CENTERS FOR MEDICARE AND MEDICAID SERVICES

Decision of the Administrator

In the case of: **Henry Ford Hospital** **Provider** **vs.** **Blue Cross BlueShield Association** **National Government Services, LLC** **Intermediary**	**Claim for:** **Determination for Cost Reporting Period Ending: December 31, 2000** **Review of:** **PRRB Dec. No. 2010-D53** **Dated: September 30, 2010**

This case is before the Administrator, Centers for Medicare & Medicaid Services (CMS), for review of the decision of the Provider Reimbursement Review Board (Board). The review is during the 60-day period in §1878(f) (1) of the Social Security Act (Act), as amended (42 USC 1395oo(f)). The Intermediary submitted comments requesting that the Administrator reverse, in part, the Board's decision on Issue No. 1, and to reverse the Board's decision in Issue No. 2. The parties were then notified of the Administrator's intention to review the Board's decision. Subsequently, the Provider submitted comments requesting that the Administrator reverse, in part, the Board's decision on Issue No. 1 and affirm the Board's decision on Issue No. 2. CMS' Center for Medicare (CM) also submitted comments requesting that the Administrator reverse, in part, the Board's decision on Issue No. 1 and reverse the Board's decision on Issue No. 2. Accordingly, the case is now before the Administrator for final administrative decision.

BACKGROUND

The Provider is a non-profit, acute care teaching hospital located in Detroit, Michigan. The Provider included Indirect Medical Education (IME) and Direct Graduate Medical Education (DGME) full time equivalents (FTEs) on its cost report for fiscal year ending

(FYE) December 31, 2000. The Intermediary audited the cost reports and adjusted the as-filed IME and DGME FTEs to its audit findings.

ISSUE NO. 1 AND BOARD'S DECISION

Issue No. 1 concerns whether the Intermediary properly determined the Provider's FTE counts used for purposes of calculating payment for direct graduate medical education (GME) and indirect medical education (IME) based on its exclusion of residents in other approved programs, including unaccredited training programs.

The Board found that the Intermediary's adjustments excluding FTEs attributable to rotations by residents in the unaccredited training programs C.S Livingood Research Fellowship, Movement Disorder Fellowship, and Cross Sectional Imaging program was proper. The Board also found that the Intermediary's exclusion of the FTE's attributable to rotations by residents in the unaccredited Cerebrovascular Disease/Stroke Fellowship was improper.

ISSUE NO. 2 AND BOARD'S DECISION

Issue No. 2 concerns whether the Intermediary properly excluded FTEs attributable to time spent by residents in research that was required by the residents' approved medical residency programs. The Board found that the Intermediary's adjustments, reducing the Provider's IME FTE resident count for the time spent by residents in research that was required by the residents' approved medical residency program, were improper. The Board remanded the issue to the Intermediary to recalculate the IME adjustment to incorporate the time spent by residents in research activities that were part of their approved medical residency training program.

SUMMARY OF COMMENTS

The Intermediary submitted comments disagreeing with the Board's conclusion that the Provider's Cerebrovascular Disease/Stroke Program (Vascular Neurology) qualified as a Medicare approved program in Issue No. 1, and requested a modification of the Board's decision. The Intermediary asserted that the American Board of Medical Specialties (ABMS) did not approve Vascular Neurology as a subspecialty until 2003, three years after the cost year in question. The Intermediary argued that the fellowship participants at issue could not have counted time spend in Cerebrovascular Disease/Stroke Program towards certification under the regulations at 42 C.F.R. §413.86(B)(2). Regarding Issue No. 2, concerning time spent in research activities, the Intermediary maintained that time

spent by residents performing research activities, not directly related to patient care, must be excluded from the resident count. Therefore, the Intermediary contended that the Board was incorrect to include IME FTEs related to research rotations, and the decision should be reversed.

The CM submitted comments agreeing with the Board's findings that the Intermediary properly disallowed the FTE residents in the C.S. Livingwood, Movement Disorder, and Cross Sectional imaging programs from the direct GME and IME counts. However, CM disagreed with the Board's decision regarding the Cerebrovascular Disease/Stroke program. The Board noted that this program, re-named Vascular Neurology, was accredited in 2005 and further that the American Board of Professional Neuropsychology (ABPN) created a grandfathering provision in which unaccredited training counted towards certification through 2009. However, CM asserted that the ABPM grandfathering period was from 2005 through 2009 and therefore non-accredited training programs that occurred prior to 2005 were not accepted by the ABPN for board certification.

