

Supporting Statement – Part A

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

A. Background

This is a request for OMB revision of Form CMS-3427, End State 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.

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 Quality Safety & Oversight Group (QSOG) 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.

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 Form CMS-3427 has collected data on dialysis facilities on an ongoing basis and 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 identifies the top 5% of ESRD facilities with poor clinical outcomes across four defined clinical measures. The CMS Mission and Priority Document (MPD) sets an expectation for States to survey all identified Tier 2 ESRD facilities (those in the top 5% 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 May 18, 2019 found the median interval between ESRD surveys in FY2018 was 3 years and 2,444 of the 7,407 ESRD facilities in 2018 were surveyed that fiscal year, which supports 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 published on October 28, 2019 (84 FR 57734). There was one comment received but it was not related to this information collection.

The 30-day Federal Register notice published on February 7, 2020 (85 FR 7306).

9. Payments/Gifts to Respondents

There are no payment or gifts.

10. Confidentiality

There are no questions which would be considered protected or confidential.

11. Sensitive Questions

There are no questions of a sensitive nature.

12. Burden Estimates (Hours & Wages)

As of FY 2019, there are 7,493 ESRD facilities according to the May 13th 2019 Quality, Certification & Oversight reports. Historically, State agencies survey approximately 33% of ESRD facilities annually. In FY2018, data show that 2,444 ESRD facilities (33%) were surveyed. Based on those data, we estimate in FY2019 33% of 7,493 facilities (2,473 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).

2,473	ESRD facilities surveyed annually
<u>x 0.333</u>	1/3 of an hour to complete Part I of Form CMS-3427 (20 minutes)
824	Hours a year of respondent burden for surveyed facilities to complete Form CMS-3427

Multiplying 824 hours of total burden hours per year by the facility administrators' total hourly wage of \$95.90 (\$47.95 hourly wage doubled for fringe benefits) finds that this information collection will cost a total of \$79,022 for the 2,473 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 5/13/2019).

The burden changed since the last approval of the CMS 3427 in 2015 due to the following reasons:

- 1) The facility administrator/manager's cost to complete the CMS 3427 increased to \$95.90 (\$47.95 doubled for fringe benefits) with the 2019 package submission. The 2019 cost estimate for completion of the CMS -3427 by the facility administrator/manager includes the fringe benefits that were not previously included in the 2015 wage and cost burden calculations.
- 2) An increase in the number of ESRD facilities surveyed annually from 2,046 facilities/681 hours in 2015 to 2,473/824 hours in 2019. There are 427 additional ESRD facilities that will be surveyed annually & 143 additional hours included in the cost estimates of the 2019 PRA package submission for 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 salary resulted in the large increase in the total annual cost estimate to complete Form CMS-3727 which changed from \$29,053 to \$79,022. 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. The annual cost of printing is \$183.25

15. Explanation of Program Changes or Adjustments

The following items have changed or been adjusted since the last approval:

1. Instructions for completion on Pg.4. under TYPES OF MODALITIES/SERVICES, DIALYSIS STATIONS, AND DAYS/HOURS OF OPERATION (ITEMS 20-29). The instructions for dialysis in nursing homes was clarified from previous language stating “new requests” to “notifications” for completion of item 22 and clarifying the term dialysis to home dialysis in this section. These minor grammatical changes do not change data collection or use of the form.
2. The number of respondents increased from 2,046 to 2,473
3. Burden hours increased from 681 hours to 824 hours
4. The annual cost burden increased by \$49,969 to \$79,022 from \$29,053 due to the increase in number of respondents, burden hours and facility administrator wage increase.
5. The wage of the facility administrator who completes the CMS Form 3427 increased to \$95.90 (\$47.95 doubled for fringe benefits) per the Bureau of Labor statistics and includes calculation of fringe benefits which was not accounted for in the previous package.

16. Publication/Tabulation Dates

Not applicable.

17. Expiration Date

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

18. Certification Statement

There are no exceptions to the certification statement.