

**Supporting Statement – Part A**  
**Quality Measures and Procedures for the Hospital Inpatient Quality Reporting Program**  
**for the FY 2020 IPPS Annual Payment Updates**

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, increased both the importance of Hospital IQR Program data and the need for a broad range of indicators. Section 931 of the Public Health Service Act requires 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 1886(q)(8)(C)(i) of the Social Security Act requires 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 1886(o) of the Social Security Act mandates 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. Hospital IQR Program Quality Measures

### a. Introduction

The FY 2020 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 2018 and December 2018. 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

We note that in the FY 2018 Inpatient Prospective Payment System (IPPS)/Long-Term Care Hospital (LTCH) PPS proposed rule, we are not proposing any new measures for the FY 2020 payment determination. In the FY 2018 IPPS/LTCH PPS proposed rule, we are proposing voluntary data collection of the Hybrid Hospital-Wide 30-Day Readmission measure with a 6-month measurement period in CY 2018 and data submission to the CMS data receiving system anticipated for the fall of 2018, as further discussed below. As a voluntary measure, there would be no impact on payment determinations for hospitals choosing not to report on this measure.

### c. Measures Finalized for Removal

We are not proposing any measures for removal in the FY 2018 IPPS/LTCH PPS proposed rule.

#### 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 one full calendar year of data for 8 self-selected eCQMs among the available eCQMs in the Hospital IQR Program (81 FR 57150 through 57159). We also finalized 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) (81 FR 57172).

In the FY 2018 IPPS/LTCH PPS proposed rule, we are proposing to modify the eCQM reporting requirements finalized for the CY 2017 reporting period/FY 2019 payment determination, such that hospitals would be required to report on 6 eCQMs and to submit 2 self-selected calendar quarters of data. Additionally, we are proposing to modify the eCQM reporting requirements for the CY 2018 reporting period/FY 2020 payment determination, such that hospitals would be required to report on 6 eCQMs and to submit data for the first three calendar quarters (Q1-Q3 2018). We are also proposing to modify our existing eCQM data validation process for the Hospital IQR Program beginning with the FY 2020 payment determination. Specifically, we are proposing to require 8 cases to be submitted per quarter for 2 quarters for eCQM validation for the FY 2020 payment determination and 8 cases to be submitted per quarter for 3 quarters for eCQM validation for the FY 2021 payment determination, if our proposals to modify the eCQM reporting requirements as described above are finalized as proposed.

#### 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)
- 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 for PC, ED, and HAI Data Submission
- CMS Quality Reporting Program APU Reconsideration Request Form
- Hospital Inpatient Quality Reporting (IQR) Program Validation Educational Review 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 Exceptions (ECE) Request Form
- CMS Hospital IQR Program Validation Review for Reconsideration Request Form
- Validation templates for each of the following measures:

- o Central line-associated bloodstream infection (CLABSI);
- o Catheter-associated urinary tract infection (CAUTI);
- o Methicillin-resistant Staphylococcus Aureus (MRSA); and
- o Clostridium Difficile infection (CDI).

Only the Hospital Inpatient Quality Reporting (IQR) Program Data Accuracy and Completeness Acknowledgement (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 Hospital Compare Request for Withholding Data from Public Reporting Form is being modified to include the names of all applicable quality reporting and pay-for-performance programs, to update the form submission information (which includes providing the form submission deadline for claims-based measures), and to update the measures listed for the upcoming preview period and *Hospital Compare* release.

The CMS Quality Reporting Program APU Reconsideration Request Form is being modified to add a signature line for the designated provider personnel's signature.

We note that we are submitting the Hospital Inpatient Quality Reporting (IQR) Program Validation Educational Review Form for the first time with this PRA package, based on our proposal to allow hospitals to use the educational review process to correct validation scores for the first three quarters of validation in the event that CMS has calculated an incorrect validation score. As discussed further below in section B.12.e, any additional burden associated with this form would be included in the burden for "*all other forms used in the data collection process*" and is expected to be negligible, as this form would not be filled out by hospitals on a regular basis.

