would have multiple potentially conflicting sources of information about a hospital's uncompensated care data or, more broadly, any cost report data that might be submitted during the rulemaking process. In addition, there are validity checks and other safeguards incorporated into the cost report submission process that would not be automatically applied to cost reports only submitted through rulemaking.

Furthermore, as noted earlier, under the deadlines established in Change Request 10378, we stated that all amended FY 2014 and FY 2015 cost reports containing a revised Worksheet S–10 (or a completed Worksheet S–10 if no data were included on the previously submitted cost report) received by January 2, 2018 would be available to be considered for purposes of the FY 2019 IPPS/LTCH PPS final rule. This date was important to allow sufficient time for reviews by MACs for potentially aberrant reports prior to the FY 2019 PPS/LTCH PPS final rule.

Also, as discussed earlier, we continue to believe that using the best data available to prospectively estimate Factor 3 is most conducive to administrative efficiency, finality, and predictability in payments (78 FR 50628; 79 FR 50010; 80 FR 49518; 81 FR 56949; and 82 FR 38195). Further, we believe that, in affording the Secretary the discretion to estimate the amount of the three factors used to determine these uncompensated care payments and by including a prohibition against administrative and judicial review of those estimates in section 1886(r)(3) of the Act, Congress recognized the importance of finality and predictability under a prospective payment system. In light of this preclusion, we do not have the ability to allow for administrative or judicial review of our estimates.

Regarding the concerns related to the Administrative Procedure Act, we note that, under the Administrative Procedure Act, a proposed rule is required to include either the terms or substance of the proposed rule or a description of the subjects and issues involved. In this case, the FY 2019 IPPS/LTCH PPS proposed rule included a detailed discussion of our proposed methodology for calculating Factor 3 and the data that would be used. We made public the best data available at the time of the proposed rule, in order to allow hospitals to understand the anticipated impact of the proposed methodology. Moreover, following the publication of the proposed rule, we continued our efforts to ensure that information hospitals properly submitted to their MAC in the prescribed timeframes would be available to be used in this final rule in the event we finalized our proposed methodology. We believe the fact that we provided data with the proposed rule while concurrently continuing to review that data with individual hospitals is entirely consistent with the Administrative Procedure Act. There is no requirement under either the Administrative Procedure Act or the Medicare statute that CMS make the actual data that will be used in a final rule available as part of the notice of proposed rulemaking. Rather, it is sufficient that we provide stakeholders with notice of our proposed methodology and the data sources that will be used, so that they may have a meaningful opportunity to submit their views on the proposed methodology and the adequacy of the data for the intended purpose. This requirement for notice and comment does not, however, extend to a requirement that we make all data that will be used to compute payments available to the public, so that they may have an opportunity to comment on accuracy of the data reported for individual hospitals. Similarly, there is no requirement that we provide an opportunity for comment on the actual payment amounts determined for each hospital.

Comment: Many commenters recommended that CMS delay the use of data from Worksheet S–10 for at least 1 year, and up to 3 years until FY 2021, as CMS had originally stated in its FY 2017 IPPS/LTCH PPS final rule, or until CMS has put processes in place to ensure accurate and consistent submissions by all hospitals as discussed in the FY 2018 IPPS/LTCH PPS final rule. Many commenters believed that this delay would allow hospitals the time to absorb the changes they have to make in order to better report their uncompensated care costs on the Worksheet S–10, as well as to prepare for potential losses due to policy changes. The commenters also believed that this delay will allow CMS the time to analyze how hospitals have

responded to the changes to the Worksheet S–10 that have already been implemented, identify problems that still remain, and develop an action plan moving forward. Specifically, a significant number of commenters requested that CMS further educate hospitals on how to accurately and consistently complete the Worksheet S–10 ''before advancing the transition to a greater use of Worksheet S–10 data.'' Although many commenters discussed how the CMS' current educational efforts—release of Transmittal 11, a Medicare Learning Network Matters article, along with Frequently Asked Questions document—were welcome and served as much needed guidance for the field, they provided recommendations for CMS to continue to partner with stakeholders in addressing these and other outstanding issues. Several commenters expressed their willingness and readiness to continue work with the agency in this particular area.

Response: We acknowledge the concerns raised by commenters regarding our proposal to use data from Worksheet S–10 in the calculation of Factor 3 for FY 2019. However, as we stated in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20394), when weighing the new information that has become available to us since the FY 2017 rulemaking in conjunction with the information regarding Worksheet S–10 data against the low-income days proxy that we have analyzed as part of our consideration of this issue in prior rulemaking, we can no longer conclude that alternative data to the Worksheet S–10 are available that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. We also note that, as part of our ongoing quality control and data improvement measures to continue to improve the Worksheet S–10 data over time, we have revised the cost report instructions (Transmittal 11) and are currently developing an audit process. Continuing our education efforts of past years, we will continue to work with stakeholders to address their concerns regarding the Worksheet S–10 data through further provider education.

Comment: Many commenters urged CMS to implement a full desk auditing process to ensure the accuracy and consistency of the Worksheet S–10 data. A large proportion of the commenters requested an audit process that would be as rigorous, detailed, and thorough as the process used for the hospital wage index, as opposed to the less rigorous HITECH audits. In addition to auditing negative, missing, or suspicious values, many commenters also requested that CMS audit the revised data resubmitted by hospitals as a result of the release of Transmittal 11. One commenter believed that the Worksheet S–10 data needs real auditing, thorough auditing, professional auditing, and not the mere desk auditing that CMS previously indicated will be introduced in 2020. Another commenter recommended an alternative audit approach of ''probe and educate'' as it has been used to review data submitted for Medicaid DSH, where hospitals are allowed a grace period before the results of audits lead to financial consequences. Regardless of the approach, many commenters stated that they cannot overemphasize the importance of auditing the Worksheet S–10 data, given the inaccurate, inconsistent, and anomalous reporting of these data, as well as the data's crucial role in the distribution of Medicare DSH uncompensated care payments, which these commenters viewed as finite and an example of a ''classic zero-sum game.'' A few commenters explained that this is because for every additional dollar gained by a hospital, which could be a result of inaccurate and inconsistent reporting, another hospital must lose a dollar. Several commenters also asked CMS to implement edits within the cost report to ensure internal consistency between the amounts for data elements that must reported on several different worksheets and that the reported amounts equal calculated amounts.

Many commenters disagreed with CMS' stance on not sharing desk review and audit protocols with hospitals. These commenters pointed out that CMS has indicated that such protocols are confidential, but they believe this opacity could lead to inconsistencies in the reporting of Worksheet S–10 data and different interpretations of the Provider Reimbursement Manual among hospitals and even MACs. The commenters encouraged CMS to release the audit criteria for non-Medicare bad debt and charity care claimed on Worksheet S–10.

One commenter believed that CMS and the MACs hide behind the ''bar to judicial review'' that exists under the provisions of the statute governing the determination of uncompensated care payments, and this allows the MACs to commit outright errors that go unchecked if a hospital is otherwise unable to convince the MAC of the error. A few commenters expressed disappointment with what they characterized as the inconsistent and arbitrary decisions made by MACs in their reviews of Worksheet S–10 data and expressed the need for CMS to provide guidance to MACs to clarify which uninsured discounts CMS expects MACs to accept when reported on amended and/or corrected cost reports. Commenters pointed out that MACs may lack sufficient guidance, instruction, and training with respect to the inclusion of all discounts under the hospital's financial assistance policy in Line 20 of Worksheet S–10. For example, one commenter mentioned that some hospitals have experienced MAC audit disallowances of certain charity care and uninsured costs reported on Worksheet S–10 and stated that such disallowances can be egregious and cause significant reductions in the hospitals' uncompensated care payments. Commenters also suggested that these disallowances highlight the need for more upfront guidance and clearly defined terms as well as consistency by the MACs in the application of that guidance in their reviews.

Several commenters also were concerned or believed that MACs had created their own audit protocols for the Worksheet S–10 for purposes of auditing Electronic Health Record incentive payments under the HITECH Act without any guidance from CMS, and that any disparate interpretations could create disparities in the accuracy of the data across MACs. This, according to one commenter, allows MACs' audits to be subject to open interpretation. Another commenter expressed concern that the MACs are overstepping their authority to determine what the requirements for hospitals' financial assistance policies should be, when in fact hospitals are free to determine these requirements. The commenter also stated that the IRS already reviews and ensures that hospitals follow their financial assistance policy, and therefore there is no need for CMS and the MACs to duplicate its efforts.

Response: With respect to the audit process, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56964), we stated that we intended to provide standardized instructions to the MACs to guide them in determining when and how often a hospital's Worksheet S–10 should be reviewed. To the extent the commenters are referring to concerns with EHR incentive payment audits, CMS strives to take lessons learned from these audits to improve the audits of Worksheet S–10 for purposes of Medicare DSH uncompensated care payments. We indicated that we would not make the MACs' review protocol public, as all CMS desk review and audit protocols are confidential and are for CMS and MAC use only. The instructions for the

MACs are still under development and will be provided to the MACs as soon as possible and in advance of any audit. We refer readers to the FY 2017 IPPS/LTCH PPS final rule for a complete discussion concerning the issues that we are considering in developing the instructions that will be provided to the MACs. Due to the overwhelming feedback from commenters emphasizing the importance of audits in ensuring the accuracy and consistency of data reported on the Worksheet S–10, we expect audits to begin in the Fall of 2018. We also will continue to work with stakeholders to address their concerns regarding the accuracy and consistency of data reported on the Worksheet S–10 through provider education and further refinement of the instructions for the Worksheet S–10 as appropriate.

Comment: Many commenters supported CMS' proposal to use a 3-year average to calculate Factor 3 for FY 2019. Other commenters opposed the use of Worksheet S–10 data to determine Factor 3 for FY 2019 and also provided suggestions for modified or alternative methodologies to calculate Factor 3 in FY 2019 and beyond. Many of the commenters recommended a delay of at least 1 year to allow for further refinement of the Worksheet S–10 instructions and the development of audit protocols to identify and remove aberrant uncompensated care costs. One commenter asked that CMS consider a permanent 50–50 percent blend of the low-income insured days proxy data and Worksheet S–10 data. Other commenters suggested that CMS freeze the methodology used in calculating Factor 3 for FY 2018, under which we used 2 years of low-income insured days data and 1 year of Worksheet S–10 data, for the foreseeable future. Some commenters who suggested this freeze also recommended using Worksheet S–10 data from FY 2015 for the FY 2019 rulemaking, rather than FY 2014 data, reasoning that FY 2015 data are more likely to be consistently reported than FY 2014 data. One commenter suggested that CMS consider a proxy that would use SSI days to adjust the uncompensated care costs used in calculating Factor 3 starting in FY 2020.

Many commenters approved of the proposal to phase-in the use of data from the Worksheet S–10. However, other commenters had other varying opinions regarding the length of the phase-in period. Some commenters agreed with the proposal to continue the 3-year phase-in. However, other commenters requested that CMS consider a longer phase-in period or delay the transition to the use of Worksheet S 10 data. These commenters recommended a minimum 5-year transition period to gradually phase-in the use of Worksheet S–10 data, once the data have been audited. According to the commenters, this longer phase-in would mitigate the effect on hospitals of the redistribution in uncompensated care payments resulting from the inclusion of data from the Worksheet S–10.

Some commenters stated that the proposed methodology of using 1 year of low-income insured days and 2 years of uncompensated care data from Worksheet S–10 to compute uncompensated care payments for FY 2019 would be highly redistributive, and some commenters asked that CMS implement a stop-loss policy to protect hospitals that lose 5 to 10 percent in DSH payments in any given year as a result of transitioning to the use of Worksheet S–10 data. These commenters suggested that this stop-loss policy should extend beyond the 3-year phase-in to help hospitals with decreasing uncompensated care payments that are disproportionately affected by the transition to Worksheet S–10 data adjust to their new payment levels. However, another commenter noted that a stop-loss policy would not be warranted, given that a 3-year phase-in is an appropriate way to temporarily reduce the impact of new provisions.

Response: We appreciate the commenters' support for our proposal to use a 3-year average in the calculation of Factor 3 for FY 2019. We also appreciate the comments regarding alternative ways to blend prior years' data for purposes of incorporating Worksheet S–10 data into the calculation of Factor 3 and the suggestions for alternative methods for computing proxies for uncompensated care costs. However, our primary reason for using a 3-year average is to provide assurance that hospitals' uncompensated care payments will remain reasonably stable and predictable, and less subject to unpredictable swings and anomalies in a hospital's low-income insured days or reported uncompensated care costs between cost reporting periods. While the 3-year average effectively functions as a transition from the use of the low-income insured days proxy to the use of Worksheet S–10 data, that is not its purpose. Furthermore, as we stated in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20394), we can no longer conclude that alternative data to the Worksheet S–10 are available for FY 2014 and FY 2015 that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. Therefore, we disagree with commenters who suggested the use of a longer phase-in or alternative blends to determine Factor 3 for FY 2019 in order to provide for an extended transition to the use of the Worksheet S–10. We note that the proposals in the FY 2019 IPPS/LTCH PPS proposed rule were limited to FY 2019, and that we did not make any proposals with respect to the data that would be used to calculate Factor 3 for subsequent years. As a result, it would be premature for CMS to establish policies regarding the data that will be used to determine Factor 3 for future years in this final rule. We will consider the commenters' suggestions for further incorporating Worksheet S–10 into the calculation of Factor 3, or computing proxies for uncompensated care costs using a blend of Worksheet S–10 data, low-income insured days, or other data sources, as we develop our proposed policies for determining uncompensated care payments for FY 2020 and subsequent years.

Regarding the commenters' recommendation that we adopt a stop-loss policy, we believe that the use of 3 years of data to determine Factor 3 for FY 2019 already provides assurance that hospitals' uncompensated care payments will remain reasonably stable and predictable, and would not be subject to unpredictable swings and anomalies in a hospital's low-income insured days or reported uncompensated care costs. As a result, because there is already a mechanism that has the effect of smoothing the transition from the use of low-income insured days to the use of Worksheet S–10 data in place, we do not believe a stop-loss policy is necessary.

Comment: A few commenters stated that the current CCR trimming methodology is not adequate to address the data anomalies in the Worksheet S–10 data reported by certain hospitals. Other commenters supported the current methodology. A few commenters also stated that hospitals that have been identified as potential outliers should have the opportunity to explain their data and correct errors before the trim methodology is applied, which would facilitate data validity. Other commenters requested that the trimming methodology not be finalized until an audit of the data has been conducted, and that hospitals with extremely high CCRs be audited and an appropriate CCR determined instead of applying an arbitrary trim to a statewide average. Several commenters expressed concern over the proposed trim methodology because hospitals that are considered ''all-inclusive rate providers'' are not required to complete

Worksheet C, Part I, which is used for reporting the CCR on Line 1 of the Worksheet S–10. Commenters noted that, as a result, the proposed trim methodology inappropriately modifies their uncompensated care costs, and that a high CCR could be accurate if the hospital's charges are close to costs, as is usually the case for all-inclusive rate hospitals. One commenter noted that CMS is proposing to continue to use the low-income patient day proxy to distribute Medicare DSH uncompensated care payments to all-inclusive rate providers. The commenter encouraged CMS to engage with hospitals in determining the best way to use Worksheet S–10 data to distribute uncompensated care payments to all-inclusive rate providers in the future and also recommended that CMS assess how the current CCR trim methodology would affect all-inclusive rate providers.

Response: We appreciate the additional information provided by the commenters related to applying trims to the CCRs. We intend to further explore which trims are most appropriate to apply to the CCRs on Line 1 of Worksheet S–10, including whether it would be appropriate to apply a unique trim for certain subsets of hospitals, such as all-inclusive rate providers. We note that all-inclusive rate providers have the ability to compute and enter their appropriate information (for example, departmental cost statistics) on Worksheet S–10, Line 1, by answering ''Yes'' to the question on Worksheet S–2, Part I, Line 115, rather than having it computed using information from Worksheet C, Part I. We intend to give additional consideration to the utilization of statewide averages in place of outlier CCRs, and will also consider other approaches that could ensure the validity of the trim methodology, while not penalizing hospitals that use alternative methods of cost apportionment. We may consider incorporating these alternative approaches through rulemaking for future years. However, as we have previously discussed, because all-inclusive rate providers have charge structures that differ from other IPPS hospitals, we did not propose to use data from the Worksheet S–10 to determine Factor 3 for these hospitals for FY 2019. Instead, we have determined Factor 3 for these hospitals using low-income insured days for FY 2013.

Regarding the commenters' view that CCR trims should not take place before we conduct audits and give providers further opportunities to explain or amend their data, we agree that, in an ideal circumstance, CCR trims without audits would not be needed. However, providers have had sufficient time to amend their data and/or contact CMS to explain that the FY 2019 DSH Supplemental Data File posted in conjunction with FY 2019 IPPS/LTCH PPS proposed rule had incorrect data. As a result, we consider CCRs greater than 3 standard deviations above the national geometric mean CCR for the applicable fiscal year to be aberrant CCRs. We are finalizing the trim methodology as proposed.

Comment: Many commenters requested that the cost of graduate medical education (GME) be included within the CCR calculation to account for the costs associated with the training of interns and residents. The commenters stated that not only does GME represent a significant portion of the overhead costs of teaching hospitals, but these trained interns and residents treat patients from all financial backgrounds, including the uninsured. Therefore, the commenters believed that including GME costs in the CCR calculation and then using this adjusted CCR for Worksheet S–10 would more accurately represent the true uncompensated care costs for teaching hospitals. Some commenters observed that GME is included in the denominator but not the numerator of the Worksheet S–10 CCR and that this discrepancy should be rectified. One commenter noted that this inconsistency occurs because Line 1 uses data from Worksheet C, Column 3 (''costs,'' which do not include GME) and Worksheet C, Column 8 (''charges,'' which do include GME). Commenters recommended using the ''costs'' definition from Worksheet B, Part I, Column 24, Line 118 to reconcile the discrepancy. Other commenters requested that the Reasonable Compensation Equivalency (RCE) be removed from the calculation of the CCR. One commenter stated that the current Worksheet S–10 ignores substantial costs hospitals incur in training medical residents, supporting physician and professional services, and paying provider taxes associated with Medicaid revenue. Therefore, this commenter recommended that CMS use the total of Worksheet A, Column 3, Lines 1 through 117, reduced by the amount on Worksheet A–8, Line 10, as the cost component of the CCR; and use Worksheet C, Column 8, Line 200, as the charge component. The commenter noted that this result would more accurately reflect the true cost of hospital services compared with the CCR currently used in Worksheet S–10.

Response: As we have stated previously in response to this issue, we believe that the purpose of uncompensated care payments is to provide additional payment to hospitals for treating the uninsured, not for the costs incurred in training residents. In addition, because the CCR on Line 1 of Worksheet S–10 is pulled from Worksheet C, Part I, and is also used in other IPPS ratesetting contexts (such as high-cost outliers and the calculation of the MS–DRG relative weights) from which it is appropriate to exclude GME because GME is paid separately from the IPPS, we hesitate to adjust the CCRs in the narrower context of calculating uncompensated care costs. Therefore, we continue to believe that it is not appropriate to modify the calculation of the CCR on Line 1 of Worksheet S–10 to include GME costs in the numerator.

With regard to the comment that the CCRs on Worksheet S–10 are reported with the RCE limits applied, we believe the commenter is mistaken. Line 1 of Worksheet S–10 instructs hospitals to compute the CCR by dividing the costs from Worksheet C, Part I, Line 202, Column 3, by the charges on Worksheet C, Part I, Line 202, Column 8. The RCE limits are applied in Column 4, not in Column 3; thus, the RCE limits do not affect the CCR on line 1 of Worksheet S–10.

Comment: Several commenters supported the proposed definition of uncompensated care as charity care plus non-Medicare bad debt. However, some commenters suggested that uncompensated care should include shortfalls from Medicaid, CHIP, and State and local indigent care programs. The most common concern expressed was the exclusion of Medicaid shortfalls from the definition of uncompensated care as captured by Worksheet S–10. Commenters stated that excluding Medicaid shortfalls from the definition of uncompensated care severely penalizes hospitals that care for large numbers of Medicaid patients because many States do not fully cover the costs associated with newly insured Medicaid recipients. One commenter noted that just because patients are covered by Medicaid does not mean that they have no remaining uncompensated care costs, and that, as the policy stands now, Medicare will significantly subsidize those States with Medicaid payment rates that cover the cost of care relative to those with lower Medicaid payment rates that do not cover the cost of care. However, some commenters noted that Worksheet S–10 provides an incomplete picture of Medicaid shortfalls and should be revised to instruct hospitals to deduct intergovernemental transfers,

certified public expenditures, and provider taxes from their Medicaid revenue. One commenter questioned why CHIP and indigent care data are collected on Worksheet S–10 if there is no plan to utilize this information in the calculation of Factor 3.

Several commenters urged CMS to use Worksheet S–10, Line 31 to identify a hospital's share of uncompensated care costs rather than Line 30. These commenters did not believe that Line 30 adequately captures a hospital's uncompensated care because it excludes unreimbursed costs for State and local indigent care programs. Commenters also believed that CMS' use of Line 30 results in a mismatch between payment and costs for care furnished to the uninsured and underinsured due to lack of clear reporting guidelines. The commenters believed that this is because many States support uncompensated care through supplemental Medicaid programs funded through their Federal Medicaid DSH allotment or a Medicaid waiver program. The commenters stated that these supplemental payments are likely reported on Worksheet S–10 as Medicaid revenue while some of the hospital's uncompensated care costs are reported as charity care, as such reporting was at a hospital's discretion at the time of cost report filing.

In addition to comments about the Medicaid shortfalls, commenters observed that States differ in how they define uncompensated care costs, and that not all costs incurred by hospitals in treating the uninsured are categorized as charity care and bad debt, such as in the case of discounts to the uninsured who are unable to pay or unwilling to provide means-tested information. One commenter supported CMS' definition of uncompensated care costs as the cost of all charity care and non-Medicare bad debt but expressed concerns with the proposed expansion under Transmittal 10 to include discounts to the uninsured. The commenter stated that its health system has a long history of providing discounts to the uninsured through a voluntary agreement with the Attorney General's Office. The commenter also argued that higher adoption of high-deductible health plans should be considered.

Response: In general, we will attempt to address commenters' concerns through future cost report clarifications to further improve and refine the information that is reported on Worksheet S–10 in order to support collection of the information necessary to implement section 1886(r)(2) of the Act. With regard to the comments regarding Medicaid shortfalls, we recognize commenters' concerns but continue to believe there are compelling arguments for excluding Medicaid shortfalls from the definition of uncompensated care, including the fact that several key stakeholders, such as MedPAC, do not consider Medicaid shortfalls in their definition of uncompensated care, and that it is most consistent with section 1886(r)(2) of the Act for Medicare uncompensated care payments to target hospitals that incur a disproportionate share of uncompensated care for patients with no insurance coverage.

Conceptual issues aside, we note that even if we were to adjust the definition of uncompensated care to include Medicaid shortfalls, this would not be a feasible option at this time due to computational limitations. Specifically, computing such shortfalls is operationally problematic because Medicaid pays hospitals a single DSH payment that in part covers the hospital's costs in providing care to the uninsured and in part covers estimates of the Medicaid ''shortfalls.'' Therefore, it is not clear how CMS would determine how much of the ''shortfall'' is left after the Medicaid DSH payment is made. In addition, in some States, hospitals return a portion of their Medicaid revenues to the State via provider taxes, making the computation of ''shortfalls'' even more complex.

With regard to the comments that States differ in how they define uncompensated care costs, and that hospitals' costs of treating the uninsured are not always categorized as charity care and bad debt, such as in the case of discounts to the uninsured who are unable to pay or unwilling to provide income information, we believe the commenters are referring to the Worksheet S–10 instructions for Line 20, revised in Transmittal 10, which state, in part, ''Enter in column 1, the full charges for uninsured patients and patients with coverage from an entity that does not have a contractual relationship with the provider who meet the hospital's charity care policy or FAP.'' We believe that hospitals have the discretion to design their charity care policies as appropriate and may include discounts offered to uninsured patients as ''charity care.'' Accordingly, for the reasons discussed in the proposed rule and previously in this final rule, we are finalizing our proposal to define uncompensated care costs as the amount on Line 30 of Worksheet S–10, which is the cost of charity care (Line 23) and the cost of non-Medicare bad debt and non-reimbursable Medicare bad debt (Line 29).

Comment: Many commenters had several specific concerns regarding the instructions for reporting charity care and Medicare bad debt on the Worksheet S–10. Commenters acknowledged that while Transmittal 11 helped provide clarification, certain aspects of the instructions remain vague and ambiguous. For example, one commenter asked whether non-Medicare bad debt expenses must meet requirements equivalent to the statutory requirements applicable to Medicare bad-debt as described in CMS Pub. 15–1 Chapter 3. In addition, some commenters questioned whether guidance related to the recognition of bad debt expense for purposes of Medicare bad debts is also applicable for non-Medicare bad debt. A few commenters also suggested that CMS allow bad debt related to unpaid coinsurance and deductibles to be included on the Worksheet S–10 without multiplying these amounts by the CCR, similar to the modification made for charity care.

A few commenters also expressed concerns about the Financial Accounting Standards Board (FASB) update 2014–09 Topic 606. These commenters noted that the FASB guidelines indicate that bad debt is to be reported based on historical experience and that recoveries may not correlate to reported bad debt expense on the general ledger. Specifically, commenters asked that CMS address whether bad debt should still be reported net of recoveries on the Worksheet S–10.

Several commenters also expressed concerns that instructions pertaining to Worksheet S–10, Line 20 are not clear. The commenters stated, for example, that many hospitals incorrectly report ''insured'' charity care on Worksheet S–10, Line 20, Column 2 (which is not reduced by CCR), citing, as an example, noncovered Medicaid charges, which need to be reported as ''uninsured'' on Worksheet S–10 and reduced by CCR, as stated in the Worksheet S–10 instructions. The commenters pointed out that this inconsistency with respect to the reporting of charity care costs is commonly due to misinterpretation of instructions because of lack of clarity, and may be contributing to the overstatement of charity care costs.

Several commenters also pointed out that some hospitals may interpret the instructions literally, while other hospitals do not. The commenters asked CMS to correct this uncertainty and ambiguity to avoid inconsistent interpretations. In relation to this, one commenter asserted that contradictory and confusing language in the instructions leaves key terms undefined,

such as determination of uninsured status. The commenter believed that the focus in determining whether a patient is ''uninsured'' should be on whether the patient has coverage for the specific services provided, in the same manner that CMS defines ''uninsured'' and ''no health insurance'' for purposes of Medicaid DSH.

Some commenters questioned whether guidance on determining indigence of a Medicare beneficiary should be applicable to non-Medicare patients to determine whether charity care was furnished. Several commenters also suggested improvements that could be made to the instructions of Worksheet S–10, such as adding a requirement to report utilization data to add context to the monetary amounts reported for uncompensated care.

Response: We thank commenters for sharing their concerns and making suggestions regarding potential revisions to the instructions for Worksheet S–10. Some of these questions and concerns have been raised in previous rulemaking. (For example, we refer readers to the related discussion in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38219 and 38220).) We also note that a number of these questions and concerns are addressed by the updated instructions for Worksheet S–10 that were issued in November 2016 through Transmittal 10, as well as those issued on September 2017 through Transmittal 11, where we clarified definitions and the instructions for reporting uncompensated care, non-Medicare bad debt, nonreimbursed Medicare bad debt, charity care, and modified the calculations relative to uncompensated care costs. Additional reference materials include the MLN article titled ''Updates to Medicare's Cost Report Worksheet S–10 to Capture Uncompensated Care Data'', available at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE17031.pdf* as well as the Worksheet S–10 Q&As on the CMS DSH website in the download section, available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/Worksheet-S-10-UCC-QandAs.pdf*. To the extent that commenters have raised new questions and concerns, we will continue to work with stakeholders to address their questions and concerns through further refinement of the instructions to the Worksheet S–10 as appropriate.

Comment: Several commenters supported the proposal to use one cost report beginning in each fiscal year to derive the uncompensated care costs for that year, and to annualize Medicaid days and uncompensated care data for hospitals with less than 12 months of data. However, one commenter noted that this proposal may lead to double counting of the uncompensated care costs of acquired hospitals with short cost reporting periods and recommended that CMS modify its methodology to ensure that the data for acquired hospitals is not annualized twice. In addition, for acquired hospitals with more than one cost report beginning in the same Federal fiscal year, the commenter recommended that CMS not automatically select the one with the longer cost reporting period, in order to avoid double-counting. The commenter also recommended that CMS include the report record number in the DSH Supplemental File.

