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 for revisions to the currently approved collection, CMS-2746 Death Notification. 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. Also, the conditions of coverage for participating in the Medicare program (section 405.2133 of CFR 42) states:

"ESRD facility, laboratory performing histocompatibility testing, and organ procurement agency furnishes data and information in the manner and at the intervals specified by the Secretary, pertaining to its ESRD patient care activities and costs, for inclusion in a national ESRD medical information system and in compilations relevant to program administration, including claims processing and reimbursement. Such information is treated as confidential when it pertains to individual patients and is not disclosed except as authorized by Department regulations on confidentiality and disclosure (see CFR Part 5, 5b, and 20 CFR Parts 401 and 422 (Subpart E)."

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

CMS has initiated the Vital Information System to Improve Outcomes in Nephrology (VISION) project. This project is focused on the development of electronic reporting tools for use by the dialysis facilities. VISION is currently being utilized by over 200 dialysis providers that have volunteered to participate in this project. This voluntary participation by independent providers (those not owned by the major dialysis corporations) is continuing. CMS is also working with the major dialysis chain organizations (representing approximately 65 percent of all dialysis providers) in developing VISION for their organizations. However, most other independently owned providers are not equipped to send this information electronically to their respective ESRD Network at this time. The data are most often submitted to the Networks in hardcopy form. The use of VISION, by renal, providers will be mandated in the revised Conditions for Participation for dialysis providers. The Conditions are currently in the clearance process in CMS.

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 for this collection published on May 26, 2006.

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 nongovernement 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.

12. Burden Estimates (Total Hours & Wages)

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

The estimated hour burden:
- Respondents – 4,719 renal facilities.
- Completion Time - .50 hours
- Responses/Year/Respondent 16 (Average based on number of 2004 deaths)
- Cost to repondents:
  $17.00/hour x 8 hours for completion = $136.00

The total amount of requested burden hours is 37,752.

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

The following annualized costs are incurred by the Federal Government to maintain activities necessary to collect and process the Death Notification, CMS-2746:

- Equipment $ 16,578.00
- Printing $ 2,916.00
- Staffing $ 5,557.00
- Mailing $ 1,265.00
- Storage $ 1,761.00
- TOTAL $ 28,077.00

15. Program Changes

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