CENTERS FOR MEDICARE AND MEDICAID SERVICES

Decision of the Administrator

In the case of:	**Claim for:**
University Medical Center **Provider**	**Provider Cost Reimbursement Determination for Cost Reporting Period Ending: 06/30/00, 06/30/01 and 06/30/02**
vs.	
Blue Cross and Blue Shield Association **Intermediary**	**Review of:** **PRRB Dec. No. 2010-D45** **Dated: September 16, 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)). Accordingly, the parties were notified of the Administrator's intention to review the Board's decision. Comments were received from the Intermediary, CMS Center for Medicare (CM) and the Provider. All comments were timely received. Accordingly, this case is now before the Administrator for final agency review.

ISSUE NO. 1 AND BOARD'S DECISION

Issue No. 1 is whether the Intermediary properly excluded resident rotations for research and scholarly activities when calculating the resident full time equivalent (FTE) count for indirect medical education (IME) adjustment purposes.

The Board held that the Intermediary's adjustments excluding research time from the FTE resident count used to calculate the Provider's adjustment for IME were improper. The Intermediary's adjustments were reversed for FYs 2000, 2001 and the portion of 2002 occurring prior to October 1, 2001.

ISSUE NO. 2 AND BOARD'S DECISION

The issue is whether the Intermediary's calculation of the new program add-on to the Provider FTE cap was improper by virtue of the fact that it omitted time spent by residents in research and scholarly activities.

The Board held that the FTE cap must be adjusted to include the research time disallowed by the Intermediary. The Board remanded the new program add-on to the IME FTE cap issue to the Intermediary to incorporate the Board's finding and include previously excluded resident research time. The Board instructed the Intermediary to revise all of the Provider's cost reports beginning with FY 2000, utilizing the correct IME cap add-on.

SUMMARY OF COMMENTS

The Intermediary commented requesting that the Administrator review and reverse the Board's decision on the research issue and affirm the Board on the scholarly/didactic activities issues. The Intermediary stated that, under the Medicare program, time spent by residents performing research activities that are not directly related to the care of patients should be excluded from the resident FTE count. As such, the Board incorrectly found the Intermediary's removal of time spent in research from the FTE count to be improper. In addition, the Board incorrectly instructed the Intermediary to adjust the Provider's FTE cap to include research time.

The CM submitted comments requesting that the Administrator reverse the Board's decision in Issue No. 1 and affirm the Board's decision in Issue No. 2. The CM disagreed with the Board's conclusions concerning counting research time for purposes of IME payment and believe that the Intermediary's adjustments for research time were correct because the IME adjustment is a payment for patient care. The CM also argued that the IME regulations must be read in context with other regulations in order to show that residents in research and scholarly activities must be excluded from the FTE count for IME purposes. The CM also stated that the August 1, 2001 Federal Register is a clarification of long standing policy that supports the Board's reversal by the Administrator.

The CM stated that when the Medicare program began, hospitals were paid based on their allowable costs. In general, in order to be allowable, costs had to be considered both reasonable and necessary, and related to patient care (42 CFR §413.9). Hospitals were required to separate operating costs, i.e. patient care costs, from costs

for other activities such as research and advertising to consumers. Non-patient care costs were not allowed.

The CM stated that 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" (Report to Congress Required by the Tax Equity and Fiscal Responsibility Act of 1982, December 1982, pp. 48-49).

In passing the IPPS legislation, the House Committee on Ways and Means also acknowledged the link between higher patient care costs of teaching hospitals, and listed two reasons for the IME adjustment, similar to those stated in the Secretary's 1982 Report, stating that: 1) teaching hospitals typically offer more technologically advanced treatments to their patients, and therefore, patients who are sicker and need more sophisticated treatment are more likely to go to teaching hospitals; and 2) the presence of inefficiencies associated with teaching residents resulting from the additional tests or procedures ordered by residents and the demands put on physicians who supervise, and staff that support, the residents. Thus, the reasons for the IME adjustment enumerated by Congress and by the Secretary are directly linked to the involvement of residents in patient care. That is, because teaching hospitals attract sicker patients, they incur higher costs in caring for those sicker patients, whether due to additional tests ordered by residents or more intensive treatments provided in an educational setting.

