

Supporting Statement – Part A, End Stage Renal Disease (ESRD) Annual Facility Survey Form (CMS-2744; OMB Number 0938-0447)

A. Background

The Program Management and Medical Information System (PMMIS) collects provider-specific and aggregate patient population data on ESRD beneficiaries treated by dialysis and transplant providers. Each facility certification/survey record represents one provider. The CMS-2744 captures certification and other information about ESRD facilities approved by Medicare to provide kidney dialysis and transplant services. Additionally, the CMS-2744 captures activities performed during the calendar year, as well as, aggregate year-end population counts for both Medicare beneficiaries and non-Medicare patients. The data elements include basic provider information such as provider certification and type of ownership; aggregated dialysis patient data such as the number of patients, number of deaths, and number of patients receiving different types of dialysis; dialysis treatment data; kidney transplant data such as number of transplants, type of transplants, and number of patients awaiting transplants; and the total number of each method used to obtain kidneys for transplants. The CMS-2744 collects data on hemodialysis patients dialyzing, vocational rehabilitation, and staffing. The accuracy of the Facility Survey depends on complete reporting by each facility. Modification to the CMS-2744 are a) collection of days the dialysis facility is open; b) shifts dialysis is provided; c) adding “failed” to “return after transplant” for clarity; d) removing questions related to vocational rehabilitation; and e) aligning instructions with revisions.

This request is to modify the previously approved collection CMS-2744. There has been changes to the collection instrument such as: a) collection of days the dialysis facility is open; b) shifts dialysis is provided; c) adding “failed” to “return after transplant” for clarity; d) removing questions related to vocational rehabilitation; and e) aligning instructions with revisions.

Therefore, this package is classified as a reinstatement with change.

B. Justification

1. Need and Legal Basis

Collection of the data contained in the CMS-2744, End Stage Renal Disease Facility Survey Form is necessary for the establishment and maintenance of the legislatively mandated single, nationwide database containing patient-medical, specific demographic and billing data, and provider-specific certification and patient population data, the (ESRD) PMMIS. It is the Agency’s responsibility to collect, maintain, disseminate, on a national basis, uniform data pertaining to ESRD patients and their treatment of care. All renal providers who are approved to participate in the ESRD program are required by P.L. 95-292 to supply data to the ESRD PMMIS. The conditions of coverage for participation in the Medicare program (section 494.180(h) of CFR 42) states:

(h) *Standard: Furnishing data and information for ESRD program administration.* Effective February 1, 2009, the dialysis facility must furnish data and information to CMS and at intervals as specified by the Secretary. This information is used in a national ESRD information system and in compilations relevant to program administration, including claims processing and reimbursement, quality improvement, and performance assessment. The data and information must—

(1) Be submitted at the intervals specified by the Secretary;

- (2) Be submitted electronically in the format specified by the Secretary;
- (3) Include, but not be limited to—
 - (i) Cost reports;
 - (ii) ESRD administrative forms;
 - (iii) Patient survival information; and
 - (iv) Existing ESRD clinical performance measures, and any future clinical performance standards developed in accordance with a voluntary consensus standards process identified by the Secretary.

The ESRD Facility Survey (CMS-2744) is completed by all Medicare-approved ESRD facilities once a year. The CMS-2744 was designed to collect information concerning treatment trends, utilization of services and patterns of practice in treating ESRD patients.

2. Information Users

The aggregate patient information is collected from each Medicare-approved provider of dialysis and kidney transplant services. The information is used to assess and evaluate the local, regional and national levels of medical and social impact of ESRD care and is used extensively by researchers and suppliers of services for trend analysis. The information is available on the CMS Dialysis Facility Compare website and will enable patients to make informed decisions about their care by comparing dialysis facilities in their area.

The data are used by CMS to validate and monitor patient specific information and to determine the ESRD Network annual budget from the reported number of treatments provided to dialysis patients (as required by Section 9335 of P.L. 99-509 of the Omnibus Reconciliation Act of 1986 (OBRA) which amended Section 1881(c) of the Social Security Act). The data are also provided to the United States Renal Data System (USRDS), through a contract with the National Institutes of Health, for use in studies relating to the ESRD program.

3. Use of Information Technology

The CMS-2744 ESRD Annual Facility Survey Form is currently submitted through the ESRD Quality Reporting System (EQRS). The EQRS system went into production nationally on November 9, 2020. The ESRD Networks are responsible for reviewing and reconciling the submitted data to ensure accuracy.

4. Duplication of Efforts

There is no other form that collects this information. CMS is the only agency that annually surveys all renal facilities for dialysis patient population and transplant data. Since the renal facilities are required to report on all activities that occurred during the year, CMS is able to obtain information on the Medicare and non-Medicare ESRD population, therefore providing a more comprehensive overview of renal disease occurrence in the United States.

5. Small Businesses

A small business would be described as a provider that is not a member of a chain organization

and/or has a small dialysis patient population. These providers are legislatively required to maintain the same patient information and to report on this information in the same manner as all other providers of renal services. Therefore, there are no methods to minimize burden for these providers. However, this collection does not have a significant economic impact on small businesses.

