CENTERS FOR MEDICARE AND MEDICAID SERVICES

Decision of the Administrator

In the case of:	**Claim for:**
Rhode Island Hospital **Provider** **vs.** **Blue Cross/ Blue Shield Association/ Arkansas Blue Cross & Blue Shield** **Intermediary**	**Provider Cost Reimbursement Determination for Cost Reporting Period Ending: 06/30/96** **Review of: PRRB Dec. No. 2005-D67 Dated: September 13, 2005**

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 §1878(f) (1) of the Social Security Act (Act), as amended (42 USC 1395oo (f)). Accordingly, the parties were notified of the Administrator's intention to review the Board's decision. Comments were received from the Intermediary, CMS Center for Medicare Management (CMM) and the Provider. All comments were timely received. Accordingly, this case is now before the Administrator for final agency review.

ISSUE AND BOARD'S DECISION

The issue is whether the Intermediary's adjustment, reducing the Provider's full-time equivalent (FTE) resident count for purpose of calculating the Indirect Medical Education (IME) adjustment, was proper.[1]

[1] The Intermediary excluded 12.06 FTEs from the resident count used to determine the Provider's IME payment. The parties stipulated that all 100 residents, which includes the 12.06 FTEs, were enrolled in an approved teaching program. Stipulation, dated December 17, 2004.

The Board held that the Intermediary's adjustment excluding research time from the FTE resident count used to calculate the Provider's adjustment for IME was improper. The Board held that 42 C.F.R. §412.105(f) did not exclude research time from the IME resident count, nor did it require resident time to be related to patient care. The Board determined that the regulation allowed research time spent by residents to be included in the IME calculation if the residents were enrolled in an approved teaching program and were assigned to either the area of the hospital subject to the IPPS or the hospital's outpatient department. Therefore, since the residents at issue were enrolled in an approved graduate medical education (GME) program and they worked in either the portion of the Provider's facility subject to inpatient prospective payment system (IPPS) or an outpatient area, the Intermediary's adjustment was improper. The Board noted that its findings were consistent with the court's ruling in *Riverside Methodist Hospital v. Thompson*, No. C2-02-94 (S.D. Ohio, July 31, 2003) (Riverside) in which the court also concluded that the policy concerning research in the August 1, 2001 Federal Register represented a change in policy, and therefore, could not be applied retroactively to the FYE 1996 cost reporting period

SUMMARY OF COMMENTS

The Intermediary commented requesting that the Administrator review and reverse the Board's decision. The Intermediary incorporated by reference its argument outlined in its Post Hearing Memorandum.

CMM submitted comments requesting that the Administrator reverse the Board's decision. CMM disagreed with the Board's determination that time spent by residents engaged in research not related to patient care, be included for IME purposes.

CMM argued that the residents in question were not assigned to areas of the hospital subject to IPPS or outpatient areas. To support this argument, CMM noted that the Provider rotation schedules distinguished between resident rotations occurring in the IPPS, outpatient areas of the hospital and residents assigned to research. CMM further argued that the regulation cannot be read in isolation. CMM argued that the regulation must be read in context with other regulations. When read in conjunction with the other regulations, it shows that Medicare never intended to pay for nonpatient care activity. In addition, a plain reading of 42 CFR §412.105(f) requires that a resident be "assigned to" either the inpatient PPS or outpatient areas of the hospital in order to be counted. Thus, since the residents, when involved in research, are not assigned to either the IPPS or outpatient areas of the hospital, time spent by residents assigned to research should not be included in the IME adjustment.

Finally, CMM argued that the Board inappropriately drew conclusions from *Riverside Methodist Hospital* because the FTE resident time at issue in *Riverside* was time spent in journal clubs and seminars, not research activities. Finally, CMM disagreed with the Board's determination that the August 1, 2001 *Federal Register* represented a change in policy that couldn't be applied retroactively. CMM stated that there are long-standing regulations concerning research, and 42 CFR §412.150(f)(1)(iii)(B) is simply the codification of existing policy in the IME regulation text.

The Provider submitted comments requesting that the Administrator affirm the Board's decision. The Provider argued that the IME rules in effect in 1996 only required that a resident be enrolled in an approved program and be assigned to an IPPS area or outpatient department. The Provider disagreed with CMM's contention that the residents were not assigned to an IPPS area or an outpatient department because their rotation schedules listed "Research" as their "service Area." The Provider stated no resident at issue was assigned to psych, rehab or vent units. All residents were assigned to an IPPS unit during their research rotation. In addition, the fact that the residents continued to take call, attend rounds, and participate in continuity clinics during their research rotations is persuasive evidence that the residents were assigned to a PPS unit.

