CENTERS FOR MEDICARE AND MEDICAID SERVICES

Decision of the Administrator

In the case of:	**Claim for:**
Greenville Hospital Center **Provider** **vs.** **Blue Cross Blue Shield Association** **Palmetto Government Benefits Administration** **Intermediary**	**Provider Cost Reimbursement Determination for Cost Reporting Periods Ended: 09/30/96** **Review of:** **PRRB Dec. No. 2010-D6** **Dated: November 25, 2009**

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)). The parties were notified of the Administrator's intention to review the Board's decision. The Intermediary and CMS' Center for Medicare Management (CMM) submitted timely comments, requesting reversal of the Board's decision. The Provider submitted timely comments requesting affirmation of the Board's decision. Accordingly, this case is now before the Administrator for final agency review.

ISSUE AND BOARD'S DECISION

The issue is whether the Intermediary's disallowance of resident time spent in didactic activities for purposes of the indirect medical education (IME) adjustment was proper.

The Board held that the Intermediary's calculation of the Provider's IME reimbursement was improper. The Board found that the time spent by residents in didactic activities that are

a part of an approved residency program should be included in the IME calculations. The regulation at 42 C.F.R. §412.105(f) that was in effect during the subject cost reporting period did not require resident time to be related to patient care in order to be included in the IME calculation.

The Board found that the residents at issue in this case were enrolled in an approved graduate medical education (GME) program and that they worked in either the portion of the Provider's facility subject to the inpatient prospective payment system (IPPS), or an outpatient area, as required under the regulation. Therefore, the time spent by the Provider's residents meets the regulatory requirement for inclusion in the IME full time equivalent (FTE) count.

SUMMARY OF COMMENTS

CMM submitted comments requesting that the Administrator overturn the Board's decision. CMM disagreed with the Board's decision and stated that the Intermediary's adjustment was correct. CMM stated that the IME adjustment is a payment for patient care. Under Medicare, original costs had to be reasonable and necessary and related to patient care. Non-patient care costs were not allowed. CMM asserted that it has been Medicare's longstanding policy, consistent with the statute and legislative history, that only direct patient care activities are to be included as "allowable" time in calculating the IME FTE count. The indirect costs of teaching programs are the higher patient care costs incurred by hospitals with medical education programs. The learning process in which residents are engaged results in more intensive and therefore more costly treatment regimes that relate to the delivery of patient care. Therefore, didactic activities such as classroom time, seminars, and journal club are not direct patient care.

CMM also stated that the Board's conclusion, that the August 1, 2001 and August 18, 2006 *Federal Registers* represent changes in policy that cannot be applied retroactively to the subject 1996 cost reporting period, is incorrect. CMM argued that the Board ignored the fact that the regulations and the Provider Reimbursement Manual (PRM) prohibiting the counting of residents engaged exclusively in research has been in place since 1988, because it represents activities not related to patient care. Because of these longstanding regulations, it is evident that the patient care requirements are not new regulations, but simply the codification of existing policy. Moreover, there is no duty to promulgate regulations that address every conceivable question.

Further, the August 16, 2007 Federal Register noted that there is a difference in the rules for counting FTE resident time for IME and direct GME when residents are training in a hospital. For direct GME payment purposes, residents in an approved program working in all areas of the hospital complex may be counted, In contrast, for IME payment purposes, only time spent in patient are activities in the hospital may be counted. CMM also stated that the First Circuit Court's decision in Rhode Island Hospital v. Leavitt, 54 F.3d 29 (1st Cir. 2008), affirmed CMS' longstanding policy that only direct patient care activities are to be included as "allowable" time in calculating the IME FTE count.

The Intermediary submitted comments stating that Board's decision is improper and is contrary to Medicare regulation and program instructions and, therefore, should be reversed.