Additionally, we are resubmitting the Centers for Medicare & Medicaid Services (CMS) Quality Reporting Program Extraordinary Circumstances Exceptions (ECE) Request Form to note a terminology modification. Specifically, we are proposing to refer to this policy as "Extraordinary Circumstances Exceptions" (instead of "Extraordinary Circumstances Exemptions/Extensions") for the Hospital IQR Program, beginning October 1, 2017, to align terminology with other quality reporting and pay-for-performance programs that have policies to provide exceptions from program requirements to facilities that have experienced extraordinary circumstances.

The Validation templates for the CLABSI, CAUTI, MRSA, and CDI measures in the Hospital IQR Program are updated annually to reflect the annual changes in fiscal year and beginning reporting quarter, as well as new CDC pathogen lists, with each new selection of hospitals for validation.

All of the other information collection forms listed above will continue to be used in the Hospital IQR Program without any modifications and are not being revised with this PRA package.

## 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.

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 Hospital Inpatient Quality Reporting (IQR) Program Data Accuracy and Completeness Acknowledgement (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 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. This form is being modified to include the names of all applicable quality reporting and pay-for-performance programs, to update the form submission information (which includes providing the form submission deadline for claims-based measures), and to update the measures listed for the upcoming preview period and *Hospital Compare* release.

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 adopted 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 expanded 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 (81 FR 57174 through 57178).

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 for PC, ED, and HAI Data Submission. Hospitals that do not have an Obstetrics Department and do not deliver babies may use this 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 this 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. This 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. For reconsideration requests related specifically to the validation requirements, hospitals may use the CMS Hospital IQR Program Validation Review for Reconsideration Request Form.

In the FY 2018 IPPS/LTCH PPS proposed rule, we are proposing that hospitals may use the educational review process to correct disputed chart-abstracted measure validation results for the first three quarters of validation. To submit a formal request, hospitals can utilize the Educational Review Request Form listed in section A.1.e of this file. We note that should the results of an educational review not be favorable to a hospital, a hospital may still also request

reconsideration of those results using the CMS Hospital IQR Program Validation Review for Reconsideration Request Form.

In the FY 2018 IPPS/LTCH PPS proposed rule, we are proposing to refer to our existing policy of allowing a hospital to request an exception or extension from quality measure data reporting in the event of an extraordinary circumstance as “Extraordinary Circumstances Exceptions” (instead of “Extraordinary Circumstances Exemptions/Extensions”) for the Hospital IQR Program, beginning October 1, 2017, to align terminology with other quality reporting and pay-for-performance programs that have policies to provide exceptions from program requirements to facilities that have experienced extraordinary circumstances. Consequently, we are resubmitting the Extraordinary Circumstances Exception (ECE) Request Form in this PRA package to note this terminology modification.

The Validation templates for the CLABSI, CAUTI, MRSA, and CDI measures in the Hospital IQR Program are updated annually to reflect the annual changes in fiscal year and beginning reporting quarter, as well as new CDC pathogen lists, 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 (81 FR 57174 through 57178).

As noted above, we must select measures for the Hospital VBP Program from among measures (other than measures of readmissions) in the Hospital IQR Program. 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.

## 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 eQMs, 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 of 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 and eQMs 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 2019 program year.



## 6. Less Frequent Collection

We have designed the collection of quality measure data to be the minimum necessary for data validation and for 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.

## 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 (82 FR 19796) of the FY 2018 IPPS/LTCH PPS proposed rule published on April 28, 2017. Comments will be submitted on this notice, and we will respond to those comments accordingly.

CMS is supported in this initiative by The Joint Commission, National Quality Forum (NQF), Measure Applications 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)

### a. Background

Under Section 1886(b)(3)(B)(viii)(V) of the Social Security Act, we are required to add other measures that reflect consensus among affected parties and, to the extent feasible and practicable, must include measures set forth by one or more national consensus building entities. In the FY 2018 IPPS/LTCH PPS proposed rule, we are not proposing any new measures for the Hospital IQR Program, however, we are proposing other modifications to program requirements for the FY 2020 payment determination and subsequent years. These burden estimates include a new hybrid measure for voluntary data collection, as well as other activities that potentially impact burden for hospitals. It excludes burden associated with the NHSN and Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) measures, which are submitted under separate OMB control numbers.

