

**Supporting Statement – Part A**  
**Data Collection for Quality Measures Using the Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb) (CMS-10569)**

**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 End-Stage Renal Disease Quality Incentive Program (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 this 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 National Healthcare Safety Network 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. 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. 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.

The ESRD QIP is updating this PRA package to account for new measures that were finalized for Payment Year 2021 (Calendar Year 2019) to ensure that the PRA package remains up to date and specific to reporting and validating CROWNWeb data.

**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’ National Quality Strategy (NQS)

and the Center for Medicare and Medicaid Services Quality Strategy. 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.

The majority of measures currently finalized for use in the ESRD QIP are extracted from Medicare claims and therefore require no additional effort on the part of dialysis facilities to report.<sup>1</sup> 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 Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN). The burden associated with submitting measure data to the NHSN Healthcare Personnel Influenza Vaccination and Bloodstream Infection Modules<sup>2</sup> and for the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems survey (ICH CAHPS)<sup>3</sup> 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 2018 ESRD QIP

The CY 2017 End Stage Renal Disease (ESRD) Prospective Payment System (PPS) final rule with comment period finalized quality measures, administrative processes, and data submission requirements for the CY 2018 (Payment Year 2020) ESRD QIP (81 FR 77834 through 77979). During CY 2018, we will collect data for the following measures using the CROWNWeb system:

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

Pain Assessment and Follow-Up Reporting Measure (79 FR 66206): Facility reports in CROWNWeb one of the six conditions listed for each qualifying patient once before August 1 of the Performance Period and once before February 1 of the year following the Performance Period.

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.

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<sup>1</sup> 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.

<sup>2</sup> Both the NHSN Bloodstream Infection and NHSN Healthcare Personnel Influenza Vaccination measure are accounted for under OMB Control Number 0920-0666.

<sup>3</sup> OMB Control Number 0938-0926.

Serum Phosphorus Reporting Measure (81 FR 77912): Facilities must report serum or plasma phosphorus data to CROWNWeb at least once per month for each qualifying patient.

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 clinical 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.

**Table A. Measures Collected via CROWNWeb in CY 2018**

<b>NQS Goal</b>	<b>NQF Endorsement Number</b>	<b>Measure Title</b>	<b>Data Collected</b>
Clinical Care	NQF #1454	Hypercalcemia	Uncorrected serum calcium
Clinical Care	N/A	Dialysis Adequacy Comprehensive	Kt/V Value
Clinical Care	N/A	Pain Assessment and Follow-Up	One of six pain assessment and follow up conditions
Clinical Care	N/A	Clinical Depression Screening and Follow-Up	One of six clinical depression screening and follow up conditions
Clinical Care	Based on NQF #0255	Serum Phosphorus Reporting Measure	Serum or plasma phosphorus data
Clinical Care	Based upon NQF #2701	Ultrafiltration Rate Reporting Measure	<ul style="list-style-type: none"> <li>• Hd Kt/V Date</li> <li>• Post-Dialysis Weight</li> <li>• Pre-Dialysis Weight</li> <li>• Delivered Minutes of BUN Hemodialysis</li> <li>• Number of sessions of dialysis delivered by the dialysis unit to the patient in the reporting month</li> </ul>

b. The CY 2019 ESRD QIP

In the CY 2018 ESRD PPS final rule (82 FR 50738 through 50797), we finalized the removal of two measures from the ESRD QIP's measure set and we are replacing them with two new

measures, which will be calculated in part using data collected in CROWNWeb. Specifically, we replaced the Vascular Access Type (VAT) fistula and Catheter  $\geq$  90 days measures with the Hemodialysis Vascular Access: Standardized Fistula Rate Clinical Measure and the Hemodialysis Vascular Access: Long-Term Catheter Rate Clinical Measure.

We will continue to collect data for the other above-stated measures using CROWNWeb. We will 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 Prospective Payment System final rule (77 FR 67475) and further clarified in the CY 2015 ESRD Prospective Payment System final rule (79 FR 66171 through 66173).

