# PROVIDER REIMBURSEMENT REVIEW BOARD DECISION

2006-D40

**PROVIDER -**
Loma Linda University Kidney Center
Loma Linda, California

Provider No.: 05-2550

**vs.**

**INTERMEDIARY -**
BlueCross BlueShield Association/
United Government Services, LLC - CA

**DATE OF HEARING -**
June 10, 2004

ESRD Window End Date -
August 30, 2000

**CASE NO.:** 01-2872

**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.

MEDICARE STATUTORY AND REGULATORY BACKGROUND:

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

The Medicare program was established to provide health insurance to the aged and disabled. 42 U.S.C. §§1395-1395cc. 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 charged with administering the Medicare program. CMS' payment and audit functions under the Medicare program are contracted out to insurance companies known as fiscal intermediaries. Fiscal intermediaries determine payment amounts due the providers under Medicare law and under interpretive guidelines published by CMS. See 42 U.S.C. §1395h, 42 C.F.R. §§413.20(b) and 413.24(b).

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.

Regarding the exception request, 42 U.S.C. §1395rr(b)(7) states, in relevant part, that:

> Each application for such an exception shall be deemed to be approved unless the Secretary disapproves it by no later than 60 working days after the date the application is filed.

Similarly, 42 C.F.R. §413.180(h)(2000)[2] states:

> Approval of an exception request. An exception request is deemed approved unless it is disapproved within 60 working days after it is filed with the intermediary.

This case involves whether the denial was timely under these provision.

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[1] 42 U.S.C. §1395rr and the regulations at 42 C.F.R. §413.180 et seq.

[2] 70 Fed. Reg. 70116, 70331 (November 21, 2005), recodified this subsection, in full text, effective January 1, 2006, to 42 C.F.R. §413.80(g).

STATEMENT OF THE CASE AND PROCEDURAL HISTORY:

Loma Linda University Kidney Center (Provider) is located in Loma Linda, California. The Provider performs in-facility hemodialysis as well as home peritoneal dialysis for its patients. The Provider has filed an appeal pertaining to the denial of the Provider's application for relief from the composite payment rate established for its Medicare certified renal dialysis facility.

The procedural history of this case upon which the Board's findings and conclusions are based is as follows:

August 28, 2000 –The record indicates that the Provider's request for an exception to the composite payment rate[3] was received by United Government Services, LLC-CA (Intermediary) on this date.[4] The Provider sought an exception amount of $186.59 (or an increase of $51.64 for maintenance hemodialysis) and of $184.38 for home program peritoneal dialysis (or an increase of $49.43) under the atypical patient mix exception criteria.[5]

September 19, 2000- The Intermediary issues a letter to CMS recommending a composite rate of $181.52 for maintenance hemodialysis and $179.55 for home program peritoneal dialysis.[6]

November 15, 2000- CMS issues a letter to the Intermediary stating that the Provider should continue to be paid its composite rate of $134.95 for outpatient maintenance and home program dialysis.[7]

November 29, 2000- The Intermediary issues an exception request denial to the Provider[8] enclosing CMS's November 15, 2000 letter.

April 16, 2001- The Provider subsequently filed a timely request for a hearing with the Provider Reimbursement Review Board (Board) and has met the jurisdictional requirements of 42 C.F.R. §§405.1835-1841.

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[3] Provider Exhibit (Ex.) 1

[4] See references in Intermediary Ex. 1, Provider Exs. 2 and 6.

[5] Provider Ex. 1, p.3 (Exception Request).

[6] See references at Intermediary Ex 1, Provider Ex. 2 (copy of September 19, 2000 letter is not in this record)

[7] See Intermediary Ex.1, Provider Ex.2 at 9. The Board notes that on September 19, 2005, the Board issued a subpoena duces tecum to the Intermediary requesting the envelope containing CMS' November 15, 2000 letter as well as any and all other evidence in the Intermediary's possession which substantiates the exact date such letter was mailed from CMS to the Intermediary. On October 4, 2005, the Intermediary responded that it was unable to find the November 15, 2005 letter.

[8] Provider Ex. 3.

The Provider was represented by Jack Ahern and Jeffrey A. Lovitky, Esq. The Intermediary was represented by Bernard Talbert, Esquire, of Blue Cross and Blue Shield Association.

Provider position:

The Provider contends that because it did not receive notification of the denial of its exception request within 60 working days after the date the application was filed, the request should be approved pursuant to 42 U.S.C. §1395rr(b)(7) and 42 C.F.R. §413.180(h). The Provider explains that to have been timely, ". . . the 60 working days limit required that notification of the CMS determination . . . [be] received by the Provider on or before November 24, 2000."[9] The Provider notes that the denial was not communicated to the Provider until the Intermediary's letter dated November 29, 2000 letter; moreover, as there is no evidence that the notification was faxed or sent via overnight mail, it would be reasonable to conclude that the receipt of notification would have added 5 additional days to the process. Also, the Intermediary's belief that the Exception Request was timely processed by virtue of CMS' November 15, 2000 letter contradicts Congress' intent to simplify and expedite the exception request process. Moreover, previous PRRB decisions established that the date of the CMS decision did not necessarily stop the 60 working days clock.[10]

Intermediary/CMS position:

The Intermediary argues that the denial was timely made by CMS and transmitted before the 60 working-day deadline expired.[11] Moreover, the Administrator has rejected the Provider's position that actual notice of CMS' disapproval must be received by the Provider within 60 working days.[12]

FINDINGS OF FACT, CONCLUSIONS OF LAW AND DISCUSSION:

The Board majority finds that pursuant to 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 Intermediary after the 60 working day deadline.

