NOTE TO REVIEWER
OMB No. 0938-0386

This submission is considered a revision of an existing collection, as most of the information requirements of the End-Stage Renal Disease facility Conditions for Coverage (CfCs) are currently approved under OMB # 0938-0386 (CMS-R-52), with an expiration date of July 31, 2017. This revision is necessary to renew the current package, and to include new disclosure requirements established in recent rulemaking (CMS-3337-IFC, published on December 14, 2016).

CMS is also revising this package in order to comply with the recent nationwide preliminary injunction issued by the District Court for the Eastern District of Texas against the December 14, 2016 IFC. The court issued a preliminary injunction on January 25, 2017 preventing the rule from going into effect while it considers a lawsuit challenging the validity of the rule. Depending on the outcome of that litigation, the Department may submit a non-material change request to reinstate the disclosure requirements (42 CFR 494.70(c) and 494.180(k)), as the public has had an opportunity to comment on the disclosures. For administrative purposes, the burden remains the same.

Supporting Statement For Paperwork Reduction Act Submissions

End Stage Renal Disease (ESRD) Conditions for Coverage and Supporting Regulations

A. Background

The Centers for Medicare and Medicaid Services (CMS) is requesting revision of OMB Control number 0938-0386 (CMS-R-52) in compliance with the Paperwork Reduction Act (PRA). This package applies to existing Medicare End-stage Renal Disease (ESRD) conditions for coverage (CfCs) at 42 CFR 405, Subpart U, and at 42 CFR 494.

Section 299I of the Social Security Amendments of 1972 (P.L. 92-603) originally extended Medicare coverage to insured individuals, their spouses, and their dependent children with ESRD who require dialysis or transplantation. Subsequently, the ESRD Amendments of 1978 (Pub. L. 95-292) amended title XVIII of the Social Security Act (the Act) by adding section 1881. Section 1881(b)(1) of the Act authorizes the Secretary to prescribe health and safety requirements (known as conditions for coverage) that a facility providing dialysis and transplantation services to ESRD patients must meet to qualify for Medicare reimbursement. Final regulations were published June 3, 1976. Subsequent to the publication of the final regulations, the ESRD Amendments of 1978 were enacted to amend title XVIII of the Act to include section 1881(c). This section establishes ESRD network areas and Network organizations to assure the effective and efficient administration of ESRD program benefits. The requirements from section 1881(b) and (c) are implemented in regulations at 42 CFR part 405, subpart U, Conditions for Coverage for ESRD facilities.

On April 7, 1986, the Consolidated Omnibus Budget Reconciliation Act of 1975 (COBRA) (P.L. 99-272) was enacted which requires the Secretary to maintain renal disease Network organizations as authorized under section 1881(c) of the Act, and not merge the Network organizations into other organizations or entities. On April 15, 1986, we published a notice of proposed rulemaking to implement section 9214 of P.L. 99-272. A final rule (HSQ-115) was published August 26, 1986. This rule revised the requirements in regulations pertaining to the ESRD networks and organizations and establishes new, more efficient Network organizations.

Revisions resulting from two additional rules: HSQ-137--ESRD: Responsibilities of Network Organizations, published January 21, 1988; and BERC-434--Medicare Program: Standards for the Reuse of Hemodialyzer Filters and Other Dialysis Supplies, published October 2, 1987, are also included. Currently, these requirements are approved under OMB control number 0938-0386.

A major revision of the ESRD CfCs at 42 CFR 494 was issued in a final rule on April 15, 2008. This final rule focused on the patient and the results of care provided to the patient, established performance expectations for facilities, encouraged patients to participate in their plan of care and treatment, eliminated many procedural requirements from the

previous conditions for coverage, and preserved strong process measures when necessary to promote meaningful patient safety, well-being, and continuous quality improvement.

