



| TOPIC | PROPOSED RULE | FINAL RULE |
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| <p><u>FY2018 MS-DRG Documentation and Coding Adjustment</u></p> <p><u>Specific MS-DRG Classifications</u></p> | <p align="center"><u>Medicare Severity Diagnosis-Related Group (MS-DRG) Classifications and Relative Weights</u></p> <p>CMS proposes to implement a FY 2018 +0.4588 percent adjustment for the Documentation and Coding Adjustment as required by the 21st Century Cures Act.</p> <p>Conversion of MS-DRGs to ICD-10: CMS is altering the deadline to request updates to MS-DRGs to November 1 to provide CMS staff with an additional 5 weeks of time for data analysis and review. Input can be submitted to MSDRGClassificationChange@cms.hhs.gov.</p> | <p>CMS finalized this proposal (p. 105).</p> <p>CMS reiterated the new deadline and cited the FY 2019 deadline for requested updates to MS-DRGs will be November 1, 2017 (p. 110).</p> <p>Some commenters expressed concerns about the proposed relative weights for some MS-DRGs for which CMS did not make a specific proposal but fluctuated based on the incorporation of the new ICD-10 data:</p> <ul style="list-style-type: none"> • MS-DRG 215 (Other Heart Assist System Implant): concern that this had the largest decrease (~35%) and could result in access issues (p. 112). There was also concern that AHA Coding Clinic guidance for external heart assist devices will result in higher cost patients being assigned to MS-DRG 215 as well as that patients who receive heart assist devices might also be assigned to Pre-MDC MS-DRGs 001 and 002 (<i>Heart Transplant or Implant of Heart Assist System</i>) (p. 114). In response to the concerns, CMS states that it will review for FY 2019 the current ICD-10 logic for Pre-MDC MS-DRGs 001 (Heart Transplant or Implant of Heart Assist System with MCC), MS-DRG 002 (Heart Transplant or Implant of Heart Assist System without MCC), MS-DRG 215 (Other Heart Assist System Implant), MS-DRG 268 (Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC), and MS-DRG 269 (Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC) (p. 118). |

- Requests that CMS limit fluctuations including specific recommendations that CMS cap the percentage by which an MS-DRG can be reduced ([p. 113](#)).
- Comments that the fluctuations do not support a smooth transition from ICD-9 ([p. 113](#))

MDC 1 (Diseases and Disorders of the Nervous System):

Functional Quadriplegia: CMS proposes to reassign cases for functional quadriplegia to the following MS-DRGs: MS-DRG 091 (Other Disorders of Nervous System with MCC), MS-DRG 092 (Other Disorders of Nervous System with CC), MS-DRG 093 (Other Disorders of Nervous System without CC/MCC).

CMS received support to remove the functional quadriplegia codes from MS-DRGs 052 and 053 because they did not involve a spinal disorder; however, the commenter suggested that the proposed MS-DRGs were also inappropriate because the codes were also not descriptive of a nervous system disorder ([p. 125](#)). The commenter recommended assignment to MS-DRG 947 (*Signs and Symptoms with MCC*) and MS-DRG 948 (*Signs and Symptoms without MCC*). CMS conducted its usual analysis ([p. 126](#)) and concurred. Therefore, **CMS did not finalize its proposal and instead finalized the reassignment of the functional quadriplegia diagnosis codes to MS-DRG 947 and MS-DRG 948** ([p. 127](#)).

Responsive Neurostimulator (RNS®) System:

CMS proposed to reassign all cases with a principal diagnosis of epilepsy and a selected set of ICD-10 code combinations indicating the use of a neurostimulator generator inserted into the skull to MS-DRG 023 even if there is no MCC reported.

CMS finalized its proposal ([p. 143](#)). **In addition, CMS added a number of codes that also describe epilepsy to the list of codes impacted by the policy** (See, [table on p. 141](#) for full list of epilepsy codes).

CMS also proposes to change the title of MS-DRG 023 to “Craniotomy with Major Device Implant or Acute Complex Central Nervous System (CNS) Principal Diagnosis (PDX) with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator.”

CMS also finalized its name change to MS-DRG 023 ([p. 143](#)).

Precerebral Occlusion or Transient Ischemic Attack with Thrombolytic:

CMS proposes to move diagnosis codes for non-specific CVA and precerebral occlusion without infarction and transient ischemia to MS-DRGs 061, 062, and 063 when reported as the principal diagnosis and paired with an ICD-10 procedure code describing the use of a thrombolytic agent (e.g. tPA).

CMS received support for the proposal in that it will “encourage appropriate physician documentation for a precerebral occlusion or transient ischemic attack when patients are treated with tPA and that it will more accurately reflect proper payment for stroke care.” ([p. 150](#)). **CMS finalized its proposal** ([p. 150](#)).

CMS proposes to retitle the MS-DRGs as follows: MS-DRG 061 (Ischemic Stroke, Precerebral Occlusion or Transient Ischemia with Thrombolytic Agent with MCC), MS-DRG 062 (Ischemic Stroke,

In addition, **CMS finalized its proposal to retitle the related MS-DRGs** ([p. 151](#)).

Precerebral Occlusion or Transient Ischemia with Thrombolytic Agent with CC), MS-DRG 063 (Ischemic Stroke, Precerebral Occlusion or Transient Ischemia with Thrombolytic Agent without CC/MCC), MS-DRG 069 (Transient Ischemia without Thrombolytic).

[MDC 2 \(Diseases and Disorders of the Eye: Swallowing Eye Drops \(Tetrahydrozoline\)\)](#): CMS proposes MS-DRG changes to reflect that the treatment following the swallowing of eye drops is a case of poisoning, not a “Disorder of the Eye.”

CMS finalized its proposal ([p. 155](#)).

[MDC 5 \(Diseases and Disorders of the Circulatory System\)](#):

[Percutaneous Cardiovascular Procedures and Insertion of a Radioactive Element](#): CMS proposes the removal of six ICD-10 procedure codes assigned to MS-DRGs describing percutaneous cardiovascular procedures that describe the insertion of a radioactive element from the percutaneous cardiovascular procedure MS-DRGs (246, 247, 248 and 249) and maintaining their assignment to MS-DRG 264.

CMS finalized its proposal ([p. 159](#)).

[Percutaneous Cardiovascular Procedure MS-DRGs Terminology](#): CMS is proposing the following revisions “to better reflect the ICD-10 terminology of ‘arteries’ and ‘vessels’”: MS-DRG 246: Percutaneous Cardiovascular Procedures with Drug-Eluting Stent with MCC or 4+ ~~Vessels~~ Arteries or Stents, MS-DRG 248: Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent with MCC or 4+ ~~Vessels~~ Arteries or Stents

CMS finalized its proposal ([p. 160](#)).

[Transcatheter Aortic Valve Replacement \(TAVR\) and Left Atrial Appendage Closure \(LAAC\)](#): CMS does not propose to create new MS-DRGs where TAVR and LAAC procedures are performed in combination.

CMS finalized its proposal to maintain its current MS-DRG structure ([p. 164](#)).

[Percutaneous Mitral Valve Procedures](#): CMS agreed that all cardiac valve replacement procedures should be grouped within the same DRG. CMS agreed that eight new procedure codes that describe tricuspid valve replacement procedures performed with percutaneous and transapical types of percutaneous approaches should also be assigned to MS-DRGs 266 and 267.

CMS finalized its proposal to reassign the four percutaneous mitral valve replacement codes ([see table on p. 166](#)) to MS-DRGs 266 and 267 and assign the eight new procedure codes that describe percutaneous and transapical, percutaneous tricuspid valve replacement procedures ([see table on p. 167](#)) to MS-DRGs 266 and 277 ([p. 169](#)).

[Percutaneous Tricuspid Valve Repair](#): CMS does not propose reassigning the ICD-10 procedure code 02UJ2 (Supplemental tricuspid valve with synthetic substitute, percutaneous approach) as it believes it is clinically coherent with other percutaneous procedures performed on the heart valves that are currently assigned to MS-DRGs 216 through 221.

[MDC 8 \(Diseases and Disorders of the Musculoskeletal System and Connective Tissue\)](#):

[Total Ankle Repair Procedures](#): CMS proposes to reassign all total ankle replacements to MS-DRG 469 even when there is no MCC reported.

In addition, CMS proposes to change the titles of the MS-DRGs as follows: MS-DRG 469 (Major **Hip and Knee** Joint Replacement or Reattachment of Lower Extremity with MCC or **Total Ankle Replacement**), MS-DRG 470 (Major **Hip and Knee** Joint Replacement or Reattachment of Lower Extremity without MCC).

[Revision of Total Ankle Replacement Procedures](#): CMS proposes to maintain the MS-DRG assignments for total ankle revision procedures.

[Magnetic Controlled Growth Rods \(MAGEC® System\)](#): CMS is not proposing reassignment of the six new ICD-10 procedure codes to identify the MAGEC® System.

CMS finalized its proposal to maintain the current MS-DRG assignment ([p. 173](#)).

CMS finalized its proposals ([p. 179](#)).

CMS corrected some of the revision ICD-PCS codes listed in the proposed rule based on stakeholder feedback acknowledging that a revision is indicated by a combination of codes with the root operation "Removal and Replacement ([p. 185](#)). CMS reconducted its analyses based on the correct coding combinations ([p. 187](#)). CMS noted however that the correction of this mistake does not require reassignment from MS-DRGs 515, 516, or 517 of these cases because when correctly coded the cases would have been assigned to MS-DRGs 469 and 470 anyway. When the general finalized TAR policy is applied, these cases will be assigned to MS-DRG 469 even if there is no MCC present ([p. 188](#)).

CMS finalized its proposal to maintain the the current assignment of codes for the use of magnetically controlled growth rods in the treatment of early onset scoliosis ([p. 193](#)).

Combined Anterior/Posterior Spinal Fusion: CMS proposes to make all of the mentioned corrections to ICD-10 procedure codes for fusion using a nanotextured surface interbody fusion device that were not correctly added to the logic for the following MS-DRGs: MS-DRG 453 (Combined Anterior/Posterior Spinal Fusion with MCC), MS-DRG 454 (Combined Anterior/Posterior Spinal Fusion with CC), MS-DRG 455 (Combined Anterior/Posterior Spinal Fusion without CC/MCC). CMS also proposes to make corrections to 33 ICD-10 procedure codes on the posterior spinal fusion list that describe “an interbody fusion device in the posterior column, and therefore, are not considered clinically valid spinal fusion procedures.”

MDC 23 (Factors Influencing health Status and Other Contacts with Health Services): CMS states that if new ICD-10 codes are created for rehabilitation service encounters, CMS would address any updates to MS-DRGs 945 and 956 utilizing the new codes in future rulemaking. CMS requests any additional input on updates to MS-DRGs 945 and 956 and asks for comments on its proposal to *not* update the MS-DRGs for FY 2018

Proposed Medicare Code Editor (MCE) Changes:

Sex Conflict Edits:

CMS proposes to add the entire list of diagnosis codes for the Diagnoses for Males Only edit.

CMS also proposes to remove from the list of ICD-10 diagnosis code Q64.0 (Epispadias) because it can occur in both males and females.

Non-Covered Procedure Edit: Gender Reassignment Surgery: CMS proposes to remove the list of codes included as part of the Non-Covered Procedure edit that are not congruent with the 2014 covered services changes that allow Medicare Administrative Contractors (MACs) determine coverage on a case-by-case basis from the non-covered services list.

CMS finalized its proposals, but in response to comments also stated that for FY 2019 it would review the ICD-10 logic for the MS-DRGs where spinal fusion procedures are assigned (p. 201).

CMS finalized its proposal to not make updates to MS-DRG 945 and 945 in FY 2018 (p. 234). CMS agreed with stakeholders that it was difficult to identify shifts in the data without a specific ICD-10-CM code for encounters for rehabilitation therapy. CMS reiterated that if the CDC creates a new code effective October 1, 2018 that CMS will evaluate potential updates as part of FY 2019 rulemaking.

CMS finalized this proposal (p. 245). The full list of codes under the Males Only edit can be found on the IPPS Final Rule Web site [here](#).

CMS finalized this proposal (p. 246).

CMS finalized this proposal (p. 251). One commenter requested that CMS review its current policies related to breast implant procedures for transgender females noting that estrogen therapy by itself does not provide adequate growth tissue. CMS recommended that the commenter contact the local MAC for additional information given that there is no National Coverage Determination (NCD) for this service (p. 250).

Unacceptable Principal Diagnosis Edits:

- Bacterial and Viral Infectious Agents (B95 through B97): CMS identified 45 ICD-10 diagnosis codes within the Bacterial and Viral Infectious Agents (B95-B97) code range that it believes are not appropriate for principal diagnosis and proposes to add them to the Unacceptable Principal Diagnosis edit list.
- General Symptoms and Signs (R50 through R69): CMS proposes to add the following ICD-10 diagnosis codes to the Unacceptable Principal Diagnosis edit: R65.10 Systemic inflammatory response syndrome (SIRS) of non-infectious origin without acute organ dysfunction, R65.11 Systemic inflammatory response syndrome (SIRS) of non-infectious origin with acute organ dysfunction, R65.20 Severe sepsis without septic shock, R65.21 Severe sepsis with septic shock.
- Complications of Surgical and Medical Care, Not Elsewhere Classified (T80 through T88): CMS proposes to add the following ICD-10 diagnosis codes to the Unacceptable Principal Diagnosis edit: T81.12XD Postprocedural septic shock, subsequent encounter, T81.12XS Postprocedural septic shock, sequela.

Surgical Hierarchies. CMS is seeking comment on its proposal to move MS-DRGs 614 and 615 (Adrenal and Pituitary with CC/MCC and without CC/MCC, respectively) above MS-DRGs 622, 623, and 624 (Skin Grafts and Wound Debridement for Endocrine, Nutritional, and Metabolic Disorders with MCC, with CC and without CC/MCC, respectively).

Replaced Devices Offered without Cost or With a Credit: CMS is proposing not to add any MS-DRGs to the list of “device dependent” MS-DRGs subject to the payment policy for replaced devices offered without cost or with a credit for FY 2018.

