CENTERS FOR MEDICARE AND MEDICAID SERVICES

Decision of the Administrator

In the case of:	**Claim for:**
Toyon 1997-2001 Intern and Resident Research FTE Group	**Provider Cost Reimbursement Determination for Cost Reporting Periods Ending: Various**
Provider	
vs.	
Noridian Healthcare Solutions	**Review of:** **PRRB Dec. No. 2016-D26**
Medicare Contractor	**Dated: September 29, 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. No comments were received in this case. Accordingly, this case is now before the Administrator for final agency review.

ISSUE AND BOARD'S DECISION

The issue was whether the Medicare Contractor properly reduced the Provider's Indirect Medical Education (IME) Full Time Equivalent (FTE) resident counts, for time spent by residents in research activities.

The Board found that the MAC properly adjusted the Providers' IME FTE resident counts for time spent by residents in research activities. The Board stated that the Seventh Circuit Court of Appeals decision in *Rush Univ. Med. Ctr. v. Burwell*[1] concluded that IME research time was not allowable. The Board found this decision to be a thorough and complete analysis of the statutory and regulatory developments of the IME research question. The Board noted that the Seventh Circuit relied on the

[1] 763 F.3d 754 (7th Cir. 2014).

statutory language of 42 U.S.C. § 1395ww(d)(5)(B)(x)(II), as added by the Patient Protection and Affordable Care Act of 2010 (ACA) § 5505(b). This language permitted the Secretary to define the term "non-patient care activities", which the Secretary did in the November 2010 Final Rule when she promulgated 42 C.F.R. § 412.105(f)(1)(C)(iii) to define that term.[2] In the preamble to the Final Rule, "non-patient care activities, such as didactic conferences and seminars", were distinguished from "research time that is not associated with the treatment or diagnosis of a particular patient".[3] The Board stated that in *Rush*, the Seventh Circuit further found that Congress delegated authority to the Secretary to determine whether pure research activities should be included in the IME cost formula for the years 1983 to 2001, and that the Secretary's determination was a reasonable interpretation of the statute.[4]

The Board found that the Seventh Circuit also addressed in *Rush* the argument that ACA and the November 2010 regulations should not be applied retroactively to fiscal years before 2010. The Board noted that the Seventh Circuit held that, while retroactive application of statutes and regulations is generally disfavored, Congress explicitly adopted language in ACA §§ 5505(c)(1) and 10501(J) to allow the Secretary to apply this regulatory definition retroactively to cost reporting periods beginning on or after January 1, 1983.

The Board noted that its decision in this case was consistent with its decision in *BB&L 95-03 IME Research FTE Group v. BlueCross BlueShield Assocation*[5], despite being inconsistent with certain Board decisions issue prior to *BB&L*. The Board noted that these earlier Board decisions were made prior to the enactment of ACA and the November 2010 Final Rule implementing 42 U.S.C. § 1395ww(d)(5)(B)(x)(II) as amended by ACA § 5505(b). The Board noted that it is required to comply with all Medicare statutory and regulatory provisions, and consequently, it is bound to apply ACA §§ 5505(b), 5505(c), and 10501(j), and 42 C.F.R. §412.105(f)(ii)C), including their retroactive effect, to this case.

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[2] 75 Fed. Reg. 71,800, 72,144 (Nov. 24, 2010).

[3] Id.

[4] The Board cited to *Rush* at 762. The Board also noted that in *Henry Ford Health System v. Dept. of Health and Human Services*, 654 F.3d 660 (6th Cir. 2011) the Sixth Circuit concluded that the ambiguity in the statutory language allowed the Secretary to adopt a regulation to clarify which non-patient care activities count in the IME calculation.

[5] PRRB Dec. No. 2013-D16 (May 9, 2013).

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.

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 its inception Medicare has recognized the increased operating costs related to a provider's approved graduate medical education programs through an indirect teaching adjustment. 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."[6] 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

[6] 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).

> (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.[7]

Congress specifically provided for direct "educational" costs incurred by hospital to be reimbursable. Similarly, the regulations governing research cost, under the "reasonable cost" system of reimbursement were found in 42 C.F.R. § 405.422 (1977) *et. seq.*, and stated that the "costs incurred for research purposes over and above usual patient care, are not includable as allowable costs". The regulation at 42 C.F.R. § 405.422(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, § 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."[8] 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.