Response: We appreciate the support for our proposal to annualize cost reports that do not equal 12 months of data. We may consider adopting the commenters' recommendations regarding alternatives to the use of the longer cost report in specific situations through future rulemaking if objective and administratively feasible criteria can be developed. However, at present, we continue to believe that our current approach of annualizing the cost report data from the longest cost reporting period during the applicable fiscal year is generally the most accurate and consistent across hospitals. We do not believe it is necessary to include report record numbers in the DSH Supplemental File, as the quarterly HCRIS Public Use Files can be used to reference cost report records for this additional detail. Accordingly, for the reasons discussed in the proposed rule, and previously in this final rule, we are finalizing the proposal to use the longest cost report beginning in the applicable fiscal year and to annualize Medicaid data and uncompensated care data if a hospital's cost report does not equal 12 months of data.

Comment: A number of commenters supported the proposal to adjust a hospital's uncompensated care costs when those costs are extremely high in relation to its total operating costs for the same year. The commenters noted that this adjustment would help to control for data anomalies. However, one commenter noted that the trim currently uses a 50-percent threshold for the ratio of uncompensated care costs to total operating costs, yet the national average is 6 percent. Another commenter recommended that CMS investigate in cases where a hospital's uncompensated care value is an unrealistically high proportion of total revenue and ask for additional documentation before either allowing the value or requiring a modification. This commenter suggested that CMS could focus on providers at or near trim points initially, then expand to other providers with unlikely values.

Response: We appreciate the support for our proposal to adjust uncompensated care costs that are an extremely high ratio of a hospital's total operating costs for the same year. We believe that the proposed approach balances our desire to exclude potentially aberrant data, with our concern regarding inappropriately reducing FY 2018 uncompensated care payments to a hospital that may have a legitimately high ratio. We are finalizing this adjustment. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20399), we noted that our calculation of Factor 3 for the final rule would be contingent on the results of the ongoing MAC reviews of hospitals' Worksheet S–10 data, and in the event those reviews necessitate supplemental data edits, we would incorporate such edits in the final rule for the purpose of correcting aberrant data. After the completion of the MAC reviews, we are not incorporating any additional edits to the Worksheet S–10 data that we did not propose in the proposed rule. While, as stated earlier, we acknowledge that the Worksheet S–10 data are not perfect, we need to balance the possibility of potentially improving the accuracy of the Worksheet S–10 data for some hospitals through the creation of additional data edits against the possibility of inadvertently reducing the uncompensated care payments for other hospitals that might fail the edit, but whose data might in fact be accurate. For FY 2019, we have concluded that it is best to err on the side of not inadvertently reducing the uncompensated care payments for hospitals whose data might in fact be accurate.

Comment: Two commenters requested that CMS consider using a proxy for Puerto Rico hospitals' SSI days in computing the empirically justified DSH payment amount, or 25 percent of the amount that would have been paid for Medicare DSH prior to implementation of section 3133 of the Affordable Care Act.

Response: In the FY 2019 IPPS/LTCH PPS proposed rule, we did not propose any changes to the methodology used to calculate empirically justified Medicare DSH payments. Therefore, we consider this comment to be outside the scope of the proposed rule. However, we note that, while section 1886(r)(2)(C)(i) of the Act allows for the use of alternative data as a proxy to determine the costs of

subsection (d) hospitals for treating the uninsured for purposes of determining uncompensated care payments, section 1886(r)(1) of the Act requires the Secretary to pay an empirically justified DSH payment that is equal to 25 percent of the amount of the Medicare DSH payment that would otherwise be made under section 1886(d)(5)(F) of the Act to a subsection (d) hospital. Because section 1886(d)(5)(F)(vi) of the Act, which prescribes the disproportionate patient percentage used to determine empirically justified Medicare DSH payments, specifically calls for the use of SSI days in the Medicare fraction and does not allow the use of alternative data, we do not believe there is any legal basis for CMS to use a proxy for Puerto Rico hospitals' SSI days in the calculation of the empirically justified Medicare DSH payment under section 1886(r)(1) of the Act.

Comment: Several commenters supported the proposal to continue to use 14 percent of Medicaid days as a proxy for Medicare SSI days when determining Factor 3 of the uncompensated care payment methodology for Puerto Rico Hospitals. The commenters stated that they appreciated the attention and effort by CMS to develop a fair and appropriate method to estimate SSI days for Puerto Rico, as the SSI program is statutorily unavailable to U.S. citizens residing in the Territories.

One commenter recommended that CMS identify and seek comment on alternate sources of proxy data for Puerto Rico Hospitals for use in future years, such as using data for Medicare beneficiaries with Medicaid eligibility (dual eligible beneficiaries).

Response: We appreciate the support for our proposal to use 14 percent of a Puerto Rico hospital's Medicaid days as a proxy for SSI days. Because we are continuing to use insured low-income patient days as a proxy for uncompensated care in determining Factor 3 for FY 2019, and residents of Puerto Rico are not eligible for SSI benefits, we believe it is important to create a proxy for SSI days for Puerto Rico hospitals in the Factor 3 calculation. Regarding the recommendation that we consider using inpatient days for Medicare beneficiaries receiving Medicaid as a proxy for uncompensated care in the future, we have examined this concept and have been unable to identify a systematic source for these data for Puerto Rico hospitals. Specifically, we note that inpatient utilization for Medicare beneficiaries who are also entitled to Medicaid is not reported by hospitals on the Medicare cost report, either within or outside Puerto Rico. We expect to further address issues related to estimating the amount of uncompensated care for hospitals in Puerto Rico in future rulemaking.

After consideration of the public comments we received, and for the reasons discussed in the proposed rule and in this final rule, we are finalizing our proposal to use 2 years of Worksheet S–10 data from FY 2014 and FY 2015 cost reports in conjunction with data on low-income insured days that reflects Medicaid days from FY 2013 and SSI days from FY 2016, to calculate Factor 3 for FY 2019.

Therefore, for FY 2019, we are finalizing a policy to compute Factor 3 for each hospital by—

Step 1: Calculating Factor 3 using the low-income insured days proxy based on FY 2013 cost report data and the FY 2016 SSI ratio (or, for Puerto Rico hospitals, 14 percent of the hospital's FY 2013 Medicaid days);

Step 2: Calculating Factor 3 based on the FY 2014 Worksheet S–10 data;

Step 3: Calculating Factor 3 based on the FY 2015 Worksheet S–10 data; and

Step 4: Averaging the Factor 3 values from Steps 1, 2, and 3; that is, adding the Factor 3 values from FY 2013, FY 2014, and FY 2015 for each hospital, and dividing that amount by the number of cost reporting periods with data to compute an average Factor 3 (or for Puerto Rico hospitals, Indian Health Service and Tribal hospitals, and all-inclusive rate providers using the Factor 3 value from Step 1).

We also are finalizing the following proposals: (1) For providers with multiple cost reports beginning in the same fiscal year, to use the longest cost report and annualize Medicaid data and uncompensated care data if a hospital's cost report does not equal 12 months of data; (2) to discontinue the policy of combining cost reports for providers with multiple cost reports beginning during the same fiscal year; (3) where a provider has multiple cost reports beginning in the same fiscal year, but one report also spans the entirety of the following fiscal year such that the hospital has no cost report for that fiscal year, to use the cost report that spans both fiscal years for the latter fiscal year; and (4) to apply statistical trim methodologies to potentially aberrant CCRs and potentially aberrant uncompensated care costs.

For this FY 20019 IPPS/LTCH PPS final rule, we are finalizing a HCRIS cutoff of June 30. This cutoff also applies to revised reports from providers who were contacted by their MAC regarding potentially aberrant uncompensated care costs.

We are also finalizing our proposal to amend the regulations at § 412.106(g)(1)(iii)(C) by adding a new paragraph (*5*) to reflect the methodology for computing Factor 3 for FY 2019. We note that are making a technical correction to the uncompensated care definition in proposed paragraph (*5*) to include nonreimbursable Medicare bad debt to conform with our proposal in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20398) to define uncompensated care costs as the amount on Worksheet S–10 line 30, which includes charity care and non-Medicare and non-reimbursable Medicare bad debt), and which we are also finalizing in this final rule.

G. Sole Community Hospitals (SCHs) and Medicare-Dependent, Small Rural Hospitals (MDHs) (§§ 412.90, 412.92, and 412.108)

1. Background on SCHs and MDHs

Sections 1886(d)(5)(D) and (d)(5)(G) of the Act provide special payment protections under the IPPS to sole community hospitals (SCHs) and Medicare-dependent, small rural hospitals (MDHs), respectively. Section 1886(d)(5)(D)(iii) of the Act defines an SCH in part as a hospital that the Secretary determines is located more than 35 road miles from another hospital or that, by reason of factors such as isolated location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of inpatient hospital services reasonably available to Medicare beneficiaries. The regulations at 42 CFR 412.92 set forth the criteria that a hospital must meet to be classified as a SCH. For more information on SCHs, we refer readers to the FY 2009 IPPS/LTCH PPS final rule (74 FR 43894 through 43897).

Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area, or is located in an all-urban State but meets one of the specified statutory criteria for rural reclassification (as added by section 50205 of the Bipartisan Budget Act of 2018, Pub. L. 115–123), has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (that is, not less than 60 percent of its inpatient days or discharges during the cost reporting period beginning in FY 1987 or two of the three most recently audited cost reporting periods for which the Secretary has a settled cost report were attributable to inpatients entitled to benefits under Part A). The regulations at 42 CFR 412.108 set forth the criteria that a hospital must meet to be

classified as an MDH. For additional information on the MDH program and the payment methodology, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51683 through 51684).

2. Implementation of Legislation Relating to the MDH Program

a. Legislative Extension of the MDH Program

Since the extension of the MDH program through FY 2012 provided by section 3124 of the Affordable Care Act, the MDH program has been extended by subsequent legislation. Most recently, section 50205 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), enacted on February 9, 2018, extended the MDH program for FYs 2018 through 2022 (that is, for discharges occurring before October 1, 2022). (Additional information on the extensions of the MDH program after FY 2012 and through FY 2017 can be found in the FY 2016 interim final rule with comment period (80 FR 49596).)

Section 50205 of the Bipartisan Budget Act of 2018 amended sections 1886(d)(5)(G)(i) and 1886(d)(5)(G)(ii)(II) of the Act to provide for an extension of the MDH program for discharges occurring on or after October 1, 2017, through FY 2022 (that is, for discharges occurring on or before September 30, 2022).

We noted in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20401) that, consistent with the previous extensions of the MDH program, generally, a provider that was classified as an MDH as of September 30, 2017, was reinstated as an MDH effective October 1, 2017, with no need to reapply for MDH classification. However, if the MDH had classified as an SCH or cancelled its rural classification under § 412.103(g) effective on or after October 1, 2017, the effective date of MDH status may not be retroactive to October 1, 2017. We refer readers to the FY 2018 IPPS notice that appeared in the **Federal Register** on April 26, 2018 (CMS–1677–N; 83 FR 18303) for more information on the MDH extension in FY 2018.

b. MDH Classification for Hospitals in All-Urban States

In addition to extending the MDH program, section 50205 amended section 1886(d)(5)(G)(iv) of the Act to include in the definition of an MDH a hospital that is located in a State with no rural area (as defined in paragraph (2)(D)) and satisfies any of the criteria in section 1886(d)(8)(E)(ii)(I), (II), or (III) of the Act, in addition to the other qualifying criteria.

Section 50205 of the Bipartisan Budget Act of 2018 also amended section 1886(d)(5)(G)(iv) of the Act by adding a provision following section 1886(d)(5)(G)(iv)(IV), which specifies that new section 1886(d)(5)(G)(iv)(I)(bb) of the Act applies for purposes of the MDH payment under sections 1886(d)(5)(G)(ii) of the Act (that is, 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate from certain specified base years) only for discharges of a hospital occurring on or after the effective date of a determination of MDH status made with respect to the hospital after the date of the enactment of this provision. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20401), we noted that, under existing regulations, the effective date for a determination of MDH status is 30 days after the date the MAC provides written notification of MDH status. We also noted that we were proposing in section IV.G.3. of the preamble of the proposed rule to change the effective date for a determination of MDH status. We stated that if the proposal is finalized, the policy would not be effective until FY 2019 (October 1, 2018) and therefore would not apply to hospitals applying for MDH classification before October 1, 2018. Furthermore, this new provision also specifies that, for purposes of new section 1886(d)(5)(G)(iv)(I)(bb) of the Act, section 1886(d)(8)(E)(ii)(II) of the Act shall be applied by inserting ''as of January 1, 2018,'' after ''such State'' each place it appears. Section 50205 of the Bipartisan Budget Act also made conforming amendments to sections 1886(b)(3)(D) (in the language proceeding clause (i)) and 1886(b)(3)(D)(iv) of the Act.

Section 1886(d)(8)(E) of the Act provides for an IPPS hospital that is located in an urban area to be reclassified as a rural hospital if it submits an application in accordance with CMS' established process and meets certain criteria at section 1886(d)(8)(E)(ii)(I), (II), or (III) of the Act (these statutory criteria are implemented in the regulations at § 412.103(a)(1) through (3)). A subsection (d) hospital that is located in an urban area and meets one of the three criteria under § 412.103(a) can reclassify as rural and is treated as being located in the rural area of the State in which it is located. However, a hospital that is located in an all-urban State is ineligible to reclassify as rural in accordance with the provisions of § 412.103 because the State in which it is located does not have a rural area into which it can reclassify. Prior to the amendments made by the Bipartisan Budget Act, a hospital could only qualify for MDH status if it was either geographically located in a rural area or if it reclassified as rural under the regulations at § 412.103. This precluded hospitals in all-urban States from being classified as MDHs. The newly added provision in the Bipartisan Budget Act of 2018 allows a hospital in an all-urban State to be eligible for MDH classification if, in addition to meeting the other criteria for MDH eligibility, it satisfies one of the criteria for rural reclassification under section 1886(d)(8)(E)(ii)(I), (II), or (III) of the Act (as of January 1, 2018, where applicable), notwithstanding its location in an all-urban State.

As noted earlier, prior to the enactment of the Bipartisan Budget Act of 2018, a hospital in an all-urban State was ineligible for MDH classification because it could not reclassify as rural. With the new provision added by section 50205 of the Bipartisan Budget Act of 2018, a hospital in an all-urban State can apply and be approved for MDH classification if it can demonstrate that: (1) It meets the criteria at § 412.103(a)(1) or (3) or the criteria at § 412.103(a)(2) as of January 1, 2018, for the sole purposes of qualifying for MDH classification; and (2) it meets the MDH classification criteria at § 412.108(a)(1)(i) through (iii), which, as amended, would be redesignated as § 412.108(a)(1)(i) through (iv). We noted in the proposed rule that for a hospital in an all-urban State to demonstrate that it would have qualified for rural reclassification notwithstanding its location in an all-urban State (as of January 1, 2018, where applicable), it must follow the applicable procedures for rural reclassification and MDH classification at § 412.103(b) and § 412.108(b), respectively. We also noted that we were not proposing any changes to the reclassification criteria under § 412.103 and that a hospital in an all-urban State that qualifies as an MDH under the newly added statutory provision will not be considered as having reclassified as rural but only as having satisfied one of the criteria at section 1886(d)(8)(E)(ii)(I), (II), or (III) of the Act (as of January 1, 2018, as applicable) for purposes of MDH classification, in accordance with amended section 1886(d)(5)(G)(iv) of the Act.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20402), we proposed to make conforming changes to the regulations at § 412.108(a)(1) and (c)(2)(iii) to reflect the extension of the MDH program for FY 2018 through FY 2022 and the additional MDH classification provision made for hospitals located in all-urban States by section 50205 of the Bipartisan Budget

Act of 2018. We proposed a similar conforming change to § 412.90(j) to reflect the extension of the MDH program through FY 2022.

Comment: Commenters supported our proposals to make conforming changes to the regulations to reflect the legislation extending the MDH provision.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are adopting as final the proposed conforming changes to the regulations text at §§ 412.90 and 412.108 to reflect the extension of the MDH program through FY 2022 and the additional MDH classification provision made for hospitals located in all-urban States in accordance with section 50205 of the Bipartisan Budget Act of 2018. We are finalizing the proposed changes in paragraphs (a)(1) and (c)(2)(iii) of § 412.108 and paragraph (j) of § 412.90 without modification.

3. Change to SCH and MDH Classification Status Effective Dates

The regulations at 42 CFR 412.92(b)(2)(i) set forth an effective date for SCH classification of 30 days after the date of CMS' written notification of approval. Similarly, § 412.92(b)(2)(iv) specifies that a hospital classified as an SCH receives a payment adjustment effective with discharges occurring on or after 30 days after the date of CMS' approval of the classification.

Section 401 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act (BBRA) of 1999 (Pub. L. 106–113, Appendix F) amended section 1886(d)(8) of the Act to add paragraph (E) which authorizes reclassification of certain urban hospitals as rural if the hospital applies for such status and meets certain criteria. The effective date for rural reclassification status under section 1886(d)(8)(E) of the Act is set forth at 42 CFR 412.103(d)(1) as the filing date, which is the date CMS receives the reclassification application (§ 412.103(b)(5)). One way that an urban hospital can reclassify as rural under § 412.103 (specifically, § 412.103(a)(3)) is if the hospital would qualify as a rural referral center (RRC) as set forth in § 412.96, or as an SCH as set forth in § 412.92, if the hospital were located in a rural area. A geographically urban hospital may simultaneously apply for reclassification as rural under § 412.103(a)(3) by meeting the criteria for SCH status (other than being located in a rural area), and apply to obtain SCH status under § 412.92 based on that acquired rural reclassification. However, the rural reclassification is effective as of the filing date, while the SCH status is effective 30 days after approval. In addition, while § 412.103(c) states that the CMS Regional Office will review the application and notify the hospital of its approval or disapproval of the request within 60 days of the filing date, the regulations do not set a timeframe by which CMS must decide on an SCH request. Therefore, geographically urban hospitals that obtain rural reclassification under § 412.103 for the purposes of obtaining SCH status may face a payment disadvantage because they are paid as rural until the SCH application is approved and the SCH classification and payment adjustment become effective 30 days after approval.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20402 and 20403), to minimize the lag between the effective date of rural reclassification under § 412.103 and the effective date for SCH status, we proposed to revise § 412.92(b)(2)(i) and (b)(2)(iv) so that the effective date for SCH classification and for the payment adjustment would be the date that CMS receives the complete SCH application, effective for SCH applications received on or after October 1, 2018. However, as discussed in response to comments below, because the MAC receives SCH applications and not CMS, we are clarifying in this final rule that under our policy, as finalized below, the effective date is the date that the MAC receives the complete application. We have revised our finalized regulatory text and this preamble throughout to reflect that the MAC, and not CMS, receives the SCH application. A complete application includes a request and all supporting documentation needed to demonstrate that the hospital meets criteria for SCH status as of the date of application, which includes documentation of rural reclassification in the case of a geographically urban hospital. We stated in the proposed rule that for an application to be complete, all criteria must be met as of the date CMS receives the SCH application, but, similar to above, we are clarifying in this final rule and revising this preamble discussion to reflect that all criteria must be met as of the date the MAC receives the SCH application, because the MAC, and not CMS, receives SCH applications. For example, a hospital applying for SCH status on the basis of a § 412.103 rural reclassification must submit its § 412.103 application no later than its SCH application in order to be considered rural as of the date the MAC receives the SCH application.

Similar to rural reclassification obtained under § 412.103, we proposed that the effective date for SCH status would be the date that CMS receives the complete application. We also proposed conforming changes to the effective date at § 412.92(b)(2)(ii) for instances when a court order or a determination by the Provider Reimbursement Review Board (PRRB) reverses a CMS denial of SCH status and no further appeal is made. In the interest of a clear and consistent policy, we proposed that this change in the SCH effective date would also apply for hospitals not reclassifying as rural under § 412.103, such as geographically rural hospitals obtaining SCH status. We stated that we believe these proposals to update the regulations at § 412.92 to provide an effective date for SCH status that is consistent with the effective date for rural reclassification under § 412.103 would benefit hospitals by minimizing any payment disadvantage caused by the lag between the effective date of rural reclassification and the effective date of SCH status. We also stated that we believe this proposal to align the SCH effective date with the § 412.103 effective date supports agency efforts to reduce regulatory burden because it would provide for a more uniform policy.

In addition, we proposed to make parallel changes to the effective date for an MDH status determination under § 412.108(b)(4). As discussed earlier, section 50205 of the Bipartisan Budget Act of 2018 extended the MDH program through FY 2022 by amending section 1886(d)(5)(G) of the Act. Similar to the proposed change in effective date for SCH status approvals, we proposed that a determination of MDH status would be effective as of the date that CMS receives the complete application, for applications received on or after October 1, 2018, rather than the current effective date at § 412.108(b)(4) of 30 days after the date the MAC provides written notification to the hospital. However, as discussed in response to comments below, because the MAC receives MDH applications and not CMS, we are clarifying in this final rule that under our policy, as finalized below, the effective date is the date that the MAC receives the complete application. We have revised our finalized regulatory text and this preamble throughout to reflect that the MAC, and not CMS, receives the MDH application. Similar to applications for SCH status, a complete application includes a request and all supporting documentation needed to demonstrate that the hospital meets criteria for MDH status as of the date of application. We stated in the proposed rule that for an application to be complete, all criteria must be met as of the date CMS receives

the MDH application, but, similar to above, we are clarifying in this final rule and revising our preamble discussion to reflect that all criteria must be met as of the date the MAC receives the SCH application, because the MAC, and not CMS, receives MDH applications. For example, a cost report must be settled at the time of application for a hospital to use that cost report as one of the cost reports required in § 412.108(a)(1)(iii)(C) (redesignated as § 412.108(a)(1)(iv)(C) pursuant to our finalized changes to this regulation, as discussed in the prior section), and a hospital applying for MDH status on the basis of a § 412.103 rural reclassification must submit its § 412.103 application no later than its MDH application in order to be considered rural as of the date the MAC receives the MDH application. (We noted that a hospital in an all-urban State that applies for MDH status under the expanded definition at section 50205 of the Bipartisan Budget Act of 2018 would need to submit its application for a determination that it meets the criteria at § 412.103(a)(1) or (3) or the criteria at § 412.103(a)(2) as of January 1, 2018 (as discussed in the previous section) no later than its MDH application in order for the application to be considered complete.)

We stated that we believe that concurrently changing the SCH and MDH status effective dates from 30 days after the date of approval to the date the complete application is received would allow for consistency in the regulations governing effective dates of special rural hospital status. In addition, we stated that this proposal would benefit urban hospitals that are requesting § 412.103 rural reclassification at the same time as MDH status because it would synchronize effective dates to eliminate any payment consequences caused by a lag between effective dates for rural reclassification and MDH status.

Comment: Commenters supported this proposal and agreed with CMS that this policy to change the effective dates of SCH and MDH classifications will streamline the process, reduce burden, and align the SCH and MDH status timeline with the rural reclassification process in some cases. The commenters further agreed with CMS that this policy change would benefit hospitals by minimizing the disadvantages associated with a lag between reclassification and SCH or MDH status, and encouraged CMS to finalize this policy as proposed. Other commenters supported the proposal as a positive change expediting the effective date of these classifications but noted that the SCH and MDH regulations at § 412.92(b)(l)(i) and § 412.108(b)(2) require those applications to go to the MAC, rather than to CMS. The commenters therefore requested clarification regarding the proposed effective date of ''the date CMS receives the complete application''.

Response: We appreciate the commenters' support for our proposal as a positive change that would benefit hospitals by reducing burden and minimizing potential payment disadvantages. The commenters' observation that the regulations require that SCH and MDH applications be submitted to the MAC, rather than to CMS, is correct and we are making the appropriate changes in the regulation and clarifying our policy in the preamble to this final rule. Specifically, we are finalizing that the effective date of SCH and MDH classification status is the date that the MAC (rather than CMS) receives the complete application.

After consideration of the public comments we received, we are finalizing our proposed changes to § 412.92(b)(2)(i) and (b)(2)(iv), with modification, so that for applications received on or after October 1, 2018, the effective date for SCH classification and for the payment adjustment is the date that the MAC, rather than CMS, receives the complete SCH application. We also are finalizing with modification conforming changes to the effective date at § 412.92(b)(2)(ii) for instances when a court order or a determination by the PRRB reverses a CMS denial of SCH status and no further appeal is made, so that if the hospital's application for SCH status was received on or after October 1, 2018, the effective date is the date the MAC receives the complete application.

Similarly, we are finalizing our proposed changes to § 412.108(b)(4), with modification, to specify that for applications received on or after October 1, 2018, a determination of MDH status made by the MAC is effective as of the date the MAC receives the complete application.

4. Conforming Technical Changes to Regulations

We note that, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20403), we also proposed to make technical conforming changes to the regulations in § 412.92 and § 412.108 to reflect the change CMS made some time ago to identify fiscal intermediaries as Medicare administrative contractors (MACs).

We did not receive any public comments on the proposed conforming changes to the regulations text at §§ 412.92 and 412.108 to reflect the change CMS made some time ago to identify fiscal intermediaries as MACs. Therefore, in this final rule, we are adopting as final the proposed revisions to § 412.92 and § 412.108 without modification.

H. Hospital Readmissions Reduction Program: Updates and Changes (§§ 412.150 Through 412.154)

1. Statutory Basis for the Hospital Readmissions Reduction Program

Section 1886(q) of the Act, as added by section 3025 of the Affordable Care Act, amended by section 10309 of the Affordable Care Act, and further amended by section 15002 of the 21st Century Cures Act, established the Hospital Readmissions Reduction Program. Under the Program, Medicare payments under the acute inpatient prospective payment system for discharges from an applicable hospital, as defined under section 1886(d) of the Act, may be reduced to account for certain excess readmissions. Section 15002 of the 21st Century Cures Act requires the Secretary to compare peer groups of hospitals with respect to the number of their Medicare-Medicaid dual-eligible beneficiaries (dual-eligibles) in determining the extent of excess readmissions. We refer readers to section IV.E.1. of the preamble of the FY 2016 IPPS/LTCH PPS final rule (80 FR 49530 through 49531) and section V.I.1. of the preamble of the FY 2018 IPPS/LTCH PPS final rule (82 FR 38221 through 38240) for a detailed discussion of and additional information on the statutory history of the Hospital Readmissions Reduction Program.

2. Regulatory Background

We refer readers to the following final rules for detailed discussions of the regulatory background and descriptions of the current policies for the Hospital Readmissions Reduction Program:

- FY 2012 IPPS/LTCH PPS final rule (76 FR 51660 through 51676);
- FY 2013 IPPS/LTCH PPS final rule (77 FR 53374 through 53401);
- FY 2014 IPPS/LTCH PPS final rule (78 FR 50649 through 50676);
- FY 2015 IPPS/LTCH PPS final rule (79 FR 50024 through 50048);
- FY 2016 IPPS/LTCH PPS final rule (80 FR 49530 through 49543);
- FY 2017 IPPS/LTCH PPS final rule (81 FR 56973 through 56979); and
- FY 2018 IPPS/LTCH PPS final rule (82 FR 38221 through 38240).

These rules describe the general framework for the implementation of the Hospital Readmissions Reduction Program, including: (1) The selection of measures for the applicable conditions/procedures; (2) the calculation of the excess readmission ratio, which is used,

in part, to calculate the payment adjustment factor; (3) beginning in FY 2018, the calculation of the proportion of ''dually eligible'' Medicare beneficiaries (described below) which is used to stratify hospitals into peer groups and establish the peer group median excess readmission ratios (ERRs); (4) the calculation of the payment adjustment factor, specifically addressing the base operating DRG payment amount, aggregate payments for excess readmissions (including calculating the peer group median ERRs), aggregate payments for all discharges, and the neutrality modifier; (5) the opportunity for hospitals to review and submit corrections using a process similar to what is currently used for posting results on *Hospital Compare;* (6) the adoption of an extraordinary circumstances exception policy to address hospitals that experience a disaster or other extraordinary circumstance; (7) the clarification that the public reporting of excess readmission ratios will be posted on an annual basis to the *Hospital Compare* website as soon as is feasible following the Review and Correction period; and (8) the specification that the definition of ''applicable hospital'' does not include hospitals and hospital units excluded from the IPPS, such as LTCHs, cancer hospitals, children's hospitals, IRFs, IPFs, CAHs, and hospitals in Puerto Rico.

We also have codified certain requirements of the Hospital Readmissions Reduction Program at 42 CFR 412.152 through 412.154.