For the purposes of burden estimation, we assume all of the activities associated with the Hospital IQR Program for 3,300 IPPS hospitals and 1,100 non-IPPS hospitals will be completed by Medical Records and Health Information Technicians. 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;<sup>1</sup> however, obtaining data on other overhead costs is challenging. Overhead costs vary greatly across industries and organization size. 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 organization 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. Therefore, using these assumptions, we estimate an hourly labor cost of \$32.84 (\$16.42 base salary + \$16.42 fringe).

### b. Modified Estimates for the FY 2019 Payment Determination

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<sup>1</sup> Occupational Outlook Handbook. Available at: <http://www.bls.gov/oes/2012/may/oes292071.htm>.

We note that in the FY 2018 IPPS/LTCH proposed rule, we are proposing to modify the eCQM reporting requirements for the CY 2017 reporting period/FY 2019 payment determination such that hospitals would be required to report 6 eCQMs and to submit 2 self-selected calendar quarters of data, as opposed to submitting one full calendar year of data for 8 eCQMs, as finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57150 through 57159). Consequently, we expect actual reporting burden for CY 2017 eCQM reporting to be less than our previously finalized estimates, which are approved under this OMB control number.

With regard to the Hospital IQR Program requirements proposed for the FY 2019 payment determination, we estimate a total burden decrease of 14,667 hours associated with our proposed policy changes as compared to our previously submitted estimates for FY 2019, due to the proposal to require 6 eCQMs over 2 self-selected calendar quarters for the CY 2017 reporting period. Taken with our estimated wage rate of \$32.84, we estimate a cost decrease of approximately \$481,664. The estimated total burden decrease was calculated as follows:

As in previous years, we believe the total burden associated with the eCQM reporting policy will be similar to that previously outlined in the Medicare EHR Incentive Program Stage 2 final rule (77 FR 54126 through 54133). Under that program, the burden estimate for a hospital to report 1 eCQM is 10 minutes per record per quarter. We believe this estimate is accurate and appropriate to apply to the Hospital IQR Program because we align the eCQM reporting requirements between both programs. Therefore, using the estimate of 10 minutes per record per quarter, we anticipate our proposal to require: (1) reporting on 6 of the available eCQMs; and (2) submission of 2 calendar quarters of eCQM data, will result in a burden reduction of 3 hours and 20 minutes (200 minutes) per hospital for the FY 2019 payment determination, as compared to our previous estimates. This estimate was calculated by considering the burden difference between the eCQM reporting requirements newly proposed for the CY 2017 reporting period/FY 2019 payment determination (10 minutes per record x 6 eCQMs x 2 quarters = 120 minutes for 2 quarters of reporting) and the eCQM reporting requirements finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57157 through 57159) and approved previously under this OMB control number (10 minutes per record x 8 eCQMs x 4 quarters = 320 minutes for 4 quarters of reporting). Through these calculations (120 minutes – 320 minutes), we arrived at a reduction of 200 annual minutes per hospital, or 3 hours and 20 minutes per hospital per year for the FY 2019 payment determination.

In total, for the FY 2019 payment determination, we expect our proposal to require hospitals to report data on 6 eCQMs for 2 self-selected calendar quarters (as compared to our previously finalized requirement to report data on 8 eCQMs for 4 quarters) to represent an annual burden reduction of 11,000 hours across all 3,300 IPPS hospitals participating in the Hospital IQR Program (-200 minutes per hospital / 60 minutes per hour x 3,300 hospitals = -11,000 hours) and a reduction of 3,667 hours across 1,100 non-IPPS hospitals (-200 minutes per hospital / 60 minutes per hour x 1,100 hospitals = -3,667 hours), for a total reduction of 14,667 hours.

