CMS Manual System

Pub 100-04 Medicare Claims Processing

Transmittal 781

Department of Health & Human Services (DHHS)

Center for Medicare & Medicaid Services (CMS)

Date: DECEMBER 16, 2005

Change Request 4188

SUBJECT: Revised Manual Instructions for Processing End Stage Renal Disease (ESRD) Exceptions Under the Composite Rate Reimbursement System

I. SUMMARY OF CHANGES: 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. 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.

NEW/REVISED MATERIAL

EFFECTIVE DATE: January 01, 2006

IMPLEMENTATION DATE: January 17, 2006

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R = REVISED, N = NEW, D = DELETED – *Only One Per Row.*

R/N/D	Chapter / Section / SubSection / Title
R	8/40/Table of Contents
N	8/40.1 General Instructions for Processing Requests Under the Composite Rate Reimbursement System
N	8/40.2 Criteria for Approval of ESRD Exception Requests

N	8/40.3 Procedures for Requesting Exceptions to ESRD Payment Rates
N	8/40.4 Period of Approval : Payment Exception Request
N	8/40.5 Criteria for Re-filing a Denied Exception Request
N	8/40.6 Responsibility of Intermediaries
N	8/40.7 Payment Exception: Pediatric Patient Mix
N	8/40.8 Payment Exception: Self Dialysis Training Costs in Pediatric Facilities

III. FUNDING:

No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2006 operating budgets.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

**Unless otherwise specified, the effective date is the date of service.*

Attachment - Business Requirements

Pub. 100-04	Transmittal: 781	Date: December 16, 2005	Change Request 4188

SUBJECT: Revised Manual Instructions for Processing End Stage Renal Disease (ESRD) Exceptions Under the Composite Rate Reimbursement System

I. GENERAL INFORMATION

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".

B. Policy: 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. 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.

II. BUSINESS REQUIREMENTS

“Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
4188.1	Contractors shall process all pediatric exception requests in accordance with the new policy. Only a pediatric ESRD facility that did not have an approved exception rate as of October 1, 2002 shall file for an exception to its updated composite payment rate.	X								
4188.2	Contractors shall process all pediatric exception requests in accordance with the new policy. A pediatric ESRD facility shall be defined as a renal facility with at least 50 percent of its patients under the age of 18.	X								
4188.3	Contractors shall process all pediatric exception requests in accordance with the new policy. CMS has eliminated three of the five exception criteria (isolated essential facilities, extraordinary circumstances, and frequency of dialysis), and CMS shall retain the revised exception criterion for “pediatric patient mix”.	X								
4188.4	Contractors shall process all pediatric exception requests in accordance with the new policy. Because some pediatric facilities may qualify for an exception on the basis of higher self-dialysis training costs, CMS shall retain the exception criterion for “self-dialysis training costs in pediatric facilities”.	X								
4188.5	Contractors shall process all pediatric exception requests in accordance with the new policy. Pediatric ESRD facilities should file for an exception to its composite payment rate at any time it is in operation for 12 consecutive months.	X								

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
4188.6	Contractors shall process all pediatric exception requests in accordance with the new policy. A pediatric ESRD facility that has been denied an exception rate should immediately file another exception request.	X								

III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
4188.7	A provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established "medlearn matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin and incorporated into any educational events on this topic. Contractors are free to supplement Medlearn Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X								

IV. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: NA

X-Ref Requirement #	Instructions

B. Design Considerations: NA

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: NA

D. Contractor Financial Reporting /Workload Impact: NA

E. Dependencies: NA

F. Testing Considerations: NA

V. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: January 1, 2006 **Implementation Date:** January 17, 2006 **Pre-Implementation Contact(s):** Michael Powell, 410-786-4557 **Post-Implementation Contact(s):** Michael Powell, 410-786-4557	**No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 operating budgets.**

***Unless otherwise specified, the effective date is the date of service.**

Medicare Claims Processing Manual

Chapter 8 - Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims

---

Table of Contents

(Rev.781, 12-16-05)

40 - Processing Requests for Composite Rate Exceptions

(Rev.781, Issued: 12-16-05, Effective: 01-01-06, Implementation: 01-17-06)

40.1 – General Instructions for Processing Exceptions Under the Composite Rate Reimbursement System