The Secretary and the Congress recognized that the learning process in which the residents are engaged results in more intensive, and therefore more costly treatment regiment. Thus, the purpose of the IME adjustment is limited to the unique characteristics and conditions of teaching hospitals that relate directly to the delivery of patient care. The first and foremost mission of all hospitals, teaching or otherwise, is to care for patients. Likewise, the Medicare program is a health insurance program that pays hospitals for costs incurred in caring for Medicare beneficiaries, not for the costs incurred in relation to research activities. Since the purpose of the IME adjustment is rooted in patient care, there is a clear and compelling reason to limit, where reasonable and possible, IME reimbursement to the time spent by residents in unusual patient care; that is, in the diagnosis and the treatment of the hospital's patients. Clearly, prior to the implementation of the IPPS, no costs of the resident's time doing research could be paid by Medicare since these are not patient care costs. Therefore, CM stated that not counting residents engaged in research that are not patient care is consistent with that Medicare policy.

Contrary to the Board's argument that the IME regulations at 42 CFR 412.105(f) do not exclude time spent by residents in research and scholarly activities from being counted, CM stated that the regulation is an integral step in the process of determining whether an FTE resident should be counted for IME purposes. However, it is by no means the only regulation to be used and it should not be read in a vacuum. For example, it would be pointless to suggest that, simply because residents are assigned to portions of the hospital subject to the IPPS (as stated under §412.105(f)(1)(ii)), a hospital should include all of them in the count for purposes of IME payment if, as a result, the hospital would count more FTE residents than are allowed under the statutorily mandated FTE resident cap.

Similarly, it would be unreasonable to count a resident that is "assigned to" the outpatient department, but, in fact, is working in the medical library, since this resident's activities will not affect the patient care costs of the hospital. If the FTE time spent in research were included in the IME resident count, Medicare would effectively be reimbursing a provider for a non-patient care activity, for which it was never intended to pay. Thus, it is both appropriate and necessary for CMS, in addition to the general requirements at §412.105(f)(ii), to consider and apply other regulations that govern when FTE resident time may be counted for purposes of calculating IME payments, including those at §§413.9 and 413.90, which were relevant under reasonable cost reimbursement, and continue to be relevant under the current regulations for counting FTEs for IME.

The CM points to the August 1, 2001 Federal Register where CMS clarified 42 CFR 412.105(f)(1)(iii)(B) to state its long standing policy that the time spent by a resident in research that is not associated with the treatment or diagnosis of a particular patient is not countable. In addition to this clarification, the Board ignored the fact that the PRM prohibiting the counting of residents engaged exclusively in research has been in place since 1988. Because of these longstanding regulations on research, it is evident that the regulations text on research at §412.105(f)(1)(iii)(B) is not a new regulation, but is simply the codification of an existing policy in the IME regulations text.

Therefore, under the general Medicare principle that Medicare pays for costs directly associated with patient care in regulations at §§ 413.9 and 413.90, as well as in accordance with 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 FTE resident count for the time spent by residents in research in FYs 2000-2002.

The CM concurred with the Board's determination allowing the inclusion of the time spent on non-research scholarly activities and stated that the recent changes at Section 5505 of the Affordable Care Act supports this decision since it applies retroactively to 1983 for open cost reports.

The Provider submitted comments requesting that the Administrator affirm the Board's decision. The Provider stated that the Board's decision is consistent with the final outcome of prior appeals on the same issue. For fiscal years ending June 30, 1998 and June 30, 1999, the Provider litigated an issue relating to the inclusion of residents involved in hospital-based research rotations in the Provider's FTE resident count for purposes of the IME payment calculation. The Federal District Court in Arizona ruled that a resident's time spent in research must be included in the resident FTE count for IME purposes. See *University Medical Center v. Leavitt*, 2007 WLO 891195 (D. Ariz. 2007)("UMC '98-99"). Both the issues in the Provider's appeals for its fiscal years 2000 through 2002 involve the exact same IME research time issue.

The Provider also stated that the Affordable Care Act and the Seventh Circuit Court of Appeals require upholding the Board's decision. In the first analysis of the IME research time issue since the adoption of the Patient Protection and Affordable Care Act, the Seventh Circuit Court of Appeals weighed in on the side of the hospitals concerning the requirement to include such time in the calculation of IME payment adjustment. *See University of Chicago Medical Center v. Sebelius*, No. 09-3429 (7th Cir. Aug. 25, 2010). In doing so, the Seventh Circuit expressly disagreed with a decision favorable to CMS that was issued by the First Circuit less than two years earlier on the same IME research time issue. *Rhode Island Hospital v. Leavitt*, 548 F. 3d 29 (1st Cir. 2008).

