

# 2019 Hospital Inpatient Prospective Payment System (IPPS)

A SIDE-BY-SIDE COMPARISON OF KEY PROVISIONS FROM THE PROPOSED AND FINAL RULES  
FOR FY 2019

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TOPIC

PROPOSED RULE

FINAL RULE

[MS-DRG Documentation and Coding Adjustment](#)

[Specific MS-DRG Classifications](#)

**Medicare Severity Diagnosis-Related Group (MS-DRG) Classifications and Relative Weights**

CMS proposes a +0.5 percent adjustment for FY 2019 to the standardized amount as directed under MACRA (which would be a permanent adjustment to the rates). CMS plans to make the future adjustments as mandated through MACRA through 2023 in future rulemaking.

**Conversion of MS-DRGs to ICD-10:** Input for FY 2020 must be submitted by November 1, 2018. Input can be submitted to [MSDRGClassificationChange@cms.hhs.gov](mailto:MSDRGClassificationChange@cms.hhs.gov).

**Pre-MDC:**

- **Heart Transplant or Implant of Heart Assist System:** CMS had previously requested input on these MS-DRGs. The current relevant MS-DRGs are:
  - MS-DRG 001 (*Heart Transplant or Implant of Heart Assist System with MCC*)
  - MS-DRG 002 (*Heart Transplant or Implant of Heart Assist System without MCC*)

The MS-DRGs are based on ICD-10 procedure codes that identify a heart transplant procedure and ICD 10 procedure codes that identify the implantation of a heart assist system.

- **LVAD:** CMS agreed to maintain the current assignments to MS-DRGs 001 and 002 and will continue to monitor the data for MS-DRGs 001 and 002.

CMS received input that it misinterpreted the FYs 2018 and 2019 directives ([p. 61](#)). Based on the believed interpretations, commenters submitted that FY 2018 and FY 2019 updates should be +0.7% instead of +0.5% ([p. 62](#)). ***CMS disagreed and finalized its proposal to implement a +0.5% adjustment to the FY 2019 standardized amount, as it believes MACRA directed ([p. 63](#)).***

CMS reiterated the FY 2020 deadline of November 1, 2018 with submissions going to [MSDRGClassificationChange@cms.hhs.gov](mailto:MSDRGClassificationChange@cms.hhs.gov) ([p. 67](#)).

There are 33 procedure code combinations (which involve removal or revision of devices) ([table on pp. 71-74](#)).

[Table beginning on p. 75](#) provides examples of common clinical scenarios involving an LVAD and included procedure codes reported under ICD-9 based MS-DRGs compared with ICD-10 MS-DRGs. In response to requests for coding guidance, ***CMS reminded stakeholders that coding advice is issued independent of payment policy, and CMS works with the AHA Coding Clinic for ICD-10 to issue such guidance ([p. 78](#)).***

CMS provided claims analysis in a [table on p. 78](#) and [p. 79](#). CMS received comments in support of the current MS-DRG assignments. Therefore, ***CMS finalized its proposal to maintain the current structure of MS-DRG 001 and MS-DRG 002 ([p. 90](#)).***

- MS-DRG 215 (Other Heart Assist System Implant): CMS agreed to continue to monitor the data and propose modifications as necessary for MS-DRG 215. CMS proposes to not make any changes to MS-DRG 215 for FY 2019.

- Extracorporeal Membrane Oxygenation (ECMO): CMS received a request to review claims data for procedures involving (ECMO) in combo with insertion of a percutaneous short-term external heart assist device for appropriate MS-DRG assignment. However, CMS proposed to keep the cases as currently assigned until there is a way to specifically identify percutaneous ECMO in claims data. Until that was available, CMS stated it would not be clear what proposal to make.

- 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): CMS agreed with the recommendation to maintain the structure of MS-DRGs 268 and 269 and will continue to analyze data for future updates.

- Brachytherapy: CMS received a request to create a new Pre-MDC for “all procedures involving CivaSheet® technology, an implantable, planar brachytherapy source designed to enable delivery of radiation to the site of the cancer tumor excision or debulking, while protecting the neighboring tissue.” However,

**CMS finalized its proposal to not make no changes to MS-DRG 215 FY 2019 (p. 96).**

CMS received input that new ICD-10 procedure codes identifying percutaneous ECMO procedures were made available in May 2018 (p. 99). Commenters suggested this data showed that the procedure codes should be reassigned to several different MS-DRGs based on different interpretations of which MS-DRG has the most similar clinical characteristics and resource utilization (p. 100). CMS states that the new procedure codes created to describe percutaneous ECMO were not finalized at the time of the proposed rule, and therefore, CMS made no proposed MS-DRG reassignments (p. 101). The CMS clinical advisors reviewed the different risks between percutaneous ECMO and central ECMO (p. 102).

- **CMS clinical advisors do not support assigning peripheral ECMO procedures to the same MS-DRG as open ECMO (p. 102).**
- **CMS clinical advisors do not support designating percutaneous ECMO as an “O.R. procedure” because the procedure is less intensive than compared to open ECMO (p. 102).**
- **CMS is revising MS-DRG titles and assignments involving percutaneous ECMO as seen in the [table on p. 103](#).**
- **CMS recognizes the difference in use of percutaneous ECMO with percutaneous external heart assist device, and maintains this code combination assignment to MS-DRG 215 (p. 104).**

**CMS finalized its proposal to maintain the structure of MS-DRGs 268 and 269) (p. 109).**

CMS received several comments including that lack of adequate Medicare payment does not allow more widespread use, which contributes to the lack of claims data for ratesetting (p. 113). CMS acknowledged some errors in the data table, which it updated in [the table in the final rule](#). However, **CMS finalized its proposal to maintain the current assignments, but continue to**

CMS only identified 4 cases in the claims data. Therefore, CMS did not propose a new MS-DRG for procedures involving CivaSheet® technology for FY 2019.

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

***Epilepsy with Neurostimulator:*** CMS received a request to include two additional codes to the listing of epilepsy diagnosis codes for cases assigned to MS-DRG 023 (*Craniotomy with Major Device Implant or Acute Complex Central Nervous System (CNS) Principal Diagnosis (PDX) with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator*):

- G40.109 (*Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, without status epilepticus*)
- G40.111 (*Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, with status epilepticus*)

CMS proposed to add the list of epilepsy diagnosis codes to the list of cases assigned to MS-DRG 023.

***MDC 5 (Diseases and Disorders of the Circulatory System):***

***Pacemaker Insertions:*** CMS clinical advisors recommended that pacemaker insertion procedures *involving a complete pacemaker system (device combined with insertion of pacemaker lead)* be assigned to surgical MS-DRGs “because the patients receiving these devices demonstrate greater treatment difficulty and utilization of resources when compared to procedures that involve the insertion of only the pacemaker device or the insertion of only the pacemaker lead.” In order to affect this, CMS made a series of proposals:

CMS proposed to recreate pairs of procedure code combinations involving both the insertion of a pacemaker device with the insertion

***explore mechanisms to address rare diseases and low volume MS-DRGs*** ([p. 114](#)).

***Additional Reviews:*** CMS also finalized policies related to:

- Laryngectomy ([p. 114](#))
- Chimeric Antigen Receptor (CAR) T-Cell Therapy ([p. 116](#))

***CMS finalized its proposal to add the ICD-10 diagnosis codes to MS-DRG 023*** ([p. 128](#)).

***Additional Reviews:*** CMS also finalized proposals related to Neurological Conditions with Mechanical Ventilation ([p. 129](#)).

CMS reiterates the procedure codes involving the insertion of a cardiac rhythm related device classified as a type of pacemaker insertion in [a table on p. 159](#).

***CMS finalized this proposal*** ([p. 176](#)).

of a pacemaker lead to act as a combination designated to O.R. procedures outside of MDC 5 when reported together.

CMS proposed to designate pacemaker insertion procedures or insertion of a pacemaker lead (when reported “as a single, individual stand-alone code”) as non-O.R. procedures.

CMS also provided a list of procedure codes (describing the *removal or revision* of a cardiac lead and removal or revision of a cardiac rhythm related (pacemaker) device) for which it seeks comment on whether they should be designated as non-O.R. procedures when reported as a single, individual stand-alone code.

CMS also sought input on whether a series of codes describing the *insertion and revision of intracardiac pacemakers* should be classified into all surgical unrelated MS-DRGs outside of MDC 5.

***MSC 6 (Diseases and Disorders of the Digestive System):***

**Bowel Procedures:** CMS responded to a request to reassign several ICD-10 procedure codes that describe the positioning of the colon and takedown of end colostomy. The commenter suggested that the resources needed for procedures repositioning the specified segments of the large bowel are more aligned with the procedures in the “major” MS-DRGs (e.g. repositioning of the large intestine).

CMS proposed to maintain the current assignment of the bowel repositioning procedures to MS-DRGs 344, 345, and 346.

However, CMS proposed to reassign the added list of bowel procedures to MS-DRGs 344, 345, and 346.

***CMS finalized this proposal*** ([p. 178](#)).

CMS received input that these codes maintain their designation as O.R. procedures. CMS noted that it did not make a specific proposal to redesignate the procedures at this time but was seeking input. Nonetheless, ***CMS will maintain the designation of these procedure codes as O.R. procedures and will continue to analyze incoming claims data*** ([p. 182](#)).

CMS reiterated that it did not make a specific recommendation to change the designation of the procedure codes in this rule and the procedures are already classified as extensive O.R. procedures ([p. 184](#)). ***CMS will maintain the O.R. designation of the procedure codes describing insertion and revision of intracardiac pacemakers*** ([p. 185](#)).

**Additional Review:** CMS also finalized its policies related to Drug-Coated Balloons in Endovascular Procedures ([p. 185](#)).

CMS relists the ICD-10 codes and MS-DRGs in [tables beginning on p. 199](#).

***CMS finalized its proposal*** ([p. 201](#)).

***CMS did not finalize this proposal*** ([p. 204](#)). CMS received input that the codes identifying “reposition” may be used “for the takedown of a stoma, as well as to treat a specific medical condition such as malrotation of the intestine, and that “Repair” is the root operation of last resort when no other ICD-10-PCS root operation applies, and therefore, is used for a wide range of procedures of varying complexity.” ([p. 203](#)). Commenters also noted that the AHA Coding Clinic issued guidance for these codes in late

2016/early 2017, and therefore, there is not a full 2 years of data that has come in post-guidance release.

Additional Review: CMS also finalized policies related to Benign Lipomatous Neoplasm of Kidney on [p. 196](#).

***MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)***

Spinal Fusion: In FY 2018, CMS made several reassignments for spinal fusion procedure codes. CMS did not propose any changes for FY 2019 to the MS-DRGs for spinal fusion procedures, but in response to a request, provided [results from the CMS analysis of its September 2017 update of the FY 2017 MedPAR claims data](#) for MS-DRGs for spinal fusion procedures.

CMS received several comments describing spinal fusion coding confusion, including ([p. 211](#)):

- Whether spinal fusion codes can be used when no bone graft or bone graft substitute is used (i.e. instrumentation only), but the medical record documentation refers to the procedure as a “spinal fusion”
- Need for additional refinements to the ICD-10 spinal fusion coding guidelines to clarify appropriate reporting
- Hope that planned October 1, 2018 deletion of 2310 ICD-10 fusion procedure codes with the device value of “Z” (i.e. “no device”) would eliminate confusion regarding spinal procedures

CMS agreed that there had been coding confusion and stated it will continue to monitor claims data for spinal fusion procedures and collaborate with the AHA Coding Clinic on guidance for spinal procedure coding ([p. 212](#)).

***MDC 18 (Infectious and Parasitic Diseases (Systematic of Unspecified Sites)):***

Systemic Inflammatory Response Syndrome (SIRS) of Non-Infectious Origin: CMS clinical advisors recommended the review of two diagnosis codes because they describe conditions of a non-infectious origin. CMS proposes reassignment of ICD-10 diagnosis codes R65.10 and R65.11 to MS-DRG 864 and to revise the title of MS-DRG 864 to “Fever and Inflammatory Conditions”

***CMS finalized its proposal*** ([p. 275](#)).

CMS also finalized policies for the following MDCs:

- MDC 6 (*Diseases and Disorders of the Skin, Subcutaneous Tissue, and Breast*): Cellulitis with Methicillin Resistant Staphylococcus aureus (MRSA) Infection ([p. 212](#))
- MDC 10 (*Endocrine, Nutritional and Metabolic Diseases and Disorders*): Intermittent Porphyria ([p. 216](#))
- MDC 11 (*Diseases and Disorders of the Kidney and Urinary Tract*): Admit for Renal Dialysis ([p. 221](#))
- MDC 14 (*Pregnancy, Childbirth and the Puerperium*) ([p. 225](#))



- MDC 21 (*Injuries, Poisonings and Toxic Effects of Drugs*): Corrosive Burns ([p. 275](#))

#### **Medicare Code Editor (MCE) Changes:**

##### Sex Conflict Edit

- *Females Only Edits*: CMS proposed diagnoses codes for addition and removal to the edit
- *Males Only Edits*: CMS proposed diagnosis codes for addition to the Males Only edit

##### Manifestation Code as Principal Diagnosis Edit:

In the proposed rule, CMS stated that manifestation codes are not to be used for the principal diagnosis as the manifestation codes describe the manifestation of an underlying disease and not the disease itself. CMS proposed to add two ICD-10 diagnosis codes to the Manifestation Code as Principal Diagnosis Edit:

- K82.A1 (Gangrene of gallbladder in cholecystitis): instead CMS states the type of cholecystitis would be reported first
- K82.A2 (Perforation of gallbladder in cholecystitis): instead CMS states the type of cholecystitis would be reported first

***Surgical Hierarchies:*** CMS proposed several changes to the surgical hierarchy under MDC 14 (Pregnancy, Childbirth & the Puerperium)

##### ***Operating Room (O.R.) and Non-O.R. Issues:***

Percutaneous and Percutaneous Endoscopic Excision of Brain and Cerebral Ventricle: CMS proposed to add the 22 listed ICD-10 procedure codes for transcranial brain and cerebral ventricle excision procedures as O.R. procedures.

Open Extirpation of Subcutaneous Tissue and Fascia: CMS proposed to maintain the status of the 22 ICD-10 procedure codes as non-O.R. procedures.

***CMS finalized its proposals*** ([p. 292](#)).

***CMS finalized its proposal*** ([p. 296](#)). The list of codes added to the *Males Only* edit list can be found in a [table on p. 295](#).

***CMS finalized this proposal*** ([p. 297](#)).

Additional Reviews: CMS also finalized policies in the following categories:

- Age Conflict Edit ([p. 283](#))
- Unacceptable Principal Diagnosis Edit ([p. 305](#))

***CMS finalized its proposals*** ([p. 315](#)).

***CMS finalized its proposal*** ([p. 391](#)). The list of codes can be found in a table on p. 390.

***CMS finalized its proposal to maintain these procedures as non-O.R. procedures*** ([p. 395](#)). CMS disagreed with commenters that suggested the procedures should be designated as O.R. procedures. CMS stated that its clinical advisors continue to believe the the open extirpation codes that were listed can be performed outside of the the O.R. (e.g. in a radiology suite with CT or MRI guidance). CMS clinical advisors also disagreed that the



Open Scrotum and Breast Procedures: CMS proposed adding the 13 ICD-10 procedure codes to the list of O.R. procedures with corresponding MS-DRG assignments.

Open Parotid Gland and Submaxillary Gland Procedures: CMS proposed to designate 8 procedure codes as O.R. procedures with an MS-DRG assignment of MS-DRG 139 (Salivary Gland Procedures).

Endoscopic Dilation of Ureter(s) with Intraluminal Device: CMS proposed to designate the 3 procedure codes as O.R. procedures with corresponding MS-DRG assignment.

Thoracoscopic Procedures of Pericardium and Pleura: CMS proposed to add nine ICD-10 procedure codes as O.R. procedures with corresponding MS-DRG assignments).

Open and Insertion of Totally Implantable and Tunneled Vascular Access Device: CMS did not agree that the procedures describing *tunneled VAD procedures* submitted by requestors typically require the resources of an operating room. Therefore, CMS proposed to only designate the procedure codes describing *totally implantable VAD procedures* as O.R. procedures and made corresponding MS-DRG assignments.

Endoscopic Destruction of Intestine: CMS proposed to remove four procedure codes from the list of designated O.R. procedures.

Drainage of Lower Lung Via Natural or Artificial Opening Endoscopic Diagnostic: CMS proposed to remove 5 codes from the list of O.R. designated procedures.

procedures were similar to open drainage procedures ([p. 394](#)). The codes can be found in [a table on p. 392](#).

***CMS finalized its proposal to designate the procedures as “O.R. procedures”*** ([p. 397](#)). The codes can be found in a [table starting on p. 395](#).

***CMS finalized its proposal to designate the codes as “O.R. procedures”*** ([p. 398](#)). The codes can be found in [a table on p. 397](#).

