CENTERS FOR MEDICARE & MEDICAID SERVICES

Decision of the Administrator

In the case of:	Claim for:
Gundersen Lutheran Hospital **Provider** **vs.** **Blue Cross Blue Shield Association/ United Government Services, LLC - WI** **Intermediary**	**Provider Cost Reimbursement Determination of Reasonable Costs for ESRD Window End Date – July 2, 2001** **Review of:** **PRRB Decision 2006-D51** **Dated: September 14, 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 parties were notified of the Administrator's intention to review the Board's decision. The Provider and CMS' 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[1] system. In the instant case, the ESRD

[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).

window end date was July 2, 2001. The parties agreed to the following facts. The Provider, an outpatient renal dialysis facility, filed a composite rate exception request with its Intermediary, on July 2, 2001. The 60th working day after July 2, 2001 is September 25, 2001.[2] The Intermediary forwarded the Provider's composite rate exception request and its recommendation to CMS. CMS' decision denying the Provider's exception request was dated September 21, 2001 and was sent to the Intermediary on that date.[3] The Intermediary letter transmitting CMS' decision to the Provider was dated October 1, 2001.[4]

ISSUE AND BOARD DECISION

The issue before the Board was whether the denial of the Provider's request for an exception to the end stage renal disease (ERSD) composite rate was in compliance with 42 C.F.R. §413.180(h).

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,[5] that the regulation has been interpreted as allowing CMS to strictly enforce time limits applicable to providers making an exception request.[6] The Board found that it is only reasonable that the same strict enforcement principles found in the same regulations apply to time limits for CMS. The Board majority further found that CMS chose to establish a cumbersome two-tiered notification system despite the 60 working day limit and to describe the action required as "disapproval." Because the regulations are silent as to time limits for other steps in the process, 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.

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

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[2] See Provider and Intermediary Joint Stipulation No. 3 (Provider Exhibit 18).
[3] See Joint Stipulation No. 4
[4] See Intermediary's letter, Provider Exhibit P-2.
[5] See e.g. Mount Clemens General Hospital, PRRB Dec. No. 2002-D26.
[6] Children's Hospital of Buffalo v. Shalala, No. 00-6187, 2001 App. Lexis 979 (Jan. 24, 2001).

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 working 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 the Provider'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 four 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' September 21, 2001 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 with the 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.[7] Thus, CMM concluded that CMS' September 21, 2001 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 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 working day deadline had already expired, as the Provider received notice of CMS' denial 66 days after the request was filed. The Provider asserted that prompt notification of the Intermediary was

[7] 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.

not made in the instant case, so the Provider's exception should be deemed approved.

The Provider disputed the CMS contention that in order to have a sound basis for challenging the tardiness of exception request disapproval, a claim of prejudice of the Provider's rights must reasonably be made. The Provider maintained that the claim of prejudice requirement provides no metric to determine either how late notification can be, or how much damage a provider must incur in order to substantiate a claim. The Provider also contested CMS' assertion that "prior to receipt of CMS' denial, the Provider made no inquiry of CMS regarding the decision." The Provider argued that the record is mute with regard to whether an inquiry was made or not, and that the inference that a provider must contact CMS within 60 days effectively shifts the burden of notification to the provider in direct contradiction of applicable regulation and statute.

The Provider also contended that CMS has the burden of notification which is an essential part of the process of exception request adjudication. Without notification, the decision process is incomplete and the decision itself is left unfinished. The Provider argued that nowhere in the applicable statute, regulation, and manual provisions is there a provision that notification can be delayed until serious damage is incurred by the provider.

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.[8] The criteria for granting an exception is set forth at §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.

[8] See also §2720 of the PRM.

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 and regulatory 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 Secretary implemented the statutory provision at 42 C.F.R. §413.180(h) which states that:

> An exception request is deemed approved unless it is disapproved within 60 working days after it is filed with its intermediary.

In this case, 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 deemed approved. CMM argues that the statutory language requires that CMS' disapproval must be only rendered within the 60 working 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 issued by, or received by, the provider within 60 working days after the application is filed.[9] 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."[10] 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 Intermediary did not transmit the disapproval within the 60-working day period.[11]

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[9] See also 42 C.F.R. §413.180 (h)

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

[11] Regarding a previous case involving the counting of the 60 working day period, the Administrator found that the record did not show that CMS' disapproval was "rendered" within the statutory 60 working day time frame.

The Administrator finds that CMS' September 21, 2001 disapproval of the Provider's exception request satisfied the statutory and regulatory requirements in that it was made within 60 working days after the request was filed with the Intermediary. Therefore, the Administrator finds the disapproval of the request was timely.

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: 10/26/06

/s/
Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services