# PROVIDER REIMBURSEMENT REVIEW BOARD DECISION

2008-D23

## **PROVIDER** –

University of Texas M.D. Anderson Cancer Center Houston, TX

Provider No.: 45-0076

VS.

## **INTERMEDIARY** –

BlueCross BlueShield Association/ TrailBlazer Health Enterprises **DATE OF HEARING -**

July 31, 2007

Cost Reporting Periods Ended -August 31, 2000 and August 31, 2001

**CASE NOs**: 04-1953 and 05-1582

# **INDEX**

| Issues  | 2 |
|---|---|
| Medicare Statutory and Regulatory Background        | 2 |
| Statement of the Case and Procedural History        | 3 |
| Parties' Contentions                                | 3 |
| Findings of Fact, Conclusions of Law and Discussion | 6 |
| Decision and Order                                  | 7 |

#### **ISSUES:**

1. Whether the Intermediary properly disallowed the Provider's request for an adjustment to the TEFRA rate-of-increase ceiling to account for the cost of new drugs that were not approved in the 1983 base year.

2. Whether the Intermediary properly calculated the Provider's 1996 reasonable cost that were included in the denominator of the fraction used to determine the payment-to-cost ratio for purposes of the Outpatient Propsective Payment System (OPPS) hold harmless payment.

#### MEDICARE STATUTORY AND REGULATORY BACKGROUND:

This is a dispute over the amount of Medicare reimbursement due a provider of medical services.

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 (DHHS) 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).

At the close of its fiscal year, a provider must submit a cost report to the fiscal intermediary showing the costs it incurred during the fiscal year and the portion of those costs to be allocated to Medicare. 42 C.F.R. §413.20. The fiscal intermediary reviews the cost report, determines the total amount of Medicare reimbursement due the provider and issues the provider a Notice of Program Reimbursement (NPR). 42 C.F.R. §405.1803. A provider dissatisfied with the intermediary's final determination of total reimbursement may file an appeal with the Provider Reimbursement Review Board (Board) within 180 days of the issuance of the NPR. 42 U.S.C. §139500(a); 42 C.F.R. §405.1835.

Generally, the operating costs of inpatient hospital services are reimbursed by Medicare primarily through the Prospective Payment System (PPS). See, 42 U.S.C. § 1395ww(d). PPS provides Medicare payment for hospital inpatient operating and capital-related costs at predetermined, specific rates for each hospital discharge. However, cancer hospitals are exempt from PPS for the operating costs of their inpatient services and afforded special exemptions under PPS for the outpatient services that they furnish.

The issues in this case involve the proper treatment of the Provider's claimed cost as a cancer facility.

#### STATEMENT OF THE CASE AND PROCEDURAL HISTORY:

The University of Texas M.D. Anderson Cancer Center (Provider) is one of the nation's ten federally-designated comprehensive cancer centers. As a cancer hospital, the Provider is exempt from the prospective payment system for the operating costs of its inpatient services. The Provider receives reimbursement for those services on a reasonable cost basis, subject to a rate-of-increase ceiling on operating costs of inpatient hospital services as established by the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA). The Provider is also subject to a hold-harmless provision under PPS for hospital outpatient services (OPPS) that became effective on August 1, 2000. Under that provision, payments to the Provider for designated services covered by OPPS are based upon a payment-to-cost ratio derived from the Provider's fiscal year ended 8/31/96. The Provider filed a request for a rebasing and/or adjustment to its FY 2000 and 2001 TEFRA rate-of-increase ceilings and for an adjustment to its hold harmless status. TrailBlazer Health Enterprises (Intermediary) in coordination with CMS denied the Provider's request for a rebasing and only partially granted its request for an adjustment to the TEFRA rate-of-increase ceiling. In addition, the Intermediary denied the Provider's request for an adjustment to its hold harmless status.

The Provider appealed the Intermediary's determinations to the Board and met the jurisdictional requirements of 42 C.F.R. §§405.1835 - 405.1841. The Provider was represented by Christopher L. Keough, Esq., of Vinson and Elkins LLP. The Intermediary was represented by Bernard M. Talbert, Esq., of Blue Cross Blue Shield Association.