The Hospital Readmissions Reduction Program strives to put patients first by ensuring they are empowered to make decisions about their own healthcare along with their clinicians, using information from data-driven insights that are increasingly aligned with meaningful quality measures. We support technology that reduces costs and allows clinicians to focus on providing high quality health care for their patients. We also support innovative approaches to improve quality, accessibility, and affordability of care, while paying particular attention to improving clinicians' and beneficiaries' experiences when interacting with CMS programs. In combination with other efforts across the Department of Health and Human Services, we believe the Hospital Readmissions Reduction Program incentivizes hospitals to improve health care quality and value, while giving patients the tools and information needed to make the best decisions for them.

We note that we received public comments on the effectiveness and design of the Hospital Readmissions Reduction Program in response to the FY 2019 IPPS/LTCH PPS proposed rule. While we appreciate the commenters' feedback, because we did not include in the proposed rule any proposals related to these topics, we consider the public comments to be out of the scope of the proposed rule. Therefore, we are not addressing most of these comments in this final rule. All other topics that we consider to be out of scope of the proposed rule will be taken into consideration when developing policies and program requirements for future years.

Comment: Several commenters requested that CMS study the continued viability of the Hospitals Readmissions Reduction Program. Some commenters believed that certain level of readmissions may be necessary for patient care as defined by medical research on this subject, which means some of the program's measures may have reached the point of diminishing returns. Other commenters expressed concerns about the possibility of unintended patient consequences resulting from the Hospital Readmissions Reduction Program, such as the potential for mortality to increase as readmissions decrease. Some commenters requested that CMS and/or AHRQ undertake a study on any unintended consequences arising from the program.

Response: We believe that the Hospital Readmissions Reduction Program has successfully reduced readmissions which are both harmful to patients and costly for the health care system. Patient well-being is one of our highest priorities, and we welcome any research reports pertaining to the unintended consequences of the program. We are committed to monitoring any unintended consequences over time, such as the inappropriate shifting of care or increased patient morbidity and mortality, to ensure that the Hospital Readmissions Reduction Program improves the lives of patients and reduces cost.

Comment: Some commenters suggested that CMS review the Hospital Readmissions Reduction Program in the context of all quality improvement programs, determine whether the program is worth retaining, and assess whether the program has achieved its purpose or should give way to a new approach.

Response: As part of the Meaningful Measures Initiative, which we discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20404) and in greater detail below, we have taken a holistic approach to evaluating the appropriateness of the Hospital Readmissions Reduction Program's current measures in the context of the measures used in two other IPPS value-based purchasing programs. The focus of the Hospital Readmissions Reduction Program is on care coordination measures, which address the quality priority of promoting effective communication and care coordination within the Meaningful Measures Initiative. In addition, we will continue to monitor the program to ensure that each program is meeting its intended goals within the larger context of CMS' value-based purchasing programs.

We would like to clarify for the commenters that the Hospital Readmissions Reduction Program is required by statute, and we cannot decline to administer it.

Comment: Several commenters expressed concern that, under the Hospital Readmissions Reduction Program, hospitals can undertake and perform reasonable acts to avoid readmissions, but still be penalized because their performance might remain relatively worse when compared to peer group hospitals' performance.

Response: We understand the commenters' concern. We continue to encourage hospitals to reduce avoidable readmissions through proven care coordination and communications quality improvement tools, such as CMS Quality Improvement and Innovation Network efforts (*https://qioprogram.org/qionews/topics/care-coordination*).

However, we note that the basic readmissions payment adjustment formula for assessing readmissions and penalties under the Hospital Readmissions Reduction Program are specified in the Act, and we are required to implement the statute as written. In particular, the 21st Century Cures Act, which amended section 1886(q) of the Act, directs the Hospital Readmissions Reduction Program to develop a transitional methodology based on dual-eligible beneficiaries that allows for separate comparisons for hospitals within peer groups to determine a hospital's payment adjustment factor. It also allows the program to consider other risk-adjustment methodologies, taking into account studies conducted and recommendations made by the Secretary in reports required under section 2(d)(1) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act), Public Law 113–185. We will continue to review our risk-adjustment methodologies and monitor

our quality reporting and incentive programs for any unintended and negative consequences, and we will take the commenters' views into account when reviewing Hospital Readmissions Reduction Program data.

3. Summary of Policies for the Hospital Readmissions Reduction Program

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20403 through 20407), we proposed to: (1) Establish the applicable period for FY 2019, FY 2020 and FY 2021; (2) codify the previously adopted definition of ''dual-eligible''; (3) codify the previously adopted definition of ''proportion of dual-eligibles''; and (4) codify the previously adopted definition of ''applicable period for dual-eligibility.''

These proposals are described in more detail below.

4. Current Measures for FY 2019 and Subsequent Years

The Hospital Readmissions Reduction Program currently includes six applicable conditions/procedures: Acute myocardial infarction (AMI); heart failure (HF); pneumonia; total hip arthroplasty/total knee arthroplasty (THA/TKA); chronic obstructive pulmonary disease (COPD); and coronary artery bypass graft (CABG).

By publicly reporting quality data, we strive to prioritize patients by ensuring that they, along with their clinicians, are empowered to make decisions about their own healthcare using information aligned with meaningful quality measures. The Hospital Readmissions Reduction Program, together with the Hospital VBP Program and the HAC Reduction Program, represents a key component of the way that we bring quality measurement, transparency, and improvement together with value-based purchasing to the inpatient care setting. We have undertaken efforts to review the existing measure set in the context of these other programs, to identify how to reduce costs and complexity across programs while continuing to incentivize improvement in the quality and value of care provided to patients. To that end, we have begun reviewing our programs' measures in accordance with the Meaningful Measures Initiative that we described in section I.A.2. of the preambles of the proposed rule (82 FR 20167 through 20168) and this final rule.

As part of this review, we have taken a holistic approach to evaluating the appropriateness of the Hospital Readmissions Reduction Program's current measures in the context of the measures used in two other IPPS value-based purchasing programs (that is, the Hospital VBP Program and the HAC Reduction Program), as well as the Hospital IQR Program. We view the three value-based purchasing programs together as a collective set of hospital value-based purchasing programs. Specifically, we believe the goals of the three value-based purchasing programs (the Hospital VBP, Hospital Readmissions Reduction, and HAC Reduction Programs) and the measures used in these programs together cover the Meaningful Measures Initiative quality priorities of making care safer, strengthening person and family engagement, promoting coordination of care, promoting effective prevention and treatment, and making care affordable,—but that the programs should not add unnecessary complexity or costs associated with duplicative measures across programs. The Hospital Readmissions Reduction Program focuses on care coordination measures, which address the quality priority of promoting effective communication and care coordination within the Meaningful Measures Initiative. The HAC Reduction Program focuses on patient safety measures, which address the Meaningful Measures Initiative quality priority of making care safer by reducing harm caused in the delivery of care.

As part of this holistic quality payment program strategy, we believe the Hospital VBP Program should focus on the measurement priorities not covered by the Hospital Readmissions Reduction Program or the HAC Reduction Program. The Hospital VBP Program would continue to focus on measures related to: (1) The clinical outcomes, such as mortality and complications (which address the Meaningful Measures Initiative quality priority of promoting effective treatment); (2) patient and caregiver experience, as measured using the HCAHPS survey (which addresses the Meaningful Measures Initiative quality priority of strengthening person and family engagement as partners in their care); and (3) healthcare costs, as measured using the Medicare Spending per Beneficiary measure (which addresses the Meaningful Measures Initiative priority of making care affordable). We believe this framework will allow hospitals and patients to continue to obtain meaningful information about hospital performance and incentivize quality improvement while also streamlining the measure sets to reduce duplicative measures and program complexity so that the costs to hospitals associated with participating in these programs does not outweigh the benefits of improving beneficiary care.

Measures in the Hospital Readmissions Reduction Program are important markers of quality of care, particularly of the care of a patient in transition from an acute care setting to a non-acute care setting. By including these measures in the Program, we seek to encourage hospitals to address the serious problems indicated by the necessity of a hospital readmission and to reduce them and improve care coordination and communication. Therefore, after thoughtful review, we have determined that the six readmission measures in the Hospital Readmissions Reduction Program, which we proposed for removal from the Hospital IQR Program as discussed in section VIII.A.5.b.(3) of the preambles of the proposed rule and this final rule, are nevertheless appropriately included as part of the Hospital Readmissions Reduction Program.

We continue to believe that the measures that we have adopted adequately address the conditions and procedures specified in the Hospital Readmissions Reduction Program statute. Therefore, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20404), we did not propose to adopt any new measures.

We note that we received public comments on the program's measures and our holistic approach to the value-based purchasing program and the program's measures. Because we did not propose any measure changes to the program in the FY 2019 IPPS/LTCH PPS proposed rule, we consider these public comments out of the scope of the proposed rule and, therefore, we are not addressing most of them in this final rule. All other topics that we consider to be out of the scope of the proposed rule will be taken into consideration when developing policies and program requirements for future years. However, we address some public comments pertaining to our holistic review of the value-based purchasing programs below.

Comment: Some commenters supported CMS' holistic view of the various hospital value-based purchasing programs and quality reporting programs in an effort to ease provider reporting burden and better focus quality and patient safety efforts. The commenters agree that the reduction of duplicative measures across various programs will help streamline quality measure reporting for hospitals, enhance provider focus on important clinical outcomes, and reduce cost. Other commenters appreciated and encouraged the greater focus on outcome focus rather than process.

Response: We thank the commenters for their support.

Comment: One commenter requested that CMS ensure ample time is provided to the organizations for implementation of new processes such as data collection measures/processes, operations change to align with the Meaningful Measures Initiative, and CMS' holistic approach to the value-based purchasing programs.

Response: We thank the commenter for its comment. As changes occur to implement these initiatives, we will, to the greatest extent possible, work to operationalize our policies in the most seamless way possible. In instances where we expect disruption to stakeholders, we will welcome an ongoing conversation to ensure that providers can continue to focus on patients.

Comment: One commenter opposed removing Hospital Readmissions Reduction Program measures from the Hospital IQR Program because the commenter believed that measures should be initially adopted into the Hospital IQR Program to allow for a period of measure validation, and for health systems to gain familiarity with the measures before they are moved into value-based programs. Other commenters requested that CMS require that any measures newly added to the Hospital Readmissions Reduction Program be publicly reported either in the Hospital IQR Program or within the program without penalty implications for at least 1 year to ensure that hospitals have time to familiarize themselves with the measure and that there are no adverse unintended consequences of the measure use. One commenter urged CMS to not introduce measures with financial impact on providers until after an initial transition period that allows hospitals and CMS to become accustomed to reporting and measuring these items.

Response: We are cognizant of stakeholder concerns and understand the importance of providing hospitals with an opportunity to gain familiarity with a quality measure prior to its implementation in a payment program. We will consider how to best implement new measures in the payment programs before proposing additional measures for the programs, but we do not believe it is appropriate to address how we would adopt new measures into the program at this time. We note also that we did not propose to add any measures to the Hospital Readmissions Reduction Program in the FY 2019 IPPS/LTCH PPS proposed rule.

We received numerous comments from stakeholders regarding our holistic approach to evaluating the appropriateness of measures previously adopted under the Hospital Readmissions Reduction Program, the Hospital VBP Program, the HAC Reduction Program, and the Hospital IQR Program and our vision for the future of these programs. While program-specific comments and policies are discussed in more detail in each program-specific section of this final rule, we would like to clarify that, in light of our mission to prioritize patients in the provision of services, we are expanding the stated scope of the Hospital VBP Program to include patient safety measures. While we initially sought to delineate measure focus areas between the Hospital VBP Program and the HAC Reduction Program, we agree with commenters that patient safety is a critical component of quality improvement efforts. Therefore, we believe it is appropriate and important to provide incentives under more than one program to ensure that hospitals take every reasonable precaution to avoid adverse patient safety events. In addition, we believe including patient safety measures in both the HAC Reduction Program and the Hospital VBP Program will best promote transparency through publicly reporting hospital performance on these measures, as stakeholders will be able to see both hospitals' performance compared to all other hospitals and hospitals' performance improvement over time. Finally, we note that this approach will also reduce provider burden associated with safety measure data collection and reporting because these measures are being finalized for removal from the Hospital IQR Program, as discussed in section VIII.A.5.b.(2) of the preamble of this final rule.

Comment: One commenter expressed concern about unintended consequences of making care coordination the sole feature of the Hospital Readmissions Reduction Program and not related measures in an incentive program. This commenter believed that, without the possibility of receiving an incentive payment for performing well, hospitals outside of the penalty portion of the programs would cease trying to improve.

Response: We thank the commenter for its comment. The Hospital Readmissions Reduction Program scores a hospital's performance in relation to its peer institutions' performance. We believe that peer comparison provides appropriate incentives for hospitals to strive for continuous improvement in readmission rates, while also recognizing the impacts of hospital case-mix and other characteristics on a hospital's performance rates.

5. Maintenance of Technical Specifications for Quality Measures

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50039) for a discussion of the maintenance of technical specifications for quality measures for the Hospital Readmissions Reduction Program. Technical specifications of the readmission measures are provided on our website in the Measure Methodology Reports at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. Additional resources about the Hospital Readmissions Reduction Program and measure technical specifications are on the QualityNet website on the Resources page at: *http://www.qualitynet.org/dcs/ContentServer?=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772412995*.

6. Applicable Periods for FY 2019, FY 2020 and FY 2021

Under section 1886(q)(5)(D) of the Act, the Secretary has the authority to specify the applicable period with respect to a fiscal year under the Hospital Readmissions Reduction Program. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51671), we finalized our policy to use 3 years of claims data to calculate the readmission measures. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53675), we codified the definition of ''applicable period'' in the regulations at 42 CFR 412.152 as the 3-year period from which data are collected in order to calculate excess readmissions ratios and payment adjustment factors for the fiscal year, which includes aggregate payments for excess readmissions and aggregate payments for all discharges used in the calculation of the payment adjustment. The applicable period for dual-eligibles is the same as the applicable period that we otherwise adopt for purposes of the Program.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20405), for FY 2019, consistent with the definition specified at § 412.152, we proposed that the ''applicable period'' for the Hospital Readmissions Reduction Program would be the 3-year period from July 1, 2014 through June 30, 2017. In other words, we proposed that the proportion of dual-eligibles, excess readmissions ratios and the payment adjustment factors (including aggregate payments for excess readmissions and aggregate payments for all discharges) for FY 2019 would be calculated using data for

discharges occurring during the 3-year period of July 1, 2014 through June 30, 2017.

In the FY 2019 IPPS/LTCH PPS proposed rule, for FY 2020, consistent with the definition specified at § 412.152, we proposed that the ''applicable period'' for the Hospital Readmissions Reduction Program would be the 3-year period from July 1, 2015 through June 30, 2018. As noted earlier, we define the applicable period for dual-eligibles as the applicable period that we otherwise adopted for purposes of the Program; therefore, for FY 2020, the applicable period for dual-eligibles would be the 3-year period from July 1, 2015 through June 30, 2018.

In addition, in the FY 2019 IPPS/LTCH PPS proposed rule, for FY 2021, consistent with the definition specified at § 412.152, we proposed that the ''applicable period'' for the Hospital Readmissions Reduction Program would be the 3-year period from July 1, 2016 through June 30, 2019. The applicable period for dual-eligibles for FY 2021 would similarly be the 3-year period from July 1, 2016 through June 30, 2019.

Comment: Some commenters supported the applicable periods for FY 2019, FY 2020, and FY 2021 as proposed.

Response: We thank commenters for their support.

Comment: Some commenters expressed concern about the proposed performance period for FY 2019 because it combines data collected under both the ICD–9 and ICD–10 coding sets. Commenters also requested that CMS provide further empirical analysis in the final rule to show that measure reliability and validity are not compromised by using two different coding systems and ensure that the ICD–10 versions of the measures in the Hospital Readmissions Reduction Program are NQF-endorsed as soon as practicable.

Response: As we stated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38223), the readmission measures in the Hospital Readmissions Reduction Program all completed ''maintenance of endorsement,'' a periodic evaluation of measures to assess impact and potential unintended consequences, in December 2016 and are NQF-endorsed. The NQF requires developers to submit all ICD–9 and ICD–10 diagnosis and procedure codes used to define the measure cohorts. We identified all ICD–10 codes that corresponded with ICD–9 codes used in the measure cohort definitions using the General Equivalence Mappings tool (GEMs). The ICD–10 codes identified using GEMs were reviewed by measure and clinical experts and made public as a part of the maintenance of endorsement process. We will submit testing results in claims data coded with ICD–10 in future cycles of NQF endorsement maintenance.

In addition, we have examined changes in risk-standardized readmission rates at the hospital level and the distribution of changes in rates for all claims-based readmission measures, comparing the results of the 2015, 2016, 2017, and 2018 reporting periods. These analyses suggest no more than typical year-to-year variability in hospital-level rates before and after the introduction of ICD–10 codes for most measures. Year-to-year changes between 2015 and 2016, which both contained only ICD–9 claims, are similar to year-to-year changes for the following years, which included a mix of ICD–9 and ICD–10 claims. Risk-standardized readmission rates for 2018 public reporting are similar to those for 2015, 2016, and 2017 public reporting, which also indicates that the results using ICD–9 codes and ICD–10 codes are comparable. Overall, these results suggest that we have successfully created measure specifications in ICD–10 that align with the intent of the measure, which allows us to compare rates with measures calculated using ICD–9 codes and ICD–10 codes.

We will continue to use a 3-year measurement period rather than a 1-year measurement period, despite the implementation of ICD–10. We use a 3-year measurement period because some small and rural hospitals do not have at least 25 admissions for Medicare FFS patients who are 65 years and older for each of the measure conditions in a single year or even over the course of 2 years. The 3-year period allows us to include the maximum possible number of hospitals in scoring and public reporting.

Comment: One commenter encouraged CMS to include feedback from providers and other stakeholders through previewing model results prior to releasing hospital-specific reports.

Response: We thank commenter for its input. We agree with the need for transparency and providing stakeholders with data to confirm their dual proportion assignment. We also are seeking input from stakeholders and considering different options to provide hospitals with early individualized feedback regarding their peer grouping and payment adjustment.

Comment: One commenter believed that a 1-year performance period is more appropriate than the 3-year period because a 3-year performance period is too long, as some hospitals may demonstrate significant improvement year-over-year and it requires the combination of data from ICD–9 and ICD–10. Another commenter believed the lag time between actual performance and public reporting is troublesome as patients and hospitals may be relying on stale data. This commenter further recommended the consideration of electronic health records (EHRs) to derive more accurate and timely metrics.

Response: We continue to believe the 3-year period as codified at 42 CFR 412.152 is appropriate. We use a 3-year period of index admissions to increase the number of cases per hospital used for measure calculation, which improves the precision of each hospital's readmission estimate. While this approach utilizes older data, it also identifies more variation in hospital performance and still allows for improvement from one year of reporting to the next. We are maintaining the 3-year period as previously adopted because we continue to believe it balances the needs for the most recent claims and for sufficient time to process the claims data and calculate the measures to meet the program implementation timeline. With respect to EHRs, the Hospital Readmissions Reduction Program relies on claims data; therefore, we question whether EHRs would provide much more timely information.

After consideration of the public comments we received, we are finalizing as proposed, without modification, the applicable period of the 3-year time period of July 1, 2014 through June 30, 2017 for FY 2019; the applicable period of the 3-year time period July 1, 2015 through June 30, 2018 for FY 2020; and the applicable period of the 3-year time period of July 1, 2016 through June 30, 2019 for FY 2021 to calculate readmission payment adjustment factor for FYs 2019, FY 2020, and FY 2021, respectively, under the Hospital Readmissions Reduction Program.

7. Identification of Aggregate Payments for Each Condition/Procedure and All Discharges

When calculating the numerator (aggregate payments for excess readmissions), we determine the base operating DRG payment amount for an individual hospital for the applicable period for such condition/procedure, using Medicare inpatient claims from the MedPAR file with discharge dates that are within the applicable period. Under our established methodology, we use the update of the MedPAR file for each Federal fiscal year, which is updated 6 months after the end of each

Federal fiscal year within the applicable period, as our data source.

In identifying discharges for the applicable conditions/procedures to calculate the aggregate payments for excess readmissions, we apply the same exclusions to the claims in the MedPAR file as are applied in the measure methodology for each of the applicable conditions/procedures. For the FY 2019 applicable period, this includes the discharge diagnoses for each applicable condition/procedure based on a list of specific ICD–9–CM or ICD–10–CM and ICD–10–PCS code sets, as applicable, for that condition/procedure, because diagnoses and procedure codes for discharges occurring prior to October 1, 2015 were reported under the ICD–9–CM code set, while discharges occurring on or after October 1, 2015 (FY 2016) were reported under the ICD–10–CM and ICD–10–PCS code sets.

We only identify Medicare FFS claims that meet the criteria described above for each applicable condition/procedure to calculate the aggregate payments for excess readmissions (that is, claims paid for under Medicare Part C or Medicare Advantage, are not included in this calculation). This policy is consistent with the methodology to calculate excess readmissions ratios based solely on admissions and readmissions for Medicare FFS patients. Therefore, consistent with our established methodology, for FY 2019, we proposed to continue to exclude admissions for patients enrolled in Medicare Advantage as identified in the Medicare Enrollment Database.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20405), for FY 2019, we proposed to determine aggregate payments for excess readmissions, aggregate payments for all discharges using data from MedPAR claims with discharge dates that are on or after July 1, 2014, and no later than June 30, 2017. As we stated in FY 2018 IPPS/LTCH PPS final rule (82 FR 38232), we will determine the neutrality modifier using the most recently available full year of MedPAR data. However, we noted that, for the purpose of modeling the proposed FY 2019 readmissions payment adjustment factors for the proposed rule, we used the proportion of dual-eligibles, excess readmissions ratios, and aggregate payments for each condition/procedure and all discharges for applicable hospitals from the FY 2018 Hospital Readmissions Reduction Program applicable period. For the FY 2019 program year, applicable hospitals will have the opportunity to review and correct calculations based on the proposed FY 2019 applicable period of July 1, 2014 to June 30, 2017, before they are made public under our policy regarding reporting of hospital-specific information. Again, we reiterate that this period is intended to review the program calculations, and not the underlying data. For more information on the review and corrections process, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53399 through 53401).

In the proposed rule, for FY 2019, we proposed to use MedPAR data from July 1, 2014 through June 30, 2017 for FY 2019 Hospital Readmissions Reduction Program calculations. Specifically, for the final rule, we proposed to use the following MedPAR files—

- March 2015 update of the FY 2014 MedPAR file to identify claims within FY 2014 with discharges dates that are on or after July 1, 2014;
- March 2016 update of the FY 2015 MedPAR file to identify claims within FY 2015;
- March 2017 update of the FY 2016 MedPAR file to identify claims within FY 2016;
- March 2018 update of the FY 2017 MedPAR file to identify claims within FY 2017.

We did not receive any public comments on our proposal to use of the above stated MedPAR files, and therefore are finalizing as proposed, without modification, the use of the above listed MedPAR files to identify claims.

As discussed earlier, the final FY 2019 readmissions payment adjustment factors are not available at this time because hospitals have not yet had the opportunity to review and correct the data (program calculations based on the FY 2019 applicable period of July 1, 2014 to June 30, 2017) before the data are made public under our policy regarding the reporting of hospital-specific data. After hospitals have been given an opportunity to review and correct their calculations for FY 2019, we will post Table 15 (which will be available via the internet on the CMS website) to display the final FY 2019 readmissions payment adjustment factors that will be applicable to discharges occurring on or after October 1, 2018. We expect Table 15 will be posted on the CMS website in the fall of 2018.

8. Calculation of Payment Adjustment Factors for FY 2019 and Codification of Certain Definitions

As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38226), section 1886(q)(3)(D) of the Act requires the Secretary to group hospitals and apply a methodology that allows for separate comparisons of hospitals within peer groups in determining a hospital's adjustment factor for payments applied to discharges beginning in FY 2019.

To implement this provision, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38226 through 38237), we finalized several changes to the payment adjustment methodology for FY 2019. First, we finalized that an individual would be counted as a full-benefit dual-eligible patient if the beneficiary was identified as full-benefit dual status in the State Medicare Modernization Act (MMA) files for the month he/she was discharged from the hospital (82 FR 38226 through 38228). Second, we finalized our policy to define the proportion of full benefit dual-eligible beneficiaries as the proportion of dual-eligible patients among all Medicare FFS and Medicare Advantage stays (82 FR 38226 through 38228). Third, we finalized our policy to define the data period for determining dual-eligibility as the 3-year data period corresponding to the Program's applicable period (82 FR 38229). Fourth, we finalized our policy to stratify hospitals into quintiles, or five peer groups, based on their proportion of dual-eligible patients (82 FR 38229 through 38231). Finally, we finalized our policy to use the median Excess Readmission Ratio (ERR) for the hospital's peer group in place of 1.0 in the payment adjustment formula and apply a uniform modifier to maintain budget neutrality (82 FR 38231 through 38237). The payment adjustment formula would then be:

$$P = 1 - \min\{.03, \sum_{dx} \frac{NM * Payment(dx) * \max\{(\text{ERR(dx)} - \text{Median peer group ERR(dx)}),0\})}{All\ payments}\}$$

where dx is AMI, HF, pneumonia, COPD, THA/TKA or CABG and payments refers to the base operating DRG payments. The payment reduction (1–P) resulting from use of the median ERR for the peer group is scaled by a

neutrality modifier (NM) to achieve budget neutrality. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38226 through 38237) for a detailed discussion of the changes to the payment adjustment methodology, including alternatives considered, for FY 2019. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20406), we did not propose any changes to the methodology for FY 2019 or subsequent years. However, we proposed to codify our previously finalized definitions of ''applicable period for dual-eligibility'', ''dual-eligible'', and ''proportion of dual-eligibles'' at 42 CFR 412.152. The definitions which we proposed to codify are as follows:

- ''Applicable period for dual-eligibility'' is the 3-year data period corresponding to the applicable period as established by the Secretary for the Hospital Readmissions Reduction Program.
- ''Dual-eligible'' is a patient beneficiary who has been identified as having full benefit status in both the Medicare and Medicaid programs in the State MMA files for the month the beneficiary was discharged from the hospital.
- ''Proportion of dual-eligibles'' is the number of dual-eligible patients among all Medicare FFS and Medicare Advantage stays during the applicable period.

Comment: One commenter supported the proposal to codify the previously finalized definitions of applicable period for dual-eligibility, dual-eligible, and proportion of dual-eligibles. Several commenters supported the codification of previously adopted definitions for dual-eligibles to better assess disparate outcomes across patient populations at a given hospital.

Response: We thank commenters for their support.

Comment: Some commenters opposed the use of Medicare Advantage (MA) patients in the proportion of dual-eligibles definition and stated that CMS should base the peer group only on the share of FFS patients that are fully dual eligible, not on the share of all (FFS and MA) patients because the penalty does not apply to readmissions of MA patients. The commenters asserted that their risk characteristics could distort the risk profiles of hospitals because the income characteristics of FFS and MA patients may differ for particular hospitals. Other commenters opposed the use of dual-eligible as the basis for determining socioeconomic status because it does not necessarily reflect demographic or economic factors and conditions where the hospital is located or the patient resides.

Response: We would like to clarify that we did not propose any changes to the definition of dual-eligible; we merely proposed to codify it. As we stated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38221), we finalized using FFS and MA patients because calculating the dual proportion among all Medicare FFS and managed care patients more accurately represents the dual status of the hospital, particularly for hospitals in States with high managed care penetration rates. This approach enables more accurate and complete risk profiles for hospitals. There is a strong relationship between dual proportion and penalties under both the current methodology and proposed approaches, whether hospitals are stratified based on Medicare FFS patients only or based on both Medicare FFS and managed care patients. In general, this relationship is similarly positive; hospitals with higher dual proportions by either definition incur larger penalties, on average. However, the relationship between the penalty share of payments and dual proportion among FFS and managed care patients exhibits a slightly stronger upward trend. We refer readers to FY 2018 IPPS/LTCH PPS final rule (82 FR 38228 through 38229) for more information. Further, the statute directs the Secretary to use dual-eligibles to assign the peer groups during this transitional phase of risk-adjustment.

We did not propose changes with respect to our previously finalized proposals. However, commenters provided many suggestions on the Hospital Readmissions Reduction Program's risk-adjustment methodology. While we appreciate the commenters' feedback, we consider these topics to be out of the scope of the proposed rule. Therefore, we are not addressing most of them in this final rule. However, because there is stakeholder interest in this topic, we have included summaries of some of these comments with responses below. All other topics that we consider to be out of the scope of the proposed rule, even if not addressed below, will be taken into consideration when developing policies and program requirements for future years.