(Rev.781, Issued: 12-16-05, Effective: 01-01-06, Implementation: 01-17-06)

A hospital-based or independent renal dialysis facility may request CMS to approve an exception to the composite payment rate and set a higher payment rate, if the facility has an estimated allowable cost per treatment higher than its composite rate, and if the higher costs relate to the exception criteria referenced below. The costs in excess of the composite rate must be attributable to items and services provided to Medicare patients for maintenance dialysis, whether furnished at home or in a hospital-based or independent facility. All of the facility's costs with respect to all modes of outpatient maintenance dialysis (exclusive of self-dialysis training costs), for both in-facility and home dialysis patients are considered in an exception request for any mode of dialysis. For example, if the facility's peritoneal dialysis cost per treatment exceeds its composite rate payment, no exception is granted if the facility's total maintenance dialysis revenues exceed its total maintenance dialysis costs. In considering exception requests for self-dialysis training, only the costs relating to self-dialysis training are considered.

Section 623(b)(1)(D) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173 provides only for the submission of new pediatric facility exception requests in the case of a pediatric facility that did not have an approved exception rate as of October 1, 2002. The statute defines the term "pediatric facility" to mean a renal facility with at least 50 percent of whose patients are individuals under 18 years of age.

A pediatric ESRD facility can file an exception request at any time it is in operation for at least 12 consecutive months. The facility must submit its ESRD exception request in duplicate to its servicing intermediary. Upon completion of its review, the servicing intermediary can either deny the facility's exception request and furnish a copy of its denial letter to CMS, or the intermediary furnishes one copy of the facility's request together with its recommendation and original workpapers to CMS for adjudication. Upon adjudicating the documentation submitted by the facility and the intermediary, CMS will send its decision letter to the servicing intermediary, which will notify the facility of CMS's decision.

An exception request is deemed approved unless CMS disapproves a composite rate exception request within 60 working days after it is filed with the intermediary. To meet the 60 working days deadline required by law, the first day for counting is the date that the exception request is filed with all required documentation with the intermediary. Facilities are advised to send their requests by a method which documents the date of receipt during the intermediary's regular business hours.

Delivery of pediatric exception requests to intermediaries must be accomplished through a method which documents the date of receipt. A postmark or other similar date does not serve as documentation of the date of receipt.

40.2 Criteria for Approval of ESRD Exception Requests

(Rev.781, Issued: 12-16-05, Effective: 01-01-06, Implementation: 01-17-06)

The pediatric ESRD facility must demonstrate, by convincing objective evidence, that its total per treatment costs are reasonable and allowable under the relevant Medicare cost reimbursement principles and that its per treatment costs in excess of its payment rate are directly attributable to any of the following criteria:

A. Pediatric patient mix, as specified in section 40.7, and

B. Self-dialysis training costs in pediatric facilities, as specified in 40.8.

40.3 Procedures for Requesting Exceptions to ESRD Payment Rates

(Rev.781, Issued: 12-16-05, Effective: 01-01-06, Implementation: 01-17-06)

The pediatric ESRD facility is responsible for justifying and demonstrating to CMS's satisfaction that the requirements of this section and the exception criteria listed in this chapter are met in full. The burden of proof is on the facility to show that one or more of the criteria are met and that the facility's costs in excess of its composite payment rate are justifiable under the Medicare reasonable cost principles.

A . A pediatric facility filing a request for an exception must meet the following conditions:

1. Submittal of written justification.

The pediatric facility must provide written justification for supporting the facility's higher cost. The fact that the facility projects costs higher than its composite payment rate is not adequate documentation for granting an exception. The facility must provide CMS with supporting material documenting the reasons that may justify its costs in excess of its composite payment rate(s).

2. Amount requested.

The pediatric facility must list its current composite payment rates and the requested composite payment rate for each modality of treatment, i.e., outpatient maintenance (including the home program) and home training. The amount requested must be identified by specific cost component(s), for example, salaries, supplies, overhead, and laboratory with a cross reference to the narrative explanation and the work papers supporting the exception request.

