PROVIDER REIMBURSEMENT REVIEW BOARD DECISION

ON THE RECORD
2006-D51

PROVIDER -
Gundersen Lutheran Hospital
LaCrosse, Wisconsin

Provider No.: 52-0087

vs.

INTERMEDIARY -
BlueCross BlueShield Association/
United Government Services, LLC-WI

DATE OF HEARING -
December 14, 2005

Exception Request Window Closing -
July 2, 2001

CASE NO.: 02-1212

INDEX

ISSUE:

Whether the denial of the Provider's End Stage Renal Disease (ESRD) exception request was in compliance with 42 C.F.R. §413.180(h), which states:

> *(h) Approval of an exception request.* An exception request is deemed approved unless it is disapproved within 60 working days after it is filed with its Intermediary.

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 treatments 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.

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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).

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

STATEMENT OF THE CASE AND PROCEDURAL HISTORY:

Gundersen Luthern Hospital (Provider) is an acute care hospital located in LaCrosse, Wisconsin. This case concerns the Centers for Medicare and Medicaid Services' (CMS)[3] denial of the Provider's application for relief from the composite payment rate established for its Medicare-certified renal dialysis facility.

During certain periods of time 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. The exception window at issue in the present case was closed by CMS on July 2, 2001. The Provider filed its exception request with United Government Services (Intermediary) on July 2, 2001. The parties have stipulated that this filing was timely. The Medicare regulation at 42 C.F.R. §413.180(h) states that "[A]n exception request is deemed approved unless it is disapproved within 60 working days after it is filed with its intermediary." The 60th working day after July 2, 2001 is September 25, 2001.[4] CMS' decision denying the Provider's exception request was dated September 21, 2001 and was sent to the Intermediary on that date.[5] CMS' decision was mailed to the Provider by the Intermediary on October 1, 2001.[6] The Parties have stipulated[7] that the sole issue before the Provider Reimbursement Review Board (Board) is the timely notification of CMS' decision by the Intermediary. The actual exception request denial by CMS is not at issue before the Board.

The Provider filed a timely request for a hearing with the Board and has met the jurisdictional requirements of 42 C.F.R. §§405.1835-405.1841. The Provider was represented by Mr. Jack Ahern of Ahern & Associates. The Intermediary was represented by Bernard M. Talbert, Esquire, of Blue Cross Blue Shield Association.

PARTIES' CONTENTIONS:

The Provider contends that the exception request must be deemed approved because CMS failed to timely deny the exception. This contention is based upon the plain language of 42 C.F.R. §413.180(h). The Provider asserts that the processing of an exception request does not end until the provider is notified. It asserts that because the Intermediary and CMS did not notify the Provider of CMS' decision to deny its exception request within 60 working days, it must be deemed approved.

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[3] Previously called Health Care Financing Administration (HCFA).

[4] See Provider and Intermediary Joint Stipulation--Stipulation No. 3 (Provider Exhibit 18).

[5] See Joint Stipulation No. 4

[6] See Provider Exhibit P-2.

[7] See Joint Stipulation No. 1.

The Intermediary contends that the legal measure for the denial is the date of the determination, not the communication of notice. The Intermediary argues that CMS' determination was timely made within the 60-day limit, although it did not communicate that decision to the Provider within that time frame.

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 is automatically deemed approved as CMS' determination was sent to the Provider 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 well founded.[8] Congressional intent is frustrated if CMS fails to timely send notice of its decision. The 60-day limit is meaningless without communication. As the Board has noted in prior decisions,[9] the regulation has been interpreted as allowing CMS to strictly enforce time limits applicable to providers making an exception request.[10] The Board majority therefore finds that it is only reasonable that the same strict enforcement principles found in the same regulations 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 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, the Board majority believes 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 a provider to reasonably budget or restructure to avoid future losses.

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[8] 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.

[9] Id.

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

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.

BOARD MEMBER 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: September 14, 2006

Suzanne Cochran
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 Gundersen Lutheran'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 July 2, 2001. CMS made its determination to deny the request on September 21, 2001. The Provider maintains that to be timely, the 60 working day limit required that it receive notification of CMS' final determination on or before September 25, 2001, but that the denial was not communicated to the Provider until October 1, 2001.

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." 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.

We find that CMS' September 21, 2001 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.

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Gary B. Blodgett, D.D.S.

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Elaine Crews Powell, C.P.A.