CMS finalized this proposal (p. 253).

CMS finalized this proposal (p. 260).

CMS finalized this proposal (p. 263).

CMS acknowledged that a comment was made about proposing a change based on a single scenario and that CMS should conduct a more thorough analysis before finalizing the change (p. 275). CMS conducted an analysis of the volumes of cases where both sets of MS-DRGs were reported and are illustrated in [the tables on p. 276 and 277](#). CMS determined that the change to the hierarchy would result in about 6.7 percent of cases in MS-DRGs 622, 623, and 624 moving to MS-DRGs 614 and 615, and therefore the impact of this change is “limited.” Therefore, **CMS finalized this proposal (p. 279).**

CMS received no comments on this, and **CMS finalized its proposal (p. 317).** This list of MS-DRGs to which the overall policy applies is contained in a [table beginning on p. 317](#).

Add-On Payments for New Services and Technologies

[Reference to an ICD-9-CM Code in § 412.87\(b\)\(2\) of the Regulations](#)

CMS proposes to replace the term “ICD-9-CM code” with the term “inpatient hospital code.” This is defined in section 1886(d)(5)(K)(iii) of the Act as any code that is used with respect to inpatient hospital services for which payment may be made and includes an alphanumeric code issued under the International Classification of Diseases, 9th Revision, Clinical Modification (“ICD-9-CM”) and its subsequent revisions.

CMS finalized this proposal without modification ([p. 430](#)).

[Proposed FY 2018 Status of Technologies Approved for FY 2017 Add on Payments](#)

CardioMEMSTM HF (Heart Failure) Monitoring System: CMS proposes to discontinue new technology add-on payments for this technology for FY 2018.

CMS finalized this proposal without modification. ([p. 434](#))

Defitelio® (Defibrotide): CMS proposes to continue new technology add-on payments for this technology for FY 2018.

CMS finalized this proposal without modification. ([p. 437](#))

GORE® EXCLUDER® Iliac Branch Endoprosthesis (GORE IBE device): CMS proposes to continue new technology add-on payments for this technology for FY 2018.

CMS finalized this proposal without modification. ([p. 440](#))

Praxbind® Idarucizumab: CMS proposes to continue new technology add-on payments for this technology for FY 2018.

CMS finalized this proposal without modification. ([p. 443](#))

Lutonix® Drug Coated Balloon PTA Catheter and In.PACT™ Admiral™ Paclitaxel Coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter: CMS proposes to discontinue new technology add-on payments for both the LUTONIX® and IN.PACT™ Admiral™ technologies for FY 2018.

CMS finalized this proposal without modification. ([450](#))

MAGEC® Spinal Bracing and Distraction System (MAGEC® Spine): CMS proposes to discontinue new technology add-on payments for this technology for FY 2018.

CMS finalized this proposal without modification. ([455](#))

Vistogard™ (Uridine Triacetate): CMS proposes to continue new technology add-on payments for this technology for FY 2018.

CMS finalized this proposal, using new pricing data. The maximum new technology add-on payment will be \$40,130 for FY 2018. ([p. 459](#))

Blinatumomab (BLINCYTO®): CMS proposes to discontinue new technology add-on payments for this technology for FY 2018.

CMS finalized this proposal without modification. ([p. 468](#))

[FY 2018 Applications for New Technology Add-On Payments](#)

[Bezlotoxumab \(ZINPLAVA™\)](#): Because ZINPLAVA™ has a unique mechanism of action, CMS believes the technology is not substantially similar to existing technologies and, therefore, meets the newness criterion. CMS invites public comments on whether ZINPLAVA™ meets the newness criterion. CMS does not express concerns about the cost criterion, but invites public comments. CMS expresses concern related to the adverse event of cardiac failure of ZINPLAVA™ and invites public comment on whether the product meets the substantial clinical improvement criterion.

[EDWARDS INTUITY Elite™ Valve System \(INTUITY\) and LivaNova Perceval Valve \(Perceval\)](#): CMS believes these two devices are substantially similar to each other and that it is appropriate to evaluate both as one application for new technology add-on payments under the IPPS. CMS expresses concern about the newness criterion and invites public comment. With regard to the INTUITY valve, CMS states that it needs more information on cost and invites public comment on the cost criterion. With regard to the Perceval valve, CMS invites public comment on the cost criterion as well. CMS expresses concern about substantial clinical improvement for both and invites public comment on whether rapid deployment valves, specifically the two under consideration, meet the substantial clinical improvement criterion.

[Ustekinumab \(Stelara®\)](#): CMS expresses concern about the newness criterion, particularly whether the treatment is targeted at a new patient population in all circumstances, and invites public comment. CMS does not express concern about the cost criterion, but invites public comment. CMS expresses concern that it does not have enough information to determine whether Stelara® is a substantial clinical improvement over existing technologies for the treatment of moderate to severe Crohn's Disease. CMS invites comments about the substantial improvement criterion.

[KTE-C19 \(Axicabtagene Ciloleucel\)](#): CMS expresses concern about similarity to existing technologies and invites comments on both the substantial similarity and newness criteria. With regard to the substantial clinical improvement criterion, CMS expresses concern with the lack of published survival benefit results and other data it views as lacking.

CMS approved new technology add-on payments for ZINPLAVA™. Cases eligible for the payment will be identified by procedure codes XW033A3 and XW043A3. The maximum add-on payment will be \$1,900 for FY 2018. ([p. 485](#)).

CMS determined that the devices meet the criteria and sets the maximum payment at \$6,110.23 for FY 2018. Eligible cases will be identified by procedure code X2RF032. ([p. 486](#))

CMS determined that the product meets the criteria and sets the maximum payment \$2,400 for FY 2018. Eligible cases will be identified by procedure code XW033F3. ([p. 510](#))

The applicant withdrew its application. ([p. 468](#))

VYXEOS™ (Cytarabine and Daunorubicin Liposome for Injection):
CMS expresses concern about the newness of this technology and invites public comment on newness, and whether VYXEOS™ is substantially similar to existing technology, including whether the mechanism of action differs from the mechanism of action of the current treatment regiment. CMS does not express concerns about cost, but invites public comment on the cost criterion. CMS expresses concern about substantial clinical improvement and invites comment.

CMS determined the applicant was not eligible because it did not receive FDA approval before July 1, 2017. ([p. 469](#))

GammaTile™: With regard to newness, CMS expresses concern that the mechanism of action for this device may be the same or similar to current forms of radiation or brachytherapy. CMS invites comment on whether this technology meets the substantial similarity criteria and the newness criterion. With regard to the cost criterion, CMS expresses concern that the sample size was too small, and invites public comment on this criterion. CMS invites comment about the substantial clinical improvement criterion.

The applicant withdrew its application. ([p. 468](#))

Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2018

Uncompensated Care Payment

The ACA modified the payment methodology (regardless of under which method hospitals qualify) for Medicare Disproportionate Share Hospital (DSH) payments to account for expected reductions in uninsured patients. Beginning in 2014 DSHs receive 25 percent of the amount they would have otherwise received under the DSH payment methodology (the “Empirically Justified Medicare DSH Payment”); the 75 percent remaining is to be distributed as an additional payment minus a reduction intended to reflect the change in the percentage of individuals that are uninsured (“Uncompensated Care Payment”).

To determine how much of that 75 percent remaining will be paid, the statute directs that it is the product of three factors:

Factor 1: *The difference between the aggregate amount of payments that would have been made and the payments made to provide the 25 percent required or Empirically Justified Medicare DSH Payment (this calculates the 75 percent remaining or potential Uncompensated Care Payment).* CMS proposed to continue its policy for calculating Factor 1.

CMS finalized its proposal for calculating Factor 1 ([p. 795](#)). Based on all available data, CMS estimates that the Empirically Justified Medicare DSH payments (the “25%”) for FY 2018 is \$3.888 billion ([p. 796](#)). Therefore, Factor 1 (“the 75%”) is \$11,664,704,643.27 for FY 2018.

Factor 2: For FY 2018 and subsequent years, 1 minus the percent change in the percent of individuals who are uninsured by comparing the percent of individuals who were uninsured in 2013 and the percent of individuals who were uninsured in the most recent period for which data are available minus 0.2 percentage point for FY 2018 and 2019. CMS proposes to alter its data source to calculate the rate of uninsured to the estimates of the CMS Office of the Actuary as part of the Development of the National Health Expenditure Accounts (NHEA). CMS puts forward a FY 2018 Factor 2 of 58.01 percent, a higher percentage than would have been calculated based on the previous data and resulting in the availability of \$6.962 billion for Uncompensated Care Payments.

Factor 3: The quotient of the amount of uncompensated care for a period selected by the Secretary (on data determined by the Secretary) and the aggregate amount of uncompensated care for all hospitals receiving DSH payments. This creates a hospital-specific value that expresses the proportion of the estimated uncompensated care amount for each hospital. CMS proposes to rely on the Worksheet S-10 of the Medicare cost report for each hospital.

CMS finalized its proposed calculation for Factor 2 (p. 815). The final calculation using a weighted average of the projections for CY 2017 and CY 2018 result in a final uncompensated care amount available of \$6.766 billion (slightly less than estimated in the proposed rule).

CMS finalized its proposal to begin incorporating Worksheet S-10 into the calculation of Factor 3 beginning in FY 2018 (p. 850). CMS again reminded hospitals that they have been on notice since FY 2014 that Worksheet S-10 could become the data source for computing Factor 3 (p. 838). CMS estimates that this change will increase the total amount available to make uncompensated care payments by \$800 million (p. 832).

However, CMS appreciated the concerns about some data reported via Worksheet S-10 and responded positively to the idea of using a ratio of uncompensated care costs to total operating costs to identify potentially aberrant data when determining Factor 3 amounts (p. 839). Therefore, **CMS is adopting MedPAC's suggestion that uncompensated care costs in excess of half of a hospital's total operating expenses may be "potentially aberrant."** (p. 840). Then, **CMS states that in those scenarios, it would be appropriate to utilize 2015 Worksheet S-10 data to address the potentially aberrant 2014 Worksheet S-10 data** (p. 840). If a hospital has a consistently high ratio across the two years, CMS will be less likely to reduce the uncompensated care payments (p. 841). **CMS will assess the use of this adjustment or alternative adjustments in future rulemaking** (p. 841).

CMS reviewed its previous comments regarding MAC audit protocols. CMS noted that it continues to intend 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." CMS also reminded stakeholders that it will not make the MAC's review protocol public "as all CMS desk review and audit protocols are confidential and are for CMS and MAC use only." CMS stated that the MAC instructions are still under development (p. 847).

For FY 2018 it calculates Factor 3 by averaging results relying on 3 different methodologies:

- Using low-income insured days proxy based on FY 2012 cost report data and the FY 2014 SSI ratio
- Using low-income insured days proxy based on FY 2013 cost report data and the FY 2015 SSI ratio
- Using data from the FY 2014 Worksheet S-10 data.

CMS finalized this proposal ([p. 866](#)).

Quality Reporting & Value Based Purchasing Provisions

[Hospital Readmissions Reduction Program](#)

General Background: On December 13, 2016, the 21st Century Cures Act (Pub. L. 114-255) was enacted. This legislation:

- Directs 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.
- Directs MedPAC to conduct a review of overall hospital readmissions and whether such readmissions are related to any changes in outpatient and emergency services furnished. A report on the study is required to be submitted in the MedPAC's Report to Congress no later than June 2018.

A detailed summary of these statutory requirements is provided starting on [p. 907](#).

Applicable time period for FY 2018: CMS proposes that the "applicable period" for the Hospital Readmissions Reduction Program would be the 3-year period from July 1, 2013 through June 30, 2016.

CMS finalized its proposal ([p. 912](#)), despite concerns about this time period combining both ICD-9 and ICD-10 data. Test results of combined data demonstrated stability in the measure cohort, in the number of hospitals included in the measure, in the performance of the measure risk model, and in trends of modest reductions in risk-standardized readmission rates across the country. In general, the three-year period allows CMS to capture sufficient data from small and rural hospitals and to include the maximum possible number of hospitals in public reporting.

Calculation of aggregate payments for excess readmissions for FY 2018: CMS proposes to use MedPAR claims with discharge dates that are on or after July 1, 2013, and no later than June 30, 2016, consistent with its historical use of a 3-year applicable period. To identify the discharges for each applicable condition for FY 2018 to calculate the aggregate payments for excess readmissions for an individual hospital, CMS proposes to identify each applicable condition, using, for FY 2013, FY 2014 and FY 2015, the appropriate ICD-9-CM codes, and for FY 2016, the appropriate ICD-10-CM and ICD-10-PCS code sets.

CMS finalized its proposal without modification ([p. 916](#)).

Payment Adjustment Methodology: General Background

Proposed methodology for calculating the proportion of dual eligible patients for FY 2019: The 21st Century Cures Act requires the Secretary to group hospitals and apply a methodology that allows for separate comparisons of hospitals within groups in determining a hospital's adjustment factor for payments of discharges beginning in FY 2019. CMS proposes 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.

CMS also proposed 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.

Proposed methodology for assigning hospitals to peer groups: As required under the 21st Century Cures Act, CMS considered three alternative methodologies for assigning hospitals to peer groups. Its preferred approach is to stratify hospitals into quintiles (five peer groups).

Proposed Payment Adjustment Formula Calculation Methodology: CMS proposes four alternative budget neutral methodologies for calculating the payment adjustment factor. Its preferred approach is assessing performance compared to the peer group median excess readmissions ratio (ERR), rather than the current threshold of 1.0000, and scaling hospital payment adjustments by a neutrality modifier.

Accounting for Social Risk-Factors in the Hospital Readmissions Reduction Program: CMS continues to seek public comment on whether it should account for social risk factors in the Hospital Readmissions Reduction Program and, if so, what method or combination of methods would be most appropriate for accounting for social risk factors.

Starting on [p. 925](#), CMS provides a description of the current payment adjustment methodology for the Hospital Readmissions Reduction Program

CMS finalized its proposals related to dual eligible patients without modifications ([p. 927](#)).

