Supporting Statement for Paperwork Reduction Act Submissions
End Stage Renal Disease (ESRD) Conditions for Coverage and Supporting Regulations
(OMB No. 0938-0386/CMS-R-52)

A. Background

The Centers for Medicare and Medicaid Services (CMS) is requesting reinstatement 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 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 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 dialysis 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 which included information collection requirements at § 405.2112(e). 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. HSQ-137-ESRD approved information collection requirements at §§ 405.2112(f) and (j). BERC-434 approved information collection requirements stemming from the following historical sections of the CFR including §§ 405.2136(b), 405.2138(a), 405.2139(a), and 405.2140(b) and (c).

Major revisions to the CFR established new ESRD CfCs at 42 CFR 494 issued in a final rule, "*Medicare and Medicaid Programs; Conditions for Coverage for End-Stage Renal*

Disease Facilities," published on April 15, 2008 (CMS–3818–F). This rule modified, removed, added, and redesigned CfCs that dialysis facilities must meet to be certified under the Medicare program. This rule approved information collection requirements at §§ 494.30, 494.40, 494.50, 494.60, 494.70, 494.80, 494.90, 494.100, 494.110, 494.120, 494.150, 494.170, and 494.180.

An additional revision to the ESRD CfCs at 42 CFR 494 was precipitated by CMS-3818-F at 414.330(a)(2)(iii)(C). 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 and there are no longer any such entities. See 42 CFR Parts 410, 413 and 414 Medicare Program; End-Stage Renal Disease Prospective Payment System; Final Rule and Proposed Rule at the following link Federal Register https://www.govinfo.gov/content/pkg/FR-2010-08-12/pdf/2010-18466.pdf.

Therefore, there are no actual costs associated with this requirement; we removed it from this package.

An additional revision to the ESRD CfCs at 42 CFR 494 was precipitated by interim final rule, "*Medicare Program; Conditions for Coverage for End-Stage Renal Disease Facilities-Third Party Payment*," published on December 14, 2016 (CMS-3337-IFC). This rule established new requirements for Medicare-certified dialysis facilities that make payments of premiums for individual market health plans. This interim final rule established additional burden associated with §§ 494.70(c) and 494.180(k); these were quantified in the preceding information collection which expired in 2024 (OMB Control Number 0938-0386). Since these regulations were not finalized due to litigation, they are no longer in effect. Therefore, we took out these sections from this package as they do not impose any burden.

An additional revision to the ESRD CfCs at 42 CFR 494 was precipitated by final rule, "*Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers*," published September 16, 2016 (CMS-3178-F). This rule established the creation and maintenance of an Emergency Preparedness Plan at 494.62(a), an Emergency Preparedness Policies and Procedures document at 494.62(b), an Emergency Preparedness Communication Plan at 494.62(c), a training program 494.62(d), and documentation of training exercises 494.62(e). These information collections are in separate package, OMB Control number 0938-1325.

On July 5, 2024, revisions to the CfC were proposed in "*Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, Conditions for Coverage for End-Stage Renal Disease Facilities, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model*," (CMS-1805-P). This rule proposed to expand coverage of home dialysis services to patients with acute kidney injury (AKI). Since the ESRD CfCs apply to dialysis facilities, not to people with ESRD, this rule proposes to revise language in the CfCs to allow beneficiaries with AKI to utilize home dialysis. Specifically,

we refer to facilities abiding by the ESRD CfCs as 'dialysis facilities' opposed to 'ESRD facilities and all patients seeking services from dialysis facilities as 'patients' rather than 'ESRD patients.' There is no ICR burden associated with these changes however we made confirming changes to the language in this package.

The CfCs are used by Federal (CMS), State surveyors (employed by State survey agencies), or CMS authorized accrediting organizations as a basis for determining whether a dialysis facility qualifies for approval or re-approval under Medicare**.** Surveyors make an in-person visit to the dialysis facility to perform the complete survey.

The preceding information collection, which expired on March 31, 2024, estimated the total annual hourly burden as 1,260,491 hours at a cost of $64,839,657. We revise this to 800,621 hours at a cost of $49,638,502. The reduction in hours and cost is largely due to removing the burden estimates that no longer apply.

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 488.60 and 494.100-494.180).

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 so that dialysis patients can compare clinical performance when choosing where to receive dialysis care. See the Dialysis Facility Compare Website at the following link: Dialysis Facility Compare http://www.medicare.gov/dialysisfacilitycompare/.

