Supporting Statement - Part B
Submission of Information for the Hospital Outpatient Quality Reporting (OQR)
Program

Collection of Information Employing Statistical Methods

1.   Describe potential respondent universe.

All subsection (d) hospitals receiving reimbursement under the Outpatient Prospective
Payment System (OPPS) in the United States constitute the potential respondent
universe; approximately 3,350 hospitals.

2.   Describe procedures for collecting information.

Data are submitted via a secure web portal to the Hospital Quality Reporting (HQR)
system. 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 Healthcare Safety Network (NHSN) via web-based tools.

3.   Describe methods to maximize response rates.

To maximize response rates, the Hospital OQR Program provides payment consequences
related to program participation. Specifically, hospitals that do not meet program
requirements may have a 2.0 percentage point reduction in their OPPS annual payment
update. 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 Hospital
OQR Program

CMS has validation requirements for chart-abstracted patient-level data submitted
directly to CMS.[1] The Hospital OQR Program first finalized data validation requirements
for hospitals starting in the CY 2010 OPPS/ASC final rule, in which CMS finalized their
proposal to select a random sample of 7,300 cases, including up to 20 cases per
participating hospital. In the CY 2011 OPPS/ASC final rule, CMS finalized a proposal to
validate data from 800 randomly selected hospitals (approximately 20 percent of all
participating Hospital OQR Program hospitals) each year, beginning with the CY 2012
payment determination. Then in the CY 2012 OPPS/ASC final rule, CMS finalized a
policy to reduce the number of randomly selected hospitals from 800 to 450, and in
addition, finalized a proposal to select up to an additional 50 hospitals based upon
targeting criteria. Finally, in the CY 2018 OPPS/ASC final rule, we clarified the hospital

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[1] Please see the CY 2013 OPPS/ASC final rule with comment period (77 FR 68484 through 68487), the CY
2015 OPPS/ASC final rule with comment period (79 FR 66964 through 66965), and the CY 2018
OPPS/ASC final rule with comment period (82 FR 52581) for an extensive discussion of finalized policies
regarding our validation requirements. We codified these policies at 42 CFR 419.46(e).

selection process previously finalized for validation. Additional details about the history of the Hospital OQR Program validation policies are included below:

- In the CY 2010 OPPS/ASC final rule (74 FR 60647 through 60648), CMS finalized a proposal to select a random sample of 7,300 cases from all cases successfully submitted to the OPPS Clinical Warehouse by all participating hospitals from April 1, 2009 through March 31, 2010. The sample also included up to 20 cases per participating hospital. CMS chose a sample size of 7,300 because CMS believed it would enable them to detect a relative difference of 10 percent in the measured overall accuracy rate with a 95 percent (two-tailed) confidence interval and would also provide sufficient data to conduct post-hoc stratified analyses that provide meaningful feedback. These figures were based upon a power analysis assuming a population measure mismatch rate of five percent with the outcomes being either a match or a mismatch between what the hospital submitted versus what was determined by validation.

- In the CY 2011 OPPS/ASC final rule (75 FR 72104 through 72105), CMS finalized a proposal to validate data from 800 randomly selected hospitals (approximately 20 percent of all participating Hospital OQR Program hospitals) each year, beginning with CY 2012 payment determination. CMS sampled 800 hospitals because based upon sampling simulation studies using Hospital OQR Program data, sampling this number provided a sufficient number for a representative sample of hospitals on various strata (for example, urban, rural, bed-size) while significantly reducing overall hospital burden. For the CY 2012 payment determination, CMS selected only from hospitals participating for the CY 2012 payment update, so if a hospital submitted data for the CY 2011 payment update, but withdrew, this hospital would not be deemed as eligible for selection. Because 800 hospitals were selected randomly, every Hospital OQR Program participating hospital would be eligible each year for validation selection. For each selected hospital, CMS randomly selected up to a total of 48 self-reported cases from the total number of cases (12 per quarter) that the hospital successfully submitted to the OPPS Clinical Warehouse.