***CMS finalized the policy as proposed*** ([p. 403](#)). The codes can be found in a [table beginning on p. 401](#).

***CMS finalized the policy as proposed*** ([p. 406](#)). The codes can be found in [a table on p. 404](#).

***CMS finalized its proposal to redesignate ICD-10 procedure codes describing open insertion of totally implantable VAD procedures as O.R. procedures*** ([p. 410](#)). While CMS received feedback that the *tunneled VAD procedures* should also be redesignated as O.R. procedures, CMS stated that its clinical advisors continue to believe that *tunneled VAD procedures* do not typically require the use of an O.R. ([p. 411](#)). The codes can be found in [a table on p. 407](#).

***CMS finalized the policy as proposed*** ([p. 415](#)). The list of codes can be found in [a table beginning on p. 414](#).

***CMS finalized the policy as proposed*** ([p. 416](#)). The codes can be found in [a table on p. 415](#).

#### **Additional Procedure Reviews:**

- Endobronchial Valve Procedures ([p. 416](#)): In response to the FY 2019 IPPS proposed rule, CMS received input that listed 8 ICD-10 procedure codes that the stakeholder believes should be designated as O.R. procedures. The list of codes is available in [a table on p. 417](#). CMS stated that its clinical advisors disagreed that the listed

procedures typically require the use of an O.R. ([p. 417](#)). ***CMS is not changing the the designation of the codes put forward.***

- Removal and Reinsertion of Spacer; Knew Joint and Hip Joint ([p. 399](#))
- Percutaneous Joint Reposition with Internal Fixation Device ([p. 411](#))
- A list of comments that CMS viewed to be out-of-scope with respect to the O.R./non-O.R. designation review can be found [beginning on p. 418](#).

### **Add-On Payments for New Services and Technologies**

**Proposed FY 2019 Status of Technologies Approved for FY 2018 Add on Payments**

***Defitelio® (Defibrotide):*** CMS proposes to continue new technology add-on payments for this technology for FY 2019.

***CMS will continue new technology add-on payments for Defitelio® for FY 2019.*** The maximum new technology add-on payment for a case involving the use of Defitelio® is \$80,500 for FY 2019 ([p. 460](#)).

***EDWARDS INTUITY Elite™ Value System (INTUITY) and LivaNova Perceval Valve (Perceval):*** CMS proposes to discontinue new technology add-on payments for the INTUITY and Perceval valves for FY 2019.

***CMS finalized its proposal to discontinue new technology add-on payments for this technology for FY 2019*** ([p. 464](#)).

***GORE® EXCLUDER® Illiac Branch Endoprosthesis (Gore IBE Device):*** CMS proposes to discontinue new technology add-on payments for this technology for FY 2019.

***CMS finalized its proposal to discontinue new technology add-on payments for this technology for FY 2019*** ([p. 470](#)).

***PRAXBIND (idarucizumab):*** CMS proposes to discontinue new technology add-on payments for this technology for FY 2019.

***CMS finalized its proposal to discontinue new technology add-on payments for this technology for FY 2019*** ([p. 475](#)).

***Stelara® (ustekinumab):*** CMS proposes to continue new technology add-on payments for this technology for FY 2019.

***CMS will continue new technology add-on payments for Stelara® for FY 2019.*** The maximum payment for a case involving Stelara® will remain at \$2,400 for FY 2019 ([p. 477](#)).

***Vistogard™ (Uridine Triacetate):*** CMS proposes to discontinue new technology add-on payments for this technology for FY 2019.

***CMS finalized its proposal to discontinue new technology add-on payments for this technology for FY 2019*** ([p. 480](#)).

***ZINPLAVA™ (bezlotoxummab):*** CMS proposes to continue new technology add-on payments for this technology for FY 2019.

***CMS will continue new technology add-on payments for ZINPLAVA® for FY 2019.*** The maximum new technology add-on payment for a case involving ZINPLAVA will remain at \$1,900 for FY 2019. ([p. 483](#))

**FY 2019  
Applications  
for New  
Technology  
Add-On  
Payments**

**KYMRIAH™ (Tisagenlecleucel) and YESCARTA™ (Axicabtagene Ciloleucel):** CMS expresses concern about whether the technologies meet the newness criterion, believes the technologies meet the cost criterion, and expresses concern about whether the technologies meet the substantial clinical improvement criterion.

Additionally, CMS invites public comments regarding the most appropriate mechanism to provide payment to hospitals for new technologies such as CAR T-cell therapy drugs, including through the use of new technology add-on payments. CMS is also inviting public comments on how these payment alternatives would affect access to care, as well as how they affect incentives to encourage lower drug prices. In addition, CMS is considering alternative approaches and authorities to encourage value-based care and lower drug prices. CMS solicits comments on how the payment methodology alternatives may intersect and affect future participation in any such alternative approaches.

**VYXEOS™ (Cytarabine and Daunorubicin Liposome for Injection):** CMS is inviting public comments on whether the technology is substantially similar to existing technology, including whether the mechanism of action of VYXEOS™ differs from the mechanism of action of the currently available treatment regimen. CMS also is inviting public comments on whether the technology meets the newness criterion and the cost criterion. CMS expresses concern about whether the technology meets the substantial clinical improvement criterion.

**VABOMERE™ (meropenem-vaborbactam):** CMS expresses concern about whether the technology meets the substantial similarity, newness, and cost criteria. Specifically, CMS is inviting public comments as to whether the FDA endpoints demonstrating noninferiority are statistically sufficient data to support that VABOMERE™ is a substantial clinical improvement. CMS is inviting public comments regarding the lack of a comparison to other antibiotic treatments known to be effective against gram-negative uropathogens, whether the comparator the applicant used in its trial studies may have skewed the eradication rates in favor of VABOMERE™, and if the favorable results would be applicable to

**After reviewing comments, CMS believes these technologies meet all requirements for approval of new technology add-on payments.** Cases involving KYMRIAH and YESCARTA that are eligible for new technology add-on payments will be identified by ICD-10–PCS procedure codes XW033C3 and XW043C3. The maximum new technology add-on payment for a case involving the use of KYMRIAH or YESCARTA is \$186,500 for FY 2019 ([p. 487](#)).

CMS also notes that the Innovation Center is soliciting public comment in the CY 2019 OPPTS/ASC proposed rule on key design considerations for developing a potential model that would test private market strategies and introduce competition to improve quality of care for beneficiaries, while reducing both Medicare expenditures and beneficiaries' out-of-pocket spending. Given the relative newness of CAR T-cell therapy, the potential model, and the Innovation Center's request for feedback on this model approach, **CMS believes that it would be premature to adopt changes to existing payment mechanisms, including structural changes in new technology add-on payments** ([p. 550](#)).

After reviewing comments, **CMS believes this technology meet all requirements for approval of new technology add-on payments.** Cases involving the use of VYXEOS™ that are eligible for new technology add-on payments will be identified by ICD-10-PCS procedure codes XW033B3 and XW043B3. the maximum new technology add-on payment for a case involving the use of VYXEOS™ is \$36,425 ([p. 551](#)).

After reviewing comments, **CMS believes this technology meet all requirements for approval of new technology add-on payments.** The applicant did not request approval for the use of a unique ICD-10-PCS procedure code, so hospitals will be unable to uniquely identify the use of VABOMERE™ on an inpatient claim using the typical coding of an ICD-10-PCS procedure code. Thus, **FY 2019 cases involving the use of VABOMERE™ that are eligible for the FY 2019 new technology add-on payments will be identified by the NDC of 65293-009-01 (VABOMERE™ Meropenem-Vaborbactam Vial). Providers must code the NDC in data element LIN03 of the 837i Health Care Claim Institutional form in order to receive the new technology add-on payment.** The maximum new technology add-on

patients in the United States to allow for sufficient information in evaluating substantial clinical improvement.

**DURAGRAFT® Vascular Conduit Solution:** CMS expresses some concern about the sufficiency of the studies to prove substantial clinical improvement. CMS invites public comment on all criteria.

**remedē System:** CMS expresses concern about the data to support the cost criterion. CMS also expresses concern about the substantial clinical improvement criterion.

**Titan Spine nanoLOCK® (Titan Spine nanoLOCK Interbody Device):** CMS expresses concern about substantial similarity to other, existing technologies. CMS expresses concern about substantial clinical improvement.

**ZEMDRI® (plazomicin):** CMS invites comments on whether the technology is substantially similar to any existing technologies and whether it meets the newness criterion. Specifically, CMS is inviting public comments on whether Plazomicin's mechanism of action is new, including comments in response to a concern that its mechanism of action to eradicate bacteria may be similar to that of other aminoglycosides. CMS expresses concern about substantial clinical improvement.

**GIAPREZA™:** CMS expresses concern about the substantial similarity criteria, the newness criterion, and the cost criterion.

**GammaTile™:** CMS expresses concern about the substantial similarity and newness criteria. CMS also expresses concern about the substantial clinical improvement criterion.

payment for a case involving the use of VABOMERE™ is \$5,544 for FY 2019 ([p. 575](#)).

The manufacturer withdrew the application. ([p. 486](#))

After reviewing comments, **CMS believes this technology meet all requirements for approval of new technology add-on payments**. Cases involving the use of the remedē System that are eligible for new technology add-on payments will be identified by ICD-10-PCS procedures codes OJH60DZ and 05H33MZ in combination with procedure code 05H03MZ or 05H043MZ. The maximum new technology add-on payment for a case involving the use of the remedē System is \$17,250 for FY 2019 ([p. 602](#)).

**CMS is not approving new technology add-on payments for the Titan Spine nanoLock® devices for FY 2019** ([p. 637](#)).

After reviewing comments, **CMS believes this technology meets all requirements for approval of new technology add-on payments**. Cases involving ZEMDRI™ that are eligible for new technology add-on payments will be identified by ICD-10-PCS procedure codes XW033G4 and XW043G4. The maximum new technology add-on payment for a case involving the use of ZEMDRI™ is \$2,722.50 for FY 2019 ([p. 661](#)).

After reviewing comments, **CMS believes this technology meets all requirements for approval of new technology add-on payments**. Cases involving the use of GIAPREZA that are eligible for new technology add-on payments will be identified by ICD-10-PCS procedure codes XW033H4 and XW043H4. The maximum new technology add-on payment for a case involving the use of GIAPREZA is \$1,500 for FY 2019 ([p. 696](#)).

The manufacturer did not meet the deadline of July 1 for FDA approval or clearance of the technology and, therefore, **the technology is not eligible for consideration for new technology add-on payments for FY 2019**. ([p. 487](#)).

***Supersaturated Oxygen (SSO<sub>2</sub>) Therapy (DownStream® System):***

CMS expresses concern about the lack of long-term data on improvement in patient clinical outcomes, despite the lack of statistical significance.

***Cerebral Protection System (Sentinel® Cerebral Protection System):***

CMS notes that “it appears that the Sentinel® Cerebral Protection System is not substantially similar to other existing technologies.” CMS is inviting public comments on that, and whether the technology meets the newness criterion. CMS invites comment on the cost criterion. CMS expresses concern about the substantial clinical improvement criterion and invites comment.

***AZEDRA (Ultratrace® iobenguane Iodine-131) Solution:*** CMS expresses concern about the cost criterion and the substantial clinical improvement criterion and invites comments.

***The AQUABEAM System (Aquablation):*** CMS expresses concern about the newness criterion and the substantial clinical improvement criterion.

***AndexXa™ (Andexanet alfa):*** CMS expresses concern about the substantial clinical improvement criterion.

The manufacturer withdrew the application. ([p. 486](#))

After reviewing comments, ***CMS believes this technology meets all requirements for approval of new technology add-on payments.*** Cases involving the use of the Sentinel Cerebral Protection System that are eligible for new technology add-on payments will be identified by ICD-10-PCS procedure code X2A5312. the maximum new technology add-on payment for a case involving the use of the Sentinel Cerebral Protection System is \$1,400 for FY 2019 ([p. 727](#)).

The manufacturer withdrew the application. ([p. 486](#))

After reviewing comments, ***CMS believes this technology meets all requirements for approval of new technology add-on payments.*** Cases involving the AQUABEAM System that are eligible for new technology add-on payments will be identified by ICD-10-PCS procedure code XV508A4. The maximum new technology add-on payment for a case involving the use of the AQUABEAM System’s Aquablation System is \$1,250 for FY 2019. ([p. 752](#))

After reviewing comments, ***CMS believes this technology meets all requirements for approval of new technology add-on payments.*** Cases involving the use of AndexXa that are eligible for new technology add-on payments will be identified by ICD-10-PCS procedure codes XW03372 and XW04372. The maximum new technology add-on payment for a case involving the use of AndexXa is \$14,062.50 for FY 2019. ([p. 782](#))

<u>Changes to MS-DRGs Subject to the Postacute Care Transfer and MS-DRG Special Payment Policies</u>	
<p>CMS describes its postacute care transfer and special payment policies.</p> <p>CMS evaluated all MS-DRGs that were proposed to be revised to determine their qualification for the postacute care transfer policy, and if so, their qualification for the special payment methodology. Based on CMS' review, all MS-DRGs that current qualify would continue to qualify to be included on the list of MS-DRGs that are subject to the postacute care transfer policy. CMS is proposing that proposed revised MS-DRG 023 would be subject to the MS-DRG special payment methodology, effective FY 2019. CMS is proposing that MS-DRG 024 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC or Chemotherapy Implant or Epilepsy with Neurostimulator) also would be subject to the MS-DRG special payment methodology, effective for FY 2019.</p> <p>CMS notes that its analysis does not take into account the proposed change relating to discharges to hospice care, effective October 1, 2018, discussed in the next section of this proposed rule.</p>	<p>CMS describes its postacute care transfer and special payment policies. (<a href="#">p. 927</a>)</p> <p><b>Finalized as proposed. (<a href="#">p. 936</a>)</b> CMS notes that postacute care transfer policy status (<a href="#">p. 932</a>) and the special payment policy status (<a href="#">p. 936</a>) for FY 2019 for all finalized new and revised MS-DRGs remains unchanged from the proposed rule.</p> <p>CMS includes its analysis on the table starting on <a href="#">p. 932</a> for the postacute care transfer policy. The table on <a href="#">p. 936</a> reflects updated analysis for the finalized new and revised MS-DRGs subject to review of the special payment policy. Unlike with the proposed rule, both charts take into account the change relating to discharges to hospice care, effective October 1, 2018, discussed in the next section.<sup>1</sup></p>
<u>Proposed Implementation of Changes Required by Section 53109 of the Bipartisan Budget Act of 2018</u>	
<p>Consistent with Section 53109 of the BBA of 2018, effective for discharges occurring on or after October 1, 2018, if a discharge is assigned to one of the MS-DRGs subject to the postacute care transfer policy, and the individual is transferred to hospice care by a hospice program, the discharge would be subject to payment as a transfer case.</p> <p>CMS is proposing to make conforming amendments to § 412.4(c) of the regulation to include discharges to hospice care occurring on or after October 1, 2018 as qualified discharges. CMS is proposing that hospital bills with a Patient Discharge Status code of 50</p>	<p><b>Generally finalized as proposed, with one minor grammatical modification to regulation text to increase clarity. (<a href="#">p. 941</a>)</b></p> <p>CMS notes several comments received opposing the policy and raising concerns about the impact on timely election to hospice and requesting that CMS monitor the impacts of the policy. (<a href="#">p. 939</a>) CMS also notes that the BBA of 2018 requires MedPAC to conduct a detailed evaluation of the implementation and impacts of this provision, due to Congress by March 21, 2020. (<a href="#">p. 940</a>)</p>

<sup>1</sup> CMS is finalizing its proposed changes to the MS-DRGs with the exception of proposed revisions to MS-DRGs 329, 330, 331, 344, 345, and 336, which CMS is not finalizing. Therefore, these MS DRGs are not included in the updated analysis of the postacute care transfer policy and special payment policy criteria. CMS also notes that it incorrectly stated that it had used March 2018 data for the proposed rule analysis, rather than the December 2017 update. ([p. 931](#))



(Discharged/Transferred to Hospice - Routine or Continuous Home Care) or 51 (Discharged/Transferred to Hospice, General Inpatient Care or Inpatient Respite) would be subject to the postacute care transfer policy in accordance with this statutory amendment.

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

**Background.** There are two methods by which a hospital can qualify for DSH payments:

- **The Pickle Method:** Hospitals that are located in an urban area and have 100 or more beds if the hospital can demonstrate that within a cost reporting period more than 30 percent of its net inpatient care revenues come from State and local government payments for care furnished to needy patients with low incomes.
- **Statutory Methodology:** Hospitals qualify for payments under a statutory formula based on:
  - The hospital's geographic designation
  - Number of beds
  - Level of hospitals Disproportionate Patient Percentage (DPP) (relies on SSI, Medicare, and Medicaid qualification data)

**The Patient Protection and Affordable Care Act (ACA).** 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**").

### 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 previously established policy for calculating Factor 1.

CMS received substantial pushback on its transparency regarding the calculation of Factor 1. CMS stated, "we have been and continue to be transparent with respect to the methodology and data used to estimate Factor 1 and we disagree with commenters who assert otherwise" ([p. 987](#)). **CMS finalized its previously established policy for calculation of Factor 1** ([p. 991](#)).



CMS proposes that for FY 2019 Factor 1 (“the 75 percent”) will represent approximately \$12.221 billion.

**Factor 2:**

In FY 2018, CMS proposed and finalized its plan 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 proposed to use the same methodology and data source to calculate Factor 2 in FY 2019.