Regarding Issue No. 2, CM disagreed with the Board's conclusions concerning counting research time for purposes of IME payment and asserted that the Intermediary's adjustments were correct. The CM asserted that it has been a longstanding policy that research time cannot be counted for IME payment purposes. CM stated the regulations and statute indicate that Medicare never intended to provide reimbursement for research since it is not related to patient care. Specifically, under the regulations at 42 C.F.R. §§413.5 and 413.90 as well as the IME regulations at §412.105(f)(1)(ii), FTEs that are involved in non-patient care research activities may not be included in the resident count for the IME adjustment. The CM pointed out that the August 1, 2001 Federal Register clarified the long-standing Medicare policy, and supported the notion that the IME adjustment is a payment for patient care. The CM stated that the Provider Reimbursement Manual (PRM) has prohibited the counting of residents engaged exclusively in research since 1988. The CM maintained that these longstanding rules and regulations on research is evidence that the regulations text on research at 42 C.F.R. §412.105(F)(1)(iii)(B), added in 2001, was not a new regulation, but rather the codification of existing policy in the regulations text. CM reasoned that if the FTE time spent in research was included in the IME resident count, Medicare would be reimbursing a provider for a non-patient care activity for which it was never intended to pay. CM further argued that pursuant to the rules at 42 C.F.R. §412.105(F)(1)(ii), a resident must be assigned to either the "portion of the hospital subject to the prospective payment system" (i.e., the IPPS) or "the outpatient department of the hospital," to be included in the calculation. CM argued that not only did the Provider fail to document that the research in question was performed in a part of the hospital that is paid under the IPPS or in the outpatient department, but much of the

research required by accrediting organizations is bench research that is not performed in those areas of the hospitals.

The Provider commented, that the Administrator reverse, in part, the Board's decision in Issue No. 1. The Provider argued that the Administrator should affirm the Board's decision concerning the Cerebrovascular Disease/Stroke program and reverse the Board's decision concerning the C.S. Livingood Research Fellowship, Movement Disorders Fellowship, and Cross Sectional Imaging program. The Provider noted that the Board held that the Cerebrovascular Disease/Stroke program was an approved program because the ABPN created a grandfathering provision in which unaccredited training in vascular neurology counts towards certification through 2009. The Provider noted that CM asserted that this grandfathering provision only applies from 2005 through 2009. However, the Provider argued that this was incorrect, as the grandfathering provision applies to all periods prior to 2010.[1]

For the three programs that it disallowed, the Board remanded to the Intermediary to determine payment under Medicare Part B. The Provider contended that if the Administrator determines that one or more of the programs did not meet the requirements for inclusion in the DGME and IME FTE counts, that the Administrator affirm the Board's remand for residents in any program deemed to be unapproved. The Provider noted that this aspect of the issue is distinguishable from the Provider's earlier appeal in *Henry Ford Hospital I*.[2] The Provider argued that in *Henry Ford Hospital I*, the Board remanded to the Intermediary for Part B reimbursement for the services of residents in certain unaccredited programs. However, the Administrator reversed solely because the Provider had not furnished documentation supporting Part B reimbursement. The Provider asserted that in this appeal, it did furnish Part B documentation to the Intermediary prior to the hearing. Therefore, the Intermediary should review this documentation if a final administrative or judicial decision determines that any of the programs are not Medicare approved programs.

Regarding Issue No. 2, the Provider claimed that the Board properly determined that the Intermediary incorrectly removed the time spent in research as part of an approved medical residency program from the IME FTE count. The Provider asserted that prior

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[1] *See*, Provider's Position Paper, Exhibit P-80.

[2] *See*, Henry Ford Hospital, *Dec. No. 2008-D34, Medicare & Medicaid Guide (CCH)* ¶82,109 (PRRB 2008), *affirmed in part, reversed in part*, Medicare & Medicaid Guide (CCH) ¶82,212 (CMS Administrator 2008). Henry Ford Health System v. Sebelius,680 F. Supp 2d.799 (E.D. Mich., Dec. 30, 2009). Currently on appeal in the United States Court of Appeals for the Sixth Circuit.

court decisions support the Board's decision and have rejected CMS' position that research time should be excluded from the IME FTE count. Moreover, the Provider argued that the issue of where residents were assigned and whether their time was spent in activities related to patient care was not disputed in this case, as the Intermediary and Provider entered into a stipulation stating, "the IME FTEs identified in paragraphs 1 [i.e. research rotations] and 2 represent time that the residents spent while they were assigned either to areas of the Provider subject to the prospective payment system or to outpatient departments of the Provider."[3] Therefore, the Provider maintained that the Administrator should affirm the Board's decision holding that research time must be included in the IME FTE count.

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

The Secretary promulgated regulations which explained the principle that reimbursement to providers must be based on the reasonable cost of services covered under Medicare and related to the care of beneficiaries.[4] Reasonable cost includes all necessary and proper cost incurred in furnishing the services. Necessary and proper costs are costs, which are appropriate and helpful in developing and maintaining the operation of patient care facilities and activities. Accordingly, if a provider's costs include amounts not related to patient care, or costs that are specifically not reimbursable under the program, those costs will not be paid by the Medicare program.