The Provider also argued that the Intermediary's "direct patient care" requirement argument was without legal support. The Board and a Federal court in *Riverside Methodist* rightly concluded that the 2001 amendment to the IME regulation was a substantive rule change, and not a "clarification. Finally, the Provider argued that, if the research exception applied, it is nonetheless entitled to an additional 7.49 FTEs (of the total 12.06 FTE adjustments) as the evidence offered showed that the time spent by these residents in research was associated with the treatment or diagnosis of particular patients.

DISCUSSION

The entire record, which was furnished by the Board, has been examined, including all correspondence, position papers, and exhibits. The Administrator has reviewed the Board's decision. All comments received timely are included in the record and have been considered.

Prior to 1983, Medicare reimbursed providers on a reasonable cost basis. Section 1861(v)(1)(a) of the Act defines "reasonable cost" as "the cost actually incurred,

excluding therefrom any part of the incurred cost found to be unnecessary in the efficient delivery of needed health services, and shall be determined in accordance with regulations establishing the method or methods to be used, and the items to be included…." Section 1861(v)(1)(a) of the Act does not specifically address the determination of reasonable cost, but authorizes the Secretary to prescribe methods for determining reasonable cost, which are found in regulations, manuals, guidelines, and letters.

The Secretary promulgated regulations which explained the principle that reimbursement to providers must be based on the reasonable cost of services covered under Medicare and related to the care of beneficiaries.[2] Reasonable cost includes all necessary and proper cost incurred in furnishing the services. Necessary and proper costs are costs, which are appropriate and helpful in developing and maintaining the operation of patient care facilities and activities. Accordingly, if a provider's costs include amounts not related to patient care, or costs that are specifically not reimbursable under the program, those costs will not be paid by the Medicare program.

Under reasonable cost, the allowable costs of educational activities included trainee stipends, compensation of teachers and other direct and indirect costs of the activities as determined under Medicare cost finding principles. The Secretary promulgated the regulation at 42 C.F.R. §413.85 which permits reimbursement for the costs of "approved educational activities."[3] This regulation defines approved educational activities as "formally organized or planned programs of study usually engaged in by providers in order to enhance the quality of patient care in an institution.

The regulations governing research cost, under the "reasonable cost" system of reimbursement were found at 42 C.F.R. §405.422 *et*. *seq*. and stated that the "[c]osts incurred for research purposes over and above usual patient care, are not includible as allowable costs."[4] The regulation at 42 C.F.R. §405.422(b)(2) further stated that:

> Where research is conducted in conjunction with and as a part of the care of patients, the costs of usual patient care are allowable to the

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[2] *See* e.g. 42 C.F.R. §413.9.

[3] 42 C.F.R. §413.85 (b)(1998). This language has been in effect since the beginning of the Medicare program although it was formerly designated 42 C.F.R. 405.421(1977) and 20 C.F.R. §405.421 (1967).

[4] *See* 31 Fed. Reg. 14814 (Nov. 22, 1966). *See* 42 C.F.R. §405.422, re-designated 42 C.F.R. §413.5(c)(2), and now at 42 C.F.R. 412.90).

> extent that such costs are not met by funds provided for the research….[5]

Section 223 of the Social Security Act of 1972 amended section 1861(v)(1)(A) to authorize the Secretary to set prospective limits on the cost reimbursement by Medicare.[6] These limits are referred to as the "223 limits" or "routine cost limits" (RCL), and were based on the costs necessary in the efficient delivery of services. Beginning in 1974, the Secretary published routine cost limits in the *Federal Register*. These "routine cost limits" initially covered only inpatient general routine operating costs.

In 1982, in an effort to further curb hospital cost increases and encourage greater efficiency, Congress established broader cost limits than those authorized under section 1861(v)(1)(A), the existing routine cost limits. The Tax Equity and Fiscal Responsibility Act (TEFRA) added section 1886(a) to the Act, which expanded the existing cost limits to include ancillary services operating costs and special care unit operating costs in addition to routine operating costs. Pursuant to section 1886(a)(1)(ii) of the Act, these expanded cost limits, referred to as the "inpatient operating cost limits," applied to cost reporting periods beginning after October 1, 1982. The costs related to approved medical education were not subject to the routine costs limits.

Under the routine cost limits, under §1886(a)(2) of the Act, Medicare also paid for the increased indirect costs associated with a hospital's approved graduate medical education program through an indirect teaching adjustment.[7] Thus, since its inception Medicare has recognized the increased *operating* costs related to a provider's approved graduate medical education programs through an indirect teaching adjustment.[8]

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[5] *Id*.

[6] Pub. Law 92-603.

[7] Section 1886(a)(2) states that the Secretary shall provide "for such … adjustments to, the limitation … as he deems necessary to take into account—(A) … medical and paramedical education costs…."

