

Supporting Statement—Part A

Quality Measures and Administrative Procedures for the Hospital-Acquired Condition Reduction Program for the FY 2019 IPPS Program Year (CMS-10668)

A Background

The Centers for Medicare & Medicaid Services (CMS) is committed to promoting higher quality healthcare and improving outcomes for Medicare beneficiaries. The Hospital-Acquired Condition (HAC) Reduction Program is established by section 1886(p) of the Act, as added by Section 3008 of the Affordable Care Act (Pub. L. 111-148), and requires the Secretary to reduce payments to subsection (d) hospitals in the worst-performing quartile of all subsection (d) hospitals by 1 percent effective beginning on October 1, 2014 and subsequent years.

To administer its requirements, the HAC Reduction Program relies on data collection and validation processes established through the Center of Disease Control's (CDC) OMB control number, 0920-0666, and the Hospital Inpatient Quality Reporting (IQR) Program's OMB control number, 0938-1022. However, in the Fiscal Year (FY) 2019 Inpatient Prospective Payment System (IPPS)/Long-Term Care Hospital (LTCH) PPS final rule, the Hospital IQR Program is finalizing the removal of National Healthcare Safety Network (NHSN) Healthcare-associated Infection (HAI) measures and NHSN HAI validation processes beginning on January 1, 2020. Removing the NHSN HAI measures from the Hospital IQR Program, and ceasing collection and validation of these measures under the Hospital IQR Program will affect how the HAC Reduction Program administers its NHSN HAI data collection and validation in subsequent years. To continue effective administration of the HAC Reduction Program, beginning with the Q3 2020 discharges for FY 2023, the HAC Reduction Program will adopt validation templates similar to the ones retired by Hospital IQR Program to continue the HAC Reduction Program's use and validation of NHSN HAI data.

The HAC Reduction Program identifies the worst-performing quartile of hospitals by calculating a Total HAC Score derived from the CMS PSI 90 and NHSN HAI measures, which require that we collect claims-based and chart-abstracted measures data, respectively. As stated above, validation of NHSN HAI measures was previously performed by the Hospital IQR Program. Because the Hospital IQR Program is finalizing its proposal to remove and cease validation for NHSN HAI measures, the HAC Reduction Program is adopting policies to validate NHSN HAI data reported by subsection (d) hospitals to ensure that hospitals report correct NHSN HAI measure data, and the Total HAC Score is calculated using accurate data. The HAC Reduction Program is also finalizing a policy to penalize any hospitals that fail validation by assigning the maximum Winsorized z-score for the set of measures, which fail validation, for use in the Total HAC Score calculation. The collection of information for validation is necessary ensure that the HAC Reduction Program and Total HAC Score are administered fairly.

The HAC Reduction Program will continue to receive NHSN HAI data for hospitals from CDC. Because the burden associated with submitting data for the HAI measures (CDI, CAUTI,

CLABSI, MRSA, and SSI) 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.

1 HAC Reduction Program Quality Measures

a. Introduction

The FY 2020 payment determination for the HAC Reduction Program will be based on data for the CMS PSI 90 Composite using the 24-month period from July 1, 2016 through June 30, 2018, and data for NHSN HAI measures using the 24-month period from January 1, 2017 through December 31, 2018, which are consistent with the applicable periods specified in the CFR at § 412.170. Because the HAC Reduction Program is a payment program, it must ensure proper exceptions are available to hospitals that do not meet NHSN HAI data requirements and ensure the accuracy of the NHSN HAI data submissions. The HAC Reduction Program must collect information to verify hospital exceptions and data submissions. 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. Measures

We note that in the FY 2019 Inpatient Prospective Payment System (IPPS)/Long-Term Care Hospital (LTCH) PPS final rule, we did not finalize the addition or removal of any measures for the FY 2019 program year or subsequent years. The HAC Reduction Program currently has adopted six measures, which were finalized in previous rulemaking. The program uses five Centers for Disease Control and Prevention (Catheter-Associated Urinary Tract Infection (CAUTI), NHSN Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI), NHSN Central Line-Associated Bloodstream Infection (CLABSI), American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (Colon and Abdominal Hysterectomy SSI), and NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus MRSA Bacteremia (MRSA). The Program also uses Patient Safety and Adverse Events Composite (CMS PSI 90 Composite) as its sixth measure.

c. Forms Used in the Data Collection Process

To facilitate the HAC Reduction Program, validation templates to ensure data accuracy are necessary. There are 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).