## PARTIES' CONTENTIONS:

#### Issue 1: TEFRA Adjustment

Background: In 1982 Congress enacted the Tax Equity and Fiscal Responsibility Act (TEFRA) which modified the reasonable cost reimbursement methodology to create incentives for providers to render services more efficiently and economically. TEFRA imposed a ceiling on the rate-of-increase of inpatient operating costs recoverable by a hospital. The TEFRA rate-of-increase ceiling or target amount, is calculated based upon the allowable Medicare operating costs in a hospital's base year (net of certain other expenses such as capital-related and direct medical education costs) divided by the number of Medicare discharges in that year. The TEFRA target amount is updated annually based on an inflation factor. If a provider incurs costs below the applicable TEFRA target amount in a given cost reporting year, it is entitled to reimbursement for its reasonable costs plus an additional incentive payment. If a provider incurs cost above its TEFRA target amount, a portion of the excess costs may be reimbursed in accordance with the provisions of 42 C.F.R. §413.40(d)(3). In addition, 42 C.F.R. §413.40(e) established procedures by which providers may request and receive an adjustment to or an exemption from its TEFRA target amount. The statute governing the TEFRA ceiling requires CMS to provide for an adjustment to the TEFRA ceiling when events beyond a hospital's control create a distortion in the comparison of current costs to the TEFRA

base year. [42 U.S.C. §1395ww(b)(4)(A)(i)]. The statute as codified at 42 C.F.R. §413.40(g)(3) provides for an adjustment for any factor that results in a significant distortion between the base year and a subsequent year that is subject to the TEFRA rate-of-increase ceiling.

The Provider's operating costs for inpatient services furnished to Medicare beneficiaries exceeded its allowable TEFRA target amount for both FY 2000 and FY 2001. The Provider timely submitted requests for the assignment of a new TEFRA base year or for adjustments to the TEFRA target amount based on: 1) increased patient acuity for inpatients, as represented by the change in the Provider's case mix index since the 1983 TEFRA base year; 2) the migration of less costly services from the inpatient setting to the outpatient setting; and 3) the addition of new services, such as drugs that were not approved for use in the 1983 base year. CMS and the Intermediary granted partial adjustments to the target amount per discharge for ancillary departments that experienced increased staffing but allowed no adjustment for new drugs that were not approved for use in the base year.

There is no dispute over the controlling regulations or the circumstances of the case. At issue is the disallowance of the Provider's request for an adjustment to the TEFRA target amount to account for the cost of new drugs that were not approved in the 1983 base year.

Provider's Contentions: The Provider contends that Section 1886 (b)(4)(a)(i) of the Social Security Act and 42 C.F.R. §413.40(g) require the Secretary to adjust TEFRA target amount where events beyond a hospital's control create a distortion in the increase of costs for a cost reporting period. There is no dispute that the Provider's costs significantly exceeded base year costs and included new drugs not approved for use in 1983. The Provider contends that appropriate patient care standards required the use of the new drugs and that their use significantly increased the operating costs of the facility. The Provider further argues that such care standards are beyond its control and contends that it is entitled to an adjustment for its increased costs.

Intermediary's Contentions: The Intermediary contends that CMS properly denied the portion of the Provider's TEFRA exception request that was based on the cost of new drugs which were not approved by the FDA during the TEFRA base year and that CMS followed the methodology prescribed in Chapter 30 of CMS Pub. 15-1 in performing its review. The computation of the TEFRA target is based upon all aspects of a provider's base year costs – salaries of direct staff, product costs, other direct costs and overhead costs such as administrative and general. Furthermore, the methodology used for computing the TEFRA rate is based upon an "all things being equal" standard where it is assumed that each element of cost should increase no more than an inflation or update factor. While this assumption can be refuted by demonstrating an increase in inpatient acuity, justifying an exception to the target rate by simply backing into the difference between the target rate for drugs charged to patients during the base year and the cost of new drugs does not satisfy the regulatory purpose of the TEFRA target limit or adequately explain why the Provider's costs exceeded the target rate. There are other

factors which have not been ruled out. Therefore, the Intermediary concludes that the proximity between the methodological output and the cost loss is as much product of coincidence as it is a result of rebutting the critical "all things being equal" presumption upon which TEFRA reimbursement is based.

