PROVIDER REIMBURSEMENT REVIEW BOARD
HEARING DECISION

ON-THE-RECORD
99-D52

PROVIDER -
Lutheran Community Hospital

Provider No. 28-0034

vs.

INTERMEDIARY -
Blue Cross and Blue Shield of Nebraska

DATE OF HEARING-
April 27, 1999

Cost Reporting Period Ended -
February 28, 1995

CASE NO. 94-2925

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ISSUE:

Was the Intermediary's disallowance of the Provider's excess dialysis costs, based upon the Health Care Financing Administration ("HCFA's") denial of the Provider's exception request, correct?

STATEMENT OF THE CASE AND PROCEDURAL HISTORY:

Lutheran Community Hospital ("Provider") is an 85 bed general acute care hospital located in Norfolk, Nebraska. The primary service area is Madison county and portions of Stanton, Pierce and Wayne counties as well. The secondary service area includes the balance of the three counties noted above, as well as all or part of 10 additional counties. Thus, the area served by the End Stage Renal Dialysis **("**ESRD") facility at the Provider encompasses the foregoing area, and extends more than 100 miles to the west. The Provider operates a six station renal dialysis center offering only maintenance dialysis services. While there are small community hospitals in the region, there is only one other acute care facility, and the nearest ESRD facility is located 60 miles north of Norfolk at Yankton, South Dakota.

On January 21, 1994, the Provider made a formal request to the Intermediary for an exception to the ESRD composite rate from $ 121.17 to $ 155.87.[1] The Intermediary reviewed the request and recommended a rate of $ 147.26 in a letter to HCFA dated February 16, 1994.[2] On April 18, 1994, HCFA denied the Provider's exception request, stating that the Provider should continue to be reimbursed at the composite rate of $ 121.17, as it did not meet the requirements set forth in HCFA Pub. 15-1 Section 2725.3.[3] On May 18, 1994, the Provider appealed HCFA's denial to the Provider Reimbursement Review Board ("Board") pursuant to 42 C.F.R. § 405. 1835-.1841, and has met the jurisdictional requirements of those regulations.[4] The estimated amount in dispute is $ 97,056.

The Provider was represented by H. Daniel Smith, Esq., of Dwyer, Smith, Grimm, Gardner, Lazer, Pohren & Rogers, Attorneys At Law. The Intermediary was represented by Bernard M. Talbert, Esq., of the Blue Cross and Blue Shield Association.

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1 See Provider Exhibit 1.

2 See Provider Exhibit 2.

3 See Intermediary Exhibit AA.

4 See Provider Exhibit 4.

Statutory and Regulatory Background:

The Medicare program prospectively reimburses hospital based ESRD facilities on a cost per treatment basis for outpatient maintenance dialysis according to composite payment rates established by the Secretary of the Department of Health and Human Services ("Secretary"). The Medicare statute and regulations require the Secretary to reimburse dialysis facilities at a higher rate if that facility experiences unusual circumstances which meet certain criteria prescribed by the regulations. See 42 U.S.C. § 1395rr(b)(7). Under the statute and regulations a provider of such services may request an exception to its rates from HCFA if, based on prior years' costs and utilization trends, it determines it will incur additional costs meeting established criteria. (42 U.S.C. § 1395rr(b)(7) and 42 C.F.R. § 413.170 et seq). The Medicare statute and regulations also require the Secretary to reimburse dialysis facilities that are "isolated" and thus "essential" to their patients at a higher rate if that facility satisfies the standard for such classification. Id.

HCFA administers the ESRD reimbursement methodology and has promulgated regulations defining the circumstances in which it will grant exceptions requests. See 42 C.F.R. §§ 413.170, 413.174, and HCFA Pub. 15-1 § 2720 et seq. The regulations and manual instructions create a two-part standard for approval of such requests. This standard requires the facility to demonstrate by convincing objective evidence that its per treatment costs in excess of the established composite rate are directly attributable to one of the listed factors, which include a provider's qualification as an "isolated and essential facility" ("IEF"). 42 C.F.R. §§ 413.170(g) and 413.170 (f)(6)(ii) and subsection (iii). Further, the facility requesting the exception has the burden of proof. Id at subsections (f)(5) and (g).

PROVIDER'S CONTENTIONS:

The Provider contends it has provided considerable documentation to the Intermediary, and supplemented that with a consultant's report,[5] which refined its prior submission.