CMS finalized its proposal without modification ([p. 941](#)). The various proposed methodologies are described on [p. 951](#).

CMS finalized its proposal to use the median ERR plus neutrality modifier ([p. 950](#)).

Commenters were generally supportive of how the Hospital Readmissions Reduction Program is adopting a methodology for accounting for dual-eligible patients. However, commenters also stated concerns such as the need to:

- continue refinement of performance scoring and measurements to end any bias to major teaching providers;
- continue development of appropriate peer groups; and
- work to develop and apply appropriate socio-demographic status adjustments.

[Hospital Value-Based Purchasing \(VBP\) Program](#)

Update to the Extraordinary Circumstances Exception Policy: CMS proposes to update these policies by: (1) allowing the facility to submit a form signed by the facility's CEO or designated personnel; (2) clarifying that it will strive to provide formal responses notifying the facility of its decision within 90 days of receipt of the facility's request; and (3) allowing CMS to have the authority to grant ECEs due to CMS data system issues which affect data submission. These policies would apply beginning in FY 2018 as related to extraordinary circumstances that occur on or after October 1, 2017.

Accounting for Social Risk Factors in the Hospital VBP Program: CMS continues to invite comment on the appropriateness of accounting for social risk factors in the Hospital VBP Program, including which social risk factors should be included, and how to account for these social risk factors in the Hospital VBP Program. CMS also seeks comment on which social risk factors might be most appropriate for stratifying measure scores and/or potential risk adjustment of a particular measure and which data sources would be most appropriate.

Some recommendations, such as the use of a hospital-wide readmission measure, would require a statutory change. CMS will consider all suggestions as it continues to assess each measure and the overall program. It intends to explore options including but not limited to measure stratification by social risk factors in a consistent manner across programs, informed by considerations of stratification methods described in the preamble of this final rule. CMS will continue to consider options to account for social risk factors that would allow it to view disparities and potentially incentivize improvement in care for patients and beneficiaries. It will also consider providing feedback to providers on outcomes for individuals with social risk factors in confidential reports ([p. 967](#)).

CMS finalized these policies without modification ([p. 975](#)).

CMS refers readers to its discussion about stratifying hospitals into peer groups for purposes of assessing payment adjustments under the Hospital Readmissions Reduction Program, which reflects the level of analysis CMS would undertake when evaluating methods and combinations of methods for accounting for social risk factors in CMS' other value-based purchasing programs, such as the Hospital VBP Program ([p. 983](#)).

CMS believes that the path forward should incentivize improvements in health outcomes for disadvantaged populations while ensuring that beneficiaries have access to excellent care. CMS intends to consider all public suggestions as it continues to assess each measure and the overall program. CMS appreciates that some commenters recommended risk adjustment as a strategy to account for social risk factors, while others stated a concern that risk adjustment could minimize incentives and reduce efforts to address disparities for patients with social risk factors. CMS intends to conduct further analyses on the impact of strategies, such as measure-level risk adjustment and stratifying performance scoring to account for social risk factors. CMS also appreciates recommendations about specific social risk factor variables and will work to determine the

Retention and Removal of Quality Measures for the FY 2019 Program Year: CMS proposes to remove **PSI 90: Patient Safety for Selected Indicators measure** from the Hospital VBP Program beginning with the FY 2019 program year.

Proposed New Measures for the FY 2022 Program Year, FY 2023 Program Year, and Subsequent Years: CMS proposes to adopt one new measure, **Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode of Care for Pneumonia (the PN Payment measure)**, beginning with the FY 2022 program year.

Proposed New Measure for the FY 2023 Program Year and Subsequent Years: CMS proposes to adopt a modified version of the current **PSI 90** measure, entitled **Patient Safety and Adverse Events (Composite)** (NQF #0531), for the Hospital VBP Program for the FY 2023 program year and subsequent years.

feasibility of collecting these patient-level variables while evaluating burden on providers.

Since the vast majority of commenters supported removal of **PSI 90**, **CMS finalized its proposal to do so beginning with the FY 2019 year** (p. 990). A table listing previously adopted measures and finalized measure for removal for the FY 2019 and FY 2020 program years can be found on p. 995.

CMS finalized its proposal to adopt the PN Payment measure beginning with the FY 2022 program year as proposed. In response to a recommendation that CMS engage with stakeholders regarding risk adjustments for this measure, CMS reminds the public that it routinely solicits public comment on measures under development. For current and future opportunities, please visit the [CMS Quality Measures Public Comment page](#). In addition, there are opportunities for stakeholders to serve on [Technical Expert Panels](#) and provide technical input to CMS and the measure contractors on the development, selection, and maintenance of measures (p. 997).

CMS finalized its proposal to adopt the Patient Safety and Adverse Events (Composite) measure beginning with the FY 2023 program year.

In this section, CMS and AHRQ recognize commenter concerns about surveillance bias for **PSI 12**, and note that this issue was addressed in the NQF Patient Safety Steering Committee in 2015. Several research teams have examined DVT and PE rates and surveillance bias, but studies have not specifically examined whether the observed rates reflect under-diagnosis of DVT or PE at low-testing hospitals, or the underlying true incidence of symptomatic DVT or PE, and there is no evidence currently available to support the hypothesis that increased vigilance in DVT or PE detection is desirable from the perspective of patients and their families. Thus, although CMS acknowledges commenter's concerns regarding surveillance bias, it believes the **PSI 12** is an important component indicator of the Composite measure because it encourages hospitals not only to prevent DVT or PE, but also to appropriately assess a patient's risk for DVT and PE to prevent over-diagnosis and under-diagnosis (p. 1025).

Previously Adopted and Proposed Baseline and Performance Periods:

- For the **AMI Payment** and **HF Payment measures**, CMS proposes to adopt a 36-month performance period and baseline period, similar to policies previously finalized for the FY 2022 program year.
- For the **PN Payment measure**, proposed to begin with the FY 2022 program year, CMS proposes to adopt a 36-month baseline period and a 23-month performance period to ensure adoption of this measure as early as feasible into the Hospital VBP Program. For the FY 2023 program year, CMS proposes to adopt a 35-month performance period for this measure.
- In order to adopt the **Patient Safety and Adverse Events (Composite) measure** as early as feasible into the Hospital VBP Program, CMS proposes to adopt a 21-month baseline period and 24-month performance period for this measure for the FY 2023 program year. For the FY 2024 program year and subsequent years, CMS proposes to lengthen the **Patient Safety and Adverse Events (Composite) measure** baseline period to 24 months and continue to adopt a 24-month performance period because it believes the measure is most reliable with a 24-month baseline period.
- For each of the previously finalized measures in the Clinical Care domain—that is, the **MORT-30-AMI, MORT-30-HF, MORT-30-COPD, THA/TKA, and MORT-30-CABG measures**, CMS is now proposing to adopt a 36-month performance period and 36-month baseline period for these measures for the FY 2023 program year and subsequent years.
- CMS previously 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. It also adopted a 34-month performance period and 36-month baseline period for this measure for the FY 2022 program year. CMS does not propose any changes to these policies, but does propose to adopt a 36-month performance period and a 36-month baseline period for the FY 2023 program year and subsequent years.

CMS finalized these policies as proposed ([p. 1044](#)).

Starting on [p. 1059](#), CMS provides tables summarizing previously adopted and newly finalized baseline and performance periods for the FY 2019 through FY 2023 program years.

Performance Standards for the Hospital VBP Program

CMS provides background on performance standards for the Hospital VBP program starting on [p. 1063](#).

Previously adopted and newly finalized performance standards for the FY 2020 program year are summarized in a table starting on [p. 1065](#).

Newly finalized performance standards for the Person and Community Engagement domain for FY 2020 program year are summarized in a table on [p. 1067](#).

Previously adopted performance standards for the FY 2021 program year are summarized in a table starting on [p. 1069](#).

Previously adopted and newly finalized performance standards for certain measures for the FY 2022 program year are summarized in a table on [p. 1071](#).

In a table on [p. 1073](#), CMS summarizes newly finalized performance standards for the FY 2023 program year.

Domain Weighting for the FY 2020 Program Year and Subsequent Years for Hospitals That Receive a Score on All Domains: For the FY 2020 program year and subsequent years, CMS proposes to retain the same domain weighting for hospitals receiving a score on all four domains:

- Safety: 25%
- Clinical Care: 25%
- Efficiency and Cost Reduction: 25%
- Person and Community Engagement: 25%

CMS finalized this policy as proposed ([p. 1074](#)).

Proposed Domain Weighting for the FY 2019 Program Year and Subsequent Years for Hospitals Receiving Scores on Fewer than Four Domains: CMS proposes two changes to its domain scoring policies for the FY 2019 program year and subsequent years:

- To change the minimum number of measures scores a hospital must receive to receive a score on the Safety domain from three measures to two measures (since it's proposing to remove the current **PSI 90 measure** from the program beginning with FY 2019)
- That hospitals must receive a minimum of one measure score within the Efficiency and Cost Reduction domain to

CMS finalized this policy as proposed ([p. 1077](#)).

receive a domain score rather than requiring that hospitals meet the requirements to receive a **MSPB measure** score (which reflects CMS' recent expansion of the domain's measure set).

Minimum Numbers of Cases for Hospital VBP Program Measures for the FY 2019 Program Year and Subsequent Years: Efficiency and Cost Reduction Domain. CMS proposes that hospitals must report a minimum number of 25 cases per measure in order to receive a measure score for the FY 2021 program year and subsequent years.

Weighting Measures within the Efficiency and Cost Reduction Domain: CMS proposes to weight the measures within the Efficiency and Cost Reduction domain such that the **MSPB measure** comprises 50 percent of a hospital's domain score and the other condition-specific payment measures, weighed equally, comprise the remaining 50 percent of a hospital's domain score, beginning with the FY 2021 program year and for subsequent years. CMS further proposes that:

- If a hospital meets the case minimum to receive a score on the **MSPB measure**, but does not meet the minimum number of cases for any other measures in the Efficiency and Cost Reduction domain, its domain score will be based solely on its **MSPB** score;
- If a hospital does not meet the case minimum to receive a score on the **MSPB measure** but meets the minimum number of cases for any other measure or measures within the Efficiency and Cost Reduction domain, its domain score will be based on its scores on the other payment measures, weighted equally (that is, the MSPB measure's weight will be redistributed equally among the Efficiency and Cost Reduction domain measures for which the hospital is eligible receive a score); and
- If a hospital meets the case minimum to receive a score on the **MSPB measure** and one or more other measures within the Efficiency and Cost Reduction domain, but not all measures within this domain, the hospital's MSPB measure score will comprise 50 percent of its domain score and the remaining 50 percent will be divided equally among the measures for which the hospital is eligible to receive a score.

CMS finalized this policy as proposed ([p. 1083](#)).

On [p. 1085](#), CMS provides a table summarizing all previously adopted and newly finalized minimum numbers of cases, across all domains, for the FY 2019 program year and subsequent years.

CMS finalized its proposal to weight the measures within the Efficiency and Cost Reduction domain such that the **MSPB** measure comprises 50 percent of a hospital's domain score and the other condition-specific payment measures, weighed equally, comprise the remaining 50 percent of a hospital's domain score, beginning with the FY 2021 program year ([p. 1086](#)).

[Hospital-Acquired Condition \(HAC\) Reduction Program](#)

The HAC Reduction Program creates a payment adjustment resulting in payment reductions for hospitals with scores in the lowest performing quartile based on their rates of HACs.

CMS proposes specifying the dates of the time period used to calculate hospital performance for the FY 2020 HAC Reduction Program and updating the HAC Reduction Program's Extraordinary Circumstances Exception Policy, and requests comments on additional measure for potential future adoption, social risk factors, accounting for disability and medical complexity in the **CDC NHSN measures** in Domain 2.

On [p. 1094](#), CMS lists HAC Reduction Program measures for FY 2018.

CMS finalized its proposal to return to a 24-month data collection period for the calculation of HAC Reduction Program measure results ([p. 1097](#)).

In regards to feedback on new measures for potential future adoption, many commenters supported CMS's interest in measures of patient safety—particularly outcomes-focused measures which include falls and injury, adverse drug effects, glycemic events, and ventilator associated events (VAEs).

Commenters also recommended that:

- Measures reflect clinical reality by accurately measuring the intended target, be usable by providers who can use the data to implement evidence-based practices to improve care, align with one another using standardized definitions, and represent only the most important health priorities;
- That measures should be integrated in interoperable EHRs, allowing for more comprehensive measurement and requiring no extra reporting effort;
- That CMS utilize measures that were fully tested and received NQF endorsement.
- Others believe that adding more HAI measures could serve to dilute the focus on improvement efforts and that when additional measures were added, facilities were not able to prioritize the infection-related events that were most relevant to the population served and services provided in their facilities.

In regards to social risk factors, CMS refers readers to its discussion about stratifying hospitals into peer groups for purposes of assessing payment adjustments under the Hospital Readmissions Reduction Program, which reflects the level of analysis CMS would undertake when evaluating methods and combinations of methods for accounting for social risk factors in CMS' other value-based purchasing programs, such as the HAC Reduction Program.

CMS notes that measures in the HAC Reduction Program, generally, represent never events, and are often preventable conditions like central line associated bloodstream infections, catheter associated urinary tract infections, and other complications or conditions that arise after a patient was admitted to the hospital for the treatment of another condition. CMS

[Hospital
Inpatient
Quality
Reporting \(IQR\)
Program](#)

Accounting for Social Risk Factors in the Hospital IQR Program: CMS continues to seek public comment on whether it should account for social risk factors in the Hospital IQR Program, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors. CMS seeks comments on which of these factors, including current data sources where this information would be available, could be used alone or in combination, and whether other data should be collected to better capture the effects of social risk. CMS seeks comments on options for publicly displaying stratified rates using social risk factors as well as which other social risk factors besides dual eligibility should be used.

believes these events should not be influenced by social risk factors; instead, they are risk-adjusted for factors listed in specifications for the AHRQ and CDC developed measures. Nevertheless, ***CMS continues to seek public comment on whether it should account for social risk factors in the HAC Reduction Program and, if so, what method would be most appropriate.*** CMS summarizes public input received and notes its intent to explore options including, but not limited to, measure stratification by social risk factors in a consistent manner across programs. CMS will also consider providing feedback to providers on outcomes for individuals with social risk factors in confidential reports ([p. 1107](#)).

