PROVIDER REIMBURSEMENT REVIEW BOARD
HEARING DECISION

2015-D19

PROVIDER -
Loma Linda University Kidney Center
Loma Linda, California

Provider No.: 05-2550

vs.

MEDICARE CONTRACTOR -
Noridian Healthcare Solutions, LLC

DATE OF HEARING -
August 30, 2012

ESRD Window End Date -
August 30, 2000

CASE NO.: 01-2872R

INDEX

ISSUE:

Whether the denial of the Provider's request for an exception to the end stage renal disease ("ESRD") composite rate by the Centers for Medicare and Medicaid Services ("CMS") was proper.[1]

DECISION:

After considering the Medicare law and program instructions, the evidence presented and the parties' contentions, the Board finds that the Medicare Contractor: (1) properly denied the Provider's request to increase the ESRD composite rate for freestanding facilities based on an exception for atypical patient mix for the exception cycle beginning March 1, 2000; and (2) properly revoked the Provider's then-existing add-on payment to the ESRD composite rate for freestanding facilities based on an exception for self-dialysis training.

INTRODUCTION:

Loma Linda University Kidney Center (the "Kidney Center" or "Provider) is a freestanding dialysis facility located in Loma Linda, California and provides outpatient dialysis treatment. The Kidney Center's assigned Medicare contractor[2] is Noridian Healthcare Solutions, LLC. ("Medicare Contractor")

The Medicare program reimburses dialysis facilities for outpatient dialysis treatment under the ESRD prospective payment system ("ESRD PPS") which reimburses dialysis facilities on a per treatment basis using a case-mix adjusted composite payment rate. The Medicare program will adjust a dialysis facility's ESRD composite rate if it qualifies for an exception.[3] This case involves the exceptions for atypical case mix and for home and self-dialysis training.

In December 1999, CMS announced that a new exception cycle for ESRD composite rates would begin on March 1, 2000.[4] As a result, The Kidney Center filed a request that the Medicare program increase its ESRD composite rate for its in-facility outpatient maintenance dialysis and home program peritoneal dialysis based on the exception criterion for "Atypical service intensity (patient mix)" as specified in 42 C.F.R. § 413.184 (hereinafter referred to as an "atypical case mix exception"). After receiving direction from CMS, the Medicare Contractor: (1) denied the Kidney Center's request for an atypical case mix exception; and (2) revoked the Kidney Center's then-existing exception for "self-dialysis training costs" as specified in 42 C.F.R. § 413.190 (hereinafter referred to as a "self-dialysis training exception"). The Kidney Center appealed the Medicare

[1] Transcript ("Tr") at 5-6 (reflecting the parties' agreement of the issue that is before the Board).
[2] Fiscal intermediaries ("FIs") and Medicare administrative contractors ("MACs") will be referred to as Medicare contractors.
[3] *See* 42 C.F.R. Part 413, Subpart H.
[4] *See* Program Memorandum, CMS Pub. 60A, Transmittal No. A-99-59 (Dec. 1, 1999); Program Memorandum, CMS Pub. 60A, Transmittal No. A-00-06 (Feb. 1, 2000).

Contractor's decision to the Provider Reimbursement Review Board ("Board"). The Board reversed the Medicare Contactor's decision on procedural grounds but the CMS Administrator ("Administrator") reinstated the Medicare Contractor's decision.[5]

The Kidney Center appealed the Administrator's reinstatement to the U.S. District Court for the District of Columbia ("District Court"). However, the District Court remanded the case back to the Administrator for a determination on "the substantive merits," specifically whether the Kidney Center met the requirements for an exception to the ESRD composite payment rate.[6] The Administrator, in turn, remanded the case back to the Board to make this determination.[7]

Loma Linda was represented by Jack Ahern of Ahern Consulting and Jeffrey A. Lovitky, Esq. The Medicare Contractor was represented by Bernard Talbert, Esq., of the Blue Cross and Blue Shield Association.