The Provider contends its higher cost per treatment has two main components: 1. higher cost for nursing salaries, and 2. higher supply costs caused by the isolation of the facility. To establish a distinction based upon isolation, the Provider developed a comparison between itself and the Bishop Clarkson Memorial Hospital ("Clarkson") in Omaha, a non-isolated facility. Clarkson operates several end stage renal disease outpatient hemodialysis facilities. As such, it reports to HCFA in the same manner as the Provider. Accordingly, the Provider's analysis relies upon a comparison to the Clarkson outpatient renal dialysis operations.

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[5] Provider Exhibit 6

The various component costs are compared as follows:

SALARIES:

The Provider's Director of Nursing indicated that her job responsibilities include interviewing prospective nurses for the dialysis unit. In order to obtain and retain dialysis nurses at the Provider the average hourly rate (as verified by the cost report) was $ 17.43 per hour.[6] At the Clarkson center, the renal dialysis nurses are paid $ 14.84 per hour. Due to its isolation, the Provider must staff for peak demand and usually guarantees full time status to its nurses. Thus, its' staff to patient ratio is somewhat higher when compared to other facilities.

SUPPLY COSTS:

1. General Dialysis Supplies - For general hospital supplies, the Provider purchases through a buying group, the VHA. While a discount of between 15% and 30% is given on general supplies, the VHA does not deal in renal dialysis supplies. This forces the Provider to deal directly with outside manufacturers or distributors. Due to its relatively low volume of procedures, the Provider can not take advantage of volume discounts. The Provider contends that it paid
$ 11,820 more in dialysis specific supplies by not realizing low volume discounts.[7]

2. Dialyzer Costs - The Provider purchases its dialyzers at $ 18.36 each.[8] By contrast, the Clarkson facility realizes a cost per dialyzer of $ 7.47 due to its ability to reprocess the used dialyzers. The Provider, as an isolated facility, cannot justify the equipment necessary for a hemodialyzer reuse program, due to its low volume.

The Provider concludes that, based on its demonstrated higher cost per treatment, its request for the composite rate exception request should be granted.

INTERMEDIARY'S CONTENTIONS:

The Intermediary contends that the Provider is not entitled to a composite rate increase because it failed to relate its IEF status to its excess per treatment costs over the established ESRD composite rate. The Intermediary asserts that the Provider is required to submit documentation supporting its exception request according to the requirements in HCFA Pub. 15-1 § 2725.4(f), redesignated as § 2725.3 August 1993).

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6 Exhibit A of Provider Exhibit 6.

7 Provider Exhibit 6, page 2.

8 Exhibit E of Provider Exhibit 6.

The Intermediary asserts that while the Provider has established that it is isolated, it has failed to prove that the higher costs were attributable to its isolation. In its denial letter, HCFA asserts that other than general statements concerning its higher costs, the Provider did not furnish any documentation supporting the incremental costs relating to the IEF criteria. HCFA goes on to state that under the IEF criteria (HCF Pub. 15-1 § 2725.3), a renal facility must identify the incremental costs in excess of its composite rate payment which are attributable to the IEF criteria.

In further support of its position, the Intermediary cites the HCFA Administrator's Decision in the case of St. James Mercy Hospital v. Blue Cross and Blue Shield Association/Empire Blue Cross and Blue Shield, PRRB Dec. No. 92-D65, September 22, 1992, Medicare & Medicaid Guide (CCH) ¶ 40,859, revd. HCFA Administrator, November 17, 1992, Medicare & Medicaid Guide (CCH) ¶ 41,045. In that case, the Administrator found that the facility had not adequately related its costs to the "isolated and essential" exception criteria. The Provider failed to submit documentation supporting the significant variance between the projected and prior costs.

Additionally, the Intermediary cites the PRRB decision involving this Provider's prior year Medicare cost report. See Lutheran Community Hospital (Norfolk, Neb.) v. Blue Cross and Blue Shield Association/Blue Cross And Blue Shield of Nebraska, PRRB Dec. No. 96-D72, Medicare & Medicaid Guide (CCH) ¶ 44,704, declined rev. HCFA Administrator, November 8, 1996. In that case, the Provider failed to link its excess per-treatment costs to its isolated condition.

