

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Part 412****Office of the Secretary****45 CFR Part 170[CMS-1632-P]****RIN-0938-AS41****Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System Policy Changes and Fiscal Year 2016 Rates; Revisions of Quality Reporting Requirements for Specific Providers, including Changes Related to the Electronic Health Record Incentive Program**

AGENCY: Centers for Medicare and Medicaid Services (CMS), HHS

ACTION: Proposed rule

SUMMARY: We are proposing to revise the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from our continuing experience with these systems for FY 2016. Some of these changes implement certain statutory provisions contained in the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (collectively known as the Affordable Care Act), the Pathway for Sustainable Growth Reform (SGR) Act of 2013, the Protecting Access to Medicare Act of 2014, and other legislation. We also are addressing the update of the rate-of-increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost basis subject to these limits for FY 2016. We also are proposing to update the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) for FY 2016 and implement certain statutory changes to the LTCH PPS under the Affordable Care Act and the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 and the Protecting Access to Medicare Act of 2014. In addition, we are proposing to establish new requirements or to revise existing requirements for quality reporting by specific providers (acute care hospitals, PPS-exempt cancer hospitals, and LTCHs) that are participating in Medicare, including related proposals for eligible hospitals and critical access hospitals participating in the Medicare Electronic Health Record (EHR) Incentive Program. We also are proposing to update policies relating to the Hospital Value-Based Purchasing (VBP) Program, the Hospital Readmissions Reduction Program, and the Hospital-Acquired Condition (HAC) Reduction Program.

Proposed Rules Subsequent Programs:

On April 17, 2015, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule to update fiscal year (FY) 2016 Medicare payment policies and rates under the Inpatient Prospective Payment System (IPPS) and the Long-Term Care Hospital (LTCH) Prospective Payment System (PPS).

This summation is relative to CMS' proposals for the **Inpatient Quality Reporting Program only**. Please refer to the following pages for subsequent programs:

- Proposals to the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program can be found on pp. 1092–1112.
- Proposals to the Long-Term Care Hospital Quality Reporting (LTCHQR) Program can be found on pp. 1113–1180.
- Proposals to the Clinical Quality Measurement for Eligible Hospitals and Critical Access Hospitals Participating in the EHR Incentive Programs can be found on pp. 1181–1197.

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The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations, and other interpretive materials for a full and accurate statement of their contents.

Hospital Readmissions Reduction Program (Federal Register pp. 679–715)

In this proposed rule, we are proposing to—

Make a refinement to the pneumonia readmissions measure, which would expand the measure cohort, for the FY 2017 payment determination and subsequent years

For the purposes of describing the refinement of this measure, we note that “cohort” is defined as the hospitalizations, or “index admissions,” that are included in the measure. This cohort is the set of hospitalizations that meet all of the inclusion and exclusion criteria, and we are proposing an expansion to this set of hospitalizations.

The previously adopted CMS 30-day Pneumonia Readmission Measure included hospitalizations for patients with a principal discharge diagnosis of pneumonia indicating viral or bacterial pneumonia.

This proposed measure refinement would expand the measure cohort to include hospitalizations for patients with a principal discharge diagnosis of aspiration pneumonia and for patients with a principal discharge diagnosis of either sepsis or respiratory failure who also have a secondary diagnosis of pneumonia present on admission.

The data sources, exclusion criteria, and assessment of the outcome of readmission remain unchanged.

In this proposed rule, for FY 2016, we are proposing an “applicable period” for the Hospital Readmissions Reduction Program to be the 3-year period from July 1, 2011 through June 30, 2014.

Adopt an extraordinary circumstance exception policy to address hospitals that experience a disaster or other extraordinary circumstance beginning in FY 2016 and for subsequent years

We considered the feasibility and implications of excluding data for certain readmission measures for a limited period of time from the calculations for a hospital’s excess readmissions ratios for the applicable performance period. By minimizing the data excluded from the program, the proposed policy would enable affected hospitals to continue to participate in the Hospital Readmissions Reduction Program for a given fiscal year if they otherwise continue to meet applicable measure minimum threshold requirements. We believe that this approach could help alleviate the reporting burden for a hospital that is adversely impacted by a natural disaster or other extraordinary circumstance beyond its control, while enabling the hospital to continue to participate in the Hospital Readmissions Reduction Program.