In this section, CMS also discusses stakeholder feedback on risk-adjusting the **CDC NHSN** measures for disability or medical complexity ([p. 1116](#)).

CMS also discusses in this section its decision to finalize its modifications to the Extraordinary Circumstances Exception (ECE) policy as proposed ([p. 1119](#)).

Technical specifications for **Patient Safety and Adverse Events Composite** measure in Domain 1 can be found at AHRQ's website at: http://qualityindicators.ahrq.gov/Modules/PSI_TechSpec.aspx

Technical specifications for the **CDC NHSN HAI** measures in Domain 2 can be found at CDC's NHSN website at: <http://www.cdc.gov/nhsn/acute-care-hospital/index.html>

Several commenters were generally supportive of accounting for social risk factors in the Hospital IQR Program, while others voiced concerns that this approach will not address the underlying disparities that are often associated with poor health outcomes and might instead, mask potential disparities or minimize incentives to improve the outcomes for disadvantaged populations; that adjustments to quality measures could create a two-tier system of care where those with few economic or social resources are diminished in the calculation of quality measure; and that providers should not be financially penalized while caring for patients with greater needs.

Several commenters recommended that comorbidities, functional impediments, and cognitive limitations must be accounted for when assessing quality and costs. Commenters also suggested that CMS conduct analyses to determine the degree to which certain variables, such as

insurance, age, race, and ethnicity, impact admission rates before these factors are weighted as part of any quality scoring metrics.

Many commenters recommended providing this risk-adjusted data alongside unadjusted data so that interventions can be appropriately targeted, but discouraged the use of unadjusted data in publicly reported and pay-for-performance measures.

Others encouraged CMS to continue to work on developing more precise approaches to risk adjustment to account for social factors in the rural context. Some stated that CMS should implement demonstration projects to encourage hospitals to collect SDS data through their EHR. Others advised CMS to monitor the effects of changes to quality programs on hospitals serving beneficiaries with social risk factors so that future programmatic changes are made with these concerns in mind.

CMS will take commenters' input into consideration as it continues to assess the appropriateness and feasibility of accounting for social risk factors in the Hospital IQR Program. Any such changes would be proposed through future notice-and-comment rulemaking.

CMS intends to explore options including, but not limited to, measure stratification by social risk factors in a consistent manner across programs when appropriate, informed by considerations described [later in this section](#), which describes options of:

- Stratified reporting of a measure by patient factors, which highlights disparities in outcomes by patient subgroup; and
- Peer-to-peer benchmarking based on hospital's share of patient factors, which allows hospitals to compare their performance with like-peers.

In response to public input, CMS also intends to conduct further analyses on the impact of different approaches such as measure-level risk adjustment and stratifying performance scoring to account for social risk factors. In addition, it will consider conducting empirical testing of risk-adjusted quality metrics, and assess the potential impact of the findings from such testing on the prioritization of national data collection, in relation to risk adjustment methodologies. It also will work to determine the feasibility of collecting specific patient-level variables, including the reporting burden on providers, and actively perform additional research and monitor for trends to prevent unintended consequences ([p. 1325](#)).

Hospital IQR Program Measures for the FY 2019 Payment Determination and Subsequent Years. No changes proposed.

Previously adopted Hospital IQR Program measures for the FY 2019 payment determination and subsequent years are listed in a table starting on [p. 1334](#). The Hospital IQR Program has previously finalized 62 measures for the FY 2019 payment determination and subsequent years.

The technical specifications for chart-abstracted clinical process of care measures used in the Hospital IQR Program are contained in the CMS/The Joint Commission (TJC) Specifications Manual for National Hospital Inpatient Quality Measures (Specifications Manual), available on the [QualityNet website](#).

The technical specifications for electronic clinical quality measures (eCQMs) used in the Hospital IQR Program are contained in the CMS Annual Update for Hospital Quality Reporting Programs (Annual Update), posted on the [eCQI Resource Center webpage](#).

Refinements to Existing Measures in the Hospital IQR Program for the FY 2020 Payment Determination and Subsequent Years: CMS proposes refinements to two measures:

A table summarizing previously adopted Hospital IQR Program measures for the FY 2020 payment determination and subsequent years can be found on [p. 1416](#).

1) Refining the **Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey (NQF #0166) measure** for the FY 2020 Payment Determination and Subsequent Years. CMS proposes to update the HCAHPS Survey measure by replacing the three existing questions about Pain Management (HCAHPS Q12, Q13, and Q14) with three new questions that address Communication About Pain During the Hospital Stay, beginning with the FY 2020 payment determination (thus, applicable to surveys administered to patients beginning with January 1, 2018 discharges and for subsequent years). CMS also proposes to update the name of the composite measure from “Pain Management” to “Communication About Pain.”

Discussions about the **HCAHPS Survey Pain measures** starts on [p. 1339](#). ***CMS finalized the refinements to the HCAHPS Survey measure pain management questions as proposed, with a modification regarding public display. Instead of publicly reporting results beginning with October of 2019 using CY 2018 data as proposed, hospital performance data on the refined Communication About Pain composite measure questions will not be publicly reported on the Hospital Compare website until October of CY 2020, using CY 2019 data.*** CMS will provide performance results, based on CY 2018 data on the refined Communication About Pain composite measure questions to hospitals in confidential preview reports, upon the availability of four quarters of data. CMS anticipates that these confidential preview reports would be available as early as July 2019.

CMS clarifies that the current Pain Management questions in the HCAHPS Survey apply to patients who needed medicine for pain; whereas, the refined Communication About Pain composite measure will apply to patients who experienced any pain during the hospital stay. As such, when implemented, more patients will have the opportunity to answer the proposed refined Communication About Pain composite measure, providing a broader perspective on pain management in hospitals. Out of an abundance of caution and in the face of a nation-wide epidemic of opioid

over-prescription, CMS has chosen to focus the refined Communication About Pain composite measure on communication between hospital staff and patients about patients' pain. CMS believes this will emphasize the importance of communication about pain and its treatment while avoiding any potential inference that medication is the best or only way to treat pain.

In this section, CMS summarizes a wide range of comments received in response to this proposal. Several commenters supported the refinements to the HCAHPS Survey measure pain management questions, but lacked confidence that simply including communication questions regarding pain management would reflect the true perception the patients have of their experience relative to pain management. These commenters encouraged CMS to continue to explore other ways to ensure better measurement of patients' experience with pain management, such as including additional questions about whether hospital staff talked about alternatives to medication for pain management and clearly communicated to the patients the addictive potential of opioid medications. The commenters also expressed concerns the questions related to pain management pertain only to whether the caregiver discussed the patient's pain but do not reflect the patient's engagement in this discussion.

CMS also voiced appreciation for commenter's suggestion that it consider the measurement of an overall analgesia strategy as part of an ERP, but clarifies that the HCAHPS Survey was not intended or designed to ask patients about the efficacy or outcome of clinical care or treatment.

Furthermore, CMS recognized suggestions that questions should focus on patient function and regular assessment and treatment of their overall status rather than solely on their pain. CMS will consider use of multi-modal therapy and poly-pharmacy and other steps to address pain management, including additional questions about pain management, in the HCAHPS Survey in the future.

Finally, in response to a comment that CMS distinguish between hospice care (which usually occurs in the last six months of a patient's life) and palliative care (which could occur at any time during a patient's life and could re-occur at any time as well), CMS clarified that the HCAHPS Survey only asks about patient experience of care during a hospital stay. Patients who are discharged to hospice care are not eligible to receive the HCAHPS Survey. CMS has implemented a separate survey for patient experience of care in hospices.

2) Refining the **Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) following Acute Ischemic Stroke**

Hospitalization Measure for the FY 2023 Payment Determination and Subsequent Years. CMS proposes to change this measure's risk adjustment to include stroke severity (Stroke 30-Day Mortality Rate with the refined risk adjustment) obtained from ICD-10-CM codes in the administrative claims. CMS is proposing this measure now to inform hospitals that they should begin to include the NIH stroke severity scale codes in the claims they submit for patients with a discharge diagnosis of ischemic stroke. CMS would provide hospitals with dry-run results of this proposed, refined measure in their confidential hospital-specific feedback reports prior to implementation of the proposed, refined measure for the FY 2023 payment determination.

CMS does not believe the proposed changes would result in doctors and hospitals denying patients their needed pain medications, since the refined Communication About Pain questions no longer reference any specific pain treatment or circumstance but rather focus on communication about pain to address the concern that the current items may have had an unintended consequence of encouraging opioid-based treatment of pain. Nevertheless, CMS acknowledges the commenters' concerns about unintended or inappropriate consequences on legitimate patient access to needed medicines, and we will actively monitor and analyze responses to the proposed refined Communication About Pain composite measure to understand performance, relationship to other survey measures, and possible unintended consequences.

CMS finalized its proposal to refine the Stroke Mortality measure for the FY 2023 payment determination and subsequent years as proposed.

Regarding commenters' concern about the reliability and accuracy of ICD-10 coding and the comparability across sites, the refined stroke measure which includes stroke severity was developed and tested exclusively with ICD-9-coded claims. However, CMS has completed extensive testing of the current stroke mortality measure specifications in ICD-10 coded claims and of measure performance in the 3-year measurement period, which includes a combination of ICD-9 and ICD-10 coded claims. The measure cohort sizes and number of hospitals with publicly reported results are similar, and the national and hospital-level measure results as well as the performance of the risk-adjustment model are similar to the results observed when calculating the measure with only ICD-9 coded-claims in previous reporting years.

In addition, consistent with commenters' request, CMS plans to further test the refined measure using ICD-10 codes. The ICD-10-CM codes for the NIHSS were implemented in October 2016, so CMS was not able to test the ICD-10-CM codes for NIHSS score during measure development. However, since these codes have been available since October 2016 for use in claims, it will be possible for CMS to examine these data under the refined measure before both the measure dry run and implementation in the Hospital IQR Program.

Similarly, because the ICD-10 code system was implemented in October 2015, there were insufficient claims coded with ICD-10 (and the NIHSS)

submitted by hospitals to provide any testing results to NQF during the endorsement process in 2016. CMS will submit testing results in claims data coded using ICD-10 codes in future cycles of NQF endorsement.

In response to a clarification on which NIHSS assessment to use, since clinical personnel can record stroke scale scores at regular intervals on each patient, CMS clarified that the intent of the risk adjustment for stroke severity is to account for patients' clinical status at the time they are admitted to the hospital. Therefore, the refined measure would utilize only the initial NIHSS score which is administered upon admission. CMS refers readers to the clinical guidelines describing the qualifications and appropriate administration of the NIHSS.

Several commenters requested the measure add risk adjustments for tPA (tissue plasminogen activator) administration or thrombectomy, and for SES factors. CMS clarified that the measure seeks to adjust for case mix differences among hospitals based on the clinical status of the patient at the time of the index admission. CMS does not generally adjust the measures for actions taken by the hospital, such as administration of tPA, as such factors may be related to the quality of care rather than patient factors. In regards to SES adjustments, this measure was reviewed as part of NQF's trial period in which measures are assessed to determine whether risk adjustment for selected social risk factors is appropriate for these measures. The results of the NQF analysis demonstrated that the SES variables that could be feasibly incorporated into this model only have a small, though statistically significant, relationship with the outcome in multivariable modeling and that adding them in the risk model did not change hospitals' mortality rates. Although the measure was not recommended for endorsement, the exclusion of social risk factors from the risk-adjustment model was not among the concerns raised by the committee.

In response to a concern that this measure excludes patients under age 65, which impacts its generalizability to all stroke patients, CMS clarified that this measure does not include Medicare patients who are younger than 65 because these patients usually qualify for the program due to severe disability and, thus, are considered to be clinically distinct from Medicare patients 65 and over. Furthermore, this refined measure has not been tested on a population under 65 ([p. 1393](#)).

Proposed Voluntary Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (NQF #2879): CMS proposes to adopt the **Hospital-Wide All-Cause Unplanned Readmission Hybrid measure** (hereinafter referred to as Hybrid HWR measure) as a voluntary measure for the CY 2018 reporting period. CMS is considering proposing this measure as a required measure as early as the CY 2021 reporting period/FY 2023 payment determination and requiring hospitals to submit the core clinical data elements and linking variables used in the measure as early as CY 2020 to support a dry run of the measure during which hospitals would receive a confidential preview of their results in 2021.

Proposed Changes to Policies on Reporting of eCQMs: CMS proposes to decrease the number of eCQMs for which hospitals must submit data and to decrease the number of calendar quarters for which hospitals are required to submit data.

Possible New Quality Measures and Measure Topics for Future Years: CMS invites public comment on the potential future inclusion of seven measures in the Hospital IQR Program, including:

- All aspects of the **Quality of Informed Consent Documents for Hospital-Performed, Elective Procedures**, including how it would be reported (including frequency) and implemented;
- **Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life measure** (NQF #0210);
- **Proportion of Patients Who Died from Cancer Not Admitted to Hospice measure** (NQF #0215);
- **Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life measure** (NQF #0213);
- **Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days measure** (NQF #0216);
- **Nursing Skill Mix Measure** (NQF #0204). CMS seeks public comment on how many inpatient units to include and which units should be prioritized;
- **Nursing Hours per Patient Day measure** (NQF #0205). CMS

CMS finalized its decision to adopt the Hybrid HWR measure (NQF #2879) as a voluntary measure for the CY 2018 reporting period, as proposed. For additional details regarding this measure, including the risk-adjustment model, please see the proposed voluntary Hybrid HWR Measure technical report, which is posted on the [CMS website](#) (p. 1421).

After consideration of the public comment, CMS finalized a modification of its proposal, such that instead of requiring submission of 6 eCQMs for the first three calendar quarters (Q1-Q3) of CY 2018, it is further reducing requirements, such that hospitals are required to report only one, self-selected calendar quarter of data for 4 eCQMs for the CY 2018 reporting period/FY 2020 payment determination. CMS finalized the same modified policy for CQM electronic reporting requirements [under the Medicare and Medicaid EHR Incentive Programs](#) (p. 1442).

