UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

HENRY FORD HEALTH SYSTEM,
d/b/a HENRY FORD HOSPITAL

Plaintiff

v.

KATHLEEN SEBELIUS, SECRETARY
U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES,

Defendant.
_____/

Case No. 09-10195

HONORABLE SEAN F. COX
United States District Judge

OPINION & ORDER

Plaintiff Henry Ford Health System d/b/a Henry Ford Hospital ("the Hospital") filed the instant suit against Kathleen Sebelius ("the Secretary"), in her capacity as the Secretary of the United States Department of Health and Human Services ("HHS"), alleging that: 1) the Secretary improperly calculated the Hospital's Medicare payments for the fiscal years between 1991 and 1996 and 1998 through 1999 by excluding residents involved in educational research from the indirect medical education full-time equivalents count; 2) the Secretary improperly excluded two of the Hospital's residency programs from inclusion in the 1996 cap exclusion for full-time equivalents; and 3) the Secretary improperly denied a remand to the fiscal intermediary for consideration of the Hospital's claims for reasonable cost reimbursement under Medicare Part B.

The case is before the Court on the Hospital's and the Secretary's cross-motions for summary judgment [Doc. Nos. 26, 27]. Both parties have fully briefed the issues, and a hearing was held on December 3, 2009. For the reasons that follow, the Court **GRANTS IN PART** the

Hospital's motion for summary judgment [Doc. No. 27], and **HOLDS** that the Secretary could not exclude residents engaging in educational research from the Hospital's IME resident count under the 1996 version of 42 C.F.R. § 412.105(g)(1)(ii); and **FURTHER HOLDS** that the Secretary could not exclude the Hospital's Vascular and Interventional Radiology and Clinical Neurophysiology programs from the "new programs" FTE cap exception in the 1998 version of 42 C.F.R. § 412.105(f)(1)(vi). Finally, the Court **GRANTS IN PART** the Secretary's motion for summary judgment [Doc. No. 26], and **HOLDS** that the Secretary properly denied a remand to the fiscal intermediary for consideration of the Hospital's alternative claim for reasonable cost reimbursement under Part B.

BACKGROUND

Prior to 1983, hospitals received Medicare payments based on that hospital's reasonable costs of in-patient hospital services. 42 U.S.C. §§ 1395f(b)(1), 1395d(a)(1). These payments reimbursed a hospital for actual expenses incurred. However, Congress abandoned the reasonable cost system after determining that government costs were too high. *See* 42 U.S.C. § 1395x(v)(a)(A); 42 C.F.R. § 413.30.

The reasonable cost system was replaced by the Prospective Payment System ("PPS") in 1983. Under the PPS, hospitals receive payments based on a patient's diagnosis at discharge, regardless of the hospital's actual or reasonable costs associated with treating that patient. 42 U.S.C. § 1395ww(d); 42 C.F.R. § 412.60. Congress, at least in part, switched to the PPS in order to promote efficient healthcare services. *See, e.g., Riverside Methodist Hospital v. Thompson*, 2003 WL 22658129, *2 (S.D. Ohio July 31, 2003). The PPS encourages efficiency by allowing a hospital to keep the full PPS payment, even if the hospital can efficiently treat a patient at a cost

lower than the PPS payment.

Because teaching hospitals generally incur more costs than non-teaching hospitals, however, Congress grants teaching hospitals additional payments under the PPS. *See* H.R.Rep. No. 98-25(I) at 140-41 (1983), *reprinted in* 1983 U.S.C.C.A.N. 219, 359-60; S.Rep. No. 98-23, at 52-53, *reprinted in* 1983 U.S.C.C.A.N. 143, 192. These additional payments are composed of both "direct" payments, which include easily quantified costs such as a resident's salary and fringe benefits, and other, "indirect" benefits. *See* 42 U.S.C. § 1395. Direct benefits under section 1395 are not at issue in the instant case.

The parties dispute the proper amount of indirect medical education ("IME") payments that are owed to the Hospital for the years 1991 through 1996, and 1998 through 1999. IME payments are authorized by statute as follows:

> The Secretary [of HHS] 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 regulations [in effect as of January 1, 1983].

42 U.S.C. § 1395ww(d)(5)(B). The IME payment is derived by multiplying the PPS payment by the "IME Factor," also known as the "teaching adjustment factor." 42 U.S.C. § 1395ww(d)(5)(B).

The IME Factor is intended to reflect the level of teaching intensity at a teaching hospital, and it is arrived at by means of a mathematical formula created by statute in 1983. *See Id*. This formula focuses upon the ratio of full-time equivalent residents ("FTEs") to the hospital's total number of beds available. As the number of FTEs increases, the hospital's IME Factor increases, and thus the hospital receives a higher IME payment from Medicare. It is the correct manner by

which HHS should calculate FTEs that is the major subject of these cross-motions.

PROCEDURAL HISTORY

The Hospital is an inpatient hospital located in Detroit, Michigan, that receives reimbursement under the PPS and operates programs for residents. At the close of each fiscal year, the Hospital files cost reports with the Medicare Part A fiscal intermediary, a contractor to whom the Secretary has delegated day-to-day operation of the Medicare program. *See* 42 U.S.C. §§ 1395h and 1395kk-1. The Hospital claimed medical reimbursement for certain costs associated with its residency programs for the fiscal years ending in 1991-1996 and 1998-1999 in its cost reports.

The fiscal intermediary reduced the Hospital's claimed FTEs for all eight fiscal years involved, claiming that several residency programs were not "approved" programs under 42 C.F.R. §413.86(b). The fiscal intermediary also disallowed FTEs assigned to research rotations from the IME calculation for all eight years involved. Finally, the fiscal intermediary disallowed FTEs above the Hospital's 1996 FTE cap, which the Hospital claimed were participating in "new" programs in the 1998 and 1999 fiscal years.