We are proposing that the request process for an extraordinary circumstance exception begin with the submission of an extraordinary circumstance exception request form by a hospital within 90 calendar days of the natural disaster or other extraordinary circumstance.

Hospital Value-Based Purchasing (VBP) Program (Federal Register pp. 716–758)

Proposed Removal of Two Measures—

Topped-Out

- IMM-2 / Influenza Immunization

Infrequently Reported

- AMI-7a / Fibrinolytic Therapy Received within 30 Minutes of Hospital Arrival

Our evaluation of the most recently available data shows that AMI-7a is not widely reported by hospitals, and that many hospitals have less than the minimum number of cases required for reporting because most acute myocardial infarction patients receive percutaneous coronary intervention instead of fibrinolytic therapy. We are proposing to remove AMI-7a because collection of the measure data is burdensome to hospitals and measure data are infrequently reported.

Proposed Removal of Clinical Care/Process Subdomain for the FY 2018 Program Year and Subsequent Years—

As discussed, we are proposing to remove the AMI-7a and IMM-2 measures from the Hospital VBP Program, and we are not proposing to adopt any additional measures for the Clinical Care—Process subdomain.

If the proposed is finalized, only one measure, PC-01 Elective Delivery would remain in the Clinical Care – Process subdomain.

We would propose moving PC-01 to the Safety domain and to remove the Clinical Care-Process subdomain beginning with the FY 2018 program year. Not all hospitals provide maternity services, which would leave these hospitals with no Clinical Care-Process subdomain measures to report in FY 2018 if PC-01 remains the only measure in that subdomain.

**Proposed New Measure for the FY 2018 Program Year:
3-Item Care Transition Measure—**

The 3-Item Care Transition Measure (CTM-3) is an NQF-endorsed measure. We adopted this measure in the Hospital IQR Program in the FY 2013 IPPS/LTCH PPS final rule. Initial measure data were posted on *Hospital Compare* in December 2014 and the full measure specifications are available at: <http://www.caretransitions.org/documents/CTM3Specs0807.pdf>.

Specifications for the Care Transition Measure as used in the HCAHPS Survey can be found in the current HCAHPS Quality Assurance Guidelines, <http://www.hcahpsonline.org/qaguidelines.aspx>.

We are proposing this measure for the Hospital VBP Program based on the MAP recommendation, our adoption of the measure in the Hospital IQR Program and our posting of measure data on *Hospital Compare* for at least one year before the beginning of the performance period for that measure. We believe that the proposed addition of the CTM-3 measure to the Hospital VBP Program meets the statutory requirements for inclusion in the FY 2018 program year.

The CTM-3 measure adds three questions to the HCAHPS Survey—

- During this hospital stay, staff took my preferences and those of my family or caregiver into account in deciding what my health care needs would be when I left.
- When I left the hospital, I had a good understanding of the things I was responsible for in managing my health.
- When I left the hospital, I clearly understood the purpose for taking each of my medications.

Finally, we also believe that this measure, in conjunction with the HCAHPS survey, assesses an important component of quality in the acute care inpatient hospital setting. However, we emphasize that HCAHPS scores are designed and intended for use at the hospital level. We do not endorse the use of HCAHPS scores for comparisons within hospitals, such as comparison of HCAHPS scores associated with a particular ward, floor, provider, or nursing staff. Further, the pain domain questions are intended to evaluate patients' experience of their pain management. HCAHPS pain domain results are not designed to judge, or compare, appropriate versus inappropriate provider prescribing behavior.

Proposed Domain Weights—

For the FY 2018 program year, we are proposing to remove two “topped-out” measures from the Clinical Care—Process subdomain. In addition, we are proposing to move one measure (PC-01) from the Clinical Care—Process subdomain to the Safety domain and to remove the Clinical Care—Process subdomain. If these proposals are adopted, the Safety domain will include seven measures for the FY 2018 program year, including PC-01, which would be new to that domain. Because we are proposing to move one measure to the Safety domain, and because we continue to believe that hospitals should be provided strong incentives to perform well on measures of patient safety, we are proposing to increase the Safety domain’s weight by 5 percentage points. We are proposing to adopt the following FY 2018 program year domain weighting for hospitals receiving a score on all proposed newly-aligned domains:

Proposed Domain Weights for the FY 2018 VBP Program Year

| Domain | Weight |
|---|---------------|
| Safety | 25 percent |
| Clinical Care | 25 percent |
| Efficiency and Cost Reduction | 25 percent |
| Patient and Caregiver-Centered Experience of Care/Care Coordination | 25 percent |

NHSN Measures Standard Population Data—

In order to update the standard population data for all of the NHSN measures the CDC will collect CY 2015 data and adopt as the new standard population data for HAI measures. Currently, CDC calculates the “standard population data” for:

- **CAUTI** based on CY 2009 data
- **CLABSI** and **SSI** measures based on 2006 to 2008 data
- **MRSA bacteremia** and **CDI** measures based 2010 to 2011 data

If CMS does not address the *CDC’s measure update, CMS will be unable to compare the baseline and performance periods for NHSN measures in the FY 2017 and FY 2018 program years.

To address the problem, CMS intends to use the “current standard population data” to calculate performance standards and calculate and publicly report measure scores until the FY 2019 program year.

For the FY 2019 program year and subsequent years, the Hospital VBP Program will use the “new standard population data” to calculate performance standards and calculate and publicly report measure scores.

**As part of routine measure maintenance, CDC updates the “standard population data” to ensure the NHSN measures’ number of predicted infections reflect the current state of HAIs in the United States. Calculation of these measures is used in both the IQR and VBP programs.*

For FY 2017 and FY 2018 the CAUTI and CLABSI measures will use adult, pediatric, and neonatal intensive care unit (ICU) data to calculate performance standards and measure scores for the Hospital VBP Program.

Beginning in the FY 2019 program year for purposes of calculating performance standards for the CAUTI and CLABSI measures CMS intends to propose:

- Inclusion of the selected ward (non-ICU) locations in the CAUTI and CLABSI Measures
- Adopt a baseline period of January 1, 2015 through December 31, 2015
- Adopt a performance period of January 1, 2017 through December 31, 2017

Hospital-Acquired Conditions (HAC) Reduction Program (Federal Register pp. 759–778)

Effective beginning on October 1, 2014, and for subsequent program year’s payments to “applicable hospitals” will be adjusted to account for HACs with respect to discharges occurring during FY 2015 or later. For hospitals with HAC scores in the top quartile relative to other applicable hospitals for a given fiscal year, the amount of Medicare payment is reduced to 99 percent of the amount of payment that would otherwise apply to discharges.

In the FY 2015 IPPS/LTCH PPS final rule we finalized the following measures for use in the FY 2016 program:

- AHRQ PSI-90 Composite
- Central Line-Associated Bloodstream Infection (CLABSI)
- Catheter-Associated Urinary Tract Infection (CAUTI)
- Colon and Abdominal Hysterectomy Surgical Site Infection (SSI)

We are not proposing to add or remove any measures for FY 2016.

In the FY 2015 IPPS/LTCH PPS final rule CMS finalized the following measures for use in the FY 2017 program:

- AHRQ PSI-90 Composite
- Central Line-Associated Bloodstream Infection (CLABSI)
- Catheter-Associated Urinary Tract Infection (CAUTI)
- Colon and Abdominal Hysterectomy Surgical Site Infection (SSI)
- Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia
- *Clostridium difficile* (CDI)

We are not proposing any changes to this measure set for FY 2017.

Proposed Applicable Time Period for the FY 2017 HAC Reduction Program:

For the Domain 1 measure (AHRQ PSI-90 Composite measure), we would use the 24-month period from July 1, 2013 through June 30, 2015 (*The claims for all Medicare FFS beneficiaries discharged during this period would be included in the calculations of measure results for FY 2017*).

For the CDC NHSN measures previously finalized for use in the FY 2017 HAC Reduction Program (CLABSI, CAUTI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI), we would use data from CYs 2014 and 2015.

The addition of a narrative rule used in the methodology to calculate the Domain 2 score:

For the FY 2015 and FY 2016 HAC Reduction Program, if a hospital reports data for at least one of the Domain 2 measures, its Domain 2 Score is based solely on the measure(s) the hospital reported and the hospital is not assigned the maximum number of points for any non-reported measure(s).