Although CMS is not finalizing any of the following measures at this time, it **will** consider the public's feedback as it develops future policy regarding the potential Inclusion of these measures in the Hospital IQR program.

Quality of Informed Consent Documents for Hospital-Performed, Elective Procedures (p. 1473). CMS will consider public feedback as it further develops future policies about use of the Quality of Informed Consent Documents measure in the IQR. CMS also plans to submit the measure for NQF endorsement during the next appropriate call for measures.

The cohort for this measure includes informed consent documents for a randomly selected sample of qualifying elective surgical procedures performed within non-federal acute care hospitals performed on Medicare FFS beneficiaries, aged 18 years and over who are enrolled in Part A at the time of the procedure. The list of qualifying elective procedures includes procedures for which informed consent is standard practice and captures 10 specialties and various levels of invasiveness, including **neurosurgery, ophthalmology, otolaryngology, cardiothoracic, vascular, urology, OB/GYN, orthopedics, plastic surgery, and general procedures (e.g., colorectal, GI, breast, etc.)**. It excludes highly specialized procedures, such

seeks comment on how many inpatient units to include and which units should be prioritized.

as organ transplantation because they typically use unique informed consent processes; non-invasive radiographic diagnostic tests because informed consent standards may be different than standards for invasive procedures and surgeries; and procedures that are conducted over several encounters since informed consent is likely only conducted prior to the first procedure. Additional details about this measure are described in this section and also available [here](#).

A discussion of comments received on this measure starts on [p. 1487](#). Many commenters supported the measures. Others suggested being more prescriptive about the content and form of the description of alternative treatment, while others commented that the provided scoring standard is limited in the number of elements that are essential for an informed consent document. Although CMS believes the current Abstraction Tool effectively and concisely captures key elements of informed consent document quality that represent a minimum standard for informed consent documents that are meaningful to patients, it will continue to evaluate feedback and consider commenters' suggestions to refine the Abstraction Tool during ongoing measure re-evaluation work.

Others suggested that the measure better capture the informed consent discussion, and not simply the timing of when the legal document is shared, and critiqued the fact that the measure focuses on documentation rather than the actual communication process. In response, CMS noted it would consider incorporating the American College of Surgeons (ACS) principles and other aspects of shared decision-making in future versions of the measure.

In response to concerns about the administrative burden of abstraction or transmission of informed consent documents to CMS, particularly for academic centers, CMS notes it has performed testing across a diverse spectrum of hospitals and has found the measure would not be significantly burdensome.

Although the measure currently utilizes a manual abstraction process, CMS agrees with commenters that electronic extraction could potentially improve efficiency and decrease reporting burden in the future. CMS also appreciates the suggestion that this measure might be appropriate for the Advancing Care Information performance category under the Merit-based Incentive Payment System (MIPS).

Four **End-of-Life (EOL) measures** for cancer patients ([p. 1500](#)):

- **Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life** measure (NQF #0210);
- **Proportion of Patients Who Died from Cancer Not Admitted to Hospice** measure (NQF #0215);
- **Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life** measure (NQF #0213);
- **Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days** measure (NQF #0216)

CMS will consider commenter views as it develops future policy regarding the use of one or more of these EOL measures in the Hospital IQR Program.

An overview of these measures starts on [p. 1501](#). Additional information on these measures can be found [here](#).

A discussion of comments received starts on [p. 1503](#). In response to feedback, CMS will consider the possibility of pairing these measures with measures of shared care planning and any other measures that address patients with advance illness.

Others had concerns that these measures are not adjusted to exclude patients who have stated a desire to pursue aggressive treatment through the end of life. CMS clarified that prior to proposing to adopt these measures, they would require a subsequent review by the MAP to assess appropriateness for programmatic inclusion, which would include feedback on the appropriateness of exclusion criteria. CMS also may consult the measure steward to determine whether patients who have undergone aggressive treatment through the end of life should be excluded from the measurement cohort.

In response to concerns that these measures are more appropriate for the PCHQR Program, CMS noted that prior to proposing to adopting these measures for the Hospital IQR Program, they would require testing in acute care hospitals, which would provide insight on the burden associated with data collection in these settings. Testing would also help CMS identify exclusions criteria and other impact factors, such as access to ambulatory services and the impact on quality of hospitals that have an oncologist on staff versus hospitals that do not.

Two **Nurse Staffing measures** ([p. 1509](#)):

- **Nursing Skill Mix Measure** (NQF #0204).
- **Nursing Hours per Patient Day Measure** (NQF #0205)

CMS will consider public feedback as it develops future policy regarding use of the nurse staffing measures in the Hospital IQR Program.

Background on these two measures is provided starting on [p. 1509](#).

A discussion of general comments regarding both of these measures starts on [p. 1512](#). An overwhelming number of commenters supported the proposed future inclusion of the Nurse Staffing measure set in the Hospital IQR Program. The commenters also noted that reporting these data is not burdensome to hospitals, nurses, or other clinicians because the information is not being newly collected but rather, newly reported. There was also some support for publicly reporting these measures.

One commenter felt the measures fail to reflect the complexity of the patient population and any staffing challenges in the local environment (rural, labor supply, urban, etc.) and recommended they not be linked to payment and that any publication of these measures be accompanied by explanations which clarify for the reader that these are not quality-of-care measures. CMS recognized the concerns, but disagreed that these are not quality of care measures.

Others warned that the generalist ideology expected by hospital administration for its nursing staff, when specialty care nursing is often best for patient care, could be problematic. Further, staffing should not only encompass proper numbers but should also encompass nursing proficiency, education, and work environment. CMS will continue to consider additional factors that influence an appropriate nurse staffing plan and evaluate the measures for unintended consequences.

A more detailed discussion of the **Nursing Skill Mix measure** begins on [p. 1518](#). More information about this measure is also available [here](#). More specific comments about this measure begin on [p. 1523](#).

A more detailed discussion of the **Nursing Hours per Patient Day measure** begins on [p. 1524](#). More information about this measure is also available [here](#). More specific comments about this measure begin on [p. 1528](#)

CMS also is considering newly specified eCQMs for possible inclusion in future years of the Hospital IQR and Medicare and Medicaid EHR Incentive Programs:

- **Safe Use of Opioids – Concurrent Prescribing;**
- **Completion of a Malnutrition Screening within 24 Hours of Admission;**
- **Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition within 24 Hours of a Malnutrition Screening;**
- **Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment;**
- **Appropriate Documentation of a Malnutrition Diagnosis;**
- **Tobacco Use Screening (TOB-1);**
- **Tobacco Use Treatment Provided or Offered (TOB-2)/Tobacco Use Treatment (TOB-2a);**
- **Tobacco Use Treatment Provided or Offered at Discharge (TOB-3)/Tobacco Use Treatment at Discharge (TOB-3a);**
- **Alcohol Use Screening (SUB-1);**
- **Alcohol Use Brief Intervention Provided or Offered (SUB-2)/Alcohol Use Brief Intervention (SUB-2a); and**
- **Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge (SUB-3)/Alcohol & Other Drug Use Disorder Treatment at Discharge (SUB-3a).**

Form, Manner, and Timing of Quality Data Submission: CMS proposes changes to the Hospital IQR Program eCQM reporting and submission requirements to align them with the Medicare EHR Incentive Program for eligible hospitals and CAHs. CMS is not proposing any changes to its file format requirements or reporting deadlines, but it is proposing changes to its requirements related to eCQM electronic specification and certification. These include:

- For the CY 2017 reporting period/FY 2019 payment determination, to require EHR technology used for eCQM reporting to be certified to all eCQMs, but that such certified EHR technology does not need to be recertified each time it's updated to a more recent version of the eCQM electronic specifications.
- For the CY 2017 reporting period/FY 2019 payment determination, hospitals would be required to use the most recent version of the eCQM electronic specifications;
- For the CY 2018 reporting period/FY 2020 payment

CMS will consider the public's feedback as it develops future policy regarding the potential inclusion of additional eCQMs in the Hospital IQR and Medicare and Medicaid EHR Incentive Programs ([p. 1531](#)):

Safe Use of Opioids – Concurrent Prescribing. A discussion of measure begins on [p. 1533](#); discussion of comments received begins on [p. 1535](#).

- **Malnutrition measures.** A discussion of these measures begins on [p. 1539](#); a discussion of comments received begins on [p. 1543](#).
- **Tobacco Use measures.** A discussion of these measures begins on [p. 1550](#); a discussion of comments received begins on [p. 1555](#).
- **Substance Use measures.** A discussion of these measures begins on [p. 1561](#); a discussion of comments received begins on [p. 1566](#).

CMS finalized these policies as proposed ([p. 1571](#)). These policies are consistent with other policies finalized in this rule related to the EHR Incentive Program. To clarify:

- For the CY 2017 reporting period/FY 2019 payment determination and for the CY 2018 reporting period/FY 2020 payment determination, CMS will offer flexibility, such that hospitals may use: (a) EHR technology certified to the 2014 Edition; (b) EHR technology certified to the 2015 Edition; or (c) a combination of EHR technologies certified to the 2014 Edition and 2015 Edition;
- For the CY 2017 reporting period/FY 2019 payment determination and the CY 2018 reporting/FY 2020 payment determination, EHR technology certified to the 2014 or 2015 Edition must be certified to all 15 eCQMs available to report in the Hospital IQR Program;
- For the CY 2017 reporting period/FY 2019 payment determination, hospitals will be required to use the most recent version of the eCQM electronic specifications (i.e., the Spring 2016 version of the eCQM specifications and any applicable addenda);

determination, hospitals are required to use the most recent version of the eCQM electronic specification

- For the CY 2018 reporting period/FY 2020 payment determination, hospitals will be required to use the most recent version of the eCQM electronic specifications (i.e., the Spring 2017 version of the eCQM specifications and any applicable addenda); and
- An EHR certified for eCQMs under the 2014 or 2015 Edition certification criteria would not need to be recertified each time it is updated to a more recent version of the eCQM electronic specifications.

Proposed Submission Form and Method for the Proposed Voluntary Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data: CMS proposes that hospitals that voluntarily report data for the **Hybrid Hospital-Wide Readmission measure** use EHR technology certified to the 2015 Edition. It also proposes that the 13 core clinical data elements and six linking variables for the **Hybrid Hospital-Wide Readmission measure** be submitted using the QRDA I file format.

CMS finalized its proposals related to the voluntary reporting and submission of core clinical data elements and linking variables for the **Hybrid Hospital-Wide Readmission measure** as proposed, with one modification ([p. 1604](#)). Instead of requiring use of EHR technology certified to the 2015 Edition, CMS is allowing greater flexibility and will accept use of EHR technology that is:

- Certified to the 2014 Edition;
- Certified to the 2015 Edition; or
- A combination of both the 2014 Edition and 2015 Edition.

Proposed Modifications to the Validation of Hospital IQR Program Data: CMS proposes modifications to the eCQM validation process whereby hospitals would be required to submit a reduced number of cases for eCQM data validation for the FY 2020 and FY 2021 payment determinations. CMS proposes changes to its policies related to the selection of hospitals and cases for eCQM validation to: (1) expand the types of hospitals that could be excluded; and (2) expand the types of cases excluded from selection.

CMS finalized these policies as proposed ([p. 1622](#)).

Proposed Modifications to the Educational Review Process for Chart-Abstracted Measures Validation: CMS proposes to modify its educational review process for chart-abstracted measures for the FY 2020 payment determination and subsequent years, such that educational reviews would be offered quarterly for the first three quarters of validation.

CMS finalized these policies as proposed ([p. 1638](#)).

Public Display Requirements for the FY 2020 Payment Determination and Subsequent Years: CMS seeks additional public comment on which social risk factors provide information that is most valuable to stakeholders. CMS also seeks comment on the potential confidential and public reporting of the **Hospital 30-day, All-Cause, Risk-Standardized Readmission Rate Following**

As discussed earlier, for the [Hospital Readmissions Reduction Program](#), CMS, as required by the statute, proposed to use dual eligibility as a marker of poverty, one key patient social risk factor. CMS also would like to move in that direction for the Hospital IQR Program in the future. In the Hospital IQR Program, CMS is exploring methods to distinguish vulnerable patients with social risk factors, such as poverty. It intends to use dual eligible status

Pneumonia Hospitalization measure and the **Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization** measure data stratified specifically by patient dual eligibility status. CMS discusses and seeks comment on various approaches to examining disparities in outcomes rates. CMS also seeks comments on the future public reporting of these same measures stratified by patient dual eligibility status on Hospital Compare, following a period of confidential reporting.

among the over 65 year old patients included in the measures as a marker of poverty.

The Hospital Compare website currently displays readmission rates for each hospital, but does not specifically highlight a hospital's quality of care for vulnerable populations. CMS believes stratifying data by social risk factors would supplement the current reporting of the **Pneumonia Readmission** measure and the **Pneumonia Mortality** measure by highlighting disparities (i.e., differences in outcomes) within hospitals that are not simply due to differences in illness severity. To do so, CMS developed a method to quantify the disparities of readmission and mortality between these groups within each hospital after accounting for patient case mix. The disparities indicator used in the hospital specific confidential preview reports would provide information assessing the increased odds, or rates, of readmission for dual eligible patients admitted to the same hospital, after accounting for differences in age and comorbidities ([p. 1644](#)).

Starting on [p. 1651](#) CMS discusses its interest in providing hospitals with confidential preview reports containing stratified results for certain Hospital IQR Program measures, specifically the **Pneumonia Readmission** measure and the **Pneumonia Mortality** measure.

Starting on [p. 1653](#), CMS discusses a potential methodology for illuminating differences in outcomes rates among patient groups within a hospital that would also allow for a comparison of those differences, or disparities, across hospitals.

Starting on [p. 1656](#), CMS discusses an alternative methodology that compares performance for patient subgroups across hospitals, but does not provide information on hospital disparities and any additional suggested methodologies for calculating stratified results by patient dual eligible status.