The Provider also stated that litigation of IME research time is unnecessary since the issues in this case were already addressed in the 1998-1999 litigation involving this same provider and issue.

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 and considered the Medicare law and guidelines. All comments received timely are also included in the record and have been considered by the Administrator.

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 from 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 also promulgated the regulation at 42 C.F.R. § 413.9 which establishes the principle that reimbursement to providers must be based on the reasonable costs of covered services, which are related to beneficiary care. This 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 the provider's cost 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.

Acting under such authority, the Secretary promulgated the regulation at 42 C.F.R. § 413.85 which permits reimbursement for the costs of "approved educational activities."[1] 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. 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. Thus, since its inception Medicare has recognized the increased costs related to a provider's approved graduate medical education programs.

Section 223 of the Social Security Act of 1972 amended section 1861(v)(l(A) to authorize the Secretary to set prospective limits on the cost reimbursement by Medicare.[2] 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

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[1] 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).

[2] Pub. Law 92-603.

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."[3]

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

> Where research is conducted in conjunction with and as a part of the care of patients, the cost of usual patient care are allowable to the extent that such costs are not met by funds provided for the research….[5]

Thus, research costs, over and above usual patient care, have historically not been includable as allowable costs.

In contrast to direct medical education costs which are allowed due to the specific Congressional directive to include direct educational costs, the indirect teaching adjustment methodology arises out of the more limited authority granted the Secretary for administering the Medicare program and for paying costs related to patient care activities. In 1982, in an effort to further curb hospital cost increases and encourage greater efficiency, Congress established broader cost limits than those authorized under § 1861(v)(1)(A), the existing routine cost limits. The Tax Equity

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[3] 46 Fed. Reg. 33637 (June 30, 1981).
[4] *See* 31 Fed. Reg. 14814 (Nov. 22, 1966).
[5] Id.

and Fiscal Responsibility Act (TEFRA) added §1886(a) to the Act, which expanded the existing routine cost limits[6] 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.[7] 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.[8] However, as Secretary has noted, under the routine cost limits and prior to IPPS, the relevance of residents' FTEs and hence the tracking of resident activities was far from sophisticated and exact as the analyst could distinguish between allowable and nonallowance costs (such as research), but did not have the method to consistently and accurately isolate all the time spent by residents in nonpatient care activities. Therefore no consideration was given to where residents were training in the hospital or the activities of the residents with respect to patient care, or other activities.[9]

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.[10] Under IPPS, providers are reimbursed their inpatient operating costs based on prospectively determined national and regional rates for each patient discharge, rather than on the basis of reasonable operating costs. Under §§ 1886(a)(4) and (d)(1)(A) of the Act, the costs of approved medical education activities were specifically excluded from the definition of "inpatient operating costs" and, thus, were not included in the PPS hospital-specific, regional, or national payment rates or in the target amount for hospitals not subject to PPS. Instead, payment for approved medical education activities costs were separately identified

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

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

[8] 45 Fed. Reg. 21584 (April 1, 1980); 46 Fed. Reg. 33637 (June 30, 1981)(indirect teaching adjustment under pre-TEFRA cost limits)

[9] 71 Fed Reg. 47870, 48089 (Aug 18, 2008).

[10] Pub. L. 98-21 (1983).

and "pass-through," i.e., paid on a reasonable cost basis.[11] Under IPPS, all other costs that can be identified and categorized as costs of educational programs and activities is considered to be part of normal operating costs covered by the per case payments made under the IPPS for hospitals subject to that system. This approach was similar to the treatment that these costs had received since 1979 for purposes of the cost limits.

Congress recognized that teaching hospitals might be adversely affected by implementation of inpatient PPS because indirect costs, which may include increased department overhead as well as a higher volume of laboratory test and similar services,[12] would not be reflected in the PPS rates.[13] Thus, under § 1886(d) (5) (B) of the Act, hospitals subject to PPS, with approved teaching programs, receive an additional payment to reflect the IME costs.[14]

The Secretary, in discussing this new formula for IME payments, explained that:

