

Supporting Statement – Part A
Quality Measures and Procedures for the Hospital Inpatient Quality Reporting Program
for the FY 2019 IPPS Annual Payment Update

A. Background

The Centers for Medicare & Medicaid Services (CMS) seeks to empower consumers to make more informed decisions about their health care and to promote higher quality of care through its quality reporting programs. The Hospital Inpatient Quality Reporting (IQR) Program was first established to implement Section 501(b) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108-173), which authorized CMS to pay hospitals that successfully reported quality measures a higher annual update to their payment rates. It builds on a voluntary Inpatient Quality Reporting program, which remains in effect. The Hospital IQR Program, formerly known as the Reporting Hospital Quality Data for Annual Payment Update program, began with an initial set of 10 measures. Section 5001(a) of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109-171) revised the mechanism used to update the standardized amount for payment for hospital inpatient operating costs. This is reflected in Sections 1886(b)(3)(B)(viii)(I) and (II) of the Social Security Act, which provide that the annual payment update (APU) will be reduced for any “subsection (d) hospital” that does not submit certain quality data in a form and manner, and at a time, specified by the Secretary.

Section 5001(a) of the DRA also expanded the scope of the Hospital IQR Program, requiring CMS to add new measures. Sections 1886(b)(3)(B)(viii)(III) through (V) of the Social Security Act required CMS to “adopt the baseline set of performance measures as set forth in the November 2005 report by the Institute of Medicine of the National Academy of Sciences,” instructed the Secretary to “add other measures that reflect consensus among affected parties,” and allowed the Secretary to “replace any measures or indicators in appropriate cases.” When adding new measures, the law required CMS when “feasible and practical” to select measures put forward by “one or more national consensus building entities.”

Many provisions of the Affordable Care Act (ACA) drove further additions to these measure sets, and by linking Hospital IQR Program data to value-based purchasing, the ACA increased both the importance of Hospital IQR Program data and the need for a broad range of indicators. Section 3013 of the ACA modified Section 931 of the Public Health Service Act by requiring that CMS “identify, not less often than triennially, gaps where no quality measures exist and existing quality measures that need improvement, updating or expansion.” Section 3025 of the ACA amended Section 1886(q)(8)(C)(i) of the Social Security Act to require public reporting of readmission rates and to require subsection (d) hospitals to submit all data that CMS determines it needs to calculate and publicly report readmission rates.

Section 3001 of the ACA added Section 1886(o) of the Social Security Act to mandate CMS’ transition from a passive supplier of health care to an active purchaser of quality care. According to Section 1886(o)(2)(A) of the Social Security Act, CMS must select measures for the Hospital Value-Based Purchasing (VBP) Program from among measures (other than measures of readmissions) in the Hospital IQR Program. Consistent with this legislation, CMS established a Hospital VBP Program, beginning effective with payment adjustments on FY 2013

discharges, which qualifies hospitals for financial incentives based on their performance on a defined set of quality measures selected for the Hospital VBP Program from those reported under the Hospital IQR Program.

1. New Hospital IQR Program Quality Measures

a. Introduction

The FY 2019 APU determination will be based on Hospital IQR Program data reported and supporting forms submitted by hospitals on chart-abstracted measures and electronic clinical quality measures (eCQMs) between January 2017 and December 2017. In an effort to reduce burden, a variety of different data collection mechanisms are employed, with every consideration taken to employ data and data collection systems already in place.

b. New Measures

In the FY 2017 IPPS/LTCH PPS Final Rule, the following new measures are being added in the Hospital IQR Program beginning with the FY 2019 payment determination: (1) Aortic Aneurysm Procedure Clinical Episode-Based Payment Measure; (2) Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment Measure; (3) Spinal Fusion Clinical Episode-Based Payment Measure; and (4) Excess Days in Acute Care after Hospitalization for Pneumonia Measure. All of these new measures are claims-based measures that can be calculated based on data that are already reported to the Medicare program for payment purposes.

c. Measures Finalized for Removal

In the FY 2017 IPPS/LTCH PPS Final Rule, the following electronic clinical quality measures are being finalized for removal from CY 2017 reporting period and subsequent years: (1) AMI-2: Aspirin Prescribed at Discharge for AMI (NQF # 0142); (2) AMI-7a: Fibrinolytic Therapy Received Within 30 minutes of Hospital Arrival; (3) AMI-10: Statin Prescribed at Discharge; (4) HTN: Healthy Term Newborn (NQF # 0716); (5) PN-6: Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients (NQF # 0147); (6) SCIP-Inf-1a: Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision (NQF #0527); (7) SCIP-Inf-2a: Prophylactic Antibiotic Selection for Surgical Patients (NQF #0528); (8) SCIP-Inf-9: Urinary Catheter Removed on Postoperative Day 1 (POD1) or Postoperative Day 2 (POD2) with Day of Surgery Being Day Zero; (9) STK-4 Thrombolytic Therapy (NQF #0437) [in both chart-abstracted and eCQM forms]; (10) VTE-3: Venous Thromboembolism Patients with Anticoagulation Overlap Therapy (NQF #0373); (11) VTE-4: Venous Thromboembolism Patients Receiving Unfractionated Heparin (UFH) with Dosages/Platelet Count Monitoring by Protocol (or Nomogram); (12) VTE-5: Venous Thromboembolism Discharge Instructions [in both chart-abstracted and eCQM forms]; and (13) VTE-6: Incidence of Potentially Preventable Venous Thromboembolism. In addition, the following two structural measures are being finalized for removal from CY 2017 reporting period and subsequent years: (14) Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care; and (15) Participation in a Systematic Clinical Database Registry for General Surgery.

