

CENTERS FOR MEDICARE AND MEDICAID SERVICES

Decision of the Administrator

In the case of:

**Mary Imogene Bassett
Hospital--Oneonta
Satellite Dialysis Facility**

Provider

vs.

**Blue Cross Blue Shield
Association/Empire
Medicare Services**

Intermediary

Claim for:

**ESRD Exception Request for
ESRD Period: July 1, 2001**

**Review of:
PRRB Dec. No. 2005-D60
Dated: August 31, 2005**

This case is before the Administrator, Centers for Medicare & Medicaid Services (CMS), for review of the decision of the Provider Reimbursement Review Board (Board). The review is during the 60-day period in §1878(f)(1) of the Social Security Act (Act), as amended (42 USC 1395oo(f)). The parties were notified of the Administrator's intention to review the Board's decision. Comments were received from the Provider and CMS' Center for Medicare Management. Accordingly, this case is now before the Administrator for final agency review.

ISSUE AND BOARD DECISION

The issue is whether the denial of the Provider's request for an exception to the renal dialysis composite rate by the CMS was proper.

The Board, reversing CMS' denial, held that CMS' determination that the Provider is not an isolated essential facility (IEF) was improper. The Board found that the Provider qualified for an IEF exception to the end-stage renal disease (ESRD) composite rate. The Board also found that the Provider's excess costs are justifiable, reasonable, and specifically related to the IEF criteria. The Board noted that although intermediaries require hospital satellite costs be combined with the main renal

program on the Medicare cost report, CMS reviews exception requests for satellites based on segregated data. In addition, CMS evaluates the losses for both the combined hospital program and the satellite, and if losses at the satellite offset gains in the combined program, the satellite will not receive an exception. However, the Board stated that the controlling law, regulation and policy do not explicitly state whether satellite facilities should be compared to the hospital-based facilities for purposes of receiving an exception.

In this case, the Board found it illogical to compare the Hospital facility to the Satellite facility. Rather, the analysis of whether the Satellite facility qualifies for an exception should be based on evaluating the nearest non-related facilities. In this instance, the Board found that the closest facility is 53.7 miles away. Thus, given the rural roads and harsh weather conditions within this geographic area, the Board found that it would be unreasonable for the patients to bear the time and expense to use the facilities on which CMS based its denial.¹

SUMMARY OF COMMENTS

CMM commented, requesting that the Board's decision be reversed. CMM stated that the Provider did not meet all three regulatory tests to qualify for an exception. CMM pointed out that a provider must be isolated or the only supplier or renal dialysis services in its geographical area. However, based on the Provider's geographical area, there are approximately thirteen Medicare certified ESRD facilities at the time the Satellite facility filed its exception request. The Provider failed to provide complete documentation identifying where each nearby dialysis facility is located and whether they can accept patients. Further, CMM stated that a provider must be essential in that a substantial number of its patients cannot obtain renal dialysis services elsewhere without substantial additional hardship. In this case, CMM, citing specific examples, noted that based on its analyses of the traveling distances, some of the Provider's patients can travel shorter distances to another nearby ESRD facility than to the Satellite facility. Finally, CMM argued that since it determined that the Satellite facility did not meet the first two exception conditions under the IEF criteria, CMM did not review the Provider's excess costs to see if they related to the IEF criteria.

¹ The Board also found that even if it were proper to compare the Satellite facility to the Hospital facility, the Satellite would qualify for an IEF exception based on the fact that the Hospital facility was operating at capacity, as well as the existence of the area's rural roadways and severe winter weather.

The Provider submitted comments, requesting affirmation of the Board's decision. The Provider argued that this case is unlike those in which the Administrator has previously modified or reversed. Rather, this appeal concerns the question of whether a facility specifically created to service the needs of an isolated rural population that would not otherwise have access to care should be granted an IEF exception request. The Satellite facility is precisely the type of facility for which the IEF exception was created.²

DISCUSSION

The entire record, which was furnished by the Board, has been examined, including all correspondence, position papers, and exhibits. The Administrator has reviewed the Board's decision. All comments received timely are included in the record and have been considered.