> Section 1886(d)(5)(B) of the Act provides that prospective payment hospitals receive an additional payment for the indirect costs of medical education computed in the same manner as the adjustments for those costs under regulations in effect as of January 1, 1983. Under [the] regulations [then set forth at 42 C.F.R. § 412.118], we provided that the indirect costs of medical education incurred by teaching hospitals are the increase operating costs (*that is, patient care costs*) that are associated with approved intern and resident programs. These increased costs may reflect a number of factors; for example, an increase in the number of tests and procedures ordered by interns and residents relative to the number ordered by more experienced physicians or the need of hospitals with teaching programs to maintain more detailed medical records. [Emphasis added.][15]

Moreover, in a final rule implementing changes to direct GME reimbursement, CMS 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,

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[11] Section 1814(b) of the Act.
[12] *See* 50 Fed. Reg. 35646, 35681 (1985).
[13] *Id.*
[14] This IME payment is distinguished from the direct medical education costs.
[15] *See* 51 Fed. Reg. 16772 (May 6, 1986).

> "indirect costs of medical education" means those additional operating (*that is, patient care*) costs incurred by hospitals with graduated medical education programs.[16] [Emphasis added.]

Thus, from the beginning of its implementation of the Congressional directives regarding medical education costs, The Administrator finds that CMS has made it clear that Medicare would pay only for cost related to patient care even within the context of the increased costs associated with medical education programs.[17]

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 based on "the ratio of the hospital's full-time equivalent interns and residents to beds."[18] The regulation at 42 C.F.R. §412.105 governs IME payments to Medicare providers. 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.[19] The regulation further states that in order to be included in the FTE count, the resident must be enrolled in an approved teaching program and be assigned to either the IPPS portion of the hospital, or the outpatient department of the hospital.[20]

The regulation at 42 C.F.R. § 412.105 was subsequently clarified by CMS under 42 C.F.R. § 412.105(f) (2000).[21] The regulations state in pertinent part:

> For cost reporting periods beginning on or after July 1, 1991, the count of full time equivalent residents for purposes of determining the indirect medical education is determined as follows:
>
> (i) The resident must be enrolled in an approved teaching program…

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

[17] The Administrator notes that, CMS' long standing policy of requiring hospitals to distinguish between time spent by residents involved exclusively in research and time spent on patient care for purposes of the IME adjustment was reiterated in the 66 Fed. Reg. 39896, (Aug. 1, 2001) and codified in the regulations at 42 C.F.R. § 412.105(f) (1) (iii) (B).

[18] *Id.*

[19] 42 C.F.R. § 412.105(a) (1) (1998).

[20] 42 C.F.R. § 412.105(f) (1) (1998).

[21] *See* 62 Fed. Reg. 45966, 46029 (Aug. 29, 1997).

> (ii) In order to be counted, the resident must be assigned to one of the following areas:
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> (A) The portion of the hospital subject to the prospective payment system.
>
> (B) The outpatient department of the hospital.
>
> (C) Effective for discharges beginning or after October 1, 1997, the time spent by resident in a nonhospital setting in patient care activities under an approved medical residency program is counted towards the determination of full-time equivalency if the criteria set forth at § 413.86(f)(4) are met.

Consistent with the foregoing regulation, §2405.3.F of the PRM [Transmittal Rev. 345 (August 1988)] explains that: "The term "interns and residents in approved programs" means individuals participating in graduate medical education programs approved as set forth in §404.1.A. …. It is recognized that situations arise in which it may be unclear whether an individual is counted as an intern or resident in an approved program for the purpose of the indirect medical education adjustment … Intermediaries must not count an individual in the indirect medical education adjustment if any of the following conditions exist: **** The individual is engaged exclusively in research…."[22]

In 2001, CMS adopted further clarifications to the IME regulation that expressly excluded time that was spent by residents in research unrelated to the care of specific patients from the count of residents for IME.[23] Effective with discharges on or after October 1, 2001, 42 C.F.R. §412.105(f)(1)(iii)(B) states:

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

The August 1, 2001 *Federal Register* policy clarification did not represent a change in Medicare policy. As noted, 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 explained that research involved 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 provisions, it is evident that the regulation text at §405.105(f)(1)(iii)(C), which

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[22] *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

[23] 42 C.F.R. §412.105(f)(1)(iii)(B).

specifies the patient care requirement, is not a new requirement, but simply the codification of existing policy in the IME regulations text.