The Provider submitted comments stating that the disallowance of didactic time in this case was impermissible and, accordingly, the Board's decision should be affirmed. The Provider argued that the residents were enrolled in an approved teaching program; the residents were assigned to either a portion of the hospital subject to the prospective payment system or an outpatient department of the hospital; and that their full time status was based on the total time necessary to fill residency slots. Therefore, the Provider satisfied the regulation at 42 C.F.R. §412.105(g), the controlling statute and the legislative intent of the statute. Finally, the Provider argued that the Intermediary's denial runs contrary to notice and comment requirements of the Administrative Procedure Act (APA) and is prohibited since it was applied retroactively.

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 were received timely and are included in the record and have been considered.

Prior to 1983, under Title XVII of the Social Security Act, Medicare reimbursed providers on a reasonable cost basis for Part A—Hospital Insurance Benefits. Section 1861(v)(1)(A) of the Social Security Act establishes that Medicare pays for the reasonable cost of furnishing covered services to program beneficiaries, subject to certain limitations. This section of the Act also defines reasonable cost as "the cost actually incurred, excluding therefrom any part of incurred cost found to be unnecessary in the efficient delivery of needed health services." The Act further authorizes the Secretary to promulgate regulations establishing the methods to be used and the items to be included in determining such costs.

Since the inception of the Medicare program, Congress has allowed hospitals' costs for operating programs for residents' training based on the premise that "…these activities enhance the quality of care in an institution."[1] Congress explained, in enacting the Medicare program, that:

> Many hospitals engage in substantial educational activities, including the training of medical students, internship and residency programs, the training of nurses, and the training of various paramedical personnel. Educational activities enhance the quality of care in an institution and it is intended, until the community undertakes to bear such education costs in some other way, that a part of the net cost of such activities (including stipends of trainees as well as compensation of teachers and other costs) should be considered as an element in the cost of patient care, to be borne to an appropriate extent by the hospital insurance program.[2]

Congress specifically provided for direct "educational" costs incurred by hospital to be reimbursable. The establishment of payment for medical education costs was an exception under Medicare and only possible due to congressional direction. It was also limited to direct educational costs and, inter alia, by the anti-redistribution and the community support principles. Thus, to the extent the Medicare program has always historically paid the costs related to patient care, Congressional directive allowed a narrow exception for direct medical education costs to come under that "umbrella" as limited by the forgoing language.

The Secretary promulgated the regulation at 42 C.F.R. §413.85 which permits reimbursement for the costs of approved educational activities.[3] The regulation at 42 C.F.R

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[1] H.R. Rep. No. 213, 89th Cong., 1st Sess., 32 (1965); see also Report to Congress. Rethinking Medicare's Payment Policies for Graduate Medical Education and Teaching Hospitals, at 4 (Aug. 1999).

[2] S. Rep. No. 404, 89th Cong., 1st Sess. 36 (1965); H.R. No. 213, 89th Cong., 1st Sess. 32 (1965).

[3] 42 C.F.R. §413.85(b) (1991) further re-designated at 42 C.F.R. §413.90(2007). This language has been in effect since the beginning of the Medicare program although it was formerly designated 42 C.F.R. §405.421(1997) and 20 C.F.R. §405.421 (1967).. Similarly, the regulations governing research cost, under the "reasonable cost" system of reimbursement were found in 42 C.F.R. §405.422 et. seq., and stated that the "costs incurred for research purposes over and above usual patient care, are not includable as allowable costs.

§413.85 also 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"[4] As the Supreme Court in Thomas Jefferson v. Shalala, 512 US 540(1994), noted:

> Graduate medical education (GME) programs are one category of approved educational activities. GME programs give interns and residents clinical training in various medical specialties. Because participants learn both by treating patients and by observing other physicians do so, GME programs take place in a patient care unit (most often in a teaching hospital), rather than in a classroom. Hospitals are entitled to recover the "net cost" of GME and other approved educational activities, a figure "determined by deducting, from a provider's total costs of these activities, revenues it receives from tuition." §413.85(g). A hospital may include as a reimbursable GME cost not only the costs of services it furnishes, but also the costs of services furnished by the hospital's affiliated medical school. §413.17(a).