Comment: Some commenters supported the previously adopted payment adjustment methodology for FY 2019, which implemented the transitional methodology required by the 21st Century Cures Act. Commenters supported appropriate risk-adjustment methodology for the Hospital Readmissions Reduction Program. Commenters also supported organizing hospitals into peer groups and evaluating their performance in comparison to similar hospitals.

Response: We thank the commenters for their support.

Comment: Some commenters supported accounting for social risk factors in quality programs through peer grouping.

Response: We thank the commenters for their support.

Comment: One commenter recommended that, instead of peer groups, CMS find ways to direct additional resources to hospitals that serve the most disadvantaged populations to achieve health equity.

Response: We do not believe there is a provision in the statute that authorizes the Program to provide direct resources to hospitals. However, subparagraphs (D) and (E) to section 1886(q)(3) of the Act direct the Secretary to assign hospitals to peer groups, develop a methodology that allows for separate comparisons for hospitals within these groups, and allows for changes in the risk adjustment methodology. Following this transitional methodology, the Secretary is allowed to consider the recommendations in the reports required by the IMPACT Act related to risk adjustment and social risk factors to determine improved risk adjustment, but is not authorized to provide direct support to hospitals. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38221 through 38222) for more information. We also note that many programs throughout HHS, run by CMS and other agencies, provide funding and support for ''safety net hospitals.''

Comment: Some commenters questioned whether five peer groups were the appropriate number of peer groups and whether there should be more peer groups. One commenter reiterated its recommendations to use statistical analysis to create what it posits as a more natural distribution of provider performance than quintiles. Another commenter provided a different statistical approach to determine hospital groupings. Commenters urged CMS to continuously evaluate this peer groupings to avoid unintended consequences.

Response: We would like to clarify that we did not propose any changes to the policy for five peer groups. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38229 through 38231), we finalized stratifying hospitals into quintiles (five peer groups) because that policy creates peer groups that accurately reflect the relationship between the proportion of dual-eligible patients in the hospital's population without the disadvantage of establishing a larger number of peer groups. We continue to believe

preselecting peer groups of equal size and choosing the size that best meets these objectives is transparent and effective. In the future, more flexible methods for peer group formation may be considered for implementation. Any approach must be evaluated based on multiple criteria, including those described above and proposed through the rulemaking process.

Comment: Some commenters supported assignment of hospitals to peer groups (quintiles) as a first step of accounting for social risk factors, but encouraged CMS to continue to work with stakeholders to develop appropriate risk-adjustment methodologies. Commenters believed that stratifying performance by the hospital's number of dual-eligible patients is only a temporary solution, and recommended that CMS take steps to ensure that individual measures account for socio-demographic status (SDS) in the measure level risk adjustment model. Commenters asked CMS to consider whether it should continue to use dual-eligibility as an adjustment variable and whether it should move from the current peer grouping approach to one that incorporates one or more socioeconomic variables into the risk-adjustment model of Hospital Readmissions Reduction Program measures. Commenters supported CMS' efforts to adjust for socioeconomic factors. However, these commenters urged continued refinements to stay current with evolving measurement science around accounting for social risk factors.

Response: As required by the 21st Century Cures Act, we are stratifying hospitals based on dual-eligible proportion and modifying the payment adjustment factor formula to assess a hospital's performance relative to other hospitals in its peer group. This approach is transparent. We believe this approach achieves both the goal of holding all hospitals to a high standard while also ensuring we are not disproportionally penalizing hospitals serving an at-risk population. Section 1886(q)(3)(E)(i) of the Act allows the Secretary to consider studies conducted and recommendations made by the Secretary under section 2(d)(1) of the IMPACT Act in the application of risk adjustment methodologies. We will continue to monitor the progress and findings of research the Assistant Secretary for Planning and Evaluation (ASPE) is conducting as part of its IMPACT Act study and the National Quality Forum's trial period and will consider their recommendations. We also will continue to monitor the impact of accounting for dual-eligible patients in the Hospital Readmissions Reduction Program and evaluate whether future changes to include other variables or adjustments are needed. For more information, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38221 through 38222).

Comment: Some commenters believed that peer grouping by dual-eligibility has limitations or flaws limitations as a risk-adjustment method, and urged CMS to consider whether it should continue to use dual-eligibility as the adjustment variable and whether to move from the current peer grouping approach to one in which it incorporates one or more socioeconomic variables into the risk adjustment models of the Hospital Readmissions Reduction Program measures (that is, direct risk adjustment). Commenters encouraged CMS to review the evolving measurement science continually and consider NQF and National Academy of Medicine concepts as it considers best ways to risk-adjust quality measures for social factors. Other commenters urged CMS to include factors related to a patient's background—including SDS, language, and post-discharge support structure—in measure development and risk-adjustment methodology. Still other commenters recommended that CMS use census data, distressed community index, or location information to determine socioeconomic adjustment.

Response: We will continue to monitor the impact of accounting for dual-eligible patients in the Hospital Readmissions Reduction Program and evaluate whether future changes to include other variables or adjustments are needed. As we have previously noted, the Hospital Readmissions Reduction Program is required by section 1886(q)(3)(D) of the Act to use dual-eligible beneficiaries for hospital's adjustment factor beginning in FY 2019, and until the application of section 1886(q)(3)(E)(i) of the Act, at which point the Secretary may consider other risk-adjustment methodologies, taking into account the reports mandated by the IMPACT Act. The second and final report is scheduled for release in October 2019. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38221 through 38222) for more information.

Comment: One commenter urged CMS to not use social risk factors to adjust quality measures for transparency and payment.

Response: We thank the commenter for its comment. However, we note Congress mandated that the Hospital Readmissions Reduction Program account for social risk factors when it added subparagraphs (D) and (E) to section 1886(q)(3) of the Act directing the Secretary to assign hospitals to peer groups, develop a methodology that allows for separate comparisons for hospitals within these groups, and allows for changes in the risk adjustment methodology. As we have noted previously, the goal of risk adjustment is to account for factors that are inherent to the patient at the time of admission, such as severity of disease to put hospitals on a level playing field. The measures should not be risk-adjusted to account for differences in practice patterns that lead to lower or higher risk for patients to be readmitted. The measures aim to reveal differences related to the patterns of care.

After consideration of the public comments we received, we are finalizing as proposed, without modification, our decision to codify the definitions of ''applicable period for dual-eligibility''; ''dual-eligible''; and ''proportion of dual-eligibles'' as stated above at 42 CFR 412.152.

9. Calculation of Payment Adjustment for FY 2019

Section 1886(q)(3)(A) of the Act defines the payment adjustment factor for an applicable hospital for a fiscal year as equal to the greater of: (i) The ratio described in subparagraph (B) for the hospital for the applicable period (as defined in paragraph (5)(D)) for such fiscal year; or (ii) the floor adjustment factor specified in subparagraph (C). Section 1886(q)(3)(B) of the Act, in turn, describes the ratio used to calculate the adjustment factor. Specifically, it states that the ratio is equal to 1 minus the ratio of—(i) the aggregate payments for excess readmissions, and (ii) the aggregate payments for all discharges, scaled by the neutrality modifier. The calculation of this ratio is codified at § 412.154(c)(1) of the regulations and the floor adjustment factor is codified at § 412.154(c)(2) of the regulations. Section 1886(q)(3)(C) of the Act specifies the floor adjustment factor at 0.97 for FY 2015 and subsequent fiscal years.

Consistent with section 1886(q)(3) of the Act, codified in our regulations at § 412.154(c)(2), for FY 2019, the payment adjustment factor will be either the greater of the ratio or the floor adjustment factor of 0.97. Under our established policy, the ratio is rounded to the fourth decimal place. In other words, for FY 2019, a hospital subject to the Hospital Readmissions Reduction Program would have an adjustment factor that is between 1.0 (no reduction) and 0.9700 (greatest possible reduction).

Comment: One commenter supported budget neutral adjustment approach directed by the 21st Century Cures Act.

Response: We thank the commenter for its support.

Comment: Another commenter addressed what it believed is a methodological flaw in the statutory design of the penalty calculation. However, this commenter agreed that only Congress has the authority to amend the statute to correct the calculations.

Response: We thank the commenter for the feedback. As the commenter noted, we are bound by the statute's direction.

After consideration of the public comments we received, we are finalizing as proposed, without modification, the calculation of payment adjustment for FY 2019.

10. Accounting for Social Risk Factors in the Hospital Readmissions Reduction Program

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20406 through 20407), we discussed accounting for social risk factors in the Hospital Readmissions Reduction Program.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38237 through 38239), we discussed the importance of improving beneficiary outcomes including reducing health disparities. We also discussed our commitment to ensuring that medically complex patients, as well as those with social risk factors, receive excellent care. We discussed how studies show that social risk factors, such as being near or below the poverty level as determined by HHS, belonging to a racial or ethnic minority group, or living with a disability, can be associated with poor health outcomes and how some of this disparity is related to the quality of health care.[230] Among our core objectives, we aim to improve health outcomes, attain health equity for all beneficiaries, and ensure that complex patients as well as those with social risk factors receive excellent care. Within this context, reports by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academy of Medicine have examined the influence of social risk factors in CMS value-based purchasing programs.[231] As we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38404), ASPE's report to Congress found that, in the context of value-based purchasing programs, dual eligibility was the most powerful predictor of poor health care outcomes among those social risk factors that they examined and tested. In addition, as we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38237), the National Quality Forum (NQF) undertook a 2-year trial period in which certain new measures and measures undergoing maintenance review have been assessed to determine if risk adjustment for social risk factors is appropriate for these measures.[232] The trial period ended in April 2017 and a final report is available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*. The trial concluded that ''measures with a conceptual basis for adjustment generally did not demonstrate an empirical relationship'' between social risk factors and the outcomes measured. This discrepancy may be explained in part by the methods used for adjustment and the limited availability of robust data on social risk factors. NQF has extended the socioeconomic status (SES) trial,[233] allowing further examination of social risk factors in outcome measures.

In the FY 2018 and CY 2018 proposed rules for our quality reporting and value-based purchasing programs, we solicited feedback on which social risk factors provide the most valuable information to stakeholders and the methodology for illuminating differences in outcomes rates among patient groups within a hospital or provider that would also allow for a comparison of those differences, or disparities, across providers. Feedback we received across our quality reporting programs included encouraging CMS to explore whether factors could be used to stratify or risk adjust the measures (beyond dual eligibility); considering the full range of differences in patient backgrounds that might affect outcomes; exploring risk adjustment approaches; and offering careful consideration of what type of information display would be most useful to the public.

We also sought public comment on confidential reporting and future public reporting of some of our measures stratified by patient dual eligibility. In general, commenters noted that stratified measures could serve as tools for hospitals to identify gaps in outcomes for different groups of patients, improve the quality of health care for all patients, and empower consumers to make informed decisions about health care. Commenters encouraged us to stratify measures by other social risk factors such as age, income, and educational attainment. With regard to value-based purchasing programs, commenters also cautioned to balance fair and equitable payment while avoiding payment penalties that mask health disparities or discouraging the provision of care to more medically complex patients. Commenters also noted that value-based payment program measure selection, domain weighting, performance scoring, and payment methodology must account for social risk.

As a next step, CMS is considering options to improve health disparities among patient groups within and across hospitals by increasing the transparency of disparities as shown by quality measures. We also are considering how this work applies to other CMS quality programs in the future. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409) for more details, where we discuss the potential stratification of certain Hospital IQR Program outcome measures. Furthermore, we continue to consider options to address equity and disparities in our value-based purchasing programs.

We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

While we did not specifically request public comment on social risk factors in the FY 2019 IPPS/LTCH PPS proposed rule, we received a number of comments with respect to social risk factors. We thank commenters for sharing their views and their willingness to support the efforts of CMS and NQF on this important issue. We will take this feedback into account as we continue to review social risk factors on an ongoing and continuous basis. In addition, we both welcome and appreciate stakeholder feedback as we continue our work on these issues.

[230] See, for example United States Department of Health and Human Services. ''Healthy People 2020: Disparities. 2014.'' Available at: *http://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities*; or National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: National Academies of Sciences, Engineering, and Medicine 2016.

[231] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.'' December 2016. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs*.

[232] Available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*.

[233] Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86357*.

I. Hospital Value-Based Purchasing (VBP) Program: Policy Changes

1. Background

a. Statutory Background and Overview of Past Program Years

Section 1886(o) of the Act, as added by section 3001(a)(1) of the Affordable Care Act, requires the Secretary to establish a hospital value-based purchasing program (the Hospital VBP Program) under which value-based incentive payments are made in a fiscal year (FY) to hospitals that meet performance standards established for a performance period for such fiscal year. Both the performance standards and the performance period for a fiscal year are to be established by the Secretary.

For more of the statutory background and descriptions of our current policies for the Hospital VBP Program, we refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26490 through 26547); the FY 2012 IPPS/LTCH PPS final rule (76 FR 51653 through 51660); the CY 2012 OPPS/ASC final rule with comment period (76 FR 74527 through 74547); the FY 2013 IPPS/LTCH PPS final rule (77 FR 53567 through 53614); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50676 through 50707); the CY 2014 OPPS/ASC final rule (78 FR 75120 through 75121); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50048 through 50087); the FY 2016 IPPS/LTCH PPS final rule (80 FR 49544 through 49570); the FY 2017 IPPS/LTCH PPS final rule (81 FR 56979 through 57011); the CY 2017 OPPS/ASC final rule with comment period (81 FR 79855 through 79862); and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38240 through 38269).

We also have codified certain requirements for the Hospital VBP Program at 42 CFR 412.160 through 412.167.

b. FY 2019 Program Year Payment Details

Section 1886(o)(7)(B) of the Act instructs the Secretary to reduce the base operating DRG payment amount for a hospital for each discharge in a fiscal year by an applicable percent. Under section 1886(o)(7)(A) of the Act, the sum total of these reductions in a fiscal year must equal the total amount available for value-based incentive payments for all eligible hospitals for the fiscal year, as estimated by the Secretary. We finalized details on how we would implement these provisions in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53571 through 53573), and we refer readers to that rule for further details.

Under section 1886(o)(7)(C)(iv) of the Act, the applicable percent for the FY 2019 program year is 2.00 percent. Using the methodology we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53571 through 53573), we estimate that the total amount available for value-based incentive payments for FY 2019 is approximately $1.9 billion, based on the March 2018 update of the FY 2017 MedPAR file.

As finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53573 through 53576), we will utilize a linear exchange function to translate this estimated amount available into a value-based incentive payment percentage for each hospital, based on its Total Performance Score (TPS). We will then calculate a value-based incentive payment adjustment factor that will be applied to the base operating DRG payment amount for each discharge occurring in FY 2019, on a per-claim basis. We published proxy value-based incentive payment adjustment factors in Table 16 associated with the FY 2019 IPPS/LTCH PPS proposed rule (which is available via the internet on the CMS website). We are publishing updated proxy value-based incentive payment adjustment factors in Table 16A associated with this final rule (which is available via the internet on the CMS website). The proxy factors are based on the TPS from the FY 2018 program year. These FY 2018 performance scores are the most recently available performance scores hospitals have been given the opportunity to review and correct. The updated slope of the linear exchange function used to calculate the proxy value-based incentive payment adjustment factors in Table 16A is 2.8887004713. This slope, along with the estimated amount available for value-based incentive payments, has been updated based on the March 2018 update to the FY 2017 MedPAR file and is also published in Table 16A (which is available via the internet on the CMS website).

After hospitals have been given an opportunity to review and correct their actual TPSs for FY 2019, we will post Table 16B (which will be available via the internet on the CMS website) to display the actual value-based incentive payment adjustment factors, exchange function slope, and estimated amount available for the FY 2019 program year. We expect Table 16B will be posted on the CMS website in the fall of 2018.

2. Retention and Removal of Quality Measures

a. Retention of Previously Adopted Hospital VBP Program Measures and Clarification of the Relationship Between the Hospital IQR and Hospital VBP Program Measure Sets

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53592), we finalized a policy to retain measures from prior program years for each successive program year, unless otherwise proposed and finalized. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20408), we did not propose any changes to this policy.

In the FY 2019 IPPS/LTCH/PPS proposed rule (83 FR 20408), we proposed to revise our regulations at 42 CFR 412.164(a) to clarify that once we have complied with the statutory prerequisites for adopting a measure for the Hospital VBP Program (that is, we have selected the measure from the Hospital IQR Program measure set and included data on that measure on *Hospital Compare* for at least one year prior to its inclusion in a Hospital VBP Program performance period), the Hospital VBP statute does not require that the measure continue to remain in the Hospital IQR Program. We stated that the proposed revision to the regulation text would clarify that Hospital VBP Program measures will be selected from the measures specified under the Hospital IQR Program, but the Hospital VBP Program measure set will not necessarily be a subset of the Hospital IQR Program measure set. As discussed in section I.A.2. of the preamble of this final rule, we are engaging in efforts aimed at evaluating and streamlining regulations with the goal to reduce unnecessary costs, increase efficiencies, and improve beneficiary experience. In the FY 2019 IPPS/LTCH PPS proposed rule, we stated that this proposal would reduce costs, such as those discussed in section IV.I.2.b. of the preamble of the proposed rule, by allowing us to remove duplicative measures from the Hospital IQR Program that are retained in the Hospital VBP Program.

Comment: A number of commenters supported CMS' proposal to revise its regulations to clarify that once CMS has complied with the statutory prerequisites for the Hospital VBP Program, the Hospital VBP Program statute does not require that a measure continue to remain in the Hospital IQR Program. These commenters agreed that clarifying these statutory requirements would reduce the complexity and costs associated with maintaining duplicative measures across CMS quality programs.

One commenter also expressed its belief that this clarification would allow for more focused quality improvement efforts by hospitals and result in streamlined public reporting, which would be easier for the public to understand.

Response: We thank the commenters for their support.

Comment: Some commenters did not support CMS' proposal to clarify the Hospital VBP Program's regulations. These commenters expressed their belief that CMS lacks the statutory authority to remove a measure from the Hospital IQR Program that is being used in the Hospital VBP Program, and further asserted that removing such a measure would undermine the statutory requirements that created and preserve the Hospital IQR Program. Other commenters stated that initially adopting measures into the Hospital IQR Program allows for a period of measure validation and for health systems to gain familiarity with the measures before they are moved into value-based purchasing programs, and expressed concern CMS' ''holistic'' view would allow new measures to be adopted immediately into the value-based purchasing programs without this time for familiarization and validation. These commenters stated their belief that adopting measures directly into the value-based purchasing programs would result in significant harm, undue hardship, and potentially financial penalties on healthcare systems.

Other commenters expressed confusion regarding the proposed revisions to the Hospital VBP Program's regulatory text, and requested clarification about whether measures would continue to be adopted in the Hospital IQR Program and publicly reported on *Hospital Compare* for one year prior to adoption in the Hospital VBP Program.

Response: We thank the commenters for their comments, but emphasize that our proposal to revise the Hospital VBP Program regulations at 42 CFR 412.164(a) does not affect the underlying statutory requirements of the Hospital VBP or Hospital IQR Programs. As required under sections 1886(o)(2)(A) and 1886(o)(2)(C)(i) of the Act, we will continue to select measures for the Hospital VBP Program that have been specified for the Hospital IQR Program and refrain from beginning the performance period for any new measure until the data on that measure have been posted on *Hospital Compare* for at least one year. We note the statute does not require a measure that has met these statutory requirements to remain in the Hospital IQR Program at the same time as the Hospital VBP Program. The proposed revisions to the regulatory text only clarify that after a measure has met the above requirements and been adopted into the Hospital VBP Program measure set, it can be removed from the Hospital IQR Program measure set. We, therefore, disagree that this revision could result in harm, undue hardship, or financial penalties to hospitals because it does not alter the processes associated with adopting a new measure into the Hospital VBP Program.

We also disagree that removing measures from the Hospital IQR Program after adoption by the Hospital VBP Program undermines the Hospital IQR Program's statutory requirements or purpose. The Hospital IQR Program will continue to serve as the primary quality reporting program for the inpatient hospital setting of care, and its authority to collect and report data is unaffected by this revision to the Hospital VBP Program's regulatory text. We believe removing certain measures from the Hospital IQR Program that have transitioned to the Hospital VBP Program will better enable the Hospital IQR Program to consider new quality measures and collect and publicly report these data for both patients and providers without imposing an unduly high burden on providers.

Comment: A number of commenters did not support CMS' proposal to clarify the Hospital VBP Program's regulations due to concerns this clarification would reduce transparency in public reporting. Some commenters noted that the Hospital IQR Program publicly reports measure performance data but the Hospital VBP Program only reports program-specific performance scores for its measures and domains, which are not meaningful to consumers and are only indirectly tied to actual data. These commenters, therefore, expressed concern that the Hospital VBP Program's current public reporting is an insufficient substitute for the Hospital IQR Program's measure-specific reporting. A few commenters also noted that the Hospital IQR Program and *Hospital Compare* have a carefully outlined process for reviewing measure data with hospitals before releasing that data to the public, and expressed their belief that measures must be in the Hospital IQR Program in order to undergo this process. One commenter observed that the Hospital VBP Program is built around the Hospital IQR Program reporting infrastructure to establish a progression of measures to promote higher quality of care, and should be maintained as such. A number of commenters requested CMS ensure that measure-level results continue to be reported on *Hospital Compare* for all measures in the Hospital VBP program to ensure that there is no loss of information to the public. One commenter further requested that CMS consider the impact of measure removals from the Hospital IQR Program for hospitals that do not participate in the Hospital VBP Program and the potential effect on public reporting of data for these hospitals.

Response: We thank commenters for sharing their concerns, and clarify that we will continue to report measure-level data for all of CMS' quality programs in a manner that is transparent and easily understood by patients. We note that section 1886(o)(10)(A) of the Act requires the Hospital VBP Program to make information available to the public regarding the performance of individual hospitals, including performance with respect to each measure, on the *Hospital Compare* website in an easily understandable format. We currently publicly report hospital-specific measure-level information from the Hospital VBP Program along with program-specific scores, and we will continue to solicit input from and share updates with stakeholders as we move forward with plans to publicly report Hospital VBP Program data in order to ensure the publicly reported information is sufficiently streamlined to avoid confusion while also providing the information necessary to assist patients in making decisions about their care. We therefore clarify that we will continue to publicly report the quality measure data for those measures removed from the Hospital IQR Program but kept in the Hospital VBP program on the *Hospital Compare* website in a manner similar to the way the data have previously been reported under the Hospital IQR Program. We will also take commenters' concerns regarding public reporting of data for hospitals not included or not participating in the Hospital VBP Program into account as we continue to assess public reporting options.

After consideration of the public comments we received, we are finalizing the proposed revisions to our regulations at 42 CFR 412.164(a).

b. Measure Removal Factors for the Hospital VBP Program

As discussed earlier, we have adopted a policy to generally retain measures from prior year's Hospital VBP Program for subsequent years' measure sets unless otherwise proposed and finalized. We have previously removed measures from the Hospital VBP Program for reasons such as being topped out (80 FR 49550), the measure

does not align with current clinical guidelines or practices (78 FR 50680 through 50681), a more applicable measure was available (82 FR 38242 through 38244), there was insufficient evidence that the measure leads to better outcomes (78 FR 50680 through 50681), another measure was more closely linked to better outcomes (77 FR 53582 through 53584, and 53592), the measure led to unintended consequences (82 FR 38242 through 38244), and impossibility of calculating a score (82 FR 38242 through 38244).

The reasons we cited above to support the removal of measures from the Hospital VBP Program generally align with measure removal factors that have been adopted by the Hospital IQR Program. We believe that these factors are also applicable in evaluating Hospital VBP Program quality measures for removal, and that their adoption in the Hospital VBP Program will help ensure consistency in our measure evaluation methodology across our programs. Accordingly, in the FY 2019 IPPS/LTCH/PPS proposed rule (83 FR 20408 through 20409), we proposed to adopt the Hospital IQR Program measure removal factors that we finalized in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50185) and further refined in the FY 2015 IPPS/LTCH PPS and FY 2016 IPPS/LTCH PPS final rules (79 FR 50203 through 50204 and 80 FR 49641 through 49643, respectively) for use in determining whether to remove Hospital VBP Program measures:

- Factor 1. Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped out'' measures), defined as: Statistically indistinguishable performance at the 75th and 90th percentiles; and truncated coefficient of variation ≤0.10; [234]
- Factor 2. A measure does not align with current clinical guidelines or practice;
- Factor 3. The availability of a more broadly applicable measure (across settings or populations), or the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic;
- Factor 4. Performance or improvement on a measure does not result in better patient outcomes;
- Factor 5. The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic;
- Factor 6. Collection or public reporting of a measure leads to negative unintended consequences other than patient harm; and
- Factor 7. It is not feasible to implement the measure specifications.

We noted that these removal factors would be considerations taken into account when deciding whether or not to remove measures, not firm requirements. We continue to believe that there may be circumstances in which a measure that meets one or more factors for removal should be retained regardless, because the drawbacks of removing a measure could be outweighed by other benefits to retaining the measure.

Also, in alignment with proposals that were made for other quality reporting and value-based purchasing programs, we proposed to adopt the following additional factor to consider when evaluating measures for removal from the Hospital VBP Program measure set: Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

As we discuss in section I.A.2. of the preamble of the proposed rule with respect to our new Meaningful Measures Initiative and in this final rule, we are engaging in efforts to ensure that the Hospital VBP Program measure set continues to promote improved health outcomes for beneficiaries while minimizing the overall costs associated with the program. We believe these costs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. We have identified several different types of costs, including, but not limited to: (1) Provider and clinician information collection burden and related cost and burden associated with the submission/reporting of quality measures to CMS; (2) the provider and clinician cost associated with complying with other quality programmatic requirements; (3) the provider and clinician cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) the CMS cost associated with the program oversight of the measure, including measure maintenance and public display; and (5) the provider and clinician cost associated with compliance with other federal and/or state regulations (if applicable). For example, it may be needlessly costly and/or of limited benefit to retain or maintain a measure which our analyses show no longer meaningfully supports program objectives (for example, informing beneficiary choice or payment scoring). It may also be costly for health care providers to track the confidential feedback, preview reports, and publicly reported information on a measure where we use the measure in more than one program. CMS may also have to expend unnecessary resources to maintain the specifications for the measure, as well as the tools needed to collect, validate, analyze, and publicly report the measure data. Furthermore, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

When these costs outweigh the evidence supporting the continued use of a measure in the Hospital VBP Program, we believe it may be appropriate to remove the measure from the program. Although we recognize that one of the main goals of the Hospital VBP Program is to improve beneficiary outcomes by incentivizing health care providers to focus on specific care issues and making public data related to those issues, we also recognize that those goals can have limited utility where, for example, the publicly reported data (including percentage payment adjustment data) are of limited use because they cannot be easily interpreted by beneficiaries to influence their choice of providers. In these cases, removing the measure from the Hospital VBP Program may better accommodate the costs of program administration and compliance without sacrificing improved health outcomes and beneficiary choice.

We proposed that we would remove measures based on this factor on a case-by-case basis. We might, for example, decide to retain a measure that is burdensome for health care providers to report if we conclude that the benefit to beneficiaries justifies the reporting burden. Our goal is to move the program forward in the least burdensome manner possible, while maintaining a parsimonious set of meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients.

Comment: Several commenters supported the adoption of the seven measure removal factors previously adopted by the Hospital IQR Program into the Hospital VBP Program. A few commenters stated that adoption of these factors would allow for consistency in measure evaluation methodology across programs. One commenter believed that the factors are well-established and ensure that a variety of valid reasons to remove a measure are considered by CMS. Another commenter agreed the seven measure removal factors improve the

[234] We previously adopted the two criteria for determining the ''topped-out'' status of Hospital VBP Program measures in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50055).

usefulness of accepted quality measures included in the Hospital VBP Program (that is, they make them align with clinical practice, relate to good patient outcomes, do not lead to unintended adverse consequences, are feasible, and have room for improvement) and uphold the purpose behind the program to improve patient care and reduce Medicare costs. A third commenter expressed appreciation that these factors are guidelines and not firm requirements.

Response: We thank commenters for their support.

Comment: One commenter did not support adoption of measure removal Factor 1, ''measure performance among hospitals is so high and unvarying that meaningful distinctions and improvement in performance can no longer be made (''topped out'' measures)'' because the commenter believed removal of a measure immediately upon a ''topped out'' analysis would eliminate the ability to determine whether performance regresses or that the removal of the measure may result in lower quality of care over the long term. The commenter recommended CMS either consolidate measures that meet the ''topped out'' criteria but are still considered meaningful to stakeholders into a composite measure or include them as an evidence-based standard in a verification program. The commenter further recommended that CMS ask measure stewards for different data sources which may demonstrate a gap in performance, as well as assess whether a measure is topped-out across all provider types and all sub-groups of patients to identify any potential gaps before proposing to remove the measure.