Applying the applicable Medicare law and policy to the facts of this case, the Administrator holds that research activities that are not related to patient care are not included in the IME count. The Administrator finds that historically under the reasonable cost system of reimbursement, costs associated with research activities that were not related to patient care were not allowed.[24] The Administrator further finds that such costs are still not allowed under the Inpatient PPS. Moreover, under general Medicare reimbursement principles as reflected in 42 C.F.R. § 413.9, costs incurred by a hospital must be related to patient care in order to be reimbursed by Medicare. The regulation that governs when FTE resident time may be counted for purposes of calculating the IME payments must be considered within the context of the directives of Section 1861(v)(1)(A) and 42 C.F.R. §413.9, which are relevant under reasonable cost and routine cost limitation methodologies which served as the origin for the IPPS IME methodology. Section 2405.3.F.2 of the Provider Reimbursement Manual states that a resident must not be included in the IME FTE count if: "the individual is engaged exclusively in research." Consistent with this longstanding policy, the preamble language found in the August 1, 2001 *Federal Register*, explains that "exclusively" means that the research is not associated with the treatment or diagnosis of a particular patient of the hospital. Accordingly, the Administrator finds that the Intermediary properly excluded research time not associated with the delivery of patient care from the Provider's IME calculation.

The Administrator finds that the record also does not demonstrate that the residents provided patient care during the portion of the monthly research rotation[25] with respect to the 6.02 residents FTEs claimed for FY 2000, 8.11 FTEs claimed for FY 2001, and 3.59 FTEs claimed for FY 2001. The time spent by residents performing pure research activities in this case was not demonstrated to be directly related to patient care and, therefore, is to be excluded from the resident count since the Provider did not submit documentation to show that the time was, in fact, patient care related. The record also shows that the time at issue all involved time residents were participating for the most part in blanket research rotations and, thus, to the extent

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[24] *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). "Cost incurred for research purpose, over and above usual patient care, will not be included."

[25] The Provider suggested that certain residents continued to participate in rounds while on research rotations or were on call (hence may have actually participated in patient care related activities if called) during those periods but did not document the percentage of time the residents spent in these activities.

there was “other scholarly activity” it was research directed, in contrast to “nonresearch didactic” activities referenced in the Affordable Care Act.

Further, the Administrator also finds that simply “assigning” residents to portions of the hospital subject to IPPS is not alone justification for inclusion of all residents assigned to the IPPS portion of the hospital for purposes of IME payment, when the resident is not in fact involved in patient care related activities for inpatient services. The “assignment” of a resident to a particular department for calculation of the FTE cap is only one step in the process of determining whether that particular resident qualifies for IME payment calculation purposes. If a resident is assigned on paper to a particular department, but conducting a research rotation and not involved in patient care activities, that time should not be counted. When a resident is performing a research rotation, the resident is not contributing to higher patient care costs in the IPPS hospital which is the basis for the IME payment adjustment.

In addition, although the residents in this case participate in a GME program that is accredited by the ACGME, this fact alone is not sufficient to qualify all of such residents' time to be included in the IME calculation. The IME provision does not provide for participating in an approved program as the only criteria that must be met under the regulations controlling which residents' time qualify for inclusion in the IME calculation.

The Administrator recognizes that the Federal district courts, as well as the Federal Courts of Appeals, have ruled differently on the issue presented in this case. Specifically, the Federal district court ruling on the Provider's previous cost years for 1998 and 1999, ruled favorably for the Provider in *University Medical Center v. Leavitt*, 2007 WL 891195 (D. Ariz. 2007), which presented the same research issue as in this case. The district court found that all time spent by residents in research and other scholarly activities while “assigned” to the PPS portion of the hospital must be included when determining the hospital's resident count for purposes of calculating the IME payment. The court found that:

> According to the relevant information, a resident must be assigned to the “portion of the hospital a subject to the prospective payment system” or to the outpatient department in order to be included in IME…At issue here is the meaning of the word “portion.” Plaintiff contends that ‘portion’ is a geographical term, and thus all residents assigned to the hospital are included. Defendant argues that “portion” is an ambiguous term which implies, or can be construed to imply a direct patient care requirement. The residents at issue while working in the geographic “portion of the hospital subject to prospective payment system” were not working directly in patient care. The magistrate judge

> agreed with the Plaintiff and concluded that portion is a geographical term……

The court concluded that:

> In its review of a nearly identical regulation, the Ninth Circuit held that the limitation was unambiguously geographical. *Alhambra Hosp. v Thompson*, 259 F.3d 1071, 1073 (9 th Cir 2001). Because the limitation was purely geographical the Secretary's construction of the regulation was impermissible…The Court agrees with this conclusion. It is clear from the plain meaning of the phrase "portion of the hospital subject to prospective payment system" that the term is geographic in nature.[26]