The ICRs contained in this regulation are designed to assure that dialysis facilities have written policies and procedures regarding the requirements finalized. CMS and the health care industry believe that the availability to the facility of the type of records and general content of records, which this regulation specifies, is standard medical practice and is necessary in order to ensure the well-being and safety of patients and professional treatment accountability. There are 7,848 dialysis facilities that must meet these CoPs in order to receive program payment for services provided to Medicare or Medicaid patients.

3. Improved Information Technology

Dialysis facilities may use various information technologies to draft, collect, maintain, and store patient medical records as long as they are consistent with the existing confidentiality in record-keeping regulations at 42 CFR 494.170. This regulation does not specify how the facility should prepare, maintain, update or revise the required information but allows for the flexibility for facilities to take advantage of any technological advances that 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 previous data submission system, CROWNweb, has transitioned to End-Stage Renal Disease Quality Reporting System (EQRS) which launched in 2020. The Facilities have the option to submit data through traditional data entry or through “batch entry” facilitated by electronic health records. CMS also requires facilities to submit the CMS-3427 ESRD Certification form to review/approve services offered by the facility or stations dedicated for treatment The OMB control number is 0938-0360.

4. Duplication of Efforts

These requirements are specified in a way that does not require a dialysis facility to duplicate its efforts. If a facility already maintains these general records, regardless of format, they are in compliance with this requirement. The general nature of these requirements makes variations in the substance and format of these records, from one facility to another,

acceptable.

5. Small Businesses

These requirements will not have a significant impact on dialysis facilities and other suppliers that are small entities. Further, most of the requirements in this rule are part of a dialysis facility standard practices. We understand that there are different sizes of facilities and that the burden for facilities of different sizes will vary.

6. Less Frequent Collection

CMS does not collect information directly from dialysis facility and instead relies on State surveyors (employed by State survey agencies) or CMS authorized accrediting organizations to review the collection of information at the time of their certification and at the time of their facility visit. The collection of information does not prescribe the manner, timing, or frequency of the records or information that must be available. Facility records, policies, and procedures are reviewed at the time of a survey for initial or continued participation in the Medicare program. Less frequent information collection would impede efforts to establish compliance with the Medicare Conditions for Coverage which in turn, would jeopardize the health and safety of dialysis facility patients and staff and provision of quality healthcare. Surveyors make an in-person visit to the facility to conduct their survey.

7. Special Circumstances

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

- Clinical performance data submitted to CMS through the EQRS 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

The 60-day Federal Register notice published on December 23, 2024 (89 FR 104547). There were no public comments received.

The 30-day Federal Register notice published May 12, 2025 (90 FR 20166).

9. Payments/Gifts to Respondents

There were no payments/gifts to respondents.

10. Confidentiality

Confidentiality will be maintained to the extent provided by law. We pledge confidentiality of patient-specific data in accordance with the Privacy Act of 1974 (5 U.S.C. 552a) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Requirements of HIPAA's Privacy Rules (at 45 CFR 160 and 164) protect the privacy and security of an individual's protected health information.

11. Sensitive Questions

There are no sensitive questions.

12. Burden Estimates (Hours & Wages)

According to CMS' Certification and the Survey Provider Enhanced Reporting (CASPER), as of August 2024, there are 7,848 dialysis facilities. From 2019-2023, the yearly average of new dialysis facilities seeking approval was 192 facilities (Table 1). We anticipate a similar rate of new dialysis facilities over the next few years. Thus, we believe that a total of 768 (192 × 4 years = 768 facilities) new dialysis facilities will request Medicare approval over the three-year period from 2024 to 2027. For the purposes of this PRA package, we will use the historic average as the number of new facilities.

From 2019-2023, the average yearly growth in dialysis facilities was 0.99 percent (Table 1). We anticipate a similar rate of growth in dialysis facilities over the next few years. Therefore, for purposes of this PRA package, we estimate that the average number of total facilities from 2024-2027 will be 8,048 facilities (Table 2). If there are 192 new facilities, we estimate that there would 7,856 existing facilities per year (8,048 total facilities – 192 new facilities). We will use these figures in determining the burden for this rule.

