CENTERS FOR MEDICARE AND MEDICAID SERVICES

Decision of the Administrator

In the case of:	**Claim for:**
University of Louisville Hospital **Provider** **vs.** **CGS Administrators, LLC** **Medicare Contractor**	**Provider Cost Reimbursement Determination for Cost Reporting Periods Ending: Various** **Review of:** **PRRB Dec. No. 2016-D11** **Dated: May 31, 2016**

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 U.S.C. § 1395oo(f)). The parties were notified of the Administrator's intention to review the Board's decision. The Intermediary and CMS' Center for Medicare (CM) submitted timely comments, requesting that the Administrator reverse the Board's decisions on Issues Nos 1 and 3, and uphold the Board's decision on Issue No. 2. The Medicare Contractor submitted timely comments requesting that the Administrator affirm the Board's decisions on Issues No. 1 and 3, and reverse the Board's decision on Issue No. 2. The Provider submitted comments requesting that the Board's decision be upheld on Issue Nos. 1 and 3 and reversed as to Issue No. 2. Accordingly, this case is now before the Administrator for final agency review.

ISSUE AND BOARD'S DECISION

Issue No. 1 was whether the Medicare Contractor's exclusion of didactic time from the FTE counts for indirect medical education (IME) and direct Graduate Medical Education (GME) for fiscal years (FYs) 2000 to 2006 was appropriate.[1]

[1] This issue is included in Case Nos. 06-0213, 05-2117, 06-0167, 07-0976, 08-1846, and 08-2830. *See* Modifications to Stipulations of the Parties.

The Board held that the Medicare Contractor improperly excluded didactic time from the Provider's FTE counts for IME and GME prior to October 1, 2006 as it relates to the cost reports for FYs 2000 to 2006. The Board found that the Medicare Contractor properly excluded didactic time from the Provider's FTE counts for IME and direct GME beginning October 1, 2006 as it relates to the cost report for FY 2006. Thus, the Board directed the Medicare Contractor to update the current year IME and direct GME counts and the current year resident to bed ratios in the cost reports for FYs 2000 to 2006 as it relates to didactic time prior to October 1, 2006.

The Board noted that, with respect to the direct GME FTE count, it relied on 42 C.F.R. § 413.86(f)(4) (2003). The Board found that the operative language did not change in 2004 when CMS designated § 413.78 (d)-(e). With resepct to IME for FYs 2000 and thereafter, the Board noted that it relied on 42 C.F.R. § 412.105(f)(1) (2003). The Board stated that it recognized that as part of the 2006 Final Rule, the Secretary made regulatory changes that for the first time defined "patient care activities" for the purposes of direct GME and IME reimbursement. Specifically, the Board noted, CMS added regulations at 42 C.F.R. § 413.75(b) to define the term "patient care activities" as "the care and treatment of particular patients, including services for which a physician or other practitioner may bill." The Board found that the Secretary recognized that the term had not previously been defined [by regulation], and enumerated examples of where earlier policy statements required the time in non-hospital settings to be in "patient care activities" to be included in the direct GME and IME FTE count.[2] The Board noted that the Secretary characterized the new definition of both as a "clarification" of existing policy and the plain meaning of the term.[3] However, the Board also reviewed the September 24, 1999 letter from the Director of the Division of Acute Care for the CMS Plan and Provider Purchasing Policy Group, which the Provider had entered into evidence in support of its appeal. This letter was written in response to an inquiry, and purported to provide the agency's interpretation of "patient care activities" in relation to the time residents spend in nonhospital sites. The Board pointed to the letter's statement that CMS (then the Health Care Financing Administration (HCFA)) interpreted "patient care activities" broadly to include "scholarly activities, such as educational seminars, classroom lectures, research conferences, patient care related research as part of the residency program, and presentations of papers and research results to fellow residents, medical students, and faculty".[4]

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[2] The Board cited to 69 Fed. Reg. 48,916, 49,244-25 (Aug. 11, 2004).

[3] The Board cited to 71 Fed. Reg. 48,081 (Aug. 18, 2006).

[4] *See* Provider's Exhibit P-25.

The Board stated that it was unconvinced by the statements in the 2006 Final Rule that this letter did not accurately reflect CMS' then-current policy. Rather, the Board found that the letter was compelling evidence of CMS' policy during the period prior to the 2006 Final Rule as it was official correspondence which clearly provided a general policy interpretation of the phrase "patient care activities" used to determine the IME and direct GME FTE count in a nonhospital setting during the relevant period on appeal. The Board gave it great weight as it was issued by the CMS Director who had responsibility over GME and IME reimbursement policy. The Board accepted the Provider's allegation that this letter was distributed to many hospitals and universities, and that the provider community, including the Provider in this case, relied on the guidance in that letter.[5] The Board also found that didactic activities relate to patient care, noting that in conferences and seminars, residentsare encouraged to discuss how the material relates to patients whom they are treating; that journal clubs, literature reviews, case presentation, and laboratory techniques are related to patients who are being treated, and that even seminars on communication skills are related to patient care, as communication with patients, family, and other professionals is discussed in the context of how to care for current patients.[6] The Board found that the parties also stipulated that, as part of the Hospital's medical residency program, residents both engage in the direct treatment of patients and participate in classroom discussions of patient-care related issues[7], and that the parties also stipulated that the time disallowed by the Medicare Contractor in calculating the Hospital's IME and GME FTE counts was spent in these classroom discussions.[8] Thus, the Board concluded that prior to October 1, 2006, there is no regulatory requirement that "patient care activities" be specifically delineated as connected to the billable care of a particular patient. Rather, the Board noted, there is compelling evidence that CMS interpreted the phrase "patient care activities" broadly to include any patient care oriented activity that is part of the residency program, including didactic activities, and that this interpretation was widely distributed to the provider community.