The Provider in this case is located in the State of Arizona, which is within the judicial venue of the Ninth Circuit Court of Appeals. The Federal Circuit Court of Appeals for the Ninth Circuit has not addressed this specific issue, apart from the Court of Appeals decision in *Alhambra* on another IPPS regulatory provisions. The Court of Appeals for the Seventh Circuit in *The University of Chicago Medical Center v. Sebelius*, No. 09-3429 (7 th Cir. Aug. 25, 2010), supported the inclusion of all resident time based on the "assignment" of the resident to an IPPS portion of the hospital for IME payment calculation.

The Court of Appeals for the First Circuit in Rhode Island Hospital v. Leavitt, 548 F.3d 29 (1 st Cir. 2008) supported CMS' interpretation of the controlling regulations to require that residents provide "patient care" in order to satisfy the IME calculation requirements.[27] 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

[26] The Court stated that the court in *Alhambra* involved the use of the term "area" as opposed to "portion."

[27] The First Circuit Court of Appeals decision in *Rhode Island Hospital vs. Leavitt*, 548 F.3d 29 (1 st 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.

> 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 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") in the Medicare program and within the context of the Medicare program, and the purpose of the IME payment.[28] 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"[29] 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.

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[28] In the *District Memorial Hospital v. Thompson*, 364 F. 3d 513 (4 th 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."

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

In addition, even under the district court interpretation of the regulation and CMS policy for the earlier years, the facts of this case are problematic for the Provider. The district court has determined that the term "portion" is a geographical term. The court concluded that: "The residents at issue while working in the geographic 'portion of the hospital subject to prospective payment system' were not working directly in patient care." The court, adopting a geographical definition of the term "portion", was relying on a paper "non-geographical" rotation schedule in stating that the residents were "working" in the portion of the hospital subject to IPPS. The court was in fact relying on the recordation on the rotation schedule that indicated that the resident was "assigned" to the IPPS area of the hospital. However, where the resident was physically and geographically working, while conducting research is not documented and in light of the fact that it was not patient care related, raises reasonable questions as to whether it was likely to have been in the IPPS portion of the hospital.

Assuming arguendo, even if one does not adopt a policy to exclude resident time based on the fact that the resident is working on a research rotation not related to patient care, the location where the resident "actually performs work" is significant under the district court's interpretation. Some residents may be technically "assigned" to areas approved for IME purposes, but actually "perform work" in areas of the hospital that do not qualify for IME. That is, even assuming arguendo, that "portion" is a geographical term, the court's version would require a provider to demonstrate that the resident was actually physically working in the IPPS geographical portion of the hospital to meet the district court's interpretation of the criteria. The Secretary's prior decision did not address that issue as it was not necessary to reach it.

The end result can be the same whether one uses the Secretary's policy to exclude time spent in research work that does not involve patient care activities, or the district court's geographical definition of the term. The IPPS "portion" of the hospital is but a part of the whole hospital, both geographically and functionally, for purposes of payment. The hospital is not made up of only the IPPS portion and excluded units, but includes portions or areas which are not geographically part of, nor included, for payment purposes, as part of the IPPS portion (or excluded units) of the hospital. These nonreimbursable activities and related areas, include, for example, research, physician offices (part B services), etc.[30]

[30] The cost report reflects this geographical and functional reality in, among other things, non-reimbursable cost centers, which frequently capture both the direct and indirect costs (including square footage costs- the 'geographical' manifestation of the activity) of the non-reimbursable activity.

The district court concluded that the residents were involved in research activities while "working" in the IPPS portion of the hospital. However, while this record shows that a resident on a research rotation was assigned on paper to the IPPS portion of the hospital, the record does not demonstrate that the resident was working in the IPPS area of the hospital while on the research rotation. The Intermediary requested clarification as to the precise location of a number of residents in the university/hospital complex when assigned to the Provider for a research rotation, which included requests as to the rooms where the research was conducted. The Intermediary was seeking to determine where the residents "assigned" to the IPPS but involved in nonpatient care related research were in fact working, among other things, because of the existence of the research facilities on the University campus which included Steele Children's Research Center, the Arizona Respiratory Center, an Arthritis Center and the Emergency Medicine Research Center. The Intermediary also noted that the Arizona Health Science Center and the Provider and the College of Medicine were all on the same campus, with the Health Science Center and the Provider physically interconnected. The Provider did not submit a precise response to the exact location where the research was occurring, when the resident was assigned to the IPPS area of the hospital or the outpatient department. The Provider forwarded supporting documentation to answer the questions posed by the Intermediary, which consisted of rotation schedules and compiled affidavits by the Director of the GME program for the various departments. All the affidavits were identical to the following affidavit for the vascular department residents and generally stated that:

> I am familiar with the vascular Surgery residency program operated by the University of Arizona Health Science Center in Affiliation with the University Medical Center ("UMC"). The Vascular Surgery residency program has a required research component. While residents in the Vascular Surgery residency program are performing their research rotation, they are assigned to a hospital facility based on the nature of their clinical research. The University of Arizona Health Science Center prepares and maintains rotation schedules reflecting the hospital facility to which the resident is assigned during his/her research rotation, and the resident's clinical responsibilities would lie at such facility. These rotation schedules are shared with UMC and maintained in its records. Unless otherwise indicated on the rotation schedule, the residents in the vascular surgery residency program are not assigned to either the UMC psychiatric unit or UMC home health agency during their research rotation.[31]

[31] Provider Exhibit 38.

The affidavits were followed by the monthly rotation schedule for the residents "assigned" to that department and a description of the program requirements of the respective residency program. These resident activities includes "participation in research, particularly in projects that are funded following peer review and or result in publications or presentations at regional and national scientific meetings" and "offering of guidance and technical support (e.g., research design, statistical analysis) for residents involved in research." In addition, "Residents must be taught an understanding of basic research methodologies, statistical analysis, and critical analysis of current medical literature." See e.g. Exhibit 38, Program Description at 16 and 21. The program requirements include that:

> As part of the academic environment, an active research component must be included within each accredited subspecialty program, The program must ensure a meaningful, supervised research experience with appropriate protected time—either in blocks or concurrent with clinical rotations, for each resident, while maintaining the essential clinical experience. Exhibit 39, Program Description at 25

And:

> Subspecialty residents also should have experience and be given guidance in the critical evaluation of pertinent medical literature, the process of grant application, preparation of scientific articles, and medical writing. In addition they should be required to conduct research seminars and prepare reports of their research activities. These efforts should be reviewed and evaluated by supervising faculty. Exhibit 36 at 10.

None of the documentation shows where in fact the research, not related to patient care, was occurring. Certain of the Provider's responses, by electronic mail, indicated that there may have been research conducted at the Emergency Medicine Research Center and Arizona Respiratory Center, neither of which were part of the provider, much less the IPPS portion of the Provider. Moreover, the Provider's witness, in testimony,[32] stated that the training occurred at the University Medical Center

[32] Transcript of Oral Hearing (Tr.), dated January 21, 2009, at. 101-119.

"campus", but again did not specify the location of the training at the provider.[33] On cross examination, the Intermediary referred to testimony from the earlier hearing:[34]

> Q: In answer to a question about where would the research be performed as part of their training, you said it was typically performed at the Arizona Health Science Center campus, which included the Medical Center. Can you explain what you mean by that?
> A. Yeah. Again the Arizona Health Science Center is referred to as UMC, the hospital as well as the college of medicine So it's the two, it's the college like you referred to and then the medical center of the hospital.
> Q. So research rotations could be—the research could actually be done anywhere within that health science center?
> A. It could be. (Tr. 120-121.)

Further the Intermediary asked:

> Q. But if you are had the residents in a University of Arizona training program who are doing research in-they're actually performing research in a lab in the Steele Center for Pediatric Medicine, part of the University, why would you include that resident in the hospital's FTE count for IME?

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[33] The Provider also pointed to the fact that these residents were included for purposes of the GME FTE count thus demonstrating that they were doing research on the campus. However, the criteria for the GME and the IME count are not the same.