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[3] *See, Stipulation of Parties,* (September 17, 2009).109 (PRRB 2008).
[4] *See e.g.* 42 C.F.R. §413.9.

Under reasonable cost, the allowable costs of educational activities included trainee stipends, compensation of teachers and other direct and indirect costs of the activities as determined under Medicare cost finding principles. The Secretary promulgated the regulation at 42 C.F.R. §413.85 which permits reimbursement for the costs of "approved educational activities"[5] This regulation defines approved educational activities as "formally organized or planned programs of study usually engaged in by providers in order to enhance the quality of patient care in an institution.

The regulations governing research cost, under the "reasonable cost" system of reimbursement were found at 42 C.F.R. §405.422, et seq., and stated that the "[c]osts incurred for research purposes over and above usual patient care, are not includable as allowable costs."[6] The regulation at 42 C.F.R. §405.422(b)(2) further stated that: "Where research is conducted in conjunction with and as a part of the care of patients, the costs of usual patient care are allowable to the extent that such costs are not met by funds provided for the research…."[7]

Section 223 of the Social Security Act of 1972 amended section 1861(v)(1)(A) to authorize the Secretary to set prospective limits on the cost reimbursement by Medicare.[8] These limits are referred to as the "223 limits" or "routine cost limits" (RCL), and were based on the costs necessary in the efficient delivery of services. Beginning in 1974, the Secretary published routine cost limits in the Federal Register. These "routine cost limits" initially covered only inpatient general routine operating costs.

In 1982, in an effort to further curb hospital cost increases and encourage greater efficiency, Congress established broader cost limits than those authorized under section 1861(v)(1)(A), the existing routine cost limits. The Tax Equity and Fiscal Responsibility Act (TEFRA) added section 1886(a) to the Act, which expanded the existing cost limits to

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[5] 42 C.F.R. §413.85(b)(1998). This language has been in effect since the beginning of the Medicare program although it was formerly designated 42 C.F.R. §405.421(1977) and 20 C.F.R. §405.421(1967).

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

[7] *Id.* The Provider Reimbursement Manual (PRM) at §500 states that costs incurred for research purposes over and above usual patient care are not includable as reasonable costs or services. The PRM at §504.1 states that research conducted in conjunction with or as part of the usual care of patients is reimbursable to the extent such costs are not met by other forms of research funds. If research activity costs were paid by a third party, (not the Medicare program), then no indirect cost should be paid through an IME adjustment.

[8] Pub. Law 92-603.

include ancillary services operating costs and special care unit operating costs in addition to routine operating costs. Pursuant to section 1886(1)(a)(ii) of the Act, these expanded cost limits, referred to as the "inpatient operating cost limits," applied to cost reporting periods beginning after October 1, 1982. The costs related to approved medical education programs were not subject to the routine cost limits.

Under the routine cost limits, under §1886(a)(2) of the Act, Medicare also paid for the increased indirect costs associated with a hospital's approved graduate medical education program through an indirect teaching adjustment.[9] Thus, since its inception Medicare has recognized the increased *operating* costs related to a provider's approved graduate medical education programs through an indirect teaching adjustment.[10] Notably, research costs have never been includable as allowable operating costs.

In 1983, §1886(d) of the Act was added to establish the inpatient prospective payment system (IPPS) for reimbursement of inpatient hospital services furnished to Medicare beneficiaries.[11] Under IPPS, providers are reimbursed their inpatient operating costs based on prospectively determined national and regional rates for each patient discharge, rather than on the basis of reasonable operating costs. Under §§ 1886(a)(4) and (d)(1)(A) of the Act, the costs of approved medical education activities were specifically excluded

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[9] 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 educational costs …."

[10] 45 Fed. Reg. 21584 (April 1, 1980)(indirect teaching adjustment under pre-TEFRA cost limits); 46 Fed. Reg. 33637 (June 30, 1981)("We included this adjustment to account for *increased routine operating costs* that are generated by approved internship and residency programs, but are not allocated to the interns and residents (in approved programs) or nursing school cost centers on the hospital's Medicare cost report. Such costs might include, for example, increased medical records costs that result from the keeping, for teaching purposes, of more detailed medical records than would otherwise be required. Because our analysis of the data we used to develop the new limits shows that *hospital inpatient operating costs per discharge tend to increase in proportion to increases in hospital levels of teaching activity,* we have adopted a similar adjustment to the new limits. …. The increase in the percentage amount of the adjustment … results from the fact that total *inpatient operating costs,* which include special care unit and inpatient ancillary costs, are more heavily influenced than routine costs by changes in the level of teaching activity. In our opinion, this adjustment accounts for the *additional inpatient operating cost* which a hospital incurs through its operation of an approved intern and resident program." (Emphasis added.)