As such, the Board held that for the appeal periods prior to October 1, 2006, resident time spent in didactic settings while the residents were training at nonhospital sites can be included in the calculation of the IME and direct GME FTE counts. However, for the appeals period starting on October 1, 2006 through December 31, 2006, the revised IME and direct GME regulations no longer support such a finding since

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[5] *See* Provider's Consolidated Final Position Paper at p. 73.

[6] The Board cited to Provider Exhibit P-89 at p. 5.

[7] The Board cited to the Stipulation of the Parties at ¶ 8, and also Provider Exhibit P-34.

[8] The Board cited to the Stipulation of the Parties at ¶ 9, and also Provider Exhibits P-26-32.

during this later period "patient care activities" were specifically and more narrowly defined as "the care and treatment of particular patients, including services for which a physician or other practitioner may bill."[9]

Issue No. 2 was whether the Medicare Contractor's exclusion of foreign dental medical graduate residents for FYs 2000 to 2003 was appropriate.[10]

The Board held that the Medicare Contractor properly excluded dental foreign medical graduate residents from the Provider's direct GME FTE counts for FYs 2000 to 2003.

The Board found that it was bound by the controlling regulation at 42 C.F.R. § 413.86(h)(6) (2003), which specifies that only "foreign medical graduate" residents who have passed the United States Medical Licensing Examination (USMLE) may be included in the direct GME FTE resident count on or after July 1, 1993. The Board noted that the term "foreign medical graduate" is defined in 42 C.F.R. § 413.86(b) to include foreign dental graduates. Thus, the Board concluded that the literal reading and interpretation of that regulation provides no basis for an alternate finding.

The Board noted that although the Provider espoused a theory of Congressional intent to include dental foreign medical graduates who have not passed the USMLE in the direct GME FTE count, the Board found that the record contained no convincing evidence of Congressional intent specific to including those dental foreign medical graduates in the count of direct GME FTEs.

Issue No. 3 was whether the Medicare Contractor properly calculated the prior year interns and resident to bed ratio used to determine IME payment on the cost reports for FYs 2000 to 2003, and 2005 to 2006.[11]

The Board found that the regulations at 42 C.F.R. § 412.105 require the use of the prior year cost report items when determining the current year's IME payment. Thus, the Board held that, to the extent that the current year IME FTE counts are (or have

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[9] 42 C.F.R. § 413.75(b) (2006). *See* 71 Fed. Reg. 48,870 (Aug. 18, 2006) for the October 1, 2006 effective date.

[10] This issue is included in Case Nos. 06-0213, 05-2117, and 06-0167. *See* Modifications to Stipulations of the Parties. Note that Case No. 07-0976 includes the impact of prior year FTES (currently under appeal) on this appeal.

[11] This issue is included in Case Nos. 06-0213, 05-2117, 06-0167, 07-0976, 08-1846, and 08-2830. *See* Modifications to Stipulations of the Parties. Note that the Provider dropped this issue for Case No. 08-0181, which pertains to FY 2004.

been) adjusted for FYs 1999 to 2002, and 2004 to 2005, as a result of this appeal or another appeal (pending or closed), the Board directs the Medicare Contractor to update the relevant prior year resident to bed ratios in the cost reports for FYs 2000 to 2003, and 2005 to 2006, to reflect those adjustments.

SUMMARY OF COMMENTS

CM submitted comments requesting that the Administrator overturn the Board's decision with respect to reimbursement for didactic time (Issue No. 1) and calculation of the Provider's resident to bed ratio (Issue No. 3). CM concurred with the Board's ruling regarding counting foreign dental medical graduates (Issue No. 2). [12]

Regarding Issue No. 1, CM stated that the record showed that the didactic time at issue in these cases was classroom time at the dental school.[13] Thus, CM noted that the Medicare Contractor's disallowance was in accordance with the law at § 1886(h)(4)(E) in effect during the cost reporting years at issue, which states that "only time spent in activities relating to patient care shall be counted…"

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[12] CM and the Medicare Contractor also both raised jurisdictional arguments in their comments. CM noted that the appeals regarding didactic time were not timely appealed by the Provider for fiscal years ending 12/31/2000, 12/31/2001, 12/31/2002, and 12/31/2003. CM noted that for each of these fiscal years, the hospital added the didactic time issue on October 15, 2008, which was past 180 days of the revised Notice of Program Reimbursement (NPR) date. CM recommended that the Administrator overturn the Board's decision on didactic time for these fiscal years. *See* Division of Acute Care's Comments, dated June 15, 2016. The Medicare Contractor similarly commented that that Provider failed to timely appeal the didactic time issue for FYs 2000 to 2003, as they were not filed within 180 days of the revised NPR. Thus, the Medicare Contractor felt the Board lacked jurisdiction. *See* Medicare Contractor's Comments, dated June 18, 2016 and June 21, 2016. Effective August 21, 2008, new Board regulations went into effect that limited the addition of issues to appeals. 42 C.F.R. § 405.1835 (2008) provided that the Board must receive requests to add issue no later than 60 days after the expiration of the 180-day period prescribed in 42 C.F.R. § 405.1835(a). For appeals that were already pending when this regulation was promulgated, Providers were given 60 days from the date that the new regulation took effect, August 21, 2008, to add issues to their appeals. This meant that new issues had to be added to pending appeals by October 20, 2008. As the didactic time issue was added to appeals that were pending as of August 21, 2008, the Provider had until October 20, 2008 to add appeals. Thus, the addition of the didactic time issue on October 15, 2008 was timely, and the Board exercised proper jurisdiction. *See* 73 Fed. Reg. 30,190, 30,202-05 (May 23, 2008).

