Supporting Statement – Part A

Data Collection for Quality Measures Using the Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb)

A. Background

Pursuant to section 1881(h) of the Social Security Act (the Act) as amended by section 153(h) of the Medicare Improvements for Patients and Providers Act (MIPPA) the Centers for Medicare and Medicaid Services (CMS) established the End-Stage Renal Disease Quality Incentive Program (ESRD QIP) starting in 2011. The ESRD QIP is the first value-based purchasing program established by CMS, and it is aimed at promoting patient health by providing a financial incentive for renal dialysis facilities to deliver high-quality care.

In implementing the ESRD QIP, CMS believes that a successful quality incentive program will promote the delivery of high-quality health care services in the renal dialysis facility setting. Under section 1881(h)(2) of the Act, the Secretary is required to specify quality measures for evaluating the quality of care ESRD patients receive at renal dialysis facilities. While the Act outlines few mandatory measure topics, the Secretary is authorized to adopt measures on specified areas or medical topics determined appropriate by the Secretary (§ 1881(h)(2)). The ESRD QIP began in calendar year (CY) 2011 with an initial set of three quality measures and has dramatically increased its measure set over the intervening years through notice and comment rulemaking.

In order to score facility performance on quality measures, CMS must be able to collect data on these measures. CMS collects these data from multiple sources, including Medicare claims and other tools such as the In-Center Hemodialysis Consumer Assessment of Healthcare providers and Systems (ICH CAHPS) and the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) Dialysis Event Protocol. To further expand the measures used to evaluate the quality of care provided to ESRD patients in renal dialysis facilities, CMS also collects data using the Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb) system. Because of the complexity of the existing systems and because of the need to comply with the strong approved protections for private or confidential data, CROWNWeb was implemented in phases starting in February 2009. CROWNWeb went into production nationally on June 14, 2012 and brings together all of CMS' information systems that collect, maintain, and report on data about ESRD patients and provides electronic reporting tools for use by renal dialysis facilities.

The ESRD QIP is updating this PRA package to ensure that the PRA package remains up to date and specific to reporting and validating CROWNWeb data for the payment years addressed in the CY 2021 ESRD PPS proposed rule (i.e. Payment Year (PY) 2023 and PY 2024).

1. Data Collection for ESRD QIP Measures

In selecting measures for adoption into the ESRD QIP measure set, CMS strives to achieve several objectives. First, the measures should consider national priorities such as those established by the Department of Health and Human Services' Meaningful Measures Initiative. Second the measures should be tailored to the needs of improved quality in the renal dialysis facility setting; thus, the measures selected are most relevant to renal dialysis facilities. Finally, the burden of measure compliance on renal dialysis facilities should be weighed against the potential for improvements in patient health and well-being resulting from the measure's collection.

Many measures currently finalized in the ESRD QIP are extracted from Medicare claims and therefore require no additional effort on the part of dialysis facilities to report.[1] However, some quality data relevant to the care received by ESRD patients cannot be derived from Medicare claims or other administrative forms. For these measures, dialysis facilities are required to submit data via a web-based tool such as CROWNWeb or the CDC's NHSN system. The burden associated with submitting measure data to the NHSN Bloodstream Infection Modules[2] and for the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems survey (ICH CAHPS)[3] are already captured under previously approved packages; for this reason, this package is specific to the burdens associated with ESRD QIP measure data submitted via CROWNWeb.

a. The CY 2021/PY 2023 ESRD QIP

The CY 2021 ESRD Prospective Payment System (PPS) proposed rule proposes updates to program requirements for the CY 2021/PY 2023 ESRD QIP. During CY 2021/PY 2023, we will continue collecting data for the follow measures using the CROWNWeb system:

Hemodialysis Vascular Access: Standardized Fistula Rate Clinical Measure (82 FR 50776 through 50777): Measures the use of an AV fistula as the sole means of vascular access as of the last hemodialysis treatment session of the month. Facilities report in CROWNWeb the vascular access type.

Hemodialysis Vascular Access: Long-Term Catheter Rate Clinical Measure (82 FR 50777 through 50778): Measures the use of a catheter continuously for 3 months or longer as of the last hemodialysis treatment session of the month. Facilities report in CROWNWeb the vascular access type.

