

Supporting Statement – Part A

END STAGE RENAL DISEASE APPLICATION & SURVEY & CERTIFICATION REPORT (CMS-3427)

A. Background

This is a request for OMB re-instatement of Form CMS-3427, End Stage Renal Disease Application & Survey & Certification Report (formerly called End Stage Renal Disease Application/Notification and Survey and Certification Report.) The Form CMS-3427 is required for each new ESRD facility seeking initial certification and for each existing facility seeking recertification, relocation, expansion/change of service(s), or change of ownership. The form is also used for information collection purposes related to a complaint survey of an ESRD facility. The Form CMS-3427 that OMB approved in 2004 was officially discontinued in 2007 when OMB approval expired. However, revisions were made to the Form CMS-3427 to conform to the 2008 ESRD Conditions for Coverage and to address user confusion. The changed form was not sent for OMB approval when SCG personnel in other sections advised that they didn't believe it needed OMB approval.

B. Justification

1. Need and Legal Basis

Section 299I of the Social Security Amendments of 1972 (P.L. 92-603) extended Medicare coverage to insured individuals, their spouses, and dependent children with ESRD who require dialysis or transplantation. Section 1881 of the Act authorizes Medicare coverage and payment for treatment of ESRD in approved facilities, including facilities providing home dialysis training and support services. The Conditions for Coverage (CfCs) for ESRD suppliers were promulgated on April 15, 2008 and include 42 CFR 494.1 through 494.180. ESRD facilities must comply with these CfCs for Medicare certification/recertification purposes, and ensure that facilities meet health, safety, and quality standards. To ensure compliance with the CfCs, under the Social Security Act, Section 1864(c) [42 U.S.C. 1395aa], the Secretary is authorized to enter into contractual agreements with State survey agencies to conduct surveys of ESRD facilities.

Section 1881(b)(1) of the Social Security Act through 42 CFR § 488.60 requires any new ESRD facility that seeks initial certification or any existing facility that seeks to relocate, expand/change services or report a change of ownership to secure the Secretary's determination for certification/recertification.

State surveyors or ESRD facility staff complete information required in Part I of the Form CMS-3427 as part of the certification/recertification process. This section provides facility demographic information that assists State Survey Agency surveyors in assessing the ESRD facility for compliance with the Medicare requirements. Form CMS-3427 serves as the application/reapplication by providing necessary identifying information.

Under 42 CFR § 488.12, the State survey agency is required to screen ESRD facilities seeking initial certification and existing ESRD facilities seeking recertification, relocation, expansion/change of modalities/services, or reporting a change of ownership. The State Survey Agency is required to report its survey findings and to make recommendations on ESRD facility compliance to CMS. For the State to comply with these requirements, State surveyors need to use the Form CMS-3427 for information collection purposes.

2. Information Users

CMS ESRD Survey & Certification Group (SCG) and State Survey Agencies use the information collected by the Form CMS-3427 to make certification decisions, to determine access to modalities/services, to identify specific facilities, areas and regions where modalities/services are located, including dialysis in long-term care, and to assist with monitoring ESRD activities.

Since 2007 when the Form CMS-3427 OMB approval expired, data have been collected on forms revised to conform to the 2008 ESRD Conditions for Coverage and to address confusion among staff at ESRD facilities and State Survey Agency personnel about how to answer some questions. ESRD SCG personnel did not realize the Form CMS-3427 OMB approval had expired and other SCG personnel indicated OMB approval was not necessary so it was not sought.

3. Use of Information Technology

The Form CMS-3427 information is currently collected on paper. It is uploaded to the Automated Survey Processing Environment (ASPEN) system by State Agency surveyors. ASPEN provides state-level secure data collection of healthcare provider demographic, survey and certification information, with timely replication of required information into the national repository. The ASPEN system has standardized and streamlined process-intensive survey and oversight operations at both state and regional levels. At the current time, there are no specific plans to make this an online fillable form but the intent is for this form to be available with other CMS forms for download and manual completion.

4. Duplication of Efforts

The Form CMS-3427 does not duplicate any other information collection. It specifically addresses the unique regulatory Conditions for Coverage directed to ESRD facilities for participating in the Medicare program.

5. Small Businesses

Approximately 15 percent of ESRD facilities are small businesses according to the Small Business Administration's size standards (total revenues <\$38.5 million in any 1 year) as published in the Federal Register 80 No. 126, July 1, 2015, page 37859. We do not anticipate that requirements to complete Part I of Form CMS-3427 will impose any significantly different burden on small business ESRD facilities than that imposed on other

ESRD facilities. The information requested on Form CMS-3427 is demographic information about the facility and the modalities/services it provides. This is information that a small business ESRD facility should have readily available to them and they should be able to complete Part I with little difficulty. However, should the small business ESRD facility have questions or need assistance with the completion, the State agency surveyor can provide answers to their questions and assist the facility with completion of this form.

6. Less Frequent Collection

The revised Form CMS-3427 (not OMB approved) has collected data on dialysis facilities on an ongoing basis and the revised form has been included in ASPEN Central Office tracking system updates regularly. States receive a list of ESRD facilities annually before the start of the next fiscal year called the “Outcomes List.” It provides a ranking of facilities based on key outcomes from worst to best. The CMS Mission and Priority Document (MPD) sets an expectation for States to survey a 10% sample of Tier 2 ESRD facilities (those in the worst performing 20% of ESRD facilities) during the upcoming fiscal year. The MPD sets a goal for States to survey ESRD facilities in Tier 3 every 3.5 to 4 years. States are allowed discretion in which of those facilities to survey. We estimate about one-third of ESRD facilities are surveyed annually. ESRD surveyors with help from facility staff complete the Form CMS-3427 at that time. An analysis of data on September 16, 2016 found the median interval between ESRD surveys in FY2015 was 3 years and 2,027 of the 6, 138 ESRD facilities in 2015 were surveyed that fiscal year, which confirms our 33 percent estimate.

