CENTERS FOR MEDICARE & MEDICAID SERVICES

Decision of the Administrator

In the case of:	Claim for:
Loma Linda University Kidney Center **Loma Linda, California** **Provider** **vs.** **Blue Cross Blue Shield Association/** **United Government Services, LLC - CA** **Intermediary**	**Provider Cost Reimbursement Determination of Reasonable Costs for ESRD Window End Date – August 30, 2000** **Review of:** **PRRB Dec. No. 2006-D40** **Dated: July 27, 2006**

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 Section 1878(f) (1) of the Social Security Act (Act), as amended (42 USC 1395oo (f)). The Provider and Center for Medicare Management (CMM) submitted comments in this case. Accordingly, this case is now before the Administrator for final administrative review.

BACKGROUND

End Stage Renal Disease (ESRD) facilities are reimbursed for outpatient dialysis services under the composite payment rate system.[1] In the instant case, the ESRD window end date was August 30, 2000. The parties stipulated to the following facts.

[1] The term, "composite payment rate," and the term used in the regulations, "prospective payment rate" refer to the same payments. The prospective payment system (PPS) establishes a per-dialysis treatment composite payment rate, which consists of a labor portion and a non-labor portion. There are two base composite rates: one for hospital based ESRD facilities, and the other for independent facilities. Composite rates, including exception payment rates, remain in effect until CMS announces new payment rates. See 42 C.F.R. §.413.170(b) and §2702 et seq. of the Provider Reimbursement Manual (PRM).

The Provider, an outpatient renal dialysis facility, filed a composite rate exception request with its Intermediary, by letter dated August 28, 2000, seeking additional payment for outpatient dialysis services. The Provider sought a payment rate of $186.59 (or an increase of $51.64) for maintenance hemodialysis and $184.38 for home program peritoneal dialysis (or an increase of $49.43) under the atypical patient mix exception criteria.

By letter dated September 19, 2000, the Intermediary forwarded the Provider's composite rate exception request and its recommendation to CMS. By letter dated on November 15, 2000, CMS notified the Intermediary of its decision that the Provider should continue to be paid its composite rate of $134.95 for outpatient maintenance dialysis and home program dialysis. By letter dated November 29, 2000, the Provider was notified that CMS had denied its exception request. On April 16, 2001 the Provider timely appealed.

ISSUE AND BOARD DECISION

The issue before the Administrator is whether the denial of the Provider's request for an exception to the end stage renal disease (ERSD) composite rate by the Centers for Medicare and Medicaid Services (CMS) was proper, or whether it should be deemed to have been approved pursuant to §1881(b)(7) of the Act.

The Board majority found that pursuant to §1881(b) (7) of the Act [42 U.S.C. §1395rr (b)(7) and 42 C.F.R. §413.180(h)], the exception request was automatically deemed approved as CMS' determination was sent to the Provider after the 60 working day deadline. The Board majority concluded, as noted in prior decisions,[2] since CMS strictly enforces the time limits regarding the submission of composite rate exceptions requests, CMS should also strictly self-enforce purported notice requirements when rendering a determination. The Board majority further found that, once an intermediary receives a provider's timely filed exception request, the burden shifts to CMS to render a decision within the 60 working day window, and to give the provider actual notice of its determination within that same 60 working day window. According to the Board majority, the statutory and regulatory time limit for disapproval should be interpreted as including all essential elements of the entire disapproval process, including transmission of the notice.

The Board majority found that CMS did not comply with the statute when it rendered its determination within the 60 working day window, but failed to issue actual notice until after the 60-day limit. Thus, as a result of the failure of CMS to notify the Provider of the determination within 60 working days as required by

[2] See e.g. Mount Clemens General Hospital, PRRB Dec. No. 2002-D26.

§1881(b)(7) the Provider's exception request is deemed approved.

Two members of the Board dissented on the grounds that the statute, regulations and program guidance required only that CMS render its determination not later than 60 days after the exception request is filed. In the instant case, that action did occur. The Dissent argued that CMS made its decision to deny Loma Linda's exception request within the 60 working day time limit specified in the statute, regulation, and manual. The Dissent acknowledged that in a previous case involving the 60-day limit issue (Mount Clemens General Hospital, PRRB Dec. No. 2002-D26), the Provider did not receive notice of the disapproval until 14 months after the end of the 60 day working period, and the Board found that such inordinate delay may seriously prejudiced that provider's rights, including the option to drop out of the program. The Dissent maintained, however, that in the present case the Provider did not submit its exception request until the final day of the opening "window," and prior to receipt of CMS' denial, the Provider made no inquiry of CMS regarding the decision. The Dissent argued that since CMS' denial was communicated to the Provider within seven working days after the end of the 60 working day period, no claim of prejudice of Provider's rights can reasonably be made. The Dissent argued that CMS' November 15, 2000 disapproval of Provider's exception request satisfied the regulatory requirements in that it was made within 60 working days after the request was filed with Provider's Intermediary, and was therefore timely.

SUMMARY OF COMMENTS

CMM commented, requesting reversal of the Board's decision. CMM argued that the applicable statute, regulation and manual provision require that "an exception request is deemed approved unless it is disapproved within 60 working days after it is filed with its intermediary." CMM argued that CMS made its decision to deny the Provider's exception request within the 60 working day time limit specified in the statute, regulation and manual. CMM noted that prior decisions of the Administrator have upheld this position.[3] Thus, CMM concluded that CMS' November 15, 2000 disapproval of the Provider's exception request satisfied the regulatory requirements in that it was made within 60 working days after the request was filed timely with the Provider's Intermediary.

