PROVIDER REIMBURSEMENT REVIEW BOARD
HEARING DECISION

2001-D8

PROVIDER -
Geneva General Hospital
Geneva, New York

Provider No. 33-0058

vs.

INTERMEDIARY -
Empire Blue Cross Blue Shield/ Blue Cross Blue Shield Association

DATE OF HEARING-
January 11, 2000 and
June 14, 2000

Cost Reporting Period Ended -
December 31, 1994

CASE NO. 94-3107

INDEX

ISSUE:

Was HCFA's denial of the Provider's ESRD composite payment rate exception proper?

STATEMENT OF THE CASE AND PROCEDURAL HISTORY:

Geneva General Hospital ("Provider") is a 138 bed acute care hospital with three related skilled nursing units. It is located in Geneva, New York, which is in Ontario County, at the extreme east side bounding Seneca County, and is on the border of the Rochester MSA. It is approximately 50 miles outside of the Rochester, NY area. Seneca County is outside of an MSA and is, therefore considered a rural county. The Provider is less than one mile from the Seneca County border.

The Provider operates 10 medical/surgical beds, an emergency room, SNF, and outpatient services at its location in Waterloo in Seneca County. The Provider has been operating a renal dialysis unit since 1990.

The wage index for the Rochester MSA was .9761. The average wage index for New York State MSAs was .9950, with a range of .7688 to 1.4020. The Rochester index was below the statewide MSA average and was only 114% of the rural New York wage index (.8660). The closest ESRD facility is in Ithaca, located 38 miles away, and the other facilities are an average 50 miles (from 45 to 70 miles) away.

The Provider requested and filed an exception on April 20, 1994 to its End-Stage Renal Disease (ESRD) composite rate. The filing was based on criteria as an Isolated Essential Facility (IEF). HCFA denied the Provider's request for an exception and the Provider appealed to the Provider Reimbursement Review Board ("Board") pursuant to 42 C.F.R. '' 405.1835-.1841 and 42 C.F.R. '413.170, and has met the jurisdictional requirements of those regulations. The Medicare reimbursement amount in contention is approximately $295,800.

The Provider was represented by Ron Rybar of the Rybar Group. The Intermediary was represented by Eileen Bradley of the Blue Cross and Blue Shield Association, Chicago.

PROVIDER'S CONTENTIONS:

The Provider points out that it treated a total of 70 ESRD patients for fiscal year ended December 31, 1992, including 61 maintenance hemodialysis patients, and provided 7,124 hemodialysis treatments for this period.

The Provider contends that its patients travel an average of 15 miles to their facility with a range of one to fifty miles. Even though the Ithaca dialysis facility is the closest facility at 38 miles away, it cannot realistically be viewed as an alternative care center, since at the most they only had five openings available from March 1994 through March 1998. Of the 12 ESRD facilities in the Provider's area, open stations available ranged from 0 to 38 with approximately 14 available on average.

The Provider argues that it is an Essential Isolated Facility because the patients who utilize it for their dialysis treatments do not have access to other facilities due to shortage of openings, lack of public transportation, and other scheduling hardships on their families due to the average age and acuity of the patients served. The only means of transportation in this area are: Commission on Aging, Department of Social Services, Relatives, Self, Self pay(Taxi), and Ambulance. Population statistics also indicate the need to provide dialysis services in this locality.[1]

The Provider contends that it met the criteria of essential as defined in Chapter 27 section 2725 et seq. of HCFA Pub. 15-1. That section states in part:

> To document that it is essential, the facility must establish that a substantial number of its patients cannot obtain dialysis services elsewhere without additional hardship. Generally, the additional hardship incurred by ESRD patients are travel, time, and costs. However, other factors may be considered in determining if a facility is essential. The ESRD facility must document the additional hardship its patients will incur.

The Provider points out that the closest facility is reached via a two lane road and is 38 miles away. Even though the road has not been closed in winter, a significant hardship would be met by any of the patients who had to travel it to be dialyzed. At least 13 of the Provider's patients would have to travel 37 more miles each way for each dialysis session.

The Provider points out that stations in Victor, Pittsford and 12 in Rochester did not exist in 1992. Pittsford was not in existence until 1995 and Victor came on line in 1998. As such there was between a 95 and 105 mile distance along Interstate 90 without renal services if the Provider were not there. Even now, there would be an 80-90 mile stretch without renal services, if the Provider was not at its present location.

The Provider also points out that the 12 patients located at the Provider are at least 38 miles further away from the next closest dialysis facility, assuming that Ithaca could take all of them. The Provider argues that the commute, drive time, etc. would cause a tremendous increased hardship. The Provider argues that it treated patients whose ages ranged from 20 to 93. These statistics demonstrate that the patient population was somewhat fragile, and why an undue hardship to the patients would result if the Provider did not exist.

