

Supporting Statement for
Chapter 8 of the Medicare Claims Processing Manual Section 40.1 through 40.8
Contained in 42 CFR 413.170 and 413.184
CMS-9044

A. Background

Section 623 of the MMA amended BIPA 2000 to allow only pediatric ESRD facilities that did not have an approved exception rate as of October 1, 2002, to file for an exception to its updated prospective payment rate, and the pediatric facility would have to demonstrate that at least 50 percent of its patients are individuals under 18 years of age. This statutory amendment to BIPA 2000 lifted the previous prohibition on exceptions, and restored the exception process for pediatric facilities. We believe that pediatric facilities would not qualify for an exception under most of the five existing exception criteria because of the uniqueness of their pediatric patient population (at least 50 percent). In the past, ESRD facilities with high percentages of pediatric patients only qualified for exceptions under the “atypical patient mix” criterion. Therefore, we are revising the regulations by eliminating three of the five exception criteria (isolated essential facilities, extraordinary circumstances, and frequency of dialysis), and we are retaining and revising the exception criterion for “pediatric patient mix”. Since some pediatric facilities may qualify for an exception on the basis of higher self-dialysis training costs, we are also retaining the exception criterion for “self-dialysis training costs in pediatric facilities”.

In accordance with changes made by section 422 of BIPA 2000 and section 623 of the MMA, manual instructions previously contained in the Provider Reimbursement Manual, Part I, §§2720.1-2726.2 have been significantly revised and are now included in the Online Medicare Claims Processing Manual (MCP). The major changes are; (a) Only a pediatric ESRD facility that did not have an approved exception rate as of October 1, 2002 can now file for an exception to its updated composite payment rate, (b) A pediatric ESRD facility is defined as a renal facility with at least 50 percent of its patients under the age of 18, (c) The previous exception criteria have been eliminated (with the exception of self-dialysis training), (d) Pediatric ESRD facilities can file for an exception to its composite payment rate at any time it is in operation for 12 consecutive months, and (e) A pediatric ESRD facility that has been denied an exception rate may immediately file another exception request.

Please note that the regulations pertaining to the servicing intermediary’s responsibilities for reviewing ESRD exception requests have not changed.

B. Justification

1. Need and Legal Basis

Section 2145 of the Omnibus Budget Reconciliation Act of 1981 provides the authority for collection of this information.

On May 11, 1983, CMS published a final rule in the Federal Register changing the way Medicare pays for outpatient dialysis services. The payment exception requirements are stated at 42 CFR 413.184.

2. Information Users

CMS uses the information submitted to determine whether the ESRD facility qualifies for a rate increase and the amount of the increase. If reliable information is not provided, CMS could not judge the validity of the ESRD facility's exception request and could be criticized for either being too strict or too lenient in judging a facility's exception request.

3. Improved Information Technology

Since this is narrative data, which is submitted on a default basis, it does not lend itself to computerization.

4. Duplication of Similar Information

No similar information or duplication exists, since this is the only collection of ESRD exception data.

5. Small Businesses

The collection of information involves small businesses but does not impose a significant economic impact. We request the minimum information needed to judge a facility's exception request. The method used to minimize the burden was to limit the information request to only that which a provider uses to justify one of six exception criteria specified in the regulation.

6. Less Frequent Collection

Chapter 8 of the MCP Manual provides the ESRD facility the opportunity to justify if its projected operating costs will exceed its composite rate payment. Collection of this data occurs only when the ESRD facility requests an exception.

7. Special Circumstances

There are no special circumstances for collecting information.

8. Federal Register Notice/Outside Consultation

The 60-day Federal Register notice was published on January 26, 2007.

CMS published a final rule for the above regulation as mentioned in item one, This revised regulation was primarily a codification of the ESRD exceptions process from Chapter 8 of the MCP Manual. All public comments received were included in the revision. We did not conduct any outside consultation on the MCP requirements since this collection of information is based on the regulation, which was subject to public comment.

9. Payments/Gifts To Respondents

There were no payments or gifts to respondents.

10. Confidentiality

There are no assurances of confidentiality associated with this request.

11. Sensitive Questions

There are no questions of a sensitive nature associated with this request.

12. Burden Estimate (Total Hours and Wages)

Only ESRD pediatric facilities that currently do not have an exception may apply for an exception at any time. During the last exception window, CMS received 10 exception requests from ESRD pediatric facilities.

It is estimated that it would take an ESRD facility 48 hours to prepare an exception request. Therefore, the burden hours are computed as follows:

$$10 \text{ exception requests} \times 40 \text{ hours} = 400 \text{ total burden}$$

The total public burden hours and costs to respondents are calculated at the standard rate of \$20 per hour times the 400 hours of estimated paperwork burden.

13. Capital Costs

There are no capital costs to implement this collection information.

14. Costs to Federal Government

The estimated Federal cost is computed as follows:

a. Intermediary costs:

Number of exceptions	10
Intermediary review time per exception	<u>x 24</u> hours
	240 hours
Cost per hour of audit services	<u>\$ 80</u>
	\$19,200

b. CMS costs:

Number of exceptions	10
CMS review time per exception	<u>24</u> hours
	240
Average cost per hour (GS 13)	<u>\$ 50</u>
	\$ 12,000

c. Miscellaneous Costs

(Includes data entry, supplies, etc.)	\$ 3,000
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d. Total Federal Cost:

\$ 19,200	-	Intermediary review costs
12,000	-	CMS review costs
<u>3,000</u>	-	Miscellaneous cost
\$ 34,200	-	Total Federal Cost

15. Program Changes

The ESRD exception process has changed since the last submission of this report in September 2001. In accordance with changes made by section 422 of BIPA 2000 and section 623 of the MMA. The major changes are; (a) Only a pediatric ESRD facility that did not have an approved exception rate as of October 1, 2002 can now file for an exception to its updated composite payment rate. The decrease in burden is due to fewer respondents.

16. Publication and Tabulation Dates

This data will not be published or tabulated.

17. Expiration Date

CMS is requesting an exception to displaying the expiration date. Since the program manuals aren't changed or revised frequently and the process to make changes to the program manuals is a long drawn out process, it would cause a any

great burden on us to have to revise the manual instructions after each re-approval.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collection of Information Employing Statistical Methods

This information collection does not involve collection of information employing statistical methods.