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.[5] 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. Under this cost methodology, Medicare recognized the increased indirect costs associated with a teaching program. In particular, the Secretary stated:

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[4] See, 31 Fed. Reg. 1481 (Nov. 22, 1966). See 42 C.F.R. §405.422, re-designated at 42 C.F.R. §413.5(c)(2) and now at 42 C.F.R. §412.90. The regulation at 42 C.F.R. §405.433(b)(2) further stated that "where research is conducted in conjunction with and as part of the care of patients, the costs of usual patient care are allowable to the extent that such costs are not met by funds provided for the research …" Consistent with the regulation, section 500 of the Provider Reimbursement Manual explains that "costs incurred for research purposes, over and above usual patient care, are not includable as allowable costs." Where research costs include usual patient care costs in conjunction with research, a provider is required to offset costs incurred for usual patient care with applicable research funds. See section 505.1 of the PRM. Section 502 of the PRM defines Research.

[5] Pub. Law 92-603.

> 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 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… 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."[6]

Consequently, in contrast to direct medical education costs which are only allowed due to the specific Congressional directive to include direct educational costs, the indirect teaching adjustment methodology arises out of the more limited authority granted the Secretary for administering the Medicare program and for paying costs related to patient care activities. 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 routine cost limits[7] to include ancillary services, operating costs and special care unit operating costs in addition to routine operating costs. Pursuant to section 1886(1)(a)(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. Notably, the direct costs related to approved medical education were not subject to the routine cost limits. Under the routine cost limits, and pursuant to §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.[8] Thus, since its inception, Medicare has recognized the increased (patient care) operating costs related to a provider's approved graduate medical

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[6] 46 Fed. Reg. 33637 (June 30, 1981).

[7] While implemented under TEFRA, this provision relates to the routine cost limits under Section 1886(a) of the Act and not the often referred "TEFRA" limits under Section 1886(b) of the Act.

[8] 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…."

education programs through an indirect teaching adjustment.[9] However, as Secretary has noted, under the routine cost limits and prior to IPPS, the relevance of residents' FTEs and hence the tracking of resident activities was far from sophisticated and exact as the analyst could distinguish between allowable and non-allowance costs (such as research), but did not have the method to consistently and accurately isolate all the time spent by residents in nonpatient care activities. Therefore no consideration was given to where residents were training in the hospital or the activities of the residents with respect to patient care, or other activities.[10]

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.[11] 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. However, the basis for the development of these prospective rates continued to be the reasonable operating costs related to the care of hospital inpatients. Under §§1886(a)(4) and (d)(1)(A) of the Act, the costs of approved medical education activities were again specifically excluded from the definition of "inpatient operating costs" and, thus, were not included in the IPPS hospital-specific, regional, or national payment rates or in the target amount for hospitals not subject to IPPS.[12] Instead, payment for approved medical education activities costs were separately identified and paid as a "pass-through" under a cost basis.[13]

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[9] 45 Fed. Reg. 21584 (April 1, 1980) (indirect teaching adjustment under pre-TEFRA cost limits) "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 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 … 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." 46 Fed. Reg. 33637 (June 30, 1981)

[10] 71 Fed Reg. 47870 , 48089 (Aug 18, 2008).

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

[12] 48 Fed. Reg. 39764-39773 (Sept. 1, 1983).

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

However, Congress recognized that teaching hospitals might be adversely affected by implementation of IPPS because of the indirect patient care 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 payments or because they are patient care related in the GME payment. Thus, hospitals with approved teaching programs, receive an additional payment to reflect these IME costs.[14] Before Congress passed the 1983 law that included the IME adjustment and the IPPS, the Secretary submitted a report to Congress in 1982 that explained why an IME adjustment was important. The report stated that, "the indirect costs of graduate medical education are higher patient care costs incurred by hospitals with medical education programs," and that "there is no question that hospitals with teaching programs have higher patient care costs than hospitals without."[15] Consequently, the statute states at Section 1886(d)(5)(B) of the Act that:

> 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)* … [i.e., routine cost limits] (Emphasis added.)