The validation templates are dependent upon a hospital's selection for validation and may not be required by any particular hospital in any given year.

All the information to collect the templates listed above have been previously used in the Hospital IQR Program. We note that the only changes to these templates are updates to the

program name to reflect the HAC Reduction Program on the forms and that certain annual updates are made to the validation templates for the CLABSI, CAUTI, MRSA, and CDI measures 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.

Additionally, we note that the burden associated with completing and submitting:

- Hospital Inpatient Quality Reporting (IQR) Program Data Accuracy and Completeness Acknowledgement (DACA)
- Centers for Medicare & Medicaid Services (CMS) Inpatient Prospective Payment System (IPPS) Quality Reporting Programs Measure Exception Form for PC, ED, and HAI Data Submission
- Hospital Inpatient Quality Reporting (IQR) Program Validation Educational Review Form, and
- Centers for Medicare & Medicaid Services (CMS) Quality Reporting Program Extraordinary Circumstances Exceptions (ECE) Request Form

are already accounted for under OMB Control Number 0938-1022.

Only the Data Accuracy and Completeness Acknowledgement (DACA) form must be completed by all hospitals 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.

B Justification

1 Need and Legal Basis

Annually, subsection (d) hospitals covered under Section 5001(b) of the DRA must complete a 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 an acknowledgement that the data a hospital has submitted are complete and accurate. The burden associated with the DACA form is accounted for under the Hospital Inpatient Quality Reporting (IQR) Program’s OMB control number, 0938-1022.

In addition to the DACA form, the HAC Reduction Program has adopted a number of ad hoc processes for situations that may impact specific hospitals. These processes include an Extraordinary Circumstances policy, an NHSN HAI exception policy for hospitals with certain data considerations, and an Educational Review Process for hospitals that have questions regarding the validation process or its results. In order for hospitals to engage these processes, hospitals must submit forms that are currently and will be subsequently associated with the Hospital IQR Program’s PRA Package. The burden associated with each of the forms used to avail themselves to the appropriate process is accounted for under the Hospital Inpatient Quality Reporting (IQR) Program’s OMB control number, 0938-1022.

The HAC Reduction Program is a payment program that assesses hospital performance with respect to healthcare-associated infections of all subsection (d) hospitals using claims-based and NHSN HAI measures. While all claims-based data is submitted through claims processing systems that have validation methods to accept accurate Medicare claims into the claims database, the NHSN HAI data is not validated through other CMS processes. For the HAC Reduction Program to assess hospitals fairly, it must be able to ensure the accuracy of the data it collects. Validation is necessary to ensure the data used by the program is both correct and useful.

Because the Hospital IQR Program is finalizing its proposal to remove NHSN HAI measures and the accompanying validation processes, the HAC Reduction Program is adopting analogous processes to continue validation. To validate NHSN HAI data, CMS performs a random selection of up to 600 subsection (d) hospitals in the HAC Reduction 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 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 be required to produce the CLABSI and CAUTI templates and the other 300 hospitals would be required to produce only the MRSA and CDI templates.

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 submit a CMS Inpatient Prospective Payment System (IPPS) Quality Reporting Programs Measure Exception Form for NHSN HAI Data Submission. This form is accounted for under OMB Control Number 0938-1022.

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. Likewise, the HAC Reduction Program will continue to update the templates annually. 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)).

Hospitals may use the educational review process to correct disputed chart-abstracted HAI measure validation results for all quarters of validation. To submit a formal request, hospitals can utilize the Educational Review Request Form. This form is accounted for under OMB Control Number 0938-1022.

In the event of extraordinary circumstances not within the control of the hospital, a hospital can request an exemption or extension for meeting program requirements. For the hospital to receive consideration for an extension or exemption, an Extraordinary Circumstances Exceptions (ECE) Request Form must be submitted within 90 calendar days of an extraordinary circumstance event. This form is accounted for under OMB Control Number 0938-1022.