The Provider maintains that the average age of its patients is 66.5 years of age. Of those 42.6% are diabetic and uncertain alternative available services indicates hardship. 21 of the patients are 75 years or older. 3 patients are over 80 and would have to travel from Geneva to Ithaca, an increase of 38 miles each way.

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[1] See Exhibit P-4.

The Provider contends that due to geographic isolation from large population bases, it incurs additional costs arising from under-utilization and scheduling. The Provider serves a 70 ESRD patient market share in its service area. It averages enough patients to keep its 12 station unit in operation with 2 full shifts daily for 3 days, and 3 shifts for 3 days a week. However, there is not enough critical mass of patients to run at optimal efficiency, with a shift being defined as the time a patient spends receiving their dialysis treatment. This is approximately 4-6 hours. Whenever an unexpected or emergent patient condition requires treatment, the Provider operates an entire late shift for only that patient. Due to the specialization of treatment and response time, the patient cannot be referred to another unit or scheduled in an existing shift.

The Provider contends that it met the definition of "Isolated" as set out in Chapter 27 section 2725et seq. of the HCFA Pub. 15-1 which defines isolated as:

> "(g)enerally, to be considered isolated, the facility must be located outside an established metropolitan statistical area (MSA) and must provide dialysis to a permanent patient population, as opposed to a transient patient population. HCFA has not imposed a standard mileage criterion for defining an isolated facility since commuting time and demand for dialysis services vary."

The Provider points out that its main campus is located within one mile of the border of the Rochester, New York MSA. A portion of its campus (ten inpatient beds) is located in Seneca County (a rural non-MSA). The surrounding area is rural in nature with low levels of non-agricultural industry. A large portion of the commerce comes from the working farms in the area. There is no public transit system in Geneva. A portion of the town of Geneva is in rural Seneca County. Thirteen of the Provider=s patients out of 61 live within one mile, twelve live between one and ten miles, twenty nine live between eleven and 25 miles and seven live more than twenty five miles away.

The Provider contends that there is no backup or detail to the HCFA assertion regarding number of stations. The actual increase in stations came about much slower and in fewer numbers than the projections. Although HCFA argues that other providers could handle only 52 of 61 of the 1992 patient count, there is no accounting for the other 9 patients in 1992 and growth of patient demand in the future. Future patient demand growth is not addressed anywhere in HCFA's station projection analysis. The Provider contends that it shows that even with the projected increase in available stations, there were between 23 and 61 patients who would not have stations up through December of 1999.[2]

The Provider points out that because it is an isolated facility it is projected to operate at 72% capacity. Most of its patients are dialyzed 3 times per week, although statistically its average is projected at 2.2

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[2] See Exhibit P-1

(8,080/70 Patients/52 weeks) based on an historical average. Using this projection, reasonableness and justification of costs can be calculated as follows:

Projected patients	x	Maximum treatments	x	Composite rate	
70	x	3x52	x	$127.75 =	$1,395,030

Maximum limit exception amount $1,395,030/8080 = $172.65

Therefore, the projected exception limit equals $172.65(Limit per treatment), while the current composite rate is $127.75 (payment per treatment), and the difference which is the exception amount requested is $44.90 (Exception per treatment).

The Provider maintains that it employs 9 registered nurses (RNs) as its primary care givers, rather than licensed practical Nurses (LPNs). This is required by the New York State Department of Health Regulation. The nature of care requires a higher level of medical knowledge and skill. LPNs are not generally trained for in-hospital acute treatments, not allowed to administer blood products, and are not active participants in emergency care. The salary cost of RNs is $31.68 per treatment. With a minimum of 4 hours per treatment, the maximum cost per hour of treatment is projected at $7.92. Staff-per-patient ratio has historically been 2-3 patients per staff. This is expected to remain the same. The Provider also employs 5 LPNs to monitor patient's vital signs and other less intensive nursing duties. Use of LPNs where possible demonstrates that the Provider is prudent managing cost per treatment. The projected cost per treatment for LPNs is $12.40 per treatment or $3.10 per hour of treatment.

The Provider points out that the total direct patient care salaries and benefits per treatment are projected at $77.86 or 44% of the total cost per treatment of $177.76. Included in this amount is the additional cost for arranging transportation. Because of the number of patients who travel a long distance to the facility, transportation arrangements must be made to ensure their access to the hemodialysis services. The Provider employs one FTE to coordinate transportation arrangements. The Provider does not incur any direct transportation cost but does incur the coordinator cost of approximately $28,000. This relates to $2.72 per treatment.

