

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 Web site. 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 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. 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

CMS is proposing to adopt 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 proposed rule. While this is the first time that the HAC Reduction Program would be validating the NHSN HAI measures, the Hospital Inpatient Quality Reporting (IQR) Program has validated the NHSN HAI measures since the FY 2014 payment determination. The process proposed for the HAC Reduction Program is modeled from and very similar to the process already used by the Hospital IQR Program. 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).

Proposed Validation Policy for the HAC Reduction Program

The HAC Reduction Program does not currently validate NHSN HAI measures. However, the HAC Reduction Program is proposing to use the same provider sample size to for its NHSN HAI validation process as currently used in Hospital IQR Program's validation. We therefore expect that the HAC Reduction Program's validation process will have the same statistical properties as past Hospital IQR Program validation. Specifically, the HAC Reduction Program NHSN HAI validation sample is expected to produce a confidence level of plus or minus 3.25 percentage points on the estimated agreement rate (which, in FY 2018, was 90 percent for NSHN HAI measures) for each hospital. By design, the random sample is representative of all subsection (d) hospitals. The targeted sample of selected providers is non-random.

The HAC Reduction Program is proposing to select 600 hospitals for validation: 400 will be selected randomly, and the remaining 200 will be selected using the targeted criteria stated in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20431 through 20433). 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 targeting criteria. The HAC Reduction Program is proposing to select the additional 200 hospitals for validation based on 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; or
- any hospital that passed validation in the previous year, but had a two-tailed confidence interval that included 75 percent.

The validation processes and targeting criteria are proposed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20431 through 20433). The HAC Reduction Program case sample is expected to be 40 cases per year per hospital. In the past, as noted above, 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 is proposing to adopt an educational review process for hospitals that have questions or need further clarification on a particular outcome of validation (83 FR 20432). Under the proposed policy, a hospital may request a review within 30 days of the validation results being posted to the QualityNet Secure Portal.

Validation Response Rates for the Hospital IQR Program

The HAC Reduction Program has not previously validated data assessed under that Program. However, of hospitals selected for Hospital IQR Program data validation, CMS has consistently received a high percentage of selected medical records by the submission deadline. The average submission rate for the four most recent quarterly samples has been greater than 97%.

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 CDAC 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 are proposing to 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 would pass the HAC Reduction Program validation requirement. If the upper bound is below 75 percent, the hospital would fail the HAC Reduction Program validation requirement. For more information, please refer to the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20431 through 20433).

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.¹ 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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¹ Quality measure data that does not reach a certain case minimum is not reported on *Hospital Compare*.

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