

Supporting Statement – Part A

Supporting Statement For Paperwork Reduction Act Submissions

A. Background

The *PMMIS Facility Certification/Survey Record (CERTDATA & SURVDATA)* contains provider-specific and aggregate patient population data on beneficiaries treated by that provider obtained from the Annual Facility Survey form (CMS-2744). Each facility certification/survey record represents one provider. The Facility Certification portion of the record captures certification and other information about ESRD facilities approved by Medicare to provide kidney dialysis and transplant services. The Facility Survey portion of the record captures activities performed during the calendar year as well as aggregate year-end population counts for both Medicare beneficiaries and non-Medicare patients. The data elements include basic provider information such as provider certification and type of ownership; aggregated dialysis patient data such as the number of patients, number of deaths, and number of patients receiving different types of dialysis; dialysis treatment data; kidney transplant data such as number of transplants, type of transplants, and number of patients awaiting transplants; and the total number of each method used to obtain kidneys for transplants. The 2744 includes the collection on hemodialysis patients dialyzing more than 4 times per week, vocational rehabilitation and staffing. The accuracy of the Facility Survey depends on complete reporting by each facility.

B. Justification

1 . Need and Legal Basis

This is a request to reinstate the previously approved collection form. Collection of the data contained in the CMS-2744, End Stage Renal Disease Facility Survey Form is necessary for the establishment and maintenance of the legislatively mandated single, nationwide database containing patient-medical, specific demographic and billing data, and provider-specific certification and patient population data, the End Stage Renal Disease (ESRD) Program Management and Medical Information System (PMMIS). It is the Agency's responsibility to collect, maintain, disseminate, on a national basis, uniform data pertaining to ESRD patients and their treatment of care. All renal providers who are approved to participate in the ESRD program are required by P.L. 95-292 to supply data to the ESRD PMMIS. The conditions of coverage for participation in the Medicare program (section 494.180(h) of CFR 42) states:

(h) Standard: Furnishing data and information for ESRD program administration. Effective February 1, 2009, the dialysis facility must furnish data and information to CMS and at intervals as specified by the Secretary. This information is used in a national ESRD information system and in compilations relevant to program administration, including claims

processing and reimbursement, quality improvement, and performance assessment. The data and information must—

- (1) Be submitted at the intervals specified by the Secretary;
- (2) Be submitted electronically in the format specified by the Secretary;
- (3) Include, but not be limited to—
 - (i) Cost reports;
 - (ii) ESRD administrative forms;
 - (iii) Patient survival information; and
 - (iv) Existing ESRD clinical performance measures, and any future clinical performance standards developed in accordance with a voluntary consensus standards process identified by the Secretary.

The ESRD Facility Survey (CMS-2744) is completed by all Medicare-approved ESRD facilities once a year. The CMS-2744 was designed to collect information concerning treatment trends, utilization of services and patterns of practice in treating ESRD patients.

2. Information Users

The aggregate patient information is collected from each Medicare-approved provider of dialysis and kidney transplant services. The information is used to assess and evaluate the local, regional and national levels of medical and social impact of ESRD care and is used extensively by researchers and suppliers of services for trend analysis. The information is available on the CMS Dialysis Facility Compare website and will enable patients to make informed decisions about their care by comparing dialysis facilities in their area.

The data are used by CMS to validate and monitor patient specific information and to determine the ESRD Network annual budget from the reported number of treatments provided to dialysis patients (as required by Section 9335 of P.L. 99-509 of the Omnibus Reconciliation Act of 1986 (OBRA) which amended Section 1881© of the Social Security Act). 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.

3. Use of Information Technology

The ESRD Medicare-approved facilities provide the survey data to their respective ESRD Network either via hardcopy form or electronically depending upon the technological capabilities of the provider. Data are transmitted electronically to CMS by the ESRD Networks. Therefore, we estimate the information technology to be about 5%. However, it is 100% electronically available.

4. Duplication of Efforts

There is no other form that collects this information. CMS is the only agency that annually surveys all renal facilities for dialysis patient population and transplant data. Since the renal facilities are required to report on all activities that occurred during the year, CMS is able to obtain information on the Medicare and non-Medicare ESRD population, therefore providing a more comprehensive overview of renal disease occurrence in the United States.

5. Small Businesses

A small business would be described as a provider that 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. However, this collection does not have a significant economic impact on small businesses.

6. Less Frequent Collection

If these data were not collected annually, CMS would be administering a program for which it would be impossible to identify characteristics of the relationship between patients and treatments. 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

ESRD Facility Survey Data are collected on an annual basis and is not envisioned to be collected on a more frequent basis.

- There is no written response necessary in fewer than 30 days after receipt of the survey.
- Only the original/signed copy of the form is required.
- The form is required to be retained by the ESRD Network for 2 years.
- All data produced by respondents are validated by their respective ESRD Network. Only validated data is acceptable.
- There are no requirements for statistical data classification.
- No confidentiality rules apply. There is no patient-specific information gathered on this form.
- No trade secrets or confidential information is involved in this process.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on December 18, 2009.

The retention of the facility survey form and its process are necessary for the effective administration of Network functions. The process requires Medicare-approved providers to monitor their dialysis and transplant patients in the progress of their treatment.

9. Payments/Gifts to Respondents

No payment or gifts are provided to respondents for compliance with the survey process.

10. Confidentiality

A confidentiality statement is provided on the form as it related to the Privacy Act regulations.

11. Sensitive Questions

There are no questions on the facility survey that are of a sensitive nature. Only aggregate data on patients are collected.

12. Burden Estimates (Hours & Wages)

- The number of respondents – 5,465 renal providers.
- The frequency of response - once a year.
- The estimated hour burden - 8 hours.

Providers with larger patient populations may require a longer period of time to prepare the survey, estimated to 15 hours or more. However, the majority of providers should be able to respond within the annual burden hours. Completion time may also vary depending upon the electronic capabilities of respondents, e.g., some respondents may take as little as 1 hour to complete the form.

Cost to respondents: $\$21.03/\text{hour} \times 8 \text{ hours for completion} = \168.28 (*In 2006 the cost was \$19.25/hour. The 2009 cost was calculated based on a 3% per year increase in salary*)

The person completing the survey form at one provider is not necessarily a person of equivalent position at another. For example, persons completing the survey form could be the renal provider Administrator, head nurse, data coordinator, or clinical supervisor. The cost to respondents is based on an average of these salaries.

13. Capital Costs

- a. None - There isn't an equipment/software requirement for this effort
- b. None - The dialysis facility isn't responsible for monitoring, sampling, drilling and testing equipment; or record storage facilities.

The Medicare-approved dialysis facility completes the form and returns it to the End Stage Renal Disease Network in a stamped envelope.

14. Cost to Federal Government

Data analysis is not currently being performed by CMS staff due to efforts surrounding CROWNWeb.

15. Changes to Burden

The increase in the total annual hours requested is due to the increase in the number of Medicare- approved facilities filling out the annual facility survey.

16. Publication/Tabulation Dates

The results of the ESRD Facility Survey process are published annually. The time schedule for this annual process is as follows:

- Information is collected in January, February and March.
- Preliminary data are provided to CMS in April.
- Final data are provided to CMS in May.
- At this time a staff member at ESRD Network 13 voluntarily performs data analysis and submits raw data on a CD to CMS and the other ESRD Networks.
- Data is included in the United States Renal Data System Annual Report.

17. Expiration Date

CMS would like to display the 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 Facility Survey process. Only aggregate information is requested.