Hypercalcemia Clinical Measure (76 FR 72203): Proportion of patient-months with 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL.

Kt/V Dialysis Adequacy Comprehensive Clinical Measure (80 FR 69053): Percentage of all patient months for patients whose delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period

[1] For example, in the CY 2015 ESRD PPS final rule with comment period, CMS finalized 10 measures using Medicare claims as the primary data source.
[2] The NHSN Bloodstream Infection measure is accounted for under OMB Control Number 0920-0666.
[3] ICH CAHPS is accounted for under OMB Control Number 0938-0926.

Clinical Depression Screening and Follow-Up Reporting Measure (79 FR 66203): Facility reports in CROWNWeb one of the six conditions listed for each qualifying patient once before February 1 of the year following the Performance Period.

Ultrafiltration Rate Reporting Measure (81 FR 77915): Facilities must report the following data to CROWNWeb for all hemodialysis sessions during the week of the monthly Kt/V draw submitted to CROWNWeb for that month, for each qualifying patient: (1) HD Kt/V Date; (2) Post-Dialysis Weight; (3) Pre-Dialysis Weight; (4) Delivered Minutes of BUN Hemodialysis; (5) Number of sessions of dialysis delivered by the dialysis unit to the patient in the reporting month.

Medication Reconciliation for Patients Receiving Care at Dialysis Facilities Reporting Measure (83 FR 57008 through 57010): Percentage of patient-months for which medication reconciliation was performance and documented by an eligible professional.

Table A. Measures Collected via CROWNWeb in CY 2021

NQS Goal	NQF Endorsement Number	Measure Title	Data Collected
Clinical Care	NQF #2977	Hemodialysis Vascular Access: Standardized Fistula Rate Clinical Measure	Vascular Access Type
Clinical Care	NQF #2978	Hemodialysis Vascular Access: Long-Term Catheter Rate Clinical Measure	Vascular Access Type
Clinical Care	NQF #1454	Hypercalcemia	Uncorrected serum calcium
Clinical Care	N/A	Dialysis Adequacy Comprehensive	Kt/V Value
Clinical Care	N/A	Clinical Depression Screening and Follow-Up	One of six clinical depression screening and follow up conditions

NQS Goal	NQF Endorsement Number	Measure Title	Data Collected
Clinical Care	Based upon NQF #2701	Ultrafiltration Rate Reporting Measure	• Hd Kt/V Date • Post-Dialysis Weight • Pre-Dialysis Weight • Delivered Minutes of BUN Hemodialysis • Number of sessions of dialysis delivered by the dialysis unit to the patient in the reporting month
Safety	NQF #2988	Medication Reconciliation for Patients Receiving Care at Dialysis Facilities Reporting Measure	• The date of the medication reconciliation • The type of clinician who completed the medication reconciliation / personal identifier

b. The CY 2022/PY 2024 ESRD QIP

For the CY 2022/PY 2024 ESRD QIP, we will continue to collect data using CROWNWeb for the measures referenced earlier in the section for the CY 2021/PY 2023 ESRD QIP. We will also continue to collect these measures in subsequent years unless we deem their removal appropriate based on the measure removal criteria outlined in the CY 2013 ESRD PPS final rule (77 FR 67475)—further clarified in the CY 2015 ESRD PPS final rule (79 FR 66171 through 66173) and the CY 2019 ESRD PPS final rule (83 FR 56983 through 56985).

2. CROWNWeb Data Validation for the ESRD QIP

One of the critical elements of the ESRD QIP's success is ensuring that the data submitted to calculate measure scores and facility Total Performance Scores (TPS) are accurate. We began a pilot validation study program for the ESRD QIP in CY 2013. That validation study has continued in subsequent years. In the CY 2019 ESRD PPS final rule, we finalized a policy to make the CROWNWeb validation study a permanent element of the Program rather than a continued pilot study (83 FR 57001 through 57003). Making the CROWNWeb validation study permanent does not alter the methodology that we employ to validate CROWNWeb data and signals the importance that we place on accurate and complete quality data to participating ESRD facilities. Specifically, we will continue sampling the same number of records (approximately 10 per facility) from the same number of facilities (300 facilities). If a facility is randomly selected to participate in the validation study but does not provide us with the requisite medical records within 60 calendar days of receiving a request, then we will deduct 10 points from the facility's TPS.