Starting on [p. 1659](#), CMS discusses future public reporting of these measures stratified by patient dual eligibility status on the Hospital Compare website.

A discussion of the feedback received on each of these issues begins on [p. 1661](#).

CMS will consider all of the comments received as it develops policy regarding potential options for confidential and public reporting of Hospital

[PPS-Exempt
Cancer Hospital
Quality
Reporting
\(PCHQR\)
Program](#)

[Removal of Measures from PCHQR](#): CMS is proposing to remove three clinical process/cancer specific treatment measures from the PCHQR Program beginning with the FY 2020 program year because they are topped out: Adjuvant Chemotherapy is Considered or Administered Within 4 Months (120 Days) of Diagnosis to Patients Under the Age of 80 with AJCC III (Lymph Node Positive) Colon Cancer (PCH-01/NQF #0223), Combination Chemotherapy is Considered or Administered Within 4 Months (120 Days) of Diagnosis for Women Under 70 with AJCC T1c, or Stage II or III Hormone Receptor Negative Breast Cancer (PCH-02/NQF #0559) and Adjuvant Hormonal Therapy (PCH-03/NQF #0220).

IQR Program measures stratified by patient social risk factors, such as dual eligibility status and, specifically, as it develops policy regarding potential options on the future confidential and public reporting of the **Pneumonia Readmission** measure data and the **Pneumonia Mortality** measure data stratified specifically by patient dual eligibility status within the hospital, or more specifically, differences in outcome rates for the dual eligible and non-dual eligible patients in the measures. Recognizing the complexity of this task, CMS will continue to consider beginning to provide confidential hospital specific preview reports as early as summer of 2018, using data from the FY 2019 reporting period (July 1, 2014 through June 30, 2017). This would allow CMS to obtain feedback on reporting options and to ensure the information is reliable, valid, and understandable prior to any future public display on the Hospital Compare website. This information about disparities in patient outcomes within hospitals would supplement the assessment of overall hospital quality provided through the current measures of readmission and mortality rates; these measures would remain unchanged. CMS recognizes its proposed timeline might be extended in light of its plans for continued evaluation and operational considerations. If CMS makes such a determination to begin providing confidential hospital specific preview reports of measure data on these or other measures in the Hospital IQR Program stratified by patient dual eligibility status to hospitals, CMS will convey this decision through routine communication channels to hospitals, vendors, and QIOs, including, but not limited to, issuing memos, emails, and notices on the QualityNet website.

CMS finalized this proposal without modification. ([p. 1688](#)) CMS received several comments supporting its proposals, as well as comments expressing concerns or recommending ongoing reporting of the three measures as a composite measure. However, CMS continues to state that their analysis indicates that these measures meet the program's topped-out criteria, and that measure performance is so high or unvarying that no meaningful distinctions can be drawn from continued performance reporting.

FY 2020 Proposed New Measures: For the FY 2020 PCHQR program year, CMS is proposing to adopt two clinical process measures and two intermediate clinical outcome quality measures:

- Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (NQF #0210);
- Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life (NQF #0213);
- Proportion of Patients Who Died from Cancer Not Admitted to Hospice (NQF #0215); and
- Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days (NQF #0216).

Accounting for Social Risk Factors in the PCHQR Program: CMS continues to seek public comment on whether to account for social risk factors in the PCHQR Program, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors. CMS is also seeking public comment on which social risk factors might be most appropriate for reporting stratified measure scores and/or potential risk adjustment of a particular measure.

CMS finalized the adoption of all four measures without modification:

- Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (NQF #0210); ([p. 1699](#))
- Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life (NQF #0213); ([p. 1704](#))
- Proportion of Patients Who Died from Cancer Not Admitted to Hospice (NQF #0215); ([p. 1709](#)) and
- Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days (NQF #0216) ([p. 1713](#)).

In response to comments to expand measures to include palliative care services, CMS notes that they “recognize the importance of palliative care services in alleviating symptoms during the disease process, and we welcome recommendations as to additional measures related to palliative care for possible incorporation into the PCHQR Program in the future.” CMS also welcomes recommendations as to other aspects of the measure specifications that could be revised in the future, such as consideration of comorbidities that could delay timely admission, or additional measures that address issues related to timely admission to hospice, for future rulemaking.

CMS notes that these measures “are a first step that seeks to broadly assess what is happening in PCHs at the end of life, and will provide a baseline picture of existing end-of-life care at those hospitals.”

CMS remains concerned about holding providers to different standards for the outcomes of their patients with social risk factors because CMS does not want to mask potential disparities or minimize incentives to improve outcomes for disadvantaged populations. CMS believes that the path forward should incentivize improvements in health outcomes for disadvantaged populations while ensuring that beneficiaries have access to excellent care. CMS intends to consider all suggestions as it continues to assess each measure and the overall program. CMS intends to conduct further analyses on the impact of strategies such as measure-level risk adjustment and measure stratification by social risk factors, including the options suggested by commenters. As CMS considers the feasibility of collecting patient-level data and the impact of strategies to account for social risk factors through further analysis, CMS will continue to evaluate the reporting burden on providers. ([p. 1718](#))

Commenters generally supported the inclusion of the five localized prostate

Possible New Quality Measure Topics for Future Years: CMS is seeking specific suggestions for measure topics to consider for future rulemaking and is also seeking public comment on the following six measures for potential future inclusion in the PCHQR Program:

- Localized Prostate Cancer: Vitality;
- Localized Prostate Cancer: Urinary Incontinence;
- Localized Prostate Cancer: Urinary Frequency, Obstruction, and/or Irritation;
- Localized Prostate Cancer: Sexual Function;
- Localized Prostate Cancer: Bowel Function; and
- 30 Day Unplanned Readmissions for Cancer Patients.

Reporting Requirements for the Proposed New Measures: For the FY 2020 proposed new measures, CMS is proposing that the data collection period would be from July 1 of the year 3 years prior to the program year to June 30 of the year 2 years prior to the program year. Thus for the FY 2020 program year, CMS would collect data from July 1, 2017 through June 30, 2018.

Extraordinary Circumstances Exceptions (ECE) Policy under the PCHQR Program: CMS is proposing to modify the ECE policy for the PCHQR Program by: (1) extending the deadline for a PCH to submit a request for an extension or exception from 30 days following the date that the extraordinary circumstance occurred to 90 days following the date that the extraordinary circumstance occurred; and (2) allowing CMS to grant an exception or extension due to CMS data system issues which affect data submission.

cancer measures as well as the 30 Day Unplanned Readmissions for Cancer Patients measure. ***CMS will consider views as it develops further measures for use in the program.*** ([p. 1723](#))

CMS finalized the data collection period as proposed. ([p. 1730](#))

CMS finalized its proposal to extend the deadline to submit a request for an extension or exception ([p. 1733](#)) ***and its proposal to allow CMS to grant an exception or extension due to CMS data system issues*** ([p. 1735](#)). On the latter policy, CMS clarified that if CMS does not proactively notify PCHs that it plans to provide an exception to the policy after a data system issue, PCHs may still submit a request for an exception for CMS consideration.

[Long-Term Care Hospital Quality Reporting Program \(LTCH QRP\)](#)

CMS invites public comment on its proposals regarding changes to the LTCH QRP and implementation of IMPACT Act requirements.

[Accounting for Social Risk Factors in the LTCH QRP](#): CMS continues to seek public comment on whether to account for social risk factors in the LTCH QRP, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors.

[Proposed Collection of Standardized Patient Assessment Data under the LTCH QRP](#): CMS is proposing to define “standardized patient assessment data” as patient assessment questions and response options that are identical in all four PAC assessment instruments, and to which identical standards and definitions apply. CMS is proposing to adopt a policy that would allow any standardized patient assessment data adopted for the LTCH QRP to remain in effect until the data are removed, suspended, or replaced. This policy is the same as that applied for quality measures adopted under the LTCH QRP. CMS is also proposing to adopt a policy that would allow for subregulatory action to incorporate updates to standardized patient assessment data that do not substantively change the nature of the data, similar to the policy applied for quality measures under the LTCH QRP.

[FY 2020 Proposed New or Modified Measures](#): CMS is proposing to replace an existing pressure ulcer measure with a new measure, as well as adopt two new measures related to ventilator weaning. Specifically, CMS is proposing to: Remove the current pressure ulcer measure entitled Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) and replace it with a modified version of the measure entitled Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury. LTCHs would begin data collection for this modified measure beginning April 1, 2018.

CMS remains concerned about holding providers to different standards for the outcomes of their patients with social risk factors, because CMS does not want to mask potential disparities. CMS believes that the path forward should incentivize improvements in health outcomes for disadvantaged populations while ensuring that beneficiaries have access to excellent care. CMS intends to consider all suggestions as it continues to assess each measure and the overall program. CMS intends to explore options including but not limited to measure stratification by social risk factors in a consistent manner across all programs. CMS is also considering providing feedback to providers on outcomes for individuals with social risk factors in confidential reports. ([p. 1751](#))

CMS finalized as proposed the definition of standardized patient assessment data for the LTCH QRP ([p. 1755](#)). CMS finalized its proposal to apply the policy for retaining LTCH QRP measures to the standardized patient assessment data that CMS adopts for the LTCH QRP ([p. 1760](#)). CMS finalized its proposal to apply the policy for adopting changes to LTCH QRP measures to the standardized patient assessment data that CMS adopts for the LTCH QRP. ([p. 1761](#))

CMS finalized its proposal to remove the current pressure ulcer measure Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) and replace it with a modified version of the measure entitled Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, except that the implementation date would be delayed to July 1, 2018 ([p. 1791](#)).

CMS is also proposing to adopt the following two ventilation measures, both of which apply for admissions and discharges occurring on or after April 1, 2018:

- Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay (a ventilation process quality measure). This measure is calculated and reported for the following two components: (1) the percentage of patients admitted on invasive mechanical ventilation who were assessed for readiness for SBT by Day 2 of the LTCH Stay, and (2) the percentage of patients deemed medically ready for SBT who received SBT by Day 2 of the LTCH stay, and
- Ventilator Liberation Rate (a ventilation outcome quality measure). This quality measure is a facility-level measure that reports the percentage of LTCH patients admitted on invasive mechanical ventilation, for whom weaning attempts were expected or anticipated, and are fully weaned by the end of their LTCH stay. Patients who are considered fully weaned at discharge are those who did not require any invasive mechanical ventilation support for at least 2 consecutive calendar days immediately prior to discharge.

Removal of Measures from the LTCH QRP: CMS is proposing to remove the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512) from the LTCH QRP. Public reporting of this measure would end by October 2018.

Quality Measures Under Consideration for Future Years: CMS is inviting public comment on the importance, relevance, appropriateness, and applicability of each of the quality measures listed below for future years in the LTCH QRP:

- Experience of Care. This would include survey-based experience of care measures for the LTCH QRP. The survey explores experience of care across five main areas: (1) beginning stay at the hospital; (2) interactions with staff; (3) experience during the hospital stay; (4) preparing for leaving hospital; and (5) overall hospital rating
- Application of Percent of Residents Who Self-Report Moderate to Severe Pain (Short Stay) (NQF #0676)
- Advance Care Plan

CMS also finalized its proposal to adopt the measure Compliance with SBT by Day 2 of the LTCH Stay, except with a delayed implementation date of July 1, 2018 (p. 1809).

CMS finalized its proposal to adopt the measure Ventilator Liberation rate, except with a delayed implementation date of July 1, 2018. (p. 1822)

CMS finalized its proposal to remove the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512) from the LTCH QRP beginning with the FY 2019 LTCH QRP. (p. 1825)

CMS received several comments on measures under consideration for future years and notes that it will take such comments into consideration. (p. 1831)

- Patients Who Received an Antipsychotic Medication,
- Modification of the Discharge to Community-PAC LTCH QRP measure to exclude baseline nursing facility residents.

CMS also notes that they are working to develop two additional measures related to the IMPACT Act: Transfer of Information at Post-Acute Care Admission, Start or Resumption of Care from other Providers/Settings, Transfer of Information at Post-Acute Care Discharge, and End of Care to other Providers/Settings.

Standardized Patient Assessment Data Reporting for the FY 2019

LTCH QRP: CMS is proposing to characterize the following data elements as standardized patient assessment data that must be reported by LTCHs for the FY 2019 LTCH QRP: Data elements used to calculate the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) (which will be replaced for FY 2020). Successful reporting of this measure for admissions and discharges occurring in the last three quarters of CY 2017 would satisfy the requirements to report standardized patient assessment data for FY 2019.

Standardized Patient Assessment Data Reporting Beginning with the FY 2020 LTCH QRP:

CMS is proposing to characterize the following data elements as standardized patient assessment data that must be reported by LTCHs for the FY 2019 LTCH QRP: For the FY 2020 LTCH QRP and future, LTCH's would be required to report proposed data elements across the five IMPACT ACT categories (Functional Status Data, Cognitive Function and Mental Status Data, Special Services, Treatments, and Interventions Data, Medical Condition and Comorbidity Data, and Impairment Data) with respect to LTCH admissions and discharges that occur in the last three quarters of CY 2018, except for the three data elements flagged for reporting on admissions only (Brief Interview of Mental Status (BIMS), Hearing, and Vision). Future years would require full

CMS finalized its proposal that the data elements currently reported by LTCHs to calculate the current measure meet the definition of standized patient assessment data with respect to medical conditions and co-morbidities and that the successful reporting of that data would also satisfy the requirement to report standardized patient assessment data beginning October 1, 2017. (p. 1838) CMS finalized that LTCHs would be required to report this measure for the last quarter of CY 2017 to meet the requirements for reporting standardized patient assessment data. (p. 1837)

Additionally, in response to comments expressing concern with increased burden, ***CMS decided to move the release data of the LTCH CARE Data Set Version 4.00 from April 1, 2018 to July 1, 2018, which gives LTCHs an additional 3 months to prepare. (p. 1838)***

Given numerous comments regarding burden and readiness, ***CMS did not at this time finalize the standardized patient assessment data elements proposed for three of the five IMPACT Act categories due to concerns about new reporting burden: Cognitive Function and Mental Status; Special Services, Treatments, and Interventions; and Impairments. (p. 1841)*** In light of this decision, CMS does not address tehcnical comments received on the data elements in these categories.

calendar year reporting.