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

from the definition of "inpatient operating costs" and, thus, were not included in the PPS hospital-specific, regional, or national payment rates or in the target amount for hospitals not subject to PPS. Instead, payment for approved medical education activities costs were separately identified and paid as "pass-through," i.e., paid on a reasonable cost basis.[12] Later, for the cost years at issue, the direct costs of the approved graduate medical education program were paid under the methodology set forth at section 1886(h) of the Social Security Act. These provisions were promulgated at 42 C.F.R. § 413.86 (1997).

However, Congress recognized that teaching hospitals might be adversely affected by implementation of inpatient PPS because of the indirect costs of the approved graduate medical education programs. These may include the increased department overhead as well as a higher volume of laboratory test and similar services as a result of these programs which would not be reflected the IPPS rates.[13] Thus, under §1886(d)(5)(B) of the Act, hospitals subject to IPPS, with approved teaching programs, receive an additional payment to reflect these IME costs.[14] The statue states 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 section (a)(2)* [i.e. under the reasonable cost routine cost limits] …. (Emphasis added.)

The regulation at 42 C.F.R. §412.105 governs IME payments to Medicare providers. 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.[15] The resident must be enrolled in an approved teaching program. In addition, the regulation at 42 C.F.R. § 412.105(f)(ii) explains that in order to be included in the FTE count, the resident must be assigned to one of the following areas:

> (A) The portion of the hospital subject to the prospective payment system portion of the hospital;

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

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

[14] This IME payment is distinguished from the direct medical education costs.

[15] 42 C.F.R. §412.105(a)(1)(1997). *See* 49 Fed. Reg. 234 (1983) which noted that this additional payment is computed in the same manner as the indirect teaching adjustment under the notice of hospital cost limits published September 30, 1982 (47 Fed. Reg 43310).

> (B) The outpatient portion of the hospital;
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> (C) Effective for discharges occurring on or after October 1, 1997, the time spent by residents in a nonhospital setting in patient care activities under an approved medical residency training program is counted towards the determination of full-time equivalency.[16]

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

> Section 1886(d)(5)(B) of the Act provides that prospective payment hospitals receive an additional payment for 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.][17]

Consistent with the Act and the regulations, the above principles are set forth the Provider Reimbursement Manual (PRM) at §2405.3F2 and state that a resident must not be counted for the IME adjustment if the resident is engaged exclusively in research. Section 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

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[16] 42 C.F.R. §412.105(f)(1)(1997).
[17] See 51 Fed. Reg. 16772 (May 6, 1986).

> not count an individual in the indirect medical education adjustment if any of the following conditions exist:
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> ….
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> The individual is engaged exclusively in research…[18]

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

> We also note that section 1886(d)(5)(B) of the Act and section 412.115(b) of our regulations specify that hospitals with "indirect cost of medical education" will receive an additional payment amount under the prospective system. As used in section 1886(d)(5)(B) of the Act, "indirect costs of medical education" means those additional operating (that is, *patient care*) costs incurred by hospitals with graduated medical education programs.[19] (Emphasis added.)

Thus, from the beginning of its implementation of the congressional directives regarding medical education costs, Medicare has only paid for costs related to patient care even within the context of the increased direct and indirect costs associated with approved medical education programs. The Administrator notes that the Secretary's longstanding policy of requiring hospitals to identify and excluded time spent by residents involved exclusively in research for purposes of the IME count adjustment was clarified at 42 C.F.R. §412.105(f)(1)(iii)(B)(2001).[20] Consistent with longstanding policy, the regulation at 42 C.F.R. §412.105(f)(1)(iii)(B)(2001) specifically excluded all time spent by residents in research not involving the care of a particular patient by stating:

> The time spent by a resident in research that is not associated with the treatment or diagnosis of a particular patient is not countable….."[21]

With respect to DGME payments, in determining the total number of FTE residents, 42 C.F.R. §413.86(f)(1) instructs that subject to weighting factors, the count of FTE residents

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[18] Transmittal Rev. 345 (August 1998).
[19] *See* 54 Fed. Reg. 40282 (Sep. 29, 1989).
[20] *See* 66 Fed. Reg. 39896 (Aug. 1, 2001).
[21] *See* 66 Fed. Reg. 39896 (Aug. 1, 2001) for full recitation of historical overview of policy herein incorporated by reference. For further discussions, *see also* 71 Fed. Reg. 47870, 48081-48093 (August 18, 2006

includes "[r]esidents in an approved program working in all areas of the hospital complex…" Historically, the statutory definition of an "approved program" for purposes of the cost reimbursement system for inpatient hospital services expressly included only those programs that were accredited by one of several enumerated national organizations, including the predecessor to the Accreditation Council for Graduate Medical Education (ACGME). An approved medical residency training program is a residency or other postgraduate medical training program participation which may be counted toward the certification in a specialty or subspecialty and includes formal postgraduate training programs in geriatric medicine approved by the Secretary. The DGME regulation at 42 C.F.R. §413.86(b) (1999)[22] defines an approved program as meets one of the following criteria:

> (1) Is approved by one of the national organizations listed in §415.200(a) of this chapter.
>
> (2) May count towards certification of the participant in a specialty or subspecialty listed in the current edition of either of the following publications:
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> > (i) The Director of Graduate Medical Education Programs published by the American Medical Association …; or
> >
> > (ii) The Annual Report and Reference Handbook published by the American Board of Medical Specialties…
>
> (3) Is approved by the Accreditations Council for Graduate Medical Education (ACGME) as a fellowship program in geriatric medicine.