On December 14, 2016, the CfCs were amended by an Interim Final Rule (IFC) to create new disclosure requirements to prevent inappropriate steering of dialysis patients into individual market health plans rather than Medicare and/or Medicaid. These require certain facilities to make disclosures of premium assistance payments made by dialysis suppliers, funds available to patients, and complete information about the extents and limitations of all coverage options. Applicable facilities must also disclose payments (in whole or in part) of individual market plan premiums to issuers, and obtain agreement from said issuers. An explanation of the requirements and the associated burden is listed under section B12 of the supporting statement.

CMS is also revising this package in order to comply with the recent nationwide preliminary injunction issued by the District Court for the Eastern District of Texas against the December 14, 2016 IFC. The court issued a preliminary injunction on January 25, 2017 preventing the rule from going into effect while it considers a lawsuit challenging the validity of the rule. Depending on the outcome of that litigation, the Department may submit a non-material change request to reinstate the disclosure requirements, as the public has had an opportunity to comment on the disclosures. For administrative purposes, the burden remains the same.

B. Justification

1. Need and Legal Basis

The information collection requirements described herein are part of the Medicare and Medicaid Programs; Conditions for Coverage for End-Stage Renal Disease Facilities. The requirements fall into three categories: record keeping, reporting, and disclosure. With regard to the record keeping requirements, CMS uses these conditions for coverage to certify health care facilities that want to participate in the Medicare or Medicaid programs. These record keeping requirements are no different than other conditions for coverage in that they reflect comparable standards developed by industry organizations such as the Renal Physicians Association, American Society of Transplant Surgeons, National Kidney Foundation, and the American Association of Kidney Patients.

For the reporting requirements, the information is needed to assess and ensure proper distribution and effective utilization of ESRD treatment resources while maintaining or improving quality of care. All of the reports specified in this document are geared toward ensuring that facilities achieve quality and cost-effective service provision. Collection of this information is authorized by Section 1881 of the Act and required by 42 CFR 405.2100 through 405.2171 (now at 42 CFR 414.330, 488.60, and 494.100-494.180).

Depending on the outcome of litigation, disclosures may be required by Medicare-certified dialysis facilities that make payments of premiums for individual market health plans.

These requirements would apply to dialysis facilities that provide such financial assistance directly, through a parent organization, or through a third party. These requirements are intended to protect patient health and safety; improve patient disclosure and transparency; ensure that coverage decisions are not inappropriately influenced by the financial interests of dialysis facilities rather than the health and financial interests of patients; and protect patients from mid-year interruptions in coverage. These disclosures would be required by 42 CFR 494.70(c) and 494.180(k).

2. Information Users

The general record keeping requirements prescribed in this regulation are used by dialysis facilities. CMS and the health care industry believe that the availability to the facility of the type of records and general content of records are routine and consistent with health care facility standards.

The reporting associated with this regulation is used in reports to Congress, by CMS, and the facilities. The reporting requirements are to assist in improving quality of care as well as to provide the most economic services available. The reports that are submitted are used by CMS to analyze for budgetary issues, which enables CMS to maximize utilization rates and also make sure all services are available throughout the ESRD program. The reports are used by the facilities as self-assessment tools to measure their performance and available services to those facilities throughout the networks. The Secretary is required by the Act to submit to Congress each year a report on the ESRD program. The Congress uses this report as a basis to make legislative changes.

Some information is also made available to the public through the Dialysis Facility Compare Website (http://www.medicare.gov/dialysisfacilitycompare/), so that dialysis patients can compare clinical performance when choosing where to receive dialysis care.

Disclosures made in accordance with 42 CFR 494.70(c) will be used by dialysis facility patients to make health coverage decisions. Disclosures made in accordance with 42 CFR 494.180(k) will be used by facilities and market plan issuers to ensure all parties are informed of plan premium payment arrangements. Both of these disclosures are pending litigation.

3. Use of Information Technology

This regulation does not prescribe how the facility should prepare or maintain reports and records. Facilities are free to take advantage of any technological advances which they find appropriate for their needs.

