Supporting Statement – Part A
Quality Measures and Procedures for the Hospital Inpatient Quality Reporting Program for the FY 2021 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. 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 1886(o) of the Social Security Act mandates CMS' transition from a passive supplier of health care to an active purchaser of quality care. Pursuant to section 1886(o)(2)(A) of the Social Security Act, CMS must select measures for the Hospital Value-Based Purchasing (VBP) Program from the measures (other than measures of readmissions) specified under 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 the measures specified under the Hospital IQR Program.

1. Hospital IQR Program Quality Measures

a. Introduction

The FY 2021 APU determination will be based on Hospital IQR Program data reported and supporting forms submitted by hospitals on chart-abstracted, patient survey, and electronic clinical quality measures (eCQMs) for the reporing period of January 2019 through December 2019. 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.

To further reduce the regulatory burden on the healthcare industry, lower health care costs, and enhance patient care, in October 2017, we launched the Meaningful Measures Initiative.[1] This

[1] More information on the Meaningful Measures Initiative available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html.

initiative is one component of our agency-wide Patients Over Paperwork Initiative,[2,3] which is aimed at evaluating and streamlining regulations with a goal to reduce unnecessary cost and burden, increase efficiencies, and improve beneficiary experience. The Meaningful Measures Initiative is aimed at identifying the highest priority areas for quality measurement and quality improvement in order to assess the core quality of care issues that are most vital to advancing our work to improve patient outcomes. The Meaningful Measures Initiative represents a new approach to quality measures that will foster operational efficiencies and will reduce costs, including data collection and reporting burden, while producing quality measurement that is more focused on meaningful outcomes.

The Meaningful Measures framework has the following objectives:

- Address high-impact measure areas that safeguard public health;
- Patient-centered and meaningful to patients;
- Outcome-based where possible;
- Fulfill each program's statutory requirements;
- Minimize the level of burden for health care providers (for example, through a preference for EHR-based measures where possible, such as eCQMs ;
- Significant opportunity for improvement;
- Address measure needs for population-based payment through alternative payment models; and
- Align across programs and/or with other payers.

In order to achieve these objectives, we have identified 19 Meaningful Measures areas and mapped them to six overarching quality priorities as shown in the following table:

Quality Priority	Meaningful Measure Area
Making Care Safer by Reducing Harm Caused in the Delivery of Care	Healthcare-Associated Infections
	Preventable Healthcare Harm
Strengthen Person and Family Engagement as Partners in Their Care	Care is Personalized and Aligned with Patient's Goals
	End of Life Care According to Preferences
	Patient's Experience of Care
	Patient Reported Functional Outcomes
Promote Effective Communication and Coordination of Care	Medication Management
	Admissions and Readmissions to Hospitals
	Transfer of Health Information and Interoperability
Promote Effective Prevention and Treatment of Chronic Disease	Preventive Care
	Management of Chronic Conditions

[2] Remarks by CMS Administrator Seema Verma at the Health Care Payment Learning and Action Network (LAN) Fall Summit, as prepared for delivery on October 30, 2017. Available at: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-10-30.html.
[3] More information on the Patients Over Paperwork Initiative available at: https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/PatientsOverPaperwork.html

Quality Priority	Meaningful Measure Area
	Prevention, Treatment, and Management of Mental Health
	Prevention and Treatment of Opioid and Substance Use Disorders
	Risk Adjusted Mortality
Work with Communities to Promote Best Practices of Healthy Living	Equity of Care
	Community Engagement
Make Care Affordable	Appropriate Use of Healthcare
	Patient-focused Episode of Care
	Risk Adjusted Total Cost of Care

By including Meaningful Measures in our programs, we believe that we can also address the following cross-cutting measure criteria:

- Eliminating disparities;
- Tracking measurable outcomes and impact;
- Safeguarding public health;
- Achieving cost savings;
- Improving access for rural communities; and
- Reducing burden.

We believe that the Meaningful Measures Initiative will improve outcomes for patients, their families, and health care providers while reducing burden and costs for clinicians and providers as well as promoting operational efficiencies.

b. New Measures

We note that in the FY 2019 Inpatient Prospective Payment System (IPPS)/Long-Term Care Hospital (LTCH) PPS proposed rule, we did not propose to add any new measures for the FY 2021 payment determination or subsequent payment determinations.

c. Measures Finalized for Removal

After conducting an overall review of the Hospital IQR Program under the Meaningful Measures Initiative described above, we developed proposals to ensure that the Hospital IQR Program measure set continues to promote improved health outcomes for our beneficiaries while minimizing costs. Specifically, in the FY 2019 IPPS/LTCH PPS final rule, we are finalizing our proposals to remove a total of 39 measures from the Hospital IQR Program. Beginning with the FY 2020 payment determination and subsequent years, we are finalizing our proposals to remove 19 measures. Beginning with the FY 2021 payment determination and subsequent years, we are finalizing our proposals to remove five measures. Beginning with the FY 2022 payment determination and subsequent years, we are finalizing our proposals to remove 14 measures. Beginning with the FY 2023 payment determination, we finalizing our proposals to remove one measure. For a complete list of the measures finalized for removal, see section B.15 of this document.

d. Electronic Clinical Quality Measures (eCQMs)

In the FY 2018 IPPS/LTCH PPS final rule, for the FY 2019 payment determination and the FY 2020 payment determination, we required that hospitals must submit one, self-selected calendar quarter of data on four self-selected eCQMs in the Hospital IQR Program measure set (82 FR 38355 through 38361). In the FY 2019 IPPS/LTCH PPS final rule, we are finalizing our proposal to continue this requirement such that hospitals must submit one, self-selected calendar quarter of data for 4 eCQMs in the Hospital IQR Program measure set for the FY 2021 payment determination.

