Supporting Statement – Part B

Collections of Information Employing Statistical Methods

1. Describe potential respondent universe.

The End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP) Data Validation Contractor will randomly sample 300 facilities (roughly 5% of all dialysis facilities), per contract and ESRD Quality Incentive Program (QIP) rule guidelines, for participation in data validation. As a random sample, this should be a nationally representative sample of all included renal dialysis facilities. The sample pool will consist of Medicare-certified dialysis facilities that are required to submit administrative and clinical data into the ESRD Quality Reporting System (EQRS) (formerly CROWNWeb) in order to meet 42 CFR 494.180(h) of the 2008 updated Conditions for Coverage for ESRD Dialysis Facilities.

The 300 facilities will be asked to submit records that will be validated for CMS-designated Critical Performance Measures (CPMs). The patient sample size is limited to 10 patients per facility, as per contract and ESRD QIP rule guidelines. Facilities will be stratified by size before selecting random samples, based on the number of dialysis stations. Facilities with less than 20 dialysis stations will be categorized as Small; facilities with between 20 and 39 stations will be categorized as Medium; and facilities with at least 40 stations will be categorized as Large. The Data Validation Contractor will sample 10 patients (or the maximum patients possible) from each selected facility for CPM reviews. Historically, facility response rates have been sufficient for the purpose of validation of the data.

2. Describe procedures for collecting information.

Please see response to question 1 for statistical methodology for stratification and sample selection, including estimation procedure. The 300 facilities to be sampled for validation will be selected from a sample pool created by combining multiple data extracts for EQRS from March through August 2025. Data extracts will be provided by CMS, and all extracts are expected to be received by early November 2025. A second request for EQRS data extract of depression screening data for the Clinical Depression Screening and Follow-Up measure and In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) will occur in January 2026. Once received, the data extracts will be combined at the record level to create the sampling pool. As noted below in response to question 4, there are no unusual problems requiring specialized sampling procedures as our previous experience on past CMS CROWNWeb (now EQRS) CPM validation efforts have shown near universal compliance 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.

Facilities will be contacted in early spring via QualityNet using the HARP MFT option and will be asked to participate in the validation effort. As some facilities are not on HARP MFT, we also use FedEx to send the requests. The letter will provide instructions on the types of records

to be submitted, methods to submit records to the Validation Contractor, and identify patients selected for validation. Facilities that do not respond to the initial request for records are contacted via phone by the Validation Contractor and receive a final request letter in early March 2025. To maximize facility response rates, we hold a townhall around January of each year to increase facility knowledge about the validation process and purpose.

We also communicate/coordinate extensively with all facilities, using web conferences to facilitate on-time and accurate medical records submission by participating facilities. Facilities that do not respond to the request for records are subject to a 10-point reduction to their Total Performance Score (TPS).

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 to meet § 494.180(h) of the 2008 updated Conditions for Coverage for ESRD Dialysis Facilities. The previous experience on past CMS CROWNWeb (now EQRS) validation efforts have 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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