

**SUPPORTING STATEMENT**  
**End Stage Renal Disease (ESRD), Death Notification Form**  
**(CMS-2746; OMB No. 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 incost-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 reinstate the previously approved collection CMS-2746. The number of renal facilities responding to this collection and annual patient death counts have increased, the burden has increased; therefore, this package is classified as a reinstatement with change.

**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.

Furnishing data and information for ESRD program administration was previously referenced as 405.2133. The final citation is now 494.180(h). (Refer to 20452 Federal Register / Vol. 73, No. 73 / Tuesday, April 15, 2008 / Rules and Regulations.) The Conditions for Coverage Final Rule was issued in the Federal Register on April 15, 2008 (42 CFR Parts 405, 410, 413 et al. Medicare and Medicaid Programs; Conditions for Coverage for End-Stage Renal Disease Facilities; Final Rule). The provisions of this final rule are effective October 14, 2008. Compliance with § 494.30(a) (1)(i) and § 494.60(e)(1) is not required until February 9, 2009. In addition, the compliance with § 494.180(h) is

effective on February 1, 2009. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 14, 2008.

## **2. Information Use rs**

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. Improved Information Technology**

The CMS-2746 Death Notification form is currently submitted either through the Consolidated Renal Operations in a Web Enabled Network (CROWNWeb) or via hardcopy, by those providers that do not have access to CROWNWeb. The CROWNWeb system went into production nationally on June 14, 2012.

## **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's specific cause of death data.

## **5. Small Businesses**

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. The hard copy forms of CMS-2746 are retained by the ESRD Network for at least two years after the date of completion. If forms are necessary to document ongoing educational, quality assurance, or disciplinary actions beyond the retention period, the ESRD Network retains these forms for two years following the completion of that activity. Following the retention period, any forms that are patient-specific and are not maintained for the ESRD Network's use, or as documentation of actions specified above are shredded, incinerated, or otherwise completely destroyed, for patient privacy purposes.

## **8. Federal Register Notice /Outside Consultation**

The 60-day Federal Register notice published to the Federal Register (84 FR 5690) on 2/22/2019. No comments were received.

The 30-day Federal Register notice published to the Federal Register ( FR ) on TBD.

## **9. Payment/Gifts to Respondents**

No payment or gifts are provided to respondents other than remuneration of contractors or grantees.

## **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 on the Death Notification form that are of a sensitive nature.

### **12. Burden Estimates (2018)**

To derive average costs, we used data from the [U.S. Bureau of Labor Statistics’ May 2018 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.

#### **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)	29-1069	\$101.63	\$101.63	\$203.26

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:

- Respondents: 7,311 renal facilities (Number of OPEN, CERTIFIED, Medicare, Dialysis providers in CROWNWeb, as of October 2018) In 2017, there were 7,079 renal facilities.
- Completion Time per Response: .50 hour

- Responses per Year: 92,023 (Number of CMS-2728 forms submitted from January 1, 2017 thru December 31, 2017)
- The total amount of requested burden hours for 92,023 responses is 46,011.50.
- Cost per response: \$101.63
- \$4,676,148.74 is the estimated national cost (46,011.50 hours X \$101.63)

### **13. Capital Costs**

There is no estimate of a total annual cost burden to respondents to the Death Form. 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 records.

### **14. Cost to the Federal Government (2018)**

There are no additional costs to the Federal Government because the CMS-2746 forms are now created in CROWNWeb 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-2728 forms by the Government Printing office.

### **15. Program Changes**

There is a change in total estimated burden hours of 8,511.50 (46,011.50 estimated hours- 37,500 previously estimated hours) due to an increase in submission of CMS-2746 forms by 21,079 submissions (92,023 submissions from January 1, 2017 thru December 31, 2017-74,944 submissions from June 2012- June 2013).

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 Dates**

The report to be made from the data collected is the USRDS Annual Report. The Annual Data Report is divided into two volumes covering Chronic Kidney Disease in the United States and End-Stage Renal Disease in the United States. 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.

### **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.