Under section 1881(b) of the Social Security Act and 42 CFR 413.172(b) of the regulations, approved providers of renal dialysis services are reimbursed on a prospective payment basis. Under 42 CFR 413.172(b)(2), “[a]ll approved ESRD facilities must accept the prospective payment rates established by CMS as payment in full for covered outpatient maintenance dialysis.” Consistent with section 1881(b) of the Act, the regulations, at 42 CFR 413.180, also provide for granting of exceptions to these rates.³ Significant to this case, 42 CFR 413.180(g) places on the provider the burden of proving that it qualifies for an exception to the ESRD rate. The section explains that:

The facility must demonstrate to CMS's satisfaction that the requirements of this section and the criteria in §413.182 are fully met. The burden of proof is on the facility to show that one or more of the criteria are met and that the excessive costs are justifiable under the reasonable cost principles set forth in this part.

Generally, the regulations at 42 CFR 413.182 provide the criteria for approval of an exception request, and states that:

² On October 3, 2005, the Provider submitted supplemental comments. Since these comments were not timely received, they have not been considered. However, they have been made a part of the record.

³ See also Chapter 27 of the Provider Reimbursement Manual (PRM).

CMS may approve exceptions to an ESRD facility's prospective payment rate if the facility demonstrates, by convincing objective evidence, that its total per treatment costs are reasonable and allowable under the relevant cost reimbursement principles of part 413 and that its per treatment costs in excess of its payment rate are directly attributable to any of the following criteria:

...

(b) Isolated essential facility, as specified in §413.186....

Relevant to this case, the regulation, at 42 CFR 413.186(a), explains that to qualify for an exception based on being an isolated essential facility:

- (1) The facility must be the only supplier of dialysis in its geographical area;
- (2) The facility's patients must be unable to obtain dialysis services elsewhere without substantial addition hardship; and
- (3) The facility's excess costs must be justifiable.

In addition, the regulation at 42 CFR 413.186(b) and (c) provides the criteria and documentation used for determining qualification:

(b) *Criteria for determination qualification.* In determining whether a facility qualifies for an exception based on its being an isolated essential facility, CMS considers—

- (1) Local, permanent residential population density;
- (2) Typical local commuting distances from medical services;
- (3) Volume of treatments; and
- (4) The extent that other dialysis facilities are used by area residents (other than the applying facility's patients).

(c) *Documentation.* (1) *Isolated.* Generally, to be considered isolated, the facility must document that it is located outside an established Metropolitan Statistical Area and provides dialysis to a permanent patient population, as opposed to a transient patient population.

(2) *Essential*. To be considered essential, the facility must document—

(i) That a substantial number of its patients cannot obtain dialysis services elsewhere without additional hardship; and

(ii) The additional hardship the patients will incur in travel time and cost.

Moreover, the regulation at 42 CFR 413.186 provides that the facility must show that its cost per treatment is reasonable and how its excess cost relates to the isolated essential facility criteria. Finally, the regulation also provides for the additional documentation needed to qualify under the specific IEF exception criteria.

The PRM provides additional interpretation of the regulations and guidance for preparing an exception request. In particular section 2725.3 states, in relevant part, that a facility must satisfy three criteria to qualify as an IEF: 1) that it is geographical isolated; 2) that it is an essential point of access for ESRD patients; and 3) that its costs are justifiable and attributable to its isolated and essential character. Section 2725.3 of the PRM goes on to explain:

An ESRD Facility is responsible for demonstrating to [CMS's] satisfaction that each element is met ...

B. Definition of Isolated —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) and must provide dialysis to a permanent patient population, as opposed to a transient patient population ...

C. Definition of Essential —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 hardships incurred by ESRD patients are travel, time, and costs. However, other relevant factors may be considered in determining if a facility is essential. The ESRD facility must document the additional hardship its patients will incur.

D. Definition of Cost Per Treatment —One factor which may contribute to an IEF higher cost per treatment is a low number of treatments. A facility must address this issue in its exception request by providing a computation of its utilization (computed by dividing infacility maintenance treatments by total infacility maintenance treatment capacity) and justification for any unused capacity. In its justification, the ESRD facility should explain how patient volume fluctuation affects its cost per treatment.

Section 2725.3E also sets out the documentation necessary to support an IEF request. In addition, relevant to this case, section 2721 of the PRM provides guidance regarding satellite facilities, and states:

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. (Emphasis added.)