**Table 1. Modified Hospital IQR Program eCQM Reporting Burden Calculations for the FY 2019 Payment Determination**

<i>Measure Set</i>	<i>Estimated time per record (minutes) FY 2019 payment determination</i>	<i>Number reporting quarters per year FY 2019 payment determination</i>	<i>Number of hospitals reporting</i>	<i>Average number records per hospital per quarter</i>	<i>Annual burden (hours) per hospital</i>	<i>Calculation for FY 2019 payment determination</i>
<b>OTHER ACTIVITIES</b>						
<b>All Hospitals (3,300 IPPS + 1,100 non-IPPS)</b>						
Reporting six electronic Clinical Quality Measures (IPPS)	60	2	3,300	1	2	6,600
Reporting six electronic Clinical Quality Measures (Non-IPPS)	60	2	1,100	1	2	2,200

We reiterate that we are amending our approved estimates for the FY 2019 payment determination, and our proposed policy changes would result in a burden reduction compared to the previously approved FY 2019 payment determination estimates under this OMB control number. We are requesting approval of this modified burden estimate for the FY 2019 payment determination.

c. Estimates for the FY 2020 Payment Determination

With regard to the Hospital IQR Program requirements proposed for the FY 2020 payment determination, we estimate a total burden decrease of 14,533 hours associated with our proposed policy changes. Taken with our estimated wage rate of \$32.84, we estimate a total cost decrease of approximately \$477,263 across all participating hospitals. The estimated total burden decrease was calculated as follows:

As in previous years, we believe the total burden associated with the eCQM reporting policy will be similar to that previously outlined in the Medicare EHR Incentive Program Stage 2 final rule (77 FR 54126 through 54133). Under that program, the burden estimate for a hospital to report 1 eCQM is 10 minutes per record per quarter. We believe this estimate is accurate and appropriate to apply to the Hospital IQR Program because we align the eCQM reporting requirements between both programs. Using the estimate of 10 minutes per record per quarter, we anticipate our proposal to require: (1) reporting on 6 of the available eCQMs; and (2) submission of the first 3 quarters of CY 2018 eCQM data, will result in a burden decrease of 2 hours and 20 minutes per hospital for the FY 2020 payment determination as compared to the burden estimate of eCQM reporting for the FY 2019 payment determination, as described above (which is the

same burden estimate of eCQM reporting for the FY 2020 payment determination as finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57150 through 57159)). This estimate was calculated by considering the burden difference between the eCQM reporting requirements newly proposed for the CY 2018 reporting period/FY 2020 payment determination (10 minutes per record x 6 eCQMs x 3 quarters = 180 minutes for 3 quarters of reporting) and the requirements previously finalized (10 minutes per record x 8 eCQMs x 4 quarters = 320 minutes for 4 quarters of reporting). Through these calculations (180 minutes – 320 minutes), we arrived at a decrease of 140 annual minutes per hospital, or 2 hours and 20 minutes per hospital per year for the FY 2020 payment determination. This represents a burden decrease of 7,700 hours (140 minutes per hospital / 60 minutes per hour x 3,300 hospitals) across 3,300 IPPS hospitals and a burden decrease of 2,567 hours (140 minutes per hospital / 60 minutes per hour x 1,100) across 1,100 non-IPPS hospitals, for a total reduction of -10,267 hours related to eCQM reporting for the FY 2020 payment determination. In total, we expect a cost decrease of \$337,168 ( $\$32.84$  hourly wage x -10,267 annual hours = -\$337,168) across 4,400 IPPS and non-IPPS hospitals.

In previous years (79 FR 50347), we estimated a burden of 1 hour and 20 minutes (or 80 minutes) per record for validation of eCQM data. Applying the time per individual submission of 1 hour and 20 minutes (or 80 minutes) per record for the 16 records we are proposing that hospitals submit for validation for the FY 2020 payment determination, we estimate a total burden of approximately 21 hours (80 minutes x 16 records / 60 minutes per hour) for each hospital selected for participation in eCQM validation for the FY 2020 payment determination. We estimate that the total burden would be approximately 4,200 hours across the 200 IPPS hospitals selected for eCQM validation (21 hours per hospital x 200 hospitals = 4,200 hours). As compared to our total burden estimate of 8,533 hours previously estimated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57261), this represents a burden reduction of approximately 4,333 hours across up to 200 hospitals selected for eCQM validation (4,200 hours estimated in this proposed rule - 8,533 hours estimated in the FY 2017 IPPS/LTCH PPS final rule = - 4,333 hours). Using the estimated hourly labor cost of \$32.84, we estimate an annual cost reduction of \$142,296 (4,333 hours x \$32.84 per hour) across the 200 hospitals selected for eCQM validation due to our proposal to decrease the number of records collected for validation from 32 records to 16 records for the FY 2020 payment determination.