We discuss the burden reduction associated with the removal of the two chart-abstracted measures below in section 12. With regard to the removal of the 13 eCQMs, there will be a modest reduction in burden associated with the decreased number of eCQMs from which hospitals may choose, however, it will be offset by the increased burden associated with submitting data on 8 eCQMs instead of 4 eCQMs, and for 3 additional quarters of data. Lastly, there will be a negligible burden reduction due to the removal of two structural measures. We have previously estimated a burden of 15 minutes per hospital to report structural measures (80 FR 49762), as such we maintain this burden estimate, and believe the reduction in burden associated with removing these two structural measures will be sufficiently minimal that it will not substantially impact this estimate.

d. Electronic Clinical Quality Measures (eCQMs)

In the FY 2017 IPPS/LTCH PPS Final Rule, for the CY 2017 reporting period/FY 2019 payment determination and the CY 2018 reporting period/FY 2020 payment determination, we required that hospitals must submit data for 8 self-selected eCQMs among the available eCQMs in the Hospital IQR Program. We also are finalizing that hospitals are required to submit all four quarters of eCQM data on an annual basis by the end of two months following the end of the reporting period calendar year (e.g., by February 28, 2018 for the CY 2017 reporting period). Although there are no new eCQMs being added to the Hospital IQR Program, the eCQM reporting requirements are changing from 4 eCQMs to 8 eCQMs and from one quarter of data to four quarters of data in comparison to the reporting requirements for the CY 2016 reporting period/FY 2018 payment determination that was adopted in the FY 2016 IPPS/LTCH PPS Final Rule. Additionally, we are finalizing an expansion of our existing validation process to include the validation of eCQM data. Lastly, we are finalizing an update of our Extraordinary Circumstances Extension/Exemption (ECE) policy by: (1) extending the general ECE request deadline for non-eCQM circumstances from 30 to 90 calendar days following an extraordinary circumstance; and (2) establishing a separate submission deadline for ECE requests with respect to eCQM reporting circumstances of April 1st following the end of the reporting calendar year.

e. Forms Used in the Data Collection Process

In order to facilitate the quality data reporting programs, several forms are necessary. These forms include:

- Hospital Inpatient Quality Reporting Notice of Participation
- Hospital Inpatient Quality Reporting (IQR) Program Data Accuracy and Completeness Acknowledgement (DACA)
- Inpatient Hospital Compare Request for Withholding Data from Public Reporting Form
- Centers for Medicare & Medicaid Services (CMS) Inpatient Prospective Payment System (IPPS) Quality Reporting Programs Measure Exception Form
- CMS Quality Reporting Program APU Reconsideration Request Form
- Hospital Value-Based Purchasing (VBP) Program Review and Corrections Request Form
- Hospital Value-Based Purchasing (VBP) Program Appeal Request Form
- Hospital Value-Based Purchasing (VBP) Program Independent CMS Review Request Form

- Centers for Medicare & Medicaid Services (CMS) Quality Reporting Program Extraordinary Circumstances Extension/Exemption (ECE) Request Form
- CMS Hospital IQR Program Validation Review for Reconsideration Request Form
- Validation templates for each of the following measures:
 - Central line-associated bloodstream infection (CLABSI);
 - Catheter-associated urinary tract infection (CAUTI);
 - Methicillin-resistant Staphylococcus Aureus (MRSA); and
 - Clostridium Difficile infection (CDI).

Only the Data Accuracy and Completeness Acknowledgment (DACA) form must be completed by all hospitals participating in the Hospital IQR Program each year. This form only requires a hospital to check a box affirming the accuracy and completeness of the data reported. The remainder of the forms are exceptions, exemptions, or one time only forms, and hospitals may not need to complete any of these forms in any given year.

The submission instructions and definitions for the four Validation templates associated with the CLABSI, CAUTI, MRSA, and CDI measures are being revised with this PRA package to reflect the annual changes in fiscal year and beginning reporting quarter, as well as new CDC pathogen lists. Six additional information collection forms listed above are being revised with this PRA package: (1) Data Accuracy and Completeness Acknowledgement (DACA); (2) Inpatient Hospital Compare Request for Withholding Data from Public Reporting Form; (3) Hospital Value-Based Purchasing (VBP) Program Review and Corrections Request Form; (4) Hospital Value-Based Purchasing (VBP) Program Appeal Request Form; (5) CMS Quality Reporting Program Extraordinary Circumstances Extension/Exemption (ECE) Request Form; and (6) CMS Hospital IQR Program Validation Review for Reconsideration Request Form. In addition, we have developed a new form, which is the Hospital Value-Based Purchasing (VBP) Program Independent CMS Review Request Form. Three of the information collection forms listed above will continue to be used in the Hospital IQR Program but are not being revised with this PRA package: (1) Hospital Inpatient Quality Reporting Notice of Participation; (2) CMS Inpatient Prospective Payment System (IPPS) Quality Reporting Programs Measure Exception Form; and (3) CMS Quality Reporting Program APU Reconsideration Request Form.

