

Supporting Statement: End Stage Renal Disease (ESRD) Death Notification Form (CMS-2746; OMB Control Number: 0938-0448)

A. Background

The ESRD Death Notification form (CMS-2746) is completed by all Medicare-approved ESRD facilities upon death of an ESRD patient. Its primary purpose is to collect fact of death and cause of death of ESRD patients. Certain other identifying information (e.g. Name, Social Security Number, Medicare claim number, and/or date of birth) is required for matching purposes. Federal regulations require that the ESRD Networks examine the mortality rates of every Medicare-approved facility within its area of responsibility. CMS-2746 provides the necessary data to assist the ESRD Networks in making decisions that result in improved patient care and in cost-effective distribution of ESRD resources. The data is used by the ESRD Networks to verify facility deaths and to monitor facility performance. The form is also used by health care planning agencies and researchers to determine survival rates by diagnoses. Health Care planning agencies request mortality rate data to determine the need for dialysis services in a specific area, CMS-2746 is used to calculate these statistics. There is no other source of death information available to the ESRD Networks.

This request is to revise to better align with the common verbiage used on standardized forms, by other Federal agencies, including the Census Bureau. The following are additions to the CMS-2746: social security number, gender identity, questions that clarify if the patient received a transplant and treatment related to the transplant prior to death, questions surrounding hospice and palliative care and the corresponding instructions have been updated for all additional content. The number of renal facilities responding to this collection and annual patient death counts have increased, but the burden is slightly increase due to a greater incident death. This package is classified as a reinstatement with changes.

B. Justification

1. Need and Legal Basis

The ESRD Program Management and Medical Information System (PMMIS) has the responsibility of collecting, maintaining and disseminating, on a national basis, uniform data pertaining to ESRD patients and their treatment of care. All renal facilities approved to participate in the ESRD program are required by P.L. 95-292 to supply data to this system. The CMS-2746 collects information about ESRD patient deaths. Agencies within CMS use the death information provided to ensure appropriate patient Medicare coverage and pay Medicare claims. Data analysts and researchers use the data to identify and mitigate causes of death.

2. Information Users

Federal regulations require that ESRD Networks examine mortality rates for Medicare- approved providers within their network areas. The ESRD Death Notification provides the necessary data to assist ESRD Networks, as well as, dialysis facilities and individual practitioners, in reviewing and comparing outcomes related to cause of death, which guides decision making for improving patient care and cost-effective distribution of ESRD resources. The data are also used by CMS, the ESRD Networks and health care planning agencies to monitor facility performance. 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 and the data are included in the USRDS Annual Report.

3. Improve Information Technology

The CMS-2746 Death Notification form is currently submitted through the ESRD Quality Reporting System (EQRS). The EQRS system went into production nationally on November 9, 2020.

4. Duplication of Similar Information

There is no other form used by CMS that collects this information. CMS is the only agency that maintains an ESRD patient specific cause of death data.

5. Small Business

A small business would be described as a provider who 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.

6. Less Frequent Collection

If these data were not collected, CMS would be unable to identify characteristics of the relationships between patients and treatments, between the disease and the comorbid conditions, and between the disease and the causes of death for the ESRD population. 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

The frequency of the collection (only upon the death of an ESRD patient), requires respondents to report information to the agency more often than quarterly. The collection is consistent with the guidelines in 5 CFR 1320.6. Because the CMS 2746 is electronically maintained in EQRS, forms are retained indefinitely. If a CMS-2746 form is necessary to document ongoing educational, quality assurance, or disciplinary action it can be printed from EQRS.

8. Federal Registry Notice/Outside Consultation

The 60-day Federal Register notice published **XXXXXXXXXX**.

CMS collaborates with the National Institutes of Health (NIH), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) to provide reports to Congress from the data collected in the CMS-2746.

9. Payment/Gifts to Respondents

No payment or gifts are provided to respondents.

10. Confidentiality

Confidentiality is retained in regular output reports by disclosing data in 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.

Procedures are established for maintaining confidentiality of individual patient records, including the requirement that nongovernment employees who handle the data be bonded. The input is kept under strict controls; only certain authorized persons are allowed access. These persons are allowed access only in restricted areas and are required to identify themselves, the specific document(s) referred to, and the reasons for the access. Such data are kept under lock and key at all times, and may not be accessed except during normal working hours. Strict penalties will be applied to any employee who willfully and knowingly violates the prohibitions regarding confidential data.

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. The statement appearing on the form to obtain consent pledge confidentiality is as follows:

“This report is required by law (42, U.S.C. 426; 20 CFR 405, Section 2133). Individually identifiable patient information will not be disclosed except as provided for in the Privacy Act of 1974 (5 USC 5520; 45 CFR, Part 5a).”

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 of a sensitive nature.

12. Burden Estimates (2022)

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 table presents the mean hourly wage, the cost of fringe benefits, and the adjusted hourly wage for providers that are responsible for completing CMS-2746 forms.

Table 1. Salary Estimates for Providers Responsible for Completing CMS-2746 Forms

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Overhead (\$/hr)	Adjusted Hourly Wage (\$/hr)
Physicians & Surgeons (All Other)	29-1210	\$121.38	\$121.38	\$242.76

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:

Table 2. Estimated Hour Burden

Respondents (Number of Open, Certified, Medical Dialysis Providers as of February 2023)	Respondents (Number of Open, Certified, Medical Dialysis Providers in 2021)	Completion Time per Response	Responses per Year (Number of CMS-2746 forms submitted from January 1, 2021 thru December 31, 2021)	Total Requested Burden Hours	Cost per Response	Estimated National Cost
7,726	7,864	0.5 hour	101,491	50,746	\$242. 76	\$ 12,319,098.96 (50,746 hours X \$242.76)

13. Capital Costs

There are no capital costs.

14. Cost to the Federal Government (2023)

Table 3. Cost to the Federal Government

Social Security Administration Employee Salary Who Receives the Form	Time to Receive Form	Number of CMS-2746 Forms per Year	Total Requested Burden Hours	Cost per Response	Estimated National Cost
Grade 7 \$52,002	.5 hour	101,491	101,491	\$12.50	\$ 1,268,638

The cost to the federal government is 1,268,638. There are no additional costs to the Federal Government because the CMS-2746 forms are now created in EQRS and filed by dialysis facilities and/or ESRD Networks. Forms may also be downloaded from CMS.gov. CMS no longer requests printing for additional blank triplicate CMS-2746 forms by the Government Printing Office.

15. Program Changes

There is a change in total estimated burden hours of 4,734 (50,746 estimated hours – 46,012 previously estimated hours) due to an increase in submission of CMS-2746 forms by 9,468 submissions (101,491 submissions from January 1, 2021 thru December 31, 2021 – 92,023 submissions from January 1, 2017 thru December 31, 2017).

Minor changes were made to the form to better align with the common verbiage used on standardized forms, by other Federal agencies, including the Census Bureau. The grammatical

edits do not impact the estimations on burden within this section.

16. Publication and Tabulation Data

The USRDS Annual Report documents data collected from the CMS 2746 annually with quarterly updates. The CMS-2746 data supports the End-Stage Renal Disease portion of the USRDS Annual Data Report (ADR). The ADR displays analytical results of USRDS data using graphs and maps. Mortality rates are published annually in the USRDS Annual Report.

17. Expiration Date

CMS will display the expiration date and OMB control number 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 Death Notification process.