However, this regulation does require that data submitted to CMS be submitted electronically, through a web-enabled system. The web-enabled system, known as CROWNWeb, went into national use in June 2012. Facilities have the option to submit data to CROWNWeb through traditional data entry or through “batch entry” facilitated by electronic health records.

4. Duplication of Efforts

These are unique requirements which are specified in a way so as not to duplicate existing facility practice. If a facility already maintains these general records, regardless of format, they are in compliance with these requirements.

5. Small Businesses

These requirements do affect some small businesses. However, the general nature of the requirements allows the flexibility for facilities to meet the requirement in a way consistent with their existing operations.

6. Less Frequent Collection

The reporting associated with this regulation is statutorily mandated and must be collected regularly. The reports must be submitted because ESRD facilities have timeframes they must meet in order to qualify for reimbursement for the next calendar year. The Secretary establishes the rates for reimbursement based on the most recent information available. Clinical performance data submitted to CMS through the CROWNWeb system must be submitted on a monthly basis. Information about insurance options must be disclosed (pending litigation outcomes) when a patient is admitted to the facility and annually thereafter. Communication with market plan issuers occurs as needed (pending litigation outcomes), but only once per plan year.

7. Special Circumstances

There are no special circumstances for collecting information, with the following exceptions:

- Clinical performance data submitted to CMS through the CROWNWeb system must be submitted on a monthly basis.
- Patient records must be retained for a period of time not less than that required by State law, or in the absence of State law, 5 years from the date of discharge, transfer or death and 3 years for minors or until the patient reaches legal age under State law, whichever is longer, from the date of the patient's discharge, transfer or death.

8. Federal Register/Outside Consultation

CMS published a request for information on the topic of inappropriate steering of dialysis patients into individual market plans on August 23, 2016 (81 FR 57554). We received over 800 comments in response to the RFI. Based on information gathered through the RFI, we issued an interim final rule (CMS-3337-IFC) on December 14, 2016 that established new requirements for certain ESRD facilities that are subject to the PRA. We discuss new burden related to the IFC requirements in that document, and in this package. We are accepting

public comments on the IFC, including on burden estimates and assumptions, through January 11, 2017.

9. Payments/Gifts to Respondents

There were no payments/gifts to respondents.

10. Confidentiality

CMS does not pledge confidentiality.

11. Sensitive Questions

There are no sensitive questions.

12. Burden Estimates (Hours & Wages)

NOTE: We estimate the current number of ESRD facilities to be 6,700. However, due to the rapid growth in the number of ESRD facilities, we predict that approximately 255 facilities will open each year between 2016and 2019. For purposes of this PRA package, we estimate that the average number of existing facilities in each year will be 7,000 facilities, and base our calculations on this average.

414.330	***Payment for home dialysis equipment, supplies, and support services.***
(a)(2)(iii)(C)	Suppliers must report to the ESRD facility providing support services, at least every 45 days, all data (meaning information showing what supplies and services were provided to the patient and when each was provided) for each patient regarding services and items furnished to the patient in accordance with § 494.100(c)(2) of this chapter. The burden to ESRD home dialysis suppliers associated with this requirement would be the time and effort necessary to collect all data for each patient receiving home dialysis care with respect to services and items furnished. However, the payment method that covered these suppliers was eliminated in 2011 (http://www.gpo.gov/fdsys/pkg/FR-2010-08- 12/pdf/2010-18466.pdf) and there are no longer any such entities. Therefore there are no actual costs associated with this requirement.
488.60	***Special procedures for approving end stage renal disease facilities.***
(a)(1-4)	An ESRD facility that wishes to be approved or that wishes an expansion of dialysis services to be approved for Medicare coverage, in accordance with part 494 of this subchapter, must submit the documents and data as outlined in §488.60(a)(1) through (a)(4).

We estimate that it will take 40 hours for each of the 255 new and renovated facilities to gather and submit the necessary documentation for consideration by the Secretary. The estimated annual burden is 10,200 annual hours. This number of hours is previously approved.