Also, we are proposing voluntary data collection of the Hybrid Hospital-Wide 30-Day Readmission measure. This measure is made up of both claims-based data as well as a set of 13 core clinical data elements from patient EHRs. We do not expect any additional burden on hospitals to report the claims-based portion of this measure because these data are already reported to the Medicare program for payment purposes. Additionally, we are proposing to require hospitals to submit the 13 core clinical data elements and the 6 data elements required for linking with claims data for this measure using the same submission requirements required for eCQM reporting. Accordingly, we expect the burden associated with voluntarily reporting this measure to be similar to our estimates for eCQM reporting (that is 10 minutes per measure per quarter). Consistent with estimates for previous data collection of voluntary measures, such as the eCQM reporting pilot, we believe up to approximately 100 hospitals will voluntarily report the EHR-derived data for the Hybrid Hospital-Wide 30-Day Readmission measure. Therefore, using the estimate of 10 minutes per measure per quarter, we anticipate that our proposal will result in a burden increase of 0.67 hours (40 minutes) per hospital for the FY 2020 payment

determination (10 minutes per record x 1 measure x 4 quarters / 60 minutes per hour = 0.67 hours). In total, for the FY 2020 payment determination, we expect our proposal for voluntary data collection of the Hybrid Hospital-Wide 30-Day Readmission measure on a voluntary basis to represent an annual burden increase of 67 hours across up to 100 IPPS hospitals voluntarily participating (40 minutes per hospital / 60 minutes per hour x 100 hospitals = 67 hours). We expect this to represent a cost increase of \$2,200 (\$32.84 hourly wage x 67 annual hours) across up to 100 IPPS hospitals voluntarily submitting data for this measure.

In total, we estimate: (1) a decrease of 7,700 hours for IPPS hospitals due to proposed changes to our eCQM reporting policies; (2) a decrease of 2,567 hours for non-IPPS hospitals due to proposed changes to our eCQM reporting policies; (3) a decrease of 4,333 hours for IPPS hospitals due to proposed changes to our eCQM data validation procedures; and (4) an increase of 67 hours due to the proposed voluntary data collection of a hybrid measure. In total for the FY 2020 payment determination, we estimate a decrease of approximately 14,533 hours across 4,400 IPPS and non-IPPS hospitals due to proposed changes set forth in the FY 2018 IPPS/LTCH PPS proposed rule.

Please note that in addition to the revised estimates described above due to changes proposed in the FY 2018 IPPS/LTCH PPS proposed rule, we have also revised our prior burden estimates based on the availability of more current information. Specifically, we have revised our estimates for the reporting of chart-abstracted measures (ED/IMM, VTE, Sepsis, and PC-01) by non-IPPS hospitals using the average number of non-IPPS hospitals actually reporting these measures over the prior 4 quarters for which data are currently available (4<sup>th</sup> quarter 2015 through 3<sup>rd</sup> quarter 2016). We have also revised the number of records for population and sampling from 8 to 4 to reflect the reduction of measure sets used in the Hospital IQR Program for 8 measure sets to 4 measure sets, and revised the number of HAI Validation quarters from 3 to 4 to reflect the validation of 4 quarters of HAI data in the Hospital IQR Program.

**Table 2. Burden Calculations for the Hospital IQR Program Measure Set and Other Activities for the FY 2020 Payment Determination**