B. Justification

1. Need and Legal Basis

Section 1881(h)(2) of the Act requires that the Secretary specify measures for each year of the program and with each successive year of the ESRD QIP, CMS has increased the sophistication and scope of the Program's measure set. While Medicare claims can be an appropriate data source for some measures, claims do not represent the entirety of the ESRD population and are also limited in the depth of information available. For these reasons, in furtherance of our obligations under section 1881(h)(2) of the Act, we have specified several measures utilizing data reported by renal dialysis facilities using the CROWNWeb system described below. These collections are authorized under section 494.180(h) of the Conditions for Coverage of End-Stage Renal Disease Facilities, which requires renal dialysis facilities to furnish data and information (both clinical and administrative) electronically to CMS at intervals specified by the Secretary. CMS proposes and finalizes data reporting requirements for the ESRD QIP through notice and comment rulemaking.

Trend summaries included below depict the progression of measure results over the past several years to determine the impact of the ESRD QIP on improved quality and outcomes in ESRD populations. However, those trends cannot be attributed directly to the ESRD QIP. Several other national initiatives such as Fistula First, Catheter Last (a national vascular access improvement initiative), Dialysis Facility Compare (DFC), quality improvement activities by dialysis organizations, the changes to the PPS ESRD Payment Bundle, and technical support provided by the ESRD networks have all collectively contributed to improvements in ESRD care and services. The implementation of the Medicare ESRD PPS in 2011 and the ESA labeling change later that year are likely to have contributed to improvements in care for this population.

- Rates of hypercalcemia have declined, meaning improved patient calcium rates over time starting in CY 2013 when the measure was introduced in the ESRD QIP final rule. Hypercalcemia rates improved from 3.7% in CY 2012 to 1.1% in CY 2018.
- Facility performance on the vascular access type (VAT) measures (i.e. fistula and catheter) improved in the first few years that the measures were included in the program and have remained stable over the past four years. Fistula rates have increased from 62.1% in CY 2012 to 66.3% in CY 2018.
- Kt/V Comprehensive rates have improved since the measure was introduced in the ESRD QIP in PY 2019. Rates improved from 94.6% in CY 2016 to 95.9% in CY 2019.
- Performance on risk adjusted measures including readmissions, hospitalizations, and transfusions has remained stable since the measures were introduced in the ESRD QIP, with the exception of the NHSN Bloodstream Infection (BSI) ratio, where facility performance is improving slightly each year. Average BSI ratios have decreased from 1.05 in CY 2014 to 0.75 in CY 2018.
- Mortality rates have steadily declined from 2010 to 2017.
- The data show a substantial decrease in readmission rates from 30.3 in 2011 to 25.2 in 2016.

While the ESRD QIP was not solely intended as a cost saving program, below we show the Program's estimated payment reductions in recent years.

- PY 2024; $15,586,453.64 (CY 2021 ESRD PPS proposed rule)
- PY 2023; $15,586,453.64 (CY 2021 ESRD PPS proposed rule)
- PY 2022; $18,247,083.76 (84 FR 60794)

- PY 2021; $32,196,724 (83 FR 57061)
- PY 2020; $31,581,441 (81 FR 77960)
- PY 2019; $15,470,309 (80 FR 69074)
- PY 2018; $11,576,214 (79 FR 66257)
- PY 2017; $11,954,631 (79 FR 66255)

2. Information Users

Section 1881(h) of the Act requires the Secretary, generally, to adopt a set of quality measures and to assess the quality of care provided by renal dialysis facilities using those measures. CMS and others use these data to monitor and assess the quality and type of care provided to ESRD patients. Specifically, CMS uses these data to calculate performance scores on certain measures included in the ESRD QIP measure set (described in detail below) and conducts a validation study each year to ensure that those data are accurate.