494.30 ***Condition: Infection control.***

(a)(ii) New dialysis facilities must include an isolation room or request an isolation room waiver approved by the Secretary. We estimate that 90 percent (about 229) of new dialysis facilities would request a waiver. This task would take approximately 1 hour for each of these 229 newly built dialysis facilities, for a total of 229hours, annually.

494.30 ***Condition: Infection control.***

(b)(3) Facilities must report infection control issues to the dialysis facility's medical director (see § 494.150 of this part) and the quality improvement committee. We estimate that it would take staff 5 minutes per incident to notify the medical director and the quality improvement committee. Such infection control issues are rare, and so we estimate that only 1 percent of facilities would experience an incident annually. Therefore, for 70 facilities, we estimate a total annual burden of 5.8 hours.

494.30 ***Condition: Infection control.***

(c) The facility must report incidences of communicable diseases as required by Federal, State and local laws. While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice and may be required under State or local law, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

494.40 ***Condition: Water quality.***

(b)(2)(ii)(C) If the test results from the last component or carbon tank are greater than the parameters for chlorine or chloramine specified in paragraph (b)(2)(i) of this section, the facility must immediately notify the medical director. We estimate that it would take staff 5 minutes per incident to notify the medical director. Such incidents are rare, and so we estimate that only 1 percent of facilities would experience an incident annually. Therefore, for 70facilities, we estimate a total annual burden of 5.8 hours.

494.40 ***Condition: Water quality.***

(c) Facilities are required to create a corrective action plan that ensures patient

safety. Specifically, when water testing results, including but not limited to chemical, microbial, and endotoxin levels meet levels considered unsafe by AAMI or deviate from the AAMI standards, the dialysis facility must develop a corrective action plan. We estimate that it would take 70 facilities 30 minutes each to develop and implement a corrective action plan that ensures patient safety. Therefore, we estimate a total annual burden of 35 hours.

494.50 ***Condition: Reuse of hemodialyzers and bloodlines.***

(c)(1-2) The dialysis facility must monitor patient reactions, undertake evaluation of its dialyzer reprocessing and water purification system, and report any adverse outcomes to FDA and other Federal, State, or local government agencies as required by law. While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice and is required under other Federal, State, and local laws, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

494.60 ***Physical environment.***

(b) The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations. While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice and may be required under State or local law, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

494.60 ***Physical environment.***

(d)(4) The dialysis facility must have a plan to obtain emergency medical system assistance when needed, evaluate at least annually the effectiveness of emergency and disaster plans, and update them as necessary. We estimate that it will take each of the 255 new facilities 5 hours to comply with the requirements in this section. We estimate that it will take 1 hour each for 7,000 existing facilities to annually comply with the requirements in this section. The total estimated annual burden for new and existing facilities is 8,275 hours.

494.70 ***Condition: Patients' rights.***

The dialysis facility must inform patients (or their representatives) of their rights and responsibilities when they begin their treatment. The dialysis facility must prominently display a copy of the patients' rights in the facility, including the current State agency and ESRD Network mailing addresses and telephone

complaint numbers, where it can be easily seen and read by patients. We estimate that it will take 7,000 facilities 1.5 hours each on an annual basis to update their patient rights materials to comply with this requirement. The total estimated annual burden is 10,500 hours.

(c) (Note: pending litigation outcomes.) Dialysis facilities that make payments of premiums for individual market health plans (in whole or in part), whether directly, through a parent organization (such as a dialysis corporation), or through another entity (including by providing contributions to entities that make such payments), must inform each patient annually of all available health coverage options, and how each option may impact their costs and health care, about premium assistance for enrollment in an individual market health plan that may be available to the patient, and the facility's, or its parent organization's, contributions to patients or third parties that subsidize the individual's enrollment in individual market health plans for individuals on dialysis, including the reimbursements for services rendered that the facility receives as a result of subsidizing such enrollment.