Likewise, the IME regulation at 42 C.F.R. §412.105(f)(1)(i) defines an approved program as one that meets one of the following requirements:

> (A)Is approved by one of the national organizations listed in §415.200(a) of this chapter.

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[22] The regulation at 42 C.F.R. §413.86(b) was re-designated 42 C.F.R. §413.75(B) on August 11, 2004. See 69 Fed. Reg. 49,254 (Aug. 11, 2004). Unless indicated otherwise, the decision refers to the regulation at 42 C.F.R. §413.86 that was in effect during the fiscal year ending December 31, 2000, the fiscal year under appeal.

(B) May count towards certification of the participant in a specialty or subspecialty listed in the current edition of either of the following publications:

(1) The Director of Graduate Medical Education Programs published by the American Medical Association...:

(2) The Annual Report and Reference Handbook published by the American Board of Medical Specialties.

(C) Is approved by the Accreditations Council for Graduate Medical Education (ACGME) as a fellowship program in geriatric medicine.

Applying the foregoing laws and regulations above to the facts of this case on Issue No. 1, the Administrator finds that the Board correctly found that the Intermediary's exclusion of FTEs attributable to rotations by residents in unaccredited C.S. Livingood Research Fellowship, Movement Disorder Fellowship, and Cross Sectional Imaging training programs was proper. The regulations at 42 C.F.R. §413.86(b) and 42 C.F.R. §412.105(f)(1)(i) set forth the requirement of proof that the training program would count towards certification. Thus, the Provider is required to document that the training would indeed count towards certification, and absent evidence of acceptance from the certifying body, the Provider would have to furnish alternative documentation to support its assertion that the training could be counted towards certification. The Provider has not met the burden of proof to show that the C.S. Livingood Research Fellowship, Movement Disorder Fellowship, and Cross Sectional Imaging programs could be counted toward certification. The record is void of any such proof or documentation to demonstrate that its programs would count toward a certification as required under the above regulations.

Specifically, for the C.S. Livingood Research Fellowship, the Provider failed to show that the time spent in the program was required to obtain certification in dermatology. The certification requirements for the specialty of dermatology require a four year residency in an ACGME accredited program.[23] As a result, training in the C.S. Livingood Fellowship could not be counted towards certification in dermatology because it was not ACGME accredited as required by the American Board of Dermatology. The fact that a resident

[23] *See, e.g.* Transcript of Oral Hearing (Tr.) at 109-110, and Intermediary's Position Paper, Exhibit I-11.

was certified in dermatology after completing the program does not prove that the verification was dependent on the Fellowship.[24]

The Movement Disorder Fellowship requires certification prior to entering the Fellowship program and, therefore, the fellowship could not count towards certification.[25] The American Board of Neurology and Psychology (ABNP) requires a four year residency in an ACGME accredited program for certification in neurology.[26] The Provider's fellowship in Movement Disorders required that entering residents must have already completed an accredited neurology residency, and as a result, any resident training in the fellowship is already fully qualified for certification in neurology so the training would not be necessary for certification. Moreover, at the time one of the Provider's resident was enrolled in the movement Disorders Fellowship program, he was already qualified for certification in neurology, and was able to sit for the certification in neurology prior to his enrollment in the Movement Disorders fellowship.[27] As a result, the Provider cannot use certification in neurology to support its claim that the training in the fellowship would count towards certification since there is no evidence in the record that shows that the training could or would count.

For the Cross Sectional Imaging program, the Provider claimed that residents training in the unaccredited program met the requirements of 42 C.F.R. §413.86(b)(2) because the training may count towards certification in Vascular and Interventional Radiology (VIR) which is an approved program. However, the Cross Sectional Imaging Fellowship program fails to satisfy the requirements for certification in VIR contained in the Green Book. The Green Book requirements for certification in VIR require completion of a one year fellowship in an ACGME approved program and one year of practice or additional approved training.[28] For the year at issue, none of the residents enrolled in the Cross Sectional Imaging program had completed the mandatory one year VIR fellowship prior to enrollment in the Cross Sectional Imaging program. Since the subspecialty actually did

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[24] *See, e.g.*, Tr. at 111-112. The Provider witness of a C.S. Livingood fellow, who was certified in dermatology, does not support the claim that the Livingood training would count towards certification in dermatology, as the resident had already completed a residency in dermatology prior to taking the fellowship and was already fully qualified and eligible to sit for certification. Since the resident was allowed to sit for the exam without the Livingood training, there is no proof that the training counted, or could count, towards certification in dermatology. Tr. at 56-57.