Response: We thank commenter for its recommendations. As we discussed in the proposed rule, the removal factors are intended to be considerations taken into account when deciding whether or not to remove measures, but are not firm requirements. There may be circumstances in which a measure that meets one or more factors for removal should be retained regardless, because the drawbacks of removing a measure could be outweighed by other benefits to retaining the measure. We intend to take multiple considerations into account when determining whether to propose a measure for removal under Factor 1 or any of the other removal factors.

Comment: A few commenters did not support the adoption of measure removal Factor 4, ''performance or improvement on a measure does not result in better patient outcomes'' for the Hospital VBP Program because the commenters were concerned the factor could be used as a reason to remove any measure that is not directly linked to clinical outcomes. These commenters asserted there is value in including multiple types of measures in the Hospital VBP Program, not just outcomes-related measures.

Response: As we discussed in the proposed rule, the removal factors are intended to be considerations taken into account when deciding whether or not to remove measures, but are not firm requirements. There may be circumstances in which a measure that meets one or more factors for removal should be retained regardless, because the drawbacks of removing a measure could be outweighed by other benefits to retaining the measure. Although we strive to have measures in our programs that can drive improvement in patient health outcomes, we agree that other types of measures may be of value to the program as well.

Comment: A few commenters did not support the adoption of measure removal Factor 6, ''collection or public reporting of a measure leads to negative unintended consequences other than patient harm,'' because the commenters believed hospitals often claim unintended consequences as a reason to oppose quality measurement without offering evidence to support such claims. The commenters therefore recommended that CMS require documented evidence of real consequences as opposed to potential or speculative consequences before removing a measure under this factor.

Response: We thank commenters for their recommendation. We intend to take multiple sources of evidence into account when proposing to remove measures under any of the removal factors and always welcome stakeholder input.

Comment: Many commenters supported the addition of measure removal Factor 8, ''the costs associated with a measure outweigh the benefit of its continued use in the program'' to the Hospital VBP Program. Several commenters supported the adoption of measure removal Factor 8 for the Hospital VBP Program because they believe it is appropriate for CMS to consider the costs to providers and the agency itself in considering whether to remove a measure under this factor. A number of commenters stated that they believed the proposed new removal factor will provide CMS the flexibility to streamline measures to meet the goals of the Meaningful Measures Initiative by reducing measures that are inappropriately burdensome and ensuring greater consistency in measure evaluation methodologies across programs. A few commenters expressed their agreement that the five types of costs outlined in the proposed rule are important to consider when creating new or revised meaningful measures for quality and value-based payment programs. Another commenter believed that eliminating measures that are costly and have a limited benefit to program objectives allows providers to focus more efforts on reporting and improving performance on measures that benefit provider patient populations.

Response: We thank commenters for their support. We note that the five types of costs listed in the FY 2019 IPPS/LTCH PPS proposed rule were intended to provide examples of costs we would assess when removing a measure under measure removal Factor 8, and were not intended to comprise an exhaustive list of cost types. Costs assessed under this measure removal factor would include direct and indirect costs, financial and otherwise, to stakeholders including but not limited to, patients, caregivers, providers, CMS, healthcare researchers, healthcare purchasers, and other entities. We also believe that while a measure's use in the Hospital VBP Program may benefit many entities, a key benefit is to patients and their caregivers through incentivizing the provision of high quality care and through providing publicly reported data regarding the quality of care available.

Comment: Several commenters that supported the adoption of measure removal Factor 8 also requested additional information and transparency on the factors used to determine costs and benefits, including factors that deem the cost to be burdensome, whether the costs exceed the benefits, the nature of the burden that the removal of a measure relieves, and methods or criteria used to assess when the measure cost or burden outweighs the benefits of retaining it. One commenter supported measure removal Factor 8, but did not agree with how CMS applied its cost assumptions, questioning how costs can be reduced for hospitals by removing a measure from one program when the measure remains in another program.

Response: We intend to be transparent in our assessment of measures under this measure removal factor. As described above, there are various considerations of costs and benefits, direct and indirect, financial and otherwise, that we will evaluate in applying removal Factor 8, and we will take into consideration the perspectives of multiple stakeholders. However, because we intend to evaluate each

measure on a case-by-case basis, and each measure has been adopted to fill different needs in the Hospital VBP Program, we do not believe it would be meaningful to identify a specific set of assessment criteria to apply to all measures. We believe costs include costs to stakeholders such as patients, caregivers, providers, CMS, and other entities. In addition, we note that the benefits we will consider center around benefits to patients and caregivers as the primary beneficiaries of our quality reporting and value-based payment programs. When we propose to remove a measure under this measure removal factor, we will provide information on the costs and benefits we considered in evaluating the measure.

We also recognize that hospitals would still be required to monitor measures removed from one program but retained in another quality program. However, we believe that the simplification benefits hospitals because they will no longer be required to identify discrepancies in reporting and identify whether those discrepancies are due to differing measure specifications or due to potential CMS measure calculation error. Furthermore, we believe this simplification will benefit patients and caregivers because they will not need to review data submitted on the same or similar metrics through multiple programs to compare quality of care across multiple providers.

Comment: Several commenters supported the adoption of measure removal Factor 8 but also recommended specific things the commenters believed CMS should consider in the assessment of costs and benefits, including: The mode of data collection and reporting; input from relevant clinical experts and patient perspectives; the value of consistency in program measure sets; whether removing measures creates a gap in the measure set; resources required for providers to perform well on the measure; costs associated with contracting out or otherwise paying external vendors; costs associated with adding processes to collect data to inform the measure; whether new processes added to collect data on the measure will duplicate efforts with existing tasks; and whether the process involves completing more steps or tasks as it produces outputs for measurement. Commenters also requested that CMS clarify the process for seeking input of stakeholders in the decision-making process.

Response: We note that in our proposal to adopt this measure removal factor (83 FR 20409), we stated that we will evaluate costs and benefits on a case-by-case basis and identified several types of costs to provide examples of costs which we would evaluate in this analysis. These costs include, but are not limited to: (1) Provider and clinician information collection burden and related cost and burden associated with the submitting/reporting of quality measures to CMS; (2) the provider and clinician cost associated with complying with other quality programmatic requirements; (3) the provider and clinician cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) the CMS cost associated with the program oversight of the measure, including maintenance and public display; and/or (5) the provider and clinician cost associated with compliance with other federal and/or state regulations (if applicable). This was not intended to be a complete list of the potential factors to consider in evaluating measures.

The other factors suggested by commenters are additional factors that we will consider in evaluating the costs and benefits of each measure on a case-by-case basis under measure removal Factor 8. For example, resources for quality improvement is an example of a cost that would be evaluated on a case-by-case basis because we believe that investing resources in quality improvement is an inherent part of delivering high-quality, patient-centered care, and is therefore, generally not considered a part of the quality reporting program requirements. However, there may be cases where a measure would require such a specific quality improvement initiative that it would be appropriate to consider this cost to be associated with the measure. We also value transparency in our processes, and continually seek stakeholder input through education and outreach activities, such as webinars and national provider calls, stakeholder listening sessions, through rulemaking, and other collaborative engagements with stakeholders.

Comment: Several commenters did not support the adoption of proposed measure removal Factor 8 because commenters believed the factor may not adequately consider the value a measure holds for beneficiaries or consumers, and other commenters requested additional information about how the calculation applies to beneficiaries. Some commenters recommended that CMS develop a standardized evaluation and scoring system with multi-stakeholder input to ensure measure removal Factor 8 appropriately balances the needs of all healthcare stakeholders, and to consider how beneficiary decision-making occurs and ensure that policies do not demand beneficiaries make life-altering decisions based on scant information, inadequate tools, or insufficient assistance. A few commenters requested that CMS adopt a more inclusive process that accounts for the perspective of both patients and clinicians when making measure removal determinations.

Response: We believe that various stakeholders may have different perspectives on how to define costs as well as benefits. Because of these challenges, we intend to evaluate each measure on a case-by-case basis, while considering input from a variety of stakeholders, including, but not limited to: Patients, caregivers, patient and family advocates, providers, provider associations, healthcare researchers, healthcare purchasers, data vendors, and other stakeholders with insight into the direct and indirect benefits and costs (financial and otherwise) of maintaining the specific measure in the Hospital VBP Program. However, we also agree that while a measure's use in the Hospital VBP Program may benefit many entities, the primary benefit is to patients and their caregivers through incentivizing high-quality care and providing publicly reported data regarding the quality of care available. We note that we intend to assess the costs and benefits to program stakeholders, including but not limited to, those listed above.

Comment: A few commenters that did not support adoption of removal measure removal Factor 8 expressed concern that the proposal does not define how burden and benefits would be evaluated or weighted. One commenter asked how that definition is to be tested and what results will empirically determine whether there is, or is not, a cost-benefit of the measure.

Response: We believe that various stakeholders may have different perspectives on how to define costs as well as benefits. Because of these challenges, we intend to evaluate each measure on a case-by-case basis, while considering input from a variety of stakeholders, including, but not limited to: Patients, caregivers, patient and family advocates, providers, provider associations, healthcare researchers, healthcare purchasers, data vendors, and other stakeholders with insight into the direct and indirect benefits and costs, financial and otherwise, of maintaining the specific measure in the Hospital VBP Program. We note that we intend to assess the costs and benefits to all program stakeholders, including but not limited to, those listed above. We do not believe it is necessary to

empirically test measure removal factors. These factors are part of a coordinated approach to developing a balanced measure set, and may affect measures in different programs differently because of the specific needs of each program

Comment: A few commenters that did not support removal Factor 8 expressed concern that the proposal did not reference the cost to patients or to the Medicare program for the treatment people may need following events. One commenter asserted it is difficult to measure the benefits to Medicare beneficiaries (such as good quality of care, timely care, good communication between providers and individuals and their family caregivers, and quality of life) using a dollar metric. Another commenter recommended that CMS also consider whether a more efficient alternative reporting method is available to collect the performance data under this analysis. This commenter further stated that any assessments of the benefits of continued use of a given measure must account for the public's right to quality and cost transparency and consumers' reliance on publicly available information to make important healthcare decisions, in addition to the potential impact of the measure on improving care quality (for example, size of performance gap).

Response: We do intend to assess the costs and benefits to a variety of program stakeholders, including but not limited to, those listed above. As noted, the list of potential costs we described in the proposed rule was not intended to be a complete list of the potential factors to consider in evaluating measures. The other factors suggested by commenters are additional factors that we will consider in evaluating the costs and benefits of each measure on a case-by-case basis under measure removal Factor 8. We also agree with the commenter that it is useful to consider whether a more efficient alternative is available to collect performance data and believe it would be appropriate to consider this in our evaluation of measures under measure removal Factor 8. While a measure's use in the Hospital VBP Program may benefit many entities, the primary benefit is to patients and their caregivers through incentivizing provision of high quality care and through providing publicly reported data regarding the quality of care available. Therefore, we intend to consider the benefits, especially those to patients and their families, when evaluating measures under this measure removal factor.

Comment: A few commenters that did not support measure removal Factor 8 expressed concern that focusing on cost alone may be problematic and does not reflect the potential for assessing or improving care quality that are important to patients and families.

Response: We intend to balance the costs with the benefits to a variety of stakeholders. These stakeholders include, but are not limited to, patients and their families or caregivers, providers, the healthcare research community, healthcare purchasers, and patient and family advocates. Because for each measure the relative benefit to each stakeholder may vary, we believe that the benefits to be evaluated for each measure are specific to the measure and the original rationale for including the measure in the program.

We also understand that while a measure's use in the Hospital VBP Program may benefit many entities, the primary benefit is to patients and caregivers through incentivizing the provision of high quality care and through providing publicly reported data regarding the quality of care available. One key aspect of patient benefits is assessing the improved beneficiary health outcomes if a measure is retained in our measure set. We believe that these benefits are multifaceted, and are illustrated through the domains of the Meaningful Measures Initiative. When the costs associated with a measure outweigh the evidence supporting the benefits to patients with the continued use of a measure in the Hospital VBP Program we believe it may be appropriate to remove the measure from the program.

Comment: One commenter expressed its belief that a fair and appropriate number of measures should be retained in the Hospital VBP Program and that measure removals and adoptions should take into account the time and resources required to adjust and adapt to changing program requirements. The commenter specifically recommended that CMS implement a standard 24-month timeline for measure adoptions and removals in order to allow hospitals time to budget, plan, adopt, and operationalize any necessary changes to their plans and workflows.

Response: We attempt to ensure that a fair and appropriate number of measures are retained in the Hospital VBP Program. We note that in our proposal to adopt this measure removal factor (83 FR 20409), we stated that we will evaluate costs and benefits on a case-by-case basis and identified several types of costs to provide examples of costs which we would evaluate in this analysis. These costs include, but are not limited to, those listed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20409). This was not intended to be a complete list of the potential factors to consider in evaluating measures. The other factors suggested by commenters are additional factors that we will consider in evaluating the costs and benefits of each measure on a case-by-case basis under measure removal Factor 8. Regarding commenter's recommendation to implement a 24-month timeline for measure adoptions and removals, we do not believe such a timeline is necessary to adopt a measure given that hospitals would have been reporting measure data under the Hospital IQR Program prior to adoption into the Hospital VBP Program. We also believe it is important to retain flexibility in the timing of removing measures from the program, especially when we have determined that the costs of continued use in the program outweigh the benefits.

Comment: One commenter recommended that CMS adopt an additional removal factor addressing measure reliability and/or validity, under which CMS would remove an existing measure from the program when a new measure that provides results which are more reliable and/or valid becomes available. The commenter expressed its belief that such a factor would better recognize that as measure development and implementation become more sophisticated, these new measures are better able to precisely and accurately represent the quality of care provided to patients.

Response: We thank the commenter for its suggestion and will take this under consideration when considering future policies for the program. We consider validity and reliability in determining whether to adopt a measure and will continue to do so as we evaluate the ongoing measure sets.

Comment: One commenter recommended that the Hospital VBP Program also adopt measure retention factors, such as: (1) Measure aligns with other CMS and HHS policy goals; (2) measure aligns with other CMS programs, including other quality reporting programs; and (3) measure supports efforts to move the program towards reporting electronic measures.

Response: We note that the Hospital VBP Program currently has a policy to retain measures from prior program years for each successive program year, unless otherwise proposed and finalized. We thank commenter for their suggestions and also note that under the Meaningful Measures Initiative, as described in section I.A.2. of the preambles of the proposed rule and in this final rule, we will take into

consideration measures that could allow us to align across programs and/or with other payers, as well as to minimize the level of burden for health care providers (for example, through a preference for EHR-based measures where possible, such as electronic clinical quality measures).

After consideration of the public comments we received, we are finalizing our proposals to adopt for the Hospital VBP Program the measure removal factors currently in the Hospital IQR Program, and a measure removal Factor 8, where ''the costs associated with a measure outweigh the benefit of its continued use in the program'' beginning with FY 2019 program year.

In addition to the proposals discussed above, to further align with policies adopted in the Hospital IQR Program (74 FR 43864), we proposed that if we believe continued use of a measure in the Hospital VBP Program poses specific patient safety concerns, we may promptly remove the measure from the program without rulemaking and notify hospitals and the public of the removal of the measure along with the reasons for its removal through routine communication channels to hospital, vendors, and QIOs, including, but not limited to, issuing memos, emails, and notices on the QualityNet website. We would then confirm the removal of the measure from the Hospital VBP Program measure set in the next IPPS rulemaking. In circumstances where we do not believe that continued use of a measure raises specific patient safety concerns, we would use the regular rulemaking process to remove a measure.

Comment: Several commenters supported the proposal to remove a measure from the Hospital VBP Program without rulemaking if it poses a patient safety concern.

Response: We thank the commenters for their support.

Comment: A few commenters recommended that CMS be transparent in the process for determining if a measure meets this criterion and to promptly respond to stakeholders' concerns when potential patient safety concerns are identified. One commenter recommended use of the rulemaking process and stakeholder input wherever possible because partnership in reaching measure consensus will help to avoid unintended consequences for all. Another commenter requested clarification on the level of evidence needed to rapidly remove a measure from a program without rulemaking. A third commenter recommended that CMS continuously monitor the impact of measures and emerging literature to better position itself to remove measures proactively before widespread patient harm occurs rather than after harm has already occurred.

Response: We thank commenters for their recommendations. We intend to be transparent about our concerns and seek input from relevant stakeholders when possible, depending on the urgency of the patient safety concern. While we do not believe it is possible to anticipate the exact level of evidence that would be required to take such action, we would take such considerations seriously and do not anticipate making such a decision based on scant evidence. Rather, we believe that a high level of evidence would be required in most circumstances, depending on the patient safety concern at issue, such as consistent evidence from multiple sources. We currently monitor various sources to assess impacts and effects of measures and plan to continue doing so.

Comment: A few commenters did not support CMS' proposal to remove measures for patient safety concerns without rulemaking. Other commenters expressed concern with circumventing the rulemaking process and delaying opportunity for public comment from multiple stakeholders. One commenter expressed concern because numerous public and private purchasers have come to employ measures from the Hospital VBP Program in their own accountability strategies. Another commenter expressed concern with how this approach may impact a hospital's overall performance score and payment adjustment, especially for safety-net hospitals and those operating in underserved areas that treat a disproportionate share of high risk patients. A third commenter recommended that this authority should be used narrowly and rarely, if at all, and only in the most urgent of circumstances. This commenter also recommended that it be exercised transparently in ways that prioritize beneficiary safety and access to information, and, if it is used, to seek public comment, at that time, on continued use of this authority.

Response: We thank the commenters for their input. We intend to use this authority narrowly and in only those circumstances that pose specific and serious patient safety concerns. Although we may take this action outside of rulemaking, we intend to be transparent about concerns and seek input from relevant stakeholders to the extent possible, depending on the urgency of the concern. We also appreciate commenter's concern regarding the impact of a measure removal under this policy on a hospital's overall performance score and payment adjustment, and will attempt to mitigate such impacts to the extent program requirements may allow. While we note that we would remove a measure under this policy based on specific patient safety concerns, we would also analyze the potential impacts on scoring and payment adjustments. However, any changes to program requirements, including any potential changes to the minimum number of measures required for a domain score, would be proposed through rulemaking. We will also consider commenters' other suggestion regarding transparency, for the future.

After consideration of the public comments we received, we are finalizing our proposal to allow the Hospital VBP Program to promptly remove a measure without rulemaking if we believe the measure poses specific patient safety concerns.

c. Removal of Ten Measures From the Hospital VBP Program

By publicly reporting quality data, we strive to put patients first, ensuring they, along with their clinicians, are empowered to make decisions about their own healthcare using information that are aligned with meaningful quality measures. The Hospital VBP Program, together with the Hospital Readmissions Reduction Program and the HAC Reduction Program, represents a key component of the way that we bring quality measurement, transparency, and improvement together with value-based purchasing to the inpatient care setting. We have undertaken efforts to review the existing Hospital VBP Program measure set in the context of these other programs, to identify how to reduce costs and complexity across programs while continuing to incentivize improvement in the quality and value of care provided to patients. To that end, we have begun reviewing our programs' measures in accordance with the Meaningful Measures Initiative we described in section I.A.2. of the preambles of the proposed rule and in this final rule.

As part of this review, we stated in the proposed rule that we have taken a holistic approach to evaluating the appropriateness of the Hospital VBP Program's current measures in the context of the measures used in two other IPPS value-based purchasing programs (that is, the Hospital Readmissions Reduction Program and the HAC Reduction Program), as well as in the Hospital IQR Program. We view the three value-based purchasing programs together as a collective set of hospital value-based purchasing

programs. Specifically, we believe the goals of the three value-based purchasing programs (the Hospital VBP, Hospital Readmissions Reduction, and HAC Reduction Programs) and the measures used in these programs together cover the Meaningful Measures Initiative quality priorities of making care safer, strengthening person and family engagement, promoting coordination of care, promoting effective prevention and treatment, and making care affordable, but that the programs should not add unnecessary complexity or costs associated with duplicative measures across programs. The Hospital Readmissions Reduction Program focuses on care coordination measures, which address the quality priority of promoting effective communication and care coordination within the Meaningful Measures Initiative. The HAC Reduction Program focuses on patient safety measures, which address the Meaningful Measures Initiative quality priority of making care safer by reducing harm caused in the delivery of care.

As part of this holistic quality payment program strategy, we stated in the proposed rule that we believe the Hospital VBP Program should focus on the measurement priorities not covered by the Hospital Readmissions Reduction Program or the HAC Reduction Program. We stated that the Hospital VBP Program would continue to focus on measures related to: (1) The clinical outcomes, such as mortality and complications (which address the Meaningful Measures Initiative quality priority of promoting effective treatment); (2) patient and caregiver experience, as measured using the HCAHPS survey (which addresses the Meaningful Measures Initiative quality priority of strengthening person and family engagement as partners in their care); and (3) healthcare costs, as measured using the Medicare Spending per Beneficiary measure (which addresses the Meaningful Measures Initiative priority of making care affordable). We stated that we believe this framework will allow hospitals and patients to continue to obtain meaningful information about hospital performance and incentivize quality improvement while also streamlining the measure sets to reduce duplicative measures and program complexity so that the costs to hospitals associated with participating in these programs does not outweigh the benefits of improving beneficiary care.

In the FY 2019 IPPS/LTCH/PPS proposed rule (83 FR 20409 through 20412), we proposed to remove the following 10 measures previously adopted for the Hospital VBP Program:

- Elective Delivery (NQF #0469) (PC–01);
- National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138) (CAUTI);
- National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139) (CLABSI);
- American College of Surgeons-Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure (NQF #0753) (Colon and Abdominal Hysterectomy SSI);
- National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716) (MRSA Bacteremia);
- National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717) (CDI);
- Patient Safety and Adverse Events (Composite) (NQF #0531) (PSI 90); [235]
- Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Acute Myocardial Infarction (NQF #2431) (AMI Payment);
- Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Heart Failure (NQF #2436) (HF Payment); and
- Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Pneumonia (NQF #2579) (PN Payment).

In addition to the measure-specific comments discussed below, we received a number of comments addressing all measures proposed for removal as a single set.

Comment: Many commenters expressed general support for CMS' proposals to remove 10 measures that are duplicative, burdensome, or otherwise do not meet the goals of CMS' Meaningful Measure Initiative from the Hospital VBP Program. Many of these commenters expressed particular support for these measure removals because they would reduce the number of duplicative measures used across CMS' quality programs and thereby increase program alignment. Some commenters noted that removing these measures would simplify program participation requirements and reduce the time and resources required to track performance across multiple programs, and in turn allow hospitals more time to focus on implementing quality care improvements. A few commenters stated this program alignment will also reduce confusion for patients and providers associated with each program's respective focus and purpose. One commenter expressed general support for these measure removals as a way to streamline and align CMS' quality programs, but asserted the removals will not have any actual impact on the burden of reporting as the measures will continue to be used in other programs.

Response: We thank commenters for their support. We recognize that hospitals would still be required to monitor measures removed from one program, but retained in another quality program. However, we believe this simplification benefits hospitals because they will reduce the burden associated with identifying discrepancies in reporting and determining whether those discrepancies are due to differing measure specifications or due to CMS measure calculation error. Furthermore, we believe this simplification will benefit patients and caregivers because they will not need to review data submitted on the same or similar metrics through multiple programs to compare quality of care across multiple providers.

Comment: One commenter expressed particular support for a smaller set of measures in the Hospital VBP Program because the commenter believed this would enable hospitals that have historically fared poorly in the Hospital VBP Program to improve performance and potentially earn an incentive payment.

Response: We thank the commenter for its support.

Comment: A few commenters did not support CMS' proposal to remove any measures from the Hospital VBP Program. Some of these commenters asserted the measures proposed for removal are all valid for use in a value-based purchasing program and therefore did not support their removal.

Response: We agree with commenters that the measures proposed for removal from the Hospital VBP Program are valid measures; for this reason, we are not proposing to remove the measures from all of CMS' quality programs, only to reduce instances where the same measure is used in multiple programs

[235] We note that measure stewardship of the recalibrated version of the Patient Safety and Adverse Events Composite (PSI 90) is transitioning from AHRQ to CMS and, as part of the transition, the measure will be referred to as the CMS Recalibrated Patient Safety Indicators and Adverse Events Composite (CMS PSI 90) when it is used in CMS programs.

such that the costs outweigh the benefits of their continued use. We note that the AMI Payment, HF Payment, PN Payment, and PC–01 measures will continue to be used in the Hospital IQR Program. While the Hospital IQR Program is not a value-based purchasing program, we believe continued public reporting of these measures will appropriately incentivize continued high performance or improvement on these measures. We further note that, as discussed in section IV.I.2.c.(2) of the preamble of this final rule, below, we are not finalizing the removal of six safety measures and note that those measures will continue to be used both in the Hospital VBP Program and in the HAC Reduction Program.

(1) Removal of PC–01: Elective Delivery (NQF #0469)

We proposed to remove the Elective Delivery (NQF #0469) (PC–01) measure beginning with the FY 2021 program year because the costs associated with the measure outweigh the benefit of its continued use in the program—proposed removal Factor 8. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38262), we finalized both the benchmark at 0.000000 and the achievement threshold at 0.000000 for the PC–01 measure for the FY 2020 program year, meaning that at least 50 percent of hospitals that met the case minimum performed 0 elective deliveries for the measure during the baseline period of CY 2016. We refer readers to the FY 2013, FY 2014, and FY 2015 IPPS/LTCH PPS final rules (77 FR 53599 through 53605; 78 FR 50694 through 50699; and 79 FR 50080 through 50081, respectively) for a more detailed discussion of the general scoring methodology used in the Hospital VBP Program. Based on past performance on the measure, we anticipate that continued use of the PC–01 measure in the Hospital VBP Program would result in more than half of hospitals with a calculable score for this measure earning the maximum 10 achievement points. We anticipate that the remaining hospitals with a calculable score would be awarded points based on improvement only because they will not have met the achievement threshold, earning zero to nine improvement points. Therefore, we believe the measure no longer meaningfully differentiates performance among most participating hospitals for scoring purposes in the Hospital VBP Program.

We continue to believe that avoiding early elective delivery is important; however, because overall performance on the PC–01 measure has improved over time and we anticipate the measure will have little meaningful effect on the TPS for most hospitals, we believe the measure is no longer appropriate for the Hospital VBP Program. In order to continue tracking and reporting rates of elective deliveries to incentivize continued high performance on the measure, this measure would remain in the Hospital IQR Program. We believe that maintaining the measure in the Hospital IQR Program, which publicly reports measure performance, will be sufficient to incentivize continued high performance or improvement on the measure. At the same time, we believe that removing the measure from the Hospital VBP Program will reduce costs and potential confusion for providers and clinicians to track the measure in both the Hospital IQR and Hospital VBP Programs, which may include reviewing different reports and tracking slightly different measure rates across programs.

Based on the reasons described above, we believe that under the measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program, which we are finalizing in section IV.I.2.b. of the preamble of this final rule, the costs of keeping the PC–01 measure in the Hospital VBP Program outweigh the benefits because the measure is costly for health care providers and clinicians to review multiple reports on this measure that is being retained in the Hospital IQR Program and our analyses show that the measure no longer meaningfully differentiates performance among participating hospitals for scoring purposes in the Hospital VBP Program.

Therefore, we proposed to remove the PC–01 measure from the Hospital VBP Program beginning with the FY 2021 program year, with data collection on this measure for purposes of the Hospital VBP Program ending with December 31, 2018 discharges, based on proposed removal Factor 8—because the costs associated with the measure outweigh the benefit of its continued use in the program.

Comment: The majority of commenters that specifically commented on the proposed removal of PC–01 supported removal of PC–01 from the Hospital VBP Program. One commenter supported the removal of PC–01 because although hospitals should continue to strive for 100 percent of early elective deliveries to have a valid clinical indication, performance on this measure should not be expected to reach zero percent, nor should hospital payments in value-based purchasing programs be based on this benchmark. One commenter supported removal because the measure no longer meaningfully differentiates hospitals for purposes of Hospital VBP Program scoring. One commenter supported removal but believed unintended patient harm is a more appropriate rationale because the commenter believed striving for zero percent performance is not a safe practice as it may inadvertently prevent a medically indicated delivery from being performed prior to 39 weeks due to facilities trying to reach a zero percent performance threshold.

Response: We thank commenters for their support. We agree that with both the benchmark at 0.000000 and the achievement threshold at 0.000000 for the PC–01 measure for the FY 2020 program year, we believe the measure no longer meaningfully differentiates performance among most participating hospitals for Hospital VBP scoring purposes. We lack data or anecdotal evidence indicating use of this measure in CMS' quality programs is causing unintended consequences. However, because this measure will remain in the Hospital IQR Program, we will continue to monitor for any unintended consequences associated with its continued use in a CMS reporting program.