We estimate that approximately 90 percent, or 6300, facilities make payments of premiums for individual market health plans, whether directly, through a parent organization, or through another entity, and therefore, will need to comply with these disclosure requirements. We estimate that approximately 500,000 patients receive services at Medicare certified facilities. Therefore, on average, each facility provides dialysis services to approximately 72 patients annually. It is estimated that each facility will prepare, on average, a 6 page pamphlet that includes all required information. We estimate that an administrative assistant will spend approximately 40 hours (at an hourly rate of $35.10) on average to research the required information and develop a pamphlet. We estimate it will take an administrative manager (at an hourly rate of $101.98) 4 hours to review the pamphlet. The total annual burden for each facility will be 44 hours with an equivalent cost of $1,812((40 hours x $35.10 hourly rate) + (4 hours x $101.98hourly rate)). For all 6,300 facilities, the total annual burden will be 277,200 hours (44 hours x 6,300 facilities) with an equivalent cost of approximately $11,415,600 ($1,812 annual burden cost x 6,300 facilities). It is anticipated that the burden to prepare the pamphlet may be lower in subsequent years since all that will be needed is to review and update plan information, but we will use the initial year estimates in this analysis as such updates will likely require a similar number of hours, and the number of relevant insurance plans may vary from year to year. In order to print the pamphlet, we estimate that it will cost each facility $3.00 (for a six page pamphlet at $0.50 per page). For each facility, we estimate a total materials and printing cost of $216.00 ($3.00 printing and materials x 72 patients), for a total annual printing and materials burden of $1,360,800 ($216 printing and materials x 6300 facilities).

In addition to providing a copy of the pamphlet to the patients, it is assumed that a health care social worker or other patient assistance personnel at each

facility will review the information with the patients and obtain a signed acknowledgement form stating that the patient has received this information. We estimate that a lawyer (at an hourly rate of $131.02) will take 30 minutes to develop an acknowledgement form confirming that the required information was provided to be signed by the ESRD patient. The total burden for all 6,300 facilities to develop the acknowledgement form in the initial year only will be 3,150 hours (0.5 hours x 6,300 facilities) with an equivalent cost of approximately $412,713 (($131.02 hourly rate x 0.5 hours) x 6,300 facilities). While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

We estimate that a health care social worker (at an hourly rate of $51.94) will take an average of 45 minutes to further educate each patient about their coverage options. The social worker will also obtain the patient's signature on the acknowledgement form and save a copy of the signed form for recordkeeping. The total annual burden for each facility will be 54.75 hours (0.75 hours x 73 patients) with an equivalent cost of approximately $2,844 ($51.94 hourly rate x 54.75 hours). The total annual burden for all 6,300 facilities will be 344,925 hours 54.75 hours x 6,300 facilities) with an equivalent cost of approximately $17,915,436 ($2,843.72 annual burden cost x 6,300 facilities).

We note that there will likely be printing and materials costs associated with these requirements. While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

494.80 ***Condition: Patient Assessment.***

The facility's interdisciplinary team is responsible for providing each patient with an individualized and comprehensive assessment of his or her needs. The comprehensive patient assessment must be documented in the medical record. While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice and may be required under State or local law, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

494.90 ***Condition: Patient plan of care.***

The interdisciplinary team must develop and implement a written, individualized comprehensive plan of care that meets the requirements of § 494.90. While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice and may be required under State or local law, exempts the burden associated with this requirement

from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

494.100 ***Condition: Care at home.***

(a) The interdisciplinary team must provide training to the home dialysis patient, the designated caregiver, or the self-dialysis patient before the initiation of home dialysis or self-dialysis (as defined in § 494.10 of this part) and when the home dialysis caregiver or home dialysis mortality changes. While these requirements are subject to the PRA, they are exempt as stated under 5 CFR 1320.3(h)(5); facts or opinions obtained initially or in follow-on requests, from individuals under treatment or clinical examination in connection with research on or prophylaxis to prevent a clinical disorder, direct treatment of that disorder, or the interpretation of biological analyses of body fluids, tissues, or other specimens, or the identification or classification of such specimens are not subject to the PRA. In addition, facilities are required to meet these requirements as stated under Federal, State, and local laws and thereby exempt under 5 CFR 1320.3(b)(3).