**Table B. New Measures Added for PY 2021 ESRD QIP Program  
To be Collected via CROWNWeb in CY 2019**

<b>NQS Goal</b>	<b>NQF Endorsement Number</b>	<b>Measure Title</b>	<b>Data Collected</b>
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

## **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 are accurate. We began a pilot validation study program for the ESRD QIP in CY 2013. That validation study has continued in subsequent years, and we finalized in the CY 2018 ESRD PPS Final Rule that we will continue validating data collected in CROWNWeb. Specifically, we will continue sampling the same number of records (approximately 10 per facility) from the same number of facilities, which totaled 300 facilities during CY 2018. If a facility is randomly selected to participate in the pilot 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 Total Performance Score (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 its 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 CY 2013 when the measure was first introduced in the ESRD QIP final rule. In 2012, the hypercalcemia rate was 2.8% (excluding the patient months with missing value of calcium) or 11.1% (including the patient months with missing value of calcium), and by 2016 it was down to 0.9% (excluding the patient months with missing value of calcium) or 3.7% (including the patient months with missing value of calcium).
- The dialysis adequacy rate for adults for both hemodialysis and peritoneal dialysis show an improvement, with a marked increase among the adult peritoneal dialysis population. Specifically, the percent adequacy in Kt/V rose from 91.2% in 2010 to 96.1% in 2016 in adult hemodialysis patients and from 73.3% in 2010 to 89.1% in 2016 in adult peritoneal patients.
- Mortality rates have steadily declined from 2010 to 2014.
- 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 2022; \$38,114,872
- PY 2021; \$37,872,521
- 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 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 as a way 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 the Consolidated Renal Operations in a Web-Enabled Network (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. Copies of the data submission user interfaces are included with this package.

## **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. 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 submission or employing a full electronic health record, which can be

prohibitively expensive for these facilities. Thus, this effort facilitates small renal dialysis facilities’ collection and reporting of required data.

## 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. This data is then collected on the schedules provided in the 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**

<b>Measure Title</b>	<b>Measure Collection Schedule/Frequency</b>
Hypercalcemia	Monthly
Dialysis Adequacy Comprehensive	Monthly
Pain Assessment and Follow-Up	Biannually
Clinical Depression Screening and Follow-Up	Annually
Serum Phosphorus Reporting Measure	Monthly
Ultrafiltration Rate Reporting Measure	4 data elements are reported 3 times during the week of the monthly Kt/V draw, and a fifth data element is reported monthly
Hemodialysis Vascular Access Type: Standardized Fistula Rate Clinical Measure	Monthly
Hemodialysis Vascular Access Type: Long-Term Catheter Rate Clinical Measure	Monthly

## 7. Special Circumstances

Two of the measures previously adopted for use in the ESRD QIP, the Serum Phosphorous reporting measure and the Hypercalcemia clinical measure, require renal dialysis facilities to report data more often than quarterly. These measures evaluate a renal dialysis facility’s maintenance of ESRD patients’ serum calcium and serum or plasma phosphorus levels, both of which, when left unregulated, are associated with increased morbidity and mortality in ESRD patients. We therefore believe monthly collection is most appropriate to properly incentivize renal dialysis facilities to actively monitor their patients’ health and well-being.

## 8. Federal Register Notice/Outside Consultation

The CY 2018 ESRD PPS proposed rule, serving as the 60-day Federal Register notice was published on July 5, 2017 (82 FR 31190). The final rule (82 FR 50738 through 50797) published on November 1, 2017.