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 Quality Reporting Data Accuracy and Completeness Acknowledgement (DACA)
- *Hospital Compare* Request Form for Withholding/Footnoting Data for Public Reporting
- 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
- CMS Hospital IQR Program Validation Review for Reconsideration Request Form
- CMS Quality Reporting 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 Program Extraordinary Circumstances Exceptions (ECE) 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 Hospital Quality Reporting 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 or one time only forms, and hospitals may not need to complete any of these forms in any given year.

The Hospital Inpatient Quality Reporting Notice of Participation is being modified with updated hyperlinks and to clarify that optional public reporting does not impact payment determinations under the Hospital IQR Program or other hospital quality programs.

The DACA form is being modified to update the applicable program year and add references to the Hospital-Acquired Condition Reduction and Hospital VBP Programs, which would use Hospital IQR Program data collected for the FY 2020 payment determination.

The Hospital Compare Request Form for Withholding/Footnoting Data for Public Reporting is being modified with a refined title, to add/remove measures for the upcoming preview periods and *Hospital Compare* releases in 2019, including the measure removals as finalized in the FY 2019 IPPS/LTCH final rule that will impact 2019 public reporting, to include the names of all applicable quality reporting and pay-for-performance programs, and to add an option to request a footnote for claims-based measure data that are included in public reporting.

The CMS IPPS Quality Reporting Programs Measure Exception Form for PC, ED, and HAI Data Submission is being modified to add a signature line for the designated provider personnel's signature and to remove reference to the ED-1: Median Time from ED Arrival to ED Departure Time for Admitted ED Patients measure, as finalized in the FY 2019 IPPS/LTCH final rule effective with January 1, 2019 discharges.

The CMS Quality Reporting Program APU Reconsideration Request Form is being modified to clarify instructions for submitting this request form.

The CMS Hospital IQR Program Validation Review for Reconsideration Request Form is being modified to clarify instructions for submitting this request form and to add a column for National Healthcare Safety Network Event ID number.

The Hospital Quality Reporting Validation Educational Review Form is being modified with a refined title.

The CMS Quality Program Extraordinary Circumstances Exceptions Request Form is being modified with a refined title and to add the Skilled Nursing Facility Value-Based Purchasing Program.

The Validation templates for the CLABSI, CAUTI, MRSA, and CDI measures 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 and Hospital VBP Programs without any modifications and are not being revised with this PRA package, except with respect to incorporating updated PRA disclosure statements on each form.

B. Justification

1. Need and Legal Basis

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 was previously developed, referred to as the Optional Public Reporting Notice of Participation. 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 Quality Reporting 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 Form for Withholding/Footnoting Data from Public Reporting. 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 Form for Withholding/Footnoting Data from Public Reporting indicating the measures the hospital would like to withhold from public reporting for the period. As described above, this form is being modified with a refined title, to add/remove measures for the upcoming preview periods and *Hospital Compare* releases in 2019, including the measure removals as finalized in the FY 2019 IPPS/LTCH final rule that will impact 2019 public reporting, to include the names of all applicable quality reporting and pay-for-performance programs, and to add an option to request a footnote for claims-based measure data that are included in public reporting.

Hospitals that do not treat the conditions or do not have treatment locations defined for the National Healthcare Safety Network's 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 National Healthcare Safety Network 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 National Healthcare Safety Network enrollment process or entering zero denominator information for inapplicable measures for the hospitals that meet the exception requirements. We note that, as discussed in sections B.12 and B.15 below, we are finalizing our proposals to remove the ED-1 and ED-2 chart-abstracted measures in the FY 2019 IPPS/LTCH PPS final rule. As such, none of the ED measures will remain in the Hospital IQR Program by the FY 2022 payment determination, and hospitals that do not provide emergency care would not need to use the Measure Exception Form.

CMS selects up to 600 subsection (d) hospitals participating in the Hospital IQR Program on an annual basis for validation of chart-abstracted measures (78 FR 50833). 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. The Validation templates for the CLABSI, CAUTI, MRSA, and CDI measures 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. We note that, as discussed in section B.12 below, because these five HAI measures are finalized for removal from the Hospital IQR Program beginning with the FY 2022 payment determination and retained in the Hospital-Acquired Condition Reduction Program, the HAI validation activities will be transferred to the latter program beginning with the FY 2023 payment determination. 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).

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.

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 Hospital Quality Reporting Validation Educational Review 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.

The CMS Quality Program Extraordinary Circumstances Exceptions Request 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 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 Promoting Interoperability Programs' typical deadline of April 1st.

As noted above, we must select measures for the Hospital VBP Program from the measures (other than measures of readmissions) specified under 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

The information from the Hospital IQR Program will be made available to hospitals for their use in internal quality improvement initiatives. CMS provides confidential feedback reports that hospitals may use to assess their performance and operationalize quality improvement activities throughout the quality reporting period. These reports include the data that CMS has collected from the hospital and the hospital's claims, and some also include information about how the hospital's data look relative to the performance of other hospitals. For example, the Facility, State and National (FSN) Report allows hospitals to compare their performance related to a specific measure during a specific timeframe, to the average performance of other hospitals at the state and national levels.