FINDINGS OF FACT, CONCLUSIONS OF LAW AND DISCUSSION:

This case is remanded to the Board for the sole purpose of determining whether the Kidney Center substantively met the requirements for an exception to the ESRD composite payment rate for atypical case mix and for self-dialysis training. Therefore, the Board will limit its findings to this remand.

A. SUBSTANTIVE MERITS OF THE REQUEST FOR THE ATYPICAL CASE MIX EXCEPTION

At the outset, the Board notes that Medicare regulations and manual instructions limit the Board's review of CMS' denial of ESRD exception requests. Specifically, 42 C.F.R. § 413.194(c)(2) states: "The facility may not submit to the . . . PRRB . . . any additional information or cost data that had not been submitted to HCFA at the time HCFA evaluated the exception request."[8] Thus, the Board has limited its findings to the question of whether the Kidney Center met its burden of proof based upon the information and data provided in the exception request itself. The Board references hearing testimony only to clarify or confirm information in the as-submitted exception request.

The regulations governing requests for exceptions to the ESRD payment rates set forth submission requirements and criteria for approval. 42 C.F.R. 413.180(f) (1999) requires a dialysis facility to submit "its most recent cost report . . . and whatever statistics, data and budgetary projections as determined by HCFA to be needed to adjudicate each type of exception." In particular, the statistics and data must "identify elements of cost contributing to costs per treatment in excess of the facility's payment rate" and "[s]how

[5] *See Loma Linda Univ. Kidney Ctr. v Blue Cross Blue Shield Ass'n*, PRRB Dec. No. 2006-D40 (Jul. 6, 2006), *rev'd*, CMS Adm'r (Sept. 12, 2006).
[6] *See Loma Linda Univ. Kidney Ctr. v. Johnson*, Nos. 06-1926, 06-1927, 2009 WL 735639 (D.D.C. Mar. 17, 2009).
[7] *See* CMS Adm'r Order (Nov. 29, 2011).
[8] *See also* Provider Reimbursement Manual, CMS Pub. 15-1 ("PRM 15-1"), § 2726.1 (copy included at Medicare Contractor Exhibit I-3 at 731-732).

that the elements of excessive cost are *specifically attributable* to one or more of the conditions specified in § 413.182."[9] Section 413.182 (1999) states that CMS may approve an ESRD facility's exception request "if the facility demonstrates, *by convincing objective evidence*, that its total per treatment costs are reasonable and allowable . . . and that its per treatment costs in excess of its payment rate are *directly attributable* to …(a) Atypical service intensity (patient mix) as specified in § 413.184."[10] Finally, § 413.180(g) (1999) specifies that "[t]he burden of proof is on the facility to show that . . . the criteria are met and that the excessive costs are justifiable under the reasonable cost principles . . . ."

To qualify for an atypical case mix exception, § 413.184 (1999) specifies that a facility first "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." The facility further has to demonstrate that the "services, procedures or supplies and its per treatment costs are prudent and reasonable when compared to those of facilities with a similar patient mix" and that "its nursing personnel costs have been allocated properly between each mode of care"[11]

1. ATYPICAL PATIENT MIX

The Board finds that the Kidney Center has demonstrated that its patient case mix involves atypically intense dialysis services. The Kidney Center's application clearly establishes that: (1) the Kidney Center has a substantial number of patients who are over 65, diabetic, hypertensive, and/or pediatric; (2) the percentage of these patients in the Kidney Center's overall patient case mix is above average; and (3) these types of patients generally require additional intensive services.[12] Indeed, its letter dated November 15, 2000 CMS acknowledges that "it appears that [the Kidney Center] could possibly have an atypical patient mix."[13] Further, during the June 10, 2004 hearing, the CMS representative conceded that, based upon his review of the documents, he believed the Kidney Center's patient mix met the atypicality standard.[14] Accordingly, the Board, concludes that the Kidney Center demonstrated that it serves an atypical patient mix.