Comment: One commenter did not support CMS' proposal to remove the PC–01 measure from the Hospital VBP Program because it could detract focus from this important (as indicated by CMS) measure, thus the commenter recommended that the PC–01 measure be retained but allow its collection via electronic means (that is, as an eCQM) for the Hospital VBP Program, the Hospital IQR Program, and Medicare and Medicaid Promoting Interoperability Programs and, where possible, allow organizations to elect (as resources and systems allow) the ability to submit the measures electronically or via manual abstraction.

Response: As discussed in section VIII.A.5.b.(9)(e) of the preamble of this final rule, the chart-abstracted version of the PC–01 measure will be retained in the Hospital IQR Program for public reporting, which we believe will be sufficient to incentivize continued high performance or improvement on the measure. We note that the eCQM version of the PC–01 measure has not been adopted into the Hospital VBP Program. We also refer readers to sections VIII.A.5.b.(9)(e) and VIII.D.8.b. of the preamble of this final rule for a discussion about our decisions to finalize removal of the eCQM version of PC–01 from the Hospital IQR Program and the Medicare and Medicaid Promoting Interoperability Programs.

Comment: One commenter disagreed with applying measure removal Factor 8 as a rationale for CMS' proposal to remove the PC–01 measure from the Hospital VBP Program because the commenter believed removing the measure from the Hospital VBP Program while retaining it in the Hospital IQR Program is inconsistent with measure removal Factor 8.

Response: We do not agree that removing the measure from the Hospital VBP Program while retaining it in the Hospital IQR Program is inconsistent with measure removal Factor 8. We believe the costs and benefits of a measure should be evaluated on a program by program basis because the costs and benefits of continued use of a measure in one program may be different than the costs and benefits of continued use in another program. As discussed in the proposed rule (83 FR 20410), we believe that the costs associated with retaining the PC–01 measure outweigh the benefits associated with its continued use in the Hospital VBP Program because we believe the measure no longer meaningfully differentiates performance among most participating hospitals for scoring purposes in the Hospital VBP Program. We believe removing PC–01 from the Hospital VBP Program while maintaining it in the Hospital IQR Program will reduce costs and potential confusion for providers to review different reports and track slightly different measure rates across programs, while continuing to incentivize continued high performance through public reporting in the Hospital IQR Program.

After consideration of the public comments we received, we are finalizing our proposal to remove the Elective Delivery (NQF #0469) (PC–01) measure from the Hospital VBP Program beginning with the FY 2021 program year.

(2) Maintenance of Healthcare-Associated Infection (HAI) Measures and the Patient Safety and Adverse Events (Composite) Measure

We proposed to remove the following five measures of healthcare-associated infections (HAIs) from the Hospital VBP Program beginning with the FY 2021 program year because the costs associated with the measures outweigh the benefit of their continued use in the program—proposed removal Factor 8:

- National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138) (CAUTI);
- National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139) (CLABSI);
- American College of Surgeons-Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection Outcome Measure (NQF #0753) (Colon and Abdominal Hysterectomy SSI);
- National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716) (MRSA Bacteremia); and
- National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717) (CDI).

We also proposed to remove the Patient Safety and Adverse Events (Composite) (PSI 90) (NQF #0531) because the costs associated with the measure outweigh the benefit of its continued use in the program—proposed removal Factor 8.

As discussed in section IV.I.2.b. of the preamble of the proposed rule, one of the main goals of our Meaningful Measures Initiative is to apply a parsimonious set of the most meaningful measures available to track patient outcomes and impact. While we continue to consider patient safety and reducing HAIs as high priorities (as reflected in the Meaningful Measures Initiative quality priority of making care safer by reducing harms caused in the delivery of care), the six measures listed above are all used in the HAC Reduction Program, which specifically focuses on reducing hospital-acquired conditions and improving patient safety outcomes. While there are differences in the scoring methodology between the Hospital VBP Program and the HAC Reduction Program, the HAC Reduction Program's incentive payment structure, like the Hospital VBP Program, ties hospitals' payment adjustments on claims paid under the IPPS to their performance on selected measures, thereby incentivizing performance improvement on these measures among participating hospitals. In the proposed rule, we stated that we believe removing these measures from the Hospital VBP Program would reduce costs and complexity for hospitals to separately track the confidential feedback, preview reports, and publicly reported information on these measures in both the Hospital VBP and HAC Reduction Programs. We further stated that we believe retaining these measures in the HAC Reduction Program and removing them from the Hospital VBP Program would best support the holistic approach to the measures used in the three quality payment programs as described above, while continuing to keep patient safety and improvements in patient safety as high priorities. We refer readers to section IV.J.4.b., d. and h. of the preambles of the proposed rule and this final rule for how data for the same HAI measures in the HAC Reduction Program will continue to be reported by hospitals to CMS via the CDC's NHSN and posted on our *Hospital Compare* website. In the proposed rule, we stated that we believe removing these measures from the Hospital VBP Program, but retaining them in the HAC Reduction Program, would strike an appropriate balance of benefits and costs associated with these measures across payment programs.

Therefore, we proposed to remove the CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI measures from the Hospital VBP Program beginning with the FY 2021 program year, with data collection on these measures for purposes of the Hospital VBP Program ending with December 31, 2018 discharges, based on proposed removal Factor 8—because the costs associated with the measures outweigh the benefit of their continued use in the program. We also proposed to remove the PSI 90 measure from the Hospital VBP Program effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule based on proposed removal Factor 8—because the costs associated with the measure outweigh the benefit of its continued use in the program.[236] As the PSI 90 measure would not be incorporated into TPS calculations until the FY 2023 program year, we stated in the proposed rule that we could operationally remove this measure from the program sooner than the HAI measures. We also refer readers to section IV.I.4.a.(2) and b. of the preamble of the proposed rule, where we discussed our proposals to remove the Safety domain from the Hospital VBP Program and to increase the weight of the Clinical Care domain (which we proposed to rename as the Clinical Outcomes domain) if our proposals to remove all of the current Safety domain measures were adopted, beginning with the FY 2021 program year.

Comment: Many commenters did not support CMS' proposals to remove the five HAI measures and PSI 90 from the

[236] In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38256), we finalized the adoption of the PSI 90 measure beginning with the FY 2023 program year. We proposed to remove this measure effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule, meaning the measure would not be used in calculating hospitals' TPS for any program year.

Hospital VBP Program because the commenters believe patient safety measures should remain in all payment programs to sufficiently incentivize continued improvement on these measures and prioritize practices that ensure safe care. A number of commenters expressed concern that the HAC Reduction Program payment penalty does not sufficiently incentivize medium- and high-performing hospitals to continue to strive for continuous improvement. A few commenters expressed concern that removal of the HAI measures from the Hospital VBP Program sends a message to hospitals that mediocre performance on hospital safety measures is acceptable, and could result in hospitals receiving incentive payments under the Hospital VBP Program despite having a high rate of preventable infections. One commenter expressed concern that even with the HAI measures being used in both the Hospital VBP Program and HAC Reduction Program, some data may indicate hospitals have performed worse over time on four of these measures (MRSA, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI). Another commenter expressed concern that retaining the measures in only the HAC Reduction Program might result in continually penalizing hospitals that serve predominantly high-risk patients even if a hospital's individual performance improves from year to year. Another commenter expressed concern that the penalty only structure of the HAC Reduction Program could create a defeatist attitude and recommended that CMS examine ways to use simple, rationalized, and appropriately-incented payment structures to encourage quality improvement within hospitals.

Response: We agree that patient safety is a high priority focus of CMS' quality programs and, as part of the Meaningful Measures Initiative, we strive to put patients first. Within the framework of the Meaningful Measures and Patients Over Paperwork initiatives, we seek to ensure quality measurement is simultaneously useful and impactful for patients and not overly burdensome on providers such that it takes time and resources away from providing quality care to patients. In evaluating the costs and benefits of keeping certain measures in more than one CMS quality program, we found determining the right balance in using these patient safety measures in our programs a challenge with various stakeholders who may have different perspectives.

We appreciate the many commenters who provided feedback and recommendations on this important topic. In particular, we appreciate commenters who conveyed the multifaceted benefits of retaining the safety measures in more than one value-based purchasing program, and we agree that while a measure's use in the Hospital VBP Program may benefit many entities, the primary benefit is to patients and their caregivers through incentivizing the provision of high quality care. While we initially sought to clearly delineate the safety focus between the Hospital VBP Program and the HAC Reduction Program for program simplification, we agree with commenters that these measures cover topics of critical importance to quality improvement and patient safety in the inpatient hospital setting. These measures track infections and adverse events that could cause significant health risks and other costs to Medicare beneficiaries; therefore, we agree it is appropriate and important to provide appropriate incentives for hospitals to avoid them through inclusion in more than one program.

In addition, regarding performance over time on the HAI measures, we refer readers to recently updated AHRQ/CMS results that show continued improvement on several hospital acquired conditions.[237] This report indicates that national efforts to reduce hospital-acquired conditions, such as adverse drug events and injuries from falls, helped prevent an estimated 8,000 deaths and saved approximately $2.9 billion between 2014 and 2016. We believe these findings further support retaining the HAI measures and PSI 90 measure in both the Hospital VBP and HAC Reduction Programs, as both programs provide hospitals different but complimentary incentives to continually strive for improvement and high performance on these measures. Importantly, the Hospital VBP Program provides an incentive for hospitals to achieve high performance on these measures, with both positive as well as negative payment adjustments available based on each hospital's Total Performance Score; whereas the HAC Reduction Program imposes a payment reduction on only the lowest quartile of hospitals.

For these reasons, we are not finalizing our proposal to remove the five HAI measures or the PSI 90 measure from the Hospital VBP Program. We will retain the HAI measures and PSI 90 measure in both the Hospital VBP and HAC Reduction Programs. However, in order to reduce some cost and burden for providers in having to track these safety measures in multiple programs, while maintaining a strong financial incentive to perform well on the measures, we are finalizing our proposal to remove these measures from the Hospital IQR Program. We refer readers to section VIII.A.5.b.(2) of the preamble of this final rule where we discuss these measures in the Hospital IQR Program.

Comment: A number of commenters stated their belief that incentivizing performance improvement is preferable to the penalty-only structure of the HAC Reduction Program and therefore recommended that CMS should retain the HAI measures and the PSI 90 measure in the Hospital VBP Program and eliminate them from the HAC Reduction Program, or modify the HAC Reduction Program to incorporate positive payment incentives like those currently used in Hospital VBP Program. A few of these commenters expressed concern that risk adjustment strategies within the HAC Reduction Program are limited and do not always account for facility-specific populations (for example, trauma or other facilities with a high percentage of high risk or vulnerable patients), which might result in continually penalizing hospitals that serve predominantly high-risk patients even if a hospital's individual performance improves from year to year, while the Hospital VBP Program provides incentives for each facility's performance improvement as well as penalties for poor performance.

One commenter specifically recommended retaining the PSI 90 measure in the Hospital VBP Program because the commenter believes the specific measures in the composite target the most important quality priorities, directly address patient outcomes that impact vulnerable Medicare beneficiaries, and encourage hospitals to prioritize the prevention of adverse events that are costly to treat. Another commenter expressed concern that removing these measures from the Hospital VBP Program will also eliminate hospitals' ability to receive positive incentive payments for HAI measure performance in the Hospital VBP Program. A third commenter noted the importance of recognizing that each

[237] Agency for Healthcare Research and Quality (AHRQ), ''Declines in Hospital-Acquired Conditions Save 8,000 Lives and $2.9 Billion in Costs,'' News release, (June 5, 2018). Available at: *https://www.ahrq.gov/news/newsroom/press-releases/declines-in-hacs.html?utm_source=ahrq&utm_medium=en-3&utm_term=&utm_content=3&utm_campaign=ahrq_en6_5_2018*; AHRQ. *National Scorecard on Hospital-Acquired Conditions: Updated Baseline Rates and Preliminary Results 2014–2016.* (June 2018). Available at: *https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient-safety/pfp/natlhacratereport-rebaselining2014-2016_0.pdf.*

of these programs is structured differently, with different goals and policy mechanisms, and therefore recommended that CMS retain patient safety measures in the quality program that will have the most potential to influence provider behavior.

Response: We thank the commenters for their recommendations. We agree with commenters that the HAC Reduction Program and Hospital VBP Program apply different scoring methodologies and different incentive structures. The HAC Reduction Program, as outlined in section 1886(p) of the Act, reduces payments to the lowest quartile of hospitals for excess hospital-acquired conditions in order to increase patient safety in hospitals. The Hospital VBP Program, on the other hand, is an incentive program that redistributes a portion of the Medicare payments made to hospitals based on their performance on a variety of measures. All hospitals in the program are incentivized to achieve high performance on all the measures, and hospitals may receive positive as well as negative payment adjustments based on their overall performance. As stated above, we believe the critical importance of these measures to patient safety and maintaining a strong financial incentive to perform well on the measures warrant their continued inclusion in both programs.

Therefore, although these measures will continue to exist in more than one program, we clarify that they will be used and calculated under different scoring methodologies. Because we continue to consider patient safety and reducing hospital-acquired conditions high priorities (as reflected in the Meaningful Measures Initiative quality priority of making care safer by reducing harm caused in the delivery of care), we will continue to monitor the HAC Reduction and Hospital VBP Programs and analyze the impact of our program policies, including any unintended consequences associated with continuing to use these measures in more than one program. We refer readers to section VIII.A.5.b.(2) of the preamble of this final rule where we discuss finalizing our proposals to remove these measures from the Hospital IQR Program. We also refer readers to section IV.J.4.b., e. and h. of the preamble of this final rule for additional discussion of how the measures in the HAC Reduction Program will continue to be reported by hospitals, validated, and posted on the *Hospital Compare* website.

We note that all of these safety measures apply risk adjustment methodologies that have been reviewed by the NQF and are endorsed measures. We will continue to consult with the CDC and take feedback about measure risk adjustment into consideration for measure maintenance and future refinement of measure specifications.

Comment: A few commenters recommended that CMS explore other solutions to address duplication of safety measures across CMS quality programs, including adjusting reporting periods or allow hospitals to report on a measure once for use in multiple accountability programs. A few commenters believed that consolidating the measures in only a single program does not relieve a significant burden on facilities because data are submitted in the same way to be used for the various programs. One commenter noted that the costs associated with even one additional HAI in any of the impacted facility types far outweighs the estimated annual savings associated with removing the HAI measures from the Hospital VBP Program. One commenter believed that as many as 440,000 Americans die from preventable hospital errors each year.

Response: We thank commenters for their input. We recognize that there are many factors to be considered in assessing the costs and benefits of a measure under removal Factor 8. We will continue to monitor the HAC Reduction and Hospital VBP Programs and analyze the impact of our program policies, including the impact on patient safety and the reduction of preventable errors and HAIs.

Comment: Numerous commenters supported CMS' proposals to remove the five HAI measures and PSI 90 measure from the Hospital VBP Program because it would eliminate duplication of the measures with the HAC Reduction Program and thereby reduce the possibility of double penalties in two separate pay-for-performance programs. Some commenters specifically supported removing these measures because they believed the duplicative and overlapping penalties are detrimental to hospitals serving vulnerable populations. Some of these commenters also supported removing these measures because doing so would reduce the potential for conflicting signals on performance. One commenter specifically expressed its belief that removing these measures will lead to greater alignment and consistency across programs.

Response: We thank the commenters for their support of our proposals. However, for the reasons discussed above, we are not finalizing removal of these measures from the Hospital VBP Program. We believe retaining these safety measures in two value-based purchasing programs (and removing them from the Hospital IQR Program, as finalized in section VIII.A.5.b.(2) of this final rule) will at least partly address the concerns of both commenters who want to retain these measures and commenters who supported their removal and de-duplication.

Comment: Several commenters stated that transparency through continued public reporting of performance data for the HAI measures is important. One commenter recommended that CMS make public additional information demonstrating the progress made in quality, patient safety, and patient outcomes since the implementation of the Hospital VBP and HAC Reduction Programs.

Response: We agree with commenters that maximizing transparency through public reporting of performance data is a critical component of CMS' quality programs, which is why we intend to continue publicly reporting the five HAI measures and the PSI 90 measure on the *Hospital Compare* website in a consumer-friendly manner, and data will continue to be available at: *https://data.medicare.gov/*. We reiterate that removing these measures from the Hospital IQR Program will not cease or otherwise interfere with collection or public reporting of these data. The HAI data will continue to be made publicly available on a quarterly basis and the PSI 90 data on an annual basis in a consumer-friendly manner and also through downloadable files. We note that section 1886(p)(6) of the Act requires the HAC Reduction Program to make information available to the public regarding hospital-acquired conditions of each applicable hospital on the *Hospital Compare* website in an easily understandable format.

We further note that section 1886(o)(10)(A) of the Act requires the Hospital VBP Program to make information available to the public regarding the performance of individual hospitals, including performance with respect to each measure, on the *Hospital Compare* website in an easily understandable format. We currently publicly report hospital-specific measure-level information from the Hospital VBP Program along with program-specific scores, and we will continue to solicit input from and share updates with stakeholders as we move forward with plans to publicly report Hospital VBP Program data in order to ensure the publicly reported information is sufficiently streamlined to avoid confusion while also providing the information necessary to assist

patients in making decisions about their care.

After consideration of the public comments we received, we are not finalizing our proposals to remove the CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI measures from the Hospital VBP Program or our proposal to remove the PSI 90 measure from the Hospital VBP Program.

(3) Removal of Condition-Specific Payment Measures

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20411 through 20412), we proposed to remove the following three condition-specific payment measures from the Hospital VBP Program, effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule, because the costs associated with the measures outweigh the benefit of their continued use in the program—proposed removal Factor 8:

- Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Acute Myocardial Infarction (NQF #2431) (AMI Payment);
- Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Heart Failure (NQF #2436) (HF Payment); and
- Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Pneumonia (NQF #2579) (PN Payment).

As discussed in section IV.I.2.b. of the preamble of this final rule, one of the main goals of our Meaningful Measures Initiative is to apply a parsimonious set of the most meaningful measures. We also seek to reduce costs and complexity across the hospital quality programs.

Currently, the Hospital IQR and Hospital VBP Programs both include the Medicare Spending Per Beneficiary (MSPB)—Hospital (NQF #2158) (MSPB) measure, as well as the three condition-specific payment measures listed above. We continue to believe the condition-specific payment measures provide important data for patients and hospitals, and we will continue to use these measures in the Hospital IQR Program along with the Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip and/or Total Knee Arthroplasty measure, to provide more granular information to hospitals for reducing costs and resource use while maintaining quality care. However, we believe that continuing to retain the AMI Payment, HF Payment, and PN Payment measures in both the Hospital VBP and Hospital IQR Programs no longer aligns with current CMS and HHS policy priorities for reducing program costs and complexity. We believe the Hospital IQR Program's public reporting of these condition-specific payment measures provide hospitals and patients with sufficient information to make decisions about care and to drive resource use improvement efforts, while removing them from the Hospital VBP Program would reduce the costs and complexity for hospitals to separately track the confidential feedback, preview reports, and publicly reported information on these measures in both programs. We note that the Hospital VBP Program would still retain the MSPB measure, which is an overall hospital efficiency measure required under section 1886(o)(2)(B)(ii) of the Act. We also refer readers to section VIII.A.5.b.(6) of the preamble of this final rule, where we discuss finalizing our proposal to remove the MSPB measure from the Hospital IQR Program.

Therefore, we proposed to remove the AMI Payment, HF Payment, and PN Payment measures from the Hospital VBP Program effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule based on proposed removal Factor 8—because the costs associated with the measures outweigh the benefit of their continued use in the program. As the AMI Payment and HF Payment measures [238] would not be incorporated into TPS calculations until the FY 2021 program year and the PN Payment measure [239] would not be incorporated into TPS calculations until the FY 2022 program year, we can operationally remove these measures from the program effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule.

Comment: Many commenters specifically supported CMS' proposals to remove the three condition-specific payment measures from the Hospital VBP Program due to their overlap with the MSPB measure and the potential for this overlap to lead to unnecessary confusion among hospitals and patients. A number of commenters specifically noted the potential for these measures to double-count services that are already captured under the MSPB measure. One commenter expressed its belief that the condition-specific payment measures are no more actionable for providers than the MSPB measure because the measures themselves do not provide any insight into where improvements should be made in the delivery of care across the continuum. However, a number of these commenters also expressed support for the use of well-designed measures of cost and resource use and their ability to assist in assessing the value of care provided to patients. One commenter expressed particular support for CMS' proposal to remove the HF Payment measure.

Response: We thank the commenters for their support.

Comment: Several commenters supported CMS' proposals to remove the condition-specific payment measures, but expressed concern about continued use of the current MSPB measure. A few commenters noted findings from ASPE's Report to Congress indicating that differences in MSPB measure performance were driven, in part, by the higher likelihood of dual-enrolled beneficiaries to use more expensive post-acute care settings, and to have higher charges during their stays in these settings. These commenters therefore urged CMS to improve the predictive power of the MSPB measure and ensure the MSPB measure can stand alone as a reliable and valid measure of efficiency and cost reduction in the Hospital VBP Program.

Response: We thank the commenters for their support, and note the MSPB measure is a valid and reliable measure of Medicare spending that was recently re-endorsed by the NQF.[240] As part of this endorsement review, we submitted both sociodemographic and socioeconomic status adjustment measure testing indicating such adjustments had a minimal impact on hospitals' measure scores, as well as demonstrating that dual eligibility had a low impact on MSPB measure scores and hospitals on the tails of score distributions were not disproportionately affected.[241] The NQF Cost and Resource Use Workgroup also acknowledged ASPE's findings, stating ''the analysis in the appendix's

[238] In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56987 through 56992), we adopted the AMI Payment and HF Payment measures in the Hospital VBP Program beginning with the FY 2021 program year. We proposed to remove these measures effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule, meaning the measures would not be used in calculating hospitals' TPS for any program year.

[239] In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38251), we adopted the PN Payment measure in the Hospital VBP Program beginning with the FY 2022 program year. We proposed to remove this measure effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule, meaning the measure would not be used in calculating hospitals' TPS for any program year.

[240] Medicare Spending Per Beneficiary (MSPB)—Hospital, National Quality Forum, *http://www.qualityforum.org/QPS/QPSTool.aspx?m=2158&e=1.* The MSPB Measure was re-endorsed as specified on September 11, 2017.

[241] National Quality Forum, *Cost and Resource Use 2016–2017 Final Technical Report* (August 20, 2017). Available at: *http://www.qualityforum.org/Publications/2017/08/Cost_and_Resource_Use_2016-2017_Final_Technical_Report.aspx.*

Supplementary Table 7 suggest that these differences may be that measure scores are high for both duals and non-duals in these hospitals. This suggests that these hospitals are relatively higher-cost for all types of patients.'' [242] For these reasons, we continue to believe the MSPB measure is an appropriate, reliable, and valid measure of Medicare spending, and is therefore appropriate for use in the Hospital VBP Program.

Comment: Some commenters did not support CMS' proposals to remove the AMI Payment, HF Payment, and PN Payment measures because the commenters believed these measures serve as strong indicators of hospital efficiency and are key factors in ensuring hospital accountability. These commenters also noted that each of these measures, when paired with a corresponding quality measure, could provide a clear, meaningful picture of value-based care delivery. A few of these commenters also expressed concern that removing the condition-specific payment measures would revert the Hospital VBP Program to assessing efficiency and cost reduction using only the MSPB measure, which the commenters believe does not provide actionable or meaningful data to patients or providers and is difficult to operationalize at the service line level. One commenter expressed further concern that removing these measures from the Hospital VBP Program would reduce hospitals' incentives to provide quality care by reducing transparency in public reporting. Another commenter believed that although these measures cannot currently provide a full vision of the value of care because they are not linked to corresponding quality measures, the condition-specific payment measures have the potential to improve coordination and transitions of care and provide patients with more contextual data for using in medical decision-making, thereby increasing the efficiency of care across the full care continuum.

Response: We acknowledge commenters' concerns, and thank the commenters for their recommendations. Section 1886(o)(2)(B)(ii) of the Act requires that the Hospital VBP Program ''include efficiency measures, including measures of 'Medicare spending per beneficiary.' '' While we agree that condition-specific payment measures can provide hospitals with important data on payments associated with an episode of care, we continue to believe the MSPB measure also provides hospitals with valuable information because this measure captures a wide range of services provided in the inpatient hospital setting. In addition, we note the MSPB measure has been NQF-endorsed and is considered to be a valid, reliable measure of Medicare spending.

We disagree with commenters' suggestions that removing these condition-specific payment measures from the Hospital VBP Program would reduce hospitals' incentive to provide quality care by reducing transparency in public reporting or reduce patients or providers from receiving actionable or meaningful data. As listed in the tables of previously adopted measures for the Hospital IQR Program in sections VIII.A.7. and 8. of the preamble of this final rule, these three measures will remain in the Hospital IQR Program. Therefore, these three measures will continue to be publicly reported under the Hospital IQR Program. In addition, we proposed to remove these measures before they have been incorporated into hospitals' Total Performance Scores (TPS) or public reporting under the Hospital VBP Program. Therefore, removing these measures at this time will not change performance scoring or public reporting under the Hospital VBP Program.

We continue to believe that using condition-specific payment measures that can be paired directly with clinical quality measures, aligned by comparable populations, performance periods, or risk-adjustment methodologies will help move toward enabling patients, payers, and providers to better assess the overall value of care provided at a hospital. However, we believe retaining MSPB, an overall hospital efficiency measure, while removing these condition-specific payment measures will allow for reduced costs and complexity from the Hospital VBP Program and across the hospital quality programs.

After consideration of the public comments we received, we are finalizing our proposals to remove the AMI Payment, HF Payment, and PN Payment measures from the Hospital VBP Program effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule.

d. Summary of Previously Adopted Measures for the FY 2020 Program Year

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38244), we finalized the following measure set for the Hospital VBP Program for the FY 2020 program year. We note that we did not propose any changes to this measure set.

PREVIOUSLY ADOPTED MEASURES FOR THE FY 2020 PROGRAM YEAR

Measure short name	Domain/measure name	NQF #
	Person and Community Engagement Domain	
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition Measure).	0166 (0228)
	Clinical Outcomes Domain*	
MORT–30–AMI	Hospital 30-day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization.	0230
MORT–30–HF	Hospital 30-day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization.	0229
MORT–30–PN	Hospital 30-day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization.	0468
THA/TKA	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550

[242] Ibid.

PREVIOUSLY ADOPTED MEASURES FOR THE FY 2020 PROGRAM YEAR—Continued

Measure short name	Domain/measure name	NQF #
	Safety Domain	
CAUTI	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138
CLABSI	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons—Centers for Disease Control and Prevention Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	1716
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.	1717
PC–01	Elective Delivery	0469
	Efficiency and Cost Reduction Domain	
MSPB	Medicare Spending Per Beneficiary (MSPB)—Hospital	2158

* In section IV.I.4.a.(1) of the preamble of this final rule, we discuss our decision to finalize changing the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.

e. Summary of Measures for the FY 2021, FY 2022, and FY 2023 Program Years

We refer readers to the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20413 through 20414) for tables showing summaries of measures for the FY 2021, FY 2022, and FY 2023 program years if the measure removals proposed in the proposed rule were finalized. Set out below are summaries of measures for the FY 2021, FY 2022, and FY 2023 program years based on our finalized policies in this final rule.

SUMMARY OF MEASURES FOR THE FY 2021 PROGRAM YEAR

Measure short name	Domain/measure name	NQF #
	Person and Community Engagement Domain	
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition Measure).	0166 (0228)
	Safety Domain*	
CAUTI	National Healthcare Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138
CLABSI	National Healthcare Safety Network (NHSN) Central Line Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons—Centers for Disease Control and Prevention Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure.	1716
CDI	National Healthcare Safety Network (NHSN) Facility wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure.	1717
	Clinical Outcomes Domain**	
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization.	0230
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization.	0229
MORT–30–PN (updated cohort)	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization.	0468
MORT–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1893
THA/TKA	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550

SUMMARY OF MEASURES FOR THE FY 2021 PROGRAM YEAR—Continued

Measure short name	Domain/measure name	NQF #
	Efficiency and Cost Reduction Domain* **	
MSPB	Medicare Spending Per Beneficiary (MSPB)—Hospital	2158

* As discussed in section IV.I.2.c.(1) of the preamble of this final rule, we are finalizing our proposal to remove the PC–01 measure from the Hospital VBP Program beginning with the FY 2021 program year. However, as discussed in sections IV.I.2.c.(2) and IV.I.4.a.(2) of the preamble of this final rule, we are not finalizing our proposals to remove CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, and MRSA Bacteremia measures, or the Safety domain.