CMS will make available to renal dialysis facilities their scores on individual measures and their total performance score for their use in internal quality improvement initiatives. CMS will also make available to facilities information on the performance of other facilities on individual measures and their total performance score. Most importantly, facility performance on individual measures and their TPS is available to beneficiaries, as well as to the public, to assist them in making decisions about their health care. Facilities, beneficiaries, and the public do not have access to validation results. CMS intends to use information on facility performance on measures and their TPS as well as validation study results to direct its contractors to focus on areas of improvement and to develop quality improvement initiatives. This includes targeted training if underreporting or inaccurate reporting is identified and user error is suspected as the cause. CMS uses the validation study to independently sample and test the reliability and validity of the clinical data submitted electronically in CROWNWeb against providers' source medical records, and to encourage facilities to accurately report data to CROWNWeb.

3. Use of Information Technology

As noted previously, CMS developed CROWNWeb to reduce the burden to renal dialysis facilities of submitting data to CMS. This system brings together all of CMS' information systems that collect, maintain, and report on data about ESRD patients and provides electronic reporting tools for use by renal dialysis facilities. Renal dialysis facility users are required to open an account under their CMS Certification Number and are then able to complete the necessary data submission.

4. Duplication of Efforts/Similar Information

The information to be collected is not duplicative of similar information collected by the Centers for Medicare and Medicaid Services.

5. Small Businesses

Information collection requirements were designed to impose minimal burdens on small renal dialysis facilities subject to the ESRD QIP, and to facilitate the collection and reporting of required data. Specifically, the CROWNWeb system was created to allow small renal dialysis facilities to enter data via a web-based application rather than using paper-based data

submissions or employing a full electronic health record, which can be prohibitively expensive for these facilities.

6. Less Frequent Collection

Measures developers employ clinical and statistical knowledge during the measure development process to determine the optimal schedule for collecting measure data. These data are then collected on the schedules provided in Table C to best evaluate the care provided to ESRD patients. Without this frequency of information collection, CMS would be unable to assess the correlations between the endpoints collected and the health and well-being of ESRD patients treated by the renal dialysis facilities participating in the ESRD QIP.

Table C. Measure Collection Schedule/Frequency

Measure Title	Measure Collection Schedule/Frequency
Hypercalcemia	Monthly
Dialysis Adequacy Comprehensive	Monthly
Clinical Depression Screening and Follow-Up	Annually
Ultrafiltration Rate Reporting Measure	4 data elements are reported for every HD Kt/V session during the week of the monthly Kt/V draw, and Kt/V date is reported monthly
Hemodialysis Vascular Access Type: Standardized Fistula Rate Clinical Measure	Monthly
Hemodialysis Vascular Access Type: Long-Term Catheter Rate Clinical Measure	Monthly
Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec) Measure	Monthly

7. Special Circumstances

There are no special circumstances.

8. Federal Register Notice/Outside Consultation

The CY 2021 ESRD PPS proposed rule's publication, serving as the 60-day Federal Register notice, was published on July 13, 2020 (85 FR 42132).

9. Payment or Gift to Respondent

Dialysis facilities are required to submit measure data to CMS as part of the Conditions for Coverage of End-Stage Renal Disease Facilities (see 42 CFR 494.180(h)). No additional

payments or gifts will be given to respondents for compliance with the reporting requirements of the ESRD QIP measures submitted via CROWNWeb.

10. Confidentiality

CMS adheres to all confidentiality-related statutes, regulations, and agency policies. All information collected under ESRD QIP will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. The laws and regulations that may apply include, but are not limited to: The Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the EGovernment Act of 2002, the Clinger Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A–130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: All pertinent National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

SORN #: 09-70-0520 – ESRD Program Management and Medical Information System (PMMIS) published 6/17/2002 (67 FR 41244) and updated 5/8/2007 (72 FR 26126).

11. Sensitive Questions

There are no questions of a sensitive nature being collected as part of this quality assessment.

12. Burden Estimates

This burden estimate includes measures which CMS is continuing to collect as part of the ESRD QIP and the ongoing CROWNWeb data validation study. As noted in section A.1. of this supporting statement, this estimate excludes burden associated the NHSN Bloodstream Infection clinical measure and the ICH-CAHPS measure because the burden associated with these measures is captured under OMB numbers 0920-0666 (The National Healthcare Safety Network) and 0938-0926 (ICH-CAHPS Survey), respectively. This burden estimate also excludes the burden associated with training facilities to use CROWNWeb, which will continue to be accounted for in OMB Control Number 0938-0386. The burden associated with the NHSN BSI Data Validation Study is captured under OMB Control Number 0938-1340.