The Secretary promulgated the regulation at 42 C.F.R. § 413.85 which permits reimbursement for the costs of approved educational activities.[9] The regulation at 42 C.F.R § 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"[10] As the Supreme Court in *Thomas Jefferson v. Shalala*, 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

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

[8] *See* § 505.1 of the PRM. Section 502 of the PRM defines Research.

[9] 42 C.F.R. §413.85(b) (1997) 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(1977) and 20 C.F.R. §405.421 (1967).

[10] *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.

> 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).[11]

Section 223 of the Social Security Act of 1972 amended §1861(v)(1)(A) to authorize the Secretary to set prospective limits on the cost reimbursement by Medicare.[12] 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 hospital incurs through its operation of an approved intern and resident program."[13]

Consequently, the indirect teaching adjustment methodology arises out of the 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 §1861(v)(1)(A), the existing routine cost limits. The Tax Equity and Fiscal Responsibility Act (TEFRA) added §1886(a)

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[11] 512 U.S. 540 (1994).
[12] Pub. L. 92-603.
[13] 46 Fed. Reg. 33,637 (June 30, 1981).

to the Act, which expanded the existing routine cost limits[14] to include ancillary services, operating costs and special care unit operating costs in addition to routine operating costs. Pursuant to §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.[15] Thus, since its inception, Medicare has recognized the increased (patient care) operating costs related to a provider's approved graduate medical education programs through an indirect teaching adjustment.[16] However, 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. While one could distinguish between allowable and non-allowance costs (such as research), there was not a method to consistently and accurately isolate all the time spent by residents in nonpatient care activities. Therefore, at that time, 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.[17]

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.[18] 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

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

[15] 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…"

[16] 45 Fed. Reg. 21,584 (Apr. 1, 1980) (indirect teaching adjustment under pre-TEFRA cost limits).

[17] 71 Fed Reg. 47,870, 48,089 (Aug 18, 2008).

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

payment rates or in the target amount for hospitals not subject to IPPS.[19] Instead, payment for approved medical education activities costs were separately identified and paid as a "pass-through" under a cost basis.[20]

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.[21] 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."[22] 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.)

In contrast, 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 starting in 1986. The costs of educational activities (that is "direct" GME costs) were reimbursed after 1986 as part of the methodology set forth at § 1886(h) of the Act. In 1986, Congress created a new GME reimbursement formula for cost reporting

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[19] 48 Fed. Reg. 39,764-39,773 (Sept. 1, 1983).

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

[21] 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.

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

periods beginning on or after July 1, 1985.[23] 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 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.[24] 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 purpose of the IME payment was to address the additional costs that hospitals incur in treating patients. The May 6, 1986 interim final rule[25] 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 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[26] specifically stated:

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

[24] *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)), were recognized as Medicare-allowable costs and implicitly included in the definition of "costs related to patient care" at 42 C.F.R. § 413.9. 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 explicitly pays hospitals for the direct costs of these formally organized programs, such as the stipends of trainees and teachers.")

[25] 51 Fed. Reg. 16,775.

[26] 54 Fed. Reg. 40,286.

> 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."[27]

The regulation at 42 C.F.R. § 412.105 governs IME payments to Medicare providers. The regulations governing IME reimbursement were codified at 42 C.F.R. § 412.105(g)(1995).[28] 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;
> (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.[29]

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[27] *Id.*

[28] This regulation was re-designated from 42 C.F.R. § 412.105(g) to § 412.105(f) in 1997. *See* 62 Fed. Reg. 45,966, 46,029 (Aug. 29, 1997).

[29] 42 C.F.R. § 412.105(f)(1) (1997).

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.)[30]

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.[31] (Emphasis added.)

To read the regulation as allowing for the inclusion of nonpatient care time in the IME FTE count is beyond 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.[32]

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[30] *See* 51 Fed. Reg. 16,772 (May 6, 1986).

[31] *See* 54 Fed. Reg. 40,282 (Sep. 29, 1989).

[32] Notably, where Congress extended the FTE count to nonprovider settings, which otherwise would have been outside the scope of the Secretary to implement and

Accordingly, 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' time to the extent that the residents are not involved in furnishing *patient care*. 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."[33] 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.[34] This distinction between activities that are "usual patient care" and research is longstanding Medicare policy. In April 1975, at § 500 of the Provider Reimbursement Manual (PRM), it was stated:

> Costs incurred for research purposes, over and above *usual patient care*, are *not* included as allowable costs. (Emphasis added).