CMS puts forward a FY 2019 Factor 2 of 67.51 percent, resulting in the availability of \$8.250 billion for Uncompensated Care Payments.

**Factor 3:** Factor 3 is 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 express the proportion of the estimated uncompensated care amount for each hospital. Because of uncertainty about other data sources, to estimate a hospital’s level of uncompensated care in the past, CMS relied on utilization of insured low-income patients as a proxy. However, in FY 2018 CMS returned to its originally proposed data source for uncompensated care and started to rely on the Worksheet S-10 of the Medicare cost report for each hospital. CMS proposed to use data from FY 2013 (low-income insured days proxy data), FY 2014 (Worksheet S-10), and FY 2015 (Worksheet S-10) cost reports to determine Factor 3 for 2019. CMS stated that it could no longer conclude that alternative data to the Worksheet S-10 are currently available for FY 2014 and FY 2015 that are a better proxy for hospital costs of treating uninsured individuals. Therefore:

CMS proposed to use data from FY 2013 (low-income insured days proxy data), FY 2014 (Worksheet S-10), and FY 2015 (Worksheet S-10) cost reports to determine Factor 3 for 2019.

CMS proposed to use Medicaid days from FY 2013 cost reports and FY 2016 SSI ratios.

Using updated data, ***CMS states that Factor 1 for FY 2019 will be \$12.254 billion*** ([p. 991](#)).

***CMS finalized its calculation of Factor 2 as proposed*** ([p. 1005](#)).

Using updated data, ***CMS finalized a FY 2019 Factor 2 calculation of 67.51 percent, resulting in the availability of \$8.272 billion for Uncompensated Care Payments*** ([p. 1005](#)).

CMS noted that it did not make any proposals for Factor 3 for FY 2020 or subsequent fiscal years, but that “the above methodology would have the effect of fully transitioning the incorporation of data from Worksheet S-10 into the calculation of Factor 3 if used in FY 2020 ([p. 1037](#)).

***CMS finalized this policy as proposed*** ([p. 1082](#)).

***CMS finalized this policy as proposed*** ([p. 1082](#)).

CMS again proposed that uncompensated care would be defined as the amount on Line 30 of Worksheet S-10 (cost of charity care and the cost of non-Medicare bad debt and non-reimbursable Medicare bad debt).

***CMS finalized its proposal to define uncompensated care costs as the amount on Line 30 of Worksheet S-10*** (the cost of charity care (Line 23) and the cost of non-Medicare bad debt and non-reimbursable Medicare bad debt (Line 29)) ([p. 1075](#))

### **Payments for Indirect and Direct Graduate Medical Education Costs**

**Medicare GME  
Affiliated Groups  
for New Urban  
Teaching  
Hospitals**

A new urban hospital can enter into a Medicare GME affiliation agreement only if the resulting adjustment is an *increase* to its direct GME and IME FTE caps. CMS has recently received questions about whether it is possible to have a Medicare GME affiliation agreement that *only* consists of new urban teaching hospitals. CMS believes that the current regulations would not allow for this type of arrangement.

However, in an effort to provide flexibility and to facilitate training, CMS proposed to revise regulatory text to specific that new urban teaching hospitals (as already defined in regulation) may form a Medicare GME affiliated group, which would allow for a constituent hospital to receive both increases and decreases to its FTE cap.

CMS proposed that the change would be effective beginning with affiliation agreements for the July 1, 2019 through June 30, 2020 residency training year.

***CMS finalized this proposal with modification*** ([p. 1336](#)): Commenters highlighted that CMS' technical definition of a "new teaching hospital" is a hospital that started training residents "after 1996," whereas stakeholders typically think of a "new teaching hospital" as one that is still in its cap-building period. ***CMS clarified that this provision requires that at least one of the "new urban teaching hospitals participating in the Medicare GME affiliated group has established FTE caps"; if a Medicare GME affiliated group consisted "solely of new urban teaching hospitals that do not have established FTE caps, there would be no cap amounts to transfer under the agreement*** ([p. 1337](#)). CMS continues, however, that the proposal was not meant to exclude new teaching hospitals without established caps ([p. 1338](#)).

CMS also believed that a time-limited approach would provided new urban teaching hospitals the opportunity to receive decreases to caps while addressing concerns that existing hospitals not use the new teaching hospital to circumvent their FTE caps. Therefore, ***CMS modifies its proposal to require a new urban teaching hospital to wait five (5) years prior to lending its cap slots to an existing teaching hospital through a Medicare GME affiliation agreement***. CMS states that this "would demonstrate that the new teaching hospital is, infact, establishing and expanding its own new residency training programs rather than serving as a means for an existing teaching hospital to receive additional FTE caps ([p. 1348](#)). CMS provided examples of the 5 year waiting period [beginning on p. 1353](#).

***CMS finalized this proposal*** ([p. 1350](#)).

CMS listed comments received that it considered to be out-of-scope to the proposal beginning on [p. 1356](#).

[Notice of Closure of Two Teaching Hospitals and Opportunity to Apply for Available Slots](#)

<p>The ACA included provisions that allowed the HHS Secretary to redistribute residency slots after an approved medical residency program closes. In line with its previously established process for the redistribution of available slots, CMS provided notice of the closure of two programs: Affinity Medical Center (Massillon, Ohio) and Baylor Scott &amp; White Medical Center (Garland, Texas).</p> <p>CMS provided an overview of the application process for the available resident slots. Interested hospitals must submit applications to CMS no later than July 23, 2018.</p>	<p>CMS also issued new information regarding the closure of Memorial Hospital of Rhode Island (Pawtucket, Rhode Island) (<a href="#"><u>p. 1358</u></a>).</p> <p>CMS reiterated the application process for the available residency slots beginning on <a href="#"><u>p. 1359</u></a>. <b><i>Applications for the residency slots available from the closure of Memorial Hospital of Rhode Island must be received (not post-marked) no later than October 31, 2018 (<a href="#"><u>p. 1359</u></a>).</i></b></p>
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[Revisions of Hospital Inpatient Admission Orders Documentation Requirements Under Medicare Part A](#)

<p>CMS reiterated current Medicare billing rules that state:</p> <ul style="list-style-type: none"> <li>• A beneficiary becomes a hospital inpatient if <u>formally admitted pursuant to the order of a physician</u> (or other qualified practitioner) in accordance with the hospital conditions of participation (CoPs)</li> <li>• CMS requires <u>a written inpatient admission order in the medical record</u> as a specific condition of payment under Part A.</li> </ul> <p>CMS acknowledged that in the “extremely rare circumstance” that the order to admit is missing or defective, but the “intent, decision, and recommendation of the ordering physician or other qualified practitioner to admit the beneficiary as an inpatient can clearly be derived from the medical record” that the medical review contractors have discretion that the existing information satisfies the requirement that a written hospital inpatient admission order is present in the medical record. However, CMS said it has become aware that there are payment denials (for otherwise medically necessary inpatient admissions) “due to technical discrepancies<sup>2</sup> with the documentation of inpatient admission orders.” CMS stated that it was never the agency’s intent that inadvertent signature documentation issues should alone lead to payment denial.</p> <p>Therefore, CMS proposed to revise the admission order documentation requirements by removing the requirement that written inpatient orders are a specific requirement for Part A</p>	<p><b><i>CMS finalized this policy as proposed (<a href="#"><u>p. 1407</u></a>).</i></b> CMS received comments in support of the proposal claiming that the requirement that the inpatient admission be present in the medical record is duplicative (<a href="#"><u>p. 1394</u></a>). CMS</p>
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<sup>2</sup> CMS cited examples such as missing practitioner admission signatures, missing co-signatures or authentication signatures, and signatures occurring after discharge ([p. 1056](#)).

payment. This does not change the requirement that a beneficiary becomes an inpatient if formally admitted as an inpatient under an order for inpatient admission; only that CMS will no longer make specific documentation requirements of inpatient orders be present in the medical record as a condition of Part A payment.

noted that if necessary it will revise its manuals or issue additional subregulatory guidance as appropriate ([p. 1401](#)). ***The new policy will be effective beginning with admissions occurring on or after October 1, 2018*** ([p. 1404](#)).

**Concerns.** CMS also received several concerns about the elimination of the requirement, including:

- The inpatient admission order would be rendered completely insignificant;
- If no order was required in the medical record, CMS would not be able to distinguish between orders that were defective and those that were intentionally not signed
- The payment process would be made more difficult, particularly in instances where patients are not registered by hospital admissions staff, did not receive required notice of their inpatient status, and there was no valid admission order related to their visit;
- Concern that patients would not be aware of their financial liability;
- Concern that SNF coverage would be at risk if there was lack of clarity;
- Concern that it will not actually reduce administrative burden;
- Concern that the policy will create a problem for the capture of data elements needed for compliance with eCQMs ([p. 1406](#)).

CMS reminded stakeholders, however, that the proposal does not change the requirement that under Part A, a patient becomes an inpatient “when formally admitted as an inpatient under an order for inpatient admission” ([p. 1396](#)). CMS also reminded stakeholders that hospital CoPs require that all Medicare inpatients must receive written information about their hospital discharge appeal rights ([p. 1396](#)) and that this does not change the fact that hospitals are required to operate in accordance with the appropriate CoPs ([p. 1398](#)).

**Observation/Outpatient Status.** CMS received comments asking about when a patient with observation status spends two medically necessary midnights and is then discharged and whether providers are allowed to obtain an admission order any time prior to formal discharge. The commenter went on to ask if providers can “review this stay after discharge, determine the 2-midnight benchmark was met, and submit a claim for inpatient admission.” ([p. 1397](#)). CMS replied that the proposal did not change the requirement that an individual becomes an inpatient “when formally admitted as an inpatient under an order for inpatient admission.”

[Hospital Readmissions Reduction Program](#)

	<p>CMS also referred the stakeholder to the CMS comment in FY 2014 rulemaking where CMS stated “The physician order cannot be effective retroactively. Inpatient status only applies prospectively, starting from the time the patient is formally admitted pursuant to a physician order for inpatient admission, in accordance with our current policy” (<a href="#">p. 1397</a>). CMS reiterated that it is longstanding Medicare policy that retroactive orders are not permitted (<a href="#">p. 1398</a>). CMS also categorized a comment about the use of <i>condition code 44</i> as out-of scope (<a href="#">p. 1397</a>).</p> <p><b>Practitioners.</b> CMS noted that the proposal did not change requirements regarding <i>which</i> practitioners are allowed to furnish the inpatient admission order (<a href="#">p. 1399</a>).</p>
<h3>Quality Reporting &amp; Value Based Purchasing Provisions</h3>	
<p>For FY 2018 and subsequent years, the reduction is based on a hospital’s risk-adjusted readmission rate during a 3-year period for acute myocardial infarction (AMI), heart failure (HF), pneumonia, chronic obstructive pulmonary disease (COPD), total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG). After thoughtful review, CMS has determined that these six existing measures are appropriate to maintain as part of the Hospital Readmissions Reduction Program. However, CMS proposes to remove these measures from the Hospital IQR Program. CMS is not proposing to adopt any new measures for the Hospital Readmissions Reduction Program at this time.</p>	<p><b><i>CMS did not make any changes to these policies.</i></b> In response to suggestions that CMS determine whether the program is worth retaining, CMS clarified that the program is required by statute and that the agency cannot decline to administer it. CMS also acknowledged concerns that hospitals can undertake and perform reasonable acts to avoid readmissions, but still be penalized because their performance might remain relatively worse when compared to peer group hospitals’ performance. CMS noted that the basic payment adjustment formula for assessing readmissions and penalties under this program are specified in statute, and CMS is required to implement the statute as written, but that it will continue to review its risk-adjustment methodologies and monitor its quality reporting and incentive programs for any unintended and negative consequences.</p>
<p>Consistent with previously established policies, CMS proposes to establish the following “applicable periods” for this program:</p> <ul style="list-style-type: none"> <li>For FY 2019, the “applicable period” would be the 3-year period from July 1, 2014 through June 30, 2017.</li> <li>For FY 2020, the “applicable period” would be the 3-year period from July 1, 2015 through June 30, 2018.</li> <li>For FY 2021, the “applicable period” would be the 3-year period from July 1, 2016 through June 30, 2019.</li> </ul>	<p><b><i>CMS finalized these policies as proposed</i></b> (<a href="#">p. 1111</a>)</p>
<p>In regards to the calculation of the FY 2019 payment adjustment, CMS proposes to codify the following previously established definitions:</p> <ul style="list-style-type: none"> <li>Applicable period for dual-eligibility is the 3-year data period corresponding to the applicable period as established by the Secretary for the Hospital Readmissions Reduction Program.</li> </ul>	<p><b><i>CMS finalized these policies as proposed</i></b> (<a href="#">p. 1119</a>)</p>

**Hospital Value-  
Based  
Purchasing  
(VBP) Program:  
Policy Change**

- Dual-eligible is a patient beneficiary who has been identified as having full benefit status in both the Medicare and Medicaid programs in the State MMA files for the month the beneficiary was discharged from the hospital.
- Proportion of dual-eligibles is the number of dual-eligible patients among all Medicare FFS and Medicare Advantage stays during the applicable period.

**Accounting for Social Risk Factors**

CMS provides a summary of work done in this area to date and feedback that it received last year across its quality reporting programs on the topic of accounting for social risk factors.

**Retention and Proposed Removal of Quality Measures**

To reduce costs and duplication of effort, CMS proposes to revise its regulations at 42 CFR 412.164(a) to clarify that once it has complied with the statutory prerequisites for adopting a measure for the Hospital VBP Program (i.e., it has selected the measure from the Hospital IQR Program measure set and included data on that measure on Hospital Compare for at least one year prior to its inclusion in a Hospital VBP Program performance period), the Hospital VBP statute does not require that the measure continue to remain in the Hospital IQR Program.

**Measure Removal Factors**

CMS proposes to adopt the following previously finalized Hospital IQR Program measure removal factors when determining whether to remove measures from the Hospital VBP Program and other quality programs discussed in this rule:

- Factor 1. Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (“topped out” measures), defined as: statistically indistinguishable performance at the 75th and 90th percentiles; and truncated coefficient of variation  $\leq 0.10$ ;
- Factor 2. A measure does not align with current clinical guidelines or practice;
- Factor 3. The availability of a more broadly applicable measure (across settings, populations, or the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic);
- Factor 4. Performance or improvement on a measure does not result in better patient outcomes;

Although CMS did not propose or finalize any new policies, a discussion about accounting for social risk factors in the HAC Reduction Program begins on [p. 1129](#).

**Retention and Proposed Removal of Quality Measures** ([p. 1136](#))

***CMS finalized these policies as proposed.***

**Measure Removal Factors** ([p. 1142](#))

***CMS finalized these policies as proposed.***

In response to a commenter who opposed adoption of measure removal Factor 1, and other concerns expressed other factors, CMS clarified that that the removal factors are intended to be considerations taken into account when deciding whether or not to remove measures, but are not firm requirements. CMS intends to take multiple considerations into account when determining whether to propose a measure for removal under Factor 1 or any of the other removal factors.

Several commenters requested additional information and transparency on the factors used to determine costs and benefits under Factor 8. CMS noted that it intends to be transparent in its assessment of measures under this removal factor. There are various considerations of costs and benefits, direct and indirect, financial and otherwise, that it will evaluate in applying removal Factor 8, and it will take into consideration the perspectives of multiple stakeholders. However, because it intends to evaluate each measure on a case-by-case basis, and each measure has been adopted to fill

- Factor 5. The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic;
- Factor 6. Collection or public reporting of a measure leads to negative unintended consequences other than patient harm; and
- Factor 7. It is not feasible to implement the measure specifications
- Factor 8: The costs associated with a measure outweigh the benefit of its continued use in the program [note: this is a new factor being proposed, intended to align with proposals being made for other value-based purchasing programs].

CMS also proposes to allow the Hospital VBP Program to promptly remove a measure without rulemaking if it believes the measure poses specific patient safety concerns.

different needs in the Hospital VBP Program, CMS does not believe it would be meaningful to identify a specific set of assessment criteria to apply to all measures. CMS believes costs include costs to stakeholders such as patients, caregivers, providers, CMS, and other entities; the benefits it will consider center around benefits to patients and caregivers. CMS also clarifies that when it proposes to remove a measure under this measure Factor 8, it will provide information on the costs and benefits it considered in evaluating the measure.

Commenters also requested that CMS clarify the process for seeking input of stakeholders in the decision-making process. CMS noted that it values transparency and continually seeks stakeholder input through education and outreach activities, such as webinars and national provider calls, stakeholder listening sessions, through rulemaking, and other collaborative engagements with stakeholders.

Still others requested that CMS develop a standardized evaluation and scoring system with multi-stakeholder input, and adopt a more inclusive process that accounts for the perspective of both patients and clinicians when making measure removal determination. CMS reiterated here that intends to evaluate each measure on a case-by-case basis, while considering input from a variety of stakeholders, including, but not limited to: patients, caregivers, patient and family advocates, providers, provider associations, healthcare researchers, healthcare purchasers, data vendors, and other stakeholders. However, while a measure's use in the Hospital VBP Program may benefit many entities, the primary benefit is to patients and their caregivers. CMS intends to assess the costs and benefits to program stakeholders, including but not limited to, those listed above.