In summary, the Intermediary contends that, while the Provider has demonstrated that it is an IEF, and its per treatment costs were high, it has failed to establish the required linkage between the two. The record does not demonstrate that the higher costs are attributable to the IEF criteria. Based on the above, the Intermediary contends that the Board should uphold HCFA's denial of the exception request.

CITATION OF LAW, REGULATIONS, AND PROGRAM INSTRUCTIONS:

1. Law - 42 U.S.C.:

§ 1395rr(b)(7)	-	End Stage Renal Disease Program

2. Regulations - 42 C.F.R.:

§ 405.1835-.1841	-	Board Jurisdiction

§ 413.170 et seq.	-	Payments for covered outpatient maintenance dialysis treatments.
§ 413.174	-	Record keeping and cost reporting requirements for outpatient maintenance dialysis

3. Program Instructions - Provider Reimbursement Manual, Part 1 HCFA Pub. 15-1):

§ 2720 et seq.	-	General Instructions for Processing an Exception
§ 2725.4et seq. (Redesignated as § 2725.3)	-	Isolated Essential Facility

4. Cases:

St. James Mercy Hospital v. Blue Cross and Blue Shield Association/Empire Blue Cross and Blue Shield, PRRB Dec. No. 92-D65, September 22, 1992, Medicare & Medicaid Guide (CCH), ¶ 40,859, rev'd.HCFA Administrator, November 17, 1992.

Lutheran Community Hospital (Norfolk , NE) v. Blue Cross and Blue Shield Association/Blue Cross and Blue Shield of Nebraska, PRRB Dec. No. 96-D72, Medicare & Medicaid Guide (CCH) ¶ 44,704, declined rev.HCFA Administrator, November 8, 1996.

FINDINGS OF FACT, CONCLUSIONS OF LAW AND DISCUSSION:

The Board, after consideration of the facts, parties contentions, and evidence presented, finds and concludes as follows:

The Board finds that the Provider is an isolated and essential ("IEF") facility as described in the regulations at 42 C.F.R § 413.170. This is consistent with the position taken by both HCFA and the Intermediary. The Board finds, however, that mere designation as an IEF is not the sole criteria for an exception to the composite payment rate. The Board finds that the Provider failed to link its excess costs over the ESRD composite rate to its isolation, as

required by 42 C.F.R. § 413.170 et seq. The Board notes that the Provider has the burden of proof with respect to showing conclusively that it is entitled to an exception to the established composite payment rate.

The Board concludes that the Provider's exception request was lacking in several areas. Specifically, the information relating to staffing and supply costs was only found to be general in nature and was based primarily on the aspect of low utilization. HCFA Pub. 15-1 § 2725.3 recognizes that one factor contributing to an IEF's high per treatment costs is a low number of treatments. The Manual specifies that facilities must address this issue in terms of projected demands for service; the Provider must also justify its projections. Furthermore, the facility must document the specific directives initiated by management to control current expenditures due to patient fluctuations. Included in the documentation should be management planned objectives that will be implemented in order for the facility to operate in a more efficient and economical manner. The Board finds insufficient evidence in the record to support the Provider's position.

The Board notes that the Provider cited the cost of the drug Epogen as the primary reason for the increase in its supply costs. In its analysis of the Provider's exception request, HCFA pointed out that Epogen is a separately billable drug that is not included in the composite rate and is therefore not considered a basis for the granting of an exception.

The Board also notes that an undated, expert witness report was submitted as Exhibit 6 to the Provider's position paper. There is no evidence to indicate that this report was a part of the Provider's original exception request. The regulations at 42 C.F.R. 413.170 et seq. state that: [t]he facility may not submit to the intermediary or the PRRB any additional information or cost data that were not submitted to HCFA at the time the facility requested an exception to its prospective payment rate. Therefore, the Board finds that the expert witness report is untimely and is not to be considered as evidence.

The Board finds that there is not enough evidence in sufficient detail to support the Provider's request for an exception. The Board concludes that HCFA's analysis of the Provider's's request for an exception was appropriate and a reasonable interpretation of the regulations and associated Manual instructions.

DECISION AND ORDER:

HCFA's denial of the Provider's ESRD exception request is affirmed.

Board Members Participating:

Irvin W. Kues
James G. Sleep
Henry C. Wessman, Esq.
Martin W. Hoover, Esq.
Charles R. Barker

Date of Decision: June 17, 1999

FOR THE BOARD:

Irvin W. Kues
Chairman