The fiscal intermediary determined that these residents were participating in two programs, Vascular and Interventional Radiology and Clinical Neurophysiology, which had been training residents before the January 1, 1995 cutoff for "new" programs and therefore did not qualify for an exception to the FTE cap.

The Hospital appealed these disallowances to the Provider Reimbursement Review Board ("PRRB"), which held a hearing on September 19, 2007 for the fiscal years 1995, 1996, 1998,

and 1999.[1] In a decision dated September 12, 2008, the PRRB reversed all of the fiscal intermediary's disallowances except for findings that certain residency groups not at issue in this case were not "approved." The PRRB then remanded the case to the fiscal intermediary to determine the amount that was due the Hospital for the services of its unapproved residents under Medicare Part B.

The fiscal intermediary requested that the Deputy Administrator of the Centers for Medicare and Medicaid Services ("CMS") review the PRRB's decision, including the PRRB's remand for a determination of reasonable cost reimbursements under Part B. The fiscal intermediary argued there that the Hospital had not claimed these costs on its cost report, nor had it supplied any information in support of these claimed reimbursements.

The CMS Administrator agreed to review the PRRB's decision, and in a decision dated November 13, 2008, reversed the PRRB on all issues except the unapproved residency programs which are not at issue in this case.

The CMS Administrator's decision is the Secretary's final decision pursuant to 42 C.F.R. § 405.1877(a)(4). The Hospital then filed its Complaint in the instant case on January 16, 2009, seeking judicial review of the Secretary's final decision.

STANDARD OF REVIEW

The Court exercises jurisdiction over this action pursuant to 42 U.S.C. § 1395oo(f), which states that cases arising out of disputes under the Administrative Procedures Act ("APA") "shall be tried pursuant to the applicable provisions under chapter 7 of title 5." The provision of

[1] The parties stipulated that the results from this hearing would also apply to the Hospital's claims for fiscal years 1991 through 1994.

the APA that governs the scope of review in this case is 5 U.S.C. § 706, which provides that an agency's decision may be set aside only if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or "unsupported by substantial evidence." 5 U.S.C. § 706(2)(A), (E); *see also Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 413-15 (1971).

Under the substantial evidence standard, this Court may not "displace the. . . [Secretary's] choice between two fairly conflicting views, even though the court would justifiably have made a different choice had the matter been before it *de novo*." *Universal Camera Corp. v. NRLB*, 340 U.S. 474, 488 (1951). The Supreme Court has defined "substantial evidence" as "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Consolo v. Federal Maritime Commission*, 383 U.S. 607, 619-20 (1966).

An agency's construction of a statute is generally governed by *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Under *Chevron*, courts engage in a two step inquiry. First, the court determines whether Congress "has directly spoken to the precise question at issue." *Chevron*, 467 U.S. at 842-43. If Congress' intent is clear, then "that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id*. If, however, the statute is ambiguous, the court must advance to the second step of the *Chevron* inquiry, which involves determining whether the agency's interpretation is based upon a permissible construction of the statute. *Id*.

Where, as here, the construction of an administrative regulation is at issue, the Court is required to defer to an agency's interpretation of its own regulation when that regulation is ambiguous. *Christensen v. Harris County*, 529 U.S. 576, 588 (2000). However, although the

task before the Court "is not to decide which among several competing interpretations best serves the regulatory purpose," a court shall not defer to an agency's interpretation of its own regulation when an "*alternative reading is compelled by the regulation's plain language or by other indication of the Secretary's intent at the time of the regulation's promulgation*." *Thomas Jefferson University v. Shalala*, 512 U.S. 504, 512 (1994) (emphasis added).

ANALYSIS

Three issues are presented for the Court's decision in the instant motion: 1) whether residents engaged in educational research may be excluded from the Hospital's IME FTE resident count under the Secretary's 1996 regulations; 2) whether the Secretary properly classified two of the hospital's residency programs as falling outside the 1996 FTE resident cap; and 3) whether the Secretary properly denied a remand to the fiscal intermediary for the Hospital to seek Medicare Part B reimbursement for residents participating in unapproved programs. For the reasons that follow, the Court **GRANTS IN PART** the Hospital's motion for summary judgment [Doc. No. 27], and **HOLDS** that the Secretary could not exclude residents engaging in educational research from the Hospital's IME resident count under the 1996 version of 42 C.F.R. § 412.105(g)(1)(ii); and **FURTHER HOLDS** that the Secretary could not exclude the Hospital's Vascular and Interventional Radiology and Clinical Neurophysiology programs from the "new programs" FTE cap exception in the 1998 version of 42 C.F.R. § 412.105(f)(1)(vi). Finally, the Court **GRANTS IN PART** the Secretary's motion for summary judgment [Doc. No. 26], and **HOLDS** that the Secretary properly denied a remand to the fiscal intermediary for consideration of the Hospital's alternative claim for reasonable cost reimbursement under Part B.

I. Residents Engaging in Educational Research Cannot be Excluded from Hospital's IME FTE Resident Count Under the Secretary's 1996 Regulations.

At issue in this case is the Secretary's interpretation of 42 C.F.R. § 412.105(g)(1), which sets forth the type of resident activities that Medicare will include in its calculation of a teaching hospital's IME FTE resident count. In relevant part, this regulation provides as follows:

> In order to be counted, the *resident must be assigned to one of the following areas*:
>
> (A) *The portion of the hospital subject to the prospective payment system*.
>
> (B) The outpatient department of the hospital.

42 C.F.R. § 412.105(g)(1)(ii) (1996) (emphasis added)[2]. Further, from 1993 to 1996, community health centers were a third "area" that was included in the IME FTE count: ". . . any entity receiving a grant under section 330 of the Public Health Service Act. . . ." *Id*. at § 412.105(g)(1)(ii)(C). Finally, in 1997 the regulation was further amended to include in the FTE count time spent by residents providing direct patient care in non hospital settings:

> Effective for discharges occurring on or after October 1, 1997, the time spent by a resident in a nonhospital setting in patient care activities under an approved medical residency training program is counted towards the determination of [FTE] if the criteria set forth at [the DGME regulations]. . . are met.

