Supporting Statement – Part B

Collections of Information Employing Statistical Methods

1. Describe potential respondent universe.

The Data Validation Contractor will randomly sample 300 facilities, per contract and Quality Incentive Program (QIP) rule guidelines, for participation in the validation project. As a random sample, this should be a representative sample of all included facilities nationally. The sample pool will consist of Medicare-certified dialysis facilities that are required to submit administrative and clinical data into the End-Stage Renal Disease Quality Reporting System (EQRS), formerly known as CROWNWeb, to meet Section 494.180(h) of the 2008 updated Conditions for Coverage for ESRD Dialysis Facilities.

The selected facilities will be asked to submit records that will be validated for the Centers for Disease Control and Prevention National Healthcare Safety Network (NHSN) dialysis event elements. The patient sample size is limited to a total of 20 patients (or the maximum patients possible) per facility across two quarters of the calendar year, as per contract and finalized QIP rule guidelines. The medical records will be for patients with "candidate events" as well as randomly selected patients. Candidate events include positive blood cultures, intravenous antimicrobials, or vascular site infection (e.g. pus, redness, or increased swelling).

The Data Validation Contractor will segment selected facilities by CMS Network Number and by affiliation with major dialysis organizations (DaVita, DCI, Fresenius, and all others as Independent). Facilities will be randomly selected from the national collection of ESRD facilities, and will not include those facilities already selected for participation in the Clinical Performance Measures (CPM) component of the validation. Patient records across two quarters of PY 2028 will be used according to the finalized guidelines of the ESRD QIP rule.

2. Describe procedures for collecting information.

Please see response to question 1 for statistical methodology for stratification and sample selection. In accordance with guidance provided by CDC, each facility should provide the following five lists:

List 1. All patients who had one or more in-center hemodialysis treatment(s) during the validation time period;

List 2. All patients who had any positive blood cultures during the validation time period;

List 3. All patients who received any intravenous antimicrobials during the validation time period;

List 4. All patients who had any pus, redness or swelling at the vascular access site during the validation time period; and

List 5. All patients who were hospitalized for any reason during the validation time period.

Twenty (20) patient records, from each facility, should be selected to undergo medical record review:

1. Start with List 2 to identify the patient medical records.
    a. If List 2 has greater than 20 patients, randomly select 20 patients and STOP.
    b. If List 2 consists of less than 20 patients, select all the patients in that list and then move forward to List 3, 4 and 5 consecutively and randomly select patients from next list until a total of 20 patients is selected.

If Lists 2 - 5 together do not generate 20 patients, randomly select the remaining needed patients from List 1 patients who were not included in Lists 2-5.

As noted below in response to question 4, there are no unusual problems requiring specialized sampling procedures, as the previous experience on the previous CMS NHSN validation effort has shown near universal compliance by the hospitals with medical record requests. The period for data collection cycles is expected to be no more frequently than annually.

3. Describe methods to maximize response rates.

The Validation Contractor will communicate directly with each facility using the Secure File Option within QualityNet. Request letters, including all instructions on the types of records to be submitted, methods to submit records to the contractor, and identified patients selected for validation, will be sent using this method. If necessary, follow-up emails and phone calls will be made.

4. Describe any tests of procedures or methods.

As noted above, the sample pool will consist of Medicare-certified dialysis facilities that are required to submit administrative and clinical data into EQRS in order to meet Section 494.180(h) of the 2008 updated Conditions for Coverage for ESRD Dialysis Facilities. The previous experience on CMS NHSN validation efforts has shown near universal compliance with medical record requests. No additional tests of procedures or methods to be undertaken are expected.

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

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