The assumptions used to compute the estimated burdens associated with submitting ESRD QIP measure data via CROWNWeb and the ongoing CROWNWeb data validation study are described here.

We estimate the burden hours for reporting measure data using the CROWNWeb system for CY 2021/PY 2023 to be 4,993,288 hours; for CY 2022/PY 2024 this figure is also 4,993,288. We estimate that the total burden hours associated with the PY 2023 CROWNWeb validation study is 750. The total burden hours for these two activities over the 3-year OMB approval period is 9,987,326 (4,993,288 + 4,993,288 + 750). Accordingly, we estimate the annual burden for the 3-year OMB approval period to be 3,329,109 hours (9,987,326 / 3 years).

a. Data Collection for ESRD QIP Measures Using CROWNWeb

We have used the following equation to estimate the burden associated with these data collection and submission efforts.

$$\text{burden} = \#\text{ patients nationally} * \frac{\#\text{ elements}}{\text{patient year}} * \frac{\text{data entry hrs}}{\text{patient year}} * \frac{\text{wage \$}}{\text{hour}} = \frac{\text{wage \$}}{\text{year}}$$

Table D. CROWNWeb Data Collection Burden Estimate Elements

Burden Estimate Elements	CY 2021/ PY 2023	CY 2022/ PY 2024
Number of facilities[4]	7,386	7,386
Number of ESRD patients, nationally[5]	523,314	523,314
The time spent for data entry and submission per element[6]	2.5 minutes	2.5 minutes
Annual Hour Burden Nationally	4,993,288 hours	4,993,288 hours
Median hourly wage of a Medical Records and Health Information Technician (Fringe benefit is calculated at 100%).	$41.00	$41.00

We estimate the number of patients per facility by calculating the mean number of patients per ESRD PPS-eligible facility nationwide, based on CY 2018 data, even though we recognize that the number of patients per renal dialysis facility is also highly variable, and may vary from month to month within a given facility. To estimate the total burden per facility, the mean number of patients per facility is then multiplied by the number of required elements per patient-year for each measure and the estimated time per element entry, as shown in Table D1. The estimated time per element entry for the CROWNWeb measure is based on historical estimates previously finalized in the CY 2016 ESRD PPS final rule regarding the amount of time required to enter one data element for one patient (i.e. we assumed that it takes 2.5 minutes to report a data element, even though the time required is highly variable) (80 FR 69070).

To derive wage estimates, we used data from the U.S. Bureau of Labor Statistics' (BLS) May 2019 National Occupational Employment and Wage Estimates.[7] We anticipate that the labor required to collect and submit these data will be completed by either Medical Records and Health Information Technicians or similar administrative staff. The median hourly wage of a Medical Records and Health Information Technician is $20.50. Fringe benefits and overhead are calculated at 100% using current HHS department-wide guidance on estimating the cost of fringe benefits and overhead. These are necessarily rough adjustments both because fringe benefits and

[4] Total number of ESRD PPS facilities in the United States treating ESRD QIP-eligible patients.
[5] Total number of patients treated at ESRD PPS facilities in the United States
[6] As stated in the CY 2016 ESRD PPS final rule (80 FR 69070), we estimate the amount of time required to submit measure data to CROWNWeb to be 2.5 minutes.
[7] https://www.bls.gov/oes/current/oes292098.htm

overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that these are reasonable estimation methods.

Using the assumptions described above, we estimate an hourly labor cost of $41.00 as the basis of the wage estimates for all collection of information calculations in the ESRD QIP. We also estimate the total annual burden for reporting measure data using the CROWNWeb system for CY 2021/PY 2023 to be $204,724,798 and the total annual burden for reporting measure data using the CROWNWeb system for CY 2022/PY 2024 is $204,724,798.