Another commenter noted that measure removals and adoptions should take into account the time and resources required to adjust and adapt to changing program requirements. The commenter specifically recommended that CMS implement a standard 24-month timeline for measure adoptions and removals in order to allow hospitals time to budget, plan, adopt, and operationalize any necessary changes to their plans and workflows. CMS responded that it does not believe such a timeline is necessary given that hospitals would have been reporting measure data under the Hospital IQR Program prior to adoption into the Hospital VBP Program. It also believes it is important to retain flexibility in the timing of removing measures from the program.



#### Measures Proposed for Removal from the Hospital VBP Program

In order to reduce the costs and complexity of tracking measures in multiple programs, CMS proposes to remove 10 measures from the Hospital VBP Program.

CMS proposes to remove the following measures, beginning with the FY 2021 program year (i.e. ending with December 31, 2018 discharges):

- Elective Delivery (NQF #0469) (PC-01): removal factor 8
- Healthcare-Associated Infection (HAI) Measures: removal factor 8
  - National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138)
  - NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139)
  - NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus Bacteremia (MRSA) Outcome Measure (NQF #1716); and
  - NHSN Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717)
  - American College of Surgeons-Centers for Disease Control and Prevention (ACS-CDC) Harmonized Colon and Abdominal Hysterectomy Surgical Site Infection (SSI) Outcome Measure (NQF #0753)

CMS also proposed to remove the following measure with the effective date of this final rule based on proposed removal Factor 8:

- Patient Safety and Adverse Events (Composite) (PSI 90) (NQF #0531)

Another commenter recommended that CMS adopt an additional removal factor to remove an existing measure from the program when a new measure that provides results which are more reliable and/or valid becomes available. CMS will take this into consideration in the future, but clarifies that it already accounts for validity and reliability when determining whether to adopt a measure.

#### Measures Proposed for Removal from the Hospital VBP Program ([p. 1163](#))

***CMS finalized the removal of the following measure as proposed:***

- Elective Delivery ([p. 1168](#))

***CMS did NOT finalize the removal of the following measures and instead opted to retain them in the Hospital VBP Program*** ([p. 1173](#), [p. 1184](#)):

- NHSN CAUTI Outcome Measure
- NHSN CLABSI Outcome Measure
- NHSN Facility-wide Inpatient Hospital-onset MRSA Outcome Measure
- NHSN Facility-wide Inpatient Hospital-onset CDI Outcome Measure
- ACS-CDC Harmonized Colon and Abdominal Hysterectomy SSI Outcome Measure
- Patient Safety and Adverse Events (Composite) (PSI 90)

CMS opted to retain these measures due to:

- Concern that patient safety measures should remain in all payment programs to sufficiently incentivize continued improvement on these measures and prioritize practices that ensure safe care.
- Concern that removal of these measures would send the message that mediocre performance on hospital safety measures is acceptable.
- Concern that retaining the measures in only the HAC Reduction Program might result in continually penalizing hospitals that serve predominantly high-risk patients even if a hospital's individual performance improves from year to year. Similarly, there was concern about the HAC Program being penalty-only, versus the Hospital VBP, which incentivizes performance improvement.

As such, these measures will remain in both the Hospital VBP Program and the HAC Reduction Program.

CMS also proposes to remove the following condition-specific payment measures from the Hospital VBP Program as of the effective date of the FY 2019 IPPS/LTCH PPS final rule:

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

#### Accounting for Social Risk Factors

CMS provides a summary of work done in this area to date and feedback that it received last year across its quality reporting programs on the topic of accounting for social risk factors.

#### Changes to the Hospital VBP Program Domains

CMS proposed to change the domain name from Clinical Care to Clinical Outcomes, beginning with the FY 2020 program year.

***CMS finalized its decision to remove the AMI Payment, HF Payment and PN Payment measures with the effective date of this rule ([p. 1185](#), [p. 1191](#)).***

CMS clarifies that it will continue to use these measures in the Hospital IQR Program (through which they will be subject to public reporting), along with the Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip and/or Total Knee Arthroplasty measure, to provide more granular information to hospitals for reducing costs and resource use while maintaining quality care. However, CMS believes that continuing to retain these measures in both the Hospital VBP and Hospital IQR Programs will not reduce program costs and complexity. The Hospital VBP Program would still retain the MSPB measure, but CMS finalizes elsewhere in this rule to remove it from the Hospital IQR.

These measures would be removed before being incorporated into hospitals' Total Performance Scores (TPS) or public reporting under the Hospital VBP Program.

**Previously adopted measures for the FY 2020 Hospital VBP program year are listed starting on [p. 1191](#).**

**A summary of measures being finalized for the FY 2021 Hospital VBP program year are listed starting on [p. 1193](#).**

**A summary of measures being finalized for the FY 2022 Hospital VBP program year are listed starting on [p. 1194](#).**

**A summary of measures being finalized for the FY 2023 Hospital VBP program year are listed starting on [p. 1196](#).**

Although CMS did not propose or finalize any new policies, a discussion about accounting for social risk factors in the Hospital VBP Program begins on [p. 1197](#). Specific risk adjustment factors and methods of risk adjustment recommended by commenters through 2019 rulemaking are detailed in this section.

#### Changes to the Hospital VBP Program Domains ([p. 1203](#))

***CMS finalized its proposal to change the domain name from Clinical Care to Clinical Outcomes.***

CMS also proposes to remove the Safety domain from the Hospital VBP Program beginning with the FY 2021 program year and to weight the three remaining domains as follows:

- Clinical Outcomes domain – 50 percent (increased from 25 percent)
- Person and Community Engagement domain – 25 percent; and
- Efficiency and Cost Reduction domain – 25 percent

**However, after consideration of the public comments, it did not finalize its proposal to remove the Safety domain from the Hospital VBP Program beginning with the FY 2021 program year** ([p. 1210](#)). Since CMS did not finalize the removal of the five HAI measures ([CAUTI](#), [CLABSI](#), [Colon and Abdominal Hysterectomy SSI](#), [MRSA Bacteremia](#), [CDI](#)) or the removal of the [Patient Safety and Adverse Events \(Composite\) Measure \(PSI 90\)](#), it is not finalizing removal of the Safety domain.

CMS also did not finalize its proposal to use three domains, beginning with the FY 2021 program year, with the modified Clinical Outcomes domain weight. In accordance with its current policy, CMS will maintain four domains in the Hospital VBP Program, each with a weight of 25 percent, for hospitals that receive a score in all domains, and hospitals with sufficient data on only three domains will have their TPSs proportionately reweighted.

Several commenters opposed weighting the Efficiency and Cost Reduction domain at 25 percent because this domain would include only the MSPB measure. Others recommended that CMS consider further deemphasizing the weight of this domain if it continues to observe that hospitals that perform below the national average on the clinical quality measures, but perform well on the MSPB measure receive an incentive payment under the proposed approach. CMS will take these recommendations into consideration as it continues to evaluate its domain weighting policies.

#### Minimum Case Number Requirements

CMS did not propose any changes to these policies.

#### Minimum Case Number Requirements

Although no changes were proposed to this policy, previously adopted minimum case number requirements for the FY 2021 program year and subsequent years are outlined on [p. 1233](#).

#### Baseline and Performance Periods

CMS did not propose any changes to these policies.

#### Baseline and Performance Periods

Although no changes were proposed to this policy, previously adopted baseline and performance periods for the FY 2020, 2021, 2022, 2023, and 2024 program years are summarized on [pgs. 1238-1242](#).

#### Performance Standards

CMS proposed changes to the performance standards of certain domains.

#### Performance Standards

**Previously adopted and newly finalized performance standards for the Hospital VBP Program are outlined starting on [p. 1242](#).**

**Hospital-  
Acquired  
Condition  
(HAC)  
Reduction  
Program**

CMS proposes to retain the measures currently in this program because they address a performance gap in patient safety and reducing harm caused in the delivery of care.

**Administrative policies for the HAC Reduction Program or FY 2019 and Subsequent Years**

- *Data Collection Beginning CY 2019.* For the NHSN HAI measures, CMS proposes to adopt data collection processes for the HAC Reduction Program to receive CDC NHSN data beginning with January 1, 2019 infection events to correspond with the Hospital IQR Program's calendar year reporting period and maintain the HAC Reduction Program's annual performance period start date. All reporting requirements, including quarterly frequency, CDC collection system, and deadlines would not change from current Hospital IQR Program requirements to aid continued hospital reporting through clear and consistent requirements. CMS also proposes to adopt the Hospital IQR Program's exception policy to reporting and data submission requirements for the CAUTI, CLABSI, and Colon and Abdominal Hysterectomy SSI measures.

Previously adopted and newly displayed performance standards for the FY 2021 program year: Safety, Clinical Outcomes, and Efficiency and Cost Reduction Domains are outlined on [p. 1244](#).

Newly finalized performance standards for the FY 2021 Program Year: Person and Community Engagement Domain are outlined on [p. 1246](#).

Previously adopted performance standards for the FY 2022 program year are outlined on [p. 1247](#).

Previously adopted and newly displayed finalized performance standards for the FY 2023 program year on [p. 1249](#).

Newly finalized performance standards for the FY 2024 program year are outlined on [p. 1251](#).

***CMS finalized this policy.***

Previously adopted measures for FY 2019 are listed starting on [p. 1261](#).

Technical specifications for the CMS PSI 90 in Domain 1 can be found [here](#). Technical specifications for the NHSN HAI measures in Domain 2 can be found [here](#).

**Administrative policies for the HAC Reduction Program or FY 2019 and Subsequent Years ([p. 1262](#))**

***CMS finalized these policies as proposed except for the following modifications:***

- ***Although CMS finalized its proposal to adopt a validation process for the NHSN HAI measures for the HAC Reduction Program, it is delaying adoption of this NHSN HAI measure validation process into the HAC Reduction Program until Q3 2020 discharges for FY 2023 in order to align with a corresponding delay in removing these NHSN HAI measures from the Hospital IQR Program.***
- ***This delay will also impact the Provider Selection policies, Calculation of the Confidence Interval, the Education Review Process, Application of the Validation Penalty, the Validation Period, and the DACA timeline.***

- *Changes to Existing Validation Process*. CMS proposes that chart-abstracted NHSN HAI measures submitted via NHSN would be subject to validation in the HAC Reduction Program beginning with the Q3 2019 discharges for FY 2022.
- *Provider Selection*. CMS intends to include all subsection (d) hospitals in these proposed validation procedures, since all subsection (d) hospitals are subject to the HAC Reduction Program.
- *Calculation of the Confidence Interval*. CMS proposes to compute the confidence interval for the HAC Reduction Program in a manner similar to the Hospital IQR Program.
- *Educational Review Process*. Similar to the Hospital IQR Program, CMS proposes for the HAC Reduction Program, beginning with the Q3 2019 data validation, to have an educational review process, such that hospitals selected for validation would have a 30-day period following the receipt of quarterly validation results to seek educational review.
- *Application of Validation Penalty*. CMS proposes to penalize hospitals that fail validation by assigning the maximum Winsorized z-score only for the set of measures CMS validated.
- *Validation Period*. CMS proposes that the HAC Reduction Program's performance period would remain two calendar years and that the validation period would include the four middle quarters in the HAC Reduction Program performance period (i.e., third quarter through second quarter).
- *Data Accuracy and Completeness Acknowledgement (DACA)*. CMS proposes to rely on the process currently used under the Hospital IQR Program.

#### Changes to the HAC Reduction Program Scoring Methodology

CMS discusses its proposal to adopt the Equal Measure Weights approach starting in FY 2020, where it would remove domains from the HAC Reduction Program and simply assign equal weight to each measure for which a hospital has a measure score and then calculate each hospital's Total HAC Score as the equally weighted average of the hospital's measure scores.

#### Changes to the HAC Reduction Program Scoring Methodology ([p. 1304](#))

***CMS finalized these policies as proposed.***

Applicable Period FY 2021

For the FY 2021 HAC Reduction Program, CMS proposes to adopt the following applicable periods:

- For CMS PSI 90: the 24-month period from July 1, 2017 through June 30, 2019
- For the NHSN HAI measures: the 24-month period from January 1, 2018 through December 31, 2019

Request for Comments on Additional Measure for Potential Future Adoption

CMS welcomes public comment and suggestions for additional HAC Reduction Program measures, specifically on whether electronic clinical quality measures (eCQMs) would benefit the program at some point in the future.

Applicable Period FY 2021 (p. 1319)

***CMS finalized these policies as proposed.***

Request for Comments on Additional Measure for Potential Future Adoption (p. 1320)

CMS will take feedback collected into consideration as it continues to explore additional measures for potential future adoption. Comments received included:

- That all new measures, including eCQMs, be NQF-endorsed; approved by the MAP; scientifically valid, reliable, and feasible; include reliable risk-adjustment; and that such measures be reviewed to determine whether they are appropriate for review in the NQF SDS trial period.
- That new measures should be evaluated within the Meaningful Measures Initiative framework and appropriate corresponding measure removals should be considered to balance a measure's addition.
- That data elements should be accurately and efficiently gathered in the provider workflow, using data elements already collected as part of the care process and stored in EHRs or other interoperable clinical and financial technology.
- That eCQMs should provide an accurate reflection of care delivered, and be actionable to drive meaningful improvements in care delivery.
- Although claims-based reporting is far from a perfect assessment of care quality, elimination of these measures could create a significant risk to patient safety.
- Some cautioned about the potential for inherent incongruities between claims codes and the quality of care provided to the patient when using eCQMs instead of claims quality measurement.
- The HAC Reduction Program should not directly adopt new measures, including eCQMs, into the program without providing stakeholders to gain opportunity to familiarize themselves with a measure before it is used to determine their Medicare payments.

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

Accounting for Social Risk Factors

CMS provides a summary of work done in this area to date and feedback that it received last year across its quality reporting programs on the topic of accounting for social risk factors.

Public Display of Quality Measures

CMS does not propose any changes to these policies.

Meaningful Measures Initiative and the Hospital IQR Program

Although new Hospital VBP measures will be selected from the measures specified under the Hospital IQR Program, the Hospital VBP Program measure set will no longer necessarily be a subset of the Hospital IQR Program measure set due to CMS' efforts to remove duplicative measures from the Hospital IQR Program once they have been adopted into the Hospital VBP Program.

Removal Factors for Hospital IQR Measures

CMS proposes to adopt an additional factor to consider when evaluating measures for removal from the Hospital IQR Program measure set: Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. CMS proposes to remove measures based on this factor on a case-by-case basis.

- Hospitals should have the measure publicly reported for at least a year without penalty.

Although CMS did not propose or finalize any new policies, a discussion about accounting for social risk factors in the HAC Reduction Program begins on [p. 1258](#).

Public Display of Quality Measures (p. 1530)

CMS clarifies that its current policy is to report data from the Hospital IQR Program as soon as it is feasible on CMS websites such as the [Hospital Compare website](#), after a 30-day preview period (78 FR 50776 through 50778). Other information that may not be as relevant to or easily understood by beneficiaries and information for which there are unresolved display issues or design considerations are not reported on the Hospital Compare website and may be made available on other CMS websites, such as <https://data.medicare.gov/>.

Meaningful Measures Initiative and the Hospital IQR Program (p. 1531)  
***CMS adopted this policy as proposed.***

Removal Factors for Hospital IQR Measures (p. 1535)

***CMS finalized adding Factor 8 to its current list of measure removal factors.***

Previously adopted removal factors are listed on [p. 1535](#).

Many commenters who supported the adoption of removal Factor 8 also encouraged CMS to provide additional information and transparency in this final rule on how it intends to evaluate the costs and benefits associated with a measure proposed for removal, including the criteria used in assessing costs, the nature of the burden that the removal of a measure relieves, and the methods used to assess whether the costs associated with a measure outweigh the benefits of its continued use in the program. Some of those commenters stated that costs and benefits can be difficult to define and that various stakeholders may have different perspectives on the costs and benefits of measures. CMS agrees with commenters on this last point and clarified that it intends to evaluate each measure on a case-by-case basis, while considering input from a variety of stakeholders, and that its



assessment of costs and benefits is not limited to a strictly quantitative analysis.

In response to questions about whose “benefit” is considered when applying this removal factor, CMS clarified that it intends to balance the costs with the benefits to a variety of stakeholders. These stakeholders include, but are not limited to, patients and their families or caregivers, providers, the healthcare research community, healthcare payers, and patient and family advocates. CMS also believes that while a measure’s use in the Hospital IQR Program may benefit many entities, a key benefit is to patients and their caregivers through incentivizing the provision of high quality care and through providing publicly reported data regarding the quality of care available. For each measure, the relative benefit to each stakeholder may vary; thus, the benefits to be evaluated for each measure are specific to the measure itself and the original rationale for including the measure in the program.

CMS also clarified that it values transparency and has and will continually seek input from multiple stakeholders through outreach and education efforts, such as through webinars, national provider calls, stakeholder listening sessions, as well as through rulemaking and other collaborative engagements with stakeholders. However, because it intends to evaluate each measure on a case-by-case basis, and each measure has been adopted to fill different needs of the Hospital IQR Program, CMS does not believe it would be meaningful to identify a specific set of assessment criteria to apply to all measures.