2. COST JUSTIFICATION

To receive an exception, the Kidney Center must demonstrate that its atypical patients require "atypically intense dialysis services, special dialysis procedures or supplies that

[9] 42 C.F.R. § 413.180(f) (emphasis added).
[10] (Emphasis added.)
[11] 42 C.F.R. § 413.184(a)(1) - (2).
[12] *See* Provider Exhibit P-1 at 2; Provider Exhibit P-38, Tabs 3 – 6 (evidence submitted by the Kidney Center to support its assertions that its patient case mix was atypical).
[13] Provider Exhibit P-2 at 3.
[14] Provider Exhibit P-23 at 151 (page 241 of transcript from first Board hearing held on June 10, 2004 stating: "Q. . . . . But I just want to make sure that it's CMS' position that this Provider has met the atypicality standard, and . . . as a Board member I don't have to go into that analysis. A. I think that's right.").

are medically necessary . . .”[15] and that its per treatment costs are prudent and reasonable “when compared with facilities with a similar patient mix.”[16] To this end, the Kidney Center provided detail on various categories of costs from fiscal years (“FYs”) 1997 through 1999 and projected costs for FY 2000 based on actual and estimated data to show historical trend and determine the reasonableness of the costs in excess of the composite rate.[17] Based on this information, the Kidney Center requested cost exception amounts for salaries, employee benefits, supplies, and overhead.

As explained below, the Board is not convinced that the Kidney Center has met its burden of proof and established that the elements of excessive cost are “directly attributable” to the atypicality of its patient mix. The Board has set out findings on each of the exception amount requests as well as some general findings on these requests.

a.) SALARIES AND EMPLOYEE BENEFITS

The Kidney Center provided cost data showing that: (1) its cost per treatment of salaries for direct patient care was $49 for FY 1997, $56 for FY 1998, and $57 for FY 1999 and was projected to increase to $70 for FY 2000; and (2) its cost per treatment for employee benefits was $18 for FY 1997 and $19 for both FYs 1998 and 1999 and was projected to increase to $25 for FY 2000.[18] The Kidney Center explains generally that these increases by saying that it “is attributed to the severity of illness in our patient population”[19] and, with regard to the increase from FY 1999 to the projected FY 2000, explains that the increase “is due to an increase in the number of atypical patients as a percent of total from 1999 to 2000.”[20]

However, the Kidney Center’s does not provide any documentation of the increase in these atypical patients over these same time periods to support the explanations. Similarly, the Kidney Center submitted patient data for FY 1999 as part of its exception request and reported its overall cost per treatment at $183 for FY 1999.[21] Yet, the exception request contains no patient data for earlier years—FYs 1997 and 1998—when the overall cost per treatment was significantly lower at $166 and $162 respectively.[22] Without an explanation for the increase over prior years, the Board is unable to determine whether the Kidney Center’s increased costs were “specifically attributable” to an increased number, or increased need for specialized services, of its atypical patients.

Even assuming *arguendo* that there were a sufficient explanation for the increases from FYs 1997 and 1998, the Kidney Center’s request would fail because it has not adequately explained the overall per treatment cost increase from FY 1999 to the projected FY 2000. The Kidney Center simply asserts that the 9 percent increase “is primarily due to increase in salaries and benefits for direct patient care” and that the increase in salaries and

[15] 42 C.F.R § 413.184(a)(1).
[16] *Id.* at (a)(2).
[17] *See* Provider Exhibit P-38, Tab 1.
[18] *See* Provider Exhibit P- 38, Tab 1 at 255-257.
[19] *See* Provider Exhibit P-1 at 5.
[20] Provider Exhibit P-38, Tab 1 at 257.
[21] *See id.*
[22] *See id*.

benefits "is due to an increase in the number of atypical patients as a percent of total from 1999 to 2000" which "resulted in additional nursing hours."[23] The lack of information is compounded by the fact that the 9 percent increase could be significantly higher because, as the Kidney Center admitted, the FY 1999 cost per treatment contains an uncorrected and *unquantified* error regarding its overhead.[24]

Finally, the materials submitted with the Kidney Center's exception request do not demonstrate that its patient mix received specialized services that would not have been provided had it not served an atypical patient population. While it is evident from the materials submitted with the Kidney Center's exception request that its per treatment cost was rising, these materials do not contain sufficient information for the Board to determine whether the Kidney Center provided specialized services that are "directly attributable" to the atypical patient mix.