<i>Measure Set</i>	<i>Estimated time per record (minutes) - FY 2020 payment determination</i>	<i>Number reporting quarters per year - FY 2020 payment determination</i>	<i>Number of hospitals reporting</i>	<i>Average number records per hospital per quarter</i>	<i>Annual burden (hours) per hospital</i>	<i>Calculation for FY 2020 payment determination</i>
<b>CHART ABSTRACTION</b>						
<b>IPPS Hospitals (3,300)</b>						
Emergency	28	4	3,300	260	485	1,599,074

department (ED) throughput/Imm unizations (IMM)						
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
<b>Subtotal IPPS chart-based</b>					<b>1027.66</b>	<b>3,391,271</b>
<b>Non-IPPS Hospitals (1,100)</b>						
Emergency department (ED) throughput/Imm unizations (IMM)	35	4	898	55	128.33	115,243
Venous thromboembolism (VTE)	7	4	412	27	13	5,191
Sepsis measure	60	4	362	25	100	36,200
Perinatal care (PC)	10	4	334	21	14	4,676
<b>Subtotal Non-IPPS chart-based</b>						<b>161,311</b>
<b>Subtotal IPPS and Non-IPPS chart-based</b>						<b>3,552,582</b>
<b>OTHER ACTIVITIES</b>						
<b>All Hospitals (3,300 IPPS + 1,100 non-IPPS)</b>						
Population and sampling for 4 ongoing measure sets	15	4	4,400	4	4	17,600
Review reports for claims-based measure sets	60	4	4,400	1	4	17,600

HAI Validation Templates (CLABSI, CAUTI)	1,200	4	300	1	80	24,000
HAI Validation Templates (MRSA, CDI)	960	4	300	1	64	19,200
Reporting six electronic Clinical Quality Measures (IPPS)	60	3	3,300	1	3	9,900
Reporting six electronic Clinical Quality Measures (non-IPPS)	60	3	1,100	1	3	3,300
eCQM Validation	80	2	200	8	21	4,200
All other forms used in the data collection process and structural measures	15	1	4,400	1	0.25	1,100
Hybrid Hospital-Wide 30-Day Readmission Voluntary Measure	10	4	100	1	0.67	67
<b>Subtotal other activities</b>						<b>96,967</b>
<b><u>Total</u></b>						<b><u>3,649,548</u></b>

Given the proposals outlined in the FY 2018 IPPS/LTCH PPS proposed rule, we estimate a total burden decrease of 31,475 hours for the FY 2020 payment determination. Taken with our estimated wage rate of \$32.84 per hour, we estimate a total cost decrease of approximately \$1,033,639. We are requesting approval of this burden estimate for the FY 2020 payment determination.



d. Estimates for the FY 2021 Payment Determination

As compared to the estimates previously finalized under the FY 2017 IPPS/LTCH PPS final rule for validation of eCQM data for the FY 2021 payment determination, we also expect a decrease in burden if our proposals in the FY 2018 IPPS/LTCH PPS proposed rule are adopted for the FY 2021 payment determination. In previous years (79 FR 50347), we estimated a burden of 1 hour and 20 minutes per record for validation of eCQMs. Applying the time per individual submission of 1 hour and 20 minutes (or 80 minutes) for the 24 records we are proposing that hospitals submit for the FY 2021 payment determination, we estimate a total burden of approximately 32 hours (80 minutes x 24 records / 60 minutes per hour) for each hospital selected for participation in eCQM validation. We further estimate that the total burden would be approximately 6,400 hours across the 200 IPPS hospitals selected for eCQM validation (32 hours per hospital x 200 hospitals = 6,400 hours). As compared to our total burden estimate of 8,533 hours previously estimated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57261) for eCQM validation for the FY 2020 payment determination (which is the same as for the FY 2021 payment determination), this would represent a decrease of approximately 2,133.33 hours across up to 200 IPPS hospitals selected for eCQM validation for the FY 2021 payment determination (6,400 hours estimated in this proposed rule for the FY 2021 payment determination – 8,533 hours estimated in the FY 2017 IPPS/LTCH PPS final rule = -2,133 hours). Using the estimated hourly labor cost of \$32.84, we estimate an annual cost reduction of \$70,048 (2,133hours x \$32.84 per hour) across the 200 IPPS hospitals selected for eCQM validation due to our proposal to decrease the number of records collected from 32 records to 24 records for the FY 2021 payment determination.