[25] *See, e.g.*, Provider's Position Paper, Exhibit P-40 at 422.

[26] *See, e.g.*, Intermediary's Position Paper, Exhibit I-12 at 1.

[27] *See, e.g.*, Intermediary's Position Paper, Exhibit I-12 at 435, and Tr. at 116-117.

[28] *See, e.g.*, Tr. at 120-124, and Intermediary's Supplemental Position Paper at 29.

not exist in the fiscal year at issue, the time spent in that program should not be counted.[29] The Administrator finds that the time attributed to the C.S. Livingood Research Fellowship, Movement Disorder Fellowship, and Cross Sectional Imaging training programs were properly excluded from the FTE counts.

For the Cerebrovascular Disease/Stroke program, the Administrator finds that the Board incorrectly concluded that the time attributed to the program should be included in the Provider's FTE counts. The Board reasoned that the program was accredited in 2005, and further, that the ABPN created a grandfathering provision in which unaccredited training counted towards certification through 2009. The Administrator finds that there was no certification in existence in which the Cerebrovascular Disease/Stroke program could be counted during the cost reporting period in question, and the Board was incorrect in determining that the grandfathering provision counted towards certification through 2009. The training requirements specifically state, in pertinent part, that "all applications other than those initially approved during the 'grandfathering period' (2005-2009) are required to submit documentation of successful completion of one year of ACGME-accredited fellowship training…"[30] Therefore, the ABPN grandfathering period was from 2005 through 2009, and did not include prior years. The Vascular Neurology programs were not accredited by ACGME until July 1, 2005, and therefore, non-accredited training programs that occurred prior to 2005 were not accepted by the ABPN for board certification.[31] Thus, the Administrator finds that the Intermediary properly disallowed the FTE residents in the Cerebrovascular Disease/Stroke program from the direct GME and IME counts, and reverses the Board's decision.

However, the Administrator finds that the Intermediary agreed that if the programs were found to be unapproved, the Intermediary would review the Provider's documentation to determine whether costs incurred, for salary and salary-related fringe benefits, as reasonable costs under Part B were merited. Specifically, the regulation at 42 C.F.R. §415.202 states:

> (a) *General rules.* For services of a physician employed by a hospital who is authorized to practice only in a hospital setting and for the services of a resident who is not in any approved GME program,

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[29] *See, e.g.*, Tr. at 120.

[30] *See, e.g.*, The American Board of Psychiatry and Neurology, Inc., Initial Certification in the Subspecialty of Vascular Neurology, at http://www.abpn.com/vn.htm.

[31] *See, e.g.*, Tr. at 118. ABMS did not approve vascular neurology as a subspecialty until 2003, and it was not accredited by the ACGME until July 2005, all of which was subsequent to the period under appeal.

> payment is made to the hospital on a Part B reasonable cost basis regardless of whether the services are furnished to hospital inpatients or outpatients.
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> (b) *Payment.* For services described in paragraph (a) of this section, payment is made under Part B by reducing the reasonable costs of furnishing the services by the beneficiary deductible and paying 80 percent of the remaining amount. No payment is made for other costs of unapproved programs, such as administrative costs related to teaching activities of physicians.

The record indicates that the Provider's fellowship programs may have met the requirements of a non-approved educational program under the regulations at 42 C.F.R. §415.202. The existing statutes, regulations, and case law indicate that the burden of proof is on the Provider to provide timely evidence to establish its claims. In this case, the record shows that the Provider has timely documented its claims for reimbursement under Medicare Part B for the services of the residents at issue before the Board.[32] This is in contrast to the Provider's failure to present such documentation during the administrative proceedings in the earlier case. Accordingly, the Provider may be reimbursed in accordance with the regulations on a reasonable cost basis under Part B for the services furnished, if the Provider did not bill for the residents' services under the physician fee schedule and that the Provider has supplied the documentation necessary to complete Worksheet D-2 of the Medicare cost report on which the reasonable cost payment is determined. Thus, the Administrator modifies the Board's decision in accordance with foregoing opinion in Issue No. 1 in this case.

With respect to Issue No 2, as discussed above, since the inception of the Medicare program, Congress has allowed the cost of training physicians based on the premise that these activities enhance the quality of care in an institution. The IME payment amount is based, in part, on the number of intern and resident full-time equivalents participating in a provider's GME program. Applying the foregoing laws and regulations above to the facts of this case, the Administrator finds that the Board's decision on this issue was improper. The Intermediary's exclusion of research time for purposes of the IME payment was proper in this case. The Intermediary's adjustments were correct since time spent by residents performing research activities, not directly related to patient care, must be excluded from the resident count.