[13] CM referenced Exhibits I-1 through I-7.

Additionally, CM argued, the regulations in effect at 42 C.F.R. § 413.78(d) and (e) state that the time residents spend in nonprovider settings may be included in the hospital's FTE count if, among other requirements, the "resident spends his or her time in patient care activities, as defined in section 413.75(b)." CM noted that the plain meaning of "patient care activities" does not denote classroom activities, and also stated that CMS clarified the meaning as part of the FY 2007 IPPS Final Rule.

Regarding Issue No. 2, the disallowance of foreign dental graduates, CM pointed out that § 1886(h)(4)(D) of the Act states that "…in the case of an individual who is a foreign medical graduate…the individual shall not be counted as a resident…unless (I) the individual has passed the FMGEMS examination…or (II) the individual has previously received certification from, or have previously passed the examination of, the Educational Commission for Foreign Medical Graduates." Since the foreign dental graduates in question did not pass the relevant examinations, they cannot be included in the Provider's direct GME FTE count.

Regarding Issue No. 3, CM stated that the resident to bed ratios should be separately appealed by the Provider in order to effectuate a change to the resident to bed ratio in the respective cost reporting period. CM noted that in accordance with the regulations at 42 C.F.R. § 405.1811(a), because each cost report year receives its own final determination through its own NPR, and a hospital has a right to appeal specific items claimed for a cost reporting period within each NPR, the Provider would have to separately appeal the resident to bed ratio subject to each NPR in order to effectuate a change to each resident to bed ratio. Thus, CM recommended that the Administrator reverse the Board's decision as to Issue No. 3

The Medicare Contractor submitted comments stating that Administrator should overturn the Board's decision as to Issue No. 1, didactic time, and Issue No. 3, resident to bed ratio, and affirm the Board's decision as to Issue No. 2, Dental Foreign Medical Graduates.

With respect to Issue No. 1, IME and direct GME didactic time, the Medicare Contractor noted that the Administrator previously ruled in *Greenville Hosp. Center v. Blue Cross Blue Shield Ass'n./Palmetto GBA*[14], that time spent in didactic activities were not directly related to the care of patients must be excluded from the IME resident count. The Medicare Contractor noted that *Greenville* pertained to fiscal year 1996, long before the years at issue in these cases.

[14] Adm. Review of PRRB Dec. No. 2010-D6 (Nov. 25, 2009).

The Medicare Contractor referred to CMS' explanation in the FY 2007 IPPS Final Rule[15] that "[w]ith respect to training in nonhospital settings, the time that residents spend as part of an approved program, including didactic activities, cannot be included in a hospitals direct GME or IME FTE resident count." The Medicare Contractor noted that this explanation was a clarification, not a change, of long-standing CMS policy with respect to 42 C.F.R. § 413.75, which allows only time for "patient care activities".

The Medicare Contractor noted that the Board relied on a letter that has been disavowed by CMS as being contrary to its long-standing policy and interpretation, and also held that, contrary to the plain language in the FY 2007 IPPS Final Rule, the regulation was a modification rather than a clarification of CMS policy.

Regarding Issue No., 3, the Medicare Contractor argued that as the Board's decision with respect to Issue No. 1 was contrary to the regulation and the Administrator's prior decision in *Greenville*, there should be no adjustment to the resident to bed ratios.

The Provider submitted comments stating that the Administrator should affirm the Board's decision as it relates to Issue No. 1, didactic time, and Issue No. 3, resident to bed ratio, for the reasons set forth in the Board's decision, as well as the Provider's filings with the Board, which the Provider incorporated by reference. The Provider argued before the Board that the definition of "patient care activities" used by CMS and the Medicare Contractor was arbitrary and capricious, that the exclusion of didactic time was contrary to the plain meaning and intent of the GME and IME regulations in effect prior to October 1, 2006, and that CMS' definition stated in the FY 2007 IPPS Final Rule should not be applied retroactively to periods before October 1, 2006.

Regarding Issue No. 2, Dental Foreign Medical Graduate Residents, the Provider submitted that the Administrator should overturn the Board's decision for the reasons set forth in the Provider's filings with the Board in these cases. The Provider argued before the Board that the statute imposed a requirement that was impossible to meet, and that the statute should be read to comply with what it believes was Congress' intent in the Balanced Budget Act of 1997, to include all dental residents within the scope of direct GME reimbursement. The Provider also argued that it believed that current state certification procedures serve the same purpose as the USMLE, thus satisfying Congress' intent in ensuring that foreign dental graduate residents meet a standard of clinical proficiency before entering the practice of dentistry.

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[15] 71 Fed. Reg. 48, 080 (Aug. 18, 2006).

