

**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 constitute the potential respondent universe; approximately 3,300 hospitals.

2. Describe procedures for collecting information.

Data are submitted via a secure website. Data may be patient-level submitted directly to CMS, or summary or aggregate data submitted directly to CMS, or the Centers for Disease Control and Prevention (CDC) National Health Safety Network (NHSN) via Web-based tools.

3. Describe methods to maximize response rates.

The HAC Reduction Program reduces Medicare fee-for-service payments to hospitals in the worst-performing quartile of all subsection (d) hospitals by 1 percent. Hospitals that do not meet the program's overall validation requirements will receive the maximum Winsorized z-score for the measure set for which the hospital was validated, which will make failing hospitals more likely to score in the worst-performing quartile. In addition, CMS provides abstraction and submission tools, education, and technical assistance to any hospitals requiring assistance with program requirements.

4. Describe any tests of procedures or methods.

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

The HAC Reduction Program adopted validation requirements for National Healthcare Safety Network (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 IQR Program, which previously validated these measures. For information on the Hospital IQR Program validation processes, 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).

### Validation Policy for the HAC Reduction Program

The HAC Reduction Program currently selects 600 hospitals for validation, of which 400 are selected randomly, and the remaining 200 are selected using the targeted criteria stated in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20431 through 20433). In the FY 2021 IPPS/LTCH PPS proposed rule, the HAC Reduction Program is proposing to reduce that to a total of up to 400 hospitals, of which up to 200 will be selected randomly, and up to 200 will be selected using the targeted criteria described above. To be eligible for random selection for validation, a hospital must be a subsection (d) hospital. To be eligible for targeted selection for validation, the hospital must be a subsection (d) hospital and meet the proposed targeted criteria.

The HAC Reduction Program case sample is approximately 40 cases per year per hospital. In the past, this sampling has produced a confidence level of plus or minus 3.25 percentage points on the agreement rate of about 90 percent for each hospital.

The HAC Reduction Program has adopted educational review process for hospitals that have questions or need further clarification on a particular outcome of validation (83 FR 20432).

### Validation Response Rates for the Hospital IQR Program

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.

Once the 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 using a binomial approach 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 would 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.

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 the *Hospital Compare* website or its successor website.<sup>1</sup> Data is publicly reported on *Hospital Compare* 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 *Hospital Compare* website 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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<sup>1</sup> Quality measure data that does not reach a certain case minimum is not reported on *Hospital Compare*.