2 Information Users

CMS will use the information collected for the HAC Reduction Program to determine whether a hospital is within the penalty quartile of subsection (d) hospitals. As stated above, the HAC Reduction Program applies a 1-percent payment reduction or penalty to subsection (d) hospitals in the worst-performing quartile of all subsection (d) hospitals. To determine which hospitals are in the worst-performing quartile, the HAC Reduction Program uses CMS PSI 90 data and NHSN HAI measure data. The Program must collect chart-abstracted information to validate NHSN HAI data reported by subsection (d) hospitals to ensure that hospitals report correct NHSN HAI measure data, and the Total HAC Score is calculated using accurate data. The information will be made available to hospitals for their use in internal 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.

3 Use of Information Technology

To assist hospitals in standardizing data collection initiatives across the industry, CMS continues to improve data collection tools to make data submission easier for hospitals (including the collection of data from paper medical records for chart-abstracted measures) and increase the utility of the data provided by the hospitals. The NHSN HAI measures are collected through National Healthcare Safety Network, a federal registry. Chart-abstracted information may be submitted electronically, but for many hospitals there still is a manual component.

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. As required by statute, CMS maintains a set of quality measures which a hospital must report to be scored in the HAC Reduction Program.

5 Small Businesses

Information collection requirements were designed to allow maximum flexibility specifically to small hospitals having 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 HAC Reduction Program includes 1,218 small hospitals in the FY 2019 program year. An additional 15 hospitals have not reported bed size data; this could bring the "small hospital" total to as high as 1,233. We do not expect this number to change significantly by the FY 2020 program year.

No special processes or procedures are available to small hospitals to make the information collection less burdensome. We anticipate that subsection (d) hospitals, including small subsection (d) hospitals, will experience little to no change as the Hospital IQR Program ceases its validation process and the HAC Reduction Program begins its validation process. We are

finalizing policies to make the processes under the HAC Reduction Program as similar as possible to the current Hospital IQR Program processes and anticipate that small hospitals participating in the Hospital IQR Program will continue to be familiar with the information collection request required for validation.

6 Less Frequent Collection

We have designed the collection of quality measure data to be as minimally burdensome as possible while collecting the information necessary for data validation and for calculation of summary figures to be used as reliable estimates of hospital performance. Data validation is expected to occur quarterly, but as noted above, only up to 600 hospitals will be selected for validation in any given quarter. Neither less frequent collection of data nor validation of fewer cases is practicable at this time. Less frequent data collection would strain the ability for CMS to validate the submitted validation template and accompany NHSN HAI infection cases in a timely manner. Under the current process, CDAC abstractors are able to review and validate hospital submissions as those submissions are made each quarter. If the hospitals submitted data less frequently, CDAC abstractors would not have time to complete the necessary reviews of each submission before the Total HAC Score is calculated. Similarly, if the HAC Reduction Program proposed to validate fewer cases, the statistical analysis would be altered, and the Program would be less likely to generate meaningful results from validation.

7 Special Circumstances

There are no special circumstances.

8 Federal Register/Outside Consultation

A 30-day Federal Register notice of the FY 2019 IPPS/LTCH PPS final rule published on August 17, 2018 (83 FR 39162).

CMS is supported in this initiative by the Centers for Disease Control and Prevention (CDC). The CDC collaborates with CMS on an ongoing basis, providing technical assistance in developing and/or identifying quality measures.

9 Payments/Gifts to Respondents

There will be no gifts given 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

There are no sensitive questions.

12 Burden Estimates (Hours & Wages)

a. Background

Under Section 1886(p) of the Social Security Act, we are required to rank hospitals with respect to the national average in hospital-acquired conditions and reduce payment by 1 percent to the worst performing quartile. In the FY 2019 IPPS/LTCH PPS final rule, we are not finalizing any new measures for the HAC Reduction Program; however, we are finalizing other modifications to transition certain forms from the Hospital IQR Program to the HAC Reduction Program for the FY 2021 and subsequent years. These burden estimates include the burden that was formerly associated validation templates for the Hospital IQR Program. In the three-year period covered under this data collection, a total of at most 600 hospitals (beginning in FY 2021) will be selected for validation. It excludes burden associated with the NHSN HAI data collection, which is captured under a separate OMB control number: 0920-0666.