CMS will use the information collected for the Hospital VBP Program to set payment adjustments for value-based purchasing. In addition, the Hospital VBP Program Baseline Measures Report allows hospitals to compare their performance for each measure to the Program's benchmarks and achievement thresholds, which are obtained from the scores of all hospitals. These reports allow hospitals time to assess how their current performance in each measure could be scored in the upcoming Hospital VBP payment determinations, while there is still time to target improvement activities related to specific measures so that their performance and scores can be maximized. 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.

Hospital measure information is also used by CMS to direct its contractors to focus on particular areas of improvement and to develop quality improvement initiatives. Medicare beneficiaries experience a high rate of preventable readmissions, which are burdensome to patients and families, as well as costly. Quality Innovation Network-Quality Improvement Organizations (QIN-QIOs), under contract with CMS, use readmissions data from CMS to assist communities to reduce avoidable readmissions. For example, the QIN-QIO program helps communities with high readmission rates form local coalitions, identify the factors driving avoidable hospital readmissions in their area, and find ways to better coordinate care and to encourage patients to manage their health more actively.

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. Feedback from these focus groups have helped CMS understand how beneficiaries and consumers use *Hospital Compare*. Under emergency circumstances, consumers choose hospitals based on proximity, reputation, prior experience, or their doctor's recommendation. For childbirth or elective hospital admissions, when patients and their family members may have the time and motivation to consider options and engage in informed decision making, they have expressed interest in emergency department wait times, information about the hospital's (and physician's) track record in treating their condition, staff credentials, staffing ratios, and a hospital's recognized areas of expertise, as well as to take into consideration their doctor's recommendation.

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 federal registries like the National Healthcare Safety Network for HAI measures), as well as to 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. Except as otherwise noted above, 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 eCQMs in the Hospital IQR measure 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 980 participating IPPS 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. The following table details the frequency of data submission to CMS by measure type.

Measure Type	*Frequency of Data Collection*
Chart-abstracted clinical process of care	quarterly
EHR-based clinical process of care (i.e., eCQMs)	annual
Structural	annual

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 2019 IPPS/LTCH PPS proposed rule went on display on April 24, 2018, and was published in the *Federal Register* on May 7, 2018 (83 FR 20164). Comments were submitted on this notice, and we responded to those comments accordingly in the FY 2019 IPPS/LTCH PPS final rule.

The final rule was published in the *Federal Register* on August 17, 2018 (83 FR 41144).

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

No payments or gifts will be given to respondents for participation. As noted in the FY 2016 IPPS/LTCH IPPS final rule (80 FR 49762 through 49763), we reimburse hospitals directly for expenses associated with submission of charts for clinical process of care measure data validation – we reimburse hospitals at 12 cents per photocopied page; for hospitals providing charts digitally via a re-writable disc, such as encrypted CD-ROM, DVD, or flash drive, we reimburse hospitals at a rate of 40 cents per disc.

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

As discussed in section A.1.b above, in the FY 2019 IPPS/LTCH PPS proposed rule, we did not propose to add any new measures for the Hospital IQR Program. However, in the FY 2019 IPPS/LTCH PPS final rule, we are finalizing our proposals to modify other program requirements that we expect would affect our burden estimates, including: (1) updates to the eCQM reporting and submission requirements for the FY 2021 payment determination; (2) removal of three chart-abstracted measures beginning with the FY 2021 payment determination; and (3) removal of six chart-abstracted measures beginning with the FY 2022 payment determination. Details on these finalized policies, as well as the expected burden changes, are discussed below.

In addition, we are finalizing several modifications that we do not expect to affect our burden estimates. Specifically, we are finalizing our proposals to: (1) update the EHR certification requirements for the FY 2021 payment determination; (2) remove 17 claims-based measures beginning with the FY 2020 payment determination; (3) remove two claims-based measures beginning with the FY 2021 payment determination; (4) remove one claims-based measure beginning with FY 2022 payment determination; (5) remove one claims-based measure beginning with the FY 2023 payment determination; (6) remove two structural measures beginning with the FY 2020 payment determination; and (7) remove seven eCQMs beginning with the FY 2022 payment determination. Our burden estimates exclude burden associated with the National Healthcare Safety Network under OMB control number 0920-0666, the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey under OMB

control number 0938-0981, and the Medicare Promoting Interoperability Program under OMB control number 0938-1158.

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 $18.29 per hour;[4] 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 $36.58 ($18.29 base salary + $18.29 fringe).

b. Modified Estimates for the FY 2020 Payment Determination

In the FY 2019 IPPS/LTCH PPS final rule, we are finalizing our proposals to remove 17 claims-based measures and two structural measures beginning with the FY 2020 payment determination.

With regard to the Hospital IQR Program requirements finalized for the FY 2020 payment determination, we estimate no change in burden as a result of these policy changes. Because claims-based measures are calculated based on data that are already reported to the Medicare program for payment purposes, we do not anticipate removing these measures would increase or decrease reporting burden on hospitals.

We further anticipate removing two structural measures would result in a negligible burden reduction for hospitals. We are finalizing our proposal to remove the Hospital Survey on Patient Safety Culture measure because hospitals are asked only whether they administer a patient safety culture survey, and by design, this structural measure does not provide information on patient outcomes. We are also finalizing our proposal to remove the Safe Surgery Checklist Use measure for which hospitals indicate by "Yes" or "No" whether or not they use a safe surgery checklist for surgical procedures. Consistent with previous years (80 FR 49762), we estimate a burden of 15 minutes per hospital to report all four previously finalized structural measures and to complete other forms (such as the CMS Quality Program Extraordinary Circumstances Exceptions Request Form). Therefore, our burden estimate of 15 minutes per hospital remains unchanged because we believe the reduction in burden associated with removing these two structural measures is sufficiently minimal that it would not substantially impact this estimate.