**Table 3. Hospital IQR Program eCQM Validation Burden Calculations for the FY 2021 Payment Determination**

<i>Measure Set</i>	<i>Estimated time per record (minutes) - FY 2021 payment determination</i>	<i>Number reporting quarters per year - FY 2021 payment determination</i>	<i>Number of hospitals reporting</i>	<i>Average number records per hospital per quarter</i>	<i>Annual burden (hours) per hospital</i>	<i>Calculation for FY 2021 payment determination</i>
<b>OTHER ACTIVITIES</b>						
<b>All Hospitals (3,300 IPPS + 1,100 non-IPPS)</b>						
eCQM Validation	80	3	200	8	32	6,400

#### e. Additional Information on Burden Estimates

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 estimates in the FY 2016 IPPS/LTCH PPS final rule, we estimate a burden of 15 minutes per hospital to complete all 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 Exceptions (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 Center, and the End Stage Renal Disease 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 2016, 86 ECE requests were submitted by hospitals for an extension or exception from reporting requirements in the Hospital IQR Program, of which 69 ECE requests were for an exception from the first year of required eCQM reporting of CY 2016 discharge data. Based on our estimation of 15 minutes/record to submit the ECE Request Form, the total burden calculation for the submission of 86 ECE requests was 1,290 minutes (or 21.5 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 21.5 hours ECE Request Form burden estimation is accounted for in that figure.

#### 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.

## 15. Program or Burden Changes

As described above, in the FY 2018 IPPS/LTCH PPS proposed rule, we are proposing to modify our previously finalized eCQM reporting requirements such that hospitals would be required to report 2 self-selected calendar quarters of data for 6 of the available eCQMs for the CY 2017 reporting period/FY 2019 payment determination and to report the first three calendar quarters (Q1-Q3) of data for 6 of the available eCQMs for the CY 2018 reporting period/FY 2020 payment determination. These proposals represent a reduction in burden from the eCQM reporting requirements finalized 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. Additionally, in the FY 2018 IPPS/LTCH PPS proposed rule, we are proposing to modify the existing eCQM validation process to require 8 cases to be submitted per quarter for 2 calendar quarters for eCQM validation for the FY 2020 payment determination and 8 cases to be submitted per quarter for 3 quarters for eCQM validation for the FY 2021 payment determination, if our proposals related to reduced eCQM reporting requirements are finalized as proposed.

To summarize the burden changes, in total for the FY 2019 payment determination, we estimate a decrease in annual burden of 14,667 hours across 4,400 IPPS and non-IPPS hospitals associated with our proposed policy changes. Taken with our estimated wage rate of \$32.84, we estimate a total cost decrease of approximately \$481,664. In total for the FY 2020 payment determination, we estimate a decrease in annual burden of 14,533 hours across 4,400 IPPS and non-IPPS hospitals associated with our proposed policy changes. Taken with our estimated wage rate of \$32.84, we estimate a total cost decrease of approximately \$477,263.

The long-term vision for the Hospital IQR Program is to encourage hospitals to submit data directly from their EHRs, which we anticipate will reduce burden substantially. As part of that goal, in the FY 2018 IPPS/LTCH PPS proposed rule, we are proposing voluntary data collection of the Hybrid Hospital-Wide 30-Day Readmission measure, in which participating hospitals could submit a set of 13 core clinical data elements from patient EHRs to be combined with claims data for measure calculation. Incrementally requiring hospitals to electronically report a greater number of eCQMs also furthers our goal of expanding electronic reporting in the Hospital IQR Program, which we believe will improve patient outcomes by providing more robust and timely data to support quality improvement efforts. Compared to the requirements we finalized in the FY 2017 IPPS/LTCH PPS final rule, our proposed requirements in the FY 2018 IPPS/LTCH PPS proposed rule reduce the overall number of eCQMs required for reporting (from 8 to 6 eCQMs) and reduce the number of required calendar quarters of data that must be reported (from 4 quarters to 2 quarters for CY 2017 reporting and 3 quarters for CY 2018 reporting). However, we believe that the increase in requirements from the CY 2016 reporting period/FY 2018 payment determination (1 quarter of data for 4 eCQMs) reflects a better balance of hospital reporting burden for progressively expanding eCQM reporting and collection of EHR-derived quality data.

## 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](http://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 will display the approved 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](http://www.qualitynet.org)). We will also 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.