3. Cost per treatment.

A pediatric renal facility must submit a schedule showing the cost per treatment (CPT) for each component cost by mode of dialysis treatment. The cost components (i.e., salaries, supplies, depreciation) are those reported by a facility on its cost report. The CPT for each component cost must reconcile with reported costs. In addition, a facility must submit a schedule combining total outpatient and home maintenance dialysis costs, since the composite rate system is based on a single payment for all outpatient maintenance dialysis treatments (infacility and home). This schedule combines the facility's infacility outpatient maintenance costs with its home dialysis maintenance costs

and computes a CPT for these combined costs. This schedule is required for both actual and budgeted costs.

4. Budget estimate.

A pediatric facility must submit a projected budget estimate and utilization trend through the period for which the exception rate is to apply, showing that its allowable CPT is higher than its composite rate, and that the costs in excess of the composite rate are attributable to factors related to one of the below stated exception criteria. Any significant variance between budgeted treatments and actual treatments furnished in the prior year must be addressed in the supporting documentation. The documentation to support the projected budget estimate must be submitted in the following format:

- *Appropriate completed cost reporting schedules; i.e., Worksheets I-1, 2, and 3 of Form CMS-2552 (hospital-based facilities) or Form CMS-265 (independent facilities) full cost report listing the projected budget costs; and*
- *Documentation supporting any significant increases in budgeted costs over actual costs reported for prior reporting period.*

5. Reporting actual costs and cost reporting requirements.

A pediatric renal facility must submit a copy of its most recently filed cost report. When the facility submits a revised cost report, it must have received prior intermediary approval to change its cost allocation methodology in accordance with cost reporting instructions contained in CMS Pub. 15-II. No intermediary approval is needed if the facility is changing to the recommended statistics, as described in the cost report instructions. However, the facility must submit a copy of the revised cost report to its intermediary who must accept it. In addition, the facility must state that it has auditable documentation to support its statistical basis for the reallocation and must explain the reason for any shifting of costs. If the revised cost allocation is for the purpose of shifting costs to meet the exception criterion or in less costs being allocated to inpatient treatments than outpatient treatments, CMS disregards the revised cost report and uses the latest actual cost report received by the intermediary.

The facility must submit the following cost reports:

***A - Provider-based facilities**—The provider must submit the previous year's complete cost report Form CMS-2552 and Worksheets I-1, 2, and 3 (with the attached analysis of other expenses in the renal department as shown on Worksheet A, line 41 and line 59, column 2). A provider may not revise Worksheet I merely to reflect a more favorable historic financial position when filing an exception request.*

***B - Independent facilities**—The independent facilities must submit the full cost report Form CMS-265 and a copy of the facility's audited financial statement (if available) or unaudited for the accounting period specified on the cost report. An independent facility may not revise the Form CMS-265 merely to reflect a more favorable historic financial position when filing an exception request.*

6. Laboratory.

The facility must submit a list of the laboratory tests used routinely in the dialysis procedure. Laboratory tests are defined in:

- *§50-17 of the Coverage Issues Manual for hospital-based facilities; and*

- *§207.1 of the Renal Dialysis Facility Manual for independent facilities.*

7. Drugs/Medications.
The facility must submit a list of the drugs/medications covered under the composite rate (see §2710.2) that the facility furnishes to its dialysis patients.

8. Routine ancillary cost.
Routine items include laboratory, oxygen therapy, drugs/medications and supplies, and services which are commonly furnished as part of a typical dialysis service. These costs are reimbursed through the facility's dialysis composite payment rate and may not be billed separately. Also included are procedures such as the hemodialysis flow study and Doppler flow study when such procedures are used to monitor the access site.

9. Nonroutine ancillary cost.
The facility must exclude nonroutine items and services from its allowable cost because they are not considered part of the dialysis service costs that are used in computing its composite payment rate. Additional ancillary items and services that are not routinely furnished, but medically necessary for some patients, must be separately billed, justified for medical necessity, and verified by the intermediary. Nonroutine items and services such as drugs/medications, supplies, and laboratory tests are not part of the normal dialysis and are not reimbursed through the facility's rate and may therefore be billed separately.

10. Satellite facilities.
Although satellite facilities are separate facilities and receive a separate provider number for certification purposes, they are still considered to be part of the hospital complex. Their costs flow through the hospital and are reported on the hospital's cost report. Therefore, when CMS processes an exception request from a hospital-based facility that has one or more satellite facilities associated with it, CMS reviews the costs and circumstances of the entire facility including all satellites, to see if the exception criteria are met.