In contrast, 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 starting in 1986. These provisions were promulgated at 42 C.F.R. 413.86(1997). The costs of educational activities (that is "direct" GME costs) were reimbursed after 1986 as part of the methodology set forth at section '1886(h) of the Act. In 1986, Congress created a new GME reimbursement formula for cost reporting periods beginning on or after July 1, 1985.[16] Under the new scheme, the Secretary determines the average amount [of GME costs] recognized as reasonable for each hospital, per full-time resident during a designated base period, which is defined as the hospital's cost reporting period that began during fiscal year 1984. The

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[14] This IME payment is distinguished from the direct medical education costs. While GME time spent in research is includable, notably, the original research costs were not allowed in the establishment of the GME base year per resident amount. Thus, the rationale is that a provider will be penalized twice if the time is not allowed in counting the FTE as the research costs have already been removed from the calculation.

[15] *See* Report to Congress Required by the Tax Equity and Fiscal Responsibility Act of 1982, December 1982, pp. 48-49).

[16] *See*, Consolidated Omnibus Budget Reconciliation Act of 1985, Pub..L. No. 99-272, 100 Stat. 82, 171-75 (1986) ("GME statute").

average per resident amount was developed from base year costs, which included hospitals' allowable medical education costs which historically allowed certain educational activities such as those at issue here.[17] Applying a statutory formula to each hospital's base-year per-resident amount, the Secretary then calculates the hospital's GME reimbursement for subsequent cost-reporting periods.

The IME payment compensates teaching hospitals for higher-than-average operating costs that are associated with the presence and intensity of residents' training in an institution but which cannot be specifically attributed to, and does not include, the costs of residents' instruction. The IME adjustment attempts to measure teaching intensity based on "the ratio of the hospital's full-time equivalent interns and residents to beds."[18] The regulation at 42 C.F.R. §412.105 governs IME payments to Medicare providers. For fiscal year 1996, at issue in this case, the regulations governing IME reimbursement were codified at 42 C.F.R. §412.105(g)(1995).[19] The regulations state in part:

> (1) For cost reporting periods beginning on or after July 1, 1991, the count of full-time equivalent residents for the purposes of determining the indirect medical education adjustment is determined as follows:
> (i) The resident must be enrolled in an approved teaching program
> (ii) The resident must be assigned to one of the following areas:
> (A) The portion of the hospital subject to the prospective payment system;

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[17] *See* 71 Fed Reg. 47870, 48087 ("Accordingly, educational activities of hospital employees, particularly those in "formally organized or planned programs of study" as they were described in the original regulations first published on November 22, 1966 (31 FR 14814, and 20 CFR 405.421) (later redesignated as 42 CFR 405.421 on September 30, 1977 and as 42 CFR 413.85 on September 30, 1986)), were recognized as Medicare-allowable costs and implicitly included in the definition of "costs related to patient care" at 42 CFR 413.9. These specific payments for medical education activities were the basis for what later evolved into the direct GME payments, as established by Section 9202 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (Pub. L. 99-272). That is, direct GME (and also, payments for approved nursing and allied health education programs under 42 CFR 413.85) is a payment for education because it explicitly pays hospitals for the direct costs of these formally organized programs, such as the stipends of trainees and teachers.")

[18] *Id.*

[19] This regulation was re-designated from 42 C.F.R. §412.105(g) to §412.105(f). See 62 Fed. Reg. 45966, 46029 (Aug. 29, 1997).

(B) The outpatient department of the hospital

(iii) Full-time equivalent status is based on the total time necessary to fill a residency slot.