Table 1. Number of Dialysis Facilities by Year (Historical)

	Year	**Number of Dialysis Facilities by Year**	**Number of Dialysis Facilities Increased or Decreased by Year**	**Number New Dialysis Facilities by Year**	**Percent Change (based on column c)**
	(a)	**(b)**	**(c)**	**(d)**	**(e)**
	2019	7,709	235	301	3.14%
	2020	7,829	120	231	1.56%
	2021	7,953	124	188	1.58%
	2022	7,966	13	139	0.16%

	2023	7,848	-118	102	-1.48%
Average	**-**	**7,861**	**-**	**192**	**0.99%**

Table 2. Number of Dialysis Facilities by Year (Projection)

	Burden Estimate Year	**Year**	**Number of Dialysis Facilities by Year (Projected)*+**
	Year 0	2024	7,927
	Year 1	2025	8,007
	Year 2	2026	8,088
	Year 3	2027	8,170
Average	**-**	**-**	**8,048**
			*Assuming 0.99% increase in facilities + We are accounting for difference in facilities, assuming new facilities will be established, and others will terminate their contracts

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 continue to estimate that it will take 40 hours for each of the 192 new and renovated facilities to gather and submit the necessary documentation for consideration by the Secretary. The estimated annual burden is 7,680 annual hours (40 hours × 192 facilities).

494.30 Condition: Infection control.

(a)(1)(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 172 facilities) of new dialysis facilities would request a waiver. This task would take approximately 1 hour for each of these 172 newly built dialysis facilities, for a total of 172 hours, annually (1 hour × 172 facilities).

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 80 facilities, we estimate a total annual burden of 7 hours (0.08333 hour × 80 facilities).

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 80 facilities (8,048 facilities × 0.01), we estimate a total annual burden of 7 hours (0.08333 hours × 80 facilities).

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. Such incidents are rare, and so we estimate that only 1 percent of facilities would experience an incident annually. We estimate that it would take 80 facilities (8,048 facilities ×0.01) 30 minutes each to develop and implement a corrective action plan that ensures patient safety. Therefore, we estimate a total annual burden of 40 hours (0.50 hours × 80 facilities).

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 192 new facilities 5 hours to comply with the requirements in this section: for a total of 960 hours (5 hours ×192 facilities). We estimate that it will take 1 hour each for 7,856 existing facilities to annually comply with the requirements in this section: for a total of 7,856 hours (1 hour × 7,856 facilities). The total estimated annual burden for new and existing facilities is 8,816 hours (960 for new facilities + 7,856 for existing facilities).

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 8,048 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 12,072 hours (1.5 hours × 8,048 facilities).

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. 13.4% of patients perform home dialysis.[1] We

[1] https://usrds-adr.niddk.nih.gov/2023/end-stage-renal-disease/2-home-dialysis#:~:text=Highlights,%25%20(Figure%202.1a).

estimate that facilities would have to meet these requirements for 108,339 patients (808,500 dialysis patients × 0.134), and that it would take them approximately 6 hours per patient, per year. We estimate a total annual burden of 650,034 hours (6 hours × 108,339 patients).

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 192 new facilities each approximately 48 hours to meet these requirements. The annual burden associated with this requirement is estimated to be 9,216 hours (48 hours × 192 facilities).

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 8,048 facilities 12 hours annually each to meet this requirement, for a total annual burden of 96,576 hours (12 hours × 8,048 facilities).

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 (808,500 dialysis patients × 0.08) transfer annually, for an estimated 64,680 transfers per year. We estimate a total annual burden of 10,776 hours (0.1666 × 64,680).

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 192 new facilities 1 hour each to develop grievance processes**.** We estimate a total annual burden of 192 hours (1 hour × 192 facilities).

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 8,048 facilities would each have one or less patients involuntarily discharged each year. We estimate a total annual burden of 1,341 hours (0.1666 hours × 8,048 facilities).

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 8,048 facilities would be 671 hours (0.0833 hours × 8,048 facilities).

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 192 new facilities 10 minutes each to develop such a roster. We estimate that the total annual burden would be 32 hours (0.1666 hours × 192 new facilities).

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 192 new facilities 45 minutes each to develop such an agreement. We estimate that the total annual burden for new facilities would be 144 hours (0.75 hours × 192 new facilities). We estimate it would take 7,856 existing facilities 10 minutes annually each to maintain such an agreement, for a total annual burden of 1,309 hours (0.1666 hours × 7,856 facilities). We estimate a total annual burden for new and existing facilities of 1,453 hours (144 hours for new facilities + 1,309 existing facilities).

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 OMB 0938-1289.