We are proposing for FY 2017 and subsequent program years that each Domain 2 measure be treated independently when determining if a score of 10 (maximal score) should be assigned to the measure for non-submission of data without a waiver (if applicable).

The relative contribution of Domain 1 (patient safety) and Domain 2 (infection) to the Total HAC Score:

For FY 2017, we are proposing to adjust the weighting of Domains 1 and 2 so that the weight of Domain 1 would be 15 percent and the weight of Domain 2 would be 85 percent.

We are proposing to decrease the Domain 1 weight for two reasons:

- First, with the implementation of the CDC MRSA Bacteremia and CDI measures in the FY 2017 program, we believe the weighting of both domains needs to be adjusted to reflect the addition of the fifth and sixth measure in Domain 2.
- Second, among the public comments on the FY 2014 and FY 2015 IPPS/LTCH PPS final rules that were considered, MedPAC and other stakeholders recommended that Domain 2 should be weighted more than Domain 1 because they believed the CDC NHSN chart-abstracted measures were more reliable and actionable than claims-based measures.

Proposal to Include Select Ward (Non-Intensive Care Unit (ICU)) Locations in Certain CDC NHSN Measures Beginning in the FY 2018 Program Year:

We are proposing measure refinements to the CDC NHSN CLABSI and CAUTI measures that were previously adopted for the HAC Reduction Program to include select ward (non-ICU) locations beginning in FY 2018. In the FY 2014 IPPS/LTCH PPS final rule, we adopted the CLABSI and CAUTI measures inclusive of pediatric and adult patients in ICUs for the HAC Reduction Program beginning with FY 2015.

We are proposing to include data from pediatric and adult medical ward, surgical ward, and medical/surgical ward locations in addition to data from adult and pediatric ICU locations for the CDC NHSN CLABSI and CAUTI measures beginning with the FY 2018 HAC Reduction Program.

Hospital Inpatient Quality Reporting (IQR) Program (Federal Register pp. 954–1091)

Proposed Removal of Hospital IQR Program Measures for the FY 2018 Payment Determination and Subsequent Years:

We are proposing to remove the following nine measures, either in their entirety or just the chart-abstracted form, from the Hospital IQR Program measure set for the FY 2018 payment determination and subsequent years:

- STK-01: Venous Thromboembolism (VTE) Prophylaxis
- STK-06: Discharged on Statin Medication
- STK-08: Stroke Education
- VTE-1: Venous Thromboembolism Prophylaxis
- VTE-2: Intensive Care Unit Venous Thromboembolism Prophylaxis
- VTE-3: Venous Thromboembolism Patients with Anticoagulation Overlap Therapy
- IMM-1: Pneumococcal Immunization
- AMI-7a: Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival
- SCIP-Inf-4: Cardiac Surgery Patients with Controlled Postoperative Blood Glucose

We are proposing to remove the chart-abstracted versions of STK-01, STK-06, STK-08, VTE-1, VTE-2, and VTE-3 because these measures are “topped-out.” However, we are proposing to retain STK-06, STK-08, VTE-1, VTE-2, and VTE-3 as electronic clinical quality measures for the FY 2018 payment determination and subsequent years.

Proposed Additional Hospital IQR Program Measures for the FY 2018 Payment Determination and Subsequent Years:

We are proposing to add eight new measures to the Hospital IQR Program for the FY 2018 payment determination and subsequent years. We are proposing to adopt seven new claims-based measures and one new structural measure:

- Hospital Survey on Patient Safety Culture (structural)
- Kidney/UTI Clinical Episode-Based Payment Measure (claims-based)
- Cellulitis Clinical Episode-Based Payment Measure (claims-based)
- Gastrointestinal Hemorrhage Clinical Episode-Based Payment Measure (claims-based)
- Lumbar Spine Fusion/Re-Fusion Clinical Episode-Based Payment Measure (claims-based)
- Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective THA/TKA (claims-based)
- Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction (claims-based)
- Excess Days in Acute Care after Hospitalization for Heart Failure (claims-based).

Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate—

We are proposing a refinement to the previously adopted Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization measure (hereinafter referred to as the CMS 30-day Pneumonia Mortality Measure), which expands the measure cohort. The previously adopted CMS 30-day Pneumonia Mortality Measure includes hospitalizations for patients with a principal discharge diagnosis of pneumonia indicating viral or bacterial pneumonia.