#### Removal of Hospital IQR Program Measures

CMS proposes to remove a total of 39 measures from the Hospital IQR Program across the FYs 2020, 2021, 2022, and 2023 payment determination.

Beginning with the CY 2018 reporting period/FY 2020 payment determination, CMS proposes to remove the following measures from the Hospital IQR Program:

- Patient Safety measures:
  - Hospital survey on Patient Safety Culture
  - Safe Surgery Checklist Use
  - Patient Safety and Adverse Events Composite (PSI-90)

#### Removal of Hospital IQR Program Measures ([p. 1554](#))

***CMS finalized the removal of the following measures from the IQR Program as proposed, beginning with the CY 2018 reporting period/FY 2020 payment:***

- ***Patient Safety measures:***
  - ***Hospital Survey on Patient Safety Culture*** ([p. 1555](#))
  - ***Safe Surgery Checklist Use*** ([p. 1560](#))
  - ***PSI-90*** ([p. 1567](#), [1590](#))

- **Claims-Based Readmission Measures:**
    - Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0505) (READM-30-AMI);
    - Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2515) (READM-30-CABG);
    - Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1891) (READM-30-COPD);
    - Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Heart Failure (HF) Hospitalization (NQF #0330) (READM-30-HF);
    - Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization (READM-30-PN) (NQF #0506)
    - Hospital-Level 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (READM-30-THA/TKA)(NQF #1551); and
    - 30-Day Risk-Standardized Readmission Rate Following Stroke Hospitalization (READM-30-STK)
  - **Claims-Based Mortality Measures:**
    - Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (MORT-30-AMI) (NQF #0230)
    - Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization Surgery (MORT-30-HF) (NQF #0229)
  - **Resource Use Measure:**
    - Medicare Spending Per Beneficiary (MSPB) – Hospital Measure
    - Clinical Episode-Based Payment measures:
      - Cellulitis Clinical Episode-Based Payment Measure (Cellulitis Payment);
- **Claims-Based Readmission Measures (p. 1594)**
    - READM-30-AMI
    - READM-30-CABG
    - READM-30-COPD
    - READM-30-HF
    - READM-30-PN
    - READM-30-THA/TKA
    - READM-30-STK
  - **Claims-Based Mortality Measure (p. 1606, 1614)**
    - MORT-30-AMI
    - MORT-30-HF
  - **Resource Use Measure:**
    - MSPB – Hospital Measure (p. 1618)
    - Clinical Episode-Based Payment measures (p. 1622)
      - Cellulitis Payment
      - GI Payment
      - Kidney/UTI Payment

- Gastrointestinal Hemorrhage Clinical Episode-Based Payment Measure (GI Payment);
- Kidney/Urinary Tract Infection Clinical Episode-Based Payment Measure (Kidney/UTI Payment);
- Aortic Aneurysm Procedure Clinical Episode-Based Payment Measure (AA Payment);
- Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment Measure (Chole and CDE Payment); and
- Spinal Fusion Clinical Episode-Based Payment Measure (SFusion Payment)

- **AA Payment**
- **Chole and CDE Payment**
- **SFusion Payment**

Although CMS recognizes that specific clinical episode-based payment measure data can provide hospitals with more targeted and actionable feedback, it also understands that other hospitals may not benefit from the use of individual clinical episode-based payment measures because they lack a sufficient number of cases. Although the MSPB measure does not provide the same level of granularity as the individual clinical episode-based payment measures, CMS believes the most essential data elements are captured by and publicly reported under the MSPB measure in the Hospital VBP Program.

Beginning with the CY 2019 reporting period/FY 2021 payment determination, CMS proposes to remove the following measures from the Hospital IQR Program:

- Patient Safety Measures:
  - National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717);
  - NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138)
  - NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139);
  - NHSN Facility-wide Inpatient Hospital-onset Methicillin-Resistant Staphylococcus Aureus Bacteremia (MRSA) Outcome Measure (NQF #1716); and
  - American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure (Colon and Abdominal Hysterectomy SSIs) (NQF #0753)
- Chart-Abstracted Clinical Process of Care Measures:
  - Influenza Immunization Measure (IMM-2)

***CMS finalized the removal of the following measures from the IQR Program as proposed, beginning with the CY 2019 reporting period/FY 2021 payment year:***

- ***Claims-Based Mortality Measures***
  - ***MORT-30-COPD*** ([p. 1606](#))
  - ***MORT-30-PN*** ([p. 1606](#))
- ***Chart-Abstracted Clinical Process of Care Measures*** ([p. 1631](#))
  - ***IMM-2*** ([p. 1634](#))
  - ***ED-1*** ([p. 1648](#))
  - ***VTE-6*** ([p. 1641](#))

***CMS finalized the removal of the following measures from the IQR program, but instead of removing them beginning with the CY 2019 reporting period/FY 2021 payment determination as proposed, it finalized a delay in the removal of the measures until the CY 2020 reporting period/FY 2022 payment determination*** ([p. 1593](#), [p. 1567](#)):

- ***Patient Safety Measures:***
  - ***NHSN Facility-wide Inpatient Hospital-onset CDI Outcome Measure***
  - ***NHSN CAUTI Outcome Measure***
  - ***NHSN CLABSI Outcome Measure***
  - ***NHSN Facility-wide Inpatient Hospital-onset MRSA***

- Median Time from ED Arrival to ED Departure for Admitted ED patients Measures (ED-1) (NQF #0495)
- Incidence of Potentially Preventable Venous Thromboembolism Measures (VTE-6)
- Claims-Based Mortality Measures
  - Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) (NQF #1893) (MORT-30-COPD)
  - Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization (NQF #0468) (MORT-30-PN)

Beginning with the CY 2020 reporting period/FY 2022 payment determination, CMS proposes to remove the following measure from the Hospital IQR Program:

- Chart-Abstracted Clinical Process of Care Measures
  - Admit Decision Time to ED Departure Time for Admitted Patients Measures (NQF #0497) (ED-2)
- Electronic Clinical Quality Measures (eCQMs)
  - Primary PCI Received Within 90 Minutes of Hospital Arrival (AMI-8a)
  - Home Management Plan of Care Document Given to Patient/Caregiver (CAC-3)
  - Median Time from ED Arrival to ED Departure for Admitted ED Patients (NQF #0495) (ED-1)
  - Hearing Screening Prior to Hospital Discharge (NQF #1354) (EHDI-1a)
  - Elective Delivery (NQF #0469) (PC-01)
  - Stroke Education (STK-08)
  - Stroke: Assessed for Rehabilitation (NQF #0441) (STK-10)
- Claims-Based Mortality Measures
  - Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2515) (MORT-30-CABG)

- ACS-CDC Harmonized Procedure SSI Outcome Measure (Colon and Abdominal Hysterectomy SSIs)

**CMS finalized the removal of the following measures from the IQR program, beginning with the CY 2020 reporting period/FY 2022 payment determination:**

- **Chart-Abstracted Clinical Process of Care Measures**
  - ED-2 (p. 1648)
- **Electronic Clinical Quality Measures (eCQMs) (p. 1651)**
  - AMI-8a (p. 1654)
  - CAC-3 (p. 1655)
  - ED-1 (p. 1656)
  - EHDI-1a (p. 1657)
  - PC-01 (p. 1658)
  - STK-08 (p. 1655)
  - STK-10 (p. 1655)
- **Claims-Based Mortality Measures (p. 1606)**
  - MORT-30-CABG (p. 1606, 1614)

**CMS finalized the removal of the following measures from the IQR program, beginning with the CY 2021 reporting period/FY 2023 payment determination:**

- Hip/Knee Complications (p. 1614)

A table summarizing the 39 Hospital IQR Program measures newly finalized for removal can be found on [p. 1686](#).

A table summarizing the Hospital IQR Program measure set for the FY 2020 payment determination can be found on [p. 1690](#).

A table summarizing the Hospital IQR Program measure set for the FY 2021 payment determination can be found on [p. 1693](#).

A table summarizing the Hospital IQR Program measure set for the FY 2022 payment determination can be found on [p. 1696](#).

Beginning with the CY 2021 reporting period/FY 2023 payment determination, CMS proposes to remove the following measure from the Hospital IQR Program:

- Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550) (Hip/Knee Complications)

Possible New Quality Measures, Measure Topics, and Other Future Considerations

CMS also seeks comment on two potential future measures for the Hospital IQR Program:

- Claims-Only, Hospital-Wide, All-Cause, Risk-Standardized Mortality measure (MUC17-195);
- Hybrid Hospital-Wide Mortality Measure Electronic Health Record Data (MUC17-196)

CMS also is considering a newly specified eCQM for possible concurrent inclusion in future years of the Hospital IQR and Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs:

- Hospital-Harm Opioid Related Adverse Events Electronic Clinical Quality Measure (eCQM)

CMS also seeks feedback on the potential future development and adoption of eCQMs generally.

Accounting for Social Risk Factors

CMS provides a summary of work done in this area to date and feedback that it received last year across its quality reporting programs on the topic of accounting for social risk factors.

Possible New Quality Measures, Measure Topics, and Other Future Considerations ([p. 1698](#))

The Claims-Only, Hospital-Wide, All-Cause, Risk-Standardized Mortality measure and the Hybrid Hospital-Wide Mortality Measure Electronic Health Record Data are discussed starting on [p. 1699](#). Comments received are summarized starting on [p. 1713](#). CMS will consider these views as it develops future policy regarding the potential inclusion of these measures in the Hospital IQR Program.

The Hospital-Harm Opioid Related Adverse Events Electronic Clinical Quality Measure (eCQM) is discussed starting on [p. 1729](#). Comments received are summarized starting on [p. 1735](#). CMS will consider these views as it develops future policy regarding the potential inclusion of this measure in the Hospital IQR Program.

A discussion regarding the potential future development and adoption of eCQMs generally can be found starting on [p. 1745](#). CMS will take consider commenters' views as it develops future policies regarding the potential future development and adoption of eCQMs generally and for future years of the Hospital IQR Program. This solicitation of public comments is part of a larger effort to collect feedback on areas for improvement in the implementation of eCQMs under a variety of CMS programs. CMS also has been holding listening sessions with hospitals and health IT vendors about EHR and eCQM issues. CMS will share all these comments with the Office of the National Coordinator for Health Information Technology (ONC) and other partners.

Although CMS did not propose or finalize any new policies, a discussion about accounting for social risk factors in the Hospital IQR Program begins on [p. 1764](#). CMS notes here that it will continue to work with measure developers to determine the most accurate way to include and account for social risk factors within each measure, including exploring stratification of social risk factors at the individual measure level. CMS intends to continue

to study social risk factors at a program level and evaluate the effect of social risk factors on outcomes measures and quality programs.

With regard to commenters' suggestion that CMS risk-adjust measures for patient SES status when appropriate, but until risk-adjusted measures are available, publicly report stratified measure performance rates on the Hospital Compare website, CMS notes that such adjustment is not appropriate in all cases.

Recent reports from ASPE, National Academies of Sciences, Engineering, and Medicine (NAM), and NQF do not specifically make recommendations in favor of or against risk adjustment for SES at the patient level. However, they do propose to report stratified results as a potential strategy to consider.

As discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38404 through 38409), due to the complexity, and prior to any future public reporting of stratified measure data, CMS plans to provide confidential reports to hospitals for the Pneumonia Readmission measure (NQF #0506), stratified by patient dual-eligible status. The confidential hospital-specific reports will be provided for hospitals to preview from August 24 through September 24, 2018. During this confidential preview period, CMS will also provide educational materials to ensure hospitals have sufficient information to understand and interpret their disparity results. Hospital specific reports will include national and regional benchmarks for the two disparity methods. A technical report will provide detailed specifications on the two disparity methods.

CMS agrees with concerns about the impact of small samples sizes on the reliability of stratified quality measure results. Small sample sizes may be especially challenging for measure stratification because some hospitals may have few patients with social risk factors. Therefore, under the first method (the hospital-specific disparity method), disparities would be reported only for hospitals with at least 25 patients and 10 patients for each sub-group. The second method (the group-specific outcome rate method) would use a cut-off of at least 25 patients for potential public reporting. The overall sample size of 25 patients is consistent with the quality outcome measures currently implemented.

#### Form, Manner, and Timing of Quality Data Submission

CMS proposes to:

- Clarify measure logic used in eCQM development so that all eCQM specifications published in CY 2018 for the CY 2019 reporting period/FY 2021 payment determination and subsequent years will use the Clinical Quality Language (CQL), a Health Level Seven (HL7) International standard, which provides the ability to better express logic defining measure populations to improve the accuracy and clarity of eCQMs (prior to CY 2017, eCQM logic was defined by “Quality Data Model (QDM) Logic”)
- Extend previously established eCQM reporting and submission requirements for the CY 2019 reporting period/FY 2021 payment determination, such that hospitals would be required to report one, self-selected calendar quarter of data for four self-selected eCQMs for the CY 2019 reporting period/FY 2021 payment determination; and
- Require hospitals to use the 2015 Edition certification criteria for CEHRT beginning with the CY 2019 reporting period/FY 2021 payment determination to align with the Medicare and Medicaid Promoting Interoperability Programs

#### Measure Removal Factors

Similar to other hospital programs discussed in this rule, CMS proposed to adopt a new measure removal Factor 8, “the costs associated with a measure outweigh the benefit of its continued use in the program,” beginning with the effective date of the FY 2019 IPPS/LTCH PPS final rule.

#### Removal of Measures from PCHQR Program Beginning with the FY 2021 Program Year

CMS proposes to remove four web-based, structural measures from the PCHQR Program, beginning with the FY 2021 program year, because they are topped-out:

- Oncology: Radiation Dose Limits to Normal Tissues (PCH-14/NQF #0382);
- Oncology: Medical and Radiation – Pain Intensity Quantified (PCH-16/NQF #0384);

#### Form, Manner, and Timing of Quality Data Submission ([p. 1783](#))

***CMS finalized these policies as proposed.***

A clarification of the measure logic used in eCQM development and the transition to Clinical Quality Language (CQL) begin on [p. 1785](#).

Reporting and submission requirements for eCQMs for the CY 2019 reporting period/FY 2021 payment determination are discussed starting on [p. 1789](#).

Changes to the certification requirements for eCQM reporting beginning with the CY 2019 reporting period/FY 2021 payment determination are discussed starting on [p. 1795](#).

#### Measure Removal Factors

***CMS finalized this policy as proposed*** ([p. 1816](#))

#### Removal of Measure from PCHQR Program Beginning with the FY 2021 Program Year ([p. 1823](#))

***CMS finalized its decision to remove the following web-based, structural measures the PCHQR Program, beginning with the FY 2021 program year*** ([p. 1825](#)):

- ***PCH-14***
- ***PCH-16***
- ***PCH-17***
- ***PCH-18***



- Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Patients (PCH-17/NQF #0390); and
- Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Patients (PCH-18/NQF #0389).

CMS also proposes to remove two National Healthcare Safety Network (NHSN) chart-abstracted measures, beginning with the FY 2021 program year, because the costs associated with these measures outweigh the benefit of their continued use in the program (removal factor #8):

- NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (PCH-5/NQF #0138); and
- NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (PCH-4/NQF #0139)

#### New Quality Measure Beginning with the FY 2021 Program Year

- 30-Day Unplanned Readmissions for Cancer Patients (NQF #3188). CMS proposes this claims-based, fully tested measure, citing current and projected increases in cancer prevalence and costs of care.

#### Potential New Quality Measures Topics for Future Years

CMS seeks public comment on two measures for potential future inclusion in the PCHQR Program:

- Risk-Adjusted Morbidity and Mortality for Lung Resection for Lung Cancer (NQF #1790)
- Shared Decision Making Process (NQF #2962), which asks patients who have had any of seven preference sensitive

**CMS did NOT finalize removal of the following NHSN measures, beginning with the FY 2021 program year ([p. 1830](#)):**

- **PCH-5**
- **PCH-4**

CMS is conducting additional data analyses to assess measure performance based on new information provided by the CDC that was not available at the time CMS proposed the removal of these measures from the PCHQR Program. CMS will reconcile the comments received on the proposed removal of these two measures in a future 2018 final rule, most likely in the CY 2019 OPPS/ASC final rule targeted for release no later than November 2018. This deferral will not affect PCH data submission because CMS proposed to end data collection beginning in CY 2019.

#### New Quality Measure Beginning with the FY 2021 Program Year ([p. 1833](#))

**CMS finalized the 30-Day Unplanned Readmissions for Cancer Patients measure as proposed.**

While several commenters supported the use of this measure, one did not due to concern that assigning accountability will be challenging due to severity of illness. CMS disagreed, citing its belief that assessing patient readmissions is a proactive method that PCHs can use to hone in on which (if any) factors could be remedied and/or prevented with improved quality care. CMS also reminds readers that it is only assessing the care provided within a one-year timeframe, and that it excludes readmissions for patients readmitted for chemotherapy or radiation therapy treatment or with disease progression.