DISCUSSION

Issue No. 1: 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. Under general Medicare reimbursement principles, costs incurred by a hospital generally must be related to patient care in order to be reimbursed by Medicare. The regulation at 42 C.F.R. § 413.9(a) states:

> All payments to providers of services must be based on the reasonable cost of services covered under Medicare and *related to the care of beneficiaries*. (Emphasis added).

Since the inception of Medicare in 1965, the program has shared in the costs of education activities incurred by participating providers. Congress specifically provided for "direct" education costs incurred by hospital to be reimbursable.

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

The regulations at 42 C.F.R. §413.85(b) define approved educational activities to mean formally organized or planned programs of study usually engaged in by providers in order to enhance the quality of patient care in an institution. These activities include approved training programs for physicians, nurses, and certain allied health professionals. Medicare reimburses for both the direct and indirect costs of graduate medical education.

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.[16] 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. The costs of direct graduate medical education costs continued to be paid as a reasonable cost pass-through. Starting in 1986, the "direct" costs of the approved graduate medical education program were paid under the methodology set forth at §1886(h) of the Social Security Act.[17] Under § 1886(h) of the Act and the implementing regulation at 42 CFR 413 .86, Medicare reimburses hospitals for the costs of direct graduate medical education. Under this system, 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 average per resident amount was developed from base year costs, which included hospitals' allowable medical education costs which historically allowed certain educational activities.[18] 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.

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

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

[18] *See* 71 Fed Reg. 47,870, 48,087 ("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 Fed. Reg. 14,814, and 20 C.F.R. § 405.421) (later redesignated as 42 C.F.R. § 405.421 on September 30, 1977 and as 42 C.F.R. § 413.85 on September 30, 1986). These specific payments for medical education activities were the basis for what later evolved into the direct GME payments, as established by § 9202 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (Pub. L. No. 99-272). That is, direct GME (and also, payments for approved nursing and allied health education programs under 42 C.F.R. § 413.85) is a payment for education because it pays hospitals for the direct costs of these formally organized programs, such as the stipends of trainees and teachers.")

Since July 1, 1987, the Social Security Act has permitted hospitals to count for purposes of GME, the time residents spend training in non-hospital sites that are not part of the hospital.[19] Section 1886(h)(4)(E) of the Act states that the Secretary's rules concerning computation of FTE residents for purposes of GME payments shall:

> [P]rovide that only time spent in activities relating to patient care shall be counted and that all the time so spent by a resident under an approved medical residency training program shall be counted towards the determination of full-time equivalency, without regard to the setting in which the activities are performed, if the hospital incurs alt or substantially all, of the costs for the training program in that setting. (Emphasis added.)

For the cost years at issue, the regulation at 42 CFR 413.86(f)(4)[20] provided, in relevant part, that:

> For portions of cost reporting periods occurring on or after January 1, 1999, the time residents spend in nonprovider settings such as freestanding clinics, nursing homes, and physicians' offices in connection with approved programs may be included in determining the number of FTE residents in the calculation of a hospital's resident count if the following conditions are met:
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> (i) The resident spends his or her time in patient care activities.

In promulgating this provision CMS reiterated the plain language of the statute with respect to counting such GME time in nonhospital settings as being limited only to time spent in activities related to patient care. The Secretary stated that:

> Effective July 1, 1987, in accordance with section 1886(h)(4)(E) of the Act, we proposed to count the time a resident spends in nonprovider settings if there is a written agreement between the hospital and the nonprovider entity to the effect that the hospital bears substantially all the training costs in the outside setting. However, section 1886(h)(4)(E) of the Act specifies *that only time spent in activities relating to patient care may be counted* toward the hospital's FTE count. In the proposed rule. We solicited

[19] Omnibus Budget Reconciliation Act of 1986 (Pub. Law No. 99-509).
[20] This language was redesignated to 42 CFR 413.78(d) through (e) in 2004.

> comments on methods under which intermediaries can ensure that the portions of residency training programs that are spent in settings that are not a part of a hospital are spent in activities related to patient care. We specifically asked that suggestions address the data that hospitals would need to maintain to substantiate the nature of assignments to settings that are not a part of a hospital.[21]

In 1998, when CMS implemented the statute allowing FTE residents to be counted in nonhospital sites for IME under certain circumstances, CMS again restated that a hospital may only count resident training time "in nonhospital sites for indirect and direct GME, respectively, if the resident is involved in patient care."[22]

With respect to the indirect medical education adjustment, §223 of the Social Security Act of 1972 amended §186l(v)(l(A) to authorize the Secretary to set prospective limits on the cost reimbursement by Medicare.[23] 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:

> 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

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[21] 54 Fed Reg.40286 (Sept. 29, 1989) (Medicare Program; Changes in Payment Policy for Direct Graduate Medical Education Costs).
[22] 63 Fed.Reg. 40986 (July 31. 1998).
[23] Pub. Law 92-603.

> hospital incurs through its operation of an approved intern and resident program."[24]

Consequently, in contrast to direct medical education costs, the indirect teaching adjustment was authorized for paying increased indirect costs related to patient care activities relating to the presence of residents. In 1982, in an effort to further curb hospital cost increases and encourage greater efficiency, Congress established broader cost limits than those authorized under § 1861(v)(1)(A), the existing routine cost limits. The Tax Equity and Fiscal Responsibility Act (TEFRA) added §1886(a) to the Act, which expanded the existing routine cost limits[25] to include ancillary services, operating costs and special care unit operating costs in addition to routine operating costs, and 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.[26] Thus, since its inception, Medicare has recognized the increased patient care related operating costs related to a provider's approved graduate medical education programs through an indirect teaching adjustment.[27] 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

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[24] 46 Fed. Reg. 33,637 (June 30, 1981).