11. Inpatient treatments.
A hospital renal facility must submit with its current cost report the number of inpatient dialysis treatments it furnished. The hospital computes a CPT and provides an explanation if its inpatient CPT is equal to or less than the provider's outpatient CPT. An independent renal facility also provides similar information if it is furnishing inpatient treatments under arrangement.

12. Onsite review.
Any facility that requests an exception to its composite payment rate is required to maintain records and furnish information to substantiate the costs incurred and that its costs are in excess of the composite rate and are attributable to one or more of the exception criteria. CMS may determine that an onsite review of the facility is necessary to aid CMS in its review of the exception request by evaluating the efficiency and the economy of the facility's operation. The findings resulting from the onsite review are

used as a basis for adjudicating the facility's exception request. The onsite review is performed by the area servicing intermediary.

13. Materials submitted to CMS must also include the following:

(a) Separately identify elements of cost contributing to costs per treatment in excess of the facility's payment rate,

(b) Show that the facility's costs, including those costs that are not directly attributable to the exception criteria, are allowable and reasonable under the Medicare reimbursement cost principles,

(c) Show that the elements of excessive cost are specifically attributable to one or more of the exception criteria (specified in section 40.2),

(d) Specify the amount of additional payment per treatment the facility believes is required for it to recover its justifiable excess costs; and

(e) Specify that the facility has compared its most recently completed and filed cost report with cost reports from at least 2 prior years, if available. The facility must explain any material statistical data or cost changes, or both, and include an explanation with the documentation supporting the exception request, and

(f) Remove costs associated with separately billable items.

40.4 Period of approval: Payment exception request.

(Rev.781, Issued: 12-16-05, Effective: 01-01-06, Implementation: 01-17-06)

A prospective exception payment rate approved by CMS applies for the period from the date the complete exception request was filed with its intermediary until thirty days after the intermediary's receipt of the facility's letter notifying the intermediary of the facility's request to give up its exception rate and be subject to the basic case-mix adjusted composite payment rate methodology. An ESRD facility that has an existing exception rate may give up that rate if it determines that it will be paid a higher composite payment rate under the new case-mix adjusted composite rate methodology. Each ESRD facility must notify its fiscal intermediary (in writing) if it wishes to give up its existing exception rate(s) or its pediatric facility's exception rate(s). The facility will be paid based on its case-mix adjusted composite payment rate beginning thirty days after the intermediary's receipt of written notification that the facility wishes to give up its exception rate. Once a facility notifies its fiscal intermediary that it wishes to give up its exception rate, that decision can not be subsequently rescinded or reversed. ESRD facilities that retain their existing exception rates do not need to notify their intermediaries.

40.5 Criteria for Refiling a Denied Exception Request.

(Rev.781, Issued: 12-16-05, Effective: 01-01-06, Implementation: 01-17-06)

CMS denies exception requests submitted without the general documentation specified in section 40.2 and the documentation specified in the applicable exception criteria (sections 40.8 and 40.9). A pediatric ESRD facility that has been denied an exception

request may immediately file another exception request. Any subsequent exception request must address and document the issues cited in CMS' denial letter.

40.6 Responsibility of Intermediaries

(Rev.781, Issued: 12-16-05, Effective: 01-01-06, Implementation: 01-17-06)

All pediatric composite rate exception requests are to be reviewed and processed within 15 working days from the date that the exception is filed. The intermediary must verify that the exception request contains documentation to support the renal facility's position. When the renal facility fails to submit the required documentation, the exception request is returned to the facility. The 60 working days start when a pediatric renal facility files an exception request with all required documentation with the intermediary during the intermediary's regular business hours.