As indicated above, the August 1, 2001 *Federal Register* notice represents a clarification of the Secretary's longstanding policy on the treatment of research activities when

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[32] *See*, Provider's Position Paper, Exhibit P-47.

calculating IME payment. Contrary to the Board's conclusion that this notice represents a "change in policy," the Administrator finds that this notice was a clarification and reinforcement of existing and longstanding policy that sets forth the prohibition of including research and non-patient care activities in the calculation of IME payments. Such activities are not related to the provision of patient care medical services for Medicare patients and, accordingly, should not be considered for the basis of calculating Medicare reimbursement.

The historical regulations set forth above at 42 C.F.R. §405.422, §413.5(c), and presently at §412.90 represent the consistent position of policy on this issue as it relates to indirect medical education costs. Congress specifically instructed the Secretary to implement the IME adjustment under IPPS, consistent with the indirect teaching methodology in place under reasonable cost routine cost limits. Historically, the indirect teaching adjustment has been related to higher inpatient costs related to patient care activities. In addition, the PRM at §2405.3F2 which prohibits the counting of residents engaged exclusively in research has been in place since 1988. When the historical rules on research are reviewed, it is clear that the regulations and manual instructions on research that are present today reflect and support the Intermediary's decision to exclude resident activities from the IME payment calculation since those activities are non-patient care research activities unrelated to Medicare.

Contrary to the Board's opinion, the time spent by residents conducting research as part of an approved residency program in the fiscal periods at issue should not be included in the IME calculation when such activities are not related to patient care. The existing and historical policy and regulations has linked IME payments to the provision of patient care. The payment of such costs were based on the premise that for such costs to be allowable, i.e., such costs had to be reasonable, necessary and related to patient care as reflected in the regulations at 42 C.F.R. §413.9. As such, hospitals were required to separate operating costs, i.e., patient care costs, from costs for other activities such as research and advertising to consumers.

In addition, the purpose of the IME adjustment, as reflected above, is limited to the unique characteristics and conditions of teaching hospitals that relate to the delivery of patient care. The IME adjustment is an add-on to the per case payment, which is based upon the standardized amount and the relative weight of the DRG, and which recognizes that teaching hospitals have higher allowable costs than non-teaching hospitals. This premise reinforces the notion that there is an intended connection between the count of the FTE residents used to calculate the IME adjustment and patent care costs as recognized under reasonable cost principles. The FTE resident time counted for purposes of the IME payment must be limited to only encompass time spent by residents in the diagnosis and

treatment of particular patients. Otherwise, Medicare would effectively be reimbursing a provider for non-patient care activities which were never intended to be paid by the Secretary since such costs were not costs incurred in the delivery of health care services attributable to Medicare beneficiaries.

The Court of Appeals for the First Circuit in *Rhode Island Hospital v. Leavitt*, 548 F.3d 29 (1st Cir. 2008) supported CMS' interpretation of the controlling regulations to require that residents provide "patient care" in order to satisfy the IME calculation requirements.[33] The court supported the Secretary's reading of the regulatory requirement to conclude that to be assigned to a portion of the hospital means that resident must be integrated into a hospital unit dedicated to a form of patient care subject to PPS. The First Circuit stated that:

> The fact that Medicare's PPS billing applies only to inpatient (i,e., patient care) services may reasonably be read into the FTE regulation's language regarding the prospective payment system.412.6(a)(1), 412.105(g)(1)(ii)(A) Accordingly, if one adopts a functional definition of the FTE regulation's key terms one may fairly read that provision as incorporating a patient care requirement. The hospital's assertion that a patient care requirement is unsupported by the FTE regulation's text is thus without merit. 9*Id.* at n. 6.)

The Court stated that:

> We have concluded that the Secretary's reading of the FTE regulation is permissible and that this regulation does not fly in the face of substantive statutory commands.

Finally the Court noted that:

> As we have already explained the IME adjustments legislative and administrative history adequately support the Secretary's conclusion that this provision was intended to compensate teaching hospitals for added costs of patient care unremunerated by the prospective payment system. The

[33] The First Circuit Court of Appeals decision in Rhode Island Hospital vs. Leavitt, 548 F.3d 29 (1st Cir. 2008), involved the Secretary's interpretation of the regulatory requirement that to be included in the IME FTE count the resident must be assigned to the portion of the hospital subject to the PPS.

> Secretary's current reading of the FTE regulation is consistent with that intent.

The Administrator continues to find the "functional" interpretation of the regulation is supported by the regulation and the use of these terms, (i.e., "area", "portion", "assigned" "department") in the Medicare program and within the context of the Medicare program, and the purpose of the IME payment.[34] The Program recognizes allowable time when the resident is "assigned" to the inpatient PPS portion of the hospital or outpatient area, consistent with the general understanding of the term "assigned." That is, "assigned" is defined as "to appoint to a post or duty"[35] and can reasonably be interpreted to be functional in meaning. Residents are "assigned" (perform duties) in the respective areas and in this case are counted where they are performing patient care related duties as part of the IPPS area. Here, the residents are not performing such duties, if they are performing research rotations. Likewise, the functional use of the terms 'area" and "portion" as referring to a scope of operations is consistent with the overall cost accounting origin of the Medicare program.[36] Generally, as Medicare is a financing mechanism it is using such terms, not as geographical terms, but as terms that identify the scope of activities or functions or operations.