Table D1. CY 2021/PY 2023 CROWNWeb Data Collection Burden Per Measure

Note: Numbers may not add up due to rounding

MEASURE REPORTING Renal Dialysis Facilities CY 2019 Measure Set	Number of Facilities	Number of Patients Nationally	Average number of patients per facility	Number of Elements per Patient-Year	Estimated Time for Data Entry per Element (hours)	Estimated Wage plus Benefits per Hour for Data Entry	Annual Hour Burden per Facility	Annual Burden Facility
Hemodialysis Vascular Access: Standardized Fistula Rate Clinical Measure	7,386	523,314	71	12	0.042	$41.00	35.4	$1,452
Hemodialysis Vascular Access: Long-Term Catheter Rate Clinical Measure	7,386	523,314	71	12	0.042	$41.00	35.4	$1,452
Hypercalcemia	7,386	523,314	71	12	0.042	$41.00	35.4	$1,452
Comprehensive Dialysis Adequacy	7,386	523,314	71	12	0.042	$41.00	35.4	$1,452
Clinical Depression Screening and Follow-Up	7,386	523,314	71	1	0.042	$41.00	3.0	$121
Ultrafiltration Rate Reporting Measure	7,386	523,314	71	156	0.042	$41.00	460.5	$18,882
Medication Reconciliation for Patients Receiving Care at Dialysis Facilities Reporting Measure	7,386	523,314	71	24	0.042	$41.00	70.9	$2,904

Table E2. CY 2021/PY 2023 CROWNWeb Total Data Collection Burden

Note: Numbers may not add up due to rounding.

Basis	Number of Elements	Annual Hour Burden	Annual Burden
Each Facility	16,225	676	$27,717.95
National	119,838,906	4,993,288	$204,724,798

Table D1. CY 2022/PY 2024 CROWNWeb Data Collection Burden Per Measure
Note: Numbers may not add up due to rounding

MEASURE REPORTING Renal Dialysis Facilities CY 2019 Measure Set	Number of Facilities	Number of Patients Nationally	Average number of patients per facility	Number of Elements per Patient-Year	Estimated Time for Data Entry per Element (hours)	Estimated Wage plus Benefits per Hour for Data Entry	Annual Hour Burden per Facility	Annual Burden Facility
Hemodialysis Vascular Access: Standardized Fistula Rate Clinical Measure	7,386	523,314	71	12	0.042	$41.00	35.4	$1,452
Hemodialysis Vascular Access: Long-Term Catheter Rate Clinical Measure	7,386	523,314	71	12	0.042	$41.00	35.4	$1,452
Hypercalcemia	7,386	523,314	71	12	0.042	$41.00	35.4	$1,452
Comprehensive Dialysis Adequacy	7,386	523,314	71	12	0.042	$41.00	35.4	$1,452
Clinical Depression Screening and Follow-Up	7,386	523,314	71	1	0.042	$41.00	3.0	$121
Ultrafiltration Rate Reporting Measure	7,386	523,314	71	156	0.042	$41.00	460.5	$18,882
Medication Reconciliation for Patients Receiving Care at Dialysis Facilities Reporting Measure	7,386	523,314	71	24	0.042	$41.00	70.9	$2,904

Table E2. CY 2022/PY 2024 CROWNWeb Total Data Collection Burden
Note: Numbers may not add up due to rounding.

Basis	Number of Elements	Annual Hour Burden	Annual Burden
Each Facility	16,225	676	$27,717.95
National	119,838,906	4,993,288	$204,724,798

b. CROWNWeb Data Validation

We have used the following equation to estimate the burden associated with the ongoing CROWNWeb data validation study:

$$Burden = \#\ Participating\ facilities * \frac{\#\ records}{year} * \frac{.25\ hours}{record} * \frac{wage\ \$}{hour} = \frac{wage\ \$}{year}$$

Table F. CROWNWeb Data Validation Burden Estimate Elements

Burden Estimate Element	CY 2021 (PY 2023)
Number of facilities participating in the CROWNWeb data validation study, annually	300
Number of medical records per facility per year	10
Time spent for record collection and submission per facility[8]	2.5 hours (approx. 0.25 hours per record)
Hourly wage per hour engaged in data collection and submission[9]	$41.00

Under the CROWNWeb data validation study, we will randomly sample records from 300 facilities. Each sampled facility will be required to produce approximately 10 records. The burden associated with these validation requirements is the time and effort necessary to submit the requested records to a CMS contractor. We estimate that it will be take each facility approximately 2.5 hours in total, or 0.25 hours per medical record, to comply with this requirement. We therefore estimate that the total annual hourly burden for the ongoing CROWNWeb data validation study for CY 2021 to be 750 hours.

