Supporting Statement
For the Paperwork Reduction Act Submission
CMS-2728 End Stage Renal Disease Medical Evidence Report
Medicare Entitlement and/or Patient Registration
(OMB No. 0938-0046)

A. Background

The End Stage Renal Disease (ESRD) Medical Evidence (CMS-2728) is completed for all ESRD patients either by the first treatment facility or by a Medicare-approved ESRD facility when it is determined by a physician that the patient's condition has reached that stage of renal impairment that a regular course of kidney dialysis or a kidney transplant is necessary to maintain life.

The data reported on the CMS-2728 is used by the Federal Government, ESRD Networks, treatment facilities, researchers and others to monitor and assess the quality and type of care provided to end stage renal disease beneficiaries.

The data collection captures the specific medical information required to determine the Medicare medical eligibility of End Stage Renal Disease claimants. It also collects data for research and policy on this population.

The three main data systems available for evaluating the ESRD program and for monitoring epidemiology, access, and quality and reimbursement effects on quality are:

1. The United States Renal Data System (USRDS) provides basic data on patterns of incidence of ESRD in the United States. The USRDS database is intended to be used for biomedical research by investigators throughout the United States and abroad. The USRDS data is intended to supplement (and not replace) public use files produced by CMS.

2. United Network for Organ Sharing (UNOS) focus is on organ donation, transplantation and educational activities.

3. The ESRD Program Management and Medical System (PMMIS), maintained by CMS, provide the foundation data for the USRDS. This system, as required by Public Law 95-292, section C(1) (A), is designed to serve the needs of the Department of Health and Human Services in support of program analysis, policy development, and epidemiological research

The ESRD PMMIS includes information both on Medicare and non-Medicare ESRD patients and on Medicare approved ESRD hospitals and dialysis facilities. The methods of ESRD data collection (e.g., use of same forms, sharing of analysis) by CMS, UNOS, and USRDS have all agreed on a common data

collection process that will provide needed additional information on the ESRD population.

There are no changes being requested at this time.

B. Justification

This is a request to extend a currently approved collection of the CMS-2728 without modifications. Because the burden has increased due to the number of new ESRD patients, this package is classified as a revision.

1. **Need and Legal Basis**

Section 226A (2) of the Social Security Act specifically states that a person must be "medically determined to have end stage renal disease…." Similarly Section 188(a) of the law states " The benefits provided by parts A and B of this title shall include benefits for individuals who have been determined to have end stage renal disease as provided in Section 226A.

In addition, the ESRD Program Management and Medical Information System 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 (42 CFR 405.2133) state:

" ESRD facility, laboratory performing histocompatibility testing, and organ procurement agency furnished 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 (42 CFR Part 5, 5b, and 20 CFR Parts 401 and 422 (Subpart E))."

In accordance with section 226A of the law, the primary purpose of this form is to have a patient medically determined, by a physician, to have end stage renal disease for purposes of filing for Medicare benefits. In addition, this form registers a patient with the United States Renal Data System (USRDS) which was mandated by 42 U.S.C. 241a, 289c, as last amended by P.L. 100-607, November 4, 1988 under the Health Omnibus Programs Extension of 1988, for research purposes.

2. Information Users

Collection of these data are necessary for entitlement of ESRD patients to Medicare benefits and also for the establishment and maintenance of a single, nationwide kidney disease registry for dialysis, transplant, and prospective transplant patients, and will store pertinent medical facts on each registrant.

In addition, the data are used for periodic generation of reports on various aspects of medical care and practice and other related statistics. The data will enable individual practitioners and facilities to review, compare, and improve ESRD patient treatment methods, which will permit local Medical Review Boards to more effectively monitor utilization and quality of medical care.

The data are 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. Collection of the data are necessary for regular assessment and evaluation by concerned organizational elements at local, regional, and national levels of the financial, medical and social impact of ESRD care. The data are also used for the general administrative and data support required for successful implementation of various aspects of Sections 266A, 299I, and 1881 of P.L. 95-292.

The data is used by the Federal Government and others to monitor and assess the quality and type of care provided to renal patients.

3. Use of Information Technology

There are currently two major ESRD information management projects (CROWNWeb and REMIS) under way, which are focused on improved business processes within the ESRD program.

The Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb) system went into production nationally on June 14, 2012. This system brings together all of CMS' information systems that collect, maintain, and report on data about ESRD patients and provides electronic reporting tools for use by dialysis providers. Because of the complexity of the existing systems and because of the need to comply with the strong approved protections for private or confidential data, CROWNWeb was implemented in phases starting Febuary 2009.