[34] Transcript of Oral Hearing, dated January 15, 2004 (P-32, Tr. 26) (Provider witness A. The research is typically performed at the Arizona Health Science Center campus, which includes the medical center [provider])" at Tr. 26-27. "Q. And when you were discussing generally what the research is for the programs that you're contesting is a core element of the curriculum for whatever specialty? A. Correct. Q. …it was pursued for some scholarly work? A. Correct. Q. Is that—so that it could be writing a paper …., that kind of thing? A. That's correct. Q. And you said that that could take place at the Health Science Center. A. Un-hum. Q. What is the Health Science Center? A. Well [the] Health Science Center is a term that's used to describe generally, the campus of the University of Arizona and the University Medical Center. They're physically adjoined." Tr. at 32. "Q. But there is nothing in the rotation schedules that show that during the research rotation, the doctor was actually assigned to any a particular PPS area of the hospital outpatient area? A. No, they don't." Tr. at 33.

> A. Because the regulations … at that time prior to 10/01 of'01 simply stated that they needed to be assigned to the hospital, and if the rotation schedule indicates that they were assigned to the hospital and it doesn't say it was an excluded area, excluded from PPS area, then I believe we would be able to count that for indirect medical education. Tr. 144-45

The Intermediary determined that the information supplied by the Provider was inadequate to show that the research performed by the residents was directly related to patient care. Similarly, even assuming *arguendo*, if one were to apply the district court's geographical definition, the record did not demonstrate that the residents were working in the IPPS portion of the Provider. This case demonstrates that, to a great degree the Secretary's approach, to exclude research time not related to patient care, allows for easier and more efficient recordkeeping. Accordingly, the Administrator finds that the Intermediary applied the proper standard for determining when resident research time may be counted toward the resident FTE for IME purposes, i.e., the research must be related to the diagnosis and usual care of a particular hospital patient. In light of this finding, the Administrator holds that the Provider is not entitled to the 6.02 residents FTEs it claimed for FY 2000, nor 8.11 FTEs it claimed for FY 2001, or 3.59 FTEs it claimed for FY 2001.

The Administrator notes that the issue in this case was framed with respect to whether the exclusion of time spent in "research and other scholarly activities" was proper. Section 5505 of the Affordable Care Act provides that time spent in nonresearch 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 to be included prior to 2001, but specifically prohibited their post-2001 inclusion in the IME FTE count.[35]

Issue No. 2 - Calculation of the New Program Add-on to the Provider FTE Cap

With respect to Issue No. 2, as noted above, the Medicare Program makes payments to providers for the direct and indirect costs of medical education. However, in an effort to curb costs, Congress enacted the Balanced Budget Act of 1997[36] (BBA 1997), which placed a limit, or "cap," on the number of residents and interns that a

[35] Section 5505(c)(3) of the Affordable Care Act. Pub. Law. No. 111-148.
[36] Pub. L. 105-33. Section 1886(h)(4)(F) of the Social Security Act.

hospital can count for Medicare reimbursement purposes. The BBA 1997 provides that for cost reporting periods beginning on or after October 1, 1997, the total number of residents in a hospital's approved medical residency training programs in allopathic and osteopathic medicine would be limited to the hospital's unweighted full-time equivalent count for the most recent cost reporting period ending on or before December 31, 1996.[37] Thus, a hospital's resident count was "capped" at the number it had in its programs during its last cost reporting period ending before December 31, 1996, or "base period."

The regulations, however, also provide that a hospital's cap may be adjusted for new medical residency training programs established between January 1, 1995 and August 5, 1997. The regulation specifically states that the adjustment to the hospital's FTE resident limit for the new program is based on a the product of the highest number of residents in any program year during the third year of the newly established program and the number of years in which residents are expected to complete each program based on the minimum accredited length for the type of program.

In this case, between January 1, 1995 and August 5, 1996, the Provider created two new ACGME approved programs, which qualified the Provider for an add-on to its IME and GME FTE caps. The Administrator notes that there is no dispute regarding appropriateness of the cap add-on. The dispute arises with respect to the correct number of the add-ons to the Provider's IME cap. The record reflects that the Intermediary calculated an add-on for the GME cap of 3.8388, while the increase for the IME cap was only .8388. The Intermediary in this instance excluded the time spent in research and scholarly activities when calculating the add-on for the IME cap for the fiscal year at issue. Thus, the issue is whether the Intermediary properly excluded time spent by residents engaged in research and scholarly activity when calculating the number of FTE residents for purposes of the add-on to the IME cap. The Administrator finds this issue is resolved consistent with the Administrator decision in Issue No. 1. The Administrator affirms the Intermediary's calculation of the add-on for the FTE cap.

[37] *See also* 42 CFR 413.79(c)(2)(i).

DECISION

Issue No. 1

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

Issue No. 2

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

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

Date: 11/16/10 /s/

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