Congress imposed the deadline in the statute, thereby indicating its concern about CMS delays. Prior Board cases and the legislative history illustrate that Congress' concern was

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[9] Provider Post-Hearing Brief at 22, Provider Ex. 6.

[10] Supra, note 9. Tri-State Memorial Hospital v. Blue Cross and Blue Shield Association et.al., PRRB Dec. No. 2000-D-25 (Mar. 6, 2000), modified CMS Admr. (May 8, 2000).

[11] Tr. at 21-23.

[12] Charlotte Hungerford Hospital v. Blue Cross and Blue Shield Ass'n et.al, PRRB Dec. No 1996-D64 (Sept. 11, 1996), rev'd CMS Admr. Dec. (November 8, 1996); Mt. Clemens General Hospital, PRRB Dec. No. 2002-D26 (July 9, 2002) aff'd, on limited grounds, CMS Admr. (Sept. 6, 2002).

well-founded.[13] Congressional intent is frustrated if CMS fails to timely send notice of its decisions. The 60-day limit is meaningless without communication. As the Board has noted in prior decisions,[14] the regulation has been interpreted as allowing CMS to strictly enforce time limits applicable to providers making an exception request.[15] It is only reasonable that the same strict enforcement principles found in the same regulation apply to time limits for CMS.

If CMS had promulgated a regulation that addressed time limits for the full process, including notice, and that established a regulatory grace period for transmission of the decision within a reasonable time after the decision was made, such regulation would likely pass muster as being consistent with the statute. But CMS chose instead to establish a cumbersome two-tiered notification system despite the statutory 60-day limit and to describe the action required only as "disapproval." Because the regulations are silent as to time limits for other steps in the process, we believe that the statutory and regulatory time limit for "disapproval" must therefore be interpreted as including all essential elements of the entire disapproval process, including transmission of the notice. The notice was not sent until after the 60-day limit; therefore, it must be deemed approved.

The Board majority does not dispute that the deeming regulation could be read literally as only requiring the CMS *decision* to be made within the 60-day period. Indeed, a literal reading would not even require that CMS' determination be made in writing within the 60-day time limit. However, that interpretation ignores the reality that notice is essential to the exception process and to fundamental notions of due process. Notice is not a mere formality; it triggers appeal rights and permits the Provider to reasonably budget or restructure to avoid future losses.

DECISION AND ORDER:

As a result of the failure of CMS to notify the Provider of the determination within 60 working days as required by 42 U.S.C. §1395rr(b)(7), the Provider's exception request is deemed approved. Accordingly, the substantive issue as to whether the exception denial was otherwise proper is moot. [16]

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[13] See e.g. Mount Clemens General Hospital v. Blue Cross and Blue Shield Association/United Government Services, PRRB Dec. No 2002-D26, July 9, 2002 ; Providers Post-Hearing Brief at 24.

[14] Id.

[15] Children's Hospital of Buffalo v. Shalala, No 00-6187, 2001 App. Lexis 979 (Jan. 24, 2001).

[16] See Provider Post-Hearing Brief at 20-21. The Provider claims that the Intermediary's failure to reach a conclusion on all determinative issues (i.e., atypical patient mix) is insufficient to meet the 60-day processing deadline.

BOARD MEMBERS PARTICIPATING:

Suzanne Cochran, Esq.
Gary B. Blodgett,D.D.S. (dissenting)
Elaine Crews Powell, C.P.A. (dissenting)
Anjali Mulchandani-West
Yvette C. Hayes

FOR THE BOARD:

DATE: July 27, 2006

Suzanne Cochran. Esq.
Chairperson

Dissenting Opinion of Gary B. Blodgett, D.D.S. and Elaine Crews Powell, C.P.A.

We respectfully disagree with the majority's opinion that the Provider's exception request must be deemed approved because the Provider was not notified of CMS' decision disapproving the request within 60 working days.

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." No mention is made regarding timely notifying the provider of the decision. 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 exception request at issue in this case was submitted on August 28, 2000. CMS made its determination to deny the request on November 15, 2000. The Provider maintains that to be timely, the 60 working day limit required that it receive notification of CMS' final determination on or before November 24, 2000, but that the denial was not communicated to the Provider until November 29, 2000. (We note, however, that the 60$^{th}$ working day after August 28, 2000 is November 20, 2000, not November 24$^{th}$ per the Provider's count of working days.) Therefore, the Provider did not receive notice of CMS' denial of the exception request until 67 working days after it was filed.

Board member Blodgett acknowledges that in a previous case involving the 60-day limit issue (Mount Clemens General Hospital, PRRB Dec. No. 2002-D26), he agreed with the Board majority that the provider's exception request should have been deemed approved. However, in the Mount Clemens case the provider did not receive notice of the disapproval until **14 months** after the end of the 60 working day period, and the Board majority found that such an inordinate delay may have seriously prejudiced that provider's rights, including its option to drop out of the program.

In the present case the Provider did not submit its exception request until the final day of the opening "window." Moreover, prior to receipt of CMS' denial, Provider made no inquiry of CMS regarding the decision. 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.

We find 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. Therefore, the disapproval of the request was timely.

Since the Board Majority deemed the exception request approved, we agree that the substantive issue as to whether the denial of Provider's exception request was proper is moot.

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Gary B. Blodgett, D.D.S.

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Elaine Crews Powell, C.P.A