Accordingly, the Board finds that CMS reviewer properly denied the request for a salary and employee benefits cost exception amount.

b.) SUPPLIES

The Board finds that the CMS reviewer's denial of supply cost exception proper based upon the information in the application. In particular, the Kidney Center maintains that the CMS reviewer's findings are flawed because it is based improperly on the assumption that the Kidney Center consistently re-used dialyzers 20 times.[25] However, the Board is not allowed to consider any additional information or cost data that had not been submitted to CMS at the time CMS evaluated the exception request pursuant to 42 C.F.R. § 413.194(c)(2). As the cost report included as part of the exception application represents that the Kidney Center re-uses dialyzers 20 times,[26] the Board finds that the CMS reviewer's use of that statistic was reasonable. Further, the Board notes that the Kidney Center failed to furnish the required data on peer group comparison (as discussed more fully below) and, as such, has no basis to complain about or dispute the CMS reviewer's comparison of its supply cost to the national median data. Accordingly, the Board finds that CMS reviewer properly denied the request for a supply cost exception amount.

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[23] *See id*. The Kidney Center failed to provide "objective convincing evidence" to explain the increases and establish that the costs were reasonable and prudent when compared to that of facilities with comparable patient mix. Further, as noted by the CMS reviewer, while the Kidney Center did provide a list of diagnoses and related activities that require additional nursing time, it not provide any time studies to support the number of estimated nursing minutes required for each of these diagnoses and related activities Ratner, the Kidney Center had certain patient care staff estimate the number of nursing minutes per activity and the number of times each activity is performed annually and did not provide any information on who the patient care staff were who did the estimation or the methodology the patient care staff used to make the estimations.

[24] *See id.* at 256.

[25] *See* Provider's Post-Hearing Brief at 75-77. Further, the Kidney Center did not include any information the exception request concerning labor costs associated with reuse of dialyzers.

[26] *See* Provider Exhibit P-38, Tab 23 at 426 (in response to the question on the type of dialyzers used the Kidney Center only specified only one type (hollow fiber) and stated represented that they are reused 20 time).

c.) OVERHEAD

The majority of the overhead cost per treatment consists of administrative and general costs ("A&G") – "A&G-Other" and "A&G-Salaries." The exception application reflects A&G costs of $31 for FY 1997, $36 for FY 1998, $54 for FY 1999, and $52 for the projected FY 2000. Here, the Kidney Center explains the increase from FY 1998 to FY 1999 as due in part to an uncorrected error, specifically that "the home office cost allocation in Worksheet A-8-1 was reflected twice" and "[t]he 1999 cost information does not reflect a correction of this error."[27] However, the Kidney Center does not quantify this error. As a result, it is unclear how much of an increase there is from FY 1998 to FY 1999 and from FY 1999 to the projected FY 2000. Further, the explanation for the increase does not "demonstrate, by convincing objective evidence" that this increase was "directly attributable" to the atypical patient mix as required by the regulation. Accordingly, the Board finds that CMS reviewer properly denied the request for an overhead cost exception amount.

d.) HOURS PER TREATMENT

The Board agrees that the Kidney Center has not explained why its average treatment time has been increasing. The Board finds that the CMS reviewer was reasonable in expecting training CAPD and CCPD hours per treatment to be more than non-training CAPD and CCPD. The Board finds that it is the Provider's responsibility to explain variances and unusual hours per treatment in its exception request.