494.100 ***Condition: Care at home.***

(b) The dialysis facility must document in the patient's medical record, that the patient, the caregiver, or both received and demonstrated adequate comprehension of the training. In addition, the facility must document, in the patient's medical record, that the self-monitoring data and other information from self-care were reviewed, at least every 2 months. While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice, or is required under other Federal, State, and local laws, or both, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

494.100 ***Condition: Care at home.***

(c)(1) Section 494.100(c) contains the standards for support services. As required by § 494.100(c)(1)(i), a facility must periodically monitor the patient's home adaptation. Section 494.100(c)(1)(ii) requires a member of the facilities interdisciplinary team to coordinate the home patient's care.
Section 494.100(c)(1)(iii) requires a facility to develop and periodically review each patient's plan of care. Section 494.100(c)(1)(v) that the facility must monitor the quality of water and dialysate used by home hemodialysis patients. The monitoring must include onsite evaluations and tests of the water and dialysate system. We estimate that facilities would have to meet these requirements for 66,600 care at home patients, and that it would take them approximately 6 hours per patient, per year. We estimate a total annual burden of 399,600 hours.

494.100 ***Condition: Care at home.***

(c)(2) The dialysis facility must maintain a recordkeeping system that ensures continuity of care and patient privacy. While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice and may be required under State or local law, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

494.110 ***Condition: Quality assessment and performance improvement.***

The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven quality assessment and performance improvement program that reflects the complexity of the dialysis facility's organization and services. The dialysis facility must maintain and demonstrate evidence of its quality improvement and performance improvement program for review by CMS.

The burden associated with all of the requirements of this section is the time and effort necessary to develop, implement, maintain, evaluate, and demonstrate evidence of a quality assessment and performance improvement program. It would take 255 new facilities each approximately 48 hours to meet these requirements. The annual burden associated with this requirement is estimated to be 12,240 hours.

Additionally, all facilities are subject to an annual burden to maintain, evaluate, and demonstrate evidence of a quality assessment and performance improvement program. The facility must analyze and document the incidence of infection and identify trends and establish baseline information on infection incidence; and develop recommendations and an action plan to minimize infection transmission, promote immunization, and take actions to reduce future incidents. The burden associated with this requirement is the time and effort it would take for a facility to document the incidence of infection and develop recommendations and an action plan to reduce future incidents. We estimate it would take 7,000 facilities 12 hours annually each to meet this requirement, for a total annual burden of 84,000 hours.

494.120 ***Condition: Special purpose renal dialysis facilities.***

(d) Facilities must contact the patient's physician, if possible, prior to initiating dialysis in the special purpose renal dialysis facility, to discuss the patient's current condition to assure care provided in the special purpose renal dialysis facility is consistent with the plan of care (described in §494.90 of this part). While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice and may be required under State or local law, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

494.120 ***Condition: Special purpose renal dialysis facilities.***

(e) Facilities must document all patient care provided in the special purpose facility and forward the documentation to the patient's dialysis facility, if possible, within 30 days of the last scheduled treatment in the special purpose renal dialysis facility. While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice and may be required under State or local law, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

494.170 ***Condition: Medical records.***

The dialysis facility must maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of ESRD services and all other home dialysis patients whose care is under the supervision of the facility. While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice and may be required under State or local law, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

494.170 ***Condition: Medical records.***

(a)(3) The dialysis facility must obtain written authorization from the patient or legal representative before releasing information that is not authorized by law. While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice and is required under existing law (specifically, the Health Insurance Portability and Accountability Act of 1996 (HIPAA; Pub.L. 104–191), exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

494.170 ***Condition: Medical records.***

(c) Patient records must be retained for a period of time not less than that required by State law, or in the absence of State law, 5 years from the date of discharge, transfer or death and 3 years for minors or until the patient reaches legal age under State law, whichever is longer, from the date of the patient's discharge, transfer or death. While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice, or is required under other Federal, State, and local laws, or both, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

494.170 ***Condition: Medical records.***

(d) When a dialysis patient is transferred, the dialysis facility releasing the patient must send all requested medical record information to the receiving facility within 1 working day of the transfer.