6. Less Frequent Collection

If these data were not collected annually, CMS would be administering a program for which it would be impossible to identify characteristics of the relationship between patients and treatments. These data describe those approaches to and conditions under which treatment is administered so that morbidity and mortality are kept to minimum levels. Additionally, the data in the survey regarding treatments provides the basis of the budget for the ESRD Network program.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on XXXXXXXXX (XX FR XXXXX).

9. Payments/Gifts to Respondents

No payment or gifts are provided to respondents for compliance with the survey process.

10. Confidentiality

Confidentiality is retained all data reported is in an aggregated form; that is, no specific individual is identified (either individual patient or individual practitioner) and information on the individual is part of grouped items of data produced in summary outputs. Patients and physicians are not shown on output reports by name or by identification number. Normal precautions are taken to protect data and individual identities.

The output reports, which do not identify individuals, are restricted by the number of copies provided and by the persons or institutions to whom they are provided directly; but they are not private and privileged data in the same sense as reports which do identify individuals and they will not be subject to the safeguards.

A confidentiality statement is provided on the form as it related to the Privacy Act regulations.

As required by the Privacy Act, Medicare publishes systems of records notices in the Federal Register that describe the data in each system and to whom Medicare may disclose the information. The information collected is part of a Privacy Act System of Records Notice (SORN):

End Stage Renal Disease (ESRD) Program Management and Medical Information System (PMMIS)

SORN# 09-70-0520

SORN history: 74 FR 30606 (6/26/09), *83 FR 6591 (2/14/18)

11. Sensitive Questions

12. There are no questions on the facility survey that are of a sensitive nature. Burden Estimates 2021 (Hours & Wages)

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2021 National Occupational Employment and Wage Estimates for all salary estimates. In this regard, the following information presents the mean hourly wage, the cost of fringe benefits, and the adjusted hourly wage for providers that are responsible for completing CMS-2744 forms.

Salary Estimate s for Providers Responsible for Completing CMS-2744 Forms

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Overhead (\$/hr)	Adjusted Hourly Wage (\$/hr)
Health Technologists and Technicians, All Others	29-2099	\$23.67	\$23.67	\$47.34

Except where noted, we have adjusted our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, 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. We believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

The estimated hour burden:

Estimated Hour Burden

Respondents (Number of Open, Certified, Medical Dialysis Providers as of February 2023)	Respondents (Number of Open, Certified, Medical Dialysis Providers in 2019)	Completion Time per Response	Responses per Year (Number of CMS-2744 forms submitted from January 1, 2021 thru December 31, 2021)	Total Requested Burden Hours	Cost per Response	Estimated National Cost
7,726	7,807	2 hours	7,969	15,452	\$47.34	\$731,497.68 (15,452 hours X \$47.34)

13. Capital Costs

There is no estimate of a total annual cost burden to respondents to the ESRD Annual Facility Survey. There is no capital or startup costs. The information respondents are required to report reflect the general information they are required to maintain in patient and corporate records.

14. Cost to Federal Government

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Overhead (\$/hr)	Adjusted Hourly Wage (\$/hr)
Data Scientist	15-2051 GS 13	\$ 53.67	N/A	\$53.67

CMS funds the ESRD Network program to provide administrative oversight to the data in the ESRD patient registry, EQRS. While the ESRD Network contract is a fixed price contract every ESRD Network employs data personnel to manage data for EQRS and quality improvement.

Data Scientist	Time to Receive Form	Number of CMS-2744 Forms per Year	Total Requested Burden Hours	Cost per Response	Estimated National Cost
\$217,320	1 hour	7,726	7,726	53.67	\$414,654.42 (7,726 hours X \$53.67)

There are no additional costs to the Federal Government because the CMS-2744 forms are now created in EQRS and all submission and reconciliation is done electronically.

15. Changes to Burden

There is a change in total estimated burden hours to 15,452 from the previously estimated hours of 31,312. The number of dialysis facilities has decreased and therefore the number of submissions of CMS-2744 forms to 7726 submissions estimated for January 1, 2023 thru December 31, 2023 from the previously estimate of 7,828 submissions from January 1, 2021 thru December 31, 2021.

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16. Publication/Tabulation Dates

The USRDS Annual Report documents data collected from the CMS 2744 annually through an agreement with the Network program. The Annual Data Report (ADR) reports on End-Stage Renal Disease in the United States including the number and type of dialysis present in the United States

using data from the CMS-2744. Dialysis facilities complete the CMS-2744 between January and mid-April for the previous calendar year. The USRDS ADR is provided in October follow tabulation of the data. Additionally, the data from the CMS-2744 is utilized in the Annual Reports developed by the ESRD Network program. The data is collected on the same schedule as the USRDS ADR and reported in June on the ESRD Networks website. The data is aggregated and published to the ESRD National Coordinating Center's website as an Annual Summary Report of the ESRD Network activities in December of the year following the data. Additionally, the Care Compare website uses data from the CMS-2744 to provide dialysis patients with information about the type and location of dialysis facilities to support informed choice.

17. Expiration Date

CMS will display the expiration date and OMB control number.

18. Certification Statement

There is no exception to the certification statement.

There are not

C. Collection of Information Employing Statistical Methods

No statistical methods are used for the ESRD Facility Annual Survey process.