[8] 45 Fed. Reg. 21584 (April 1, 1980)(indirect teaching adjustment under pre-TEFRA cost limits); 46 Fed. Reg. 33637 (June 30, 1981)("We included this adjustment to account for *increased routine operating costs* that are generated by approved internship and residency programs, but are not allocated to the interns and residents (in approved programs) or nursing school cost centers on the hospital's Medicare cost report. Such costs might include, for example, increased medical records costs that result from the keeping, for teaching purposes, of more detailed medical records than would otherwise be required. Because our analysis of the data we used to

In 1983, §1886(d) of the Act was added to establish the inpatient prospective payment system (IPPS) for reimbursement of inpatient hospital services furnished to Medicare beneficiaries.[9] Under IPPS, providers are reimbursed their inpatient operating costs based on prospectively determined national and regional rates for each patient discharge, rather than on the basis of reasonable operating costs. Under §§1886(a)(4) and (d)(1)(A) of the Act, the costs of approved medical education activities were specifically excluded from the definition of "inpatient operating costs" and, thus, were not included in the PPS hospital-specific, regional, or national payment rates or in the target amount for hospitals not subject to PPS. Instead, payment for approved medical education activities costs were separately identified and paid as a "pass-through," i.e., paid on a reasonable cost basis.[10] Later, for the cost years at issue, the direct costs of the approved graduate medical education program were paid under the methodology set forth at Section 1886(h) of the Social Security Act. These provisions were promulgated at 42 C.F.R. 413.86 (1997).

However, Congress recognized that teaching hospitals might be adversely affected by implementation of inpatient PPS because of the indirect costs of the approved graduate medical education programs. These may include the increased department overhead as well as a higher volume of laboratory test and similar services as a result of these programs which would not be reflected in the IPPS rates.[11] Thus, under §1886(d)(5)(B) of the Act, hospitals subject to IPPS, with approved teaching programs, receive an additional payment to reflect these IME costs. The statute states that:

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develop the new limits shows that *hospital inpatient operating costs per discharge tend to increase in proportion to increases in hospital levels of teaching activity,* we have adopted a similar adjustment to the new limits…. The increase in the percentage amount of the adjustment … results from the fact that total *inpatient operating costs,* which include special care unit and inpatient ancillary costs, are more heavily influenced than routine costs by changes in the level of teaching activity. In our opinion, this adjustment accounts for the *additional inpatient operating cost* which a hospital incurs through its operation of an approved intern and resident program." (Emphasis added.)

[9] Pub. Law 98-21 (1983).

[10] Section 1814(b) of the Act.

[11] *See* 50 Fed. Reg. 35646, 35681 (1985).

> The Secretary shall provide for an additional payment amount for subsection (d) hospitals with indirect costs of medical education, in an amount computed in the same manner as the adjustment for such costs under the regulations (in effect as of January 1, 1983) *under subsection (a)(2)* ….(Emphasis added.)

The regulation at 42 C.F.R. §412.105 governs IME payments to Medicare providers. In promulgating the regulation, the Secretary noted that this additional payment is computed in the same manner as the indirect teaching adjustment under the notice of hospital cost limits published September 30, 1982.[12] The regulation states that the Secretary "makes an additional payment to hospitals for indirect medical education costs" in part by determining the ratio of the number of FTE residents to the number of beds. The resident must be enrolled in an approved teaching program. In addition, the regulation at 42 C.F.R. 412.105(f)(1996) explains that in order to be included in the FTE count, the resident must be assigned to the portion of the hospital subject to the prospective payment system portion of the hospital or the outpatient portion of the hospital.[13]

Notably, when §1886(d) of the Act was amended to address the additional costs that teaching hospitals incur in treating patients, the Secretary discussed this new formula for IME payments and explained that:

> Section 1886(d)(5)(B) of the Act provides that prospective payment hospitals receive an additional payment for the indirect costs of medical education computed in the same manner as the adjustments for those costs under regulations in effect as of January 1, 1983. Under [the] regulations [then set forth at 42 C.F.R. §412.118], we provided that the indirect costs of medical education incurred by teaching hospitals are the increase operating costs (that is, *patient care costs*) that are associated with approved intern and resident programs. These increased costs may reflect a number of factors; for example, an increase in the number of tests and procedures ordered by interns and residents relative to the number ordered by more experienced

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[12] 42 C.F.R. §412.105(a)(1). *See* 49 Fed. Reg. 234 (1983) which noted that this additional payment is computed in the same manner as the indirect teaching adjustment under the notice of hospital cost limits published September 30, 1982 (47 Fed. Reg 43310).

[13] 42 C.F.R. §412.105(f). Effective for discharges occurring on or after October 1, 1997, the time spent by residents in a nonhospital setting in patient care activities under an approved medical residency training program is counted towards the determination of full-time equivalency.