# Issue 2: OPPS Hold Harmless Payment

Page 5

Background: In 1997, Congress passed the Balanced Budget Act of 1997 (P.L. 105-33). The new law amended section 1833 of the Act, 42 U.S.C. §1395(l) by adding section (t) which required that the secretary establish a prospective payment method for designated hospital outpatient services effective January 1, 1999. In 1999, Congress further amended section 1833(t) to establish a hold harmless provision for outpatient services furnished by cancer hospitals. Under its provisions, cancer hospitals are entitled to payment of the greater of the amount that normally would be paid under the hospital outpatient PPS fee schedule or, alternatively, the product of the hospital's reasonable cost of services furnished in the current year multiplied by the ratio of Medicare payment to the cost for outpatient services furnished in the 1996 cost reporting year. For the 1996 base year, section 1861 (v)(1)(S)(ii) of the Act further defined the reasonable cost of hospital outpatient services as including only the net amount after application of 5.8% and 10% cost reduction factors for operating and capital-related costs, respectively, of services furnished to outpatients. [42 U.S.C. §1395x(v)(1)(S)(ii).]

As a cancer hospital, the Provider is subject to the hold-harmless provision for payment under OPPS. Pursuant to the CMS instructions in Program Memorandum (PM) A-01-51, the Provider furnished the Intermediary with a calculation of its 1996 payment-to-cost ratio (PCR) by letter dated July 19, 2001 for the purpose of establishing the initial monthly interim payment rate under the OPPS. The denominator used in the submitted calculation of the PCR included the total cost of outpatient services furnished by the Provider in 1996 before the application of the 5.8% and 10% cost reduction factors prescribed in the statutory definition of "reasonable cost" in section 1861 (v)(1)(S)(ii) of the Social Security Act , 42 U.S.C. §1395x(v)(1)(S)(ii). CMS instructions governing the PCR calculation specified that the denominator of the PCR fraction should include "[t]he reasonable cost of these services for this period, without applying the cost reductions under section 1861(v)(1)(S) of the Act." The Provider contends that the denominator of the PCR faction should include only the net costs after application of the statutory reduction factors and requested a recalculation of the denominator using the reduction factors. The Intermediary denied the request.

The parties stipulated to the pertinent facts in the case and there is no dispute over the controlling regulations or the circumstances of the case. At issue is the proper amount of the Provider's 1996 reasonable cost to be included in the denominator of the fraction used to determine the payment-to-cost ratio for purposes of the outpatient PPS hold-harmless payment.

<sup>&</sup>lt;sup>1</sup> 42 C.F.R. §419.70(f)(2)(ii)(2000); <u>See also Program Memorandum A-01-51</u>, reprinted in MEDICARE & MEDICAID GUIDE (CCH) ¶ 151,818.

Provider's Contentions: The Provider contends that Section 1861(v)(1)(S)(ii) of the Act requires application of the 5.8% and 10% cost reduction factors prior to determination of reasonable costs and argues that the Intermediary's failure to apply these factors in its calculations is contrary to the plain meaning and intent of the statute. Further, the Provider argues that the CMS prescribed Medicare cost report form for the 1996 base year calculated reasonable cost for that period as the net cost after application of the 5.8% and 10% cost reduction factors and that the Intermediary's omission of the factors in subsequent periods is inconsistent with the reasonable cost that CMS paid the Provider for 1996. The Provider also argues that CMS' reliance on the instructions in PM A-01-51 makes their calculations invalid since the instructions were not adopted in accordance with the notice and comment rule making procedures mandated by the Administrative Procedure Act.

Intermediary's Contentions: The Intermediary contends that its calculations are consistent with the regulation at 42 C.F.R. §419.70 and the instructions provided by CMS through PM A-01-51. Those instructions require that a provider's base year cost, used as the denominator in calculating a PCR, do not include the 5.8% reduction for operating costs and the 10% reduction for capital-related costs that were in effect during the base year. The Intermediary argues further that the Provider's complaint alleges a disconnection between the statute and the regulation and, as such, the complaint is beyond the Board's authority to decide.

