

Supporting Statement – Part A, End Stage Renal Disease (ESRD) Annual Home Dialysis within Nursing Home Survey Form (CMS- 10842; OMB Number 0938-XXXX)

A. Background

This is a request for a new information collection. The End Stage Renal Disease (ESRD) Network program is responsible to collect, validate, and analyze data as well as to evaluate the process by which facilities determine the appropriateness of patients for a treatment modality. Additional responsibilities of the ESRD Network program include encouraging participation in the placement of patients in a self-care setting, such as home hemodialysis or peritoneal dialysis, as described in Sec. 1881. [42 U.S.C. 1395rr] (c)(1)(A)(i)(2) of the Social Security Act. On September 21, 2018, CMS clarified guidance that residents in a nursing home facility can receive dialysis either administered and/or supervised by personnel who meet the criteria for training, and competency verification at 42 CFR 494.100(a) and (b) for providing dialysis. The provision of dialysis within a nursing home requires that the dialysis facility have an agreement with the nursing home. This guidance was reinforced and updated on March 22, 2023, in a memo to the State Survey Agency Directors titled, “Guidance and Survey Process for Reviewing Home Dialysis Services in a Nursing Home REVISED”. Since the provision of dialysis within nursing homes is relatively new, CMS designed the CMS-10842 form to capture home modality information from dialysis facilities that provide dialysis within the nursing home in alignment with the Centers for Disease Control and Prevention (CDC).

The care provided to residents of a nursing home is of particular interest because of the fragile health state of the patient and the susceptibility to infection. Each facility certification/survey record represents one provider. CMS-10842 collects information on dialysis facilities providing home dialysis services within the nursing home related to the number of patients, setting of dialysis services provided, who is providing dialysis services, who is providing dressing changes to dialysis access, staff education and use of CDC Core Interventions used. This request is to establish the collection of the CMS-10842. This package is classified as a new request.

B. Justification

1. Need and Legal Basis

The statutory authority is found in Title XVIII of the Social Security Act. The statutory provisions originated in Section 299I of Public Law 92-603 which created the National End Stage Renal Disease (ESRD) Program. The ESRD program extends Medicare benefits to cover the high cost of medical care for most individuals living with ESRD.

The statutory mission of the Program, as set forth in Section 1862(g) of the Act, involves the Secretary entering into contracts with ESRD Networks for the purposes of improving cost-effectiveness, ensuring quality of care, encouraging kidney transplantation and home dialysis, and increasing program accountability.

Collection of the data contained in the CMS-10842, End Stage Renal Disease (ESRD) Annual Home Dialysis within Nursing Home 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.

2. Information Users

The aggregate patient information is collected from each Medicare-approved home dialysis provider to identify the specialized needs of the ESRD community where home dialysis is provided in Long Term Care facilities. 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 may be 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 CMS 10842 was designed to collect data related to treatment trends, utilization of services, and patterns of practice for treating ESRD patients who reside in a nursing home. Additionally, CMS uses this data for Quality Improvement purposes to improve ESRD patient outcomes by analyzing and guiding

the work of the ESRD Network program.

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 form will be 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 home renal facilities for dialysis patient population and transplant data. Since the home renal facilities are required to report on activities that occurred during the year, CMS is able to obtain information on the Medicare and non-Medicare ESRD home patient 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 for vulnerable populations within nursing homes. These data describe those approaches to and conditions under which treatment is administered so that morbidity and mortality are kept to minimum levels.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on April 5, 2024 (89 FR 24008). There were no public comments received.

The 30-day Federal Register notice published on June 14, 2024 (89 FR 50589).

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

There are no questions on the facility survey that are of a sensitive nature.

12. Burden Estimates (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-10842 forms.

Salary Estimates for Providers Responsible for Completing CMS-10842 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:

As of February 2023, the ESRD program has 7,726 certified medical dialysis providers. CMS estimates that it will take forty-five (45) minutes to complete a survey for each of the certified dialysis facilities. The salary estimated for the providers to complete the form is listed above at an hourly wage of \$47.34 per response.

Respondents (Number of Open, Certified, Medical Dialysis Providers as of February 2023)	Completion Time per Response	Total Requested Burden Hours	Cost per Response	Estimated National Cost
7,726	.75 hours	5,795	\$47.34	\$ 274,335 (5,795 hours X \$47.34)

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government: This estimate was calculated using the GS scale for an entry level data scientist, grade 13. 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. Below is the contract cost for a Data Scientist. It includes the mean hourly wage of \$52.24 and the fringe benefits \$52.24 for a total of \$104.48.

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Overhead (\$/hr)	Adjusted Hourly Wage (\$/hr)
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Data Scientist	15-2051	\$ 52.24	\$ 52.24	\$104.48
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Data Scientist	Time to Receive Form	Number of CMS-10842 Forms per Year	Total Requested Burden Hours	Cost per Response	Estimated National Cost
\$217,320	1 hour	7,726	7,726	\$104.48	\$807,212 (7,726 hours X \$104.48)

There are no additional costs to the Federal Government because the CMS-10842 forms are now created in EQRS and all submission and reconciliation is done electronically. The total annual cost to the Federal Government is \$807,212 (7,726 hours X \$104.48).

15. Changes to Burden

This is a new information collection request.16. Publication/Tabulation Dates

The USRDS Annual Data Report, published annually between April and September, (ADR provides analysis on End-Stage Renal Disease in the United States. The ADR currently provides national ESRD statistics including the number and type of dialysis facilities present in the United States. CMS 10842 would provide data that could be used to further refine and report home dialysis care as a modality within the nursing home. Additionally, the data from the CMS-10842 could be utilized for the Care Compare website to provide dialysis patients with information about the type and location of dialysis facilities within nursing homes to support their informed choice.

17. Expiration Date

CMS will display the expiration date on the collection instrument.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collection of Information Employing Statistical Methods

No statistical methods are used for the ESRD Annual Home Dialysis within Nursing Home Survey Form.