e.) LACK OF PROPER PEER GROUP COMPARISON

Finally, 42 C.F.R. § 413.184(a)(2) (1999) specifies that a provider seeking an exception request "must demonstrate clearly that these services, procedures, or supplies and its per treatment costs are prudent and reasonable *when compared to those of facilities with a similar patient mix*."[28] The Kidney Center's exception request provided comparative national data regarding staffing mix, patient mix with regard to transplantation, and mortality rates. However, the exception request is fatally flawed in general because it did not compare its per treatment costs to those of facilities with a similar patient mix as required by the regulation. In particular, while this national data may explain how the Kidney Center's cost per treatment varies from all other dialysis centers across the country, it does not "demonstrate that . . . its per treatment costs are prudent and reasonable when compared to those of facilities with a similar patient mix."[29] Without this comparative information, the Kidney Center's request cannot meet the requirements of the regulation and is fatally flawed.[30]

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[27] *See id.*

[28] (Emphasis added.)

[29] PRM 15-1 § 2720.1(A). Similarly, the Board notes that the Kidney Center stated that it had a staffing ratio of 2.45 patients to 1 staff member compared with 4 patients per staff member nationally. However, the Kidney Center provided no source documentation for this national staffing average nor does it explain how this staffing ratio compares to that of facilities with a similar patient mix. *See* Provider's Post-Hearing Brief at Tab 38, Exhibit 10 at 1.

[30] The Board recognizes that PRM 15-1 § 2723.3(D) provides certain national data on the median cost per treatment. However, contrary to the Kidney Center's assertions (*see* Provider's Post-Hearing Brief at 65),

In summary, while the Kidney Center meets the requirement for atypical patient mix, it does not fully explain how its costs per treatment compare with those of other dialysis centers with a similar patient mix as required by the regulation.

B. REVOCATION OF THE SELF-DIALYSIS TRAINING EXCEPTION

At the outset, the Board notes that CMS specified that an ESRD facility may elect to retain a previously-approved exception request for the new March 1, 2000 exception cycle if its latest filed cost report supports the fact that its cost per treatment is not less than the previously-approved exception amount; and (2) the ESRD facility certifies that the circumstances for the exception criterion have not changed since the granting of the previously-approved exception amount (*e.g.*, certify that its training program has remained basically the same as stated in its previously-submitted training exception request).[31] By letter dated March 13, 2000, the Medicare Contractor only granted the Kidney Center's request "to retain the previously approved [self-dialysis training] exception rates until new ESRD composites are issued by [CMS] or until the conditions of the [original 1994] exception approval no longer apply."[32]

The Board finds that the Medicare Contractor properly revoked the previously-approved training exception. The Board agrees with the CMS reviewer's conclusion that the Kidney Center's training program changed from the period the previous training exception was requested (*i.e.*, that the conditions of the original 1994 exception approval no longer applied).

As part of its March 13, 2000 request to retain the training exception, the Kidney Center attached a copy of its FY 1998 cost report and attested that the "latest filed cost report, 1998, shows that the cost per treatment is not less than the previously approved exception amount." However, the Kidney Center has only provided the Board with a copy of the letter without the attachment.[33] Without the FY 1998 cost report, the Board cannot verify whether the attestation that the Kidney Center made in its March 13, 2000 letter is accurate. Accordingly, the Board declines to give that attestation any weight.

Based on its review of the FY 1999 cost report that the Kidney Center submitted with the exception request for an atypical patient case mix, the Board agrees with CMS that the cost per treatment for CAPD and CCPD training for FY 1999 is significantly less than the

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this national data does not function as a peer group analysis, but rather, as explained in § 2723.3(D), it is used to supplement the peer group analysis.

[31] *See* Program Memorandum, CMS Pub. 60A, Transmittal No. A-00-06 (Feb. 1, 2000).

[32] *See* Provider Exhibit P-2 at 195.