The proposed measure refinement would expand the measure cohort to include hospitalizations for patients with a principal discharge diagnosis of aspiration pneumonia and for patients with a principal discharge diagnosis of either sepsis or respiratory failure who also have a secondary diagnosis of pneumonia present on admission. We anticipate that this refined measure will first be publicly reported on *Hospital Compare* with the proposed cohort change in CY 2016.

Electronic Clinical Quality Measures—

In this proposed rule, we are clarifying our policy for one previously adopted voluntarily reported electronic clinical quality measure for the FY 2017 payment determination. Specifically, we are clarifying our requirements for the submission of STK-01 for CY 2015/FY 2017 payment determination.

In addition, we are proposing to expand our electronic clinical quality measure policy in order to make reporting of electronic clinical quality measures **required** for the FY 2018 payment determination and subsequent years.

Previously Adopted Voluntarily Reported Electronic Clinical Quality Measures for the FY 2017 Payment Determination

In this proposed rule, we are proposing to clarify reporting requirements for the Venous Thromboembolism (VTE) Prophylaxis (STK – 01) Measure. In the FY 2016 IPPS/LTCH PPS final rule we stated that hospitals need not report the STK-01 measure as part of the STK measure set if reporting electronically, because no electronic specification existed for STK-

01. In other words, hospitals that successfully submit STK-02, STK-03, STK-04, STK-05, STK-06, STK-08, and STK-10 as electronic clinical quality measures are not required to also chart-abstract and submit STK-01 in order to meet Hospital IQR Program requirements for the FY 2016 payment determination. However, hospitals that do not submit the specified electronic clinical quality measures must continue to chart-abstract and submit STK-01 as previously required.

We are clarifying that this policy continues for the CY 2015/FY 2017 payment determination. Hospitals that chose to submit the STK-02, STK-03, STK-04, STK-05, STK-06, STK-08, and STK-10 as electronic clinical quality measures are not required to also chart-abstract and submit STK-01 in order to meet Hospital IQR Program requirements for the FY 2017 payment determination.

Hospitals that do not submit the specified electronic clinical quality measures must continue to chart-abstract and submit STK-01 as previously required. We note that STK-01 is proposed for removal for CY 2016/FY 2018 payment determination and refer readers to section VIII.A.3.b. of the preamble of this proposed rule for more details.

Proposed Requirements for Hospitals to Report Electronic Clinical Quality Measures for the FY 2018 Payment Determination and Subsequent Years

In this proposed rule, we are proposing to expand our electronic clinical quality measure policy in order to make reporting of electronic clinical quality measures **required**, rather than voluntary, under the Hospital IQR Program.

Specifically, we are proposing that, beginning in CY 2016/FY 2018 payment determination and subsequent years, we will require hospitals to select and submit 16 electronic clinical quality measures covering three NQS domains from the 28 available electronic clinical quality measures. For the FY 2018 payment determination and subsequent years, we are proposing that hospitals must submit Q3 and Q4 data for 16 measures chosen by a hospital and reported as electronic clinical quality measures.

For example, for the FY 2018 payment determination, hospitals would be required to submit Q3 and Q4 CY 2016 data for 16 measures of their choice. This proposal is in alignment with the Medicare EHR Incentive Program, as discussed in section VIII.D.2.b. of the preamble of this proposed rule.

| Electronic Clinical Quality Measures | |
|--------------------------------------|------------|
| AMI-2 | SCIP-Inf-9 |
| AMI-7a | STK-02 |
| AMI-8a | STK-03 |
| AMI-10 | STK-04 |
| CAC-3 | STK-05 |
| EHDI-1a | STK-06 |
| ED-1 | STK-08 |
| ED-2 | STK-10 |
| HTN | VTE-1 |
| PC-01 | VTE-2 |
| PC-05 | VTE-3 |
| PN-6 | VTE-4 |
| SCIP-Inf-1a | VTE-5 |
| SCIP-Inf-2a | VTE-6 |

We will delay publicly reporting electronic clinical quality measure data submitted by hospitals for CY 2016/FY 2018 payment determination in order to allow time for us to evaluate the effectiveness of electronically reported clinical quality measure data. In the meantime, measures reported via electronic clinical quality measure will be marked with a footnote on Hospital Compare noting that: (1) the hospital submitted data via EHR; (2) data are being processed and analyzed; and (3) CMS will eventually publicly report this data once CMS determines the data to be reliable and accurate.