42 C.F.R. § 412.105(f)(1)(ii)(C) (1997).

Effective October 1, 2001, the Secretary again amended the IME regulation. 66 Fed.Reg. 39,828, 39,933-34 (Aug. 1, 2001). For the first time, the revised regulation restricted the resident count used to calculate a hospital's FTE payment by excluding all time spent by residents in research not involving the care of particular patients. The 2001 amendment states that "[t]he

[2] The regulation was redesignated from 42 C.F.R. § 412.105(g) to § 412.105(f) in 1997, without other substantive changes being made to the regulation's text. *See* Fed.Reg. 45,966, 46,029 (Aug. 29, 1997). For ease of reference, the Court will refer to the 1996 regulation unless otherwise noted.

time spent by a resident in research that is not associated with the treatment or diagnosis of a particular patient is not countable." 42 C.F.R. § 412.105(f)(1)(iii)(B). According to the Secretary, the amendment was promulgated in order to "reiterate. . . longstanding policy regarding time that residents spend in research and. . . to incorporate this policy in the IME regulations." 66 Fed.Reg. 22,646, 22,699 (May 4, 2001). However, the 2001 amendment was added after the years involved in this lawsuit, and thus is not directly pertinent to this action.

The parties to this motion dispute the meaning of the words "areas" and "portion" in 42 C.F.R. § 412.105(g)(1)(ii). The Hospital argues that these terms are not ambiguous, and that they denote geographic areas of the hospital rather than activities pursued in those geographic areas. [Pl.'s Br., Doc. No. 27, p.18]. In contrast, the Secretary argues that the regulation is ambiguous, and that "[t]he residents' physical location *alone* cannot trump the requirement to provide inpatient services. . . ." [Def.'s Reply, Doc. No. 35, p.11]. Again, this Court must defer to the Secretary's interpretation of her own regulation unless: 1) an alternative reading is compelled by the regulation's plain language - i.e., the statute is not truly ambiguous; or 2) by other indication of the Secretary's intent at the time of the regulation's promulgation. *See Thomas Jefferson University v. Shalala*, 512 U.S. 504, 512 (1994).

For the reasons that follow, though the Court agrees with the Secretary that the word "areas" as used in 42 C.F.R. § 412.105(g) is facially ambiguous, the Court nonetheless holds that the Secretary's interpretation of that ambiguity fails both prongs of the *Thomas Jefferson University* analysis. The Court therefore **GRANTS IN PART** the Hospital's motion for summary judgment [Doc. No. 27], and **HOLDS** that the Secretary could not exclude residents engaging in educational research from the Hospital's IME resident count under the 1996 version

of 42 C.F.R. § 412.105(g)(1)(ii).

A. Under 42 C.F.R. § 412.105(g) (1996), an Alternative Definition of "Areas" is Compelled by the Plain Language of the Regulation.

The Secretary argues that the words "areas" and "portion" in 42 C.F.R. § 412.105(g)(1)(ii) are ambiguous, and that their interpretation - i.e., that only certain "activities" conducted by residents contribute to the FTE calculation - should be given deference. For the reasons that follow, however, the Court finds that, under *Thomas Jefferson University*, "an alternative reading is compelled by the regulation's plain language."

There is a split in authority among the federal district and circuit courts that have examined 42 C.F.R. § 412.105, or other similar HHS regulations with similar language, regarding the ambiguity of the words "areas" and "portion." Every federal district court that has considered this issue has held that 42 C.F.R. § 412.105(g) is not ambiguous, and requires a geographic, rather than a functional or activities-based, definition of the word "areas," though in one of those districts the outcome was reversed on appeal.[3] The only Court of Appeals to review the issue, however, found that the regulation *was* ambiguous, and therefore deferred to the Secretary's interpretation. *See Rhode Island Hospital v. Leavitt*, 548 F.3d 29 (1st Cir. 2008). Two Courts of Appeals have also interpreted the word "area" in a similar Medicaid reimbursement regulation - 42 C.F.R. § 412.106 - and have arrived at differing results.[4] While

[3] *See, e.g., Riverside Methodist Hospital v. Thompson*, 2003 WL 22658129 (S.D. Ohio July 31, 2003); *University Medical Center Corp. v. Leavitt*, 2007 WL 891195 (D. Ariz. March 21, 2007); *Rhode Island Hospital v. Leavitt*, 501 F.Supp.2d 283 (D. R.I. 2007), reversed, 548 F.3d 29; *University of Chicago Medical Center v. Sebilius*, 2009 WL 2382514 (N.D. Ill. Aug. 3, 2009).

[4] *Compare, e.g., District Memorial Hospital v. Thompson*, 364 F.3d 513 (4th Cir. 2004) (holding that word "area" in 42 C.F.R. § 412.106 was ambiguous); *Alhambra Hospital v. Thompson*, 259 F.3d 1071 (9th Cir. 2001) (holding that word "area" in 42 C.F.R. § 412.106 was not ambiguous).

the logic of each of these cases holds persuasive value, the Sixth Circuit has not yet decided this issue.

Those Circuit Courts that have found the word "areas" to be ambiguous - i.e., the First and Fourth Circuits - based their holdings upon the fact that the word "areas" is susceptible to more than one definition:

> A cursory review of a dictionary reveals that "assign" and "area" often have a functional connotation. *See American Heritage Dictionary* (4th ed. 2006) (defining "assign" as to "set apart for a particular purpose," "select for duty," or to "give out as a task); *id*. (defining "area" as a "distinct part or section, as of a building, set aside for a specific function," or a "division of experience, activity, or knowledge"). Accordingly, the Secretary suggests that to be "assigned" to a "portion" of the hospital subject to the prospective payment system a resident must be integrated into a hospital unit dedicated to a form of patient care subject to PPS billing. . . In light of the various definitions of 42 C.F.R. § 412.105(g)(1)(ii)'s key terms, neither party's interpretation of the FTE regulation is completely beyond the pale.