[33] It appears that the Kidney Center was unable to locate a copy of the FY 1998 cost report that it had attached to its February 13, 2000 letter (or even the copy that was attached to the exception requested as noted therein at Provider Exhibit P-1 at 3). As a result, the Kidney Center requested that information from the Medicare Contractor. However, the Medicare Contractor also was not able to locate it. Contrary to the Kidney Center's claims of prejudice (*see* Provider's Post-Hearing Brief at 108-109), the Kidney Center bears the burden of responsibility of the FY 1998 cost report because the Kidney Center should have retained copies of its correspondence and cost reports and the Kidney Center has the burden of proof. *See* 42 C.F.R. § 413.180(g) (1999).

previously-approved accelerated training exception rates of $426.66 and $460.05 for CAPD and CCPD respectively and even less than the updated 2000 training base rates of $146.95 and $154.95 for CAPD and CCPD respectively.[34] In its FY 1999 cost report, the Kidney Center claims that its average cost per treatment for CAPD and CCPD is $151.02 and $117.87.[35] The reported costs per treatment are improperly inflated because, contrary to 42 C.F.R. § 413.190(d) (1999), the reported cost per treatment improperly include indirect costs (*e.g*., home office overhead costs not directly attributable to the training). Once the indirect costs are factored out,[36] it is clear that the reported FY 1999 costs per treatment are well below the updated 2000 training base rates.[37] In further support of its finding, the Board notes that it also agrees with the CMS reviewer that the training sessions for FYs 1997-2000 have materially decreased from the eight hours in its 1994 exception request.[38] As a result, the Board finds that the Medicare Contractor properly revoked the original 1994 training exception because the conditions of its approval no longer existed.

In summary, the Board finds that: (1) the Kidney Center met the exception criteria for an atypical case mix but failed to meet its burden proof to show "that the facility's costs, in excess of its composite rate, are justifiable under reasonable cost principles. . . ."[39]; and (2) the conditions upon which the 1994 exception for self-dialysis training had changed to warrant its revocation. Therefore, based on the information and data submitted by the Kidney Center with the exception request, the Board finds that the Medicare Contractor properly denied the Kidney Center's request for an ESRD exception for atypical patient mix and properly revoked the Kidney Center's exception for self-dialysis training.

DECISION AND ORDER:

After considering the Medicare law and program instructions, the evidence presented and the parties' contentions, the Board finds that the Medicare Contractor: (1) properly denied the Kidney Center's request to increase the ESRD composite rate for freestanding facilities based on an exception for atypical case mix for the exception cycle beginning March 1, 2000; and (2) properly revoked the Kidney Center's then-existing add-on

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[34] *See* Medicare Contractor Exhibit I-1 at 639-640. .
[35] *See* Provider Exhibit P-38, Tab 23 at 436.
[36] For example, a material part of the FY 1999 average training costs (approximately 30 percent) is based on administrative and general ("A&G") salaries and other costs allocated down from the home office. *See* Provider Exhibit P-38, Tab 23 at 433.
[37] The Board found a similar result occurs when it reviewed the reported costs per treatment for the projected FY 2000. *See* Provider Exhibit P-38, Tab 2 at 264, 266 (showing that the average cost per treatment claimed by the Kidney Center for the projected FY 2000 was improperly inflated by approximately 26 percent due to inclusion of A&G and that exclusion of the A&G would bring the claimed average cost per treatment below the updated 2000 training base rates).
[38] In its FY 1999 cost report, the Kidney Center claimed an average time for peritoneal dialysis training of 7.50 hours for FY 1999 and this is materially below the 8 hours that the Kidney Center claimed when the original 1994 training exception was granted. *See* Provider Exhibit P-38, Tab 23 at 426. Further, the workpapers from the CMS reviewer show its findings on the analysis of FYs 1997 through the projected FY 2000 that the training hours for each of those fiscal years were significantly less the original 8 hours. *See* Medicare Contractor Exhibit I-1 at 815.
[39] PRM 15-1 § 2721. *See also* 42 C.F.R. § 413.180(g) (1999).

payment to the ESRD composite rate for freestanding facilities based on an exception for self-dialysis training.

BOARD MEMBERS PARTICIPATING:

Michael W. Harty
Clayton J. Nix, Esq.
L. Sue Andersen, Esq.

FOR THE BOARD:

/s/
Michael W. Harty
Chairman

DATE: September 1, 2015