> physicians or the need of hospitals with teaching programs to maintain more detailed medical records. (Emphasis added.)[14]

Moreover, in a final rule implementing changes to direct GME reimbursement, the Secretary further explained:

We also note that section 1886(d)(5)(B) of the Act and section 412.115(b) of our regulations specify that hospitals with "indirect cost of medical education" will receive an additional payment amount under the prospective system. As used in section 1886(d)(5)(B) of the Act, "indirect costs of medical education" means those additional operating (that is, *patient care*) costs incurred by hospitals with graduated medical education programs.[15] [Emphasis added.]

Thus, from the beginning of its implementation of the Congressional directives regarding medical education costs, Medicare has only paid for costs related to patient care even within the context of the increased direct and indirect costs associated with approved medical education programs.[16] Consistent with the Act and the regulations, the above principles were set forth in the Provider Reimbursement Manual (PRM) at §2405.3F.2 and state that a resident must not be counted for the IME adjustment if the resident is engaged exclusively in research. (Rev. 345, Aug 1988)

In this case, the Provider argues that during the subject cost reporting periods, the regulation at §412.105(f) and statute does not specifically exclude research time from inclusion in the IME count or require that training be related to patient care. The Board agreeing with the Provider's analysis also found that, since the residents are in an approved residency program, the time residents spend performing research as part of an approved residency program should be included in the IME calculation based upon the pertinent statute and controlling regulations.[17]

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[14] *See* 51 Fed. Reg. 16772 (May 6, 1986).

[15] *See* 54 Fed. Reg. 40282 (Sep. 29, 1989)

[16] The Administrator notes that the Secretary's longstanding policy of requiring hospitals to identify and excluded time spent by residents involved exclusively in research for purposes of the IME count adjustment was clarified at 42 C.F.R. §412.105(f)(1)(iii)(B)(2001). *See* 66 Fed. Reg. 39896 (Aug. 1, 2001).

[17] The time spent by residents in exclusively research with respect to GME is not at issue. Such time is similarly not allowed under GME payments, however, the costs so associated were removed from the base year costs used to calculate the average per resident amount.

Applying the foregoing Medicare law and policy to the facts of this case, the Administrator finds that historically under the reasonable cost system of reimbursement, costs associated with research activities that were not related to patient care were not reimbursed and allowed. This exclusion extended to the indirect education (or teaching) adjustment paid under reasonable cost limits for the higher operating costs incurred by hospitals with medical education programs. The Administrator further finds that the indirect teaching adjustment methodology used under the reasonable cost limits was adopted under §1886(d)(5)(B) of the Act. Under both the reasonable cost and IPPS methodology, only the indirect costs of teaching programs relating to patient care (operating costs) is intended to be reimbursed by Medicare. Thus, to the extent that the residents' time at issue in this case is spent exclusively in research activities (not related to patient care), the time must be excluded from the IME FTE count pursuit to the above principles.

The Administrator also finds that 42 C.F.R. §412.105(f) requires that the residents time be spent in an IPPS or out-patient area of the hospital in order to be included in the FTE count. The record shows that the residents at issue were not assigned to either the IPPS area or the outpatient area of the hospital in patient care activities. Instead, the record shows that the Provider's rotation schedules listed each resident's name, month, and the "service area" to which the resident was assigned during that month. Among the "service areas" that the Provider listed were ICU (Intensive Care Unit) and MAS (Medical/Surgical). The record also shows that the "service area" specified for the residents' time at issue was "Research." The Administrator thus finds that the Provider failed to demonstrate that the residents were assigned to an IPPS or out-patient area as required by the above regulation.

However, the Provider has also argued that 7.49 FTEs of the total of 12.06 FTEs time was spent by residents in research related to the treatment or diagnosis of particular patients. The Administrator finds that a review of the record shows that the Provider did not demonstrate that these residents were involved in research activities related to patient care. To the extent the research times is alleged to be patient care related, the record does not show the percentage of time residents saw patients during a monthly research rotation and the research, if any, they may have engaged in that was related to patient care.[18] This in contrast to other evidence in the Provider's exhibits that these residents were involved in research activities using

[18] Moreover, there is a conflict in the record as to how many hours residents worked each week at the Provider's facility. A study conducted by the Provider shows that residents worked a 50 hour work week. However, Dr. Murphy testified that resident worked 70 to 75 hours weekly. Tr. at 312-14. This study was prepared under the auspices of Deloitte Touche and authored by Mr. Christopher Francazio. The Board declined to recognize Mr. Francazio as an expert. Tr. at 138.

animals and other laboratory research conducted outside patient care areas.[19] Accordingly, the Administrator finds that the Provider failed to provide sufficient contemporaneous documentation to support its claim that the time spent by residents in research was related to patient care.

[19] Dr. Edstrom in particular described the activities of one resident as, "2 months research, some patient related, but mostly chicken and mice." Intermediary's Exhibit I-30, L at 4.

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: 11/10/05 /s/

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Centers For Medicare & Medicaid Services