The Data Accuracy and Completeness Acknowledgement (DACA) is being modified to: (1) update the applicable program year; (2) remove the language “if submitted” for eQMs, since submission for the Hospital IQR Program is mandatory per the FY 2016 IPPS/LTCH PPS Final Rule (80 FR 49693 through 49698); and (3) add the Influenza Vaccination Coverage Among Healthcare Personnel (HCP) measure per the FY 2012 IPPS/LTCH PPS Final Rule (76 FR 51636 through 51637).

The Inpatient Hospital Compare Request for Withholding Data from Public Reporting Form is being modified to remove the statement regarding notification authority and to add new measures for the upcoming July 2016 preview period and October 2016 *Hospital Compare* release.

The Hospital Value-Based Purchasing (VBP) Program Review and Corrections Request Form and the Hospital Value-Based Purchasing (VBP) Program Appeal Request Form are being

modified to include *QualityNet* secure web portal submission information, per the FY 2013 IPPS/LTCH PPS Final Rule (77 FR 53580 through 53581).

The CMS Quality Reporting Program Extraordinary Circumstances Extension/Exemption Request Form is being modified to reflect the finalized updated submission deadlines for non-eCQM and eCQM related requests for the Hospital IQR Program and other quality reporting programs. Specifically, the form indicates that for non-eCQM circumstances, the request must be submitted within 90 calendar days of an extraordinary circumstance event for all programs. In addition, the form now indicates that for eCQM reporting circumstances in the Hospital IQR Program, the request must be submitted by April 1st following the end of a reporting period calendar year, which is intended to align with the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs' typical deadline of April 1st. In the FY 2016 IPPS/LTCH PPS Final Rule (80 FR 49713), CMS finalized a policy that hospitals may use the Extraordinary Circumstances Extension/Exemption Request Form to request an exemption from the Hospital IQR Program's eCQM reporting requirement under certain circumstances. Additionally, the form was modified to include extraordinary circumstance extension or exemption requests for the End Stage Renal Disease (ESRD) Quality Incentive Program.

The CMS Hospital IQR Program Validation Review for Reconsideration Request Form is being modified to add the submission deadline, which is no later than 30 days from the date identified on the Hospital IQR Program Annual Payment Update Notification Letter provided to the hospital, as codified at 42 CFR § 412.140(e).

The Hospital Value-Based Purchasing (VBP) Program Independent CMS Review Request Form is being instituted as part of the independent CMS review process for the Hospital VBP Program, as finalized in the CY 2014 OPPI Final Rule (78 FR 75120). The independent CMS review process was implemented as an additional appeal process available to hospitals, beyond the existing review and corrections process (77 FR 53578 through 53581 and 76 FR 74544 through 74547) and appeal process codified at 42 CFR § 412.167.

B. Justification

1. Need and Legal Basis

Continued improvement of the quality measure set is consistent with the letter and spirit of both the DRA and the ACA. CMS' transition from a passive reporter of quality information to an active purchaser of care under the Hospital VBP Program in particular raises the stakes for meaningful quality measurement in a manner that reflects the breadth of quality care delivered in the hospital. As reflected by the addition of four new claims-based measures, and the removal of fifteen measures (2 structural measures and 13 eCQMs, including 2 measures in both electronic and chart-abstracted forms), every effort has been made to reduce burden by using secondary data or removing measures based upon our established measure removal criteria. However, claims-based measures have the disadvantage of not representing patients across all population and payer groups and also are limited in the depth of information available.

To begin participation in the Hospital IQR Program, all hospitals must complete a Hospital Inpatient Quality Reporting Notice of Participation. The Notice of Participation explains the participation and reporting requirements for the program. Subsection (d) hospitals covered under Section 5001(b) of the DRA must complete this Notice of Participation. The form explains that in order to receive the full market basket update (or APU), the hospitals are agreeing to allow CMS to publish their data for public viewing according to Sections 1886(b)(3)(B)(viii)(I) and (II) of the Social Security Act. Hospitals not covered under Section 5001(b) of the DRA may also wish to voluntarily submit data and have their data published for public viewing. In order to accommodate those hospitals, and to allow hospitals covered under Section 5001(b) of the DRA to submit data on measures that may not be required under Sections 1886(b)(3)(B)(viii)(I) and (II) of the Social Security Act, a separate section of the participation form has been developed. This participation portion gives CMS permission to collect and publish data that are voluntarily submitted by a hospital. These hospitals may choose to suppress a measure or measures prior to their posting on the CMS *Hospital Compare* website. In order to reduce burden, a hospital that indicated its intent to participate will be considered an active Hospital IQR Program participant until the hospital submits a withdrawal to CMS. Hospitals that no longer wish to participate in the Hospital IQR Program or those that no longer wish to submit data for publishing on *Hospital Compare* can notify CMS of their decision via the same Notice of Participation form discussed above.

Annually, subsection (d) hospitals covered under Section 5001(b) of the DRA must complete a Data Accuracy and Completeness Acknowledgment (DACA) form at the end of each reporting year. This requirement was added based on a U.S. Government Accountability Office report from 2006 that recommended that CMS require hospitals to “formally attest to the completeness of the quality data that they submit.” This form is simply an acknowledgement that the data a hospital has submitted are complete and accurate and is completed annually.

Hospitals that submit data not required by Sections 1886(b)(3)(B)(viii)(I) and (II) of the Social Security Act may elect to have those data withheld from public reporting by completing the Inpatient Hospital Compare Request for Withholding Data from Public Reporting Form. Once the form is submitted, data can be withheld for the quarter in which the form is submitted. However, the data will be released on *Hospital Compare* for subsequent releases unless the hospital submits a new Request for Withholding Data from Public Reporting Form indicating the measures the hospital would like to withhold from public reporting for the period.