[25] 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.

[26] 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…."

[27] 45 Fed. Reg. 21,584 (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. 33,637 (June 30, 1981)

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.[28]

As noted, in 1983, the enactment of IPPS again changed the method of payment for hospitals. Pursuant to §1886(d)(5)(B) of the Act, 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. 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."[29] Consequently, the statute states at §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.)

The purpose of the IME payment was to address the additional costs that hospitals incur in treating patients. The May 6, 1986 interim final rule[30] stated:

> 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 those regulations, we provided that the indirect costs of medical

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[28] 71 Fed Reg. 47,870 , 48,089 (Aug 18, 2006).

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

[30] 51 Fed. Reg. 16,775.

> education incurred by teaching hospitals are the increased operating costs (that is, *patient care costs*) that are associated with approved intern and resident programs'' (Emphasis added).

Additionally, the September 29, 1989 final rule[31] specifically stated:

> As used in section 1886(d)(5)(B) of the Act, 'indirect medical education' means those additional costs (that is, patient care costs) incurred by hospitals with graduate medical education programs. The indirect costs of medical education might, for example, include added costs resulting from an increased number of tests ordered by residents as compared to the number of tests normally ordered by more experienced physicians" (Emphasis added).

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."[32]

For IME payment purposes, hospitals were first allowed to count the time residents spend training in nonhospital sites for discharges occurring on or after October 1. 1997. Section 1886(d)(5)(B)(iv) of the Act was amended by §4621(b)(2) of the Balanced Budget Act of 1997 (Pub. L. 105-33) to provide that:

> "[A]ll the time spent by an intern or resident in patient care activities under an approved medical residency program at an entity in a nonhospital setting shall be counted towards the determination of full-time equivalency if the hospital incurs all, or substantially all, of the costs for the training program in that setting" (emphasis added).

The regulation at 42 C.F.R. §412.105 governs IME payments to Medicare providers. With respect to IME for FYs 2000 and thereafter,42 C.F.R. §412.105(f)(1), which states:

> For cost reporting periods beginning on or after July 1, 1991, the count of fulltime equivalent residents for the purposes of determining the indirect medical education adjustment is determined as follows:

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[31] 54 Fed. Reg. 40,286.

[32] *Id.*

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> (C) Effective for discharges beginning on or after October 1, 1997, the time spent by residents in a nonhospital setting in patient care activities under an approved medical residency program is counted towards the determination of full-time equivalency if the criteria set forth at §413.86(f)(4) are met.

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.)[33]

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*) costs incurred by hospitals with graduate medical education programs.[34] (Emphasis added.)

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[33] *See* 51 Fed. Reg. 16,772 (May 6, 1986).
[34] *See* 54 Fed. Reg. 40,282 (Sep. 29, 1989).

Prior to October 1, 1997, for IME payment purposes, hospitals were not permitted to count the time residents spent training in non-hospital settings. revised §1886(d)(5)(B) of the Act to allow providers to count time residents spend training in non-hospital sites for IME purposes, effective for discharges occurring on or after October 1, 1997. Section 1886(d)(5)(B)(iv) of the Act was amended to provide that:

> [A]ll the time spent by an intern or resident in *patient care activities* under an approved medical residency program at an entity in a nonhospital setting shall be counted towards the determination of full-time equivalency if the hospital incurs all or substantially all, of the costs for the training program in that setting. (Emphasis added.)

The regulation was amended to read at 42 C.F.R. §412.105(f)(1)(ii)(C) (1999) that:

> Effective for discharges occurring on or after October 1, 1997, the time spent by a resident in a nonhospital setting in *patient care activities* under an approved medical residency program is counted towards the determination of full time equivalency if the criteria set forth at 413.86(f)(4)[35] are met. (Emphasis added.)

Consistent with the purpose of IME payments and general Medicare reimbursement principles, in determining the FTE count with respect to the IME adjustment, it has been longstanding CMS policy not to include residents to the extent that the residents are not involved in furnishing patient care.[36] In addition, it is longstanding principle to define patient care as relating to the treatment or diagnosis of a particular patient. In the 2001 *Federal Register*, the Secretary adopted clarifying language that expressly excluded time that was spent by residents in research unrelated to the patient care, i.e., the care of a specific patient, from the count of residents for IME.[37] This principle was codified in 2001, at 42 C.F.R. §412.105(f)(1)(iii)(B) in further explaining that with respect to research time not related to "patient care" meant "the time spent by a resident that is not associated with the treatment or diagnosis of a

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[35] Redesignated at 413.78(c) and 413.78(d).

[36] GME payment for graduate medical education costs incurred for a hospital has historically been for medical education costs, not patient care related costs (residents stipends, etc.,) and therefore with respect to hospital site GME payments (as opposed to nonhospital site related GME payments) did not need to address this as a criteria.

[37] 42 C.F.R. §412.105(f)(1)(iii)(B).

particular patient is not countable."[38] That is, "related to patient care" was by definition, time associated with the treatment or diagnosis of a particular patient.

