PROVIDER REIMBURSEMENT REVIEW BOARD DECISION

2006-D45

PROVIDER -
The Milton S. Hershey Medical Center
Hershey, Pennsylvania

Provider No.: 39-0256

vs.

INTERMEDIARY -
BlueCross BlueShield Association/
Veritus Medicare Services

DATE OF HEARING -
July 22, 2004

ESRD Window Date -
June 20, 2001

CASE NO.: 02-0224

INDEX

ISSUE:

Was the Centers for Medicare and Medicaid Services' (CMS) denial of the Provider's request for an exception to the End Stage Renal Disease (ESRD) composite rate proper?

MEDICARE STATUTORY AND REGULATORY BACKGROUND:

This is a dispute over the amount of Medicare payments due a provider of dialysis services for ESRD patients.

The Medicare program provides health insurance to aged and disabled persons. 42 U.S.C. §§1395-1395cc. The Secretary of the Department of Health and Human Services (Secretary) is authorized to promulgate regulations prescribing the health care services covered by the program and the methods of determining payments for those services. The Centers for Medicare and Medicaid Services (CMS), formerly the Health Care Financing Administration (HCFA), is the operating component of the Department of Health and Human Services (DHHS) charged with the program's administration. CMS has entered into contracts with insurance companies known as fiscal intermediaries to maintain the program's payment and audit functions. Intermediaries determine payment amounts due providers of health care services (e.g., hospitals, skilled nursing facilities, home health agencies and dialysis centers) under Medicare law and interpretative guidelines issued by CMS.

ESRD facilities are reimbursed for outpatient dialysis services under the "composite rate" system.[1] Under this system, a provider of dialysis services receives a prospectively determined payment for each dialysis treatment that it furnishes. An ESRD facility must accept the composite prospective payment rate established by CMS as payment in full for covered outpatient dialysis unless it qualifies for one of the exceptions in accordance with the procedures established under 42 C.F.R. §413.180 et seq.

STATEMENT OF THE CASE AND PROCEDURAL HISTORY:

The Milton S. Hershey Medical Center (Provider) is a hospital-based dialysis facility located in Hershey, Pennsylvania. The hospital is an academic medical center and is also a regional referral center for rural Pennsylvania. The Provider furnishes dialysis services to residents of Hershey and Central Pennsylvania as well as to transient patients who vacation in the Hershey area.

During certain periods of time generally referred to as exception windows, an ESRD provider may request an exception to its composite rate in accordance with the procedures established under 42 C.F.R. §413.180. HCFA[2]opened such an exception window commencing on April 1, 2001. On June 20, 2001 the Provider submitted a timely exception request to the composite rate for maintenance dialysis services to Veritus Medicare Services (Intermediary). The Provider sought an exception in the amount of $39.36 per treatment on the basis of atypical service

[1] Section 1881(b) of the Social Security Act and the regulations at 42 C.F.R. §413.180 et seq.,

[2] CMS was known as the Health Care Financing Administration ("HCFA") at the time denial actions were taken. This decision will refer to the name of the agency as CMS unless otherwise required by context.

intensity. Following a review of the Provider's exception request, the Intermediary forwarded the request to CMS and recommended its denial, citing cost report deficiencies. CMS did not address the Intermediary's concerns in the denial of the exception request, but rather denied the request claiming that the Provider's submitted clinical data did not satisfy the atypical patient mix criteria as specified in 42 C.F.R. §413.184.

The Provider timely appealed CMS' denial to the Provider Reimbursement Review Board (Board) pursuant to 42 C.F.R §413.194 and has met the jurisdictional requirements set forth in 42 C.F.R §§405.1835- 405.1841. The Provider was represented by John A. Snyder, Esquire, of McQuaide, Blasko, Schwartz, Fleming & Faulkner, Inc. The Intermediary was represented by Bernard M. Talbert, Esquire, of the Blue Cross Blue Shield Association.

PROVIDER'S CONTENTIONS:

The Provider contends that it satisfied the atypical service intensity criteria set forth in 42 C.F.R §413.184 and Provider Reimbursement Manual (PRM) §2725.1 in that its exception request provides solid evidence that its level of patient acuity was higher than the national average. The Provider argues that the instant exception request was primarily driven by the atypicality of its 60 non-transient, in-facility hemodialysis patients. The Provider claims that those 60 patients consumed 99% of the treatments delivered by the Provider for the time period in question[3] and, therefore, that demographic was the focus of the exception request. The Provider furnishes numerous examples of atypical variations between the Provider's patient population and the national norms:

- Diabetic Patients – Nationally, 33% of all ESRD patients are diabetic. 58% of the Provider's non-transient, outpatient hemodialysis population and 45.4% of the Provider's total population were diabetic.
- Elderly Patients – Nationally, 36.6% of ESRD patients are elderly (65 and older). 53.3% of the Provider's non-transient, in facility outpatient hemodialysis population is elderly. Even when home peritoneal dialysis patients are included, 41.1% of the Provider's total patient population is elderly. When all patients – in-facility, home and transient – are included, the Provider's elderly patient population is 39.2% compared to the national average of 36.6%.
- Pediatric Patients – Nationally, .07% of all ESRD patients are pediatric (0-14 years old). 1.7% of the Provider's non-transient, outpatient hemodialysis population and 7.8% of its population (when including home patients) were pediatric patients.