**A table below summarizing the PCHQR Program measure set for the FY 2021 program year can be found on [p. 1845](#).**

#### Potential New Quality Measures Topics for Future Years ([p. 1850](#))

- Risk-Adjusted Morbidity and Mortality for Lung Resection for Lung Cancer (NQF #1790) ([p. 1851](#)). Despite support for this measure, concerns were raised that not all cancer hospitals participate in the Society of Thoracic Surgeons (STS) General Thoracic Surgery program. Further, participation in the STS program incurs cost and considerable burden given that the measure is registry-based and

surgical interventions (total hip/knee, lower back surgery for spinal stenosis or herniated disc, radical prostatectomy for prostate cancer, mastectomy for early stage breast cancer or percutaneous coronary intervention (PCI) for stable angina) to report on the interactions they had with their providers when the decision was made to have the surgery

CMS is also currently assessing whether it should redefine the scope of new quality metrics it implements in the PCHQR Program in future years. As such, it seeks public comment and specific suggestions on the inclusion of quality measures that examine general cancer care (i.e., outcome measures that assess cancer care) versus the inclusion of quality measures that examine cancer-specific clinical conditions (e.g., prostate cancer, esophageal cancer, colon cancer, or uterine cancer) in future rulemaking.

requires manual abstraction of cases. The commenters urged CMS to consider whether this measure can be collected in a less burdensome manner before incorporating it into the PCHQR Program. Commenters also requested that CMS work to clarify the data collection and submission process, measure calculation process, and any appropriate risk adjustment. Other concerns were raised about the omission of small volume centers in the model that STS used to validate the risk adjusted morbidity and mortality for lung cancer resection metric as able to sort out high performing vs. acceptable vs. low performing centers. It was also pointed out that the data used for developing the models are older and may not fit as well with current figures. CMS will share these concerns, including the impact of the cost and burden of participation in the STS General Thoracic Surgery Program, and will work with the measure steward (where appropriate) to address these concerns, should it decide to move forward with a proposal to adopt this measure in future years of the PCHQR Program.

- Shared Decision Making Process (NQF #2962) ([p. 1854](#)). Some supported this measure, but suggested that CMS consider the need for expanded psychometric testing of the patient-reported outcome (PRO) survey and further specification and validation of the patient-reported outcome performance measure (PRO-PM) for breast and prostate cancer. Others felt the measure may pose significant tracking, reporting, and validation challenges because data collection for this measure would require significant changes to how EHRs are currently structured. Also, in the absence of tools to validate the fulfillment of this measure, implementing the measure may not result in the practice change it is intended to achieve. Further, most shared decision-making processes associated with lung cancer resection occurs in an outpatient setting, in a clinic, or in a private office, and may not be easily or even accurately attributed to a particular hospital. This has the potential to require redundant record keeping in order to demonstrate auditable compliance with the metric. Also, the description of the measure antedates lung cancer screening, which was not included in the data to develop the measure. Finally, some felt the measure's essential elements are transactional and lack the specificity required to prevent "check-the-box" activity, while others suggested wording revisions for the specified questions. Although CMS did not agree with all of these concerns, it will

	consider these views as it develops future policy regarding the potential inclusion of the Shared Decision Making Process measure in the PCHQR Program.
<p><u>Accounting for Social Risk Factors</u></p> <p>CMS provides a summary of work done in this area to date and feedback that it received last year across its quality reporting programs on the topic of accounting for social risk factors.</p>	<p><u>Accounting for Social Risk Factors</u></p> <p>Although CMS did not propose or finalize any new policies, a discussion about accounting for social risk factors in the PCHQR begins on <a href="#">p. 1846</a>. CMS notes here that it will continue to work with measure developers to determine the most accurate way to include and account for social risk factors within each measure, including exploring stratification of social risk factors at the individual measure level.</p>
<p><u>Future Measurement Topic Areas</u></p> <p>CMS is trying to assess whether it should redefine the scope of new quality metrics in the PCHQR Program in future years. CMS sought comment on future topics as part of its effort to determine whether the PCHQR Program would most benefit from the inclusion of more quality measures that examine general cancer care (i.e., outcome measures that assess cancer care) or more measures that examine cancer-specific clinical conditions (e.g., prostate cancer, esophageal cancer, colon cancer, or uterine cancer).</p>	<p><u>Future Measurement Topic Areas</u> (<a href="#">p. 1861</a>)</p> <p>Comments received include:</p> <ul style="list-style-type: none"> <li>• Support for a balanced portfolio of general and specific cancer care measures.</li> <li>• Support for the PCHQR Program moving towards general cancer care measures based on its belief that as cancer care is increasingly built around a multi-disciplinary team.</li> <li>• Support for the development and adoption of claims-based metrics of survival for major cancer types, with careful attention to attribution and risk-adjustment.</li> <li>• Support for addressing gaps related to patient experience in this space.</li> <li>• Support for the development of more measures around end-of-life conversations.</li> </ul> <p>CMS will consider these views as it develops future policy regarding the inclusion of quality measures in the PCHQR program.</p>
<p><u>Public Display Requirements</u></p> <ul style="list-style-type: none"> <li>• CMS proposes to delay the public reporting of data for the <u>Colon and Abdominal Hysterectomy SSI</u>, <u>MRSA</u>, <u>CDI</u>, and <u>Influenza Coverage Among Healthcare Personnel</u> (HCP) measures until CY 2019, which are reported to the NHSN under this program. Performance data for these measures are new, and do not span a long enough measurement period to draw conclusions about their statistical significance at this point.</li> </ul>	<p><u>Public Display Requirements</u> (<a href="#">p. 1865</a>)</p> <ul style="list-style-type: none"> <li>• <b><i>CMS finalized a modification to its proposed deferment of public display for these four measures so that performance data would be displayed as soon as practicable (i.e., if useable data is available sooner than CY 2019, CMS will publicly report it on Hospital Compare via the next Hospital Compare release)</i></b> (<a href="#">p. 1868</a>). CMS will continue to monitor the progress of the current rebaselining efforts being made by CDC. Previously finalized public display requirements for the FY 2020 program year can be found on <a href="#">p. 1866</a>. A summary of public display requirements for the FY 2021 program year are listed in a table on <a href="#">p. 1870</a>.</li> </ul>

**Long-Term Care  
Hospital  
Quality  
Reporting  
Program (LTCH  
QRP)**

- For the newly proposed 30-Day Unplanned Readmissions for Cancer Patients measure, CMS proposes 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.

***CMS finalized the reporting requirements for the 30-Day Unplanned Readmissions for Cancer Patients measure (p. 1871)***

**New Measure Removal Factor for Previously Adopted LTCH QRP Measures**

CMS proposes to adopt an additional factor to consider when evaluating potential measures for removal from the LTCH QRP measure set: Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. CMS is proposing that it would remove measures based on this factor on a case-by-case basis.

**New Measure Removal Factor for Previously Adopted LTCH QRP Measures (p. 1879)**

***CMS finalized this policy as proposed.***

**Accounting for Social Risk Factors**

CMS provides a summary of work done in this area to date and feedback that it received last year across its quality reporting programs on the topic of accounting for social risk factors.

**Accounting for Social Risk Factors**

Although CMS did not propose or finalize any new policies, a discussion about accounting for social risk factors in the LTCH QRP begins on p. 1876. CMS notes here that it will continue to work with measure developers to determine the most accurate way to include and account for social risk factors within each measure, including exploring stratification of social risk factors at the individual measure level.

**Removal of Three LTCH QRP Measure**

CMS proposes to remove three measures from the LTCH QRP measure set:

**Removal of Three LTCH QRP Measure (p. 1891)**

The LTCH QRP currently has 19 measures for the FY 2020 program year, which are outlined in a table on p. 1888.

- NHSN Facility-wide Inpatient Hospital-Onset Methicillin-Resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (NQF #1716), beginning with the FY 2020 LTCH QRP.
- NHSN Ventilator-Associated-Event (VAE) Outcome Measure, beginning with the FY 2020 LTCH QRP.
- Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680), beginning with the FY 2021 LTCH QRP.

***CMS finalized its proposed removal of the following three measures from the LTCH QRP measure set:***

- ***NHSN Facility-wide Inpatient Hospital-Onset MRSA Bacteremia Outcome Measure, beginning with the FY 2020 LTCH QRP (p. 1892)***
- ***NHSN VAE Outcome Measure, beginning with the FY 2020 LTCH QRP (p. 1898)***
- ***Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay), beginning with the FY 2021 LTCH QRP (p. 1905)***

IMPACT Act Implementation Update: Transfer of Health Information and Care Preferences

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38449), CMS noted its intent to specify two measures that would satisfy the domain of accurately communicating the existence and provision of the transfer of health information and care preferences under section 1899B(c)(1)(E) of the Act no later than October 1, 2018, and its intent to propose to adopt them for the FY 2021 LTCH QRP with data collection beginning on or about April 1, 2019. In the FY 2019 IPPS/LTCH PPS proposed rule, CMS noted that as a result of public input, TEP input, and pilot measure testing conducted in 2017, it continues to work to develop these two measures, including supplementary measure testing and providing the public with an opportunity for comment in 2018. CMS reconvened a TEP for these measures in April 2018. CMS intends to specify them no later than October 1, 2019 and intends to propose to adopt the measures for the FY 2022 LTCH QRP, with data collection beginning with April 1, 2020 admissions and discharges.

Form, Manner, and Timing of Data Submission under the LTCH QRP

CMS is seeking input on whether it should move the implementation date of any new version of the LTCH CARE Data Set from the usual release date of April to October in the future.

Changes to the LTCH QRP Reconsideration Requirements

CMS proposes to revise its regulations to expand the methods by which CMS would notify an LTCH of noncompliance with the LTCH QRP requirements for a program year. Revised regulations would state that CMS would notify LTCHs of noncompliance with the LTCH QRP requirements via a letter sent through at least one of the following notification methods: the QIES ASAP system, the United States Postal Service, or via an email from the Medicare Administrative Contractor (MAC).

IMPACT Act Implementation Update: Transfer of Health Information and Care Preferences (p. 1910)

CMS did not receive any comments regarding this updates, but refers readers to public testing results available [here](#).

Form, Manner, and Timing of Data Submission under the LTCH QRP (p. 1911)

Commenters were generally supportive of moving the implementation date of the new version of the LTCH CARE Data Set from April to October. CMS did not finalize anything related to this policy and clarifies that in proposing any updates to the LTCH CARE Data Set, the implementation date of the new version of the LTCH CARE Data Set would not occur until the following year at the earliest. For example, if CMS proposes this change in April 2019, the implementation of the new version of the LTCH CARE Data Set would not occur until October 1, 2020 at the earliest, as opposed to April 1, 2020. This would give LTCHs an additional 6 months (April-October) to update their systems so that they can comply with new reporting requirements.

Changes to the LTCH QRP Reconsideration Requirements (p. 1912)

***CMS finalized this policy as proposed.***

## Changes to the Medicare and Medicaid EHR Incentive Programs (now referred to as the Medicare and Medicaid Promoting Interoperability Programs)

### [Renaming the EHR Incentive Program](#)

CMS proposes to rename the Medicare and Medicaid EHR Incentive Programs to the Promoting Interoperability (PI) Programs

***CMS finalized this policy as proposed.***

### [Certification Requirements Beginning in 2019](#)

Beginning with the EHR reporting period in CY 2019, participants in the PI Programs are required to use the 2015 Edition of CEHRT pursuant to the definition of CEHRT under § 495.4. CMS did not propose to change this policy.

***CMS continues to believe it is appropriate to require the use of 2015 Edition CEHRT beginning in CY 2019.*** CMS recognizes the burden associated with developing and deploying new technology, but believes the 2015 Edition includes key updates to functions and standards that support improved interoperability and clinical effectiveness. For example, the Provide Patients Electronic Access to Their Health Information measure's technical requirements are updated in the 2015 Edition and support health care providers' interest in providing patients with access to their data in a manner that is helpful to the patient and aligns with the API requirement in the PI Program. This includes a new function that supports patient access to their health information through email transmission to any third party the patient chooses and through a second encrypted method of transmission.

### [Revisions to the EHR Reporting Period in 2019 and 2020](#)

CMS proposes the EHR reporting periods in 2019 and 2020 for new and returning participants attesting to CMS or their State Medicaid agency would be a minimum of any continuous 90-day period within each of the calendar years 2019 and 2020. 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 finalized its proposed revisions to the EHR Reporting Period for 2019 and 2020.*** CMS clarifies here that 2015 Edition CEHRT does not need to be implemented on January 1, 2019. Rather, it must be implemented for the reporting period, which is a minimum of 90 days. In response to requests that CMS maintain this policy in 2021, CMS stated that it's premature to establish policies beyond CY 2020.

### [Scoring Methodology for Eligible Hospitals and CAHs Attesting Under the Medicare PI](#)

CMS proposes a new performance-based scoring methodology with fewer measures, which would move away from the threshold-based methodology currently in use. CMS believes this change would provide a more flexible, less burdensome structure, allowing eligible hospitals and CAHs to put their focus back on patients. The new methodology would include a combination of new measures, as well as existing Stage 3 measures, broken into a smaller set of four objectives and scored based on performance and participation. The four newly proposed objectives are: e-Prescribing, Health Information Exchange, Provider to Patient Exchange, and Public Health and Clinical Data Exchange. CMS also proposes to reduce the overall number of required measures from 16 to 6.

***CMS finalized with modification the proposed performance-based scoring methodology. The modifications are highlighted in bold italics in the tables below.*** CMS clarifies that for an eligible hospital or CAH to earn a score greater than zero, in addition to completing the actions included in the Security Risk Analysis measure, the hospital must submit their complete numerator and denominator or yes/no data for all required measures. The numerator and denominator for each performance measure will translate to a performance rate for that measure and will be applied to the total possible points for that measure. The eligible hospital or CAH must report on all of the required measures across all of the objectives in order to earn any score at all. A total score of 50 points or more will satisfy the meaningful use requirements and thus allow the hospital to earn an incentive payment and/or avoid a Medicare payment reduction.

Eligible hospitals and CAHs would be required to report certain measures from each of the four objectives, with performance-based scoring occurring at the individual measure-level. The eligible hospital or CAH would need to report on all of the required measures across all objectives in order to earn any score at all. Failure to report the numerator and denominator of any required measure, or reporting a “no” response on a required yes/no response measure, unless an exclusion applies would result in a score of zero.

Each measure would be scored based on the eligible hospital or CAH’s performance, except for the Public Health and Clinical Data Exchange objective, which would require a yes/no attestation. The scores for each of the individual measures would be added together to calculate the total PI score of up to 100 possible points for each eligible hospital or CAH. A total score of 50 points or more would satisfy the requirement to report on the objectives and measures of meaningful use under § 495.24, and thus earn an incentive payment and/or avoid a Medicare payment reduction. Eligible hospitals and CAHs scoring below 50 points would not be considered meaningful EHR users. CMS views this as a significant overhaul of the existing program requirements, which include six objectives, scored on a pass/fail threshold basis.

The proposed scoring methodology is as follows:

**Proposed Performance-Based Scoring Methodology for EHR Reporting Periods in 2019**

Objectives	Measures	Maximum Points
<b>e-Prescribing</b>	e-Prescribing	10 points
	<i>Bonus:</i> Query of PDMP	5 points bonus
	<i>Bonus:</i> Verify Opioid Treatment Agreement	5 point bonus
<b>Health Information Exchange</b>	Support Electronic Referral Loops by Sending Information	20 points
	Support Electronic Referral Loops by Receiving and Incorporating Information	20 points

**Finalized Performance-Based Scoring Methodology for EHR Reporting Periods in 2019**

Objectives	Measures	Maximum Points
<b>e-Prescribing</b>	e-Prescribing	10 points
	<i>Bonus:</i> Query of PDMP	5 points bonus
	<i>Bonus:</i> Verify Opioid Treatment Agreement	5 point bonus
<b>Health Information Exchange</b>	Support Electronic Referral Loops by Sending Information	20 points
	Support Electronic Referral Loops by Receiving and Incorporating Information	20 points



<b>Provider to Patient Exchange</b>	Provide Patients Electronic Access to Their Health Information	40 points
<b>Public Health and Clinical Data Exchange</b>	Syndromic Surveillance Reporting (Required)*  Choose one or more additional: <ul style="list-style-type: none"> <li>• Syndromic Surveillance Reporting</li> <li>• Immunization Registry Reporting</li> <li>• Electronic Case Reporting</li> <li>• Public Health Registry Reporting</li> <li>• Clinical Data Registry Reporting</li> <li>• Electronic Reportable Laboratory Result Reporting</li> </ul>	10 points

<b>Provider to Patient Exchange</b>	Provide Patients Electronic Access to Their Health Information	40 points
<b>Public Health and Clinical Data Exchange</b>	<b>Choose any two of the following*:</b> <ul style="list-style-type: none"> <li>• Syndromic Surveillance Reporting</li> <li>• Immunization Registry Reporting</li> <li>• Electronic Case Reporting</li> <li>• Public Health Registry Reporting</li> <li>• Clinical Data Registry Reporting</li> <li>• Electronic Reportable Laboratory Result Reporting</li> </ul>	10 points

*Note: Security Risk Analysis is retained and required, but not included as part of the scoring methodology.*

*\*In response to concerns, CMS decided that the Syndromic Surveillance Reporting measure should not be required since some hospitals and local jurisdictions are not able to send and receive syndromic surveillance files. Instead, CMS will permit hospitals and CAHs to report on any two measures of their choice to promote flexibility and allow them to focus on measures most relevant to their patient populations. Note that the rule does not clearly state whether this modified policy would apply in 2019, but CMS staff responsible for PI policies confirmed that it would.*

**Proposed Performance-Based Scoring Methodology for EHR Reporting Periods in 2020**

Objectives	Measures	Maximum Points
<b>e-Prescribing</b>	e-Prescribing	5 points
	Query of PDMP	5 points
	Verify Opioid Treatment Agreement	5 points
<b>Health Information Exchange</b>	Support Electronic Referral Loops by Sending Information	20 points
	Support Electronic Referral Loops by Receiving and Incorporating Information	20 points
<b>Provider to Patient Exchange</b>	Provide Patients Electronic Access to Their Health Information	35 points
<b>Public Health and</b>	Syndromic Surveillance Reporting (Required)	10 points

**Finalized Performance-Based Scoring Methodology for EHR Reporting Periods in 2020**

Objectives	Measures	Maximum Points
<b>e-Prescribing</b>	e-Prescribing	5 points
	Query of PDMP	5 points
	<b>Bonus: Verify Opioid Treatment Agreement</b>	<b>5 point bonus</b>
<b>Health Information Exchange</b>	Support Electronic Referral Loops by Sending Information	20 points
	Support Electronic Referral Loops by Receiving and Incorporating Information	20 points
<b>Provider to Patient Exchange</b>	<b>Provide Patients Electronic Access to Their Health Information</b>	<b>40 points</b>
<b>Public Health and</b>	<b>Choose any two of the following*:</b> <ul style="list-style-type: none"> <li>• Syndromic Surveillance Reporting</li> </ul>	10 points

<b>Clinical Data Exchange</b>	Choose one or more additional: <ul style="list-style-type: none"> <li>• Immunization Registry Reporting</li> <li>• Electronic Case Reporting</li> <li>• Public Health Registry Reporting</li> <li>• Clinical Data Registry Reporting</li> <li>• Electronic Reportable Laboratory Result Reporting</li> </ul>	
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An example of how the proposed scoring methodology would be applied is provided on [p. 1950](#) [of final rule].