- In the CY 2012 OPPS/ASC final rule (76 FR 74484 through 74485), CMS finalized a policy to reduce the number of randomly selected hospitals from 800 to 450. Because these 450 hospitals are selected randomly, every Hospital OQR Program participating hospital is eligible each year for validation selection. To be eligible for random selection for validation, a hospital must be coded as open in the Certification and Survey Provider Enhanced Reporting (CASPER) system at the time of selection and must have submitted at least 10 encounters to the OPPS Clinical Warehouse during the data collection period for the CY 2013 payment determination. In addition, CMS finalized a proposal to select up to an additional 50 hospitals based upon targeting criteria. A hospital could be selected for validation based on targeting criteria if it:
  - Fails the validation requirement that applies to the CY 2012 payment determination; or

- Has an outlier value for a measure based on the data it submits.[2]

- In the CY 2018 OPPS/ASC final rule (82 FR 52581), we noted that the criteria for targeting 50 outlier hospitals, described above, does not specify whether high or low performing hospitals will be targeted. Therefore, we clarified that hospitals with outlier values indicating specifically poor scores on a measure (for example, a long median time to fibrinolysis) will be targeted for validation. In other words, an ''outlier value'' is a measure value that is greater than 5 standard deviations from the mean of the measure values for other hospitals and indicates a poor score.

Current Validation Policy for Hospital OQR Program

CMS selects 500 hospitals for validation; 450 are selected randomly, and the remaining 50 are selected using the targeted criteria stated in the CY 2013 OPPS/ASC final rule (77 FR 68484 through 68487) and clarified in the CY 2018 OPPS/ASC final rule with comment period (82 FR 52581). To be eligible for random selection for validation, a hospital must be coded as open in the Certification and Survey Provider Enhanced Reporting (CASPER) system at the time of selection and must have submitted at least 12 encounters to the Hospital OQR Program Clinical Warehouse during the quarter containing the most recently available data (79 FR 66965). The quarter containing the most recently available data is defined based on when the random sample is drawn (79 FR 66965). The additional 50 hospitals are selected for validation based on targeting criteria: having failed the validation requirement that applied to the previous year's payment determination or having an outlier value for a measure based on finalized criteria from the CY 2012 OPPS/ASC final rule (76 FR 74485). Hospitals with outlier values indicating specifically poor scores on a measure (for example, a long median time to fibrinolysis) will be targeted for validation (82 FR 52581). In the CY 2022 OPPS/ASC final rule, we finalized an additional targeting criterion used to select the 50 additional hospitals (86 FR 63872). We believe that this policy will improve data quality by increased targeting of hospitals with possible or confirmed past data quality issues. We finalized the addition of the following as criteria for targeting the hospitals: (1) any hospital that has not been randomly selected for validation in any of the previous 3 years; and (2) add to the targeting criteria finalized in the CY 2013 payment determination by identifying hospitals that passed validation in the previous year but had a two-tailed confidence interval that included 75 percent. Relative to hospitals whose confidence interval lies entirely above the target reliability rate of 75 percent, a confidence interval

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[2] In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485), CMS defined an "outlier value" for purposes of this targeting as a measure value that appears to deviate markedly from the measure values for other hospitals. For a normally distributed variable, nearly all values of the variable lie within 3 standard deviations of the mean; very few values lie past the 3 standard deviation mark. One definition of an outlier is a value that exceeds this threshold. In order to target very extreme values, CMS finalized a policy of targeting hospitals that greatly exceed this threshold because such extreme values strongly suggest that the data submitted is inaccurate. Specifically, CMS finalized a policy to select hospitals for validation if their measure value for a measure is greater than 5 standard deviations from the mean, placing the expected occurrence of such a value outside of this range at 1 in 1,744,278. If more than 50 hospitals meet either of the above targeting criteria, then up to 50 would be selected randomly from this pool of hospitals.

that includes 75 percent would indicate a higher level of uncertainty as to the reliability of data for that particular hospital. In the CY 2023 OPPS/ASC final rule (87 FR 71748), we finalized that hospitals with less than four quarters of data subject to validation due to receiving an Extraordinary Circumstance Exceptions (ECE) for one or more quarters and with a two-tailed confidence interval that is less than 75 percent will be targeted for validation in the subsequent validation year. However, these hospitals will not be penalized for payment. Hospitals will still be subject to both payment penalization and targeting for the subsequent year if they either (a) have less than four quarters of data but do not have an ECE or waiver for one or more quarters and do not meet the 75 percent threshold; or (b) have four quarters of data subject to validation and do not meet the 75 percent threshold.