We received comments on the CROWNWeb data validation study. One commenter requested that CMS make the results of the CROWNWeb validation publicly available. Another commenter questioned whether CMS has not released any validation results because those results would show that CROWNWeb is not a reliable data collection tool. One of our main goals for validation is to assess the integrity of data reported to the systems that are used to calculate facility scores and to incentive accurately reported data. At this time we do not think it would be beneficial to make the results public. Further, given the small sample size, we are concerned that publicly releasing the information would threaten the confidentiality and privacy of facilities that are chosen to participate in the validation study. To date, our validation studies have not shown any concerns with the reliability of data reported to CROWNWeb. In fact, our most recent CROWNWeb Validation Study found an overall error rate of 3.4 percent (95 percent confidence interval of 1.3 percent to 5.5 percent) for the CROWNWeb system. Given stakeholders concerns, we will consider providing a national summary report, validation fact sheet, or similar document that summarizes high-level aggregate results from each validation study in future years.

A third commenter questioned why CMS continues to refer in the ESRD QIP to a “validation study” rather than an audit program of CROWNWeb data submissions and the NHSN BSI clinical Measure. However, the data validation studies are not designed to be an audit, but rather to assess the capacity of renal dialysis facilities to provide accurate and complete data on performance measures, and to find ways to assist them in improving their data reporting.

## **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**

All information collected under the ESRD QIP will be maintained in strict accordance with statutes and regulations governing confidentiality requirements for CMS data, including the Privacy Act of 1974 (5 U.S.C. 552a), the Health Insurance Portability and Accountability Act (HIPAA), and the Quality Improvement Organizations confidentiality requirements, which can be found at 42 CFR Part 480. CMS maintains this information in the CMS data warehouse, which contains all information collected under this and other quality reporting and value-based purchasing programs. In addition, the tools used for transmission and storage of data are considered confidential forms of communication and are HIPAA compliant.



## 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, the NHSN Healthcare Personnel Influenza Vaccination reporting measure, and the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems measure because the burden associated with these measures is captured under OMB numbers 0920-0666<sup>4</sup> (The National Healthcare Safety Network) and 0938-0926 (In-Center Hemodialysis CAHPS Survey), respectively. This burden estimate also excludes the burden associated with training facilities to use CROWNWeb, 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.

### 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:

$$\text{Burden} = \# \text{ Patients nationally} * \frac{\# \text{ elements}}{\text{pt} * \text{ year}} * \frac{0.042 \text{ hours}}{\text{element}} * \frac{\text{wage } \$}{\text{hour}} = \frac{\text{wage } \$}{\text{year}}$$

**Table D. CROWNWeb Data Collection Burden Estimate Elements**

<b>Burden Estimate Elements</b>	<b>CY 2018</b>	<b>CY 2019</b>
Number of facilities <sup>5</sup>	6,824	6,814
Number of ESRD patients, nationally <sup>6</sup>	497,542	497,542
The time spent for data entry and submission per element <sup>7</sup>	0.042 hours (2.5 minutes)	0.042 hours (2.5 minutes)
Annual Hour Burden Nationally	4,074,679 hours	4,576,198 hours

<sup>4</sup> Both the NHSN Bloodstream Infection and NHSN Healthcare Personnel Influenza Vaccination measure are accounted for under OMB Control Number 0920-0666.

<sup>5</sup> Total number of ESRD PPS facilities in the United States treating ESRD QIP-eligible patients.

<sup>6</sup> Total number of patients treated at ESRD PPS facilities in the United States

<sup>7</sup> As stated in the CY 2018 ESRD PPS final rule, we estimate the amount of time required to submit measure data to CROWNWeb to be 2.5 minutes.

<b>Burden Estimate Elements</b>	<b>CY 2018</b>	<b>CY 2019</b>
Mean hourly wage of a Medical Records and Health Information Technician (Fringe benefit is calculated at 100%).	\$39.86	\$39.86

The estimated number of patients per facility is estimated by calculating the mean number of patients per ESRD PPS-eligible facility nationwide, based on CY 2016 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. The estimated time per element entry for the CROWNWeb measures is based on historical estimates in the ESRD PPS proposed and final rules 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). We estimate the total burden hour for reporting measure data using the CROWNWeb system for CY 2018 to be 4,074,679 hours and the total burden hour for CY 2019 to be 4,576,198 hours. Accordingly, we estimate the annual burden for the 3-year OMB approval to be 2,883,626 hours ((be 4,074,679 + 4,576,198 ) / 3 years).