[4] Occupational Outlook Handbook. Available at: https://www.bls.gov/oes/2016/may/oes292071.htm.

c. Modified Estimates for the FY 2021 Payment Determination

In the FY 2019 IPPS/LTCH final rule, we are finalizing our proposals to remove three clinical process of care measures beginning with the FY 2021 payment determination and to continue the eCQM reporting requirements previously adopted for the FY 2019 payment determination and FY 2020 payment determination of requiring one, self-selected quarter of data for four, self-selected eCQMs.

As discussed below, we estimate a total burden decrease of 1,117,182 hours, and a total cost decrease of approximately $41 million, across all participating hospitals associated with the policy changes finalized for the FY 2021 payment determination.

Finalized Measure Removals

For IPPS hospitals, we estimate removing the ED-1 and IMM-2 measures beginning with the FY 2021 payment determination will result in a total burden reduction of 741,074 hours across all IPPS for the FY 2021 payment determination. This estimate was based on calculating the burden for reporting only the ED-2 measure[5] ([15 minutes per record x 260 records per hospital per quarter x 4 quarters] / 60 minutes per hour x 3,300 hospitals = 858,000 hours), minus the previously estimated burden for reporting the combined global population set (ED-1, ED-2, and IMM-2) of 1,599,074 hours. Through these calculations (858,000 hours - 1,599,074 hours), we estimate reduction of 741,074 hours across all IPPS hospitals, or approximately 225 hours per hospital per year (741,074 hours / 3,300 hospitals) and approximately $27.1 million (741,074 hours x $36.58 per hour) across all IPPS hospitals for the FY 2021 payment determination.

For non-IPPS hospitals, we estimate removing the ED-1 and IMM-2 measures beginning with the FY 2021 payment determination will result in a burden reduction of 65,853 hours across all participating non-IPPS hospitals for the FY 2021 payment determination. This estimate was based on calculating the burden for reporting only the ED-2 measure[6] ([15 minutes per record x 55 records per hospital per quarter x 4 quarters] / 60 minutes per hour x 898 hospitals[7] = 49,390 hours), minus the previously estimated burden for reporting the combined global population set (ED-1, ED-2, and IMM-2) of 115,243 hours. Through these calculations (49,390 hours - 115,243 hours), we estimate a reduction of 65,853 hours across all non-IPPS hospitals, or approximately 73 hours per hospital per year (65,853 hours per hospital / 898 hospitals) and approximately $2.4 million (65,853 hours x $36.58 per hour) across all participating non-IPPS hospitals for the FY 2021 payment determination.

We anticipate a reduction in burden for hospitals as a result of the finalized removal of the VTE-6 chart-abstracted measure. For IPPS hospitals, we have previously estimated a total of 304,997 hours across all 3,300 IPPS hospitals associated with reporting the VTE-6 measure, or

[5] Estimated 15 minutes per case for reporting ED-2 measure based on average Clinical Data Abstraction Center abstraction times for 3Q 2016, 4Q 2016, and 1Q 2017 discharge data.
[6] Estimated 15 minutes per case for reporting ED-2 measure based on average Clinical Data Abstraction Center abstraction times for 3Q 2016, 4Q 2016, and 1Q 2017 discharge data.
[7] Based on data from previous years' data collection, we estimate 898 non-IPPS hospitals voluntarily submit data for the ED throughput/IMM-2 measure set.

approximately 92 hours per hospital per year (304,997 hours / 3,300 hospitals), and therefore estimate a corresponding burden decrease of 304,997 hours and approximately $11.2 million (304,997 hours x $36.58 per hour) for the FY 2021 payment determination. For non-IPPS hospitals, we have previously estimated a reporting burden of 5,191 hours across all participating non-IPPS hospitals associated with reporting the VTE-6 measure, or approximately 13 hours per hospital per year (5,191 hours / 412 hospitals[8]), and therefore estimate a corresponding burden decrease of 5,191 hours and approximately $190,000 (5,191 hours x $36.58 per hour) for the FY 2021 payment determination.

In sum, we anticipate a total burden decrease of 1,117,115 hours (806,927 hours for removal of ED-1 and IMM-2 [741,074 hours IPPS hospitals + 65,853 hours non-IPPS hospitals] + 310,188 hours for removal of VTE-6 [304,997 hours IPPS hospitals + 5,191 hours non-IPPS hospitals]), and a total cost decrease of approximately $41 million (1,117,115 hours x $36.58 per hour), across all participating hospitals associated with our finalized measure removals for the FY 2021 payment determination.

Measure Validation Impacts

As noted in the FY 2016 IPPS/LTCH IPPS final rule (80 FR 49762 and 49763), we have previously reimbursed hospitals directly for expenses associated with submission of charts for clinical process of care measure data validation. Therefore, we do not anticipate any change in burden associated with submission of validation charts as a result of the finalized removals of the three clinical process of care measures because hospitals would no longer be required to submit, or be reimbursed for submitting, these data to CMS.