Rhode Island Hospital, 548 F.3d at 35-36. Thus, in *Rhode Island Hospital*, the First Circuit deferred to the Secretary's expertise due to the existence of a facial ambiguity in the regulation - i.e., due to word usage in the English language, the word "areas" was susceptible to more than one meaning. The Fourth Circuit - interpreting the word "area" in 42 C.F.R. § 412.106 - came to it's holding that the regulation was ambiguous on a similar analysis. *See District Memorial Hospital v. Thompson*, 364 F.3d 513, 519 (4th Cir. 2004).

As the Sixth Circuit has noted, however, "even facially ambiguous provisions can have their meanings clarified and rendered unambiguous by reference to the statute's [or in this case, the regulation's] structure or to other unambiguous terms in the statute." *Bower v. Federal Express Corp.*, 96 F.3d 200, 208-09 (6th Cir. 1996), citing *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291 (1988). Here, while the word "areas" in 42 C.F.R. § 412.105 is susceptible to

more than one possible definition, and thus facially ambiguous, reference to the context of that word's usage within the structure of the regulation renders the word "areas" unambiguous.

Importantly, the First Circuit did not attempt to clarify the facial ambiguity in the Secretary's usage of the word "areas" in this manner before simply accepting the Secretary's interpretation. Admittedly, the word "areas" in 42 C.F.R. § 412.105 is susceptible to more than one possible definition: either as a *geographic* connotation (i.e., the *area*, or wing of the hospital devoted to oncology), or a *functional* connotation (i.e., that someone works "in the *area* of oncology"). Importantly, however, the word "areas" can only have one of these connotations relative to the regulation, not both. Otherwise, had the Secretary meant to allow for two *classifications* of residents to quality for the FTE calculation, she would have used two *different words* to describe those classifications instead of one word.

The canon of statutory construction known as *noscitur a sociis*, or "a word is known by the company it keeps" resolves the facial ambiguity in 42 C.F.R. § 412.105. The Sixth Circuit has favorably cited this canon of statutory construction on several recent occasions. *See, e.g., United States v. Ossa-Gallegos*, 491 F. 3d 537, 540 (6th Cir. 2007) ("the meaning of an undefined term may be deduced from nearby words under noscitur a sociis."); *see also Ware v. Tow Pro Custom Towing and Hauling, Inc.*, 2008 WL 2871762 (6th Cir. July 25, 2008). Applying this canon of statutory construction, it is evident that the word "areas" only makes sense in a *geographic* connotation, not a *functional* connotation, for purposes of this regulation.

The relevant portion of 42 C.F.R. § 412.105 lists a series of "areas" residents may be assigned to while still being included in a hospital's FTE. At one time or another, four separate classifications have been listed as satisfying the "areas" requirement in the regulation, as shown

below:

> In order to be counted, the *resident must be assigned to one of the following areas*:
>
> (A) *The portion of the hospital* subject to the prospective payment system.
> (B) *The outpatient department of the hospital*.
> (C) [1993-1996 version] . . . any *entity* receiving a grant under section 330 of the Public Health Service Act [i.e., a *community health center*].
> (C) [1997 - present version] . . . time spent by a resident *in a nonhospital setting* in patient care activities. . . .

Thus, each of the four classifications listed, at one time or another, satisfied the Secretary's definition of what it meant to be an "area" residents could be assigned to and still count for purposes of the FTE calculation - a "portion of the hospital," the "outpatient department," a "community health center," or "a nonhospital setting."

The Secretary's argument in this case is that the word "areas" should properly be construed as a *functional* requirement as opposed to a *geographic* requirement. As such, only those *functions* of "[t]he portion of the hospital subject to the prospective payment system" - i.e., treating patients - should be counted in the FTE calculation for a hospital's IME payment.

Admittedly, the Secretary's proposed interpretation is reasonable as applied to subsection (A) of 42 C.F.R. § 412.105(g)(1)(ii), and under normal circumstances, would be entitled to deference. *Christensen v. Harris County*, 529 U.S. 576, 588 (2000). If true, however, the Secretary's proposed *functional* definition would also apply *to the other three categories*. It is here where the Secretary's proposed definition comes unraveled.

All three other classifications which, at one time or another, satisfied the "areas" requirement in 42 C.F.R. § 412.105 unequivocally refer to *geographic areas*, not functions. While a "portion of the hospital" arguably can be considered a *function* in some circumstances,

the same cannot be said for an "outpatient department" in § 412.105(g)(1)(ii)(B), nor for an "entity"/community health center in the pre-1997 version of § 412.105(g)(1)(ii)(C), nor for a "nonhospital setting" in the post-1997 version of § 412.105(g)(1)(ii)(C). When referencing these other three categories, the only definition of "areas" which makes sense is the *geographic*, not *functional*, use of the word. Similar analyses were made by the District Courts in Arizona and Rhode Island when they reviewed this regulation, and both courts similarly arrived at the same outcome as this Court reaches in the instant case. *See University Medical Center*, 2007 WL 891195 at *2; *Rhode Island Hospital*, 501 F.Supp.2d at 289.

Furthermore, the Secretary's proposed functional interpretation of the word "areas" in § 412.105(g)(1)(ii) runs afoul of the canon of statutory construction known as *expressio unis est exclusio alterius*, or "the express mention of one thing excludes all others." Like the doctrine of *noscitur a sociis*, the Sixth Circuit has also recently recognized the authority of this canon. *See, e.g., Nestle Waters N.A., Inc. v. Bollman*, 505 F.3d 498, 506 (6th Cir. 2007); *United States v. Pingleton*, 2007 WL 438087, *3 (6th Cir. Feb. 6, 2007).