CMS performs a random selection of up to 600 subsection (d) hospitals participating in the Hospital IQR Program on an annual basis for validation of chart-abstracted measures. Each hospital selected for validation is to produce a list of patients/lab results associated with the particular measure being validated. This process includes the use of validation templates for each of the CLABSI, CAUTI, MRSA, and CDI measures. In the FY 2015 IPPS/LTCH PPS Final Rule (79 FR 50262 through 50273), we finalized our policy to divide these 600 hospitals selected for validation into two halves: approximately 300 would need to produce the CLABSI and CAUTI templates and the other 300 hospitals would need to only produce the MRSA and CDI templates. In the FY 2017 IPPS/LTCH PPS Final Rule, we are finalizing the expansion of the existing process for validation of Hospital IQR Program data to include eCQM data

validation for up to 200 randomly selected hospitals, for a total of up to 800 hospitals for validation for the FY 2020 payment determination and subsequent years.

Hospitals that do not treat the conditions or do not have treatment locations defined for the National Healthcare Safety Network's (NHSN) Healthcare-Associated Infection (HAI) measures used in the Hospital IQR Program (CLABSI, CAUTI, and Surgical Site Infection) have the option to either complete the enrollment process with NHSN and indicate that they do not have patients who meet the measures requirements or they can submit a CMS Inpatient Prospective Payment System (IPPS) Quality Reporting Programs Measure Exception Form. Hospitals that do not have an Obstetrics Department and do not deliver babies also may use the Measure Exception Form for the PC-01: Elective Delivery measure. In addition, hospitals that do not have an Emergency Department (ED) and do not provide emergency care may use the Measure Exception Form for the ED-1: Median Time from ED Arrival to ED Departure Time for Admitted ED Patients measure and the ED-2: Admit Decision Time to ED Departure Time for Admitted Patients measure. The Measure Exception Form will reduce the burden of completing the entire NHSN enrollment process or entering zero denominator information for inapplicable measures for the hospitals that meet the exception requirements.

When CMS determines that a hospital did not meet one or more of the Hospital IQR Program requirement(s), the hospital may submit a request for reconsideration to CMS using the CMS Quality Reporting Program APU Reconsideration Request Form, by the deadline identified on the Hospital IQR Program Annual Payment Update Notification Letter it received.

Hospitals may appeal the calculation of their performance assessment with respect to the performance standards, as well as their Total Performance Score (TPS), for the Hospital VBP Program. Hospitals may review and request recalculation of their hospital's performance scores on each condition, domain, and TPS using the Hospital Value-Based Purchasing (VBP) Program Review and Corrections Request Form within 30 calendar days of the posting date of the Value-Based Percentage Payment Summary Report. Hospitals may submit an appeal using the Hospital Value-Based Purchasing (VBP) Program Appeal Request Form within 30 calendar days of the date of receiving an adverse determination from CMS on their review and corrections request. Hospitals may submit a Hospital Value-Based Purchasing (VBP) Program Independent CMS Review Request Form within 30 days after they receive an adverse determination from CMS on their appeal.

Per the FY 2017 IPPS/LTCH PPS Final Rule, the CMS Quality Reporting Program Extraordinary Circumstances Extension/Exemption (ECE) Request Form is being modified to reflect the updated submission deadlines for non-eCQM and eCQM requests for the Hospital IQR Program and other quality reporting programs. Specifically, the form indicates that for non-eCQM circumstances, the request must be submitted within 90 calendar days of an extraordinary circumstance for all programs. In addition, the form now indicates that a separate submission deadline for eCQM reporting circumstances in the Hospital IQR Program measure set is April 1st following the end of the reporting period calendar year to align with the Medicare and Medicaid EHR Incentive Programs' typical deadline of April 1st. Per policy finalized in the FY 2016 IPPS/LTCH PPS Final Rule (80 FR 49713), hospitals may utilize the existing Extraordinary

Circumstances Extension/Exemption (ECE) Request Form to request an exemption from the Hospital IQR Program's eCQM reporting requirement under certain circumstances.

The Validation templates for the CLABSI, CAUTI, MRSA, and CDI measures in the Hospital IQR Program are updated annually with each new selection of hospitals for validation. Currently, the templates are only utilized by up to 600 hospitals annually that have been selected for validation (400 hospitals are randomly selected for validation and up to 200 additional hospitals are chosen based on targeting criteria (78 FR 50833)). In the FY 2017 IPPS/LTCH PPS Final Rule, CMS finalized an expansion of the existing validation process to also include validation of eCQM data for up to 200 hospitals (for a total of 800 hospitals to be selected for annual validation), beginning with the FY 2020 payment determination.

2. Information Users

CMS will use the information collected for the Hospital VBP Program to set payment adjustments for value-based purchasing. The information will be made available to hospitals for their use in internal quality improvement initiatives. The information is used by CMS to direct its contractors to focus on particular areas of improvement and to develop quality improvement initiatives. Most importantly, this information is available to beneficiaries, as well as to the public, to provide hospital information to assist them in making decisions in choosing their health care providers. CMS sometimes conducts focus groups or market testing prior to publicly reporting hospital quality data on the *Hospital Compare* website in order to get feedback on ways to make the website more user-friendly. We refer readers to section A.1.e of this document for more details on the specific forms that are being used for the Hospital VBP Program.