The Provider contends that it is very cost conscious with respect to the purchase of supplies. For general or non-renal specific supplies, purchases are made through Rochester Regional Hospital Association (RRHA) of which the Provider is a member. RRHA is a large group of hospitals which negotiates with suppliers as a large group in order to secure lower prices on supplies. When the RRHA does not have access to the unique supplies required for renal dialysis, it puts the product out for bids. Total supply and drug costs per treatment is projected at $45.32 or 25% of the total cost per treatment.

The Provider points out that its administrative and general costs are $25.89 per treatment and represent 15% of the total cost of treatment. Capital costs including building and equipment are $20.23 or 11% of the total treatment cost. There are 16 machines and 12 stations. The remaining 4 are for use when a machine is being repaired or having routine maintenance done. Maintenance, repairs and other costs per

treatment are $7.95 or 4.5% of total cost. Overall, total volume in the unit was projected to increase from 7,124 in 1992 to 8,080 in 1994. This is an increase of 13.4%.

The Provider contends that if it did not provide dialysis service, 79% of current dialysis patients that travel 20 miles or less would be forced to seek dialysis in outlying facilities. Since most outlying facilities do not have many openings, an emergency situation could be created for many patients. Given the unlikely scenario that the Provider's patients could receive dialysis at the nearest available facility (Ithaca 38 miles, Rochester 45 miles, Syracuse 55 miles), additional travel costs and major inconvenience for elderly patients is clearly evident.

The Provider contends that the Intermediary did not disprove the fact that there were not sufficient open stations to care for its patients. The Intermediary relied on an unsubstantiated 1994 projection, which upon review, shows to have overestimated the actual station growth. The station counts used to demonstrate availability were not in place until 1995 or later.

INTERMEDIARY'S CONTENTIONS:

The Intermediary contends that the Provider has not complied with the instructions in HCFA Pub. 15-1 ' 2723 et seq which explain the requirements to receive an exception to its composite rate for an Isolated Essential Facility (IEF). The Intermediary points out that the Provider is not an IEF.

The Intermediary contends that the Provider is located in the Rochester MSA geographic area. In HCFA's denial of the Provider's exception request, it was pointed out that based on the Provider's analysis there are 24 openings in the surrounding area. Additionally, HCFA maintains that an additional 41 stations will be opening, and 21 of these stations were to be opened in 1994. The Provider is not an isolated facility in relation to the location of other facilities.

The Intermediary points out that HCFA Pub. 15-1 ' 2725 et seq states in part:

"The term "isolated" refers to the geographical location of the ESRD facility requesting the rate increase in relation to other ESRD facilities. Generally, to be considered isolated, the facility must be located outside an established Metropolitan Statistical Area (MSA)."

The Intermediary contends that in the Moses Taylor Hospital v. Blue Cross and Blue Shield Association /Blue Cross and Blue Shield of Western Pennsylvania, PRRB Dec. No. 93-D47, June 17, 1993 - Medicare & Medicaid Guide (CCH) & 41,572, HCFA Adm. Dec. August 11, 1993, Medicare & Medicaid Guide (CCH) & 41,689, the Provider requested an exception to its ESRD composite rate as an IEF. The PRRB ruled in favor of the provider. The provider was located in a MSA geographic area. There were other facilities located in the same MSA geographic area. There were four facilities located approximately 19, 42 and 52 miles respectively, from the provider's facility. The HCFA Administrator ruled that the provider was not isolated and reversed the PRRB decision, in favor of the intermediary.

The Intermediary asserts that the location of the Provider is not essential for access to care for its ESRD beneficiaries. HCFA Pub. 15-1 '2725 et seq states in part:

> The term "essential" refers to access to care for ESRD beneficiaries. To document that it is essential the facility must establish that a substantial number of its patients cannot obtain dialysis services elsewhere without additional hardship. Generally, the additional hardship incurred by ESRD patients will be travel time and costs. However, other relevant factors may be considered in determining if a facility is essential. The ESRD facility must demonstrate the additional hardship its patients will incur.

The Intermediary maintains that based on an analysis by the Provider showing the location of other facilities and the location of its patients homes, the average travel distance for the Provider's 61 ESRD patients would be 21.6 additional miles. The Intermediary contends that the foregoing contradicts the Provider's argument that its patients have to travel 45 to 70 miles to other facilities.

The Intermediary points out that the Provider states that the nearest facility in Ithaca, New York is 38 miles away. The Provider asserts that its patients would incur hazardous road conditions between its facility and Ithaca. In HCFA's denial, HCFA notes that the Provider has not submitted information to support its argument of hazardous road conditions. The Intermediary points out that the Provider did not indicate the amount of snowfall, the number of days the highway was closed due to weather conditions, or the number of patients that missed dialysis treatments due to weather conditions.