A - Inform CMS central office of pediatric composite rate exception requests

To track the start of the 60 working day requirement, intermediaries must call CMS central office the day a pediatric composite rate exception is received. The contact person is listed on telephone number (410) 786-5472. The following information is provided:

- *The name and provider number of the pediatric renal facility;*
- *The date the exception is received;*
- *The type of exception, e.g., pediatric patient mix;*
- *The amount requested;*
- *A phone number and contact person at the intermediary.*

B – Composite rate exception log

- *The intermediary maintains a composite rate exception log. The purpose of this log is to monitor the 15 working days and to ensure the timely processing of all pediatric composite rate exceptions. In addition, the log documents the starting date for processing composite rate exceptions. This is in case a renal pediatric facility alleges that its composite rate exception was not processed within 60 working days. The following information is included in the log:*
- *The date the exception is received by the intermediary. (The intermediary date stamps each request.);*
- *The renal pediatric facility's reason for requesting the exception;*
- *The intermediary's reason for returning the exception;*
- *The intermediary's recommendation to either approve or deny the facility's request. (All workpapers supporting the intermediary's decision must accompany the facility's exception request when mailed to CMS central office.); and*
- *The date the exception is mailed to CMS central office.*

C – Intermediary review

The following procedures are applied after receiving a facility's pediatric composite rate exception request:

- *The intermediary reviews the exception request, the cost report, the facility's projected costs, and any other documentation submitted by the facility to assure*

that it is complete and accurate. If the renal facility fails to submit the required documentation, the exception request is returned to the facility.

- *Mailing of the exception request. After completing its review of the renal facility's exception request, the intermediary mails the facility's exception request plus its recommendation with all its supporting work papers to CMS central office. To expedite the exception process, the intermediary mails all exception requests using an overnight delivery service. In its cover letter, the intermediary must state the date the exception request was received in its office.*
- *Determination of reasonable and allowable costs. The intermediary determines that Medicare principles of reimbursement were used to ensure that only reasonable and allowable costs are included in the facility's costs. The facility reviews the following reimbursement areas:*
    1. *Bad Debts--Facilities are not to include an allowance for doubtful accounts in reported costs but submit separately the total dollar amount of bad debts actually incurred. Allowable bad debts include only uncollectible deductibles and coinsurance related to covered composite rate services furnished to Part B beneficiaries. Renal facilities may not claim the 50 cents reduction required by §9335(j) of OBRA 1986 as an expense on their Medicare cost reports. The intermediary verifies that renal facilities have properly treated this 50 cents reduction before the facility calculates it reimbursable bad debts or files for an exception request. (See §§300 and 2714.)*
    2. *Allowable Compensation for Physician Owners and Medical Directors—Compensation, including fringe benefits, paid to a physician owner or medical director may not exceed the reasonable compensation equivalent (RCE) limits currently in effect for a specialty of internal medicine for a metropolitan area of greater than one million people. See §2182 for a description of the RCE limits and §2182.6 for the current salary limit for a specialty of internal medicine. The physician's salary reported as a Medicare allowable cost for administrative services may not exceed the RCE limit. Furthermore, the facility must adjust the RCE limit by the time spent by the physician as owner or medical director performing administrative services for the facility. Based on Medicare program statistics, the median amount of time spent by physicians in ESRD facilities on administrative duties is 25 percent. If a facility reports that a physician spends more than 25 percent of his or her time performing administrative type services, the facility must document its claim. If no documentation is furnished and the facility is reporting physicians' time in excess of 25 percent, the intermediary limits the physician's compensation to the lower of the amount claimed or 25 percent of the RCE limit in effect. If the physician as owner or medical director furnishes services to more than one facility, his or her total time may not exceed 25 percent unless the facility has documentation to support its claim. A renal facility may adjust the 25 percent limit to reflect special facts or circumstances, e.g., a medical director may spend more time at a renal facility that furnishes a large number of treatments and other medical services than most renal facilities.*

If a renal facility claims a higher percentage of time, it must be able to document the medical director's actual time spent performing administrative duties.