3. Use of Information Technology

To assist hospitals in standardizing data collection initiatives across the industry, CMS continues to improve data collection tools in order to make data submission easier for hospitals (e.g., the collection of electronic patient data in EHRs for eCQMs, the collection of data from paper medical records for chart-abstracted measures, or the collection of data from clinical registries for structural measures), as well as increase the utility of the data provided by the hospitals.

For the claims-based measures, this section is not applicable, because claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes. Therefore, no additional information technology will be required for hospitals for these measures.

4. Duplication of Similar Information

The information to be collected is not duplicative of similar information collected by CMS. The purpose of this effort is to reduce the reporting burden for the collection of quality of care information by allowing hospitals to submit electronic data in lieu of submitting paper charts or to utilize electronic data that they currently report to The Joint Commission for accreditation. As required by statute, CMS maintains a set of quality measures which a hospital must report in order to receive the full APU, and to qualify for payment incentives under the Hospital VBP

Program. Except as otherwise noted above, all measures are aligned with The Joint Commission whenever possible. The Joint Commission-accredited hospitals already collect and submit data on all chart-abstracted measures in the expanded set.

5. Small Business

Information collection requirements were designed to allow maximum flexibility specifically to small hospitals wishing to participate in hospital reporting. This effort will assist small hospitals in gathering information for their own quality improvement efforts. We define a “small hospital” as one with 1-99 inpatient beds. The Hospital IQR Program includes 990 participating small hospitals in the FY 2018 program year.

6. Less Frequent Collection

We have designed the collection of quality measure data to be the minimum necessary for data validation and calculation of summary figures to be used as reliable estimates of hospital performance. Data collection may vary (monthly, quarterly, annually, etc.) based on how a quality measure is specified. Please refer to Table 2, in section B. 12 of this document for the data provided for the Hospital IQR Program measure set.

7. Special Circumstances

Although participation in the Hospital IQR Program is voluntary on the part of subsection (d) hospitals, all eligible hospitals must submit these data and meet all other Hospital IQR Program requirements in order to receive their full APU for the given fiscal year. If a hospital does not submit the required data and meet all other Hospital IQR Program requirements, it would be subject to a reduced APU for a given fiscal year.

8. Federal Register Notice/Outside Consultation

A 60-day *Federal Register* notice of the FY 2017 IPPS/LTCH PPS Proposed Rule (81 FR 24946 et seq.) went on display on April 18, 2016 and was published on April 27, 2016. Comments were submitted on this notice, and CMS responded to those comments accordingly in the FY 2017 IPPS/LTCH PPS Final Rule (81 FR 56762 et seq.), which went on display on August 2, 2016 and was published in the *Federal Register* on August 22, 2016.

CMS is supported in this initiative by The Joint Commission, National Quality Forum (NQF), Measures Application Partnership, Centers for Disease Control and Prevention, and Agency for Healthcare Research and Quality. These organizations collaborate with CMS on an ongoing basis, providing technical assistance in developing and/or identifying quality measures, and assisting in making the information accessible, understandable, and relevant to the public.

9. Payment/Gift to Respondent

Under Section 1886(b)(3)(B)(viii) of the Social Security Act, as modified by both the MMA and the DRA, hospitals are required to submit these data in order to receive their full APU and to

qualify for additional Hospital VBP Program incentives under Section 1886(o) of the Social Security Act. No other payments or gifts will be given to respondents for participation.

10. Confidentiality

All information collected under this initiative will be maintained in strict accordance with statutes and regulations governing confidentiality requirements for Quality Improvement Organizations, which can be found at 42 CFR Part 480. In addition, the tools used for transmission of data are considered confidential forms of communication and are Health Insurance Portability and Accountability Act (HIPAA) compliant. The CMS clinical data warehouse also voluntarily meets or exceeds the HIPAA standards.

11. Sensitive Questions

Case-specific clinical data elements will be collected and are necessary to calculate statistical measures. These statistical measures are the basis of all subsequent improvement initiatives derived from this collection and cannot be calculated without the case specific data. These sensitive data will not, however, be released to the public. Only hospital-specific data will be released to the public after consent has been received from the hospital for the release. The patient-specific data remaining in the CMS clinical data warehouse after the data are aggregated for release for public reporting will continue to be subject to the strict confidentiality regulations in 42 CFR Part 480.

12. Burden Estimate (Total Hours & Wages)

This burden estimate includes newly finalized measures and existing measures used in the program, as well as other activities resulting in hospital reporting burden. It excludes burden associated with the NHSN and HCAHPS measures, which are submitted under separate OMB control numbers.

The assumptions used to compute these estimates are described below. All abstraction time estimates for the global (ED/IMM) population sets came directly from our Clinical Data Abstraction Contractor (CDAC) experience. Numbers of cases per topic area for these measure sets and stroke and VTE were extrapolated from data submitted to the clinical data warehouse between the 3rd quarter in 2014 and the 2nd quarter in 2015. Based on that time period, the individual measure set data are as follows:

Table 1. Hospital IQR Program Measure Set Data

Name of Measure Set	Number of Measures in Set
Emergency department (ED) throughput	2
Immunizations (IMM)	1
Stroke (STK)	4
Venous thromboembolism (VTE)	4
Sepsis	1

Perinatal Care (PC)	1
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Volume estimates for the perinatal care and sepsis measures were estimated from data on the number of expected claims per hospital from the National Hospital Discharge Survey 2010. Abstraction time estimates per record for perinatal care and sepsis were assessed based on complexity and similarity with other measure sets. The mean times reported by our CDAC are rounded to the nearest five minutes and used for all hospitals.