7. Special Circumstances

No special circumstances exist for this information collection.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice seeking initial public comment was published on November 16, 2015 in Volume 80, Number 220 on page 70807.

The 30 day Federal Register notice providing a second opportunity for public comment was published on March 1, 2016 in Volume 81, Number 40 on page 10628.

9. Payments/Gifts to Respondents

No payment or gifts will be made to ESRD facilities that complete Form CMS-3427.

10. Confidentiality

There are no questions of a sensitive or protected nature on Part I of Form CMS-3427

11. Sensitive Questions

There are no questions of a sensitive nature associated with Form CMS-3427.

12. Burden Estimates (Hours & Wages)

In FY2015, there were 6,138 ESRD facilities according to the July 16, 2015 Dialysis Facility Compare database. In FY2016, there are 6,598 ESRD facilities in that database as of July 16, 2016. Historically, State agencies survey approximately 33% of ESRD facilities annually. In FY2015, data show that 2,027 ESRD facilities (33%) were surveyed. Based on those data, we estimate in FY2016 33% of 6,598 facilities (2,178 facilities) will be surveyed.

The Form CMS-3427, Part I, is completed by the facility and reviewed by the State agency in Part II. We estimate that the average length of time to complete each Form CMS-3427 is 20 minutes (1/3 of an hour).

2,178	ESRD facilities surveyed annually
<u>x 0.333</u>	1/3 of an hour to complete Part I of Form CMS-3427 (20 minutes)
726	Hours a year of respondent burden for surveyed facilities to complete Form CMS-3427

Dividing the \$45.43 hourly wage of the facility administrator by 3 to account for the estimated 20 minutes to assist in completing the Form CMS-3427 survey, the cost for an administrator's time (20 minutes) at a facility is \$15.15. This information collection will cost a total of \$32,997 for the 2,178 ESRD facilities that we estimate will be surveyed annually. Wage information is based on the Bureau of Labor Statistics' Quick Facts: Medical and Health Services Managers, the way the BLS classifies a healthcare administrator. <http://www.bls.gov/ooh/Management/Medical-and-health-services-managers.htm> (accessed 9/19/2016).

The burden changed from 2003 when the Form CMS-3427 was last approved related to:

- 1) The position and wage of the facility staff [administrative assistant @ \$12.00 per hour to facility administrator/manager @ \$45.43 per hour] who provides providing information to the ESRD surveyor to complete Form CMS-3427; and
- 2) An increase in the estimated number of ESRD facilities to be surveyed [from 1,320 facilities 2003 @ 440 hours to complete the Form CMS-3427 to 2,178 facilities in 2016 @ 726 hours to complete the Form CMS-3427].

No change was made to the 20 minutes we estimate to complete the form.

The increase in number of facilities and change in staff position and salary resulted in the large increase in the total annual cost estimate to complete Form CMS-3727 from \$5,280 in 2003 (\$4.00 per facility) to \$32,997 in 2016 (\$15.15 per facility). We have no data to project the wage increase for ESRD facility administrators/managers but using data on growth in the number of certified ESRD facilities over time, we project this will be about 2-3% per year.

13. Capital Costs

There are no capital costs associated with this collection.

14. Cost to Federal Government

Cost to the Federal government includes incidental cost to print the form. These costs may be reduced by posting the form on the CMS Web site for download as needed.

15. Explanation of Program Changes or Adjustments

See the document entitled Changes Table for change-by-change information and rationale. We request the Form CMS-3724 be reinstated with changes. Changes to the Form CMS-3427 under Part I included such things as adding a disclosure statement, adding email contact for the facility administrator, clarifying the address needed for the administrator was the business address, clarifying if the facility is a dialysis facility or SNF/NF, revising the question to clarify type of facility for the dialysis facility, whether the dialysis facility is located or provides services in an SNF/NF with data on what to report, for facilities requesting recertification added modalities/services that weren't on the original form, revised for clarification for new facilities requesting certification modalities/services that weren't on the original form, revised question and instructions related to patients who do dialysis within the LTC facility and modalities, clarifying the questions is asking for current stations and not to count home training rooms (response to comment), clarifying question related to request for additional stations (response to comment), clarification for isolation to comply with 2008 ESRD Conditions for Coverage and waivers, clarifying facility days/times for in-center shifts and operating hours for home only facilities.

Changes to the Form CMS-3427 under Part II included a revision to text to conform to the instructions in the CMS 855A related to the MAC. Changes to the instructions for Form CMS-3427 included deletion of certificate of need statement, clarifying what changes in services need to be reported, clarifying in instructions for Items 2-19 that facility is a dialysis facility, clarifying for current modalities and new modalities what needs to be reported including information about dialysis provided in LTC facilities and home dialysis as well as in-center shift days/times and hours of operation for home only facilities, information about what to report in remarks, including adding licensing and certificate of need if applicable, and finally, the revising the instructions under Part II to comply with CMS-855A related to the MAC.

16. Publication/Tabulation Dates

Not applicable.

17. Expiration Date

We request that OMB approval of the Form CMS-3427 reinstatement with changes ICR be granted for the maximum 3 year period. Providing a 3-year approval allows assures that dialysis suppliers and State Survey Agency personnel become accustomed to using this form, understanding the questions asked and what information should be provided for

greater consistency and reliability of data reporting, collection and analysis.

We will display the expiration date on the Form CMS-3427.

18. Certification Statement

There are no exceptions to the certification statement.