As early as 1975, §500 of the Provider Reimbursement Manual (PRM), stated explained that: "Costs incurred for research purposes, over and above *usual patient care*, are *not* included as allowable costs." Section 502 of the 1975 PRM in turn, defined the term "usual patient care", as:

> Usual patient care is the care which is medically reasonable, necessary, and ordinarily furnished (absent any research programs) in the treatment of patients by providers under the supervision of physicians as indicated by the medical condition of the patients. Also, this definition intends that the appropriate level of care criteria must be met for the costs of this care to be reimbursable. Such care is represented by items and services (routine and ancillary) which may be diagnostic, therapeutic, rehabilitative, medical, psychiatric, skilled nursing, and other related professional health services.

As the Secretary explained in discussing the meaning of patient care activities in the August 1, 2001 Final Rule, that:

> Resident time spent "engaged exclusively in research" means time not associated with the care of a particular patient (see proposed §412.105(f)(1)(iii)(B)); thus, any research time that is associated with the treatment or diagnosis of a particular hospital patient or, effective on or after October 1, 1997, of patients in nonhospital settings, that is, usual patient care, is countable for IME payment purposes. We note that this distinction between activities that are "usual patient care" and research activities is, again, longstanding Medicare policy. In April 1975, at section 500 of the PRM, we stated the principle that "Costs incurred for research purposes, over and above usual patient care, are not included as allowable costs." Indeed, since the inception of Medicare, we have distinguished between activities that are "usual

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[38] *See* 66 Fed. Reg. 39, 828, 39,896 *et. seq*. (Aug. 1, 2001) for full recitation of historical overview of policy. For further discussions, *see also* 71 Fed. Reg. 47,870, 48,081-48,093 (Aug. 18, 2006). As CMS explained more fully in the August 1, 2001 Federal Register As with IME payment, Medicare is not and has not been reimbursing teaching Hospitals under direct GME for the costs incurred for residents associated with research unrelated to patient care as such time/costs were part of the excluded non reimbursable costs centers in calculating the per resident amount.

> patient care' and activities that are outside this scope, such as research activities.[39]

The Secretary further explained that:

> The question as far as IME payments are concerned is whether or not the research is associated with the diagnosis and treatment of a particular patient. As explained above, teaching hospitals receive Medicare IME payments to pay hospitals for Medicare's share of the additional costs these hospitals incur associated with patient care costs; if the research is not associated with usual patient care costs, then the resident research time is not reimbursable.[40]

Therefore, the Medicare program has defined patient care since the beginning of the Medicare program as care related to the treatment and diagnoses of a particular patient. Notably, where Congress extended the FTE count to nonprovider settings, which otherwise would have been outside the scope of the Secretary authority to implement, Congress itself imposed the patient care requirement.

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 and GME.[41] The Secretary noted the August 1, 2001 final rule (66 Fed. Reg. 39,897) stated that, "we do not include residents in the IME count to the extent that the residents are not involved in furnishing patient care…"[42] 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." (Emphasis added).[43] At the same time, the Secretary explained that "patient care activities" for IME and GME purposes meant "the care and treatment of particular patients, including services for which a physician or other practitioner may bill."[44] The Secretary repeated that, with respect to residency training in the hospital, CMS'

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[39] Fed. Reg. 39,828, 39,898

[40] 66 Fed. Reg. 39,828, 39,899.

[41] 42 C.F.R. §412.105(f)(1)(ii)(C); 66 Fed. Reg. 39828, 39889 (Aug 1, 2001).

[42] 71 Fed. Reg. 47,480, 48,081 (Aug. 18, 2006).

[43] 42 C.F.R. §412.105(f)(1)(iii)(C)(2006).

[44] 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)."

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.[45] The FY 2007 IPPS Final Rule specifically addressed didactic time, stating:

> We have most recently received questions as to whether the time residents spend in nonhospital sites in didactic activities such as journal clubs or classroom lectures may be included in determining the allowable FTE resident counts. To respond to these inquiries and to resolve any confusion, in the FY 2007 IPPS proposed rule (71 FR 24114 and 24115), we included a clarification of our policy concerning the counting of time spent in nonpatient care activities for the purpose of direct GME and IME payments in both hospital and nonhospital settings. With respect to training in nonhospital settings, the time that residents spend in nonpatient care activities as part of an approved program, including didactic activities, cannot be included in a hospital's direct GME or IME FTE resident count. This longstanding policy is based on the statutory requirements for counting FTE residents training in nonhospital sites.[46]

The Secretary further noted that it understood that as part of an approved medical residency program, residents are often require to participate in didactic activities, some of which may take place in nonhospital sites. The Secretary pointed out, that:

> In implementing section 1886(h)(4)(E) of the Act for direct GME payment purposes, we specifically stated that "only time spent in activities relating to patient care may be counted [in nonhospital sites]" (54 FR 40292, September 29, 1989). In 1998, when we implemented the statute allowing FTE residents to be counted in nonhospital sites for IME, we reiterated that a hospital may only count resident training time "in nonhospital sites for indirect and direct GME, respectively, if the resident is involved in patient care" (63 FR 40986, July 31, 1998).[47]

The Secretary stated that the meaning of the term "patient care" was well established in the Medicare program even prior to the issuance of the first rules on counting FTE residents for purposes of direct GME and IME payments. Regarding didactic time, CMS noted:

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[45] 71 Fed. Reg. 47,870, 48,082 (Aug. 18, 2006).
[46] 71 Fed. Reg. 47,870, 48,080 (Aug. 18, 2006)
[47] *Id.*