While it is usual and customary for healthcare providers to send medical information to another provider when a patient transfers care, it is not typically done within 1 working day. The burden associated with this requirement is the time and effort it would take for a facility to compile, copy, and send the information requested. This could be a simple task if the facilities involved use interoperable electronic health records, but it could take longer for facilities that keep paper records. We estimate it would take facilities 10 minutes per transferring patient, and that approximately 8% of patients (estimating 500,000 dialysis patients) transfer annually, for an estimated 40,000 transfers per year. We estimate a total annual burden of 6,667 hours.

494.180 ***Condition: Governance.***

(e) Section 494.180(e) discusses the standard for a facility's internal grievance process. This section requires that the facility's internal grievance process be implemented so that the patient may file an oral or written grievance with the facility without reprisal or denial of services. In addition, § 494.180(e)(1)-(3) details the required contents of the process. The burden associated with this requirement is the time and effort necessary to develop and implement the internal grievance process. We estimate that it will take 255new facilities 1 hour each to develop grievance processes**.** We estimate a total annual burden of 255 hours.

494.180 ***Condition: Governance.***

(f)(4)(ii) The interdisciplinary team must notify the patient with a 30-day written notice of planned involuntary discharge, and also notify the ESRD Network that services the area and the State agency of the discharge. The burden associated with this requirement is the time and effort it would take for the team to notify the patient and ESRD Network 30 days prior to the involuntary discharge and the State agency at the time of involuntary discharge. We estimate it would take 10 minutes to provide such notification. We expect that 7,000 facilities would each have one or less patients involuntarily discharged each year. We estimate a total annual burden of 1,167 hours.

494.180 ***Condition: Governance.***

(f)(4)(iii) The interdisciplinary team must obtain a written physician's order that must be signed by both the medical director and the patient's attending physician concurring with the patient's discharge or transfer from the facility. They must

also document any attempts to place the patient in another facility and notify the State survey agency of the involuntary transfer or discharge.

While obtaining one patient discharge physician signature is a usual and customary business practice, or is required under other Federal, State, and local laws, or both, the requirement for the second signature from the medical director is new. We estimate that it would take 5 minutes to for the medical director to sign the discharge order. We expect that one or less patients would be involuntarily discharged from a facility annually. We estimate that the total annual additional burden for 7,000 facilities would be 583 hours.

494.180 ***Condition: Governance.***

(g)(2) The dialysis facility must have available at the nursing/monitoring station, a roster with the names of physicians to be called for emergencies, when they can be called, and how they can be reached. We estimate that it would take 255 new facilities 10 minutes each to develop such a roster. We estimate that the total annual burden would be 42.5 hours.

494.180 ***Condition: Governance.***

(g)(3) The dialysis facility must have an agreement with a hospital that can provide inpatient care, routine and emergency dialysis, and other hospital services, and emergency medical care that is available 24 hours a day, 7 days a week. We estimate that it would take 255 new facilities 45 minutes each to develop such an agreement. We estimate that the total annual burden for new facilities would be 191 hours. We estimate it would take 7,000 existing facilities 10 minutes annually each to maintain such an agreement, for a total annual burden of 1,167 hours. We estimate a total annual burden for new and existing facilities of 1,358 hours.

494.180 ***Condition: Governance.***

(h) The dialysis facility must furnish data and information (both clinical and administrative) electronically to CMS at intervals specified by the Secretary, which meet the requirements referenced in this section. These requirements are subject to the PRA, and are currently approved under the following OMB approval numbers: 0938-0046 and 0938-0657.