Finalized eCQM Submission Requirements

In the FY 2019 IPPS/LTCH PPS final rule, we are finalizing our proposal to require that hospitals submit one, self-selected calendar quarter of data for four eCQMs in the Hospital IQR Program measure set for the FY 2021 payment determination. Because these are the same eCQM reporting requirements that were finalized for the FY 2020 payment determination in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38355 through 38361), we do not expect this finalized policy to change our previously determined burden estimates because we are finalizing a continuation of existing policies. 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 one 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, for IPPS hospitals, we anticipate our finalized policy to require: (1) reporting on four of the available eCQMs; and (2) submission of one quarter of CY 2019 eCQM data, will result in the continued burden of 0.67 hours per hospital per year ([10 minutes per record x 4 eCQMs x 1 quarter] / 60 minutes per hour = 40

[8] Based on data from previous years' data collection, we estimate 412 non-IPPS hospitals voluntarily submit data for the VTE-6 measure.

minutes for 1 quarter of reporting, or 0.67 hours), or a total of 2,200 hours (0.67 hours per hospital x 3,300 hospitals) and approximately $80,500 (2,200 hours x $36.58 per hour) across all IPPS hospitals associated with eCQM reporting. For non-IPPS hospitals, we estimate our eCQM policy will result in the continued burden of 0.67 hours per hospital per year ([10 minutes per record x 4 eCQMs x 1 quarter] / 60 minutes per hour = 40 minutes for 1 quarter of reporting, or 0.67 hours), or a total of 733 hours (0.67 hours per hospital x 1,100 hospitals) and approximately $26,800 (1,100 hours x $36.58 per hour) across all non-IPPS hospitals associated with eCQM reporting. As these are the same eCQM reporting requirements that were finalized for the FY 2020 payment determination in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38355 through 38361) and the same burden estimates, we do not expect our finalized policy to change our burden estimates for the FY 2021 payment determination because we are finalizing a continuation of existing policies.

Table 1. Burden Calculations for the Hospital IQR Program Measure Set and Other Activities for the FY 2021 Payment Determination

Measure Set	***Estimated time per record (minutes) - FY 2021 payment determination***	***Number reporting quarters per year - FY 2021 payment determination***	***Number of hospitals reporting***	***Average number records per hospital per quarter***	***Annual burden (hours) per hospital***	***Calculation for FY 2021 payment determination***
CHART ABSTRACTION						
IPPS Hospitals (3,300)						
Emergency department (ED) throughput	15	4	3,300	260	260	858,000
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					**711**	**2,345,200**
Non-IPPS Hospitals (1,100)						
Emergency department (ED) throughput	15	4	898	55	55	49,390
Sepsis measure	60	4	362	25	100	36,200
Perinatal care (PC)	10	4	334	21	14	4,676

Subtotal Non-IPPS chart-based					**169**	**90,266**
Subtotal IPPS and Non-IPPS chart-based						**2,435,466**
OTHER ACTIVITIES **All Hospitals (3,300 IPPS + 1,100 non-IPPS)**						
Population and sampling for the 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 four electronic Clinical Quality Measures (IPPS)	40	1	3,300	1	0.67	2,200
Reporting four electronic Clinical Quality Measures (non-IPPS)	40	1	1,100	1	0.67	733
eCQM Validation	80	1	200	8	11	2,200
All other forms used in the data collection process	15	1	4,400	1	0.25	1,100
Subtotal other activities						**84,633**
Total						**2,520,100**

Summary

In total, we estimate: (1) a decrease of 1,046,071 hours (-741,074 hours for ED-1 and IMM-2 removal + -304,997 hours for VTE-6 removal) and approximately $38.3 million (1,046,071 hours x $36.58 per hour) across all 3,300 IPPS hospitals due to the finalized removal of three chart-abstracted measures; (2) a decrease of 71,044 hours (-65,853 hours for ED-1 and IMM-2 removal + -5,191 hours for VTE-6 removal) and approximately $2.6 million (71,044 hours x $36.58 per hour) across participating non-IPPS hospitals due to the finalized removal of three chart-abstracted measures; and (3) a decrease of 67 hours and approximately $2,400 due to the discontinuation of voluntary data collection of the Hybrid Hospital-Wide Readmission measure.[9] In total for the FY 2021 payment determination, we estimate a burden decrease of approximately 1,117,182 hours (-1,046,071 hours + -71,044 hours + -67 hours) and approximately $41 million (-1,117,182 hours x $36.58 per hour) across all participating IPPS and non-IPPS hospitals due to the finalized changes set forth in the FY 2019 IPPS/LTCH PPS final rule.

Given the estimated burden reduction summarized above, we estimate a total burden of 2,520,100 hours for the FY 2021 payment determination. With our estimated wage rate of $36.58 per hour, we estimate a total cost of approximately $92.2 million. We reiterate that we are amending our approved estimates for the FY 2021 payment determination, and our finalized policy changes would result in a burden reduction compared to the previously approved total burden estimate under this OMB control number. We are requesting approval of this modified burden estimate for the FY 2021 payment determination.

d. Modified Estimates for the FY 2022 Payment Determination

In the FY 2019 IPPS/LTCH PPS final rule, we are finalizing our proposals to remove six chart-abstracted measures (ED-2, a clinical process of care measure, and five HAI measures) beginning with the FY 2022 payment determination. We anticipate removing the one clinical process of care measure will reduce the reporting burden for hospitals. Because the burden associated with submitting the HAI measure data (specifically, CLABSI, CAUTI, MRSA, CDI, and SSI measures) to the Centers for Disease Control and Prevention's National Healthcare Safety Network is captured under a separate OMB control number, 0920-0666, we do not provide an independent estimate of the burden associated with these measures for the Hospital IQR Program. For this reason, we do not anticipate a reduction in data collection and reporting burden associated with the removals of the HAI measures from the program. We note that we anticipate a reduction in burden associated with validation activities for the HAI measures, as discussed further in section B.12.e below (*Modified Estimates for the FY 2023 Payment Determination*).