> We have applied and continue to apply the plain meaning of the statutory terms "patient care activities" and "activities relating to patient care" in the context of approved GME programs. That is, the plain meaning of patient care activities would certainly not encompass didactic activities. Rather, the plain meaning refers to the care and treatment of particular patients, or to services for which a physician or other practitioner may bill. Time spent by residents in such patient care activities may be counted for direct GME and IME payment purposes in the nonhospital site. Time spent by residents in other activities in the nonhospital site that do not involve the care and treatment of particular patients, such as didactic or "scholarly" activities, is not allowable for direct GME and IME payment purposes.[48]

While the Secretary recognized that didactic activities contribute to 'the development of clinicians, it noted:

> Medicare GME payments were never intended to cover the total costs of medical education, as is evidenced most obviously by the fact that direct GME payments are based on Medicare's share of the costs of training an FTE resident. Rather, we are merely distinguishing between activities that concern the treatment and diagnosis of particular patients (that is, patient care), and activities that are didactic in nature (that is, not patient care), as this distinction is necessary to ensure that Medicare funds for medical education are paid appropriately. Direct GME has historically been considered to be the payment for the direct costs of education. Accordingly, the direct educational costs incurred by a hospital in providing didactic activities are more appropriately paid for via the direct GME payment.
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> The IME adjustment serves an entirely different purpose. Specifically, the IME adjustment is a payment under the IPPS to recognize the higher operating costs that teaching hospitals incur in furnishing patient care; it is intended to pay a teaching hospital for those additional indirect patient care costs, not the direct costs associated with didactic learning.

[48] *Id.* at 48,081.

> Furthermore, while we do not dispute that didactic activities are essential to and integrated with the residents' patient care experience, this does not mean that the didactic activities are patient care activities.[49]

Consequently, CMS amended §413.75(b) to explicitly add a definition of the term "patient care activities" which means, "the care and treatment of particular patients, including services for which a physician or other practitioner may bill." In addition, CMS amended the IME regulations at §412.105 (f)(1)(iii) to add a paragraph (C) to state that "In order to be counted, a resident must be spending time in patient care activities, as defined in §413.75(b)." CMS also made conforming changes to the regulations text at §412.105(f)(1)(iii)(C), and §413.78(c)(1), (d)(1), and (e)(1) for residency training in nonhospital settings.

The Administrator finds that the August 1, 2001[50] and the later August 18, 2006 *Federal Register* Notices do not represent changes in policy. As earlier noted, there have been longstanding regulations and Manual provisions for example concerning research,[51] which excluded costs not related to patient care and defined related to patient care as care *associated with the diagnosis and treatment of a particular patient*. As noted, the PRM prohibiting the counting of residents engaged exclusively in research (and segregating out time spent in "patient care related activities. i.e., *the diagnosis and treatment of a particular patient*) has been in place prior to the years at issue in this case. Because of these longstanding regulations and interpretative

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[49] *Id*. at 48,085.

[50] The cost years in this case are 12/31/2000 through 12/31/2006 and, hence, even assuming, *arguendo*, one gave no weight to the clear pronouncements in the PRM definition, etc., as to the definition of "patient care", CMS clearly expressed in the August 2001 *Federal Register* preamble that patient care related activities were defined as activities associated with the treatment or diagnosis of a particular patient." Finally, the letter heavily relied upon by the Board as evidence of CMS' policy is contrary to prior and subsequent uses of the term and was not subject to the clearance process used for manuals, transmittals, *Federal Registers*, and other interpretative and rulemaking documents typically used for documents and statements of policy when they are widely disseminated to the Hospital community or Medicare contractors. The document was written to one provider and signed by a lower level official. The Hospital did not indicate in its final position paper (contrary to the Board's suggestion) that it was in fact contemporaneously aware of the document.

[51] Historically this was set forth at §405.422, then moved to §413.5(c)(2), and now are at §412.90.

Manual provisions, the regulation text at §405.105(f)(1)(iii)(C), which specifies the patient care requirement for nonhospital sites, are not new regulations, but simply the codification of existing policy in the IME and GME regulation text. This policy applies to both pure research and didactic activities, since neither activity, although part of an approved program, are patient care activity as that term has been historically used.

In this case, the Provider signed an affiliation agreement with the University of Louisville in 1996, under which the Provider agreed to serve as the principal teaching hospital of the University, and agreed to be available for the teaching, research, and clinical care program of the University of Louisville Medical School and Dentistry School. Pursuant to this agreement, the Provider has worked with the Dental School to train oral surgery and dental general practice residents in the Dental School's approved graduate medical education programs. As part of their training, residents participate in classroom (didactic) discussions in the nonhospital rotation. For the cost years at issue in each case, the Medicare Contractor excluded the classroom (didactic) time, which also included conferences and seminars, from the number of full time equivalent (FTE) hours used to calculate reimbursement for the Provider for the nonhospital site rotation. The Administrator finds that the FTEs time at issue was spent in a nonhospital setting. The Administrator finds that the FTEs time at issue involved didactic activities[52] and were not related to the treatment and diagnoses of individual patients and must be excluded from the GME/IME FTE resident count. Thus, the Medicare Contractor's exclusion of didactic time from the FTE counts for GME and IME for fiscal years 2000 to 2006 was appropriate.[53]

Issue No. 2: The controlling regulation at 42 C.F.R. §413.86 (2003), specifies that:

> (h) Determination of weighting factors for foreign medical graduates.
> (1) The weighting factor for a foreign medical s passed FMGEMS; or graduate is determined under the provisions of paragraph (g) of this section if the foreign medical graduate—
> (i) Has passed FMGEMS; or
> (ii) Before July 1, 1986, received certification from, or passed an examination of, the Educational Committee for Foreign Medical Graduates.