In addition to the comparisons above, the Provider asserts that it is one of only five pediatric facilities in Pennsylvania, and its pediatric patients skew the average age of the patients in its population towards typicality. However, the Provider points out that its population of elderly patients over 75 is still 33% when transient patients are included.

The Provider asserts that further evidence of atypicality was provided in its exception request under its discussion of transfer patients. The Provider represents that the facility is not only an

[3] Tr. at 87-88 and Provider Exhibit 23, p.1

academic medical center, but also a regional referral center for rural Pennsylvania. The Provider states that it receives transfer patients from eight lower acuity facilities, and claims that its referral pattern (80% of "transfers in" are from freestanding units and at least 77% of "transfers out" are to freestanding facilities), meets the PRM §2725.1 criteria for aytpicality as sicker than average patients are being referred to its facility.

The Provider also claims that due to its transplant program and proximity to major public attractions, the facility treats a significant number of transient patients who appear for one or two treatments and then do not return. The Provider argues that these transient patients should be excluded or discounted from the analysis performed to determine atypicality, as transient patients account for less than 1% of total treatments. While the Provider stresses that its patient population is atypical even when transient patients are included, the atypicality of its patients is even more pronounced when they are removed. The Provider argues that since the controlling regulation, 42 C.F.R. §413.184, requires the provider to demonstrate that "a substantial portion of its outpatient maintenance dialysis treatments involve atypically intense dialysis services," excluding transient patients from the analysis would be appropriate, since they represent such a small percentage of total treatments.

The Provider argues that the CMS denial was based on the agency's insistence that transient and home patients be included in the Provider's patient population statistics, and further, that doing so diluted the atypical attributes of the population because the number of treatments provided to transient patients comprised only 1% of total treatments. The Provider also argues that since the regulation requires it to prove that a substantial portion of its treatments involve atypical dialysis services rather than that its patients are atypical, CMS improperly reviewed its exception request and based its denial on a criterion not supported by the regulation. Moreover, the Provider argues that CMS unilaterally implemented more stringent criteria to determine atypicality than are set forth in PRM §2725.1. The Provider asserts that CMS testified at the hearing[4] that numerous criteria must be met to establish atypicality, whereas the manual section clearly states at §2725.1 ". . . the burden of proof is on the facility to show that one or more of the criteria are met." Also, §2725.1 B states, "In order for an exception request to be granted, any one of the following criteria must be met. . . ."

The Provider also addresses the exception request denial recommendation made by the Intermediary to CMS regarding the use of the revised I-series cost report schedules in the exception request rather than the I-series schedules which were part of the original cost report submission. The Provider asserts that the revised I-series cost report schedules submitted to the Intermediary prior to the submission of the exception request should be utilized in the review of the exception request, as the original I-series schedules contained errors. The Provider claims that it submitted the revised I-series during the audit of the cost report in question and was under the impression that the cost report would be revised to reflect the correct data. When the Intermediary failed to incorporate the changes into the cost report, the Provider claims it did not have sufficient time to go through a formal amendment process, and therefore submitted the revised schedules again as part of the exception process. The Provider claims its approach in utilizing the revised schedules was entirely reasonable under the circumstances and should not be a basis for an outright denial of the exception request.

[4] Tr. at 298 and 309-310

INTERMEDIARY'S CONTENTIONS:

The Intermediary contends that CMS properly denied the Provider's exception request pursuant to the governing regulation at 42 C.F.R. §413.184. Under the regulation, a provider must demonstrate that its per treatment costs in excess of its composite rate are reasonable, allowable and directly attributable to serving an atypical patient mix. Since the Provider did not substantiate an atypical patient mix, it failed to meet the specific exception requirements under 42 C.F.R. §413.184.

Upon receipt of the Provider's exception request, the Intermediary reviewed the request and recommended to CMS that the exception be denied, based upon the Provider's submission and use of revised Worksheet I-series cost report schedules in the exception request. However, CMS did not deny the exception request based on the use of revised I-series schedules, but instead, completed a review on the merits of the exception for atypical services. CMS did not accept or reject the use of amended Worksheet I-series schedules in the computation of an exception amount, as it found that the Provider was not entitled to an adjustment of its composite rate due to the provision of atypical services.