The regulation states that CMS "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 IME adjustment is an add-on to the per-case payment which is based upon the standardized amount originally derived from the reasonable routine operating costs for providing patient care.[20]

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

> Section 1886(d) 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 physicians or the need of hospitals with teaching programs to maintain more detailed medical records. (Emphasis added.)[21]

Moreover, in a final 1989 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 payment 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*)

[20] 42 C.F.R. §412.105(f)(1) (1997)

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

> costs incurred by hospitals with graduate medical education programs.[22] (Emphasis added.)

Finally, the Administrator notes that the Secretary's longstanding policy of requiring hospitals to identify and exclude time spent by residents involved exclusively in pure research underscores the fact that activities not related to direct patient care are excluded from the count. This principle was codified at 42 C.F.R. §412.105(f)(1)(iii)(B) (2001). Specifically, that section states that "the time spent by a resident that is not associated with the treatment or diagnosis of a particular patient is not countable."[23] In 2001, the Secretary adopted clarifying language that expressly excluded time that was spent by residents in research unrelated to the care of a specific patient from the count of residents for IME.[24]

In 2006, the Secretary promulgated further clarification of the IME regulations that specified residents must be spending time in patient care activities, in both hospital and non-hospital settings, to be counted in the FTE resident count for IME.[25] The Secretary noted the August

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

[23] *See* 66 Fed. Reg. 39896 (Aug. 1, 2001) for full recitation of historical overview of policy. For further discussions, *see also* 71 Fed. Reg. 47870, 48081-48093 (August 18, 2006). The Administrator finds that the August 1, 2001 and August 18, 2006 *Federal Register* Notices do not represent changes in policy. There have been longstanding regulations concerning research, (which historically were at §405.422, then were moved to §413.5(c)(2), and now are at §412.90) which included costs not related to patient care. In addition, the PRM prohibiting the counting of residents engaged exclusively in research has been in place since 1988. Because of these longstanding regulations, it is evident that the regulation text at §405.105(f)(1)(iii)(C), which specifies the patient care requirement, are not new regulations, but simply the codification of existing policy in the IME regulations text. This policy applies to both pure research and didactic activities, since neither activity, although part of an approved program, are patient care activity. Consistent with the foregoing regulation, §2405.3.F of the PRM [Transmittal Rev. 345 (August 1988)] explains that:: "The term "interns and residents in approved programs" means individuals participating in graduate medical education programs approved as set forth in §404.1.A. … It is recognized that situations arise in which it may be unclear whether an individual is counted as an intern or resident in an approved program for the purpose of the indirect medical education adjustment … Intermediaries must not count an individual in the indirect medical education adjustment if any of the following conditions exist: **** The individual is engaged exclusively in research…."

[24] 42 C.F.R. §412.105(f)(1)(iii)(B).

[25] 42 C.F.R. §412.105(f)(1)(ii)(C); 66 Fed. Reg. 39828, 39889 (Aug 1, 2001).

1, 2001 final rule (66 Fed. Reg. 39897) which states that, "we do not include residents in the IME count to the extent that the residents are not involved in furnishing patient care…"[26] The clarifying regulatory provisions state: "[i]n order to be counted, a resident must be spending time in patient care activities, as defined in 42 C.F.R. §413.75(b) of this subchapter."[27] At the same time, the Secretary explained that "patient care activities" for IME purposes as "the care and treatment of particular patients, including services for which a physician or other practitioner may bill."[28] The Secretary repeated that, with respect to residency training in the hospital, our policy limiting the IME count to only time spent in patient care activities is rooted in the creation and the purpose of the IME adjustment. The IME adjustment is a payment to a teaching hospital for its higher costs of patient care.[29]

In this case, on February 13, 2004, the Intermediary issued a Notice of Program Reimbursement (NPR) for the Provider's fiscal year 1996 cost report in which classroom time on the interns/residents rotation schedules was excluded from both the allowable time and the total time used in the calculation of FTEs for direct graduate medical education (GME) and indirect medical education (IME). The exclusion of the time in this manner resulted in no significant effect on the resident count. On September 27, 2007, the Intermediary reopened the fiscal year 1996 cost report to remove the classroom time and other didactic activities from the allowable IME FTE count by including the hours designated as classroom time on the rotation schedules in the total time (denominator) and excluding the hours from the allowable time (numerator) of the FTE calculation. The Intermediary relied upon activity sheets prepared by the Provider in connection for each rotation for each GME program[30] that identified time designated as classroom time. Pursuant to the joint stipulation of the facts, this resulted in 9.59 resident FTEs being excluded from the IME FTE count.