As stated in the CY 2013 OPPS/ASC final rule (77 FR 68486 through 68487), after the random selection has been completed, the CMS Clinical Data Abstraction Center (CDAC) sends record requests by a trackable mail method to the designated Medical Record Contact at the hospital. In the CY 2022 OPPS/ASC final rule, we changed the time period given to hospitals to submit medical records to the CDAC contractor to 30 calendar days, beginning with medical record submissions for encounters in Quarter (Q) 1 of CY 2022 (86 FR 63871 through 63872). Each hospital is required to submit the requested documentation to the CDAC within 30 calendar days of the date of the request (as documented on the request letter). If the hospital fails to comply within 30 days, a "zero" score is assigned to each data element for each selected case, and the case will fail for all measures in the same topic.

Validation Response Rates for the Hospital OQR Program

CMS has consistently achieved high response rates from hospitals selected for validation in the Hospital OQR Program. The response rates for the last four quarterly samples are:

Q4 2017 (October 1 – December 31) – 99.9%
Q1 2018 (January 1 – March 31) – 100%
Q2 2018 (April 1 – June 30) – 100%
Q3 2018 (July 1 – September 30) – 100%

To ensure consistently high response rates from selected hospitals for validation, the CMS-designated contractor provides a 15-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. A confidence interval using a binomial approach is used in the calculation of validation scores to account for sample variability, the data being analyzed are binary (match, do not match), and to account for the possibility of small sample sizes. To receive a full annual

payment update, hospitals must obtain at least a 75 percent validation score for the designated time period based upon this validation process (77 FR 68487).
CMS uses these validation efforts to provide assurance of the accuracy of chart-abstracted patient-level data submitted by hospitals to the Hospital OQR Program. Hospital OQR Program data for selected time periods become public as required by section 1833 (t)(17)(E) of the Social Security Act and are posted by the corresponding hospital CMS Certification Number (CCN) on the *Care Compare* website.[3] Data are publicly reported on *Care 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 Hospital OQR Program measure performance information publicly available on the *Care Compare* website whether or not the data submitted by hospitals for measure calculation have been validated.

Measure Sampling

Claims-based measures are assessed for current code usage as well as tested for validity and reliability. The OQR Program does not require validation of claims-based measures beyond standard claims validation activities conducted by CMS Medicare Administrative Contractors (MACs). However, the Program also employs other types data submission modes, including web-, survey-, and the proposed PRO-based, for data collection, subject to validation as noted above. Some of these measures also allow for hospitals to submit samples case sizes of their population of either 63 cases for hospitals with a population size of between 0 and 900 and 96 cases for hospitals with a population size of greater than 900 to reduce burden. Hospitals that choose to sample must ensure that the sampled data represents their outpatient population by using either the simple random sampling or systematic random sampling method and that the sampling techniques are applied consistently within a quarter. For example, quarterly samples for a sampling population must use consistent sampling techniques across the quarterly submission period.

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

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[3] Quality measure data that does not reach a certain case minimum is not reported on Hospital Compare. For those hospitals that treat a low number of patients but otherwise meet the submission requirements for a particular quality measure, in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74482) CMS finalized a policy that hospitals that have five or fewer encounters (both Medicare and non-Medicare) for any measure included in a measure topic in a quarter would not be required to submit patient level data for the entire measure topic for that quarter. Even if hospitals would not be required to submit patient level data because they have five or fewer encounters (both Medicare and non-Medicare) for any measure included in a measure topic in a quarter, we noted that they may voluntarily do so. Please see the CY 2011 OPPS/ASC final rule with comment period (75 FR 72100 through 72103) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74482 through 74483) for further discussions of our policy that hospitals may voluntarily submit aggregate population and sample size counts for Medicare and non-Medicare encounters for the measure populations for which chart-abstracted data must be submitted.