The total time required per hospital is highly variable. The time required per record measure set also varies. The number of records per hospital per measure set depends on the bed size of the hospital and the patient case mix. Moreover, the distribution of hospital bed sizes varies by measure set.

With regard to the Hospital IQR Program requirements finalized for the FY 2019 payment determination, we estimate a total burden decrease of 1,717,444 hours associated with our finalized policy changes, which equates to a decrease of approximately \$56.4 million. Overall, we estimate a total burden decrease of 2.1 million hours for 3,300 IPPS hospitals and a burden decrease of 83,000 hours for another 1,100 non-IPPS hospitals, for a total decrease of approximately 2.2 million hours associated with the FY 2017 IPPS/LTCH PPS Final Rule policies (i.e., removal of measures, addition of measures, increased eCQM reporting requirements, and expansion of the data validation process) and also as a result of updated measure collection calculations (i.e., the amount of time to collect data for a certain measure set). The average reporting burden per hospital is smaller for non-IPPS hospitals than for IPPS hospitals. This is mainly because the non-IPPS hospitals submit measures voluntarily and therefore may choose to do so for only a subset of the measure sets.

The estimated total burden decrease of 1,717,444 hours was calculated as follows:

With regard to removal of the chart-abstracted form of the STK-4 measure per the FY 2017 IPPS/LTCH PPS Final Rule, because it was the only STK measure left in the Hospital IQR Program, we calculated the total burden hours as follows: 0 hours (time required to report in CY 2017) - 303,534 hours (time required to report in CY 2016) = -303,534 hours for the STK measure set. With regard to the VTE measure set, we used an updated estimate (based on data from the third quarter of 2014 through second quarter of 2015) that the time per record (that is, to report all 4 of the VTE measures in the Hospital IQR Program during the noted time period) is 28 minutes; thus we estimated a burden reduction of 7 minutes for removing one VTE measure. Based on this estimate, we deducted 21 minutes from the 28 minute estimate to account for the removal of VTE-1, VTE-2, and VTE-3 per the FY 2016 IPPS/LTCH PPS Final Rule (80 FR 49645) and subsequent removal of VTE-5 per the FY 2017 IPPS/LTCH PPS Final Rule, for a total of 7 minutes to report on the one remaining VTE-6 chart-abstracted measure in the Hospital IQR Program. We then calculated the estimated total hours of burden per hospital for reporting the remaining VTE-6 measure as follows: 7 minutes per record/60 minutes per hour x 4 reporting quarters per year x 198.05 records per hospital per quarter = 92.4233333 burden hours per hospital. Because there are 3,300 IPPS hospitals, we then multiplied 92.4233333 hours per hospital x 3,300 hospitals to get a total annual burden estimate of 304,997 hours to report the one remaining measure in the VTE measure set (i.e., VTE-6). The reduction in the total burden

hours for VTE per the FY 2017 IPPS/LTCH PPS Final Rule is calculated as follows: 304,997 (FY 2017 total annual estimate) - 1,742,840 (FY 2016 total annual estimate) = -1,437,843 hours for the VTE measure set.

We believe that the total burden associated with the eCQM reporting policy per the FY 2017 IPPS/LTCH PPS Final Rule will be similar to that previously outlined in the Medicare EHR Incentive Program’s meaningful use Stage 2 final rule (77 FR 54126 through 54133). In that final rule, the burden estimate for a hospital to report all 16 eCQMs is 2 hours and 40 minutes (160 total minutes, or 10 minutes per measure) per submission for a 3 month period (77 FR 54127). We believe that this estimate is accurate and appropriate to apply to the Hospital IQR Program because we are aligning the eCQM reporting requirements between both programs. Therefore, using the estimate of 10 minutes per measure per quarter, we expect our eCQM reporting policy requiring hospitals to report data on 8 eCQMs for 4 quarters to represent a burden increase of 15,400 hours across all 3,300 IPPS hospitals participating in the Hospital IQR Program. This figure was derived by calculating the difference between the FY 2017 burden estimate of 17,600 hours (80 minutes per record/60 minutes per hour x 4 reporting quarters per year x 1 record per hospital per quarter x 3,300 hospitals) and the FY 2016 burden estimate of 2,200 hours (20 minutes per record/60 minutes per hour x 1 reporting quarter per year x 1 record per hospital per quarter x 3,300 hospitals) (80 FR 49763), for an incremental increase of 15,400 hours.

Lastly, we derived the estimate associated with the expansion of the existing validation process for the Hospital IQR Program to include validation of eCQM data based on previous years’ calculations. Historically, we estimated a total burden of 16 hours (960 minutes) for the submission of 12 records, which will equal 1 hour and 20 minutes per record (960 minutes/12 records) (79 FR 50347). Applying the time per individual submission of 1 hour and 20 minutes (or 80 minutes) for the 32 records that hospitals would submit beginning with the FY 2020 payment determination, we estimate a total burden of approximately 43 hours (80 minutes x 32 records/60 = 42.6666667) for each hospital selected for participation in eCQM data validation. We estimate that 42.6666667 hours of work for up to 200 hospitals will increase the eCQM data validation burden hours from 0 hours (as this is the first instance where eCQM data validation is being added as a requirement) to 8,533 labor hours (42.6666667 hours/hospital x 200 hospitals).