We anticipate that the labor required to collect and submit this data will be completed by either Medical Records and Health Information Technicians or similar administrative staff. The mean hourly wage of a Medical Records and Health Information Technician is \$39.86 per hour. Fringe benefit is calculated at 100 percent. Therefore, using these assumptions, we estimate an hourly labor cost of \$39.86 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. Nonetheless, there is no practical alternative, and we believe that these are reasonable estimation methods. Accordingly, we estimate the total annual burden for reporting measure data using the CROWNWeb system for CY 2018 to \$162 million and the total annual burden for CY 2019 to be \$182 million.

**Table E1. CY 2018 CROWNWeb Data Collection Burden Per Measure**

<b>MEASURE REPORTING Renal Dialysis Facilities CY 2018 Measure Set</b>	<b>Number of Facilities</b>	<b>Number of Patients Nationally</b>	<b>Average Number of Patients per Facility</b>	<b>Number of Elements per Patient-Year</b>	<b>Estimated Time for Data Entry per Element (hours)</b>	<b>Estimated Wage plus Benefits per Hour for Data Entry</b>	<b>Annual Hour Burden per Facility</b>	<b>Annual Burden Facility</b>
Hypercalcemia	6,814	497,521	73	12	0.042	\$39.86	37	\$1,46
Dialysis Adequacy Comprehensive	6,814	497,521	73	12	0.042	\$39.86	37	\$1,46
Serum Phosphorus Reporting Measure	6,814	497,521	73	12	0.042	\$39.86	37	\$1,46
Clinical Depression Screening and Follow-Up	6,814	497,521	73	1	0.042	\$39.86	3	\$12
Pain Assessment and Follow-Up	6,814	497,521	73	2	0.042	\$39.86	6	\$24
Ultrafiltration Rate Reporting Measure	6,814	497,521	73	156	0.042	\$39.86	478	\$19,06

**Table E2. CY 2018 CROWNWeb Total Data Collection Burden**

<b>Basis</b>	<b>Number of Elements</b>	<b>Annual Hour Burden</b>	<b>Annual Burden</b>
Each Facility	14238	598	\$23,835.84
National	97,016,595	4,074,697	\$162,417,422.02

**Table E3. CY 2019 CROWNWeb Data Collection Burden Per Measure**

<b>MEASURE REPORTING Renal Dialysis Facilities CY 2018 Measure Set</b>	<b>Number of Facilities</b>	<b>Number of Patients Nationally</b>	<b>Average Number of Patients per Facility</b>	<b>Number of Elements per Patient-Year</b>	<b>Estimated Time for Data Entry per Element (hours)</b>	<b>Estimated Wage plus Benefits per Hour for Data Entry</b>	<b>Annual Hour Burden per Facility</b>	<b>Annual Burden Facility</b>
Hypercalcemia	6,814	497,521	73	12	0.042	\$39.86	37	\$1,46
Dialysis Adequacy Comprehensive	6,814	497,521	73	12	0.042	\$39.86	37	\$1,46
Serum Phosphorus Reporting Measure	6,814	497,521	73	12	0.042	\$39.86	37	\$1,46
Clinical Depression Screening and Follow-Up	6,814	497,521	73	1	0.042	\$39.86	3	\$12
Pain Assessment and Follow-Up	6,814	497,521	73	2	0.042	\$39.86	6	\$24
Ultrafiltration Rate Reporting Measure	6,814	497,521	73	156	0.042	\$39.86	478	\$19,06
Standardized Fistula Rate	6,814	497,521	73	12	0.042	\$39.86	37	\$1,46
Long-Term Catheter Rate	6,814	497,521	73	12	0.042	\$39.86	37	\$1,46