The performance-based scoring methodology would apply to eligible hospitals and CAHs that submit an attestation to CMS under the Medicare PI Program beginning with the EHR reporting period in CY 2019. This would include “Medicare-only” eligible hospitals and CAHs, as well as “dual-eligible” eligible hospitals and CAHs.

CMS does not propose to apply the performance-based scoring methodology to “Medicaid-only” eligible hospitals (those that are only eligible to earn a Medicaid incentive payment for meaningful use of CEHRT and not subject to Medicare meaningful use payment adjustments) that submit an attestation to their State Medicaid agency for the Medicaid PI Program. Instead, CMS proposes to give States the option to adopt the performance-based scoring methodology along with the measure proposals discussed in this rule for their Medicaid PI Programs through their State Medicaid HIT Plans.

CMS also considered an alternative approach in which scoring would occur at the objective level, instead of the individual measure level, and eligible hospitals or CAHs would be required to report on only one measure from each objective to earn a score for that objective. Instead of six required measures, the eligible hospital or CAH’s total PI score would be based on only four measures, one measure from each objective. Bonus points would be awarded for reporting any additional measures beyond the required four.

<b>Clinical Data Exchange</b>	<ul style="list-style-type: none"> <li>• Immunization Registry Reporting</li> <li>• Electronic Case Reporting</li> <li>• Public Health Registry Reporting</li> <li>• Clinical Data Registry Reporting</li> <li>• Electronic Reportable Laboratory Result Reporting</li> </ul>	
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*Note: Security Risk Analysis is retained and required, but not included as part of the scoring methodology.*

*\*In response to concerns, CMS decided that the Syndromic Surveillance Reporting measure should not be required since some hospitals and local jurisdictions are not able to send and receive syndromic surveillance files. Instead, CMS will permit hospitals and CAHs to report on any two measures of their choice to promote flexibility and allow them to focus on measures most relevant to their patient populations*

For purposes of comparison, CMS provides an overview of the current objectives, measures, and reporting requirements in a table on [p. 1929](#). The current Stage 3 objectives and measures require hospitals and CAHs to report on six objectives that include 16 measures. This structure requires the eligible hospital or CAH to report on all measures and meet the thresholds for most of the measures or claim an exclusion to avoid the payment adjustment.

In general, CMS’ rationale for doing away with the current threshold-based scoring methodology is that the newly finalized performance-based policy, paired with the 50 point minimum score, will allow hospitals the flexibility to focus on measures that are most applicable to how they delivery care to patients and give them the opportunity to push themselves on measures they do well in, while continuing to improve in challenging areas.

In regards to the 50-point minimum PI score, despite requests that CMS lower this score, CMS feels it provides the necessary benchmark to encourage progress in interoperability and also allows CMS to continue to adjust this benchmark as eligible hospitals and CAHs progress in HIT. It also allows participants to achieve high performance in one area to offset performance in an area where a participant may need additional improvement.

In response to concerns about vendor’s ability to accommodate these new changes, CMS clarified that the changes should only require consolidation of

[Measures for Eligible Hospitals and CAHs Attesting Under the Medicare Promoting Interoperability Program](#)

Removal of Measures

CMS proposes to remove six measures from this program.

- Two of the measures CMS proposes to remove – Request/Accept Summary of Care and Clinical Information Reconciliation – would be replaced by the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure, which combines the functionalities and goals of the two Stage 3 measures it is replacing.
- Four of the measures – Patient-Specific Education; Secure Messaging; View, Download or Transmit; and Patient Generated Health Data – would be removed because they have proven burdensome to health care providers in ways that were unintended and detract from health care providers’ progress on current program priorities.

existing workflows and actions, and that the certification criteria and standards remain the same as finalized in the October 16, 2015 final rule titled “2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications.”

CMS declined to finalize the alternative proposed approach to scoring, citing concerns that it would deemphasize the Public Health and Clinical Data Exchange objective by reducing the reporting requirement to only one measure. It also cited the fact that both of the newly added measures in the e-Prescribing objective are optional for reporting in CY 2019; thus, this objective could already result in reporting on only one measure.

In regards to the Security Risk Analysis measure, CMS does not believe that it should be scored because it includes actions required under HIPAA that hospitals and CAHs should already be performing.

CMS also clarifies that for a measure to count, the eligible hospital or CAH must submit a numerator of at least one patient.

Removal of Measures

In general, CMS acknowledges that changes to measures require additional time and resources for EHR developers, vendors and providers to perform necessary updates to CEHRT and workflows, as well as training of staff. CMS is committed to reducing burden as well as being responsive to the concerns of stakeholders in the PI Programs and considered many factors prior to proposing changes to the requirements.

The table on [p. 1971](#) provides a summary of the measures CMS is finalizing in this final rule.

***CMS finalized the removal of the six measures as proposed.*** A summary of comments received on this proposal begins on [p. 1965](#). CMS clarifies that it did not propose to remove these functionalities from CEHRT.

Removal of the Request/Accept Summary of Care measure is discussed on [p. 2015](#).

Removal of the Clinical Information Reconciliation measure is discussed on [p. 2018](#).

### New Measures

CMS also proposes to add three new measures.

1. Query of Prescription Drug Monitoring Program (PDMP), which would be added to the e-Prescribing objective and supports HHS initiatives related to the treatment of opioid and substance use disorders
2. Verify Opioid Treatment Agreement, which would be added to the e-Prescribing objective and supports HHS initiatives related to the treatment of opioid and substance use disorders.

CMS proposes to apply the same policies for the existing e-Prescribing measure to both the Query of PDMP and Verify Opioid Treatment Agreement measures, including the requirement to use CEHRT as the sole means of creating the prescription and for transmission to the pharmacy. Eligible hospitals and CAHs have the option to include or exclude controlled substances in the e-Prescribing measure denominator as long as they are treated uniformly across patients and all available schedules and in accordance with applicable law. However, because the intent of these two new measures is to improve prescribing practices for controlled substances, eligible hospitals and CAHs would have to include Schedule II opioid prescriptions in the numerator and denominator of the Query of PDMP and Verify Opioid Treatment Agreement measures or claim the applicable exclusion. Eligible hospitals and CAHs that claim the broader exclusion under the e-Prescribing measure would automatically receive an exclusion for all three of the objective's measures.

CMS seeks comment on:

- Whether it should further refine the measure to limit queries of the PDMP to once during the stay regardless of whether multiple eligible medications are prescribed during this time.

Removal of Patient Generated Data measure is discussed on [p. 2040](#).

Removal of Secure Messaging measure is discussed on [p. 2043](#).

Removal of View, Download, or Transmit measure is discussed on [p. 2045](#).

### New Measures

***CMS finalized the new measures Query of PDMP and Verify Opioid Treatment Agreement, as proposed, except that for the fact that the Verify Opioid Treatment Agreement measure would remain optional in 2020 while the Query of PDMP measure would be required in 2020, as reflected in the tables above.***

The finalized measures read as follows:

#### Query of PDMP

- **Description:** For at least one Schedule II opioid electronically prescribed using CEHRT during the EHR reporting period, the eligible hospital or CAH uses data from CEHRT to conduct a query of a PDMP for prescription drug history, except where prohibited and in accordance with applicable law.
- **Denominator:** Number of Schedule II opioids electronically prescribed using CEHRT by the eligible hospital or CAH during the EHR reporting period.
- **Numerator:** The number of Schedule II opioid prescriptions in the denominator for which data from CEHRT is used to conduct a query of a PDMP for prescription drug history except where prohibited and in accordance with applicable law.
- **Exclusions beginning with an EHR reporting period in CY 2020:** Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions for controlled substances and is not located within 10 miles of any pharmacy that accepts electronic prescriptions for controlled substances at the start of their EHR reporting period; and any eligible hospital and CAH that could not report on this measure in accordance with applicable law.

#### Verify Opioid Treatment Agreement

- **Description:** For at least one unique patient for whom a Schedule II opioid was electronically prescribed by the eligible hospital or CAH using CEHRT during the EHR reporting period, if the total duration

- Whether ONC should consider adopting standards and certification criteria to support the query of a PDMP, and if such criteria were to be adopted, on what timeline should CMS require their use to meet this measure.
- Challenges associated with querying the PDMP with and without CEHRT integration and whether this proposed measure should require certain standards, methods or functionalities to minimize burden.
- Limiting the exclusion criteria to electronic prescription for controlled substances and whether there are circumstances which may justify any additional exclusions for both measures.
- Challenges and concerns associated with opioid treatment agreements and how they could impact the feasibility of the proposal.
- Pathways to facilitate the identification and exchange of treatment agreements and opioid abuse treatment planning.
- What characteristics should be included in an opioid treatment agreement and incorporated into CEHRT.

Whether CMS should explore adoption of a measure focused only on the number of Schedule II opioids prescribed and the successful use of EPCS for permissible prescriptions electronically prescribed.

of the patient's Schedule II opioid prescriptions is at least 30 cumulative days within a 6-month look-back period, the eligible hospital or CAH seeks to identify the existence of a signed opioid treatment agreement and incorporates it into CEHRT.

- **Denominator:** Number of unique patients for whom a Schedule II opioid was electronically prescribed by the eligible hospital or CAH using CEHRT during the EHR reporting period and the total duration of Schedule II opioid prescriptions is at least 30 cumulative days as identified in the patient's medication history request and response transactions during a 6-month look-back period.
- **Numerator:** The number of unique patients in the denominator for whom the eligible hospital or CAH seeks to identify a signed opioid treatment agreement and, if identified, incorporates the agreement in CEHRT.

A more general discussion about the e-Prescribing objective measures begins on [p. 1971](#). Many commenters requested that the [Query of PDMP](#) and [Verify Opioid Treatment Agreement](#) measures remain optional in 2020 as the timeline for implementation is unreasonable especially without certification criteria and standards. CMS recognizes that these measures could require hospitals to incur additional burden due to workflow changes at the point of care and that hospitals that have integrated PDMPs within an EHR may be required to manually calculate the measure, as automated functionality for this measure is not currently supported through certification criteria for Health IT Modules. However, CMS notes that, at least for the [Query of PDMP](#) measure, providers would have the flexibility to query the PDMP in any manner allowed under their State law, including the use of relevant capabilities of their CEHRT, such as those required by the 2015 Edition electronic prescribing criterion at 45 CFR 170.315(b)(3).

CMS anticipates that integration of PDMPs into CEHRT will become more widespread, increasing efficiency with health care provider workflows. Thus, it believes that requiring the [Query of PDMP](#) measure beginning in 2020 is appropriate and that the optional reporting policy for 2019 will allow additional time for the measure to be tested and for expansion of PDMP integration into EHRs. On the other hand, for the [Verify Opioid Treatment Agreement](#), there are no current exact standards for identification or exchange of treatment agreements, which is one of the reasons this measure will be optional for two years.

A more specific discussion about the Query of PDMP measure starts on [p. 1978](#). Some points of clarification include:

- This measure does not specify whether providers' CEHRT connects to PDMPs directly or through HIEs. Therefore, use of HIEs to access Schedule II opioid prescription drug history is acceptable.
- An "Open API" is another way PDMPs can make it easier for providers to connect their CEHRT to PDMPs.
- CMS declined to finalize additional exclusion criteria, as recommended by the commenters, since providers may query the PDMP in any manner that is allowed by their State. In addition, CMS is adopting exclusion criteria for hospitals not able to report on this measure in accordance with applicable law when the measure is required beginning in CY 2020.
- CMS recognizes that there is work to be done to resolve various real and perceived barriers to achieving the full potential of interoperable HIT and health information exchange to improve patient care and outcomes. It plans to continue collaborating with its colleagues across HHS, including ONC, on standards and requirements specific to the PI Programs.
- Next year, CMS intends to propose in rulemaking that EHR-integrated PDMP querying would be required beginning in CY 2020 as part of this measure. It also intends to propose an additional exclusion for providers in States where integration with a Statewide PDMP is not yet feasible or not yet widely available.

A more specific discussion about the Verify Opioid Treatment Agreement measure starts on [p. 1993](#). Some points of clarification include:

- CMS recognizes that the capabilities to which health IT must be certified do not include the ability to automatically track prescriber behaviors addressed by this measure. However, CMS disagrees that this measure cannot be implemented at this time (e.g., such as through the use of the C-CDA care plan template that is currently optional in CEHRT or the "patient health data capture" functionality which is part of the 2015 Edition) and believes that some providers are currently verifying if there is an opioid treatment agreement in place before they prescribe.
- CMS also recognizes that a provider's attempt to verify whether a treatment agreement is in place may be difficult to capture in an automated fashion in cases where a machine readable treatment agreement cannot be queried.



- ***As a result of these issues, CMS is finalizing that this measure will be optional for hospitals in 2019 and 2020.*** CMS expects this measure is likely to be adopted by a limited set of providers in treatment arrangements that already possess the infrastructure to support capture and calculation of this measure. It intends to revisit this measure along with the necessary data elements in future rulemaking.
- CMS disagrees that this measure will result in unintended consequences, such as the decline of pain management therapies. CMS is only including patients where the total duration of the patient's Schedule II opioid prescriptions is at least 30 cumulative days within a 6-month look-back period. CMS believes this measure could encourage discussion and additional treatment options between health care providers and patients. It could also help to rule out issues related to pain management therapies for certain post-surgical patients and those recovering from acute illnesses.
- CMS understands that certain medical conditions and diagnoses could necessitate prescribing for over 30 days. It is not CMS' intention to be a barrier to the most effective and clinically appropriate pain alleviating therapies available to patients in need, or to impose an undue burden on health care providers. CMS recognizes that Opioid treatment agreements may be more commonly used by outpatient programs where use of CEHRT is limited, however it believes their verification in other care settings such as hospitals would improve prescribing practices through identification of overutilization of controlled substances.
- Since this measure is optional for both years, CMS declined to include an exclusion for patients with certain diagnoses or settings, such as terminal or end stage conditions, cancer and hospice settings.
- CMS declines to modify the denominator for this measure since it is seeking the cumulative days for an opioid prescription over a 6 month look back period to identify egregious cases. CMS understands that each prescription would include a quantity based on the number of doses allowed. However, the intent is to also look at prescriptions from other health care providers as well for episodes of prescription shopping.
- CMS re-clarifies that the 6 month look back would begin on the date in which the eligible hospital or CAH electronically transmits its Schedule II Opioid prescription using CEHRT.



3. Support Electronic Referral Loops by Receiving and Incorporating Health Information, which would be added to the Health Information Exchange objective and builds upon and replaces the existing Request/Accept Summary of Care and Clinical Information Reconciliation measures.

***CMS finalized the third new measure Support Electronic Referral Loops by Receiving and Incorporating Health Information (p. 2006, p. 2019).*** CMS clarifies that eligible hospitals and CAHs may use any document template within the C-CDA standard for purposes of the measures under the Health Information Exchange objective. CMS disagreed with commenter's concern regarding being accountable for another health care provider's actions. CMS is moving to a new phase of EHR measurement with an increased focus on interoperability, coordination of care, and improving patient access to health information. CMS also clarified that the denominator language includes "the number of summary of care records received using CEHRT," therefore, an eligible hospital or CAH would not increment the denominator if a summary of care record was not received.