In light of the foregoing, the Administrator finds that the time spent by residents in didactic activities that are not directly related to the care of patients must be excluded from the IME resident count. Moreover, to this extent, the program recognizes allowable time when the resident is "assigned" to the inpatient PPS area of the hospital or outpatient area, consistent

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[26] 71 Fed. Reg. 47480, 48081 (Aug. 18, 2006).
[27] 42 C.F.R. §412.105(f)(1)(iii)(C)(2006).
[28] 42 C.F.R. §413.75(b)(2006). See 42 C.F.R. §412.105(f)(1)(iii) added paragraph (C) which states "In order to be counted a resident must be spending time in patient care activities as defined in 413.75(b).
[29] 71 Fed. Reg. 47,870, 48,082 (Aug. 18, 2006).
[30] The Provider had, *inter alia*, an internal medicine, family practice, obstetric/gynecology, pediatrics, general surgery, orthopedic and transitional year programs.

with the general understanding of the term "assigned." That is, "assigned" is defined as "to appoint to a post or duty"[31] and can reasonably be interpreted to be functional in meaning. Residents are "assigned" (perform duties) in the respective areas and in this case are counted where they are performing duties as part of the IPPS area. Here, the residents are not performing such duties if they are performing didactic activities, a fact which is further highlighted in that they are not located in the IPPS or outpatient areas (patient care areas) of the hospital during the didactic activities.[32]

The Administrator notes that the Provider argued the same points regarding the exclusion of time spent in didactic activities from the IME FTE count that were raised by commenters in the Secretary's clarification of its existing policy at the FFY 2007 Final IPPPS rule (71 Fed. Reg.47870 (August 18, 2006)). The Provider argued, inter alia, that the residents were involved with patient care activities while taking part in the lectures and seminars as the lectures discussed individual patients, were on call and available at all times to respond to patient needs. The Provider stated that that CMS' interpretation of "patient care activities" ignores CMS' longstanding definition of "costs related to patient care," which is the basis for much of CMS' analysis, because educational activities like conferences and seminars for hospital employees have always been allowable costs under Medicare, and therefore, should be allowed for purposes of the IME as well. The Provider also argued during the time the residents are involved in didactic activities, these costs are in no way reduced, since the "patients remain just as ill as they were before, the hospital continues with its resident-related inefficiencies, the hospital continues to provide specialized services, and the services are just as intense. In addition, the Provider objected to the IME calculation as not the same as that performed under the routine cost limits where the activities of the resident were not recorded. These arguments were extensively addressed by the Secretary in the final rule, and such responses are herein incorporated by reference.[33]

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[31] Webster New Collegiate Dictionary, pg. 67 (1975).

[32] The record shows that the didactic classroom activity locations were not in the "patient care" areas of the hospital. The didactic activities took place in areas such as the conference rooms, medical staff auditoriums and conference dining rooms, as opposed to the inpatient care area of the hospital (Exhibit P-36). Residents that attended these didactic activities were not directly related to the care and treatment of individual patients that would be considered "patient care" activities for Medicare reimbursement purposes. Moreover, even if one were to adopt a geographic interpretation, as opposed to a functional interpretation, as the Provider's proposes, the residents were not geographically located in the IPPS areas during these times.

[33] 71 Fed. Reg. 47870, 48080-48092 (August 18, 2006).