The Intermediary argues that the Provider's contention that its patients do not have access to other facilities due to a shortage of openings is not factual. The Intermediary maintains that there is no shortage of openings in the geographic area. The Intermediary points out that there are 24 openings and an additional 41 openings are anticipated for the surrounding area. The Intermediary contends that in the near future, there will be enough openings to service most of the Provider's ESRD patients. Therefore, the Intermediary contends that the Provider does not meet the essential hardship criteria for an IEF exception request to its present ESRD composite rate.

The Intermediary contends that the Provider's reasonable cost analysis is not applicable. The Provider has not met the elements of HCFA Pub. 15-1 '2725 et seq. The elements are:

1. The facility is isolated.
2. It is essential for access to care for ESRD beneficiaries.
3. Its costs in excess of the composite rate are attributable to items 1 and 2.

The Intermediary contends that the Provider has not demonstrated to HCFA that elements 1 and 2 have been met by the facility. Therefore, element 3 is not applicable in this case.

CITATION OF LAW, REGULATIONS AND PROGRAM INSTRUCTIONS:

1. Regulations 42 C.F.R:

'' 405.1835-.1841	-	Board Jurisdiction
' 413.170 et seq.	-	Payment for End -Stage Renal Disease (ESRD) Services

2. Program Instructions - Provider Reimbursement Manual (HCFA Pub. 15-1):

' 2723 et seq.	-	Responsibilities of Intermediaries
' 2725 et seq.	-	Specific Instructions for adjudicating ESRD Exception request

3. Cases:

Moses Taylor Hospital v. Blue Cross and Blue Shield Association/Blue Cross and Blue Shield of Western Pennsylvania, PRRB Dec. 93-D47, June 17, 1993 Medicare & Medicaid Guide (CCH) &41,572, HCFA Adm. Dec. August 11, 1993, Medicare & Medicaid Guide (CCH) & 41,689.

FINDINGS OF FACT, CONCLUSIONS OF LAW AND DISCUSSION:

The Board, after consideration of the controlling laws, regulations and program instructions, facts, parties= contentions, and evidence presented at the hearings, finds and concludes that the Provider is an Isolated Essential Facility (IEF).

The Board finds that the Provider met the regulatory requirements of 42 C.F.R. '413.170 et seq which states in part: AThe facility is the only supplier of dialysis in its geographical area, its patients cannot obtain dialysis services elsewhere without substantial hardship,....@ The Board finds that the Provider also met the HCFA Pub. 15-1 ' 2725 et seq requirements which state in part: AGenerally, to be considered isolated, the facility must be located outside an established Metropolitan Statistical Area (MSA) and must provide dialysis to a permanent patient population,....@ The Board notes that the manual provision uses the word AGenerally,@ which means most of the time but not always.

The Board finds that although the Provider is located within the Rochester MSA, it is on the border of the MSA and the area in that part of the MSA is rural. The Board notes that the regulations make no reference to the MSA criteria which the Intermediary contends requires a provider to be located outside of an MSA to be considered rural.

The Board finds that the Intermediary=s contention that there were 24 openings in the surrounding area and that 21 additional stations will be opened in 1994 is not valid. The Board finds that the openings contended by the Intermediary did not occur until after the end of the Provider=s fiscal year.

The Board finds that the Provider supplied a list of patients and the distances from home to the Provider=s facility. The list describes the ages, and poor health conditions of many of its patients and demonstrated that the patients would undergo substantial hardship if they were to travel a great distance to another facility. Based on the listing the Board finds that the patients would incur additional commuting time and cost if they were required to travel to other facilities. This demonstrates the additional hardship the patients would incur if they were forced to travel to other facilities.

The Board notes the Intermediary=s assertion that the average distance to be traveled by the Provider=s 61 patients would be 21.6 miles. The Board finds that using an average is not appropriate. An average is not appropriate in determining the additional hardship that would be endured by each of the patients. A more appropriate test would be to analyze the extra miles each patient would incur.

The Board notes the Intermediary=s contention that the Provider did not submit information to support it=s argument of hazardous road conditions. However, based on the Board=s review of the maps showing the Provider=s location and the nearest facilities, it finds that the roads are rural in nature and may have been hazardous or difficult to drive during the winter months.

Based on the above mentioned findings the Board concludes that the Provider is an Isolated Essential Facility. The Board also notes that even though it is not dealing with the cost at this time, the Intermediary recommended a $45 increase per treatment. The Board further notes that HCFA did not analyze the cost components submitted by the Provider in its exception request.

DECISION AND ORDER:

The Intermediary=s decision denying the Provider=s request to be an Isolated Essential Facility was improper. The Intermediary=s decision is reversed.

Board Members Participating:

Irvin W. Kues
Henry C. Wessman, Esquire
Martin W. Hoover, Jr., Esquire
Charles R. Barker
Stanley J. Sokolove

Date of Decision: January 11, 2001

For the Board

Irvin W. Kues
Chairman