Again, at one time or another, the Secretary created four classifications, or "areas," in which residents were to be included in the FTE calculation: 1) the "portion of the hospital subject to the [PPS]," 2) "the outpatient department of the hospital," 3) an "entity" known otherwise as a community health center, and 4) the "nonhospital setting" described in the post-1997 version of § 412.105(g)(1)(ii)(C). With respect to the "nonhospital setting" classification, however, the Secretary saw fit to place a qualification on this "area's" scope: all time spent by residents in a nonhospital setting did not count for purposes of the FTE calculation, but rather only "time spent by a resident in a nonhospital setting *in patient care activities*." None of the other three "areas"

in which the Secretary counts residents for FTE purposes has this "patient care activities" qualification. Under *expressio unis est exclusio alterius*, by qualifying only one of these four "areas" with a "patient care activities" requirement, the Secretary is implicitly *not* so qualifying the other three classifications.

Interpreting § 412.105(g) as the Secretary argues runs afoul of yet another canon of statutory construction related to this "patient care activities" qualification: that courts "construe statutes, where possible, so as to avoid rendering superfluous any parts thereof." *Astoria Fed. Savings & Loan Ass'n v. Solimino*, 501 U.S. 104, 112 (1991). The Secretary argues for a *functional* interpretation of "areas" in § 412.105(g), that only certain activities performed by residents in each of the four "areas" - i.e., activities related to patient care, as opposed to research - count for a hospital's FTE calculation. If true, however, there would be no reason for the Secretary to have restricted the "nonhospital setting" residents in the 1997 version of § 412.105(g)(1)(ii)(C) with a requirement that those residents specifically be involved "in patient care activities," *as that requirement would already be implicit* in the word "areas."

In conclusion, while usage in the English language renders the word "areas" susceptible to more than one potential definition, the facial ambiguity in this case is resolved by construing the word "areas" in accordance with well-respected canons of statutory construction. As such, no ambiguity remains in § 412.105(g)(1)(ii), and the Secretary's interpretation is therefore not entitled to deference.

B. Even if Ambiguous, the Secretary's Proposed Interpretation Contravenes Her Intent at the Time of the Regulation's Promulgation.

For the reasons explained above, the Court finds no ambiguity remaining in the definition

of "areas" as used in 42 C.F.R. § 412.105(g), and that the Secretary's proposed interpretation is therefore not entitled to deference. Assuming, *arguendo,* that there was such an ambiguity however, the Secretary's proposed interpretation runs contrary to her "intent at the time of the regulation's promulgation," *Thomas Jefferson University v. Shalala*, 512 U.S. 504, 512 (1994), and therefore is still not entitled to deference. As with the statutory construction analysis *supra*, the First Circuit in *Rhode Island Hospital* also failed to consider whether the Secretary's prior intent at the time of the regulation's promulgation was contravened by her current interpretation. The record is replete with evidence that, when the Secretary first promulgated 42 C.F.R. § 412.105, only a *geographic* usage of the word "areas" was envisioned.

Prior to enacting the PPS, Congress imposed limits on a hospital's allowable inpatient costs in Section 223 of the Social Security Amendments of 1972 ("Section 223 Limits"). In 1979, the Secretary excluded the costs of approved graduate medical education programs from the calculation of Section 223 Limits. 44 Fed.Reg. 31,906 (June 1, 1979). In 1980, however, the Secretary determined that there was still a "high degree of correlation" between a hospital's inpatient routine operating costs and its level of "teaching activity," and therefore, the Section 223 Limits were adjusted upward to account for higher "indirect" operating costs that statistically correlated with the ratio of residents to hospital beds. 45 Fed.Reg. 21,582, 21,584 (Apr. 1, 1980). The initial adjustment for indirect medical education costs was implemented for the 1981 fiscal year, and was based on a hospital's FTE count. That FTE count was subject to only two exclusions: 1) interns and residents not physically present at the hospital; and 2) residents not in an approved training program. *Id*. Notably, no exclusion was made for interns or residents physically present at the hospital, but engaged in activities other than direct patient care.

In 1982, the Secretary recommended to Congress that the PPS account for "indirect costs of graduate medical education." *Report to Congress Required by the Tax Equity and Fiscal Responsibility Act [TEFRA]of 1982* (Dec. 1982), *reprinted in* CCH Rep. No. 474, extra ed. 1983 at 48-49.

When it enacted the PPS in 1983, Congress adopted the Secretary's recommendation and incorporated an IME payment adjustment twice the amount of the Secretary's IME adjustment under the Section 223 Limits. *See* S.Rep. No. 98-23, at 52; H.R. Rep. No. 98-25, at 140. When issuing new regulations pursuant to TEFRA, however, the Secretary simply used the same methodology to determine the resident count for the IME adjustment that she had used under the Section 223 Limits - a methodology which did not consider the activities engaged in by the residents. 47 Fed.Reg. 43,296, 43,302 (Sept. 30, 1982).

In codifying the IME payment at issue, Congress provided that "[t]he Secretary [of HHS] 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 regulations [in effect as of January 1, 1983]." 42 U.S.C. § 1395ww(d). The January 1, 1983 Regulations referenced in that statute were the TEFRA IME adjustments rules published by the Secretary in the *Federal Register* on September 30, 1982 - regulations which determined the FTE count based solely on the resident's employment status. *See* 48 Fed.Reg. 39,752, 39,778 (Sept. 1, 1983); *see also* 47 Fed.Reg. at 43,310. The FTE count was *not* adjusted based upon the particular activities performed by the residents, such as research. *Id*.