The Administrator also notes that the regulations must be read and applied within the context of the reasonable cost regulations that likewise uses such terms as they relate to the inpatient hospital scope of patient care related activities for purposes of identifying costs. The Intermediary and Provider stipulated that "these FTEs represent the time that was spent while the residents were assigned either to areas of the Provider subject to the prospective payment or to the outpatient department of the Provider." The record is not in dispute that the Providers were involved in research while notated as "assigned to" these departments in the hospital. However, even if the research activities conducted by the

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[34] In the *District Memorial Hospital vs. Thompson*, 364 F. 3d 513 (4th Cir. 2004), the Court of Appeals found that the term area may refer to physical geographical space or may refer to a sphere or scope of operations. Similarly, the court found that "areas of the hospital that are subject to the prospective payment system would encompass activities that are defined by whether they are reimbursed under the[PPS], regardless of where the activities geographically took place."

[35] Webster New Collegiate Dictionary, p. 67 (1975).

[36] Not only is the use of the term "area" and IPPS "portion" consistent with the 'functional nature of the Medicare use of these terms but so is the use of the term outpatient "department." One example of this is a cost allocation method under Medicare that is referred to as the "departmental method" and hence the term "department" has a functional definition under Medicare.

residents while they were notated as assigned to IPPS/OP departments in the hospital, such activities would not be reimbursable since the activity itself is not related to patient care and has no affect on the cost of such care. In fact, the "area" or scope of the residents' activities was "research" within that department.

The record shows that the Provider did not demonstrate that the research involved inpatient or outpatient patient care related activities in the department. Instead, the record indicates that the residents were doing research in the respective departments. As CM noted, simply because resident are assigned to portions of the hospital subject to the IPPS, it does not mean such activities performed by the resident should be counted. It would be unreasonable to count a resident that is listed as "assigned to" an approved department, such as the outpatient department, but in fact, was involved in performing research activities at the medical library or elsewhere on the hospital "complex", since this resident's activities, in that scenario, will not affect the patient care costs of the hospital. While notated as assigned to that department, the residents here were performing "pure" "research" activities that may come under the broader educational umbrella of that department, but the activities are not related to the patient care scope of that department. The intent of listing where the resident is assigned is to identify the scope of her activities, which for these residents, is acknowledged to be "100% research"[37] and, hence, involves a research rotation. Otherwise, to ignore the residents' activities would allow a provider to craft a rotation list which best maximizes Medicare reimbursement, without regard to the residents' activities.[38]

The Administrator also notes that Section 5505 of the Affordable Care Act provides that time spent in non-research didactic and scholarly activities may be included in the IME calculation effective retroactively to 1983 for open cost reports. However, the record would not support a finding that the time at issue in this case involves includable "non-research" didactic activities. All the disallowed time was designated as for example, blanket research rotations, as opposed to singular didactic activities. Consequently, the recent statutory change does not affect the outcome of this case for these cost years. Notably, the Affordable Care Act explicitly left open the issue of whether research time is

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[37] *See, e.g.*, Stipulation Attachment A, IME Research.

[38] Moreover, many of the residency research activities are supported by grants, which fund the students for the year that they spend conducting research in the lab. If one were to reimburse the providers for these research activities, they would, in essence, be receiving double reimbursement for the resident's research, as the research time is not contributing to higher inpatient operating costs.

to be included prior to 2001, but specifically prohibited their post-2001 inclusion in the IME FTE count.[39]

Accordingly, the Board's decision in Issue No. 2 is reversed. The Board was incorrect to allow the time for research activities conducted by residents not related to patient care to be included in the IME calculation.[40]

[39] Section 5505(c)(3) of the Affordable Care Act. Pub. Law. No. 111-148.

[40] "*Henry Ford I" (Henry Ford Health System vs. Sebelius*, 680 F. Supp 2d 799 (E.D. Mich., Dec. 30, 2009), concerns the same provider and includes the research issue for different costs years is currently on appeal in the United States Court of Appeals for the Sixth Circuit.

DECISION

Issue No. 1

The decision of the Board is modified as to Issue No. 1 in accordance with the foregoing opinion.

Issue No. 2

The decision of the Board is reversed as to Issue No 2 in accordance with the foregoing opinion.

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

Date: 11/3/10 /s/

Marilyn Tavenner
Principal Deputy Administrator and Chief Operating Officer
Centers for Medicare & Medicaid Services