CROWNWeb allows dialysis facilities to enter data via the Web and the ESRD forms, including the CMS-2728, are generated from within CROWNWeb. The reporting of data directly from the dialysis providers via CROWNWeb was mandated through the Conditions of Coverage for End-Stage Renal Disease Facilities; Final Rule. The Conditions for Coverage Final Rule was published on April 15, 2008 which mandated a mandatory requirement for all providers to report data to CMS electronically.

4. Duplication of Efforts

The CMS –2728 is the only form completed by a physician to provide the medical information needed to determine a claimant's entitlement to ESRD Medicare. The evidence is not supplied by a physician anywhere else.

5. Small Businesses

The Medical Evidence must be completed by physicians, hospitals, and dialysis providers. The data is collected initially when the patient is determined to have end stage renal disease.

6. Less Frequent Collection

This form is completed initially when a patient is determined to have end stage renal disease. It is also completed for purposes of re-entry into the Medicare program if a person's benefits have been terminated 36 months post transplant or 12 months post stopping dialysis treatment in accordance with Section 226 A of P.L. 92-603.

If these data were not collected, CMS would have no medical determination of ESRD as required by law. We would be unable to identify characteristics of the relationships between patients and treatment. Additionally, we would not be able to identify between the disease and comorbid conditions, and between the disease and death for this population.

7. Special Circumstances

This collection is consistent with the guidelines in 5 CFR 1320.6.

8. Federal Register Notice/Outside Consultation

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

9. Payment or Gift to Respondent

No payments or gifts are made to respondents.

10. Confidentiality

Confidentiality is retained in regular output reports by disclosing data in aggregate 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 non-government 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 referred to, and the reasons for 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 data transmitted via CROWNWeb and REMIS are encrypted and secured.

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

"The collection of this information is authorized by Section 226A of the Social Security Act. The information provided will be used to determine if an individual is entitled to Medicare under the End Stage Renal Disease provisions of the law. The information will be maintained in system No. 09-70-0520, "End Stage Renal Disease Program Management and Medical Information System (ESRD PMMIS)", published in the Privacy Act Issuance, 2002 Compilation, Vol. 67, No. 67, pages 41244-41250, June 17, 2002 or as updated and republished. Collection of your Social Security number is authorized by Executive Order 9397. Furnishing the information on this form is voluntary, but failure to do so may result in denial of Medicare benefits. Information from the ESRD PMMIS may be given to a congressional office in response to an inquiry from the congressional office made at the request of the individual; an individual or organization for research, demonstration, evaluation, or epidemiological project related to the prevention of disease or disability, or the restoration or maintenance of health. Additional disclosures may be found in the Federal Register notice cited above. You should be aware that P.L. 100-503, the Computer Matching and Privacy Protection Act of 1988, permits the government to verify information by way of computer matches."

11. <u>Sensitive Questions</u>

There are no questions of a sensitive nature that are being required on this form.

12. <u>Burden Estimates (2013)</u>

Respondents:	130,000
Completion time:	.75 hour
Responses per year	130,000 (responding once a year)
Total Burden:	97,500 (130,000 responses x .75 hours per response)

It takes the respondent 45 minutes to complete a form. The cost of labor is estimated at $25 per hour. The total cost estimate to the respondent is $2,437,500 (.75 hours per response x 130,000 responses x $25 per hour)

13. Capital Cost

There are no capital costs.

14. Cost to Federal Government (2013)

The following annualized cost is incurred by the Federal Government to maintain the activities necessary to collect and process the CMS-2728:

Printing $2,000.00 (quantity-5,700 forms requested by SSA)

15. Changes to Burden

The changes to the burden are as a result of the increasing number of new ESRD patients.

16. Publication and Tabulation Dates

The form requests patient identifying information as authorized by 42 CFR 405.2133. "The ESRD facility, laboratory performing histocompatibility testing, and organ procurement agency furnished 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 or confidentiality and disclosure (see 45 CFR Part 5, 5b, and 20 CFR Part 401 and 422 Subpart E)."

Information from the CMS-2728 is entered into the ESRD Program Management and Medical Information System, which is a national system, used as a focal point for ESRD data supplied to the ESRD Network Organizations, physicians, Health Systems Agencies, Regional Offices, Congressional Representatives, the National Institute of Health, and Private industries under the regulations on confidentiality and disclosure cited above. It is a system that provides timely administration in measuring and evaluating the care furnished those persons receiving benefits as a result of the ESRD Medicare provision. This information provides the basis for the United States Renal Data System (USRDS) established in 1986 and operated by a coordinating center.

The reports to be made from the data collected are summaries and management reports such as:

USRDS Annual Report
Mortality and morbidity analysis
Provider Specific Reports

17. Expiration Date

CMS would like an exemption from displaying the expiration date as these forms are used on a continuing basis. To include an expiration date would result in having to discard a potentially large number of forms.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collection of Information Employing Statistical Methods

This information collection does not employ the use of statistical methods.