The CMS exception denial letter, dated August 23, 2001 and addressed to the Intermediary,[5] identified certain regulatory references which outline documentation requirements in support of an atypical services exception. C.F.R. §413.184(b)(1) states as follows in pertinent part:

> A facility must submit a listing of all outpatient dialysis patients (including home patients) treated during the most recently completed fiscal or calendar year…

CMS asserted that the analysis included in the Provider's exception request did not include data for the Provider's 35 home patients or its transient patients. CMS argues that as the costs of the Method I home patients are included in the composite rate, they must also be included in the population utilized in determining whether a provider treats an atypical patient mix. CMS, therefore, had to recast the Provider analysis to include the home patients.

In its August 23, 2001 denial letter, CMS summarized its analysis of the Provider's ESRD patient population based on data for 100 hemodialysis and 30 peritoneal dialysis patients. Based on the comparison made, CMS found that the Provider's patient population was not atypical in comparison to the national averages. CMS argues that its analysis showed that the category of diabetic patients was the only category in which the Provider's patient population exceeded the national average and could be considered "marginally atypical." CMS also identified in its denial letter, that in four other categories; (patients over 65, mortality rate, new patient start rate and average length of stay), the Provider's patient population fell below the national average. Therefore, based on the totality of the evidence, CMS concluded that the Provider did not demonstrate an atypical patient mix justifying entitlement to an atypical services exception, and that the exception denial was appropriate.

[5] Intermediary Position Paper, Exhibit 10

FINDINGS OF FACT, CONCLUSIONS OF LAW AND DISCUSSION:

After consideration of the Medicare law and program instructions, evidence presented and the party's contentions, the Board finds as follows:

The applicable regulation states in pertinent part as follows:

> A facility must demonstrate that a substantial proportion of the facility's outpatient maintenance dialysis *treatments* involve atypically intense dialysis services, special dialysis procedures, or supplies that are medically necessary to meet special medical needs of the facility's patients. (emphasis added)

42 C.F.R. §413.184(a)(1)

In reviewing an ESRD exception request for atypical services, CMS uses the condition of patients as a proxy for atypicality, because certain conditions or factors are recognized as requiring more intense services and/or greater consumption of time and resources. Examples of patient proxies used are diabetic patients, elderly (over 65) patients, pediatric patients, and new patients. National averages have been developed for certain conditions and those averages are utilized as being the normative standard.

The Board has concerns that the normative standards used by CMS for comparisons are grossly outdated and that the source of the standards used has not been disclosed. For example, it is unclear if the provider data used to develop the normative standards includes facilities which render atypical services. Also, as the source for the data has not been disclosed, the data is not subjected to verification by the provider community. In addition, the normative data does not include all of the patients categories which could render an ESRD population atypical. For example, there is no data regarding Alzheimer's patients or patients with other mental health problems.

The relative percentage of atypical versus typical patients may be an indicator of the number of atypical versus typical treatments; however, circumstances may distort the equating of an atypical number of patients to an atypical number of treatments. For example, a high number of short-term patients with no atypical service requirements, as may be the case with this provider,[6] may not properly equate to atypical treatments. An example was provided at the hearing by Ms. Campos, the Provider's witness, who testified that transient patients who are healthy enough to travel would typically not require atypical tasks or services. However, although such short-term patients with no atypical service requirements would tend to significantly reduce the Provider's percentage of atypical patients relative to total patients, these patients would have much less impact in reducing the Provider's percentage of atypical treatments relative to total treatments, as they would receive far fewer treatments throughout the cost reporting year compared to Provider's full-time dialysis patients.

[6] Tr. at 132.

In effect, CMS does take into account the atypicality of transient patients, such as patients coming out of the hospital and referred to the Provider for stabilization before transferring to another facility for regular treatment, and the categorization of short-term patients recognizes that a large number of short-term patients can impact overall costs and have a disparate impact on overall statistics. However, in its determination of the Provider's exception request, the Intermediary counted each such patient the same as a full-time diabetic, elderly or pediatric patient in the determination of Provider's atypical patient percentage, even though the patient may have received only one dialysis treatment during the Provider's cost reporting year while each of its full-time patients would have received more than 150.

The Board finds that to comply with the regulation, the atypical number of patients must be converted to an atypical number of treatments. The analysis provided by the Provider in its ESRD exception request and by CMS in its denial revolves around the Provider's patient population mix and how it compares to national averages rather than the facility's outpatient maintenance dialysis treatments, as is required in the regulation.

The review completed by CMS was too shallow to make a proper determination of atypicality. It did not show how patient population factors result in its conclusion that the Provider failed to demonstrate, ". . . that a substantial proportion of the facility's outpatient maintenance dialysis *treatments* involve atypically intense dialysis services. . . . " The Board majority concludes that, while the submission of a patient listing is required under the regulation, and the examination of the patient population is helpful in reaching a decision, CMS must also take into account how each segment of the population impacts the treatments rendered.