We note that there is a burden associated with this requirement that involves training individuals in ESRD facilities to use the electronic data submission system under development. Training is available through in-person or web-based training program. We estimate that it would take 255 new facilities 8 hours each for one individual to complete the training program. We estimate that the total annual burden would be 2,040 hours.

494.180 ***Condition: Governance.***

(j) In accordance with §§ 420.200 through 420.206 of this chapter, the governing body must report ownership interests of 5 percent or more to its State survey agency. These requirements are subject to the PRA, and are currently approved under OMB approval number 0938-0685.

494.180 ***Condition: Governance.***

(k) (Note: pending litigation outcomes.) In accordance with §494.180(k), dialysis facilities that make payments of premiums for individual market health plans, whether directly, through a parent organization, or through another entity, must ensure issuers are informed of and have agreed to accept the payments for the duration of the plan year. We estimate that approximately 7,000 patients that receive such payments are enrolled in individual market plans. Therefore, we estimate that 6,300 facilities will be required to send approximately 7,000 notices.

We estimate that, for each facility during the initial year, it will take a lawyer one hour to draft a letter template notifying the issuer of third party payments and requesting assurance of acceptance for such payments. While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

We further estimate that it will require an administrative assistant approximately 30 minutes (at an hourly rate of $35.10) to insert customized information and email the notification to the issuer, send any follow-up communication, and then save copies of the responses for recordkeeping. The total annual burden for all facilities for sending the notifications will be 3,500 hours (7,000 notifications x 0.5 hours) with an equivalent cost of $122,850 ($35.10 hourly rate x 3,500 hours).

There are an estimated 468 issuers in the individual market. It is assumed that the approximately 7,000 patients are uniformly distributed between these issuers. Issuers will incur a burden if they respond to the notifications from dialysis facilities and inform them whether or not they will accept third party payments. While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

13. Capital Costs

There are no capital costs associated with this regulation.

14. Cost to Federal Government

There is no significant additional survey cost since collection and reporting requirement compliance is generally accomplished by record review and data submission rather than extensive onsite survey activity. We estimate that the annual cost of the CROWNWeb data collection system is approximately $1.3 million.

15. Changes to Burden

The estimated burden for this request is based on the current number of Medicare-participating ESRD facilities, with a prediction for 255 new facilities each year. Changes to ongoing burden reflect these new facility counts. There have been new paperwork requirements implemented since the last revision of CM-R-52.

Through CMS-3337-IFC, published on December 14, 2016 new information and disclosure requirements for dialysis facilities were established. Specifically, dialysis facilities that make payments of premiums for individual market health plans, whether directly, through a parent organization, or through another entity, must provide patients with information about health insurance options and disclose facility premium payments. Such facilities must also ensure issuers are informed of and have agreed to accept the third party premium payments for the duration of the plan year. This has increased burden by 29,453,382. From 2012-2016, the average yearly growth in dialysis facilities seeking approval was 3.65 percent. We anticipate a similar rate of growth in dialysis facilities over the next few years. Thus, we believe that a total of 1,275 new and renovated dialysis facilities will request Medicare approval over the five-year period from 2017 to 2021. We estimate the average number of new facilities per year requesting approval would be 255 facilities per year, over 5 five years. We estimate the average number of existing facilities each year from 2017 to 2021 to be 7,000 facilities. Since these provisions are currently in effect, we are using 2015 estimates of the numbers for new and renovated dialysis facilities for one- time burdens. Therefore, there has been an increase of 26,042,030 in some burden estimates due to the number of respondents.

16. Publication/Tabulation Dates

There are no publication or tabulation dates. Some information collected through CROWNWeb is available to the public, so that dialysis patients can compare clinical performance when choosing where to receive dialysis care. This information will be shared through CMS websites.

17. Expiration Date

There are no forms associated with this information collection request. However, upon receiving OMB approval, CMS will publish a notice in the Federal Register to inform the public of both the approval as well as the expiration date. In addition, the public will always be able

to access the expiration date on OMB's web site by performing a search on the OMB control number.