When the original version of the regulation in question was promulgated in 1983, the Secretary explained that residents assigned to excluded units, such as the psychiatric ward and

rehabilitation units, could not be included in the IME FTE count because those units continued to be paid under the former "reasonable cost" system, and "already included the indirect cost of medical education." 48 Fed.Reg. At 39,778. When read in this context, 42 C.F.R. § 412.105(g)(1)(ii)(A)'s requirement to be a "portion of the hospital subject to the [PPS]" becomes clear: residents working in geographic portions of the hospital paid under the old "reasonable cost" system were not to be counted for purposes of the FTE.

In 1985, the Secretary stated this even more explicitly: "time spent in. . . excluded units is not counted for purposes of [IME] payment since these settings are not subject to the [PPS]." 50 Fed.Reg. 35,646, 35,678 (Sept. 3, 1985). Also in 1985, the Secretary acknowledged that time spent "on call" - i.e., *not directly treating patients* - was properly included in the IME FTE count. 50 Fed.Reg. At 35,680-81. If, as the Secretary now alleges, it was always the policy of HHS to consider the *function* of residents - to ensure reimbursement was only being made for patient treatment - it is inconceivable that she would have promulgated a regulation allowing for reimbursement where residents were "on call," and therefore *not treating patients at all*.

In 1990, the Secretary promulgated the version of this regulation that was effective for the years at issue in this lawsuit. Documentation from hospitals would be required by HHS to determine "the time the residents are assigned to a *setting* other than the inpatient area other than the inpatient area subject to the [PPS]." 55 Fed.Reg. 35,990, 36,060 (Sept. 4, 1990) (emphasis added). The Secretary further explained that "it is our experience that most hospitals do not keep records that indicate the *areas of the hospital where residents spend their time*." *Id*. at 36,061.

Further, prior to the Secretary's 2001 amendment to the regulation, neither the Secretary's Medicare Intermediary Manual ("MIM") nor her Provider Reimbursement Manual ("PRM"),

required that research time be excluded from the count of IME FTEs. For example, the MIM explains the process for a fiscal intermediary to audit IME resident counts, and instructs fiscal intermediaries to apply the following test to "verify" the resident's "location":

> Test that the following [interns and residents] are not included in the [IME] count:
> - in unapproved programs;
> - working at another provider;
> - assigned to excluded units;
> - replacing non-physician anesthetists; or
> - assigned to freestanding clinics such as family practice centers or non-provider clinics.

MIM, Part 4, Ch. 2 § 4198 (AR at 1113). The clear focus of this manual provision is to identify residents who are not in approved programs and who should not be counted *at all* in the FTE count. This provision does not instruct intermediaries to determine the time spent by such residents in approved programs that was spent performing hands-on patient care. As the Northern District of Illinois noted in *University of Chicago Medical Center*:

> Indeed, the Secretary's own auditors followed this manual during an extensive four-year audit that determined the physical *location* of these residents, while completely ignoring the *function* of the residents. If the Secretary had in fact been applying a functional definition in 1996, the Secretary's own fiscal intermediary auditors would have been aware of a need to investigate a resident's function.

University of Chicago Medical Center, 2009 WL 2382514, *7.

For these reasons, even if 42 C.F.R. § 412.105 is ambiguous regarding either a functional or a geographic inquiry into the activities of residents for purposes of the FTE calculation, the Secretary's clear treatment of the word "areas" as exclusively a geographic inquiry until the promulgation of the 2001 amendment requires this Court to afford the Secretary's interpretation no deference pursuant to *Thomas Jefferson University v. Shalala*, 512 U.S. 504, 512 (1994). Therefore, the Court **GRANTS IN PART** the Hospital's motion for summary judgment [Doc.

No. 27], and **HOLDS** that the Secretary could not exclude residents engaging in educational research from the Hospital's IME resident count under the 1996 version of 42 C.F.R. § 412.105(g)(1)(ii).

II. The Secretary Improperly Classified the Hospital's Two Programs as Outside the FTE Cap, Because they Were "New" Programs Under the Regulation.

The Hospital also challenges the Secretary's determination that two of its residency programs did not qualify for the FTE calculation as "new programs." That challenge arises out of the fact that, for cost years after October 1, 1997, Congress capped Medicare reimbursement for IME at the number of residents that the hospital trained in 1996, but instructed the secretary to provide a limited exception for residency programs established after January 1, 1995.

The Hospital argues that though two of its residency programs - the Vascular and Interventional Radiology ("VIR") program and the Clinical Neurophysiology program - were training residents prior to the January 1, 1995 cutoff, they were not "established" as defined by the Secretary's regulations due to the fact that those programs were not certified as accredited at that time. For the reasons that follow, the Court **GRANTS IN PART** the Hospital's motion for summary judgment [Doc. No. 27], and **HOLDS** that the Secretary could not exclude the Hospital's Vascular and Interventional Radiology and Clinical Neurophysiology programs from the "new programs" FTE cap exception in the 1998 version of 42 C.F.R. § 412.105(f)(1)(vi).

For cost reporting periods beginning on or after October 1, 1997, the Medicare program established a cap on the number of residents a hospital can count for purposes of IME payments, based on the hospital's number of resident FTEs during the most recent fiscal year that ended on or before December 31, 1996. *See* Fed.Reg. at 46,004. However, the regulation also allowed for

adjustments to this cap based on the addition of residents in "medical residency training programs established on or after January 1, 1995." 62 Fed.Reg. at 46,005. Specifically, the relevant regulation states as follows:

> (6) If a hospital established a new medical residency training program as defined in this paragraph (g) after January 1, 1995, the hospital's FTE cap described under paragraph (g)(4) of this section may be adjusted as follows:
>
> *****
>
> (ii) If a hospital had residents in its most recent cost reporting period ending before January 1, 1995 *the hospital's unweighted FTE cap may be adjusted for new medical residency training programs established on or after January 1, 1995* and on or before August 5, 1997. . . .
>
> (7) For purposes of paragraph (g) of this section, a new medical residency training program *means a medical residency that receives initial accreditation by the appropriate accrediting body or begins training residents on or after January 1, 1995.*

42 C.F.R. § 413.86(g) (1998) (emphasis added).[5]

The Hospital argues that this regulation allows them to obtain an increase in their FTE cap for their "new medical residency programs that either began training residents between January 1, 1995 and August 5, 1997 *or* gained accreditation during that period." [Pl.'s Br., Doc. No. 27, p.13 (emphasis in original)]. Specifically, its VIR program was not accredited until March 9, 1995, and its Clinical Neurophysiology program was not accredited until July 1, 1996. The Hospital further argues that the Secretary's current interpretation runs contrary to her intent at the time of the regulation's promulgation. *Id*. at 43.