# FINDINGS OF FACT, CONCLUSIONS OF LAW AND DISCUSSION:

After considering the Medicare law and program instructions, the evidence presented the parties' contentions and stipulations, the Board finds and concludes as follows:

#### Issue 1: TEFRA Adjustment

The issue presented for the Board's consideration required an examination of the controlling statute and CMS implementing instructions in their totality. It is undisputed that Section 1886 (b)4(a)(i) of the Act and 42 C.F.R. §413.40(g) allow the Secretary to adjust TEFRA target amounts where events beyond a hospital's control create a distortion in the increase of costs in a cost reporting period. However, the Board's examination indicated that, while the statute allows for an exception, it offers no instruction relative to its calculation. CMS Pub. 15-1 at Chapter 30 provides a detailed explanation of the allowance and sets out the criteria that must be met to support an increase. In pertinent part, those criteria require that the hospital's allowable excess costs be attributable to the circumstances specified and separately identified by the hospital. The criteria require that a Provider document its costs with sufficient detail and clarity to identify the specific source of the cost increase within its current Medicare cost per discharge versus the base year cost per discharge.

This case turns on whether the Provider has adequately documented how much the costs of new drug technologies exceed the comparable cost of drugs that were included in the base year. The Board acknowledges that the specific cost of new drugs were not included

in the base year. However, their impact cannot be estimated without an analysis of the services provided to Medicare recipients that demonstrates which drug applications are new and which are replacement services. The Provider assumed that all new drugs were for new treatments and replaced or agumented old protocols. Based upon the documentation provided, the Board concludes that the Provider failed to quantify the net impact of the new drug technologies so that the increase in drug costs could properly be mitigated to the extent that they replaced existent drugs, therapies and/or ancillary services such as surgery and radiation. The Board concludes that the Intermediary's denial of the Provider's request for an adjustment to the TEFRA rate-of-increase ceiling was proper.

# Issue 2: OPPS Hold Harmless Payment

The primary issue before the Board is whether the determination of reasonable costs for use in the PCR calculation requires the application of 5.8% and 10% cost reduction factors for operating and capital-related costs of services furnished to outpatients. It is uncontested that the controlling statute at §1861(v)(1)(S)(ii) requires that payments to providers under the section be reduced. At issue is whether "reasonable costs" require reduction as well. The Board's examination of the statute indicated that its language requires the determination of reasonable cost<sup>2</sup> as a first step. The subsequent application of the 5.8% and 10% factors is a reduction to determine payments and do not equate a second calculation of reasonable costs. Further, the Board can find nothing in the statute which requires that reasonable costs be adjusted downward for determining the PCR. Absent a requirement in the statute, the Board is bound by the requirements of the regulation at 42 C.F.R. §419.70 and CMS' implementing instructions which collectively preclude application of the factors to determine reasonable costs. Accordingly, the Board concludes that the Intermediary's calculation which omitted their application was proper.

# **DECISION AND ORDER:**

#### Issue 1: TEFRA Adjustment

The Provider failed to quantify the net impact of the new drug technologies. The Intermediary's denial of the Provider's request for an adjustment to the TEFRA rate-of-increase ceiling was proper.

#### Issue 2: OPPS Hold Harmless Payment

The regulation at 42 C.F.R. §419.70 and CMS implementing instructions preclude application of the 5.8 % and 10% cost reduction factors to determine reasonable costs. The Intermediary's calculation which omitted their application was proper.

<sup>&</sup>lt;sup>2</sup> <u>See</u>, 65 Fed. Reg. 67798, 67814-15 (November 13, 2000).

# **BOARD MEMBERS PARTICIPATING:**

Suzanne Cochran, Esquire Elaine Crews Powell, C.P.A. Yvette C. Hayes Michael D. Richards, C.P.A.

# FOR THE BOARD:

Suzanne Cochran, Esquire Chairperson

<u>DATE</u>: April 4, 2008