On September 7, 1999, the Mary Imogene Bassett Hospital opened its Satellite Dialysis Facility. The Satellite Facility is located in Oneonta, New York, while the Hospital renal dialysis facility is located in Cooperstown, New York. The Cooperstown location has had an approved IEF exception rate since January 4, 1994, and was extended in early 2000. The Satellite Facility was excluded from this exception rate. On June 25, 2001, Satellite Facility, submitted to its Intermediary a request for an ESRD exception to the prospective payment rate based upon the IEF exception established at 42 CFR 413.186. The Satellite Facility asked for a payment rate of \$139.48.⁴ By letter, dated July 9, 2001, the Intermediary forwarded the Provider's exception request to CMS.⁵

By letter dated September 17, 2001, CMS denied the request. CMS found that the Satellite Facility had not met the criteria of being isolated and essential.⁶ CMS, in its denial, provided a list of 13 ESRD certified facilities which are located in the

⁴ See Provider Exhibit P-1.

⁵ See Intermediary Exhibit I-7.

⁶ See Intermediary Exhibit I-2.

geographical area of the Satellite. CMS stated in its denial that the facilities appear to have a sufficient number of stations to accommodate the patients should the Satellite Facility close. CMS further stated that the Satellite Facility did not provide documentation that these other ESRD facilities were contacted. Thus, CMS stated that:

Although [the Hospital Facility] met the “geographical” criteria of an IEF at that time, the existence of [the Hospital Facility] and the other facilities listed ... disqualifies the [Satellite Facility] in meeting the “geographical” criteria for an IEF. [The Hospital Facility's] surrounding “geographical” area has changed. Based on [the Satellite Facility's] “geographical” area, we have determined that there are approximately thirteen Medicare certified ESRD facilities in this geographical area of New York. Seven of these facilities were certified after the closing of the last ESRD exception window in April 1994. [The Satellite Facility] did not provide documentation stating whether these seven new facilities ... will be able to accommodate [the Satellite Facility's] patients should [it] close or cease to provide outpatient ESRD services.⁷

CMS went on to explain that the Satellite Facility has not demonstrated that a substantial number of patients could not obtain dialysis services elsewhere without substantial additional hardship. CMS also noted that although the Satellite Facility identified the location of other ESRD facilities, it appeared that based on the geographic location of patient residencies there are other ESRD facilities closer to the patient that could furnish ESRD services. CMS stated that:

Over 50% of [the Satellite Facility's] patients drive themselves. [The Satellite Facility] did not include [the Hospital Facility] in Cooperstown in their discussion of nearby facilities. We do not agree since [the Hospital Facility] is only 24 miles from [the Satellite Facility] and are connected by Interstate 88. Some of the patients are closer to Cooperstown than to [the Satellite Facility]. In fact, according to [the Hospital Facility's] exception approved March 29, 1994, 16% of the same patients that received dialysis services at [the Hospital Facility] are now receiving dialysis services at [the Satellite Facility]. Since the parent hospital-based ESRD unit was not

⁷ *Id.*

considered, it appears that [the Satellite Facility] has eliminated any competition and in essence has created its own isolated area.⁸

After reviewing the applicable statutes and regulations, the Administrator finds that CMS' decision that the Provider does not meet the criteria for an IEF exception to the ESRD prospective payment rate is proper. The Provider in this instance did not meet its burden of proving that it met CMS' definition of isolated and essential, required by the regulations. As noted above, when ESRD facility seeks an exception, the entire facility including satellite facilities are examined. Further with respect to the "isolated" criterion, section 2725.3B of the PRM, generally provides that isolation is indicated by a provider's location outside an MSA, and its provision of services to a permanent, rather than a transient, patient population. In order to be isolated under the regulations, a facility must be the "only supplier of dialysis services in its geographical area." Accordingly, a provider must also prove that it is geographically isolated from other facilities.