3. *Allowable Compensation for Owners, Administrators, and Assistant Administrators—-Reasonable compensation, including fringe benefits, paid to owners, administrators, and assistant administrators is an allowable cost. (See §904.) In most instances, compensation paid to these individuals may not exceed $120,000. When these individuals spend less than 100 percent of their time performing services, adjust the $120,000 to reflect the actual time spent at the facility. If an individual provides services to more than one renal facility, the individual's time must be prorated among the different entities and may not exceed 100 percent. In certain circumstances, a renal facility could claim more than the $120,000 limit, e.g., it may be reasonable for a renal facility furnishing a large volume of dialysis treatments and other medical services to pay an individual in excess of $90,000. In these circumstances, an intermediary may survey other renal facilities to determine if the higher amount is reasonable.*
4. *Depreciation--An appropriate allowance for depreciation on building and equipment is an allowable cost. Payment for services includes depreciation on all depreciable type assets that are used to provide covered services to beneficiaries. (See §104.)*
5. *Start-up and/or Organizational Costs--Start-up and organizational costs are allowable costs under the program. The start-up and organizational costs incurred must be amortized over an appropriate period of time. (See §2132.)*
6. *Interns and Residents--Reasonable costs for an approved intern and resident teaching program, if comparable to the costs of other similar facilities that have educational programs, are reimbursable to the hospital under the program. (See §404.)*
7. *Nursing School--An approved nursing education program must be operated by a provider (or jointly by a group of providers) for students of the provider(s) for Medicare to recognize the costs of the program as allowable costs of the provider(s). (See §404.)*
8. *Medical Records--The reasonable cost of medical records is reimbursable under the program.*
9. *Cost to Related Organizations--This cost represents the cost applicable to services, facilities, and supplies furnished to the facility by organizations related to the facility by common ownership or control and is included in the allowable cost of the facility at the cost to the related organization. (See §1005).*
10. *Home Office Costs—These costs directly related to those services performed for individual facilities which relate to patient care plus an appropriate share of indirect costs (overhead, rent, administrative salaries, etc.) are allowable to the extent they are reasonable. (See §2150.)*
11. *Prudent Buyer--Facilities are to utilize the prudent buyer concept by refusing to pay more than the going price for an item or service. This is especially so when the buyer is an institution or organization which makes*

bulk purchases and can, therefore, often obtain discounts because of the size of its purchases. (See §2103.)

12. *Dietary--Facilities are not to include the cost of meals served to patients in the outpatient renal department in their reported total costs. However, the reasonable cost of dieticians' salaries is reimbursable under the program.*

- *Cost Report Review--The intermediary performs a limited review of the cost reports prior to submitting to CMS.*

  1. The intermediary reviews all the cost reporting forms and information submitted in accordance with CMS Pub.15-II to ensure that all the applicable items have been properly completed. All cost reporting forms must be completed. Those items not applicable are submitted and annotated as N/A (not applicable).

  2. The intermediary identifies changes in the CPT, lists the requested CPT by modality (i.e., hemodialysis, peritoneal dialysis, and home program),and compares this data with the CPT in the most current cost report. Then, the intermediary determines whether the facility has adequately explained any variances in its narrative documentation.

  3. The intermediary performs a clerical review by cross footing cost item columns.

  - *Submission of Documentation--The intermediary submits the exception request, a preliminary recommendation, including appropriate workpapers and the reason for the decision, and the cost report and supporting documentation to the following address:*

    Centers for Medicare and Medicaid Services

    Centers for Medicare Management

    Chronic Care Policy Group

    Division of Chronic Care Management

    7500 Security Boulevard

    Baltimore, Maryland 21244-1850

    To provide that all filings by the provider are handled by the intermediary, the intermediary instructs the provider to:

    - *Mail all exceptions separately from any other material, e.g., Medicare cost reports that are not related to exception requests, and*
    - *Use specially marked envelopes to forward the exception to the intermediary.*

40.7 Payment exception: Pediatric patient mix.

(Rev.781, Issued: 12-16-05, Effective: 01-01-06, Implementation: 01-17-06)

A. General.

An exception to the composite payment rate for pediatric patient mix is allowed under specific circumstances. This exception is limited to those situations where the facility can demonstrate that it expects to incur higher than average per treatment costs which are directly related to at least 50 percent of its patients (individuals under 18 years of age), and because of their complex medical needs require more intense care, special dialysis procedures or supplies during an outpatient maintenance dialysis session.

B. Criteria.

To qualify for an exception to its prospective payment rate based on its pediatric patient mix a facility must demonstrate the following--

(1) The provider must document that for the most recently completed and filed cost reporting year that at least 50 percent of its dialysis outpatients (including home patients) are individuals under 18 years of age;

(2) The provider must submit data which demonstrates that its pediatric patients will receive significantly more nursing (refers to RNs, LPNs, technicians and aides) hours per treatment than patients receive in other facilities. The increased hours of nursing service must be justified by data that demonstrate that the higher hours per treatment and thus the higher per treatment costs are necessitated by the special needs of the pediatric patients.