Therefore, to calculate the total burden change due to the FY 2017 IPPS/LTCH PPS Final Rule policies finalized for the Hospital IQR Program, we added -303,534 hours for the STK measure set + -1,437,843 hours for the VTE measure set + 15,400 hours for eCQM reporting + 8,533 hours for eCQM data validation to get a total of -1,717,444 hours across all 3,300 IPPS hospitals.

Table 2. Burden Calculations for the HIQR Measure Sets and Other Activities for FY 2017

<i>Measure Set</i>	<i>Estimated time per record (minutes)</i>	<i>Number reporting quarters per year</i>	<i>Number of hospitals reportin</i>	<i>Average number records per</i>	<i>Annual burden (hours) per</i>	<i>Calculation for FY 2019 payment</i>
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	<i>FY 2019 payment determinatio n</i>	<i>FY 2019 payment determinat ion</i>	<i>g</i>	<i>hospital per quarter</i>	<i>Hospital</i>	<i>determinati on</i>
CHART ABSTRACTION						
IPPS Hospitals (3,300)						
Emergency department (ED) throughput/Immunizations (IMM)	28	4	3,300	260	485	1,599,074
Stroke (STK)	0	4	3,300	39	0	0
Venous thromboembolism (VTE)	7	4	3,300	198	92	304,997
Sepsis Measure	60	4	3,300	100	400	1,320,000
Perinatal care (PC)	10	4	3,300	76	51	167,200
Subtotal IPPS chart-based					1027.66	3,391,271
Non-IPPS Hospitals (1,100)						
Heart failure (HF)	15	4	1,100	0	0	0
Pneumonia (PN)	35	4	1,100	0	0	0
Surgical care improvement project (SCIP)	50	4	1,100	0	0	0
Emergency department (ED) throughput/Immunizations (IMM)	35	4	1,100	55	128	140,320
Stroke (STK)	0	4	1,100	1	0	0

Venous thromboembolism (VTE)	7	4	1,100	27	13	13,932
Sepsis Measures	60	4	3,300	0	0	0
Perinatal care (PC)	10	4	1,100	21	14	15,400
Subtotal Non-IPPS chart-based						169,652
Subtotal IPPS and Non-IPPS chart-based						3,560,923
OTHER ACTIVITIES						
All Hospitals (3,300 IPPS + 1,100 non-IPPS)						
Population and sampling for 8 ongoing measure sets	15	4	4,400	8	8	35,000
Review reports for claims-based measure sets	60	4	4,400	1	4	20,000
HAI Validation Templates (CLABSI, CAUTI)	1,200	3	300	1	60	18,000
HAI Validation Templates (MRSA, CDI)	960	3	300	1	48	14,000
Reporting all available electronic Clinical Quality Measures (IPPS)	80	4	3,300	1	5.33	17,600
Reporting all available electronic Clinical Quality Measures (non-IPPS)	80	4	1,100	1	5.33	5,867
eCQM Validation	80	1	200	8	43	8,533
All other forms used in the data	15	1	4,400	1	0.25	1,100

collection process and structural measures						
Subtotal other activities						120,000
Total						<u>3,681,023</u>

Time estimates for activities other than abstracting charts, including completion of web-based forms for structural measures, completion of the forms listed in section A.1.e above other than the HAI Validation Templates, routine reporting of population and sampling numbers for ongoing measures, set up and reporting of population and sampling for new measures, and review of reports were made in consultation with our Hospital IQR Program support contractor, which is responsible for routine interface with hospitals and Quality Improvement Organizations regarding Hospital IQR Program requirements. We define “*all other forms used in the data collection process*” as the forms listed in section A.1.e above other than the HAI Validation Templates, which are included in the burden estimate for validation. Consistent with what we stated in the FY 2016 IPPS/LTCH PPS Final Rule, we estimate a burden of 15 minutes per hospital to complete applicable forms and also to report structural measure data. The estimate of 15 minutes includes all previously adopted structural measures in the Hospital IQR Program (80 FR 49762).

The burden associated with “*all other forms used in the data collection process*” is expected to be negligible, as they will not be filled out by hospitals on a regular basis. Because the CMS Quality Reporting Program Extraordinary Circumstances Extension/Exemption (ECE) Request Form will be used across nine quality reporting programs (Hospital Inpatient, Inpatient Psychiatric Facility, PPS-Exempt Cancer Hospital, Hospital Value Based-Purchasing, Hospital-Acquired Condition Reduction, Hospital Readmissions Reduction, Hospital Outpatient, Ambulatory Surgical Centers, and the ESRD Quality Incentive Program), we included a burden calculation using this form as an example of “all other forms” within this PRA package. This form is intended to be submitted by participants only in the event of an extraordinary circumstance or disaster if they seek an extension or exemption from data reporting requirements due to such extraordinary circumstance. In CY 2015, 25 ECE requests were submitted by hospitals for an extension or exemption from reporting requirements in the Hospital IQR Program. Based on our estimation of 15 minutes/record to submit the Extraordinary Circumstances Extension/Exemption (ECE) Request Form, the total burden calculation for the submission of 25 ECE requests was 375 minutes (or 6.25 hours) across 3,300 IPPS hospitals. Note that non-IPPS hospitals have no need for this form because they participate in quality data reporting on a voluntary basis. We were conservative in our estimate (provided in Table 2 above) of 1,100 hours across IPPS and non-IPPS hospitals, thus this 375 minute ECE Request form burden estimation is accounted for in that figure.