[9] In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38350 through 38355), we finalized our proposal to collect data on a voluntary basis for the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (NQF #2879) for the FY 2020 payment determination. We estimated that approximately 100 hospitals would participate in voluntarily reporting data for this measure, resulting in a burden of 0.67 hours per hospital per year, or a total burden of 67 hours across all 100 participating hospitals for the FY 2020 payment determination (82 FR 38504). Because we only finalized voluntary collection of data for one year, voluntary collection of these data will no longer occur beginning with the FY 2021 payment determination and subsequent years, resulting in a reduction in burden of 67 hours across all participating hospitals.

As discussed below, we estimate a total burden decrease of 907,390 hours, and a total cost decrease of approximately $33.2 million, across all participating hospitals associated with the policy changes as finalized for the FY 2022 payment determination.

Finalized Measure Removals

We anticipate a reduction in burden for hospitals as a result of the finalized removal of the ED-2 chart-abstracted measure, which would be the only ED measure left in the Hospital IQR Program; as a result, removing this measure would also remove all remaining burden associated with reporting this measure data. As discussed above, we estimate reporting the ED-2 measure takes approximately 260 hours per hospital per year ([15 minutes per record x 260 records per hospital per quarter x 4 quarters] / 60 minutes per hour), or a total of 858,000 hours (260 hours x 3,300 hospitals) across all IPPS hospitals. We therefore estimate a corresponding burden decrease of 858,000 hours and approximately $31.4 million (858,000 hours x $36.58 per hour) for the FY 2022 payment determination as a result of the finalized removal of the ED-2 measure from the Hospital IQR Program.

For non-IPPS hospitals, as discussed above, we estimate reporting the ED-2 measure takes approximately 55 hours per hospital per year ([15 minutes per record x 55 records per hospital per quarter x 4 quarters] / 60 minutes), or a total of 49,390 hours (55 hours x 898 hospitals[10]) across participating non-IPPS hospitals. We therefore estimate a corresponding burden decrease of 49,390 hours and approximately $1.8 million (49,390 hours x $36.58 per hour) for the FY 2022 payment determination as a result of the finalized removal of the ED-2 measure from the Hospital IQR Program.

In sum, we anticipate a total burden decrease of 907,390 hours, or a total cost decrease of approximately $33.2 million, across all participating hospitals associated with the finalized removal of ED-2 for the FY 2022 payment determination.

Measure Validation Impacts

As noted in the FY 2016 IPPS/LTCH IPPS final rule (80 FR 49762 and 49763), we have previously reimbursed hospitals directly for expenses associated with submission of charts for clinical process of care measure data validation. Therefore, we do not anticipate any change in burden associated with submission of validation charts as a result of the finalized removal of the ED-2 measure because hospitals would no longer be required to submit, or be reimbursed for submitting, these data to CMS.

Table 2. Burden Calculations for the Hospital IQR Program Measure Set and Other Activities for the FY 2022 Payment Determination

[10] Based on data from previous years' data collection, we estimate 898 non-IPPS hospitals voluntarily submit data for the ED throughput/IMM-2 measure set.

Measure Set	*Estimated time per record (minutes) - FY 2022 payment determination*	*Number reporting quarters per year - FY 2022 payment determination*	*Number of hospitals reporting*	*Average number records per hospital per quarter*	*Annual burden (hours) per hospital*	*Calculation for FY 2022 payment determination*
CHART ABSTRACTION						
IPPS Hospitals (3,300)						
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					**451**	**1,487,200**
Non-IPPS Hospitals (1,100)						
Sepsis measure	60	4	362	25	100	36,200
Perinatal care (PC)	10	4	334	21	14	4,676
Subtotal Non-IPPS chart-based					**114**	**40,876**
Subtotal IPPS and Non-IPPS chart-based						**1,528,076**
OTHER ACTIVITIES **All Hospitals (3,300 IPPS + 1,100 non-IPPS)**						
Population and sampling for the 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 four electronic	40	1	3,300	1	0.67	2,200

Clinical Quality Measures (IPPS)						
Reporting four electronic Clinical Quality Measures (non-IPPS)	40	1	1,100	1	0.67	733
eCQM Validation	80	2	200	8	21	2,200
All other forms used in the data collection process and structural measures	15	1	4,400	1	0.25	1,100
Subtotal other activities						**84,633**
Total						**1,612,710**

Summary

In total, we estimate: (1) a decrease of 858,000 hours and approximately $31.4 million across all 3,300 IPPS hospitals due to the finalized removal of the ED-2 chart-abstracted measure; and (2) a decrease of 49,390 hours and approximately $1.8 million across participating non-IPPS hospitals due to the finalized removal of the ED-2 chart-abstracted measure, as discussed above. In total for the FY 2022 payment determination, we estimate a decrease of approximately 907,390 hours (-858,000 hours + -49,390 hours) and $33.2 million (-907,390 hours x $36.58 per hour) across all participating IPPS and non-IPPS hospitals due to the finalized changes set forth in the FY 2019 IPPS/LTCH PPS final rule.