However, one of many important points made in the Secretary's response to the commenters is that these arguments generally failed to recognize the different purposes and statutory and congressional authorities for the IME adjustment payment and the direct GME payment.[34] In contrast to direct medical education costs which historically were only allowed due to the specific Congressional directive to include direct educational activities costs, the indirect teaching adjustment methodology arises historically out of the more limited regulatory authority granted the Secretary for administering the Medicare program and for paying costs related to patient care activities. Would Congress not have authorized direct medical education costs to be reimbursed under Medicare, to a large extent, such allowances historically would have been outside the scope of the Secretary's authority to grant. Conversely, to read the regulation as allowing for the inclusion of nonpatient care time in the IME FTE count likewise goes outside the scope of the authority granted the Secretary in her rulemaking capacity when first implementing the teaching adjustment. With respect to the indirect patient care costs that result from residents' patient care practices, Congress has not spoken to extend the IME payment to cover activities outside of direct patient care activities.[35]

The Provider also raised the issue that the hours recorded in didactic activities are over stated as the Intermediary was auditing records kept for purposes of residents accreditation. These reports it claims understated the number of hours that the residents were working and thus gave disproportionate weight to the hours spent in didactic activities. The Secretary has agreed that:

> As the regulations state, the concept of the total time necessary to fill a residency slot is used to determine the part-time or full-time status of the resident. If it is determined that the resident is not working the number of hours necessary to fill a residency slot (between all the resident's hospital and nonhospital training sites), the resident would be considered part-time, and the proportion of total time the resident is working in all training sites would be adjusted accordingly. For purposes of determining a hospital's count of FTE residents, the important word in the regulatory phrase is “based.” That is, the

[34] Not only were educational costs included in the base year of the GME methodology but, for direct GME payment purposes, residents in an approved program working in all areas of the hospital complex may be counted.

[35] Notably, where Congress extended the FTE count to nonprovider settings, which otherwise would have been outside the scope of the Secretary to implement and outside the Secretary's authority under sections 1861, 1886(a) and 1886(d) of the Act, Congress itself imposed the patient care requirement.

> starting point (denominator) for determining the allowable FTE count is the total time necessary to fill a residency slot. However, the hospital must then subtract (from the numerator) all nonallowable training time, such as time spent at other providers, time spent in IPPS-excluded distinct part units (for IME), didactic activities (for IME), and so on. Thus, while a hospital's allowable FTE count is certainly "based" on the total time necessary to fill a resident slot, the total time is often greater than the FTE time a particular hospital is permitted to count for IME and direct GME payment purposes.[36]

In addition, the Secretary stated that:

> For purposes of determining what portion of an FTE resident a hospital may count for a resident that is training at the hospital (after first determining whether the resident is a part-time or full-time resident based on the total necessary to fill the residency slot), it is important and necessary to first determine the actual total time worked by the resident. Accordingly, if 80 hours per week is established as the total time necessary to fill the residency slot, and if a resident works an 80-hour week and works 40 hours per week at each of two hospitals, each hospital would count no more than one half of an FTE for the resident. The FTE determination for that resident cannot be based on 40 hours, since that would result in both hospitals counting the same resident as a full FTE. Thus, in calculating the FTE count, it would be inappropriate to compare the time spent in patient care activities to a 40 hour week and not to the total time worked by the resident.[37]

While the Secretary has recognized that a resident may work in excess of a 40 hour work, problematic in this case is the fact that the Provider did not otherwise submit documentation upon which an alternative basis for determining total hours worked may be based when excluding the didactic time. Therefore, the Intermediary used the best available data for the calculation of the FTEs to be included in the IME count. Accordingly, the Administrator finds that, as didactic activities are not direct patient care activities, and as such, are not allowable time for calculation of the IME FTE count, the Intermediary's adjustments are affirmed.

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[36] 71 Fed Reg. 48085-86.
[37] 71 Fed Reg. 48085-86.

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: 1/27/2010

/s/
Michelle Snyder
Acting Deputy Administrator
Centers for Medicare & Medicaid Services