SUPPORTING STATEMENT
FOR THE PAPERWORK REDUCTION ACT SUBMISSION

End Stage Renal Disease (ESRD), CMS-2746 Death Notification Form
(OMB No. 0938-0448)

A. Background

The ESRD Death Notification (CMS-2746) is completed by all Medicare-approved ESRD facilities upon the 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, Medicare claim number, and 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. The Death Form 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 Death 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, the Death Form is used to calculate these statistics. There is no other source of death information available to the Networks.

B. Justification

1. Need and Legal Basis

This is a request to extend a currently approved collection of the CMS-2746 Death Notification without modifications. Because 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 revision. 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 Users

Collection of these data are necessary for the periodic generation of reports on various aspects of medical care and practice and other related statistics which enable individual practitioners and facilities to review, compare, and improve ESRD patient treatment methods and permit local medical review boards to more effectively monitor utilization and quality of medical care.

Federal regulations require that the Networks examine mortality rates for Medicare-approved providers within their network areas. The ESRD Death Notification provides the necessary data to assist networks in making decisions, which result, in improved patient care and in 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 is currently submitted either via hardcopy or through the Consolidated Renal Operations in a Web Enabled Network (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 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 this 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

This form is completed only upon the death of an ESRD patient. The collection is consistent with the guidelines in 5 CFR 1320.6. The form is required to be retained for a period of 2 years.

8. Federal Register Notice/Outside Consultation

The 60-day Federal Register notice published on July 12, 2013. There were no public comments received.

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)."

11. Sensitive Questions

There are no questions on the Death Notification form that are of a sensitive nature as there are no changes to the questions on this form.

12. Burden Estimates (Total Hours & Wages)

The frequency of response is based upon the death of an ESRD patient.

The estimated hour burden:
- Respondents – 5,964 renal facilities. (Number of renal providers in CROWNWeb as of June 2013)
- Completion Time - .50 hours
- Responses/Year/Respondent - 75,000 (Number of Death Forms submitted from June 2012 – June 2013 = 74,944)
- Cost of respondents:
  $25.00/hour

The total amount of requested burden hours is 37,500.
$937,500.00 is the national cost. (37,500 hours X $25)

13. Capital Costs

There is no estimate of a total annual cost burden to respondents to the Death Form. There is no capital or start up 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

There are no additional costs because the forms are now created in CROWNWeb and kept by the facilities and ESRD Networks. Death data is provided electronically in lieu of mailing forms. CMS has not put in any request with the Government Printing office for printing additional blank 2-part CMS 2746 forms.

15. Program Changes

The changes to the total annual reporting or record keeping hour burden reflects increases

in the cost of respondents, responses and corresponding deaths each year.

16. Publication and Tabulation Dates

Mortality rates are published annually in the USRDS Annual Report.

17. Expiration Date

CMS would like to display expiration date.

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.