(3) Data must be submitted that show that higher staff-to-patient ratios represent nursing assessment/intervention based upon the pediatric patient acuity levels. The provider must demonstrate that its nursing personnel costs are allocated properly between each mode of care and that the additional nursing hours per treatment are not the result of an excess number of employees in the outpatient maintenance renal area, compared to facilities treating a similar patient mix ;

(4) The provider must also show that excess supply cost per treatment is related to the special needs of the pediatric patients and not the result of inefficiency. CMS uses, as a guideline, manufacturer and supplier price lists, and cost reporting information from other facilities.

(5) There are infrequent instances when higher overhead costs may be justifiable, such as when an isolated area is required for a hepatitis patient. General statements regarding a facility's higher overhead costs are not acceptable in meeting the criteria.

(6) A listing of patients by diagnosis and general statements submitted regarding the medical conditions of a facility's pediatric patient population without showing the adverse effects of patient mix on facility costs are unacceptable in meeting this exception criteria. Therefore, documentation that does not identify both the specific additional items and/or services to be rendered which are in addition to a routine dialysis service and the incremental costs of these items and/or services do not qualify for an exception under this section. Also, a one-month time sampling is not sufficient documentation to verify the acuity of a facility's ESRD patient population nor to justify increased salary costs. In the event that a time study is used, the general Medicare principles regarding the adequacy of periodic time sampling as described in §2313 must be followed.

C.Documentation.

(1) A pediatric ESRD facility must submit a listing of all outpatient dialysis patients (including all home patients) treated during the most recently completed and filed cost report showing--

(i) Age of patients and percentage of patients under the age of 18;

(ii) Individual patient diagnosis;

(iii) Home patients and ages;

(iv) In-facility patients, staff-assisted, or self-dialysis;

(v) Diabetic patients; and

(vi) Patients isolated because of contagious disease.

(2) The facility also must-

(i) Submit documentation on costs of nursing personnel (registered nurses, licensed practical nurses, technicians, and aides) incurred during the most recently completed and filed fiscal year cost report showing-

(A) Amount each employee was paid;

(B) Number of personnel;

(C) Amount of time spent in the dialysis unit; and

(D) Staff-to-patient ratio based on total hours, with an analysis of productive and nonproductive hours.

(ii) Submit documentation on supply costs incurred during the most recently completed fiscal or calendar year cost report showing-

(A) By modality, a complete list of supplies used routinely in a dialysis treatment;

(B) The make and model number of each dialyzer and its component cost; and

(C That supplies are prudently purchased (for example, that bulk discounts are used when available).

(iii) Submit documentation on overhead costs incurred during the most recently completed fiscal or calendar year cost reporting year showing:

(A)The basis of the higher overhead costs;

(B) The impact on the specific cost components; and

(C) The effect on per treatment costs.

40.8 Payment Exception: Self-dialysis Training Costs in Pediatric Facilities.

(Rev.781, Issued: 12-16-05, Effective: 01-01-06, Implementation: 01-17-06)

A – General.

Self dialysis and home dialysis training are programs that train ESRD patients to perform self dialysis in the facility or home dialysis (including CAPD and CCPD) with little or no professional assistance. They also train other individuals to assist patients in performing self dialysis or home dialysis. A facility that has training costs greater than its composite training rate may apply for an exception to its training rate. However, the burden of proof is on the facility and it is responsible to demonstrate to CMS that its per treatment

costs are reasonable and allowable. Further, the facility must train an average of three patients over a two year period (if 2 years are available.

B . Criteria.

To qualify for an exception to the prospective payment rate based on self-dialysis training costs, the pediatric ESRD facility must establish that it incurs per treatment costs for furnishing self-dialysis and home dialysis training that exceed the facility's payment rate for the training sessions.

To justify its exception request, a facility must--

(1) Separately identify those elements contributing to its costs in excess of the composite training rate; and

(2) Demonstrate that its per treatment costs are reasonable and allowable.