Given the estimated burden reduction summarized above, we estimate a total burden of 1,612,710 hours (2,520,100 hours - 907,390 hours) for the FY 2022 payment determination. With our estimated wage rate of $36.58 per hour, we estimate a total cost of approximately $59.0 million. We note that our finalized policy changes in the FY 2019 IPPS/LTCH PPS final rule will result in a burden reduction compared to the total burden estimated for the FY 2021 payment determination described above. We are requesting approval of this burden estimate for the FY 2022 payment determination.

e. Estimates for the FY 2023 Payment Determination

In the FY 2019 IPPS/LTCH PPS final rule, we are finalizing our proposal to remove one claims-based measure beginning with the FY 2023 payment determination. We do not anticipate that removal of this claims-based measure will result in a change in burden. We do anticipate a change in burden associated with Hospital IQR Program validation activities for the HAI measures beginning with the FY 2023 payment determination. As the HAI measures are being

finalized for removal from the Hospital IQR Program beginning with the FY 2022 payment determination, the last year of HAI validation under the Hospital IQR Program will be conducted for the FY 2022 payment determination. As discussed in the FY 2019 IPPS/LTCH PPS final rule, because the HAI measures will be retained in the Hospital-Acquired Condition Reduction Program, the HAI validation activities will be transferred to the latter program beginning with the FY 2023 payment determination.

As discussed below, we anticipate a total burden decrease of 43,200 hours, and a total cost decrease of approximately $1.6 million, across all participating hospitals associated with the policy changes as finalized for the FY 2023 payment determination.

Finalized Measure Removal

As discussed above, we are finalizing our proposal to remove one claims-based measure beginning with the FY 2023 payment determination, Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty. We estimate no change in burden as a result of this finalized policy. Because claims-based measures are calculated based on data that are already reported to the Medicare program for payment purposes, we do not anticipate removing this measure would increase or decrease reporting burden on hospitals.

Measure Validation Impacts

While we did not propose to make any changes to our validation requirements related to chart-abstracted measures, we believe that hospitals would experience an overall reduction in burden under the Hospital IQR Program (OMB control number 0938-1022) associated with HAI measure validation beginning with the FY 2023 payment determination as a result of the finalized removal of five HAI measures beginning with the FY 2022 payment determination.

Because we are finalizing our proposals to remove all five of the HAI measures from the Hospital IQR Program and transfer HAI data validation to the Hospital-Acquired Condition Reduction Program, where the HAI measures will be retained, and because hospitals selected for validation currently are required to submit validation templates for the HAI measures, we anticipate a reduction in burden under the Hospital IQR Program associated with the HAI data validation effort beginning with the FY 2023 payment determination. We have previously estimated a reporting burden of 80 hours per hospital selected for chart-abstracted measure validation per year ([1,200 minutes per record x 1 record per hospital per quarter x 4 quarters] / 60 minutes per hour) to submit the CLABSI and CAUTI validation templates, and 64 hours per hospital selected for chart-abstracted measure validation per year ([960 minutes per record x 1 record per hospital per quarter x 4 quarters] / 60 minutes per hour) to submit the MRSA and CDI validation templates. We therefore estimate a total burden decrease of 43,200 hours ([-80 hours per hospital to submit CLABSI and CAUTI templates + -64 hours per hospital to submit MRSA and CDI templates] x 300 hospitals selected for validation) and approximately $1.6 million (43,200 hours x $36.58 per hour) as a result of discontinuing HAI validation under the Hospital IQR Program beginning with the FY 2023 payment determination.

Table 3. Burden Calculations for the Hospital IQR Program Measure Set and Other Activities for the FY 2023 Payment Determination

Measure Set	***Estimated time per record (minutes) - FY 2023 payment determination***	***Number reporting quarters per year - FY 2023 payment determination***	***Number of hospitals reporting***	***Average number records per hospital per quarter***	***Annual burden (hours) per hospital***	***Calculation for FY 2023 payment determination***
CHART ABSTRACTION						
IPPS Hospitals (3,300)						
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					**451**	**1,487,200**
Non-IPPS Hospitals (1,100)						
Sepsis measure	60	4	362	25	100	36,200
Perinatal care (PC)	10	4	334	21	14	4,676
Subtotal Non-IPPS chart-based					**114**	**40,876**
Subtotal IPPS and Non-IPPS chart-based						**1,528,076**
OTHER ACTIVITIES **All Hospitals (3,300 IPPS + 1,100 non-IPPS)**						
Population and sampling for the 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
Reporting four electronic Clinical Quality Measures (IPPS)	40	1	3,300	1	0.67	2,200

Reporting four electronic Clinical Quality Measures (non-IPPS)	40	1	1,100	1	0.67	733
eCQM Validation	80	2	200	8	21	2,200
All other forms used in the data collection process and structural measures	15	1	4,400	1	0.25	1,100
Subtotal other activities						**41,433**
Total						**1,569,510**

Summary

In total, we estimate: (1) no change in burden across all participating hospitals due to the finalized removal of the one claims-based measure; and (2) a decrease of 43,200 hours and approximately $1.6 million associated with the discontinuation of HAI data validation under the Hospital IQR Program, as discussed above.

Given the estimated burden reduction summarized above, we estimate a total burden of 1,569,510 hours (1,612,710 hours - 43,200 hours) for the FY 2023 payment determination. With our estimated wage rate of $36.58 per hour, we estimate a total cost of approximately $57.4 million. We note that our finalized policy changes in the FY 2019 IPPS/LTCH PPS final rule will result in a burden reduction compared to the total burden estimated for the FY 2022 payment determination described above. We are requesting approval of this burden estimate for the FY 2023 payment determination.

f. 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 chart-abstracted measures, set up and reporting of population and sampling for new measures, if any, 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 separately 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 (80 FR 49762).