The Functional Status Data category proposal includes data elements currently reported to calculate the measure, Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).

The Medical Condition and Comorbidity Data category proposal includes data elements needed to calculate the current measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), and the proposed measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury. This includes data on the presence of pressure ulcers, diabetes, incontinence, peripheral vascular disease or peripheral arterial disease, mobility, as well as low body mass index.

CMS did finalize as proposed the standardized patient assessment data elements for the IMPACT Act category of Functional Status, which are those data elements required to calculate the measure Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631) (p. 1848), and for the IMPACT ACT category of Medical Conditions and Co-Morbidities, which are those data elements required to calculate the current measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), and the proposed measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury (p. 1851). These data elements meet the definition of standardized patient assessment data, and successful reporting of such data will also satisfy the requirement to report standardized patient assessment data. CMS notes that the data elements for these two categories are already required, and therefore finalizing these categories does not create a new reporting burden or otherwise necessitate a delay. (p. 1842)

Regarding the three non-finalized categories, although CMS believes that the proposed standardized patient assessment data elements would promote transparency around quality of care and price, CMS notes that the data elements proposed for each of these categories would have imposed a new reporting burden on LTCHs. CMS agrees that it would be useful to evaluate further how to best identify the standardized patient assessment data that would satisfy each of these categories; would be most appropriate for CMS' intended purposes including payment and measure standardization; and can be reported by LTCHs in the least burdensome manner. As part of this effort, CMS intends to conduct a national field test that allows for stakeholder feedback and to consider how to maximize the time LTCHs have to prepare for the reporting of standardized patient assessment data in these categories. CMS intends to make new proposals for these categories no later than in the FY 2020 IPPS/LTCH PPS proposed rule. (p. 1841)

CMS generally finalized as proposed their policies to apply existing LTCH

Regulatory changes to incorporate standardized patient assessment data into reporting requirements (starting with p. 1851):

CMS is proposing several regulatory changes to incorporate requirements around reporting of standardized patient assessment data with reporting requirements for the LTCH QRP. That is, CMS is proposing that the same policies that apply for reporting quality measures under the LTCH QRP (as identified in the list below) would apply to reporting of standardized patient assessment data. These include (but are not limited to):

- Data submission requirements, including regarding form, manner, and timing for new LTCHs, reporting mechanism, and reporting schedule
- Exception and extension requirements
- Reconsideration requirements
- Data completion thresholds

QRP reporting requirements to the reporting of standardized patient assessment data on the items included in the list below.

- Data submission requirements, including regarding form, manner, and timing for new LTCHs ([p. 1851](#)) and reporting mechanism ([p. 1852](#))
- Exception and extension requirements ([p. 1863](#))
- Reconsideration requirements ([p. 1864](#))
- Data completion thresholds ([p. 1866](#))

With respect to the reporting schedule, CMS notes that the FY 2019 LTCH QRP will be determined using standardized patient assessment data collected from October 1, 2017 through December 31, 2017 using the current measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678). Additionally, CMS is moving the implementation of the LTCH CARE Data Set Version 4.00 from April 1, 2018 to July 1, 2018. As a result of this delayed implementation, the FY 2020 LTCH QRP will be determined using the standardized patient assessment data from the first two quarters of CY 2018 using the current measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), and the last two quarters of CY 2018 using the standardized patient assessment data from the finalized measures, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury and Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631). For the FY 2020 LTCH QRP, LTCHs will be required to report measures and standardized patient assessment data for LTCH admissions and discharges during the last two quarters of CY 2018 using the LTCH CARE Data Set Version 4.00, which will be released July 1, 2018. This is an exception to CMS' standard policy, under which new releases of LTCH Care Data Set versions occur on April 1 of a given year, and subsequent releases will revert to their April 1 release schedule. Tables included on [page 1857](#) illustrate the finalized reporting cycle. In sum, CMS finalized its proposal for requiring standardized patient assessment data beginning with the FY 2019 LTCH QRP, but also finalized the exception related to the timing for the FY 2020 LTCH QRP discussed above. ([p. 1858](#))

Due to the delayed implementation of the LTCH Care Data Set Version 4.00 to July 1, 2018, for the FY 2020 LTCH QRP, CMS clarifies that "in addition to the currently adopted measures in the LTCH QRP, LTCHs will be required to submit data on the finalized measures, Change in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, Compliance with SBT by Day 2 of the LTCH Stay,

and Ventilator Liberation Rate, beginning with the last two quarters of CY 2018. LTCHs will also submit data on the previously finalized measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, beginning with the last two quarters of CY 2018 for the FY 2020 LTCH QRP.” Starting in CY 2020 for the FY 2021 LTCH QRP, LTCHs will be required to submit data for the entire calendar year. The finalized LTCH Care Data Set Version 4.00 is available for review on the [CMS website](#). (p. 1860)

CMS finalized its proposal to remove the program interruption items from the LTCH CARE Data Set Version 4.00, effective July 1, 2018. (p. 1862)

Removal of Interrupted Stay Items from LCDS: CMS is proposing to remove the program interruption items from the LCDS, specifically (1) A2500, Program Interruption(s); (2) A2510, Number of Program Interruptions During This Stay in This Facility; and (3) A2525, Program Interruption Dates, as CMS does not use this information.

Public Display of Measure Data: CMS is proposing to publicly report data the following data on the Long-Term Care Hospital Compare Website, pending the availability of data, in addition to previously finalized measures.

- For CY 2018 public reporting: CMS is proposing to publicly report data for the following 3 assessment-based measures: Percent of LTCH Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631); (2) Application of Percent of LTCH Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631); and (3) Application of Percent of Residents Experiencing One or More Falls with Major Injury (NQF# 0674). In addition, CMS is proposing to publicly report 3 claims-based measures on a fiscal year basis, starting October 2018: (1) Medicare Spending Per Beneficiary-PAC LTCH QRP; (2) Discharge to Community-PAC LTCH QRP; and (3) Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP.
- For CY 2020 public reporting: CMS is proposing to publicly report data for the assessment-based measure Functional Outcome Measure: Change in Mobility Among Patients Requiring Ventilator Support (NQF #2632).

CMS finalized all policies as proposed for public display of measure data, except that CMS does not specifically address a final policy on its proposal regarding LTCHs with fewer than 20 or 25 eligible cases, as applicable (p. 1878).

CMS also notes that the public display of NHSN Facility-wide Inpatient Hospital-onset MRSA Bacteremia Outcome Measure (NQF #1716) and NHSN Facility-wide Inpatient Hospital-onset CDI Outcome Measure (NQF #1717) were initially expected be based on data collected from January 1, 2015, through December 31, 2015 and displayed based on four rolling quarters. However, CMS clarifies that the initial public display of data for these two quality measures (MRSA and CDI) will be based on data collected from January 1, 2016 through December 31, 2016 (CY 2016), as the CY 2015 data is not available for display using the Standardized Infection Ratio (SIR) metric. Rather, this data (CY 2015) was used by the CDC to calculate the “predicted” number of infections (the number of infections that would be expected to occur based on previously reported data) for each LTCH, so that subsequent data could be used to calculate the SIR for each of these quality measures. The SIR is a summary statistic that compares the “predicted” number of infections to the “observed” or actual number of infections for a given LTCH. This process or “rebaselining” of data occurs periodically when the CDC determines that referent period of data or “baseline” is no longer meaningful due to changes in the quality measure protocols or changes in provider populations. When the CDC uses a specific year’s data to inform newly

CMS is also proposing to remove the following claims-based measure “All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from LTCHs” from the LTCH QRP and public reporting by October 2018.

CMS is proposing to remove the following assessment-based measure “Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678)” and to replace it with a modified version of the measure entitled “Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury” from the LTCH QRP and public reporting by October 2020.

CMS is also proposing special treatment with LTCHs have fewer than 20 eligible cases (for assessment-based measures and the Medicare Spending Per Beneficiary-PAC LTCH QRP measure) or 25 eligible cases for the other two claims-based measures, such that performance would not publicly be reported.

calculated “predicted” number of infections, CMS is unable to use that specific year of data to calculate the SIR, and for this reason, CMS is unable to display the MRSA and CDI performance data using the CY 2015 LTCH NHSN data, and will use the CY 2016 data to inform the SIR calculations when it publicly displays the SIRs for these measures in Fall 2017. ([p. 1868](#))

Proposed Modifications to the CQM Reporting Requirements for the Medicare and Medicaid EHR Incentive Programs for CY 2017: For eligible hospitals and CAHs reporting CQMs electronically in CY 2017, CMS proposes to: (1) decrease the number of calendar quarters for which such hospitals are required to submit data; and (2) decrease the number of CQMs for which such hospitals must submit data (further discussion below).

CMS proposes to modify the CQM reporting period for eligible hospitals and CAHs reporting CQMs electronically for the Medicare and Medicaid EHR Incentive Programs in CY 2017 - for eligible hospitals and CAHs demonstrating meaningful use for the first time in 2017 or that have demonstrated meaningful use in any year prior to 2017, the reporting period would be two self-selected quarters of CQM data in CY 2017. CMS proposes to modify the reporting criteria regarding the required number of CQMs for eligible hospitals and CAHs that are reporting electronically for the reporting periods in CY 2017 under the Medicare and Medicaid EHR Incentive Programs - if only participating in the EHR Incentive Program, or participating in both the EHR Incentive Program and the Hospital IQR Program, eligible hospitals and CAHs would report on at least 6 (self-selected) of the available CQMs. CMS does not propose to modify any other aspects of the policies for reporting CQMs electronically for CY 2017, including the submission periods, nor does CMS propose any changes to its policies for reporting CQMs by attestation. CMS invites public comment on its proposals to modify the CY 2017 CQM reporting requirements for the Medicare and Medicaid EHR Incentive Programs as described above.

CQM Reporting Period for the Medicare and Medicaid EHR Incentive Programs in CY 2018: CMS proposes the following CQM reporting period for the Medicare and Medicaid EHR Incentive Programs and the following submission period for the Medicare EHR Incentive Program:

- For eligible hospitals and CAHs reporting CQMs electronically that demonstrate meaningful use for the first time in 2018 or that have demonstrated meaningful use in any year prior to 2018, the reporting period would be the first 3 quarters of CY 2018, and the submission period would be the 2 months following the close of the calendar year, ending February 28, 2019.

CMS finalized a modified version of its proposals regarding the previously finalized CQM reporting requirements for the CY 2017 reporting period, such that eligible hospitals and CAHs are required to electronically report on 4 self-selected available CQMs (instead of 8 available CQMs) for one, self-selected calendar quarter of data (instead of a full calendar year (consisting of four quarterly data reporting periods)), whether reporting only for the EHR Incentive Program or reporting for both the Hospital IQR Program and the EHR Incentive Program (p. 1951).

CMS finalized the CY 2018 reporting requirements as proposed, except for proposals pertaining to the electronic reporting of CQM reporting period and reporting criteria, which CMS is finalizing with modifications (p. 1969). For CY 2018, the CQM reporting period for the Medicare and Medicaid EHR Incentive Programs and the submission period for the Medicare EHR Incentive Program are as follows:

- For eligible hospitals and CAHs reporting CQMs electronically that demonstrate meaningful use for the first time in 2018 or that have demonstrated meaningful use in any year prior to 2018, the reporting period is one, self-selected calendar quarter of CY 2018 data, and the submission period is the 2 months following the close of the calendar year, ending February 28, 2019.

- For eligible hospitals and CAHs that report CQMs by attestation under the Medicare EHR Incentive Program as a result of electronic reporting not being feasible, and for eligible hospitals and CAHs that report CQMs by attestation under their state’s Medicaid EHR Incentive Program, CMS established a CQM reporting period of the full CY 2018 (consisting of 4 quarterly data reporting periods)

CMS also established an exception to this full-year reporting period for eligible hospitals and CAHs demonstrating meaningful use for the first time under their state’s Medicaid EHR Incentive Program; under this exception, the CQM reporting period is any continuous 90-day period within CY 2018.

CMS proposes the submission period for eligible hospitals and CAHs reporting CQMs by attestation under the Medicare EHR Incentive Program would be the 2 months following the close of the CY 2018 CQM reporting period, ending February 28, 2019.

CMS provides States with the flexibility to determine the method of reporting CQMs (attestation or electronic reporting) and the submission periods for reporting CQMs, subject to prior approval by CMS.

CQM Reporting Criteria for the Medicare and Medicaid EHR Incentive Programs in CY 2018:

CMS proposes the following reporting criteria under the Medicare and Medicaid EHR Incentive Program for eligible hospitals and CAHs reporting CQMs electronically for the reporting period in CY 2018:

- For eligible hospitals and CAHs participating only in the EHR Incentive Program, or participating in both the EHR Incentive Program and the Hospital IQR Program, report on at least **six (self-selected)** of the available CQMs
- For eligible hospitals and CAHs that report CQMs by attestation under the Medicare EHR Incentive Program because electronic reporting is not feasible, and for eligible hospitals and CAHs that report CQMs by attestation under their state’s Medicaid EHR Incentive Program, for the reporting period in CY 2018 - report on all 16 available CQMs.

- For eligible hospitals and CAHs that report CQMs by attestation under the Medicare EHR Incentive Program as a result of electronic reporting not being feasible, and for eligible hospitals and CAHs that report CQMs by attestation under their State’s Medicaid EHR Incentive Program, CMS established a CQM reporting period of the full CY 2018 (consisting of 4 quarterly data reporting periods).

CMS also established an exception to this full-year reporting period for eligible hospitals and CAHs demonstrating meaningful use for the first time under their State’s Medicaid EHR Incentive Program. Under this exception, the CQM reporting period is any continuous 90-day period within CY 2018.

The submission period for eligible hospitals and CAHs reporting CQMs by attestation under the Medicare EHR Incentive Program is the 2 months following the close of the CY 2018 CQM reporting period, ending February 28, 2019.