C.Criteria for determining proper cost reporting. *CMS considers the pediatric ESRD facility's total costs, cost finding and apportionment, including its allocation of costs, to determine if costs are properly reported by treatment modality. Under the composite rate, the cost of the home program is reimbursed at the same rate as infacility dialysis. Therefore, it is important that the pediatric ESRD facility keep its home program and home dialysis training cost separated.*

D - Limitation of exception requests. *Exception requests for a higher training rate are limited to those cost components relating to training such as technical staff, medical supplies, and the special costs of education (manuals and education materials). These requests may include overhead and other indirect costs to the extent that these costs are directly attributable to the additional training costs.*

E - Documentation. *The pediatric ESRD facility must provide the following information to support its exception request:*

(1) A copy of the facility's training manual and training program. The training manual must be submitted with the first training request. Thereafter, the facility submits only the changes to the training manual. The training program must be submitted with each training request.

(2) Computation of the facility's cost per treatment for maintenance sessions and training sessions including an explanation of the cost difference between the two modalities.

(3) Class size and patients' training schedules.

(4) Number of training sessions required, by treatment modality, to train patients and the length of time required for each session.

(5) List of patients trained for the current year and the prior 2 years (except for a newly certified provider which submits only 12 months of data) on a monthly basis by modality, number of treatments, completed training, retrained or cross-trained. The number of training treatments must reconcile with the number of training treatments reported on the latest completed and filed cost report.

(6) Projection for the next 12 months of future training candidates and the number of training sessions required by treatment modality to train them and the length of time for each session.

(7) The number and qualifications of staff at training sessions and the rationale in allocating staff time to home training, home support and other duties.

(8) Supplies – A higher composite training rate is granted if the ESRD pediatric facility is able to document that its cost in excess of the composite training rate is attributable to supplies required to train patients. For example, an ESRD pediatric facility may incur higher supply costs to train its patients because of wastage. To justify supply cost, the facility must submit the following information:

- *A list of supplies used during a training and maintenance dialysis session;*
- *A cost per treatment computation for supplies listed above;*
- *An explanation of any difference in cost and type of supplies between maintenance and training dialysis session; and*
- *A comparison and projection of the five most expensive supply costs with the catalog list price or notification of higher charges by its suppliers.*

(9) Special education costs – An ESRD pediatric facility which incurs costs in excess of its composite training rate and which are attributable to educational materials or equipment used to train patients, may be granted an increase to its composite training rate. For cost in excess of the composite training rate to be reimbursed, the ESRD facility needs to document its cost per treatment for these special education items and it projected costs. To justify its request for exception, a facility needs to provide the following information:

- *A description of the educational item;*
- *Its costs (number purchased and unit cost);*
- *Its useful life, if it is reusable; and*
- *A projection of training sessions and patients to be trained.*

F - Accelerated training exception. *(1) A pediatric ESRD facility may only bill Medicare for a dialysis training session when a patient receives a dialysis treatment (normally three times a week for hemodialysis). If a pediatric ESRD facility elects to train all its patients using a particular treatment modality more often than during each dialysis treatment and, as a result, the number of billable training dialysis sessions is less than the number of actual training sessions, the facility may request a composite rate exception, limited to the lesser of the--*

(i) Facility's projected training cost per treatment; or

(ii) Cost per treatment the facility receives in training a patient if it had trained patients only during a dialysis treatment, that is, three times per week.

(2) Continuous cycling peritoneal dialysis (CCPD) and continuous ambulatory peritoneal dialysis (CAPD) are daily treatment modalities, and ESRD facilities are paid the equivalent of three hemodialysis treatments for each week that CCPD and CAPD treatments are provided. An ESRD facility may bill a maximum of 25 training sessions per patient for hemodialysis training and 15 sessions for CCPD and CAPD training. In computing the payment amount under an accelerated training exception, CMS uses a minimum number of training sessions per patient (15 for hemodialysis and 5 for CAPD and CCPD) when the facility actually provides fewer than the minimum number of training sessions.

(3) To justify an accelerated training exception request, an ESRD facility must document that a significant number of training sessions for a particular modality are provided during a shorter but more condensed period. The facility must submit with the

exception request a list of patients, by modality, trained during the most recently completed and filed cost report. The list must include each beneficiary's--

(i) Name;

(ii) Age; and

(iii) Training status (completed, not completed, being retrained, or in the process of being trained).

The total treatments from the above patient list must be the same as the total treatments reported on the cost report filed with the request. Further, retraining sessions are not considered in determining the minimum number of training sessions because retraining sessions are only for patients that have previously been trained and are completed in one or two days.