As discussed in section B.12.b above, we anticipate removing the two structural measures would result in a negligible burden reduction for hospitals and continue to estimate 15 minutes per hospital for the burden associated with *"all other forms used in the data collection process"*, as the forms listed in section A.1.e would not be filled out by hospitals on a regular basis. Because the CMS Quality Reporting Program Extraordinary Circumstances Exceptions (ECE) Request Form would be used across ten quality programs (Hospital IQR Program, Hospital Outpatient Reporting Program, Inpatient Psychiatric Facility Quality Reporting Program, PPS-Exempt Cancer Hospital Quality Reporting Program, Ambulatory Surgical Center Quality Reporting Program, Hospital VBP Program, Hospital-Acquired Condition Reduction Program, Hospital Readmissions Reduction Program, End Stage Renal Disease Quality Incentive Program, and Skilled Nursing Facility Value-Based Purchasing 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 exception 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 Tables 1, 2, and 3 above) of 1,100 hours across all 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 $96,970 for an additional cost of $290,910.

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 2019 IPPS/LTCH PPS final rule, we are finalizing our policy to continue the eCQM reporting requirements previously adopted for the FY 2019 payment determination and FY 2020 payment determination, such that hospitals must submit one, self-selected calendar quarter of data for four eCQMs in the Hospital IQR Program measure set for the FY 2021 payment determination. This finalized policy represents no change in burden from the eCQM reporting requirements finalized in the FY 2018 IPPS/LTCH PPS final rule for the FY 2019 payment determination and the FY 2020 payment determination.

Beginning with the FY 2020 payment determination and subsequent years, we are finalizing removal of 19 measures: (1) Patient Safety and Adverse Events Composite Measure (PSI 90); (2) Hospital 30-day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization; (3) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure Hospitalization; (4) Hospital 30-Day All-Cause Risk-Standardized Readmission Rate Following Acute Myocardial Infarction (AMI) Hospitalization; (5) Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization; (6) Hospital 30-Day, All-Cause, Unplanned, Risk-Standardized Readmission Rate Following Coronary Artery Bypass Graft (CABG) Surgery; (7) Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Heart Failure Hospitalization; (8) Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Pneumonia Hospitalization; (9) 30-day Risk-Standardized Readmission Rate Following Stroke Hospitalization; (10) Hospital-Level 30-Day, All-Cause Risk-Standardized Readmission Rate Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty; (11) Payment Standardized Medicare Spending Per Beneficiary (MSPB); (12) Cellulitis Clinical Episode-Based Payment Measure; (13) Gastrointestinal Hemorrhage Clinical Episode-Based Payment Measure; (14) Kidney/Urinary Tract Infection Clinical Episode-Based Payment Measure; (15) Aortic Aneurysm Procedure Clinical Episode-Based Payment Measure; (16) Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment Measure; (17) Spinal Fusion Clinical Episode-Based Payment Measure; (18) Safe Surgery Checklist Use; and (19) Hospital Survey on Patient Safety Culture.

Beginning with the FY 2021 payment determination and subsequent years, we are finalizing removal of five measures: (1) Median Time from ED Arrival to ED Departure for Admitted ED Patients (ED-1) chart-abstracted measure; (2) Influenza Immunization (IMM-2); (3) Incidence of Potentially Preventable VTE (VTE-6); (4) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD); and (5) Hospitalization and Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization.

Beginning with the FY 2022 payment determination and subsequent years, we are finalizing removal of fourteen measures: (1) Facility-Wide Inpatient Hospital-Onset Clostridium difficile Infection Outcome (CDI); (2) Catheter-Associated Urinary Tract Infection Outcome (CAUTI); (3) Central Line-Associated Bloodstream Infection Outcome (CLABSI); (4) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant Staphylococcus Aureus Bacteremia Outcome (MRSA); (5) American College of Surgeons – Centers for Disease Control and Prevention

Harmonized Procedure-Specific Surgical Site Infection (SSI) Outcome Measure for Colon Procedures and Hysterectomy Procedures (Colon and Abdominal Hysterectomy); (6) Admit Decision Time to ED Departure Time for Admitted Patients (ED-2) chart-abstracted measure; (7) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery measure; (8) Primary Percutaneous Coronary Intervention Received within 90 Minutes of Hospital Arrival eCQM; (9) Home Management and Plan of Care Document Given to Patient/Caregiver eCQM; (10) Median Time from ED Arrival to ED Departure for Admitted ED Patients eCQM[11]; (11) Hearing Screening Prior to Hospital Discharge eCQM; (12) Elective Delivery Prior to 39 Completed Weeks Gestation eCQM; (13) Stroke Education eCQM; and (14) Assessed for Rehabilitation eCQM.

Beginning with the FY 2023 payment determination, we are finalizing removal of one measure, Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty.

To summarize the burden changes, we anticipate no change in burden estimation for the FY 2020 payment determination. For the FY 2021 payment determination, we estimate a decrease in annual burden of 1,117,182 hours and approximately $41 million across all participating hospitals associated with our finalized policy changes. For the FY 2022 payment determination, we estimate a decrease in annual burden of 907,390 hours and approximately $33.2 million across all participating hospitals associated with our finalized policy changes. For the FY 2023 payment determination, we estimate a decrease in annual burden of 43,200 hours and approximately $1.6 million across all participating hospitals associated with our finalized policy changes.

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.

[11] In the FY 2019 IPPS/LTCH PPS final rule, we are finalizing our proposals to remove Median Time from ED Arrival to ED Departure for Admitted ED Patients (ED-1) in both chart-abstracted and eCQM forms.

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). 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.