In regard to the Medicaid EHR Incentive Program, CMS provides States with the flexibility to determine the method of reporting CQMs (attestation or electronic reporting) and the submission periods for reporting CQMs, subject to prior approval by CMS.

CMS finalized modified reporting criteria for 2018. For the CY 2018 reporting period, the reporting criteria under the Medicare and Medicaid EHR Incentive Program for eligible hospitals and CAHs reporting CQMs electronically is as follows

- For eligible hospitals and CAHs participating only in the EHR Incentive Program, or participating in both the EHR Incentive Program and the Hospital IQR Program, report on at least **4 self-selected** CQMs of the available CQMs.
- For eligible hospitals and CAHs that report CQMs by attestation under the Medicare EHR Incentive Program as a result of electronic reporting not being feasible, and for eligible hospitals and CAHs that report CQMs by attestation under their State’s Medicaid EHR Incentive Program, for the reporting period in CY 2018 report on all 16 available CQMs.

[Clinical Quality Measurement for Eligible Professionals \(EPs\) Participating in the Medicaid EHR Incentive Program in 2017](#)

CQM Reporting Form and Method for the Medicare EHR Incentive Program in 2018: For CY 2018, CMS proposes to continue its policy regarding the electronic submission of CQMs, which would require the use of the most recent version of the CQM electronic specification for each CQM to which the EHR is certified (see <https://ecqi.healthit.gov/>).

CMS also proposes to require that an eligible hospital or CAH would need to have its EHR technology certified to all 16 available CQMs in order to meet the reporting requirements for CY 2018.

Starting in CY 2018, CMS proposes to further require the use of EHR technology certified to the 2015 Edition for CQM reporting. Furthermore, CMS proposes that an EHR certified for CQMs under the 2015 Edition certification criteria would not need to be recertified each time it is updated to a more recent version of the CQMs.

[Proposed Modifications to the CQM Reporting Period for EPs in 2017:](#) CMS proposes to change the CQM reporting period for EPs who report CQMs electronically in the Medicaid EHR Incentive Program to match the performance period established under MIPS in the quality performance category for MIPS eligible clinicians. CMS proposes a minimum of a continuous 90-day period during CY 2017 for EPs electronically reporting CQMs for the Medicaid EHR Incentive Program.

[Proposed Modifications to CQM Reporting Requirements for Medicaid EPs under the Medicaid EHR Incentive Program:](#) CMS proposes to align the specific CQMs available to EPs participating in the Medicaid EHR Incentive Program with those available to clinicians participating in MIPS who submit CQMs through their EHR. Specifically, CMS proposes that the CQMs available for Medicaid EPs in 2017 would consist of the list of available CQMs for reporting from an EHR for MIPS in 2017, available in the Appendix of the CY 2017 Quality Payment Program final rule with comment period, which are denoted with a CMS e-Measure ID number.

For CY 2018, CMS will continue its policy regarding the electronic submission of CQMs, which requires the use of the most recent version of the CQM electronic specification for each CQM to which the EHR is certified. For the CY 2018 electronic reporting of CQMs, this means eligible hospitals and CAHs are required to use the Spring 2017 version of the CQM electronic specifications and any applicable addenda available on the eCQI Resource Center webpage at: <https://ecqi.healthit.gov/>.

In addition, ***CMS will require that an eligible hospital or CAH will need to have its EHR technology certified to all 16 available CQMs in order to meet the reporting requirements for CY 2018*** ([p. 1980](#)).

CMS finalized a modified version of its proposal to require the use of EHR technology certified to the 2015 Edition for the CQM reporting period in CY 2018. ([p. 1976](#)) For the CY 2018 CQM reporting period, eligible hospitals and CAHs will have the flexibility to use EHR technology certified to the 2014 Edition or 2015 Edition, or a combination of both Editions.

CMS finalized its proposal to change the CQM reporting period to any continuous 90-day period during CY 2017 for Medicaid EPs electronically reporting CQMs ([p. 1985](#)).

CMS finalized its proposals without modification ([p. 1991](#)). For 2017, the CQMs available for Medicaid EPs will consist of the list of 53 available CQMs for reporting from an EHR for MIPS for 2017 performance periods.

CMS also proposes to eliminate the requirement to report on CQMs across 3 of the 6 NQS domains that existed in previous years of the Medicaid EHR Incentive Program, for improved alignment with the data submission criteria for the MIPS quality performance category.

CMS proposes that for 2017 Medicaid EPs would be required to report on any six measures that are relevant to the EP's scope of practice.

[Changes to the Medicare and Medicaid EHR Incentive Programs](#)

Proposed Revisions to the EHR Reporting Period in 2018: CMS proposes to modify the EHR reporting periods in 2018 for new and returning participants attesting to CMS or their State Medicaid agency from the full year (CY 2018) to a minimum of any continuous 90-day period within CY 2018. Specifically, EPs that attest directly to a State for the State's Medicaid EHR Incentive Program and eligible hospitals and CAHs attesting to CMS or the State's Medicaid EHR Incentive Program would attest to meaningful use of CEHRT for an EHR reporting period of a minimum of any continuous 90-day period from January 1, 2018 through December 31, 2018.

CMS proposes corresponding changes to the definition of "EHR reporting period" and "EHR reporting period for a payment adjustment year" at 42 CFR 495.4. CMS invites public comment on its proposal.

Exception for Decertified EHR Technology for EPs, Eligible Hospitals, and CAHs Seeking to Avoid the Medicare Payment Adjustment: CMS proposes to add a new exception for EPs who demonstrate through an application process that compliance with the requirement for being a meaningful EHR user is not possible because the certified EHR technology used by the EP has been decertified under the Office of the National Coordinator for Health Information Technology (ONCHIT, or "ONC") Health IT Certification Program. CMS proposes this exception for the CY 2018 payment adjustment year, which is the final year of the payment adjustment for EPs under section 1848(a)(7)(A) of the Act. CMS proposes an EP may qualify for this exception if their certified EHR technology was decertified either before or during the applicable EHR reporting period for the CY 2018 payment adjustment year, which is any continuous 90-day period in CY 2016 or 2017, depending on whether the EP has successfully demonstrated meaningful use in a prior year. CMS also proposes that

CMS finalized a 90-day EHR reporting period in CY 2018 to allow participants additional time for testing and implementation of the 2015 Edition, including the new application programming interface (API) functionality requirement for Stage 3 ([p. 1994](#)). Specifically, ***for new and returning EPs, eligible hospitals, and CAHs attesting to CMS or their State Medicaid agency, an EHR reporting period in CY 2018 as a minimum of any continuous 90 days between January 1, 2018 through December 31, 2018, as proposed*** ([p. 1996](#)).

CMS finalized corresponding changes to the definitions of "EHR reporting period" and "EHR reporting period for a payment adjustment year" in the regulations under 495.4 ([p. 1996](#))

CMS finalized the policy as proposed. CMS also finalized as proposed the corresponding changes to § 495.102(d) for EPs, § 412.64(d)(4) for eligible hospitals and § 413.70(a)(6) for CAHs. ([p. 2001](#))

the EP must demonstrate in its application and through supporting documentation if available that the EP intended to attest to meaningful use for a certain EHR reporting period and made a good faith effort to adopt and implement another CEHRT in advance of that EHR reporting period. CMS proposes an EP seeking to qualify for this exception would submit an application in the form and manner specified by the agency by October 1, 2017, or a later date specified by the agency. CMS proposes to add a new category of exception for eligible hospitals that demonstrate through an application process that compliance with the requirement for being a meaningful EHR user is not possible because the certified EHR technology used by the eligible hospital has been decertified under ONC's Health IT Certification Program. CMS proposes that this exception would be available beginning with the FY 2019 payment adjustment year. CMS proposes an eligible hospital may qualify for this exception if their certified EHR technology was decertified either before or during the applicable EHR reporting period for the payment adjustment year. CMS also proposes to add a new category of exception for CAHs that demonstrate through an application process that compliance with the requirement for being a meaningful EHR user is not possible because the certified EHR technology used by the CAH has been decertified under ONC's Health IT Certification Program. CMS proposes this exception would be available beginning with the FY 2018 payment adjustment year. CMS proposes a CAH may qualify for this exception if their certified EHR technology was decertified either before or during the applicable EHR reporting period for the payment adjustment year. CMS invites public comment on these proposals. CMS requests public comments on whether the proposed 12-month period preceding the applicable EHR reporting period is reasonable or whether another period should be considered.

Ambulatory Surgical Center (ASC)-based Eligible Professionals (EPs):

CMS proposes two alternative definitions of an ASC-based EP and requests public comment to determine the final definition.

- Option 1: CMS proposes to define an ASC-based EP as an EP who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the codes used in the HIPAA standard transaction as an ASC setting in the calendar year that is two years before the payment adjustment year.
- Option 2: CMS proposes to define an ASC-based EP as an EP

CMS finalized the definition of ASC-based EP under Option 1: using 75 percent or more to define eligible professionals who furnish “substantially all” of their covered professional services in an ASC, which aligns with the hospital-based MIPS eligible clinician definition under the Quality Payment Program ([p. 2003](#)).

who furnishes 90 percent or more of his or her covered professional services in sites of service identified by the codes used in the HIPAA standard transaction as an ASC setting in the calendar year that is two years before the payment adjustment year.

CMS proposes to use Place of Service (POS) code 24 to identify services furnished in an ASC and is requesting public comment on whether other POS codes or mechanisms to identify sites of service should be used in addition to or in lieu of POS code 24.

Certification Requirements for 2018: CMS invites public comment on options for offering flexibility in CY 2018 with regard to EHR certification requirements.

CMS finalized Place of Service (POS) code 24 to identify services furnished in an ASC, as well as the definition of “ASC-based EP” in the regulations under § 495.4 (p. 2005).

CMS finalized a policy to allow health care providers to use either 2014 Edition or 2015 Edition CEHRT, or a combination of 2014 Edition and 2015 Edition CEHRT, for an EHR reporting period in CY 2018. As discussed elsewhere in this final rule, for the CY 2018 CQM reporting period, eligible hospitals and CAHs will have the flexibility to use EHR technology certified to either the 2014 Edition or 2015 Edition, or a combination of both Editions.

- All new and returning participants attesting to CMS or their State Medicaid agency have the option to attest to the Modified Stage 2 objectives and measures for the EHR reporting period in 2018 using 2014 Edition CEHRT, 2015 Edition CEHRT, or a combination of 2014 and 2015 Edition CEHRT, as long as the EHR technology they possess can support the objectives and measures to which they plan to attest.
- All new and returning participants attesting to CMS or their State Medicaid agency have the option to attest to the Stage 3 objectives and measures for the EHR reporting period in 2018 using 2015 Edition CEHRT or a combination of 2014 and 2015 Edition CEHRT, as long as their EHR technology can support the functionalities, objectives and measures for Stage 3.

Accordingly, CMS will revise the definition of “Certified electronic health record technology (CEHRT)” at § 495.4, the meaningful use criteria at § 495.22 and § 495.24, and the requirements for demonstrating meaningful use under § 495.40 to specify the flexible options for using CEHRT in 2018 and the objectives and associated measures to which health care providers using these options would attest. (p. 2014)

| <u>Changes Relating to Survey & Certification Requirements</u> | |
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| <u>Application and Re-application Procedures for National Accrediting Organizations and Postings of Survey Reports and Acceptable Plans of Corrections (PoCs)</u> | <p>CMS proposes to require AOs with CMS-approved accreditation programs to post final accreditation survey reports and PoCs on public facing websites designated by the AO. CMS proposed to revise current regulations to incorporate the proposed requirement.</p> <p>CMS also proposes to add a new standard to require that each national AO applying or reapplying for CMS-approval of its Medicare provider or supplier accreditation program provide a statement acknowledging that it agreed to make all Medicare provider or supplier final accreditation survey reports (including statements of deficiency findings) as well as acceptable PoCs publicly available on its website within 90 days after such information is made available to those facilities for the most recent 3 years.</p> <p>CMS did not finalize the proposed changes (p. 2041). Section 1865(b) of the Act prohibits CMS from disclosing survey reports or compelling the AOs to disclose their reports themselves. The suggestion by CMS to have the AOs post their survey reports may appear as if CMS was attempting to circumvent the provision of section 1865(b) of the Act. Therefore, this provision is effectively being withdrawn.</p> |
| <u>Physician Owned Hospitals</u> | |
| Request for Information | <p>CMS made a very brief request for comments on “the appropriate role of physician-owned hospitals in the delivery system.” The request specifically seeks guidance on how the current scope of and restrictions on physician owned hospitals affect health care delivery and the impact on Medicare beneficiaries.</p> <p>CMS did not address its request for comments on physician-owned hospitals in the Final Rule.</p> |
| <u>Physician Certification Requirement for Payment of Inpatient CAH Services Under Medicare Part A</u> | |
| <u>Audit Priority</u> | <p>CMS provides notice that it will direct QIOs, MACs, and Supplemental Medical Review Contractor (SMRC) to make the CAH 96 hour certification requirement a low priority for medical record reviews conducted on or after October 1, 2017. CMS states that this means that contractor will not be conducting medical record reviews (unless there is concern about fraud, waste, or abuse). QIOs and MACs may continue medical record reviews for compliance with other requirements (e.g. beneficiary complaints, quality of care reviews, higher weighted DRG reviews, readmission reviews, and the requirement that procedures be medically necessary).</p> <p>CMS noted that some commenters requested the permanent removal of the 96 hour requirement and will be advocating for a legislative solution. CMS also acknowledged the conflict between the 96 hour certification requirement and the 96 hour annual average CoP requirement (p. 1206). CMS acknowledged comments that the 96-hour certification requirement has imposed significant burdens on the surgical community and creates conflict with EMTALA requirements (p. 1210).</p> <p>CMS reiterates that it will direct QIOs, MACs, and the Supplemental Medical Review Contractor (SMRC) to make the CAH 96 hour certification requirement a low priority for medical record reviews conducted on or after October 1, 2017 (p. 1208; p. 1211). However, CMS again stated that the 96-hour certification requirement is statutory and cannot be amended without legislation (p. 1210).</p> |