In § 502 of the 1975 PRM, which defined the terms "research", "usual patient care", and "extraordinary patient care", the term "usual patient care" was defined 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,

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outside the Secretary's authority under sections 1861, 1886(a) and 1886(d) of the Act, Congress itself imposed the patient care requirement.

[33] *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). 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.

[34] 42 C.F.R. § 412.105(f)(1)(iii)(B).

> therapeutic, rehabilitative, medical, psychiatric, skilled nursing, and other related professional health services.

Thus, it has always been Medicare policy to require that hospitals distinguish between time spent by residents involved exclusively in research, and time spent on *patient care* activities. As was noted in the August 1, 2001 Final Rule:

> 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.[35]

The Administrator finds that the August 1, 2001 *Federal Register* Notice did not represent a change 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. In addition, the PRM prohibiting the counting of residents engaged exclusively in research has been in place since 1988. Consistent with the foregoing regulation, §2405.3.F of the PRM 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…[36]

Because of these longstanding regulations and PRM, it is evident that the regulation text at 42 C.F.R. §405.105(f)(1)(iii)(B) (2001), which specified the patient care requirement, was simply the codification of existing policy in the IME regulations text.

Thus, from the beginning of its implementation of the Congressional directives regarding medical education costs, Medicare has only paid for research costs related

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[35] 66 Fed. Reg. 39,828, 39,899.

[36] Transmittal Rev. 345 (Aug. 1988).

to patient care even within the context of the increased direct and indirect costs associated with approved medical education programs.

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.[37] The Secretary noted the August 1, 2001 final rule (66 Fed. Reg. 39,897) 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…"[38] 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).[39] 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."[40] 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.[41]

In 2010, Congress passed the Patient Protection and Affordable Care Act (ACA). Section 5505(b) of ACA amended § 1886(d)(5)(B)(x)(III) of the Social Security Act, adding:

> In determining the hospital's number of fulltime equivalent residents for purposes of this subparagraph, all the time spent by an intern or resident in an approved medical residency training program in research activities that are not associated with the treatment or diagnosis of a particular patient, as such time and activities are defined by the Secretary, shall not be counted toward the determination of full-time equivalency.

Regarding the effective date, § 5505(c) noted:

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[37] 42 C.F.R. § 412.105(f)(1)(ii)(C); 66 Fed. Reg. 39828, 39889 (Aug 1, 2001).
[38] 71 Fed. Reg. 47,480, 48,081 (Aug. 18, 2006).
[39] 42 C.F.R. § 412.105(f)(1)(iii)(C)(2006).
[40] 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)."
[41] 71 Fed. Reg. 47,870, 48,082 (Aug. 18, 2006).

> (1) IN GENERAL.—Except as otherwise provided, the Secretary of Health and Human Services shall implement the amendments made by this section in a manner so as to apply to cost reporting periods beginning on or after January 1, 1983.
> (2) GME.—Section 1886(h)(4)(J) of the Social Security Act, as added by subsection (a)(1)(B), shall apply to cost reporting periods beginning on or after July 1, 2009.
> (3) IME.—Section 1886(d)(5)(B)(x)(III) of the Social Security Act, as added by subsection (b), shall apply to cost reporting periods beginning on or after October 1, 2001. Such section, as so added, shall not give rise to any inference as to how the law in effect prior to such date should be interpreted.

On November 24, 2010, the Secretary promulgated a final rule amending the GME and IME regulation in light of ACA.[42] As noted in the preamble:

> From the outset of the Medicare program, research costs have not been considered reasonable costs of patient care, unless the research is associated with the treatment or diagnosis of a particular patient. (S. Rept. No. 89–404, Part I, p. 36 (June 30, 1965) (''Identifiable expenses for medical research * * * over and above the costs closely related to normal patient care, would not be met from the trust fund.'')); 31 FR 14814, Nov. 22, 1966 (promulgating prior version of 42 CFR 413.90(a)).[43]

Regarding the effective date, CMS noted:

> The existing regulations regarding the exclusion of research for IME merely reiterate longstanding policy, as we explained in the August 1, 2001 final rule (66 FR 39896) and, therefore, that the regulation at 42 CFR 412.105(f)(1)(iii)(B) does not have an effective date. We did not include the October 1, 2001 effective date of the exclusion of research time for IME payment purposes in our proposed regulations for the same reason. Congress specified the date we reiterated in our policy by regulation as an effective date for the statutory exclusion of research time for IME. However, Congress did not state that research activities prior to October 1, 2001, are allowed. Rather, Congress deferred to the Secretary to interpret and implement policy regarding research time for IME payment purposes prior to October 1, 2001. This is the meaning

[42] 74 Fed. Reg. 71,800.
[43] *Id.* at 72,144.

of the statement in section 5505 that is quoted by the commenter, that ''such section, as so added, shall not give rise to any inference as to how the law in effect prior to such date should be interpreted.'' This language further means that, subject to the limitations of section 5505(d), in the instances where providers disagree with the Secretary's interpretation of research policy in cost reports prior to October 1, 2001, and the providers appeal research time that was disallowed from their IME FTE counts in those cost reports, the matter would be reserved for adjudication in the courts.

However, there has been some confusion regarding the application of this provision of the Affordable Care Act. Some individuals, and one court decision, have interpreted section 5505(b)'s allowance of nonpatient care activities for IME as of January 1, 1983 to include research time as well. We believe that this interpretation is contrary to the express intent of the statute, which clearly distinguishes ''research activities that are not associated with the treatment or diagnosis of a particular patient'' from ''nonpatient care activities, such as didactic conferences and seminars,'' and which unmistakably excludes research time. In addition, as explained above, Congress clearly provided that the October 1, 2001 effective date ''shall not give rise to any inference'' as to how any research time prior to that effective date should be counted for IME. Several other commenters on the proposed rule shared CMS' understanding of section 5505(c) within their comments. These commenters acknowledged that ''the law does not opine on the status of IME research time prior to October 1, 2001, stating that research provision of the law 'shall not give rise to any inference as to how the law in effect prior to such date should be interpreted''' (emphasis added). This widespread understanding of section 5505(c) aligns with CMS' understanding of this Affordable Care Act language, and is consistent with our view that the Secretary has the authority to interpret section 1886(d)(5)(B) of the Act, as amended by section 5505, and implement policy regarding the time spent in research activities prior to October 1, 2001, as the Secretary determines appropriate.

For all these reasons, we are exercising our authority to define the term ''nonpatient care activities,'' as used in section 5505(b) of the ACA, to adopt proposed § 412.105(f)(1)(iii)(C), which excludes research activities not related to the treatment or diagnosis of a particular patient from the category of allowable ''nonpatient care activities.'' Instead, such research activities would continue to be excluded under §

> 412.105(f)(1)(iii)(B). In addition to the language and structure of section 5505, as discussed above, we believe such a decision is also supported by important differences between these research activities and the types of nonpatient care activities, for example, didactic conferences and seminars, enumerated in section 5505. For example, interns and residents are often assigned to blocks of research time, whereas didactic conferences and seminars may occur during periods when an intern or resident is otherwise assigned to a rotation primarily requiring the provision of patient care. In addition, such didactic conferences and seminars may involve presentations or discussions related to the treatment of current patients. It has been our consistent policy to exclude research activities, as we clarified in rulemaking in 2001. We also engaged in rulemaking in 2006 to clarify that didactic time would also not be counted for GME and IME purposes. Set against this background, we read section 5505 as reflecting Congress' clear intent to reverse our 2006 policy regarding didactic time and to ratify our policy regarding research time from October 1, 2001, forward, while also indicating that it was not directing any result as to research activities before October 1, 2001.[44]

Thus, the Administrator reiterates that it has been longstanding policy, made law by Congress and upheld by several courts, to exclude any research time spent by a resident that was not associated with the treatment or diagnosis of a particular patient. In this case, the disallowed time was spent in research activities not directly related to patient care.[45] Thus, the Medicare Contractor's exclusion of research time from the FTE counts for IME for the cost reporting periods at issue was appropriate.

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[44] *Id.* at 72,145-6.

[45] *See* Provider Final Position Paper at 3.

DECISION

The decision of the Board is modified in accordance with the foregoing opinion.

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

Date: 11/14/2016

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