The Provider argued that the Board's decision was consistent with Medicare law and due process notions of agency notice. The Provider asserted that the notice of denial was submitted to the Intermediary after the 60 day deadline had already expired, as the Provider received notice of CMS' denial 67 days after it was filed. The Provider

[3] Tri-State Memorial Hospital, PRRB Dec. No. 2000-D25, rev'd Admr. May 11, 2000, and Charlotte Hungerford Hospital, PRRB Dec. No. 96-D64, rev'd Admr. Nov. 8, 1996.

asserted that prompt notification of the Intermediary was not made in the instant case, which differed substantially from the cases referenced by CMM.[4]

The Provider also claimed that pursuant to the record, the Intermediary was unable to find the November 15, 2000 letter which substantiates the exact date the denial notification letter was sent from CMS to the Intermediary. The Provider commented that a letter that is not in the record, and possibly not sent in a timely manner, cannot be the basis for satisfying the 60 day limit. The Provider contended that this case is similar to Board's Decision No. 2002-D26 (Mount Clemens General Hospital), which deemed that an ESRD exception request approved because notice of disapproval was not sent to the Provider within the 60 working day time period allowed for processing the exception, as mandated per §1881(b) (7) of the Social Security Act. The Board's decision to approve the Mt. Clemens exception was affirmed, on limited grounds, because the record did not clearly demonstrate that CMS disapproved a provider's request within the 60-day time limit.

The Provider also contended that in the instant case, CMS did not send its notification to the Intermediary until after the 60-day deadline expired. As such, even assuming *arguendo* that notification of the Provider is not subject to the 60-day time limit, the Provider argued that CMS has not satisfied its requirement to provide notification to the Intermediary within the 60 day period. The Provider claimed that the fact that the Intermediary is unable to produce a copy of the November 15 letter in response to the Board's subpoena raises substantial doubts as to when the letter was created. The Provider concluded its comments by requesting that the Administrator affirm the Board's decision to approve the Provider's exception request.

DISCUSSION

The entire record furnished by the Board has been examined, including all correspondence, position papers, exhibits, and subsequent submissions. All comments timely received have been included in the record and considered.

In general, Medicare Part A reimburses approved providers of renal dialysis services on a prospective payment rate basis pursuant to §1881(b) of the Act, and 42 C.F.R. 413.170 *et seq.* However, providers may apply for exceptions to the prospective payment composite rate pursuant to §1881(b) of the Act, and the implementing regulations at §413.170.[5] The criteria for granting an exception is set forth at

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[4] Tri-State Memorial Hospital, PRRB Dec. No. 2000-D25, rev'd Admr. May 11, 2000, and Charlotte Hungerford Hospital, PRRB Dec. No. 96-D64, rev'd Admr. Nov. 8, 1996.
[5] See also §2720 of the PRM.

§413.170(g), which states that an exception request may be granted if the Provider demonstrates with "convincing objective evidence" that its per treatment costs are reasonable and allowable, and directly attributable to any of the listed criteria. The regulations at §413.170(f) establish that the burden falls upon the provider to demonstrate to the satisfaction of CMS that it has met the criteria for receiving an exception to the prospective payment rate.

In this case, however, the parties dispute not the merits of the denial of the Provider's exception request, but rather the interpretation of the pertinent statutory language governing the timing of CMS determination on composite rate exception requests. The determinative language is found at §1881(b) (7) of the Act, which states:

> [E]ach application for such exception shall be deemed to be approved unless the Secretary disapproves it not later than 60 working days after the date the application is filed. [Emphasis added.]

The Provider did not receive notice of the Board's decision until November 29, 2000. The Provider argues that, because it did not receive notice of CMS' decision within 60 working days after it filed the exception request, the language at §1881(b)(7) renders its request accepted in full as a "deemed approval." CMM argues that the statutory language requires that CMS' disapproval must be only rendered within the 60 days or the exception will be deemed approved.

The Administrator finds that the statute states that an exception request "shall be deemed to be approved unless the Secretary disapproves it not later than 60 working days after the date the application is filed." [Emphasis added] The statute does not state that the actual notice of the disapproval must be received by the provider within 60 working days after the application is filed. The Administrator notes that the key word in §1881(b) (7) is "disapproves," which is defined in ordinary use as, "to refuse to approve; reject."[6] The Administrator finds the plain language of the statute using the word "disapproves" requires that CMS render the disapproval of the ESRD exception request within the 60-working day statutory period. The statute does not require that the Provider receive the disapproval, or have notice of the disapproval, within that statutory time period. Thus, the Administrator finds the Board erred in holding that the exception request was deemed approved because the Provider did not receive notice of the disapproval within the 60-working day period.[7]

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[6] See American Heritage Dictionary, 4th Ed. (Houghton Mifflin) (2000).

[7] In reference to the Provider's comments regarding a previous case involving the 60-day limit issue (Mount Clemens General Hospital, PRRB Dec. No. 2002-D26), the Administrator applied the word "disapproved" as above. The Administrator found, in

Thus, the Administrator finds that CMS' November 15, 2000 disapproval of Provider's exception request satisfied the statutory requirements in that it was made within 60 working days after the request was filed with Provider's Intermediary. Therefore, the Administrator finds the disapproval of the request was timely.

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that case, that the record did not show that CMS' disapproval was rendered within the statutory 60 day time frame.

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: 9/12/06 /s/

Leslie V. Norwalk, Esq.
Deputy Administrator
Centers for Medicare & Medicaid Services