In contrast, the Secretary argues that "[i]t is undisputed. . . that these programs were training residents in these specialties before January 1, 1995. Indeed, Medicare was reimbursing

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[5] The IME specifically incorporates this requirement for adjustments to the IME cap for new medical residency programs. *See* 42 C.F.R. § 412.105(f)(1)(vi).

the hospital for residents in these programs prior to 1995. Consequentially, these programs were not "established" on or after January 1, 1995." [Def.'s Br., Doc. No. 26, p.31]. Essentially, the Secretary concedes that these programs are "new" within the definition of § 413.86(g)(7), but that they are not "established on or after July 1, 1995" under § 413.86(g)(6)(ii). Or, put another way, the Secretary contends "that a medical residency training program may be 'established' before it is 'new.'" [Pl.'s Reply, Doc. No. 43, p.12].

The Court holds, as did the PRRB, that the Secretary's "interpretation of the regulation requiring a 'two-fold' determination is without merit as the plain language of the regulation is clear." (AR at 131). Section 413.86(g) clearly states that there are two separate and distinct ways for a residency program to be considered "new" for purposes of the FTE cap adjustment: 1) begin training residents on or after January 1, 1995; *or* 2) receive accreditation on or after January 1, 1995. *See* 42 C.F.R. § 413.86(g)(7) (1998).

The Secretary's regulation defines "established" by reference to the exact same date range in which a program is deemed to be "new": between January 1, 1995 and August 5, 1997. Because the programs at issue received initial accreditation between January 1, 1995 and August 5, 1997, FTEs from these programs are eligible to be added under the plain language of the cap.

Assuming, *arguendo*, that there was an ambiguity for the Secretary to interpret within § 413.86(g), the Secretary's current contention that a program can be "established" before it is "new" is contrary to indications of the Secretary's intent at the time of § 413.86(g)'s promulgation. *Thomas Jefferson Univ.*, 512 U.S. at 512.

When the Secretary issued the regulation governing new medical residency training programs, she specifically acknowledged that a hospital could qualify for the cap increase despite

having residents previously training in a program:

> The hospital's FTE caps are adjusted for the incremental increase in residents participating in the new medical residency training program which are not reflected in the hospital's cost reporting period ending during calendar year 1996.

63 Fed.Reg. 26,318, 26,334 (May 12, 1998).

Two years later, the Secretary's designee, the Deputy Administrator of the Centers for Medicare and Medicaid Services ("CMS"), issued Program Memorandum A-99-51, which instructed fiscal intermediaries how to implement the FTE cap adjustment. CMS described a simple, two-step process for determining whether a hospital is entitled to cap adjustment for new medical residency training programs:

> The new residency program policy may be more easily explained as a two step process. First, determine if the hospital's residency program qualifies as "new," meaning, it received initial accreditation by the appropriate accrediting body on or began training residents on or after January 1, 1995. Second, determine whether or not the hospital had residents before January 1, 1995.

HFCA Pub. 60A Transmittal No. A-99-51 (Dec. 1, 1999). This first step only requires fiscal intermediaries to determine whether the hospital was accredited *or* began training residents after January 1, 1995. Importantly, CMS *did not* instruct its fiscal intermediaries to determine whether they *both* trained residents *and* became accredited *before January 1, 1995*. CMS's failure to mention any requirement to exclude programs that trained residents before 1995 strongly indicates that, when this document was produced in 1999, the Secretary did not interpret the regulation to exclude programs such as the Hospital's from the FTE cap adjustment.

The Secretary argues, however, that in 1998 she rejected suggestions that programs "established" prior to January 1, 1995 be allowed to reach their minimum accredited length before being subjected to the cap:

> Comment: We received comments stating that an adjustment should be made to the FTE cap for programs established prior to January 1, 1995, that had not reached their third year or minimum accredited length for the type of program during the cost reporting period ending on or before December 31, 1996.
> Response: Section 1886(h)(4)(H) states that the Secretary shall prescribe rules for application of the FTE cap and the 3-year rolling average "in the case of medical residency training programs established on or after January 1, 1995." Our policy of limiting adjustments to FTE caps for medical residency training programs established on or after January 1, 1995 is consistent with this statutory requirement.

63 Fed.Reg. 26,318, 26,334 (May 12, 1998).

As the Hospital points out, however, "the passage addresses a comment requesting cap additions for programs accredited prior to January 1, 1995." [Pl.'s Reply, Doc. No. 43, p.13]. As such, it is not applicable to the Hospital's programs that were accredited after this time frame.

For these reasons, even if 42 C.F.R. § 413.86(g) is ambiguous, the Secretary's clear treatment of that regulation requires this Court to afford the Secretary's interpretation no deference pursuant to *Thomas Jefferson University v. Shalala*, 512 U.S. 504, 512 (1994). Therefore, the Court **GRANTS IN PART** the Hospital's motion for summary judgment [Doc. No. 27], and **HOLDS** that the Secretary could not exclude the Hospital's Vascular and Interventional Radiology and Clinical Neurophysiology programs from the "new programs" FTE cap exception in the 1998 version of 42 C.F.R. § 412.105(f)(1)(vi).