Support Electronic Referral Loops by Receiving and Incorporating Health Information

- **Description:** For at least one electronic summary of care record received for patient encounters during the EHR reporting period for which an eligible hospital or CAH was the receiving party of a transition of care or referral, or for patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patient, the eligible hospital or CAH conducts clinical information reconciliation for medication, medication allergy, and current problem list.
- **Denominator:** Number of electronic summary of care records received using CEHRT for patient encounters during the EHR reporting period for which an eligible hospital or CAH was the receiving party of a transition of care or referral, and for patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patients.
- **Numerator:** The number of electronic summary of care records in the denominator for which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication – Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy – Review of the patient's known medication allergies; and (3) Current Problem List – Review of the patient's current and active diagnoses.

#### Modifications to Measures

CMS also proposes the following modifications:

- To rename Send a Summary of Care measure to Support Electronic Referral Loops by Sending Health Information
- To rename the Patient Electronic Access to Health Information objective to Provider to Patient Exchange objective, and to rename the remaining measure, Provide Patient Access to Provide Patients Electronic Access to Their Health Information.
  - CMS also proposes to revise the measure description for the Provide Patients Electronic Access to Their Health Information measure to change the threshold from more than 50 percent to at least one unique patient in accordance with the proposed scoring methodology
- To rename the Public Health and Clinical Data Registry Reporting objective to Public Health and Clinical Data Exchange objective
  - Eligible hospitals and CAHs would be required to attest to the Syndromic Surveillance Reporting measure and at least one additional measure from the following options: Immunization Registry Reporting; Clinical Data Registry Reporting; Electronic Case Reporting; Public Health Registry Reporting; and Electronic Reportable Laboratory Result Reporting.

CMS intends to propose in future rulemaking to remove the Public Health and Clinical Data Exchange objective and measures no later than CY 2022, and seeks public comment on whether hospitals will continue to share such data with public health entities once the Public Health and Clinical Data Exchange objective and measures are removed, as well as other policy levers outside of the PI Program that could be adopted for continued reporting to public health and clinical data registries, if necessary. It also seeks public comment on the role that each of the public health and clinical data registries should have in the future of the PI Programs and whether the submission of this

#### Modifications to Measures

***CMS finalized its proposal to rename Send a Summary of Care measure to Support Electronic Referral Loops by Sending Health Information. (p. 2011)***

***CMS finalized its proposal to rename the Patient Electronic Access to Health Information objective to Provider to Patient Exchange objective and to rename the remaining measure, Provide Patient Access, to Provide Patients Electronic Access to Their Health Information (p. 2029). The measure's description was finalized as proposed and can be found on p. 2039.*** Commenters requested that CMS base this measure on the total percentage of their patient population who have electronic access to their medical records, as opposed to the proposed number/denominator performance-based scoring that includes the entire patient population. CMS notes that it is committed to making sure that patients have access to their data electronically and believe this number will increase rapidly over the years. Thus, it is in the best interest of the PI Program to include all patients in the denominator to ensure every patient is provided access and to better understand the amount of patients accessing their data electronically. CMS also declined to change the definition of "timely," noting that providing patients access to their health information is a top priority for the program and it has not received compelling evidence to indicate that 36 hours is not feasible.

***CMS also finalized its decision to rename the Public Health and Clinical Data Registry Reporting objective to Public Health and Clinical Data Exchange objective, but modified the requirement to allow for reporting on any two measures of the eligible hospital or CAH's choice, rather than requiring attestation to the Syndromic Surveillance Reporting measure (p. 2047).***

Many commenters also strongly opposed CMS' intent to remove public health measures in the future of the program as they believed that interoperability of public health data is still evolving and incentivizes health care providers to share data with public health agencies. CMS appreciates this feedback and understands the importance of reporting to public health and clinical data registries. It will continue to focus on burden reduction as well as other platforms and venues for reporting data to public health and clinical data registries outside of the PI Programs. It also will continue to monitor the data it compiles specific to the public health reporting

data should still be required when the incentive payments for meaningful use of CEHRT will end in 2021.

#### Potential New Future Measures

CMS seeks public comment on two potential new measures under the Health Information Exchange objective that would enable eligible hospitals and CAHs to exchange health information through health IT supported care coordination across a wide range of setting:

- Support Electronic Referral Loops by Sending Health Information Across the Care Continuum
- Support Electronic Referral Loops by Receiving and Incorporating Health Information Across the Care Continuum

CMS sought comment on multiple issues, including:

- Whether these measures should be combined into one.
- In regards to the denominator, whether the potential new measures should be limited to transitions of care and referrals specific to long-term and post-acute care, skilled nursing care, and behavioral health care settings.

Whether additional settings of care should be considered for inclusion in the denominators

#### Exclusion Criteria

CMS also proposes to remove the exclusion criteria from all of the retained Stage 3 measures, except for the measures associated with the e-Prescribing objective, Public Health and Clinical Data Exchange objective and the new measures, which would include exclusion criteria.

CMS proposes to give States the option to adopt the proposed new scoring methodology together with the measures proposed for their Medicaid Promoting Interoperability Programs.

In connection with these proposals regarding the scoring methodology and measures, CMS proposes to require “dual-eligible” eligible hospitals and CAHs (those eligible for payment adjustments under Medicare for meaningful use of CEHRT and also eligible to earn a Medicaid incentive payment for meaningful use) to demonstrate meaningful use for the PI Program to CMS, and not to their

requirements and take the commenters’ concerns into consideration related to future actions.

#### Potential New Future Measures

CMS discusses feedback received in regards to the two potential new measures under the Health Information Exchange objective starting on [p. 2055](#). Many commenters opposed the addition of these types of measure as they believed that the current measures in the Health Information Exchange objective accurately capture the exchange of health information to other settings such as long term care facilities and an additional measure such as this would be redundant. Others requested that CMS to convene stakeholder discussions with providers who would be included in this type of measure to identify what data elements are most valuable for them. Some noted that adoption of CEHRT in postacute care settings could be a slow process. CMS will consider this feedback as it develops future policies.

#### Exclusion Criteria

***CMS finalized the removal of the exclusion criteria, as proposed, from all of the Stage 3 measures retained except for the measures associated with the Electronic Prescribing objective, Public Health and Clinical Data Exchange objective and the new measure, Support Electronic Referral Loops by Receiving and Incorporating Health Information. The table on [p. 1971](#) provides a summary of the measures CMS is finalizing in this final rule.***

***CMS finalized these Medicaid PI policies as proposed.***

[Proposed Application of Proposed Scoring Methodology and Measures Under the Medicaid Promoting](#)

Interoperability Program

respective State Medicaid agency, beginning with the EHR reporting period in CY 2019.

CMS also proposes to amend the requirements for State reporting to CMS under the Medicaid Promoting Interoperability Program under § 495.316(g), so that States would not be required to report, for program years after 2018, provider-level attestation data for each eligible hospital that attests to the State to demonstrate meaningful use.

Proposed Modifications to the Medicaid Promoting Interoperability Program

In regards to prior approval of Requests for Proposals (RFPs) and contracts in support of the Medicaid PI Program, CMS proposes that the prior approval dollar threshold in § 495.324(b)(3) would be increased to \$500,000, and that a prior approval threshold of \$500,000 would be added to § 495.324(b)(2).

***CMS finalized these policies as proposed.***

In regards to funding availability to States to conclude the Medicaid PI Program, CMS proposes to amend § 495.322 to provide that the 90 percent FFP for Medicaid PI Program administration would no longer be available for most State expenditures incurred after September 30, 2022. CMS proposes a later sunset date (September 30, 2023) for the availability of this enhanced match for State administrative costs related to Medicaid PI Program audit and appeals activities, as well as costs related to administering incentive payment disbursements and recoupments that might result from those activities. States would not be able to claim any Medicaid PI Program administrative match for expenditures incurred after September 30, 2023.

Promoting Interoperability Program Future Direction

CMS seeks public comment on whether participation in the Trusted Exchange Framework and Common Agreement (TEFCA) should be considered a HIT activity that could count for credit within the Health Information Exchange objective in lieu of reporting on measures for this objective.

Many commenters expressed support for introducing health IT activities in lieu of reporting on measures and indicated an approach such as this would reduce provider burden associated with these reporting activities; some disagreed with this approach. CMS will consider this and other feedback as it develops future policy regarding the future direction of the PI Program.

CMS welcomes general feedback on the concept of adopting HIT activities and recommendations on other HIT activities through which eligible hospitals and CAHs could earn credit in lieu of reporting on specific measures, and which add value for patients and health care providers, are relevant to patient care and clinical workflows, support alignment with existing objectives, promote

flexibility, are feasible for implementation, are innovative in the use of health IT and promote interoperability.

Proposed CQMs for Reporting Periods Beginning with CY 2020:

CMS proposes to remove eight eCQMs, from the 16 eCQMs currently in the measure set, beginning with the reporting period in CY 2020:

- 1) Primary PCI Received Within 90 Minutes of Hospital Arrival (NQF #0163) (AMI-8a)
- 2) Home Management Plan of Care Document Given to Patient/Caregiver (CAC-3)
- 3) Median Time from ED Arrival to ED Departure for Admitted ED Patients (NQF #0495) (ED-1)
- 4) Hearing Screening Prior to Hospital Discharge (NQF #1354) (EHDI-1a)
- 5) Elective Delivery (NQF #0469) (PC-01)
- 6) Stroke Education (STK-08)
- 7) Assessed for Rehabilitation (NQF #0441) (STK-10)
- 8) Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF 0496) (ED-3)

The first seven measures on this list are currently included in the Hospital IQR Program. CMS believes that a coordinated reduction in the overall number of eCQMs in both the Hospital IQR Program and Medicare and Medicaid PI Programs will reduce certification burden on hospitals, improve the quality of reported data by enabling eligible hospitals and CAHs to focus on a smaller, more specific subset of CQMs while still allowing eligible hospitals and CAHs some flexibility to select which eCQMs to report that best reflect their patient populations and support internal quality improvement efforts.

ED-3 is an outpatient measure and is not in the Hospital IQR Program. CMS proposes to remove it so the eCQMs would align completely between the two programs in order to reduce burden and enable hospitals to easily report electronically through the Hospital IQR Program submission mechanism.

***CMS adopted the removal of eCQMs as proposed ([p. 2071](#)).***

**The current list of CQMs for eligible hospitals and CAHs, beginning with CY 2017, is available on [p. 2066](#).**

Proposed CQM Reporting Periods and Criteria for the Medicare and Medicaid Promoting Interoperability Programs in CY 2019

- For CY 2019, CMS proposes the same CQM reporting periods and criteria as established in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38479 through 38483) for CY 2018.
- In regards to reporting criteria, for CY 2019, eligible hospitals and CAHs participating only in the PI Program, or participating in both the PI Program and the Hospital IQR Program, would have to report on at least 4 self-selected CQMs from the set of 16 available CQMs. Eligible hospitals and CAHs that report CQMs by attestation under the Medicare PI Program as a result of electronic reporting not being feasible, and eligible hospitals and CAHs that report CQMs by attestation under their State's Medicaid Promoting Interoperability Program, would have to report on all 16 available CQMs
- For CY 2019, CMS also proposes that CQMs be electronically reported through the QualityNet Portal.

A discussion regarding the CQM reporting periods and criteria for CY 2019 begins on [p. 2071](#). The CQM reporting form and methods for 2019 are discussed on [p. 2073](#).

[Participation in the Medicare Promoting Interoperability Program for Subsection \(d\) Puerto Rico Hospitals](#)

CMS proposes multiple policies related to the definition of an eligible "subsection (d) Puerto Rico hospital," the EHR period that would apply to these hospitals, the payment adjustments that would apply, the duration and timing of incentive payments, and the treatment of MA-affiliated hospitals and their participation in the Medicare Advantage PI Program.

***CMS finalized all of the policies in this section as proposed.***

[RFI on Promoting Interoperability and Electronic Healthcare Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid Participating Providers and Suppliers](#)

CMS solicits feedback on how it could use the CMS health and safety standards that are required for providers and suppliers participating in the Medicare and Medicaid programs (i.e., the Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RfPs) for Long Term Care Facilities) to further advance electronic exchange of information that supports safe, effective transitions of care between hospitals and community providers. Specifically, CMS might consider revisions to the current CMS CoPs for hospitals such as: requiring that hospitals transferring medically necessary information to another facility upon a patient transfer or discharge do so electronically; requiring that hospitals electronically send required discharge information to a community provider via electronic means if possible and if a community provider can be identified; and requiring that hospitals make certain information available to patients or a specified third-party application (e.g., required discharge instructions) via electronic means if requested.

CMS also solicits ideas on how best to accomplish the goal of fully interoperable health IT and EHR systems for Medicare- and Medicaid-participating providers and suppliers more generally. It is particularly interested in identifying fundamental barriers to interoperability and health information exchange, including those specific barriers that prevent patients from being able to access and control their medical records, as well as innovative thoughts on addressing these barriers, specifically through revisions to the current CMS CoPs, CfCs, and RfPs for hospitals and other participating providers and suppliers. CMS has received stakeholder input on the need to address HIT adoption and interoperability among providers that were not eligible for the Medicare and Medicaid EHR Incentives program, including long-term and post-acute care providers, behavioral health providers, clinical laboratories and social service providers, and it also welcomes specific input on how to encourage adoption of certified health IT and interoperability among these types of providers and suppliers.

CMS received approximately 313 pieces of correspondence on this RFI and appreciates the input, but does not provide any more details regarding next steps.



## **Requirements for Hospitals to Make Public a List of Their Standard Charges via the Internet**

In the proposed rule, CMS remained concerned that patients continue to face challenges due to insufficient price transparency. Specifically, CMS cited:

- Patients being surprised by out-of-network bills for physicians (e.g. anesthesiologists and radiologists) who provide services at in-network hospitals;
- Patients being surprised by facility fees and physician fees for emergency room visits;
- Chargemaster data do not provide useful information for patients in determining what the patient is likely to pay for a particular service or hospital stay.

CMS put forth the following policies:

- Effective January 1, 2019, CMS will update its guidelines to require hospitals to make available a list of their current standard charges “via the internet in a machine-readable format” (chargemaster is permissible if in machine-readable format)
- CMS will require this information to be updated at least annually (or more often as appropriate)

***CMS will continue with its plan to update the guidelines as discussed in the proposed rule*** ([p. 2142](#)). CMS received input that many hospitals already voluntarily post charges or do so because of State law requirements ([p. 2137](#)). Many commenters suggested that chargemaster information only confuses patients and does not provide patients with necessary information like potential out-of-pocket costs ([p. 2138](#)) (CMS disagreed ([p. 2139](#))). CMS received additional input:

- CMS should focus on “shoppable” services that can be scheduled in advance ([p. 2138](#))
- CMS should conduct further research and work with stakeholders to determine best approach to making information available to consumers ([p. 2138](#))
- The updated guidelines conflict with State requirements and increase administrative burden if hospitals must report charge information in incongruent ways ([p. 2140](#))
- The definition of “standard charges” is unclear ([p. 2141](#))

CMS also sought public comment in several areas in order to encourage hospitals to engage with more consumer-friendly communication of their charges, to help patients better understand their potential financial liabilities, and to provide information that allows for patients to compare charges for similar services across hospitals under several general headings.

- Transparency
- Enforcement
- Medigap Coverage

CMS received input on several activities already undertaken to address the issues cited by CMS, including:

- Hospitals providing patients with payer specific-cost estimates ([p. 2138](#))
- Hospitals provided Web-based tools that allow patients to estimate out-of-pocket expenses ([p. 2138](#))
- State efforts to provide patients with more information that could be obtained from chargemaster ([p. 2141](#))

CMS also received the following guidance:

- Payers are a better source of information about cost of care and should be the primary source of information about out-of-pocket costs ([p. 2139](#)), including information on deductible status and out-of-pocket spending limits ([p. 2140](#))
- Require insurance companies to provide cost calculators and other tools for patients to calculate patient-specific costs ([p. 2140](#))
- Payers and providers should work together to provide the information ([p. 2140](#))
- Challenges in what information would be provided to patients that receive free or discounted care ([p. 2140](#))
- Concern that patients could forego needed care if they are informed of charges in advance ([p. 2142](#))
- The quality of cost information can be misleading to patients ([p. 2142](#))

### **Revisions Regarding Physician Certification and Recertification of Claims**

CMS' regulations specify the requirements for physician statements that certify and periodically recertify as to the medical necessity of certain types of covered services provided to Medicare beneficiaries. Through its regulatory relief efforts, CMS has been made aware that the provisions of § 424.11(c) which state that it will suffice for the statement to indicate where the information is to be found may be resulting in unnecessary denials of Medicare claims. As currently worded, this last sentence of § 424.11(c) can result in a claim being denied merely because the physician statement technically fails to identify a specific location in the file for the supporting information, even when that information nevertheless may be readily apparent to the reviewer. CMS believes that continuing to require the location to be specified in this situation is unnecessary.

CMS proposes to delete the last sentence of § 424.11(c). In addition, CMS proposes to relocate the second sentence of § 424.11(c) (indicating that supporting information contained elsewhere in the provider's records need not be repeated in the certification or recertification statement itself) to the end of the immediately preceding paragraph (b), which describes similar kinds of flexibility that are currently afforded in terms of completing the required statement.

***CMS finalized the proposal without modification*** ([p. 2144](#)).

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