In addition, the Board majority finds that although the Provider did not include the as-filed cost report data in the exception analysis compiled for the exception request, the as-filed cost report was included as Attachment 15 of the initial exception request[7]. Therefore, the Provider met the requirement of the regulation, which was to include a copy of the latest as-filed cost report.

DECISION AND ORDER:

The Board majority finds that CMS improperly denied the Provider's request for an exception to the ESRD composite rate based on its analysis of the Provider's patient population rather than its outpatient maintenance dialysis treatments, as is required by C.F.R. §413.184. This case is remanded to the Intermediary for a determination of atypicality based on the number of treatments.

BOARD MEMBERS PARTICPATING:

Suzanne Cochran, Esquire
Gary B. Blodgett, D.D.S.
Elaine Crews Powell, C.P.A. (Dissenting)
Anjali Mulchandani-West

[7] Provider Position Paper -Exhibit 14

FOR THE BOARD:

DATE: September 7, 2006

Suzanne Cochran
Chairperson

Dissenting Opinion of Elaine Crews Powell

The majority found that CMS' denial of the Provider's exception request was improper and that it should be remanded to the Intermediary for a determination based on the atypical nature of the outpatient maintenance dialysis treatments versus the atypicality of the patients the Provider serves. I respectfully dissent. I find that CMS properly denied the Provider's exception request.

In my opinion both the Intermediary and the CMS reviewer performed diligent, detailed reviews of the Provider's patient mix, the revised cost allocations, and the statistical data the Provider furnished in the exception request. When that data was determined to be inadequate and unreliable, the Intermediary recommended denial of the request, and the CMS reviewer agreed. Both the Intermediary and CMS issued well reasoned decisions regarding the Provider's exception request. Any finding that "a substantial proportion of the facility's outpatient maintenance dialysis treatments involve atypically intense dialysis services"[8] must be based on an analysis of each and every patient's condition and the additional time, supplies, etc. that it takes to provide his/her dialysis treatments.

Even though the Provider's exception request was flawed, CMS elected to perform a detailed review. The exception request was based on statistical data and cost allocation methodologies contained in revised cost reporting schedules that differed significantly from the schedules filed by the Provider in its latest filed cost report for the FYE 06/30/00 cost report. Supporting documentation was not available for review by the Intermediary's auditors when the exception request was reviewed on site at the hospital.[9] The cost per treatment analysis furnished by the Provider also did not include its home dialysis patients and their treatments. In my opinion this was done for the specific purpose of avoiding the diluting effect that home patients' treatments would have on the conclusion regarding the Provider's provision of a substantial proportion of atypical treatments.

For the purpose of the hearing, the Provider included information that was not considered by the Intermediary or CMS when the exception request was reviewed. The Intermediary's counsel properly objected to these exhibits, which included P-22, P-23, P-24 and P-25. Exhibit P-22 was objected to because the affidavit contained therein elaborates on clinical points regarding dialysis services to pediatric patients not elaborated upon in the exception request. Portions of Provider Exhibit P-23 raised for the first time the Provider's argument that its transient patients should be excluded for purposes of the Age Profile of the Provider's patients. Schedules included in P-23 demonstrate the impact of including and excluding these patients from the Age Profile. Exhibits P-24 appears to be a copy of an unsigned and undated time study to document the additional time it takes to provide dialysis services to patients with certain conditions, again documentation that

[8] 42 C. F. R. 413.184(a)(1)

[9] At Intermediary Exhibit I-9, page 3 the Intermediary discusses the time studies the Provider used to supports its revised allocations of costs within the modified Worksheet I series included in the exception request. The Provider maintains that it tested two months -- December 1999 and March 2000. However, the Provider was unable to provide the supporting documentation for the test in December. The Intermediary went on to discuss the requirements for time studies and how the Provider failed to meet the basic requirements of Provider Reimbursement Manual (PRM) (HCFA Pub. 15-1) § 2314(E)(2) which requires that "a minimally acceptable time study must encompass at least one full week per month during the cost reporting period." Clearly, the Provider's revised Worksheet I series was based on data that was not supported by the Provider.

was not considered in the adjudication of the exception request. Finally Exhibit P-25 was objected to because it contains audit workpapers prepared by the Intermediary during an audit for the FYE 06/30/01 which was done in April 2003. Since 42 C.F.R. 413.194(c)(2) prohibits the Board from reviewing any documentation not furnished to the reviewers, these documents should not have been included in the record of this case.

The exception regulation places the onus squarely on a provider to support every aspect of its exception request, something that Milton Hershey simply failed to do.

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Elaine Crews Powell, CPA