III. The Hospital Cannot Now Seek Part B Reimbursement for Residents Participating in Unapproved Programs.

For purposes of both its direct and indirect graduate medical education reimbursements, the Hospital originally sought to count residents participating in unaccredited programs that it asserted were "approved." The Secretary rejected this contention, and the Hospital does not challenge that aspect of the Secretary's decision [*See* Complaint, Doc. No. 1, ¶5]. Instead, the

Hospital now contends that it should be allowed to start fresh with the fiscal intermediary by claiming these costs as "reasonable costs" of residents serving in unapproved programs under Part B. *Id*. at ¶¶62-63. The Secretary disagreed in her final decision, and this Court finds that no reason exists to disturb that determination. Therefore, the Court **GRANTS IN PART** the Secretary's motion for summary judgment [Doc. No. 26], and **HOLDS** that the Secretary properly denied a remand to the fiscal intermediary for consideration of the Hospital's alternative claim for reasonable cost reimbursement under Part B.

It is the Hospital's burden to prove evidence of reasonable costs to the fiscal intermediary. *See Rush Univ. Med. Center*, 535 F.3d at 741; 42 C.F.R. § 413.24(a). Contrary to this directive, however, the Hospital did not provide any information to support a claim for reasonable costs before the fiscal intermediary.

The PRRB's rules also required the Hospital to support its claim for Part B reimbursement before the Board ruled. Upon receiving notice from the fiscal intermediary, the Hospital was required to "identify the aspects" of the notice of program reimbursement "with which the provider is dissatisfied," to "explain why the provider believes the determination is incorrect in such particulars," and to provide "*any documenting evidence the provider considers necessary to support its position*." 42 C.F.R. § 405.1841(a)(1) (2007). At no time "prior to the commencement of the hearing proceedings," or afterward did the Hospital present the fiscal intermediary with reasonable cost information about these residents.

Furthermore, the fiscal intermediary and the Hospital agreed to a joint scheduling order that contemplated the Hospital submitting documentation supporting their Part B reimbursement arguments, which the fiscal intermediary would review in advance of a PRRB determination.

See AR at 1279. Instead, the Hospital appears to have chosen to contest only the determination that the programs were not "approved" before both the PRRB and the Secretary, and to wait to submit data to support its alternate theory until after its first argument had been rejected by the PRRB.

While the PRRB may remand a decision that a fiscal intermediary *improperly* denied a claim for lack of evidence, 42 C.F.R. § 405.1871(b)(5), no authority exists for the PRRB to remand a claim that the fiscal intermediary *properly* denied, so that more evidence can be offered in support of an alternative claim. Here, the Hospital did not present *any* evidence to the PRRB to support an alternative claim to Part B reimbursement. Thus, the Board could not properly remand this issue to the fiscal intermediary, and the Secretary properly modified the PRRB's decision on this issue.

Analogous holdings have been reached by several other federal courts considering similar issues. In *Little Company of Mary Hosp. v Shalala*, 165 F.3d 1162, 1165 (7th Cir. 1999), the Seventh Circuit held that a provider could not pursue an alternate theory of reimbursement without first having effectively raised the issue before the fiscal intermediary. Noting that the Sixth Circuit lacked a decision on point, the Western District of Michigan relied on *Little Company of Mary Hosp.* in holding the PRRB lacked jurisdiction to remand an issue for consideration of an alternative argument not first raised before the fiscal intermediary. *See Battle Creek Health System v. Leavitt*, 2006 WL 3055959, *6 (W.D. Mich. Oct. 26, 2006).

The Hospital contends, however, that the fiscal intermediary already agreed to review the Hospital's Part B costs in the event the Hospital did not prevail on the issue of program approval. [Pl.'s Complaint, Doc. No. 1, ¶44]. This stipulation does not bind the Secretary, however, who is

not a party to PRRB proceedings, nor could such a stipulation enhance the PRRB's authority. *See, e.g., Howard Young Med. Ctr., Inc. v. Shalala*, 207 F.3d 437, 443 (7th Cir. 2000) (Secretary not bound by stipulation entered into by a fiscal intermediary).

For these reasons, the Court holds that the Secretary properly denied the Hospital's request for a remand to determine their reasonable costs under Part B. The Court therefore **GRANTS IN PART** the Secretary's motion for summary judgment [Doc. No. 26], and **HOLDS** that the Secretary properly denied a remand to the fiscal intermediary for consideration of the Hospital's alternative claim for reasonable cost reimbursement under Part B.

CONCLUSION

For the reasons above, the Court **GRANTS IN PART** and **DENIES IN PART** the summary judgment motions of each party, as follows:

1. **GRANTS IN PART** the Hospital's motion for summary judgment [Doc. No. 27], and **HOLDS** that the Secretary could not exclude residents engaging in educational research from the Hospital's IME resident count under the 1996 version of 42 C.F.R. § 412.105(g)(1)(ii); and **FURTHER HOLDS** that the Secretary could not exclude the Hospital's Vascular and Interventional Radiology and Clinical Neurophysiology programs from the "new programs" FTE cap exception in the 1998 version of 42 C.F.R. § 412.105(f)(1)(vi).

2. **GRANTS IN PART** the Secretary's motion for summary judgment [Doc. No. 26], and **HOLDS** that the Secretary properly denied a remand to the fiscal intermediary for consideration of the Hospital's alternative claim for reasonable cost reimbursement under Part B.

IT IS SO ORDERED.

s/Sean F. Cox
Sean F. Cox
United States District Judge

Dated: December 30, 2009

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

HENRY FORD HEALTH SYSTEM,
d/b/a HENRY FORD HOSPITAL

Plaintiff

v.

KATHLEEN SEBELIUS, SECRETARY
U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES,

Defendant.
_____/

Case No. 09-10195

HONORABLE SEAN F. COX
United States District Judge

PROOF OF SERVICE

I hereby certify that a copy of the foregoing document was served upon counsel of record on December 30, 2009, by electronic and/or ordinary mail.

s/Jennifer Hernandez
Case Manager