**Table E4. CY 2019 CROWNWeb Total Data Collection Burden**

<b>Basis</b>	<b>Number of Elements</b>	<b>Annual Hour Burden</b>	<b>Annual Burden</b>
Each Facility	15,990	672	\$26,769.48
National	108,957,099	4,576,198	\$182,407,258.58

b. CROWNWeb Data Validation

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

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

**Table F. CROWNWeb Data Validation Burden Estimate Elements**

<b>Burden Estimate Element</b>	<b>CY 2017</b>	<b>CY 2018</b>
Number of facilities participating in the CROWNWeb data validation study, annually	300	300
Number of medical records per facility per year	10	10
Time spent for record collection and submission per facility <sup>8</sup>	2.5 hours (approx. 0.25 hours per record)	2.5 hours (approx. 0.25 hours per record)
Hourly wage per hour engaged in data collection and submission <sup>9</sup>	\$39.86	\$39.86

Under the CROWNWeb data validation study finalized for CY 2018, we will randomly sample records from 300 facilities as part of its continuing pilot data validation program. 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 take each facility approximately 2.5 hours total, or .25 hours per medical record, to comply with this requirement. We therefore estimate the total annual hourly burden for the ongoing CROWNWeb data validation study for CY 2018 to be 750 hours.

Just as above, we anticipate that the labor required to collect and submit this data will be completed by either Medical Records and Health Information Technicians or similar administrative staff. The mean hourly wage of a Medical Records and Health Information Technician is \$19.93 per hour. Fringe benefit is calculated at 100 percent. Therefore, using these assumptions, we estimate an hourly labor cost of \$39.86 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 2018 to be \$29,895.00.

<sup>8</sup> As stated in the PY 2019 ESRD PPS final rule, we estimate the amount of time required to submit measure data to CROWNWeb to be 2.5 minutes.

<sup>9</sup> <https://www.bls.gov/oes/2016/may/oes292071.htm> (Estimates are based on 2016 national mean hourly wage).

**Table G1. CY 2018 CROWNWeb Data Validation Burden**

<b>DATA VALIDATION Renal Dialysis Facilities CY 2016</b>	<b>Number of Facilities</b>	<b>Number of Records per Year</b>	<b>Estimated Time per Record</b>	<b>Estimated Wage plus Benefits per Hour for Record Collection</b>	<b>Annual Hour Burden per Facility</b>	<b>Annual Burden per Facility</b>
CROWNWeb Data Validation	300	10	0.25	\$39.86	2.5	\$99.65

**Table H2. CY 2018 CROWNWeb Total Data Validation Burden**

<b>Basis</b>	<b>Annual Hour Burden</b>	<b>Annual Burden</b>
Each Facility	2.5	\$99.65
National	750	\$29,895.00

**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 \$1,753,968 (FY) annually for the validation contract. The estimated cost to operate the collection of data through the CROWNWeb system includes two CMS staff at the GS-13 level (approximate annually salary is \$92,000) and one at the GS-14 level (approximate annually salary is \$106,000), for an additional cost of \$290,000. This results in a total estimated cost of \$2,043,968 annually.

**15. Changes to Burden**

Due to the CY 2019/PY 2021 introduction of two new measures that will use data collected in CROWNWeb - Hemodialysis Vascular Access: Standardized Fistula Rate and Hemodialysis Vascular Access: Long-Term Catheter Rate - the total burden hours will increase by 501,519 hours in CY 2019 (from 4,074,679 hours in CY 2018 to 4,576,198 hours in CY 2019), and the total burden will increase by \$20 million in CY 2019 (from \$162 million in CY 2018 to \$182 million in CY 2019). The burden hours (averaged over 3 years) have increased from 1,917,852 to 2,883,626 due to 1) the introduction of 2 new measures in the CY 2017 ESRD PPS final rule beginning in CY 2018, 2) the introduction of 2 additional new measures in the CY 2018 ESRD

PPS final rule beginning in CY 2019, and 3) use of more recent data when estimating facility counts, patient counts, and wages in the CY 2018 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.