In this instance, since the Provider is a satellite facility of an existing ESRD hospitalbased facility, the cost and circumstances of both the Hospital-based and Satellite facility are examined. Thus, CMS, in evaluating the exception request, determined that the geographic area of the satellite facility includes the Hospital-based facility and twelve other Medicare certified ESRD facilities; seven of which were certified after the closing of the last ESRD exception window in April 1994. In addition, these thirteen facilities appear to have sufficient number of stations to accommodate the patients should the Provider close. The record reflects, however, that the Provider, in its exception request, provided documentation on only six ESRD facilities in the geographic area. Since the record lacks any documentation regarding the seven additional facilities identified which appear to have the ability to serve the Provider's patients, the Administrator finds that the Satellite facility is not the "only supplier of dialysis services in its geographical area."⁹ Thus, the Administrator concludes that the Provider did not demonstrate that it is isolated under the controlling regulation.

⁸ *Id.*

⁹ The Board's finding that the closet facility was 53.7 miles away from the Provider, does not take into account the location of the Provider's patients. The Provider's failure to provide information on these other facilities is critical to the failure of its application. For example, on its face, approximately eleven patients are listed as residing in the towns of Bainbridge, Nineh, Sidney, Afton, Walton and Unadilla, all towns located between the satellite and the Johnson City/Binghamton facility. While the satellite may be located over 50 miles from this facility, these towns are located substantially closer than 50 miles to Johnson City. Other patients are listed as being from the towns of Plymouth and Sherburne which appear to be on a main road leading to Utica or Johnson City. Another patient is listed from Middleburgh which again appears to be a closer commute to Albany. Other

With respect to whether a facility meets the “essential” requirement, section 2725.3C of the PRM explains that a facility must prove that a substantial number of its patients would face “additional hardship” if they had to rely on other ESRD providers for dialysis. “Additional hardship” might involve travel, time, and cost increases, but the PRM recognizes that a facility may establish that other factors are relevant.

CMS' denial indicated that although the Satellite Facility identified the location of other ESRD facilities, it appeared that based on the geographic location of patient residencies there are other ESRD facilities closer to the patient that could furnish ESRD services. In fact, the Hospital Facility in Cooperstown is only 24 miles from the Satellite Facility and is connected by a major interstate. Further, some of the patients are closer to Cooperstown than to the Satellite Facility. In addition, CMS noted that some the Satellite facility's patients can travel shorter distances to another nearby ESRD facility. Although CMS identified six patients who could travel shorter distances to other facilities, the Administrator notes that the record lacks any documentation or analysis with respect to patient's residencies, and travel distances to the seven additional facilities identified in CMS' denial. The Administrator finds that the Provider has not demonstrated that a substantial number of its patients would face “additional hardship” if they had to rely on other ESRD providers for dialysis. Thus, the Administrator concludes that the Provider did not demonstrate that it is essential under the controlling regulation.

With respect the third regulatory criteria for approval of an ESRD exception request, the regulation directs that an ESRD facility must demonstrate that its total per treatment costs are reasonable and allowable, and its per treatment costs, in excess of its payment rate, are directly attributable to the exception criteria. In this case, CMS noted, in its denial, that because the Satellite facility had not met the isolated and essential criteria, CMS did not review the reasonableness of the excess costs. However, the Board determined, based on the Intermediary's favorable recommendation, that the Satellite facility's excess costs are justifiable, reasonable, and specifically related to the IEF criteria.¹⁰

patients located in Andes and Margaretville may be within a commuting distance to the Catskills or Kingston facilities. Accordingly, because the Provider did not provide information on these facilities and its own parent facility, it failed to demonstrate that it met the criteria for an IEF exception.

¹⁰ In this instance, the Administrator finds that the Board exceeded its authority in determining the reasonableness of the Satellite's facility's excess costs. Assuming *arguendo*, that the Satellite facility met the isolated and essential criteria, the appropriate action by the Board should have been to remand the case to CMS for an initial determination. Thus, since CMS has not reviewed the excess costs issue and made an initial determination in this case, the Administrator is, likewise, not ruling on that issue.

DECISION

The decision of the Board is reversed in accordance with the foregoing opinion.

THIS CONSTITUTES THE FINAL ADMINISTRATIVE DECISION OF
THE SECRETARY OF HEALTH AND HUMAN SERVICES.

Date: 10/26/05

/s/

Leslie V. Norwalk, Esq.

Deputy Administrator

Centers For Medicare & Medicaid Services