Six measures (ED-1, ED-2, STK-04, VTE-5, VTE-6, and PC-01) may be reported either via chart-abstraction or as electronic clinical quality measures. For the FY 2018 payment determination and subsequent years, hospitals may either report a full year of data (Q1 through Q4) in accordance with the submission requirements for chart-abstracted data, or electronically submit two quarters of data (Q3 and Q4) for each of these 6 measures. If hospitals choose to report these 6 measures electronically, the measures can be used to count toward the Hospital IQR Program's 16 required electronic clinical quality measures. Hospitals choosing to report these 6 measures via chart-abstraction must select other electronic measures to meet the requirement to report 16 electronic clinical quality measures.

In this proposed rule, for the FY 2018 payment determination, we are proposing changes to both the reporting periods and the submission deadlines.

For the FY 2018 payment determination, we are proposing that hospitals must submit both Q3 and Q4 of 2016 data for 16 measures reported as electronic clinical quality measures. We also are proposing that for the FY 2018 payment determination, hospitals must submit the electronic clinical quality measure data for these two quarters (Q3 and Q4 of 2016) within 2 months after the end of the applicable calendar year quarter. For CY 2016, these deadlines would be November 30, 2016 for Q3 and February 28, 2017 for Q4.

Proposed CY 2016/FY 2018 Payment Determination Hospital IQR Program Electronic Reporting Periods and Submission Deadlines for Eligible Hospitals

| Discharge reporting periods | Submission deadline |
|------------------------------------|----------------------------|
| January 1, 2016-March 31, 2016 | N/A |
| April 1, 2016-June 30, 2016 | N/A |
| July 1, 2016-September 30, 2016 | November 30, 2016 |
| October 1, 2016-December 31, 2016 | February 28, 2017 |

Sampling and Case Thresholds for the FY 2018 Payment Determination and Subsequent Years

*In accordance with the policy we first adopted in the FY 2011 IPPS/LTCH PPS final rule, hospitals that have not treated patients in a specific topic area must still submit quarterly population and sample size counts for all Hospital IQR Program chart-abstracted data topics. For example, if a hospital has not treated AMI patients, the hospital is still required to submit a **zero** for its quarterly aggregate population and sample count for that topic in order to meet the requirement.*

In this proposed rule, we are proposing to revise this policy so that, beginning with the FY 2018 payment determination and subsequent years, hospitals will be required to submit population and sample size data only for those measures that a hospital submits as chart-abstracted measures under the Hospital IQR Program.

This differs from the current policy in that there may be instances where a hospital chooses to electronically submit a measure that can be submitted either via chart-abstraction or as an electronic clinical quality measure and under the proposed policy, we would not require population and sample size data in this case. Under the proposed policy, if a hospital submits a measure as an electronic clinical quality measure, or if a measure becomes voluntary or suspended, the population and sample data would not be required.

HCAHPS Requirements for the FY 2018 Payment Determination and Subsequent Years

We are not proposing any changes to HCAHPS requirements. Hospitals and HCAHPS survey vendors should check the official HCAHPS Web site at <http://www.hcahpsonline.org> for new information and program updates regarding the HCAHPS Survey, its administration, oversight and data adjustments.

Data Submission Requirements for Structural Measures for the FY 2018 Payment Determination and Subsequent Years

In this proposed rule, we are not proposing any changes to data submission requirements for structural measures.

Data Submission and Reporting Requirements for Healthcare-Associated Infection (HAI) Measures Reported via NHSN

In this proposed rule, we are not proposing any changes to data submission and reporting requirements for HAI measures reported via the NHSN.

Proposed Modifications to the Existing Processes for Validation of Hospital IQR Program Data

In the FY 2015 IPPS/LTCH PPS final rule, we finalized a validation process, which included a separate validation stratum for the Influenza Immunization (NQF #1659) measure (the immunization measure validation stratum) because that measure overlapped with the Hospital VBP Program.