** In section IV.I.4.a.(1) of the preamble of this final rule, we discuss our decision to finalize changing the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.

*** As discussed in sections IV.I.2.c.(3) of the preamble of this final rule, we are finalizing our proposal to remove two measures from the Efficiency and Cost Reduction domain (AMI Payment and HF Payment), which would have entered the program beginning with the FY 2021 program year.

SUMMARY OF MEASURES FOR THE FY 2022 PROGRAM YEARS

Measure short name	Domain/measure name	NQF #
	Person and Community Engagement Domain	
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition Measure).	0166 (0228)
	Safety Domain*	
CAUTI	National Healthcare Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138
CLABSI	National Healthcare Safety Network (NHSN) Central Line Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons—Centers for Disease Control and Prevention Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure.	1716
CDI	National Healthcare Safety Network (NHSN) Facility wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure.	1717
	Clinical Outcomes Domain**	
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization.	0230
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization.	0229
MORT–30–PN (updated cohort)	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization.	0468
MORT–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1893
MORT–30–CABG	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery.	2558
THA/TKA	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550
	Efficiency and Cost Reduction Domain***	
MSPB	Medicare Spending Per Beneficiary (MSPB)—Hospital	2158

* As discussed in section IV.I.2.c.(1) of the preamble of this final rule, we are finalizing our proposal to remove the PC–01 measure from the Hospital VBP Program beginning with the FY 2021 program year. However, as discussed in sections IV.I.2.c.(2) and IV.I.4.a.(2) of the preamble of this final rule, we are not finalizing our proposals to remove CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, and MRSA Bacteremia measures, or the Safety domain.

** In section IV.I.4.a.(1) of the preamble of this final rule, we discuss our decision to finalize changing the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.

*** As discussed in sections IV.I.2.c.(3) of the preamble of this final rule, we are finalizing our proposal to remove two measures from the Efficiency and Cost Reduction domain (AMI Payment and HF Payment), which would have entered the program beginning with the FY 2021 program year, and one measure (PN Payment) which would have entered the program beginning with the FY 2023 program year.

SUMMARY OF MEASURES FOR THE FY 2023 PROGRAM YEAR

Measure short name	Domain/measure name	NQF #
	Person and Community Engagement Domain	
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition Measure).	0166 (0228)
	Safety Domain*	
CAUTI	National Healthcare Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138
CLABSI	National Healthcare Safety Network (NHSN) Central Line Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons—Centers for Disease Control and Prevention Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure.	1716
CDI	National Healthcare Safety Network (NHSN) Facility wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure.	1717
PSI 90**	Patient Safety and Adverse Events (Composite)**	0531
	Clinical Outcomes Domain* **	
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization.	0230
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization.	0229
MORT–30–PN (updated cohort)	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization.	0468
MORT–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1893
MORT–30–CABG	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery.	2558
THA/TKA	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550
	Efficiency and Cost Reduction Domain** **	
MSPB	Medicare Spending Per Beneficiary (MSPB)—Hospital	2158

* As discussed in section IV.I.2.c.(1) of the preamble of this final rule, we are finalizing our proposal to remove the PC–01 measure from the Hospital VBP Program beginning with the FY 2021 program year. However, as discussed in sections IV.I.2.c.(2) and IV.I.4.a.(2) of the preamble of this final rule, we are not finalizing our proposals to remove CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia, and PSI 90 measures, or the Safety domain.

** In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38251 through 38256), we finalized adoption of the PSI 90 measure beginning with the FY 2023 program year.

*** In section IV.I.4.a.(1) of the preamble of this final rule, we discuss our decision to finalize changing the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.

**** As discussed in sections IV.I.2.c.(3) of the preamble of this final rule, we are finalizing our proposal to remove two measures from the Efficiency and Cost Reduction domain (AMI Payment and HF Payment), which would have entered the program beginning with the FY 2021 program year and one measure (PN Payment) which would have entered the program beginning with the FY 2023 program year.

3. Accounting for Social Risk Factors in the Hospital VBP Program

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38241 through 38242), we discussed the importance of improving beneficiary outcomes including reducing health disparities. We also discussed our commitment to ensuring that medically complex patients, as well as those with social risk factors, receive excellent care. We discussed how studies show that social risk factors, such as being near or below the poverty level as determined by HHS, belonging to a racial or ethnic minority group, or living with a disability, can be associated with poor health outcomes and how some of this disparity is related to the quality of health care.[243] Among our core objectives, we aim to improve health outcomes, attain health equity for all beneficiaries, and ensure that complex patients as well as those with social risk factors receive excellent care. Within this context, reports by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academy of Medicine have examined the influence of social risk factors in CMS value-based purchasing programs.[244] As we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38404), ASPE's report to Congress found that, in the context of value-based purchasing programs, dual eligibility was the most powerful predictor of poor health care outcomes among those social risk factors that they examined and tested. In addition, as we noted in

[243] See, for example United States Department of Health and Human Services. ''Healthy People 2020: Disparities. 2014.'' Available at: *http://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities*; or National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: National Academies of Sciences, Engineering, and Medicine 2016.

[244] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.'' December 2016. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs*.

the FY 2018 IPPS/LTCH PPS final rule (82 FR 38241), the National Quality Forum (NQF) undertook a 2-year trial period in which certain new measures and measures undergoing maintenance review have been assessed to determine if risk adjustment for social risk factors is appropriate for these measures.[245] The trial period ended in April 2017 and a final report is available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*. The trial concluded that ''measures with a conceptual basis for adjustment generally did not demonstrate an empirical relationship'' between social risk factors and the outcomes measured. This discrepancy may be explained in part by the methods used for adjustment and the limited availability of robust data on social risk factors. NQF has extended the socioeconomic status (SES) trial,[246] allowing further examination of social risk factors in outcome measures.

In the FY 2018 IPPS/LTCH PPS and CY 2018 OPPS/ASC proposed rules for our quality reporting and value-based purchasing programs, we solicited feedback on which social risk factors provide the most valuable information to stakeholders and the methodology for illuminating differences in outcomes rates among patient groups within a provider that would also allow for a comparison of those differences, or disparities, across providers. Feedback we received across our quality reporting programs included encouraging CMS: To explore whether factors that could be used to stratify or risk adjust the measures (beyond dual eligibility); to consider the full range of differences in patient backgrounds that might affect outcomes; to explore risk adjustment approaches; and to offer careful consideration of what type of information display would be most useful to the public.

We also sought public comment on confidential reporting and future public reporting of some of our measures stratified by patient dual eligibility. In general, commenters noted that stratified measures could serve as tools for hospitals to identify gaps in outcomes for different groups of patients, improve the quality of health care for all patients, and empower consumers to make informed decisions about health care. Commenters encouraged us to stratify measures by other social risk factors such as age, income, and educational attainment. With regard to value-based purchasing programs, commenters also cautioned CMS to balance fair and equitable payment while avoiding payment penalties that mask health disparities or discouraging the provision of care to more medically complex patients. Commenters also noted that value-based purchasing program measure selection, domain weighting, performance scoring, and payment methodology must account for social risk.

As a next step, CMS is considering options to improve health disparities among patient groups within and across hospitals by increasing the transparency of disparities as shown by quality measures. We also are considering how this work applies to other CMS quality programs in the future. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409) for more details, where we discuss the potential stratification of certain Hospital Inpatient Quality Reporting Program outcome measures. Furthermore, we continue to consider options to address equity and disparities in our value-based purchasing programs.

We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

Comment: Many commenters recommended that CMS risk-adjust quality and cost measures (including Medicare Spending per Beneficiary—MSPB) for social risk factors because these factors are outside of a provider's control and affect patient outcomes. Several commenters expressed that risk adjustment for social risk factors is critical because public reporting of performance on measures that have not been adjusted for social risk factors may lead consumers to conclude that providers with a high-risk patient population provide lower quality care. Other commenters noted that public reporting of performance on measures that have not been risk-adjusted may lead policy makers to not address the underlying health disparities. Some commenters recommended specific factors for risk adjustment, including: (1) Elements in the ASPE, NQF, and NAM reports; (2) availability of primary care; (3) availability of physical therapy; (4) access to medications; (5) access to appropriate food; (6) access to support services; (7) dual eligibility; (8) income; (9) education; (10) neighborhood deprivation; (11) marital status; (12) access to transportation; (13) homelessness; (14) type of residence; (15) local crime rates; (16) employment status; (17) race/ethnicity; and (18) primary language.

Response: We thank these commenters for their support and will consider these topics in our future analyses of social risk factors.

Comment: Several commenters recommended specific methods of risk adjustment to evaluate performance and calculate payment adjustments, including: (1) Risk adjustment at the domain level; (2) risk adjustment at the measure level, including requiring measures developers to build the risk adjustment in from the start through testing; (3) peer grouping of similar facilities, at either the domain or measure level; (4) stratification for public reporting; (5) confidential stratification reports; and (6) reporting hospital-specific disparities.

Response: We thank these commenters for their input and will consider these topics in our future analyses of accounting for social risk factors.

Comment: Several commenters provided recommendations for adopting processes for accounting for social risk factors. Some of these commenters recommended that CMS allow providers time to review and analyze confidential stratified measure results prior to making these data public. These commenters recommended use of the rulemaking process to identify measures for which these reports would be generated, and for which data would be publicized. Other commenters recommended that CMS perform analyses to ensure that providers are not penalized for treating disadvantaged populations. Some commenters observed that there is inconsistent data collection regarding social risk factors and recommended that CMS address this (potentially through a pilot program centered on EHR use for data collection). Some commenters requested that CMS develop and publicize a work plan and timeline for accounting for social risk factors within CMS quality reporting and value-based purchasing programs. Other commenters encouraged CMS to continue monitoring and evaluation to identify potential unintended consequences of quality reporting and value-based purchasing programs on vulnerable populations.

Response: We thank these commenters for their input and will consider these topics in our future analyses of social risk factors.

Comment: One commenter expressed concern that accounting for social risk factors in quality reporting and value-based purchasing programs minimizes incentives to improve outcomes for

[245] Available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*.

[246] Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86357*.

high-risk patients and therefore does not address the underlying disparities.

Response: We agree with the commenter that accounting for social risk factors should not come at the cost of minimizing incentives to improve outcomes for high-risk patients. We note that among our core objectives, we aim to improve health outcomes, attain health equity for all beneficiaries, and ensure that complex patients as well as those with social risk factors receive excellent care. These are the objectives that we are seeking to achieve in evaluating methods to account for social risk factors in our programs.

We thank the commenters for their views and will take them into consideration as we continue our work on these issues.

4. Scoring Methodology and Data Requirements

a. Changes to the Hospital VBP Program Domains

(1) Domain Name Change for the FY 2020 Program Year and Subsequent Years

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49553 through 49554), we renamed the Clinical Care—Outcomes subdomain as the Clinical Care domain beginning with the FY 2018 program year. As discussed in the section I.A.2. of the preamble of this final rule, we strive to have measures in our programs that can drive improvement in patients' health outcomes. We also strive to align quality measurement and value-based payment programs with other national strategies, such as the Meaningful Measures Initiative. As discussed in section IV.I.2.c. of the preamble of this final rule, we believe that one of the primary areas of focus for the Hospital VBP Program should be on measures of clinical outcomes, such as measures of mortality and complications, which address the Meaningful Measures Initiative quality priority of promoting effective treatment. The Clinical Care domain currently contains these types of measures; therefore, to better align the name of the domain with our priority area of focus, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20415), we proposed to change the domain name from Clinical Care to Clinical Outcomes, beginning with the FY 2020 program year. We believe this proposed domain name better captures our goal of driving improvement in health outcomes and focusing on those outcomes that are most meaningful to patients and their providers.

Comment: One commenter supported CMS' proposal to rename the Clinical Care domain to the Clinical Outcomes domain.

Response: We thank the commenter for its support.

Comment: One commenter expressed concern about the proposed change of the domain name from Clinical Care to Clinical Outcomes due to a perceived lack of outcome measures that meet all the criteria of strong evidence; measurable with a high degree of precision; risk-adjustment methodology including, and accurately measuring the risk factors most strongly associated with the outcome; and having little chance of inducing unintended adverse consequences. The commenter stated the importance of continuing to report good process measures that give hospitals specific data on their performance that is actionable.

Response: As discussed in section IV.I.2.b. of the preambles of the proposed rule and this final rule, we strive to have measures in our programs that can drive improvement in patients' health outcomes. We believe changing the name to the Clinical Outcomes domain better aligns with this priority. While we recognize that the measures in the Clinical Care (newly finalized as the Clinical Outcomes) domain do not account for every potential risk factor, the measures are risk adjusted and NQF-endorsed. As part of our measure maintenance process, we welcome specific feedback from stakeholders regarding ways to improve risk adjustment for the measures in the hospital programs. We refer readers to the measure methodology reports available at: *https://www.qualitynet.org*. Regarding the importance to continue reporting process measures, we agree that some process measures are valuable and may warrant inclusion in CMS' value-based purchasing programs. Currently, there are no process measures in the Clinical Care (Clinical Outcomes) domain; however, we may consider adding additional measures to the domain in the future that can drive improvement in outcomes, including process measures that can be directly linked to outcomes.

After consideration of the public comments we received, we are finalizing our proposal to change the domain name from Clinical Care to Clinical Outcomes, beginning with the FY 2020 program year.

(2) Maintenance of the Safety Domain for the FY 2021 Program Year and Subsequent Years

We previously adopted five HAI measures and the PC–01 measure for the Safety domain (82 FR 38242 through 38244). We also previously adopted PSI 90 as a measure in the Safety domain beginning with the FY 2023 program year (82 FR 38251 through 38256). However, as discussed in section IV.I.2.c.(1) and (2) of the preambles of the proposed rule and this final rule, above, we proposed to remove the PC–01 measure and the five HAI measures from the Hospital VBP Program beginning with the FY 2021 program year and to remove the PSI 90 measure effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule, as the PSI 90 measure and all five of the HAI measures will be retained in the HAC Reduction Program. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20415 through 20416), we did not propose any new measures for the Safety domain. In addition, as discussed in section IV.I.2.c. of the preamble of the proposed rule, we stated that by taking a holistic approach to evaluating the appropriateness of the measures used in the three hospital value-based purchasing programs—the Hospital VBP, Hospital Readmissions Reduction, and HAC Reduction Programs—we believed the HAC Reduction Program is the primary part of the quality payment framework that should focus on the safety aspect of care quality for the inpatient hospital setting (Meaningful Measures Initiative quality priority of making care safer by reducing harm caused in the delivery of care). We stated we believe this framework will allow hospitals and patients to continue to obtain meaningful information about hospital performance and incentivize quality improvement while also streamlining the measure sets to reduce the costs of duplicative measures and program complexity.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50056) and FY 2016 IPPS/LTCH PPS final rule (80 FR 49546), we noted that hospital acquired condition measures comprise some of the most critical patient safety areas, therefore justifying the use of the measures in more than one program. However, we have also stated that we will monitor the HAC Reduction and Hospital VBP Programs and analyze the impact of our measures selection, including any unintended consequences with having a measure in more than one program, and will revise the measure set in one or both programs if needed (79 FR 50056). In the proposed rule, we stated that we have continued to receive stakeholder feedback expressing concern about overlapping measures amongst different payment programs, such as the Hospital VBP and HAC Reduction Programs. We further stated that for the Hospital VBP Program, specifically, we believed

removing the measures in the Safety domain and retaining them in the HAC Reduction Program would address the concerns expressed by these stakeholders about the costs to hospitals participating in these programs so that the costs of participation do not outweigh the benefits of improving beneficiary care.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20415 through 20416), we proposed to remove the Safety domain from the Hospital VBP Program, beginning with the FY 2021 program year, because there would no longer be any measures in that domain if our measure removal proposals are finalized. We acknowledged that by removing the Safety domain and its measures from the Hospital VBP Program, the overall effect would be to decrease the total percent of hospital payment at risk that is based on performance on these measures (by no longer tying performance on them to Hospital VBP Program reimbursement), and that it might reduce the current incentive for hospitals to perform as well on them. However, we stated we believed hospitals would still be sufficiently incentivized to perform well on the measures even if they are only in one value-based purchasing program, and we intended to monitor the effects of this proposal, if finalized, as the patient safety measures would be maintained in the HAC Reduction Program, validated, and publicly reported on the *Hospital Compare* website.

We also referred readers to section IV.I.4.b.(2) of the preamble of the proposed rule, where we discussed how we considered keeping the Safety domain and the current domain weighting of 25 percent weight for each of the four domains with proportionate reweighting if a hospital has sufficient data on only three domains, which would include retaining in the Hospital VBP Program one or more of the measures in the Safety domain (such as measures which are also used in the HAC Reduction Program). However, based on the considerations discussed above, we decided to propose removal of the Safety domain measures and the Safety domain from the Hospital VBP Program. If our proposals to remove the Safety domain measures (PC–01, the five HAI measures, and PSI 90) were adopted, there would be no measures left in the Safety domain beginning with the FY 2021 program year.

Therefore, we proposed to remove the Safety domain from the Hospital VBP Program beginning with the FY 2021 program year.

Comment: A number of commenters did not support CMS' proposal to remove the Safety domain because they believe its removal would detract from the previously increasing focus on safety within inpatient hospitals. One commenter further stated that safe care is the foundation of high-value care and measuring hospitals' overall quality performance—and financially rewarding them based on this—is incomplete without accounting for the degree to which hospitals are safely providing care.

Response: We agree with commenters that patient safety is a high priority focus of CMS' quality programs and, as part of the Meaningful Measures Initiative, we strive to put patients first. As discussed in sections IV.I.2.c.(1) and (2) of the preamble of this final rule, above, while we are finalizing removal of the PC–01 measure from the Safety domain, we are not finalizing removal of the five HAI measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, CDI) or the removal of the Patient Safety and Adverse Events (Composite) Measure (PSI 90). For this reason, we are not finalizing removal of the Safety domain.

Comment: Many commenters supported CMS' proposal to remove the Safety domain. A few commenters supported CMS' proposal to remove the Safety domain because there would be no measures in the domain. One commenter asserted the measures currently included in the Hospital VBP Program Safety domain are adequately represented in other Medicare quality programs.

Response: We thank the commenters for their input regarding the proposed removal of the Safety domain from the Hospital VBP Program. However, as discussed in section IV.I.2.c.(2) of the preamble of this final rule, above, we are not finalizing our proposal to remove the five HAI measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, CDI) or to remove the Patient Safety and Adverse Events (Composite) Measure (PSI 90). For this reason, we are not finalizing our proposal to remove the Safety domain.

Comment: One commenter recommended that even if the measures currently in the Safety domain are removed, the Safety domain should remain in the Hospital VBP Program and CMS should adopt a number of eCQMs for this domain.

Response: We thank the commenter for their suggestion. As stated above, we are not finalizing our proposal to remove the Safety domain. Regarding the adoption of eCQMs for the Hospital VBP Program, we continue to evaluate our measure sets and may consider proposing the incorporation of eCQMs into the program in the future.

After consideration of the public comments we received, we are not finalizing our proposal to remove the Safety domain from the Hospital VBP Program beginning with the FY 2021 program year.

b. Maintenance of Existing Domain Weighting for the FY 2021 Program Year and Subsequent Years

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38266), we finalized our proposal to retain the equal weight of 25 percent for each of the four domains in the FY 2020 program year and subsequent years for hospitals that receive a score in all domains. For the FY 2017 program year and subsequent years, we adopted a policy that hospitals must receive domain scores on at least three of four quality domains in order to receive a TPS, and hospitals with sufficient data on only three domains will have their TPSs proportionately reweighted (79 FR 50084 through 50085).

In the FY 2019 IPPS/LTCH PPS proposed rule, we discussed our proposal to remove the Hospital VBP Program Safety domain beginning with the FY 2021 program year in connection with our proposal to remove all of the measures previously adopted for the Safety domain. We stated that if these proposals are adopted, there would be only three domains remaining in the Hospital VBP Program, beginning with the FY 2021 program year—Clinical Outcomes (currently referred to as the Clinical Care domain), Person and Community Engagement, and Efficiency and Cost Reduction. The Clinical Outcomes domain would have five measures of mortality and complications for the FY 2021 program year and 6 measures beginning with the FY 2022 program year, the Person and Community Engagement domain would have the HCAHPS survey with its eight dimensions of patient experience, and the Efficiency and Cost Reduction domain would include only the MSPB measure. However, as discussed in section IV.I.2.c.(2) of the preamble of this final rule, we are not finalizing the removal of the 5 HAI measures or the PSI 90 measure from the Safety domain, and as discussed in section IV.I.4.a.(2) of the preamble of this final rule, we are not finalizing removal of the Safety domain from the Hospital VBP Program. Therefore, we are not finalizing any changes to the Hospital VBP Program domain weighting policies in this final rule, as further discussed below.

In the proposed rule, we discussed that to account for these proposed changes, we assessed the weighting of scores on the three remaining domains in constituting each hospital's TPS. Specifically, we considered: (1) Weighting the Clinical Outcomes domain at 50 percent of a hospital's TPS, and to weight the Person and Community Engagement and Efficiency and Cost Reduction at 25 percent each; and (2) weighting all three domains equally, each as one-third (⅓) of a hospital's TPS. Because there would have been only three domains if our proposals to remove the Safety domain and all of the Safety domain measures were adopted, we did not propose any changes to the requirement that a hospital must receive domain scores on at least three domains to receive a TPS. Historically, when the Hospital VBP Program had three domains, scores in all three were required to receive a TPS (76 FR 74534; 76 FR 74544). We also discussed in the proposed rule that we considered keeping the current domain weighting (25 percent for each of the four domains—Safety, Clinical Outcomes, Person and Community Engagement, and Efficiency and Cost Reduction—with proportionate reweighting if a hospital has sufficient data on only three domains), which would require keeping at least one or more of the measures in the Safety domain and the Safety domain itself.

(1) Proposed Domain Weighting With Increased Weight to Clinical Outcomes

For the reasons discussed in the proposed rule, we proposed to weight the domains as follows beginning with the FY 2021 program year:

PROPOSED DOMAIN WEIGHTS FOR THE FY 2021 PROGRAM YEAR AND SUBSEQUENT YEARS

Domain	Weight (percent)
Clinical Outcomes*	50
Person and Community Engagement	25
Efficiency and Cost Reduction	25

*In section IV.I.4.a.(1) of the preamble of this final rule, we discuss our decision to finalize changing the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.

In the proposed rule, we stated that we believe the proposed domain weighting best aligns with our emphasis on clinical outcomes, which address the Meaningful Measures Initiative quality priority of promoting effective treatment, and would provide a greater weight for the domain with the greatest number of measures (Clinical Outcomes), while providing appropriate weighting to the domains that focus on patient experience and cost reduction commensurate with their continued importance. In proposing to increase the weight of the Clinical Outcomes domain from 25 percent to 50 percent of hospitals' TPSs, we stated that we took into account that the Clinical Outcomes domain will include five outcome measures for the FY 2021 program year (MORT–30–AMI, MORT–30–HF, MORT–30–COPD, MORT–30–PN (updated cohort), and THA/TKA) and six outcome measures for the FY 2022 program year (MORT–30–CABG, MORT–30–AMI, MORT–30–HF, MORT–30–COPD, MORT–30–PN (updated cohort), and THA/TKA), while the Person and Community Engagement domain includes the HCAHPS survey measure, and the Efficiency and Cost Reduction domain would include only one measure (MSPB) if our proposals to remove the condition-specific payment measures, discussed in section IV.I.2.c.(3) of the preamble of the proposed rule, were adopted.

Under the proposed domain weighting, each measure in the Clinical Outcomes domain (measures of mortality and complications) would have comprised 10 percent of each hospital's TPS for the FY 2021 program year and 8.33 percent for the FY 2022 program year and subsequent years, if a hospital met the case minimum for each measure in the domain, and no more than 25 percent for each measure if a hospital could only meet the minimum two measure scores for the Clinical Outcomes domain. The MSPB measure would continue to be weighted at 25 percent, if our proposals to remove the condition specific payment measures are adopted; and each of the eight HCAHPS dimensions would continue to be weighted at 3.125 percent for a total of 25 percent for the Person and Community Engagement domain. In the proposed rule, we stated that we believed the proposed domain weighting would better balance the contributing weights of each individual measure that would be retained in the Hospital VBP Program (assuming there were no Safety domain measures) compared to the alternative weighting we considered of equal weights (one-third (⅓) for each domain), as discussed in more detail below.

In the proposed rule, we stated that we also believed the proposal to increase the weight of the Clinical Outcomes domain would help address concerns expressed by the Government Accountability Office (GAO) in a June 2017 report.[247] In the report, GAO observed that high scores in the Efficiency and Cost Reduction domain resulted in positive payment adjustments for some hospitals that had composite quality scores below the median (the GAO assessed each hospital's composite quality score as its TPS minus its weighted Efficiency and Cost Reduction domain score). GAO also expressed concern that proportionate reweighting of the Efficiency and Cost Reduction domain (for example, from 25 percent to one-third (⅓) of a hospital's TPS in FY 2016), due to a missing domain score for another domain, amplified the contribution of the Efficiency and Cost Reduction domain to the TPS. GAO recommended that CMS take action to avoid disproportionate impact of the Efficiency and Cost Reduction domain on the TPS, and to change the proportionate reweighting policy so it does not facilitate positive payment adjustments for hospitals with lower quality scores. Other stakeholders and researchers have expressed similar concerns.[248]

Using actual FY 2018 program data,[249] we analyzed the estimated potential impacts to hospital TPSs and payment adjustment. Based on this analysis, we estimated that with the proposed domain weighting, approximately 200 hospitals with composite quality scores below the median composite quality score for all Hospital VBP Program-eligible hospitals would no longer receive a positive payment adjustment mainly driven by their high performance on the Efficiency and Cost Reduction domain. This represents an approximate 50 percent reduction in the percent of hospitals receiving positive payment adjustments that have composite quality scores below the median (from 21 percent of hospitals receiving payment adjustments to 11 percent). We refer

[247] *Hospital Value-Based Purchasing: CMS Should Take Steps to Ensure Lower Quality Hospitals Do Not Qualify for Bonuses: Report to Congressional Committees.* (GAO Publication No. GAO–17–551) Retrieved from U.S. Government Accountability Office: Available at: *https://www.gao.gov/assets/690/685586.pdf.*

[248] For example, Ryan AM, Krinsky S, Maurer KA, Dimick JB. Changes in Hospital Quality Associated with Hospital Value-Based Purchasing. N Engl J Med. 2017 June 15;376(24):2358–2366.

[249] Only eligible hospitals were included in this analysis. Excluded hospitals (for example, hospitals not meeting the minimum domains required for calculation, hospitals receiving three or more immediate jeopardy citations in the FY 2018 performance period, hospitals subject to payment reductions under the Hospital IQR Program in FY 2018, and hospitals located in the State of Maryland) were removed from this analysis.

readers to the table in section IV.I.4.b.(3) of the preamble of this final rule, below summarizing the results of this analysis.

In further analyzing the potential impacts of the proposed domain weighting on hospitals' TPSs using actual FY 2018 program data, our analysis showed that, on average, hospitals with large bed size, hospitals in urban areas, teaching hospitals, and safety net status hospitals,[250] which have historically received lower overall TPSs on average (generally due to lower average performance on the Efficiency and Cost Reduction and Patient and Community Engagement domains), moved closer to the average TPS under the proposed domain weighting (generally due to their higher average performance on the Clinical Outcomes domain). With average scores for these types of hospitals moving closer to the average TPS for all hospitals, this would increase their TPSs, on average, and thereby increase their chances for a positive payment adjustment.

On average, hospitals with small bed size, rural hospitals, and non-teaching hospitals, which were historically high scorers on average (generally due to higher average performance on the Efficiency and Cost Reduction and Patient and Community Engagement domains), also moved closer to the average TPS under the proposed domain weighting (generally due to lower average performance on the Clinical Outcomes domain). With average scores for these types of hospitals also moving closer to the average TPS for all hospitals, this would decrease their TPSs, on average, and thereby decrease their chances for a positive payment adjustment. This would also be consistent with our analysis discussed above that the proposed domain weighting would better address GAO's recommendations for the Hospital VBP Program by reducing the percent of hospitals receiving positive payment adjustments that have composite quality scores below the median.

