Supporting Statement - Part B

Submission of Information for the Hospital-Acquired Condition (HAC) Reduction Program

Collection of Information Employing Statistical Methods

1. Describe potential respondent universe.

All subsection (d) hospitals receiving reimbursement under the Inpatient Prospective Payment System (IPPS) in the United States (approximately 3,050 IPPS hospitals) constitute the potential respondent universe.

2. Describe procedures for collecting information.

Data are submitted via a secure website. Patient-level data are submitted directly to CMS, while summary or aggregate data are submitted directly to CMS or to the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) via web-based tools.

3. Describe methods to maximize response rates.

To ensure consistently high medical record submission rates from selected hospitals for validation, the CMS-designated contractor provides a 30-day reminder notice to hospitals that have outstanding medical records. In addition, during the last week of the submission period, CMS provides a daily list of hospitals with outstanding records to the CMS-designated contractor, who then makes targeted phone calls to the hospitals. CMS also removes barriers by providing data collection tools in order to make data submission easier (e.g., the free CMS Abstraction and Reporting Tool (CART) for use in collecting data from paper or electronic medical records for chart-abstracted measures, or the collection of data from federal registries like the NHSN), as well as to increase the utility of the data provided by the hospitals. Lastly, CMS has engaged a national support contractor to provide technical assistance with the data collection tool, other program requirements, and to provide education to support program participants.

4. Describe any tests of procedures or methods.

    (a) Background History on Validation Policy for Chart-Abstracted Data for the HAC Reduction Program

The HAC Reduction Program adopted validation requirements for the NHSN Healthcare-associated Infections (HAI) measures for the HAC Reduction Program in the FY 2019 IPPS/LTCH PPS final rule. The process for the HAC Reduction Program was modeled from and very similar to the process used by the Hospital Inpatient Quality Reporting (IQR) Program, which previously validated these measures. For information on the validation processes under the Hospital IQR Program and HAC Reduction Program, we

refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539 through 53553), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50822 through 50835), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50262 through 50273), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49710 through 49712), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57173 through 57181), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38398 through 38403), and the FY 2024 IPPS/LTCH PPS final rule (88 FR 59111 through 59114).

(b) Validation Policy for the HAC Reduction Program

For the HAC Reduction Program, CMS performs a random selection of up to 200 subsection (d) hospitals and an additional 200 hospitals using targeting criteria on an annual basis for validation of chart-abstracted measures. To be eligible for targeted selection for validation, the hospital must be a subsection (d) hospital and meet one or more of the following targeting criteria:

- any hospital that failed the validation requirement that applied to the previous year's payment determination;
- any hospital that submits data to NHSN after the HAC Reduction Program data submission deadline has passed;
- any hospital that has not been randomly selected for validation in the past 3 years;
- any hospital that passed validation in the previous year, but had a two-tailed confidence interval that included 75 percent;
- any hospital with a two-tailed confidence interval that is less than 75 percent, and that had less than four quarters of data due to receiving an extraordinary circumstances exception for one or more quarters; or
- any hospital which failed to report to NHSN at least half of actual HAI events detected as determined during the previous year's validation effort.

The HAC Reduction Program case sample is up to 40 cases per year per hospital.

In the FY 2019 IPPS/LTCH PPS final rule, the HAC Reduction Program adopted an educational review process for hospitals that have questions or need further clarification on a particular outcome of validation (83 FR 20432). In the FY 2024 IPPS/LTCH PPS final rule, we established a validation reconsideration process in the HAC Reduction Program beginning with the FY 2025 program year to provide hospitals the opportunity to request reconsideration of their final validation scores (88 FR 59113).

(c) Validation Response Rates for the HAC Reduction Program

Once the CMS Clinical Data Abstraction Center receives the requested medical documentation, it independently re-abstracts the same quality measure data elements that the hospital previously abstracted and submitted, and it compares the two sets of data to determine whether they match. To account for sample variability, a confidence interval based on normal distribution assumption is used in the calculation of validation scores.

For the HAC Reduction Program, we score hospitals based on an agreement rate between hospital-reported infections compared to events identified as infections by a trained CMS abstractor using a standardized protocol. We compute a confidence interval, and if the upper bound of this confidence interval is 75 percent or higher, the hospital passes the HAC Reduction Program validation requirement. If the upper bound is below 75 percent, the hospital fails the HAC Reduction Program validation requirement. For more information, please refer to the FY 2019 IPPS/LTCH PPS final rule.

The HAC Reduction Program reduces hospital payments to subsection (d) hospitals in the worst-performing 25 percent of all subsection (d) hospitals by 1 percent. Hospitals that do not meet the program's overall validation requirements will receive the maximum score for the measure set for which the hospital was validated, which will make failing hospitals more likely to score in the worst-performing 25 percent.

CMS uses these validation efforts to provide assurance of the accuracy of the NHSN HAI data submitted by hospitals for use in the HAC Reduction Program. HAC Reduction Program data for selected time periods become public as required by section 1886(p)(6) of the Social Security Act, and are posted by the corresponding hospital CMS Certification Number (CCN) on on the *Compare* tool hosted by HHS, currently available at: https://www.medicare.gov/care-compare, or its successor website(s) the .[1] The section also requires that the Secretary establish procedures for making information regarding measures available to the public after ensuring that a hospital has the opportunity to review its data before they are made public. Data are publicly reported on the Compare tool to help consumers make better informed decisions and to assist hospitals in their quality improvement initiatives by providing hospitals an opportunity to view how they are performing in comparison to other hospitals. CMS makes chart-abstracted patient-level data submitted by hospitals to the HAC Reduction Program publicly available on the Compare tool whether or not the data have been validated for payment purposes.

5.   **Provide name and telephone number of individuals consulted on statistical aspects.**

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[1] Quality measure data that does not reach a certain case minimum is not reported on the *Compare* tool or its successor website.