The finalized validation process for chart-abstracted measures included three separate validation strata:

- HAI, Immunization, and Other/Clinical Process of Care

The Immunization stratum includes only one measure, Immunization for Influenza. This Immunization measure was included in its own stratum because it is used in the Hospital VBP Program and we wanted to ensure that every hospital selected for validation would be validated in this topic area.

As discussed in section IV.F.2.b.(1) of the preamble of this proposed rule, we are proposing to remove the IMM-2 Influenza Immunization measure from the Hospital VBP Program. Given this proposed removal of the Influenza Immunization measure from the Hospital VBP Program, it is no longer necessary to ensure validation of this topic area by including a separate stratum for the Influenza measure.

We are not proposing any changes to the overall validation sample size.

Under the existing validation process, a total of eight charts are drawn for validation--five of which are drawn from the clinical process of care measures stratum and three of which are drawn from the immunization measure stratum.

Under this proposal, however, while the total number of charts drawn is the same (eight), all eight measures will be drawn from the clinical process of care measure stratum, which would then include the Influenza Immunization measure. Accordingly, one sample of charts will be drawn from the clinical process of care measures. The proposed removal of the immunization validation stratum and inclusion of the Influenza Immunization measure in the clinical process of care validation stratum would result in an expanded pool of clinical process of care topic areas sampled for validation to include STK, VTE, ED, Sepsis, and Immunization.

As described in the FY 2015 IPPS/LTCH PPS final rule, all chart-abstracted measure topic areas included in the Hospital IQR Program, with the exception of the Perinatal Care topic area, are automatically included in the validation process. We do not include this topic area because the Elective Delivery PC-01 measure is reported in aggregate form, which is not consistent with our patient-level validation process.

As a result, in this proposed rule, for the Hospital IQR Program beginning with the FY 2018 payment determination and for subsequent years, we are proposing to remove the separate immunization validation stratum and include the Influenza Immunization measure in the clinical process of care measure validation stratum. Under this proposal, we would continue to apply our chart-abstracted measure validation processes only to those chart-abstracted measures that are required under the Hospital IQR Program in a chart-abstracted form (as opposed to those measures that a hospital reports as electronic clinical quality measures, for example). This proposal is consistent with our proposed policy to require population and sample size data only for those measures that are required under the Hospital IQR Program. We refer readers to section VIII.A.10.e. of the preamble of this proposed rule for more detail on that proposal.

Data Accuracy and Completeness Acknowledgement Requirements for the FY 2018 Payment Determination and Subsequent Years

We are not proposing any changes to the DACA requirements.

Public Display Requirements for the FY 2018 Payment Determination and Subsequent Years

We refer readers to section VIII.A.8.b. of the preamble of this proposed rule, where we are proposing to delay publicly reporting electronic clinical quality measure data submitted by hospitals for CY 2016/FY 2018 payment determination in order to allow time for us to evaluate the effectiveness of electronically reported clinical quality measure data. In the meantime, measures reported via electronic clinical quality measures will be marked with a footnote on Hospital Compare noting that: (1) the hospital submitted data via EHR; (2) data are being processed and analyzed; and (3) we will eventually publicly report this data once we determine the data to be reliable and accurate.

Reconsideration and Appeal Procedures for the FY 2018 Payment Determination and Subsequent Years

We are not proposing any changes to the reconsideration and appeals procedures

Hospital IQR Program Extraordinary Circumstances Extensions or Exemptions

We are not proposing any changes to the Hospital IQR Program's extraordinary circumstances extensions or exemptions policy.

Clinical Quality Measurement for Eligible Hospitals and Critical Access Hospitals Participating in the EHR Incentive Programs in 2016

In the EHR Incentive Program Stage 3 proposed rule, beginning in 2015, we proposed to change the definition of “EHR reporting period” for EPs, eligible hospitals, and CAHs such that the EHR reporting period would begin and end in relation to a calendar year. In connection with that proposal, we are proposing that the reporting period for CQMs in 2016 for eligible hospitals and CAHs for the Medicare and Medicaid EHR Incentive Programs would also be based on the calendar year. We believe it is important to continue our goal of aligning the EHR Incentive Program with the Hospital IQR Program because alignment of these programs will serve to reduce hospital reporting burden and encourage the adoption and meaningful use of CEHRT by eligible hospitals and CAHs.