As noted in Table 2 above, we anticipate that the approximately 3.7 million hours of labor will be completed by Medical Records and Health Information Technicians for all of the activities associated with the Hospital IQR Program for 3,300 IPPS hospitals and 1,100 non-IPPS

hospitals. These staff are qualified to complete the tasks associated with the chart-abstraction of patient data from medical records, the submission of electronic data from EHRs, the submission of data to clinical registries, and the completion of any of the other applicable forms associated with activities related to the Hospital IQR Program. The labor performed can be accomplished by these staff with a mean hourly wage in general medical and surgical hospitals of \$16.42 per hour;¹ however, obtaining data on other overhead costs is challenging. Overhead costs vary greatly across industries and firm sizes. In addition, the precise cost elements assigned as “indirect” or “overhead” costs, as opposed to direct costs or employee wages, are subject to some interpretation at the firm level. Therefore, we have chosen to calculate the cost of overhead at 100% of the mean hourly wage. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method. This is a change from how we have previously accounted for the cost of overhead in the Hospital IQR Program. Therefore, using these assumptions, we estimate an hourly labor cost of \$32.84 (\$16.42 base salary + \$16.42 fringe). Accordingly, we estimate the total annual burden would be about \$121 million (3.7 million hours x \$32.84 hourly labor rate).

13. Capital Costs (Maintenance of Capital Costs)

There are no capital costs.

14. Cost to Federal Government

The cost to the Federal Government includes costs associated with the collection and validation of the data. These costs are estimated at \$10,050,000 annually for the validation and quality reporting contracts. Additionally, this program takes three CMS staff at a GS-13 level to operate. GS-13 approximate annual salary is \$92,000 for an additional cost of \$276,000.

For the claims-based measures, the cost to the Federal Government is minimal. CMS uses data from the CMS National Claims History system that are already being collected for provider reimbursement; therefore, no additional data will need to be submitted by hospitals for claims-based measures.

¹ <http://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm>

15. Program or Burden Changes

Section 3013 of ACA modified Section 931 of the Public Health Service Act by requiring CMS to “identify, not less often than triennially, gaps where no quality measures exist and existing quality measures that need improvement, updating or expansion”; and Section 1886(o) of the Social Security Act requires CMS to use data reported through the Hospital IQR Program for its Hospital VBP Program. To implement these requirements, as described above, in the FY 2017 IPPS/LTCH PPS Final Rule we are finalizing the addition of four new measures and the removal of fifteen measures. We also are finalizing a modified version of our initial proposal, such that hospitals will be required to report a full four quarters of data on an annual basis for eight of the available eQMs for the CY 2017 reporting period/FY 2019 payment determination and the CY 2018 reporting period/FY 2020 payment determination, which is an increase from the CY 2016 reporting period/FY 2018 payment determination for which hospitals are required to report only one quarter of data for four eQMs. Finally, in the FY 2017 IPPS/LTCH PPS Final Rule we are finalizing an expansion to our existing validation process to include validation of eQm data. As a result of these finalized policy changes, we estimate an overall decrease in total hospital costs.

The long-term vision for the Hospital IQR Program is to encourage hospitals to submit data directly from their electronic health records, which we anticipate will reduce burden substantially. Requiring hospitals to electronically report a greater number of eQMs furthers our goal of expanding electronic reporting in the Hospital IQR Program, which we further believe will improve patient outcomes by providing more robust and timely data to support quality improvement efforts. While our finalized requirements increase the number of required eQMs that must be reported as compared to that required for the CY 2016 reporting period/FY 2018 payment determination (i.e., from 4 to 8 eQMs), we believe that a coordinated reduction in the overall number of eQMs (from 28 to 15 eQMs) in the Hospital IQR and the Medicare and Medicaid EHR Incentive Programs will reduce certification burden on hospitals and improve the quality of reported data by enabling hospitals to focus on a smaller, more specific subset of eQMs.

16. Publication/Tabulation Data

The goal of the data collection is to tabulate and publish hospital-specific data. We will continue to display quality information for public viewing as required for the Hospital IQR Program by Section 1886(b)(3)(B)(viii)(VII) of the Social Security Act and for the Hospital VBP Program by Section 1886(o)(10) of the Social Security Act. Hospital IQR Program data from this initiative are currently used to populate the *Hospital Compare* website, www.hospitalcompare.hhs.gov. Data are presented on *Hospital Compare* in a format mainly aimed towards consumers, patients, and the general public, providing access to hospital-specific quality measure performance rates along with state and national performance rates. For certain outcome and cost measures, data are presented on *Hospital Compare* in performance categories of Better, No Different, or Worse than the National Rate. More detailed measure data, including the data used for *Hospital Compare*, are also available to the public as downloadable files at <https://data.medicare.gov>. Hospital quality data on *Hospital Compare* are updated on a quarterly basis.

17. Expiration Date

We request a three-year approval, resulting in an expiration date of 09/30/2019. We will display this expiration date on each of the forms listed above in section A.1.e, which would become available on our *QualityNet* website's Hospital IQR Program and Hospital VBP Program pages (www.qualitynet.org). We will display the approved expiration date prominently on our *QualityNet* website's Hospital IQR Program pages used to document our measure specifications and reporting guidance.

18. Certification Statement

We are not claiming any exceptions to the Certification for Paperwork Reduction Act Submissions Statement.