Our analysis also simulated that removing the Safety domain and increasing the weight of the Clinical Outcomes domain would have decreased the slope of the linear exchange function from 2.89 (actual FY 2018) to 2.78 (estimated using actual FY 2018 program data) and would have decreased the percent of hospitals receiving a positive payment adjustment from 57 percent to 45 percent. We believe this is mainly due to hospitals with greater total MS–DRGs payments (such as larger hospitals that generally have higher average performance on the Clinical Outcomes domain) earning higher TPSs relative to hospitals with smaller total MS–DRGs payments in this estimated budget-neutral program. We refer readers to the tables in section IV.I.4.b.(3) of the preambles of the proposed rule and this final rule summarizing the results of these analyses.

(2) Alternatives Considered

In the proposed rule, we stated that as an alternative, we also considered weighting each of the three domains equally, meaning that each domain (Clinical Outcomes, Person and Community Engagement, and Efficiency and Cost Reduction) would be weighted as one-third (⅓) of a hospital's TPS, which is similar to the proportionate reweighting policy when a hospital is missing one domain score due to insufficient cases to score enough measures for the domain. Our analysis showed that, on average, hospitals with small bed size, rural hospitals, non-teaching hospitals, and non-safety net status hospitals would earn TPSs relatively closer to or better than historic levels of performance, particularly with increased weighting of the Patient and Community Engagement and Efficiency and Cost Reduction domains from 25 percent each to one-third (⅓) each, domains in which these types of hospitals historically perform better than average compared to large bed size, hospitals in urban areas, teaching hospitals, and safety net status hospitals.[251] In addition, our analysis showed that equally weighting the domains does not address the GAO's concern of positive payment adjustments for hospitals with composite quality scores below the median. Based on our analyses, we estimated that approximately 20 percent of hospitals with composite quality scores below the median composite quality score for all Hospital VBP Program-eligible hospitals would receive a positive payment adjustment mainly driven by their high performance on the Efficiency and Cost Reduction domain, if we weighted the domains equally. This is approximately double the number of hospitals that we estimate would receive a positive payment adjustment with composite quality scores below the median as compared to our proposed domain weighting of increasing the Clinical Outcomes domain to 50 percent and keeping the Patient and Community Engagement and Efficiency and Cost Reduction domains at 25 percent each. We refer readers to the tables in section IV.I.4.b.(3) of the preambles of the proposed rule and this final rule summarizing the results of these analyses.

In the proposed rule, we stated that we also considered keeping the Safety domain and the current domain weighting (25 percent weight for each of the four domains with proportionate reweighting if a hospital has sufficient data on only three domains), which would include retaining in the Hospital VBP Program one or more of the measures in the Safety domain (such as measures which are also used in the HAC Reduction Program). As discussed in section IV.I.2.c.(2) of the preamble of this final rule, we are not finalizing our proposal to remove the PSI 90 and five HAI measures from the Hospital VBP Program.

(3) Analysis

In the proposed rule, we stated that our priority is to adopt a domain weighting policy that appropriately reflects hospital performance under the Hospital VBP Program, aligns with CMS policy goals, including the more holistic quality payment program strategy for hospitals discussed in the proposed rule, and continues to incentivize quality improvement. As noted in the proposed rule, to understand the potential impacts of the proposed domain weighting on hospitals' TPSs, we conducted analyses using FY 2018 program data that estimated the potential impacts of our proposed domain weighting policy to increase the weight of the Clinical Outcomes domain from 25 percent to 50 percent of a hospital's TPS and an alternative weighting policy we considered of equal weights whereby each domain would constitute one-third (⅓) of a hospital's TPS. The table below provided an overview of the estimated impact on hospitals' TPS by certain hospital characteristics and as they would compare to actual FY 2018 TPSs, which included scoring on four domains, including the Safety domain, and applying proportionate reweighting if a

[250] For purposes of this analysis, ''safety net'' status is defined as those hospitals with top 10 percentile of Disproportionate Share Hospital (DSH) patient percentage from the FY 2018 IPPS/LTCH PPS final rule impact file, available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2018-IPPS-Final-Rule-Home-Page-Items/FY2018-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending.*

[251] For purposes of this analysis, 'safety net' status is defined as those hospitals with top 10 percentile of Disproportionate Share Hospital (DSH) patient percentage from the FY 2018 IPPS final rule impact file, available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2018-IPPS-Final-Rule-Home-Page-Items/FY2018-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending.*

hospital had sufficient data on only three domains.

COMPARISON OF ESTIMATED AVERAGE TPSs AND UNWEIGHTED DOMAIN SCORES *

Hospital characteristic	Actual FY 2018 average clinical care domain score	Actual FY 2018 average person and community engagement domain score	Actual FY 2018 average efficiency and cost reduction domain score	Actual FY 2018 average TPS (4 domains) +	Proposed increased weighting of clinical care domain: Estimated average TPS	Alternative weighting: Estimated average TPS
All Hospitals **	43.2	33.5	18.8	37.4	34.6	31.8
Bed Size:						
1–99	33.4	46.0	35.7	44.6	37.2	38.4
100–199	42.2	34.5	21.0	39.2	35.0	32.6
200–299	44.5	27.9	12.9	34.4	32.4	28.4
300–399	48.2	27.3	10.0	33.3	33.4	28.5
400+	50.9	26.9	7.6	31.9	34.1	28.5
Geographic Location:						
Urban	46.8	30.7	13.7	35.7	34.5	30.4
Rural	33.7	40.5	31.7	41.9	34.9	35.3
Safety Net Status: ***						
Non-Safety Net	42.7	35.4	19.0	37.9	34.9	32.4
Safety Net	45.1	25.7	18.1	35.6	33.5	29.6
Teaching Status:						
Non-Teaching:	39.9	36.7	22.9	39.4	34.9	33.2
Teaching	48.7	27.9	11.8	34.1	34.3	29.5

* Analysis based on FY 2018 Hospital VBP Program data.

** Only eligible hospitals are included in this analysis. Excluded hospitals (for example, hospitals not meeting the minimum domains required for calculation, hospitals receiving three or more immediate jeopardy citations in the FY 2018 performance period, hospitals subject to payment reductions under the Hospital IQR Program in FY 2018, and hospitals located in the state of Maryland) were removed from this analysis.

+ Based on FY 2018 program year policies, which includes the Safety domain, and proportionate reweighting for hospitals with sufficient data on only three domains.

*** For purposes of this analysis, 'safety net' status is defined as those hospitals with top 10 percentile of Disproportionate Share Hospital (DSH) patient percentage from the FY 2018 IPPS/LTCH PPS final rule impact file: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2018-IPPS-Final-Rule-Home-Page-Items/FY2018-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending*.

The table below provided a summary of the estimated impacts on average TPSs and payment adjustments for all hospitals,[252] including as they would compare to actual FY 2018 program results under current domain weighting policies.

Summary of estimated impacts on average TPS and payment adjustments using FY 2018 program data	Actual (4 domains) +	Proposed increased weight for clinical outcomes (3 domains)	Equal weighting alternative (3 domains)
Total number of hospitals with a payment adjustment	2,808	2,701	2,701
Number of hospitals receiving a positive payment adjustment (percent)	1,597 (57%)	1,209 (45%)	1,337 (50%)
Average positive payment adjustment percentage	0.60%	0.58%	0.70%
Estimated average positive payment adjustment	$128,161	$233,620	$204,038
Number of hospitals receiving a negative payment adjustment (percent)	1,211 (43%)	1,492 (55%)	1,364 (50%)
Average negative payment adjustment percentage	−0.41%	−0.60%	−0.57%
Estimated average negative payment adjustment	$169,011	$189,307	$200,000
Number of hospitals receiving a positive payment adjustment with a composite quality score * below the median (percent)	341 (21%)	134 (11%)	266 (20%)
Average TPS	37.4	34.6	31.8
Lowest TPS receiving a positive payment adjustment	34.6	35.9	30.9
Slope of the linear exchange function	2.8908851882	2.7849297316	3.2405954322

+ Based on FY 2018 program year policies, which includes the Safety domain, and proportionate reweighting for hospitals with sufficient data on only three domains.

* ''Composite quality score'' is defined as a hospital's TPS minus the hospital's weighted Efficiency and Cost Reduction domain score.

The estimated total number of hospitals with a payment adjustment was lower under the proposed domain weighting and equal weighting alternative considered (2,701), compared to the current four domain policy (2,808), because under the proposed domain weighting and equal weighting alternative, scores would be

[252] Only eligible hospitals are included in this analysis. Excluded hospitals (for example, hospitals not meeting the minimum domains required for calculation, hospitals receiving three or more immediate jeopardy citations in the FY 2018 performance period, hospitals subject to payment reductions under the Hospital IQR Program in FY 2018, and hospitals located in the State of Maryland) were removed from this analysis.

required on all three domains (Clinical Outcomes, Person and Community Engagement, and Efficiency and Cost Reduction) to receive a TPS and hence, a payment adjustment, whereas under the current scoring policy, if a hospital has sufficient data on any three of the four domains it can receive a TPS and payment adjustment. For example, under the FY 2018 program year scoring policy, if a hospital did not have sufficient data for a score on the Clinical Outcomes domain, but received a score on the other three domains (Safety, Person and Community Engagement, and Efficiency and Cost Reduction), the hospital could have had its domain scores proportionately reweighted and received a TPS and payment adjustment, whereas under the proposed domain weighting and equal weighting alternative considered (which do not include the Safety domain and retain the requirement for at least three domain scores to receive a TPS), a hospital that does not have sufficient data for a score on the Clinical Outcomes domain would not receive a TPS or payment adjustment.

We also refer readers to section I.H.6.b. of Appendix A of the proposed rule (83 FR 20620 through 20621) for detailed discussions regarding the estimated impacts of the proposed domain weighting and equal weighting alternative on hospital percentage payment adjustments.

(4) Summary

In the proposed rule, we stated that based on our analyses and all of the other considerations discussed above, we believed our proposed domain weighting policy to increase the weight of the Clinical Outcomes domain from 25 percent to 50 percent of a hospital's TPS would best align with the goal of the Hospital VBP Program to make value-based incentive payment adjustments based on hospitals' performance on quality and cost, as well as emphasizes the Meaningful Measures Initiative's focus on high impact areas that are meaningful to patients and providers.

Because we proposed to remove the Safety domain and its measures from the Hospital VBP Program, we considered the two options for weighting the three remaining domains. Increasing the weight of the Clinical Outcomes domain from 25 percent to 50 percent of each hospital's TPS emphasizes our priority and focus on improving patients' health outcomes, without decreasing the weight of the Efficiency and Cost Reduction or Person and Communities Engagement domains. By contrast, equally weighting each of the three domains at one-third (⅓) of each hospital's TPS would result in the MSPB measure and the HCAHPS survey measure together accounting for two-thirds (⅔) of each hospital's TPS. In the proposed rule, we stated that if our proposal to remove the Safety domain beginning with the FY 2021 program year is adopted, we proposed to weight the three remaining domains as follows: Clinical Outcomes domain—50 percent; Person and Community Engagement domain—25 percent; and Efficiency and Cost Reduction domain—25 percent—beginning with the FY 2021 program year. However, as discussed in section IV.I.2.c.(2) of the preamble of this final rule, we are not finalizing the removal of the 5 HAI measures or the PSI 90 measure from the Safety domain. Therefore, we are not finalizing the removal of the Safety domain from the Hospital VBP Program, as further discussed below.

Comment: A few commenters expressed concern that ongoing changes to the program's scoring and weighting methodology create volatility for providers and do not allow for assessments of hospital performance over time. These commenters recommended that CMS create stability for the program going forward to afford providers a level of predictability and allow for comparison across time.

Response: We appreciate commenters' concerns, and will take this into account as we continue to move forward with the holistic approach to program and measure evaluation across CMS' quality programs. We note that as discussed in section IV.I.2.c.(2) of the preamble of this final rule, above, we are not finalizing the removal of the 5 HAI measures or the PSI 90 measure from the Safety domain, and as discussed in section IV.I.4.a.(2) of the preamble of this final rule, above, we are not finalizing our proposal to remove the Safety domain, and are therefore not finalizing any changes to the Hospital VBP Program domain weighting policies in this final rule.

We note that in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49568 through 49570), we adopted equal weights of 25 percent for each of the four domains in the FY 2018 program year for hospitals that receive a score in all domains. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57009 through 57010), for the FY 2019 program year, we retained this domain weighting. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38265 through 38266) we finalized our proposal to retain the equal weight of 25 percent for each of the four domains in the FY 2020 program year and subsequent years for hospitals that receive a score in all domains. Because we did not propose to change the domain weighting policies based on consideration of four domains (including retention of the Safety domain) in the FY 2019 IPPS/LTCH PPS proposed rule, and in response to stakeholder concerns of changes to the program's scoring and weighting methodology creating volatility for providers, we are not making changes to the previously finalized equal weight of 25 percent for each of the four domains for hospitals that receive a score in all domains in this final rule.

Comment: Many commenters supported the proposed increased weight to the Clinical Outcomes domain because they believed it would most fairly weight the individual measures within the program, given that the distribution of measures across the three domains. Some commenters recommended delaying implementation of the proposed domain weighting to allow hospitals time to shift quality improvement focus toward the Clinical Outcomes domain. A number of commenters recommended adopting the alternative domain weighting proposal, where each remaining domain would be weighted equally at one-third of a hospital's TPS, because it would result in a roughly equal distribution of gains and losses across hospitals participating in the Hospital VBP Program and thereby provide hospitals an opportunity to be rewarded for good performance on any one of the measure domains. A few commenters expressed concern about increasing the weight of the Clinical Outcomes domain to 50 percent because the commenters believed the domain does not provide an accurate, comprehensive view of hospital performance. Some commenters did not support adoption of any domain weighting methodology where the Safety domain is removed.

Response: We thank the commenters for their input regarding the proposed domain weighting policies for the Hospital VBP Program. As discussed in section IV.I.4.a.(2) of the preamble of this final rule, above, we are not finalizing our proposal to remove the Safety domain. For this reason, as stated above, we are not finalizing any changes to the current domain weighting in this final rule. However, we will take commenters' feedback into consideration in evaluating any potential future changes to the domain weights.

Comment: Several commenters did not support weighting the Efficiency and Cost Reduction domain at 25 percent because this domain would include only the MSPB measure and

therefore recommended reducing its weight. A few commenters recommended that CMS consider further deemphasizing the weight of the Efficiency and Cost Reduction domain if it continues to observe that hospitals that perform below the national average on the clinical quality measures but perform well on the MSPB measure receive an incentive payment under the proposed approach. Other commenters recommended reducing the weight of the Efficiency and Cost Reduction domain and increasing the weight of the Person and Community Engagement domain.

Response: We thank commenters for their input, and note that the previously finalized weight of the Efficiency and Cost Reduction domain for the FY 2019 and FY 2020 program years, which contains only the MSPB measure, is 25 percent. Because we did not consider a weight for the Efficiency and Cost Reduction domain below 25 percent in our analyses of the domain weighting options discussed in the FY 2019 IPPS/LTCH PPS proposed rule, we are not revising the previously finalized weighting of the Efficiency and Cost Reduction domain in this final rule. However, will take commenters' recommendations into consideration as we continue evaluating our domain weighting policies, including ways to address concerns about hospitals that perform below the national average on quality measures receiving incentive payments.

Comment: One commenter expressed concern about the weight placed on the Person and Community Engagement domain because it is based on only the HCAHPS patient experience survey measures, which the commenter believes are subjective, can force hospitals to overemphasize experience as opposed to making improvements to clinical care, and could lead to unintended consequences.

Response: We thank the commenter for its input, and will take this recommendation into consideration for future years of the program as we continue evaluating our domain weighting policies. Because we did not consider a weight for the Person and Community Engagement domain below 25 percent in our analyses of the domain weighting options discussed in the FY 2019 IPPS/LTCH PPS proposed rule, we are not revising the previously finalized weighting of the Person and Community Engagement domain in this final rule. As previously finalized, we believe weighting the Person and Community Engagement domain at 25 percent of hospitals' TPSs is appropriate for the domain that measures important elements of the patient's experience of inpatient care. We have adjusted HCAHPS scores for certain patient-level factors that are beyond the hospital's control but which affect survey responses. These factors include patient severity, as indicated by self-reported overall health, and patient's highest level of education, considered the most accurate single measure of socioeconomic status for older adults. We also note that AHRQ carried out a rigorous, scientific process to develop and test the HCAHPS instrument. This process entailed multiple steps, including: A public call for measures; literature reviews; cognitive interviews; consumer focus groups; multiple opportunities for additional stakeholder input; a 3-State pilot test; small-scale field tests; and notice-and-comment rulemaking. The HCAHPS Survey is NQF-endorsed and is currently the only measure in the program which uses information collected directly from patients.

Comment: One commenter specifically recommended further development of the Person and Community Engagement domain and then increasing the weight of that domain. Another commenter recommended that CMS reevaluate the measures in the program to encompass a more holistic view of quality, including improving patient's quality of life, because the commenter believed that while experience and cost are important measures of quality, they are not necessarily equivalent to high quality. A third commenter recommended that if measures are added to or removed from these domains, CMS should examine the weighting and make appropriate adjustments.

Response: We thank the commenters for their recommendations, and will take these recommendations into consideration for future years of the program.

After consideration of the public comments we received, we are not finalizing our proposal to use three domains, beginning with the FY 2021 program year, with the Clinical Outcomes domain weighted at 50 percent; the Person and Community Engagement domain weighted at 25 percent; and the Efficiency and Cost Reduction domain weighted at 25 percent. We are also not finalizing our proposal to remove the Safety domain because we are not removing all of the measures in that domain. Therefore, in accordance with our current policy, we will maintain four domains in the Hospital VBP Program, each with a weight of 25 percent, for hospitals that receive a score in all domains, and hospitals with sufficient data on only three domains will have their TPSs proportionately reweighted.

c. Minimum Numbers of Measures for Hospital VBP Program Domains for the FY 2021 Program Year and Subsequent Years

Based on previously finalized policies (82 FR 38266), for a hospital to receive a domain score for the FY 2021 program year and subsequent years:

- A hospital must report a minimum number of 100 completed HCAHPS surveys for a hospital to receive a Person and Community Engagement domain score.
- A hospital must receive a minimum of two measure scores within the Clinical Outcomes domain (currently referred to as the Clinical Care domain).
- A hospital must receive a minimum of one measure score within the Efficiency and Cost Reduction domain.

As discussed in section IV.I.4.a.(2) of the preamble of this final rule, we are not finalizing our proposal to remove the Safety domain from the Hospital VBP Program beginning with the FY 2021 program year. Therefore, based on previously finalized policies (82 FR 38266), we are clarifying in this final rule that additionally:

- A hospital must receive a minimum of two measure scores within the Safety domain.

We note that we are finalizing our proposal to remove the condition-specific payment measures from the Hospital VBP Program and, therefore, a hospital's Efficiency and Cost Reduction domain score would be based solely on its MSPB measure score. In the proposed rule (83 FR 20420), we did not propose any changes to this policy.

d. Minimum Numbers of Cases for Hospital VBP Program Measures for the FY 2021 Program Year and Subsequent Years

(1) Background

Section 1886(o)(1)(C)(ii)(IV) of the Act requires the Secretary to exclude for the fiscal year hospitals that do not report a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for the fiscal year. For additional discussion of the previously finalized minimum numbers of cases for measures under the Hospital VBP Program, we refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26527 through 26531); the CY 2012 OPPS/ASC final rule (76 FR 74532 through 74534); the FY 2013 IPPS/LTCH PPS final rule (77 FR 53608

through 53609); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50085); the FY 2016 IPPS/LTCH PPS final rule (80 FR 49570); the FY 2017 IPPS/LTCH PPS final rule (81 FR 57011); and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38266 through 38267).

(2) Clinical Care Domain/Clinical Outcomes Domain

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53608 through 53609), we adopted a minimum number of 25 cases for the MORT–30–AMI, MORT–30–HF, and MORT–30–PN measures. We adopted the same 25-case minimum for the MORT–30–COPD measure in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49570), and for the MORT–30–CABG, MORT–30–PN (updated cohort), and THA/TKA measures in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57011).

In the proposed rule (83 FR 20420), we did not propose any changes to these policies.

(3) Person and Community Engagement Domain

In the Hospital Inpatient VBP Program final rule (76 FR 26527 through 26531), we adopted a minimum number of 100 completed HCAHPS surveys for a hospital to receive a score on the HCAHPS measure.

In the proposed rule (83 FR 20420), we did not propose any changes to this policy.

(4) Efficiency and Cost Reduction Domain

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53609 through 53610), we adopted a minimum of 25 cases in order to receive a score for the MSPB measure. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50085 through 50086), we retained the same MSPB measure case minimum for the FY 2016 program year and subsequent years. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38267), we adopted a policy that hospitals must report a minimum number of 25 cases per measure in order to receive a measure score for the condition-specific payment measures (namely, the AMI Payment, HF Payment, and PN Payment measures), for the FY 2021 program year, FY 2022 program year, and subsequent years.

In the proposed rule (83 FR 20420), we did not propose any changes to these policies for the MSPB measure; however, as discussed in section IV.I.2.c.(3) of the preamble of this final rule, we are finalizing our proposals to remove the three condition-specific payment measures (AMI Payment, HF Payment, and PN Payment) from the Hospital VBP Program effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule.

(5) Summary of Previously Adopted Minimum Numbers of Cases for the FY 2021 Program Year and Subsequent Years

The previously adopted minimum numbers of cases for these measures are set forth in the table below.

As discussed in section IV.I.2.c.(1) of the preamble of this final rule, we are finalizing our proposal to remove the PC–01 measure from the Hospital VBP Program beginning with the FY 2021 program year. However, as discussed in section IV.I.2.c.(2) of the preamble of this final rule, we are not finalizing our proposals to remove the HAI measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, and MRSA Bacteremia) beginning with the FY 2021 program year, or to remove the PSI 90 measure effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule. Therefore, previously adopted minimum numbers of cases for those measures are also set forth in the table below. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53608 through 53609), we adopted a minimum of one predicted infection for NHSN-based surveillance measures (that is, the CAUTI, CLABSI, CDI, MRSA, and SSI measures) based on CDC's minimum case criteria. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50085), we adopted this case minimum for the NHSN-based surveillance measures for the FY 2016 Hospital VBP Program and subsequent years. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38267), beginning with the FY 2023 program year, we adopted a policy that hospitals must report a minimum of three eligible cases on any one underlying indicator during the baseline period in order to receive an improvement score and three eligible cases on any one underlying indicator during performance period in order to receive an achievement score on the Patient Safety and Adverse Events (Composite) (PSI 90) measure. For the purposes of the PSI 90 measure, a case is ''eligible'' for a given indicator if it meets the criterion for inclusion in the indicator measure population.

PREVIOUSLY ADOPTED MINIMUM CASE NUMBER REQUIREMENTS FOR THE FY 2021 PROGRAM YEAR AND SUBSEQUENT YEARS

Measure short name	Minimum number of cases
Person and Community Engagement Domain	
HCAHPS	Hospitals must report a minimum number of 100 completed HCAHPS surveys.
Clinical Outcomes Domain*	
MORT–30–AMI	Hospitals must report a minimum number of 25 cases.
MORT–30–HF	Hospitals must report a minimum number of 25 cases.
MORT–30–PN (updated cohort).	Hospitals must report a minimum number of 25 cases.
MORT–30–COPD	Hospitals must report a minimum number of 25 cases.
MORT–30–CABG	Hospitals must report a minimum number of 25 cases.
THA/TKA	Hospitals must report a minimum number of 25 cases.
Safety Domain	
CAUTI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
CLABSI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
Colon and Abdominal Hysterectomy SSI.	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
MRSA Bacteremia	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
CDI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.

PREVIOUSLY ADOPTED MINIMUM CASE NUMBER REQUIREMENTS FOR THE FY 2021 PROGRAM YEAR AND SUBSEQUENT YEARS—Continued

Measure short name	Minimum number of cases
Patient Safety and Adverse Events (Composite) #.	Hospitals must report a minimum of three eligible cases on any one underlying indicator.
Efficiency and Cost Reduction Domain	
MSPB	Hospitals must report a minimum number of 25 cases.

* In section IV.I.4.a.(1) of the preamble of this final rule, we discuss our decision to finalize our proposal to change the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38242 through 38244, 38251 through 38256), we removed the former PSI 90 measure beginning with the FY 2019 program year. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38251 through 38256), we adopted the Patient Safety and Adverse Events (Composite) (PSI 90) measure beginning with the FY 2023 program year.

5. Previously Adopted Baseline and Performance Periods

a. Background

Section 1886(o)(4) of the Act requires the Secretary to establish a performance period for the Hospital VBP Program that begins and ends prior to the beginning of such fiscal year. We refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56998 through 57003) for baseline and performance periods that we have adopted for the FY 2019, FY 2020, FY 2021, and FY 2022 program years. In the same rule, we finalized a schedule for all future baseline and performance periods for previously adopted measures. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38256 through 38261) for additional baseline and performance periods that we have adopted for the FY 2022, FY 2023, and subsequent program years.

b. Person and Community Engagement Domain

Since the FY 2015 program year, we have adopted a 12-month baseline period and 12-month performance period for measures in the Person and Community Engagement domain (previously referred to as the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain) (77 FR 53598; 78 FR 50692; 79 FR 50072; 80 FR 49561). In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56998), we finalized our proposal to adopt a 12-month performance period for the Person and Community Engagement domain that runs on the calendar year 2 years prior to the applicable program year and a 12-month baseline period that runs on the calendar year 4 years prior to the applicable program year, for the FY 2019 program year and subsequent years.

In the proposed rule (83 FR 20421), we did not propose any changes to these policies.

c. Efficiency and Cost Reduction Domain

Since the FY 2016 program year, we have adopted a 12-month baseline period and 12-month performance period for the MSPB measure in the Efficiency and Cost Reduction domain (78 FR 50692; 79 FR 50072; 80 FR 49562). In the FY 2017 IPPS/LTCH PPS final rule, we finalized our proposal to adopt a 12-month performance period for the MSPB measure that runs on the calendar year 2 years prior to the applicable program year and a 12-month baseline period that runs on the calendar year 4 years prior to the applicable program year for the FY 2019 program year and subsequent years (81 FR 56998).

In the proposed rule (83 FR 20421), we did not propose any changes to these policies.

d. Clinical Care Domain/Clinical Outcomes Domain

For the FY 2020 and FY 2021 program years, we adopted a 36-month baseline period and 36-month performance period for measures in the Clinical Outcomes domain (currently referred to as the Clinical Care domain) (78 FR 50692 through 50694; 79 FR 50073; 80 FR 49563).[253] In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57000), we finalized our proposal to adopt a 36-month performance period and 36-month baseline period for the FY 2022 program year for each of the previously finalized measures in the Clinical Outcomes domain—that is, the MORT–30–AMI, MORT–30–HF, MORT–30–COPD, THA/TKA, and MORT–30–CABG measures. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57001), we also adopted a 22-month performance period for the MORT–30–PN (updated cohort) measure and a 36-month baseline period for the FY 2021 program year. In the same final rule, we adopted a 34-month performance period and 36-month baseline period for the MORT–30–PN (updated cohort) measure for the FY 2022 program year.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38259), we adopted a 36-month performance period and 36-month baseline period for the MORT–30–AMI, MORT–30–HF, MORT–30–COPD, MORT–30–CABG, MORT–30–PN (updated cohort), and THA/TKA measures for the FY 2023 program year and subsequent years. Specifically, for the mortality measures (MORT–30–AMI, MORT–30–HF, MORT–30–COPD, MORT–30–CABG, and MORT–30–PN (updated cohort)), the performance period runs for 36 months from July 1, five years prior to the applicable fiscal program year, to June 30, two years prior to the applicable fiscal program year, and the baseline period runs for 36 months from July 1, ten years prior to the applicable fiscal program year, to June 30, seven years prior to the applicable fiscal program year. For the THA/TKA measure, the performance period runs for 36 months from April 1, five years prior to the applicable fiscal program year, to March 31, two years prior to the applicable fiscal program year, and the baseline period runs for 36 months from April 1, ten years prior to the applicable fiscal program year, to March 31, seven years prior to the applicable fiscal program year.

In the proposed rule (83 FR 20421), we did not propose any changes to the length of these performance or baseline periods.

e. Safety Domain

In the FY 2017 IPPS/LTCH PPS final rule, we finalized our proposal to adopt a performance period for all measures in the Safety domain—with the exception of the PSI 90 measure—that runs on the calendar year two years prior to the applicable program year and a baseline

[253] The THA/TKA measure was added for the FY 2019 program year with a 36-month baseline period and a 24-month performance period (79 FR 50072), but we have since adopted 36-month baseline and performance periods for the FY 2021 program year (80 FR 49563).