We are proposing to align the reporting period in CY 2016 for eligible hospitals and CAHs that report CQMs electronically for the Medicare EHR Incentive Program with that of the Hospital IQR Program and require quarterly reporting and submission periods for eCQMs in the 3rd and 4th CY quarters.

In addition, in this proposed rule, the Hospital IQR Program is proposing to change its submission period for eCQMs from annual to quarterly submission, and proposing to change the submission deadline from November 30, 2015 to ending 2 calendar months after the close of the reporting CY quarter (for CY 2016/FY 2018 payment determination, the proposed deadlines are November 30, 2016 for Q3 and February 28, 2017 for Q4). We refer readers to the Hospital IQR Program discussion in section VIII.A.10.d.(3) of the preamble of this proposed rule for more information about these proposals. Therefore, to coincide with the submission period in the Hospital IQR Program, we also are proposing to align the Medicare EHR Incentive Program submission period for CY 2016 with the submission period proposed for the Hospital IQR Program.

We are proposing the following CQM reporting periods and submission deadlines for eligible hospitals and CAHs participating in the Medicare EHR Incentive Program in CY 2016:

- Eligible hospitals and CAHs Reporting CQMs by Attestation
- For eligible hospitals and CAHs demonstrating meaningful use for the first time in 2016, any continuous 90-day reporting period within CY 2016; or one full calendar year reporting period for CY 2016. Attestation by February 28, 2017.
- For eligible hospitals and CAHs that demonstrated meaningful use in any year prior to 2016, one full calendar year reporting period for CY 2016. Attestation by February 28, 2017.
- Eligible hospitals and CAHs Reporting CQMs Electronically --Two full quarters of data (Q3 and Q4 of CY 2016) submitted via electronic reporting within 2 months after the close of each quarter (Q3 by November 30, 2016; Q4 by February 28, 2017).

We also are proposing that the CQM reporting period for eligible hospitals and CAHs participating in the Medicaid EHR Incentive Program would be any continuous 90-day reporting period within CY 2016 for eligible hospitals and CAHs demonstrating meaningful use for the first time; and one full calendar year reporting period of CY 2016 for eligible hospitals and CAHs that demonstrated meaningful use in any year prior to 2016. Providers should refer to their State Medicaid program for requirements on submission methods and deadlines. We note that, beginning in CY 2017 and in subsequent years, we proposed in the Stage 3 proposed rule to require a reporting period of one full calendar year for CQM reporting for all providers participating in the EHR Incentive Programs, with a limited exception for Medicaid providers demonstrating meaningful use for the first time.

Future Considerations for Electronically Specified Measures: Consideration to Implement a New Type of Measure that Utilizes Core Clinical Data Elements

We are seeking public comment on the concept of collecting core clinical data elements, and in particular, we are interested in feedback specifically regarding: (1) the use of the core clinical data elements derived from EHRs for use in risk adjustment of outcome measures as well as other types of measures; (2) the collection of additional administrative linkage variables to link a patient's episode of care from EHR data with his/her administrative claim data; and (3) the use of content exchange standards for reporting these data elements. Regarding the use of content exchange standards, we welcome input on the benefits and implementation considerations if CMS were to require QRDA-I, as well as the tradeoffs to requiring QRDA-I instead of C-CDA or other content exchange standards.

For a detailed look at CMS' concept of collecting Core Clinical Data Elements please review pages 1060 – 1075 of the Federal Register

We are inviting public comment on our proposals

CMS will accept comments on the proposed rule until June 16, 2015, at 5:00 p.m. ET and will respond to all comments in a final rule to be issued by August 1, 2015. The proposed rule can be downloaded from the *Federal Register* at: www.federalregister.gov/public-inspection.

You may submit comments in one of several ways (no duplicates, please):

1. Electronically. You may (and we encourage you to) submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the “submit a comment” tab.
2. Mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1632-P,
P.O. Box 8013,
Baltimore, MD 21244-1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. Express or overnight mail. You may send written comments via express or overnight mail to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1632-P, Mail Stop C4-26-05,

Resources:

[Preamble](#)

[Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3](#)

[Federal Register FY 2016 Proposed Rule](#)