For the purposes of burden estimation, we assume all activities associated with the HAC Reduction Program for 3,300 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 HAC Reduction 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;¹ 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. Estimates for the FY 2019 Program Year

We do not expect any burden increase associated with the HAC Reduction Program in FY 2019. Because changes to the Hospital IQR Program’s validation requirements related to chart-abstracted measures will not occur until January 1, 2020 in the FY 2021 for the HAC Reduction Program (and the FY 2023 payment determination for the Hospital IQR), we believe that hospitals will experience no increase in burden for the HAC Reduction Program in FY 2019.

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

c. Estimates for the FY 2020 Program Year

We do not expect any burden increase associated with the HAC Reduction Program in FY 2020 Program Year. Because changes to the Hospital IQR Program’s validation requirements related to chart-abstracted measures will not occur until January 1, 2020 in the FY 2021 for the HAC Reduction Program (and the FY 2023 payment determination for the Hospital IQR), we believe that hospitals will experience no increase in burden for the HAC Reduction Program FY 2020.

d. Estimates for the FY 2021 Program Year

We estimate a total burden shift of 43,200 hours associated with our proposed policy changes for FY 2021. Taken with our estimated wage rate of \$36.58, we estimate a total cost increase of approximately \$1,600,000.00 across all participating hospitals. The estimated total burden was calculated as follows:

We have previously estimated a reporting burden of 80 hours (20 hours x 1 record per hospital per quarter x 4 quarters) per hospital selected for validation per year to submit the CLABSI and CAUTI templates, and 64 hours (16 hours x 1 record per hospital per quarter x 4 quarters) per hospital selected for validation per year to submit the MRSA and CDI templates under the Hospital IQR Program. We estimate a total burden shift 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 hour²) because of the discontinuation of HAI validation under the Hospital IQR Program and transition of the validation process to the HAC Reduction Program.

Table 1. Burden Calculations for the HAC Reduction Program Measure Set and Other Activities for the FY 2021

Chart Abstraction for 3,300 IPPS Hospitals

<i>Measure Set</i>	<i>Estimated time per record (minutes) – FY 2021</i>	<i>Number reporting quarters per year – FY 2021</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 for all subsection (d) hospitals selected for validation</i>
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
Total						43,200

² In the FY 2017 IPPS/LTCH PPS final rule (82 FR 38501), we finalized an hourly wage estimate of \$18.29 per hour, plus 100 percent overhead and fringe benefits, for the Hospital IQR Program. Accordingly, we calculate cost burden to hospitals using a wage plus benefits estimate of \$36.58 per hour.

13 Capital Costs (Maintenance of Capital Costs)

There are no capital costs associated with the HAC Reduction Program's proposed policies.

14 Cost to Federal Government

The cost to the Federal Government includes costs associated with the collection and validation of the data. The cost is estimated at \$7,500,000 annually for the validation contract. Additionally, this program takes one and one-half (1.5) CMS staff at a GS-13 level to operate. Mid-level GS-13 approximate annual salary is \$109,900 (DC, M D, VA, WV, PA local) for an additional cost of \$164,850. The total annual cost to the Federal Government is \$7,664,850.

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

This is a new information collection.

16 Publication and Tabulation Dates

The goal of the data collection is to validate NHSN HAI data. We will continue to display quality information for public viewing on Hospital Compare, www.medicare.gov/hospitalcompare, as required for the HAC Reduction Program by Section 1886(p)(6) of the Social Security Act. 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. Hospital quality data on Hospital Compare are updated on a quarterly basis. One of the goals of the HAC Reduction Program is to publicly display data on all measures adopted for the Program. We note, however, that in certain circumstances we may decide to delay public display as we evaluate the accuracy of the measure data.

17 Expiration Date

We will display this expiration date on each of the forms listed above in section A.1.c, which would become available on our QualityNet website's (www.qualitynet.org) HAC Reduction Program page. We will display the approved expiration date prominently on our QualityNet website's HAC Reduction 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.