Just as noted above, we anticipate that the labor required to collect and submit these data will be completed by either Medical Records and Health Information Technicians or similar administrative staff. The median hourly wage of a Medical Records and health information Technician is $20.50 per hour. Fringe benefits and overhead are calculated at 100 percent. Therefore, using these assumptions, we estimate an hourly labor cost of $41.00 as the basis of the wage estimates for all collection of information calculations in the ESRD QIP. These are necessarily rough adjustments, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Accordingly, we estimate the total annual burden for the ongoing CROWNWeb data validation study for CY 2021 to be $30,750.

[8] As stated in the PY 2020 ESRD PPS final rule (84 FR 60788), we estimate the amount of time required to submit measure data to CROWNWeb to be 2.5 minutes.

[9] https://www.bls.gov/oes/current/oes292098.htm (Estimates are based on national median hourly wage).

Table G1. CY 2021/PY 2023 CROWNWeb Data Validation Burden

DATA VALIDATION Renal Dialysis Facilities CY 2017	Number of Facilities	Number of Records per Year	Estimated Time per Record	Estimated Wage plus Benefits per Hour for Record Collection	Annual Hour Burden per Facility	Annual Burden per Facility
CROWNWeb Data Validation	300	10	0.25	$41.00	2.5	$102.50

Table H2. CY 2021/PY 2023 CROWNWeb Total Data Validation Burden

Basis	Annual Hour Burden	Annual Burden
Each Facility	2.5	$102.50
National	750	$30,750

13. Capital Cost

There are no capital costs.

14. Cost to Federal Government

The cost to the Federal Government includes costs associated with the collection and validation of the data. The validation costs are an estimated $$535,295 (FY) annually for the validation contract. The estimated cost to manage the collection of data through the CROWNWeb system includes two CMS staff at the GS-13 Step 5 level ($116,353 annually) and one at the GS-14 Step 5 level ($137,491 annually), for an additional cost of $370,197. This results in a total estimated cost of $905,492 annually.

15. Changes to Burden

As discussed above, the ESRD QIP has consistently expanded its measure set since the inception of the ESRD QIP in CY 2011. For CY 2021, we are not adding any new measures to be collected using data entered in CROWNWeb. Therefore, we do not estimate any increased burden associated with new measures. In addition, the PY 2023 CROWNWeb reporting burden estimate in terms of dollars has decreased from the PRA package associated with the CY 2020 ESRD PPS final rule, from $211 million to $205 million. The following factor is driving this decrease:

1. The current PRA package uses an updated wage estimate for Medical Records and Health Information Technicians. This estimate uses the median, rather than the mean hourly wage rate, and is lower than the one used in the previous PRA package. We made this change to be consistent with other CMS quality reporting and payment programs, which use the median wage rate in their estimates.

The PY 2023 CROWNWeb reporting burden in terms of hours has remained the same as the currently approved PRA package, and is approximately 4.99 million hours. This is due to no changes being proposed to measures which would affect requirements for reporting data in CROWNWeb.

The CROWNWeb data validation study finalized for CY 2021 is a continuation of the study previously finalized for CYs 2015, 2016, 2017, 2018, and 2019. The burden to renal dialysis facilities for the CY 2021 CROWNWeb validation study will be similar to the burden associated with studies conducted in prior years.

The overall burden specified in this PRA package (for the CY 2021 ESRD PPS proposed rule) is lower than the overall burden specified in the currently approved PRA package (associated with the CY 2020 ESRD PPS final rule). The annual burden hours remain the same at 3,329,109 hours. The following factors are driving this decrease:

1. The current PRA package uses an updated estimate of the total number of facilities. This estimate is the same as the one used in the previous PRA package.
2. The current PRA package uses an updated estimate of the total number of patients. This estimate is the same as the one used in the previous PRA package.

16. Publication/Tabulation Date

The goal of the data collection is to evaluate facility performance on measures in the ESRD QIP measure set for the given year in order to assess the payment reductions required under section 1881(h)(1) of the Act. This data is also made publicly available pursuant to section 1881(h)(6) of the Act and is used in other programs within the Centers for Medicare and Medicaid Services, such as Dialysis Facility Compare.

17. Expiration Date

CMS will display the expiration date on the collection instruments.