We note that there is a burden associated with this requirement that involves training individuals in dialysis 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 192 new facilities 8 hours each for one individual to complete the training program. We estimate that the total annual burden would be 1,536 hours (8 hours × 192 new facilities).

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.

13. Capital Costs

There are no capital costs associated with this regulation.

14. Cost to Federal Government

The cost to federal government includes the cost to develop and submit this PRA package for OMB compliance. To develop this cost, we estimate the time it takes to develop and or update this PRA package. We estimate it takes about 90 hours per three-year period or about 30 hours per year or 0.01 FTEs to develop or update this package. Typically, a GS-13, step 1 federal government employee, located in Baltimore-Arlington, Washington D.C, Locality Pay Area of completes this PRA packages. According to The U.S. Office of Personnel Management, in 2024 the cost for this labor is $56.52 per hour. The additional cost to complete this PRA package is $1,710 per year ($57 × 30 =1,710). Doubling this to reflect overhead and fringe, the cost to the federal government is $3,420 per year.

15. Changes to Burden

The overall change in burden from the previously approved package is a decrease of 459,870 hours, or 44.62%, from 1,260,491 hours to 800,621 hours. This is a result of the revision request associated with this ICR, we removed burden associated with §§ 414.330(a)(2)(iii)(C), 488.60, 494.62, 494.70(c), and 494.180(k).

In addition to estimating burden hours, we have estimated costs for these burden hours based on average hourly wages for all providers. We obtained these average hourly wages from the United States Bureau of Labor Statistics' May 2023 National Occupational Employment and Wage Estimates United States (https://www.bls.gov/oes/current/oes_nat.htm#00-0000) accessed on August 15, 2024. In accordance with current policy and to ensure we more accurately account for overhead and fringe benefits, we have increased the amount we add to the average hourly rate for each position to an amount equal to 100 percent of the hourly rate.

For the preceding package, we estimated the average number of existing facilities each year from 2020 to 2023 to be 8,246 facilities. The average hourly wages from the United States Bureau of Labor Statistics' May 2019 National Occupational Employment and Wage Estimates United States (https://www.bls.gov/oes/2019/may/oes_nat.htm#00-0000) was $25.72/hour. The total burden of the preceding package was estimated to be $ 64,839,657 (1,260,491 hours × $51.44), which averages to $7,863 per facility ($ 64,839,657 /8,246 facilities).

For the current package, we estimated the average number of existing facilities each year from 2024 to 2027 to be 8,048 facilities. The average hourly wages from the United States Bureau of Labor Statistics' May 2019 National Occupational Employment and Wage Estimates United States (https://www.bls.gov/oes/current/oes_nat.htm#00-0000) was $31.48/hour. For this package, we estimated the total burden to be $49,638,502 (800,621 hours × $62), which averages to $6,168 per facility ($49,638,502/8,048 facilities).

Table 3. Total Hours

IC	Prior ICR Hours	Hours
42 CFR 488.60	10,880	7,680
42 CFR 494.30 (a)(1)(ii)	245	172
42 CFR 494.30(b)(3)	6.8	7
42 494.40 (b)(2)(ii)(C)	6.8	7
42 CFR 494.40(c)	41	40
42 CFR 494.60(d)(4) new facilities	1,360	960
42 CFR 494.60(d)(4) old facilities	8,246	7,856
42 CFR 494.70	12,369	12,072
42 CFR 494.70(c) part 2	326,524	X
42 CFR 494.70(c) part 3	372,905	X
42 CFR 494.100(c)(1)	399,600	650,034
42 CFR 494.110 new facilities	13,056	9,216
42 CFR 494.110 old facilities	98,952	96,576
42 CFR 494.170 (d)	6,667	10,776
42 CFR 494.180 (e)	272	192
42 CFR 494.180 (f)(4)(ii)	1,374	1,341
42 CFR 494.180 (f)(4)(iii)	687	671
42 CFR 494.180(g)(2)	45	32
42 CFR 494.180(g)(3) new facilities	204	144
42 CFR 494.180(g)(3) old facilities	1,374	1,309
42 CFR 494.180 (h)	2,176	1,536
42 CFR 494.180(k)	3,500	X
Total hours	**1,260,491**	**800,621**

16. Publication/Tabulation Dates

There are no publication or tabulation dates. Some information collected through EQRS 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

This collection does not lend itself to the displaying of an expiration date.

18. Certification Statement

There is no exception to this certification.