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[52] The Provider also points to the "workday" policy effective for cost reporting periods starting on or after October 1, 2006, to justify the inclusion of all the time as no FTEs spent the entire day in non-patient care related activities. However, that policy is not applicable for the cost years involved in this case.

[53] *See* Provider Exhibits 26-32. *See also* Provider Exhibit 34.

> (2) Before July 1, 1986, the weighting factor for a foreign medical graduate is 1.0 times the weight determined under the provisions of paragraph (g) of this section. On or after July 1, 1986, and before July 1, 1987, the weighting factor for a graduate of a foreign medical school who was in a residency program both before and after July 1, 1986 but who does not meet the requirements set forth in paragraph (h)(1) of this section is .50 times the weight determined under the provisions of paragraph (g) of this section.
> (3) On or after July 1, 1987, these foreign medical graduates are not counted in determining the number of FTE residents.
> (4) During the cost reporting period in which a foreign medical graduate passes FMGEMS, the weighting factor for that resident is determined under the provisions of paragraph (g) of this section for the part of the cost reporting period beginning with the month the resident passes the test.
> (5) On or after September 1, 1989, the National Board of Medical Examiners Examination, Parts I and II, may be substituted for FMGEMS for purposes of the determination made under paragraphs (h)(1) and (h)(4) of this section.
> (6) On or after June 1, 1992, the United States Medical Licensing Examination may be substituted for the FMGEMS for purposes of the determination made under paragraphs (h)(1) and (h)(4) of this section. On or after July 1, 1993 only the results of steps I and II of the United States Medical Licensing Examination shall be accepted for purposes of making this determination.

Thus, only foreign medical graduate residents who have passed the United States Medical Licensing Examination (USMLE) may be included in the direct GME FTE resident count on or after July 1, 1993. The term “foreign medical graduate” is defined in 42 C.F.R. §413.86(b) as:

> Foreign medical graduate means a resident who is not a graduate of a medical, osteopathy, dental, or podiatry school, respectively, accredited or approved as meeting the standards necessary for accreditation by one of the following organizations:
> (1) The Liaison Committee on Medical Education of the American Medical Association.
> (2) The American Osteopathic Association.
> (3) The Commission on Dental Accreditation.
> (4) The Council on Podiatric Medical Education. (Emphasis added.)

In this case, the foreign dental graduates whose time was at issue were ineligible to take the USMLE, as it is offered only to foreign graduates of medical schools, not dental schools.[54] As such, the foreign dental graduates at issue could not be included in the DGME FTE resident count.

Issue No. 3: In this instance the Administrator is upholding the Medicare Contractor's adjustment mooting this issue. Further, the regulations at 42 C.F.R. §412.105 require the use of the prior year cost report item when determining the current year's IME payment. Accordingly, the resident to bed ratios must be separately and timely appealed by the Provider in order to effectuate a change to the resident to bed ratio in the respective cost reporting period. Under 42 C.F.R. §405.1811(a), because each cost report year receives its own final determination through its own NPR, and a hospital has a right to appeal specific items claimed for a cost reporting period within each NPR, the Provider would have to separately and timely appeal the resident to bed ratio subject to each NPR in order to effectuate a change to each year's resident to bed ratio.[55] Thus, to the extent a final ruling would allow action contrary to that, it is incorrect. Thus, based on all of the foregoing reasons, the Administrator vacates the Board's directions with respect to this issue.

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[54] *See* Stipulations of the Parties at ¶12.

[55] The Administrator also notes that CMS has discussed the clarification of the appeal of a "predicate fact". A "predicate fact" is a factual underpinning of a specific determination of the amount of reimbursement due to a provider that first arises in (that is, the pertinent facts occur or start during, or are reported by the provider and determined by the intermediary for) an earlier period than the cost reporting period under review. CMS' practice is that the pertinent provisions of the statute and regulations provide for review and potential redetermination of such predicate fact *only by a timely appeal* or reopening of: (1) The NPR for the cost reporting period in which the *predicate fact first arose*, or was first determined; or (2) the NPR for the period for which such predicate fact was first used or applied by the intermediary to determine reimbursement. Once the 3-year reopening period has expired, neither the provider nor the intermediary is allowed to revisit a predicate fact that was *not changed through the appeal* (as that term is defined in the foregoing sentences) or reopen the cost report for the fiscal period in which such predicate fact first arose or for the fiscal period for which such fact was first determined by the intermediary. Moreover, the reopening regulation was revised to clarify this longstanding policy in a final rule published December 10, 2013 (78 Fed. Reg. 74,826, 75,162-69).

DECISION

Issue No. 1: The decision of the Board is reversed in accordance with the foregoing opinion.

Issue No. 2: The decision of the Board is upheld in accordance with the foregoing opinion.

Issue No. 3: The decision of the Board is vacated in accordance with the foregoing opinion.

THIS CONSTITUTES THE FINAL ADMINISTRATIVE DECISION OF THE SECRETARY OF HEALTH AND HUMAN SERVICES

Date: 8/01/2016

/s/
Patrick H. Conway, M.D., MSc
Acting Principal Deputy Administrator
Centers for Medicare & Medicaid Services