UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

COTTAGE HEALTH SYSTEM,

Plaintiff,

v.

Civil Action No. 08-098 (JDB)

KATHLEEN SEBELIUS,¹ Secretary, U.S. Department of Health and Human Services,

Defendant.

MEMORANDUM OPINION

The Secretary of the Department of Health and Human Services ("defendant" or "the Secretary"), through the Centers for Medicare and Medicaid Services ("CMS"), is responsible for administering the Medicare statute, Title XVIII of the Social Security Act, 42 U.S.C. § 1395 <u>et seq.</u> Cottage Health System ("plaintiff") seeks judicial review of the Secretary's decision to deny it certain supplemental medical education payments authorized by the Balanced Budget Act of 1997 ("BBA '97"), Pub. L. No. 105-33, 111 Stat. 251. Plaintiff also seeks review of the Secretary's decision not to count medical residents providing patient care in non-hospital settings in calculating medical education payments.

Now before the Court are the parties' cross-motions for summary judgment. For the reasons explained below, the Court will grant in part and deny in part each party's motion for summary judgment and will remand the case to the Secretary for further proceedings.

¹ Former Secretary of the Department of Health and Human Services Michael O. Leavitt was named as the original defendant in this case. Pursuant to Federal Rule of Civil Procedure 25(d), the Court automatically substitutes the current Secretary of the Department of Health and Human Services, Kathleen Sebelius, as the defendant.

BACKGROUND

I. Statutory and Regulatory Background

A. Claims Under Medicare Parts A & C

The Medicare program is divided into several parts, of which parts A and C are relevant here. Part A covers "inpatient hospital services" furnished to Medicare beneficiaries by participating providers, like hospitals. 42 U.S.C. § 1395d(a)(1). CMS itself is directly responsible for the costs of part A services. <u>Id.</u> To coordinate billing by and payment to hospitals under part A, Medicare contracts with fiscal intermediaries (usually private insurance companies) pursuant to 42 U.S.C. § 1395h. Claims for payment under part A are governed by the regulations set forth at 42 C.F.R. § 424.30 <u>et seq.</u>, which provide that "[c]laims must be filed in all cases except when services are furnished on a prepaid capitation basis by a health maintenance organization (HMO), a competitive medical plan (CMP), or a health care prepayment plan (HCPP)." The regulations also provide time limits for filing claims with the fiscal intermediary:

(a) Basic limits. Except as provided in paragraph (b) of this section, the claim must be mailed or delivered to the intermediary or carrier, as appropriate--

- On or before December 31 of the following year for services that were furnished during the first 9 months of a calendar year; and
- (2) On or before December 31 of the second following year for services that were furnished during the last 3 months of the calendar year.

42 C.F.R. § 424.44.

Medicare part C was created by BBA '97. Under part C, beneficiaries may receive

Medicare benefits through private health insurance plans called "Medicare+Choice" plans. <u>See</u> 42 U.S.C. § 1395w-21(a)(1). Such plans -- referred to by the parties as "Medicare HMOs" -- are themselves responsible for the costs of part C services. Medicare HMOs receive payment in advance from CMS according to a complex formula, and the Medicare HMOs themselves coordinate billing and payment with the hospitals once services have been provided. <u>See</u> 42 U.S.C. § 1395mm(a). The regulations governing claims under part A expressly do not apply for services furnished to Medicare HMO enrollees. 42 C.F.R. § 424.30 (excepting claims for services "furnished on a prepaid capitation basis by a [Medicare HMO]").

Claims for services provided are submitted by hospitals -- either to fiscal intermediaries (for services provided under part A) or to Medicare HMOs (for services provided under part C) -and paid over the course of the year. At year-end, hospitals file cost reports with the fiscal intermediaries, which reconcile interim payments made over the course of the year with actual reimbursement due. <u>See</u> 42 C.F.R. § 405.1803. The fiscal intermediary makes a final determination, which is appealable to the Provider Reimbursement Review Board ("PRRB"). 42 U.S.C. § 139500(a). The PRRB's decision is subject to further review by the CMS Administrator, and a hospital may seek review of the Administrator's decision in federal district court. <u>See</u> 42 U.S.C. § 139500(f).

B. Medical Education Payments

The Medicare program also pays teaching hospitals for certain costs related to graduate medical education. Medicare makes both an "indirect graduate medical education payment" ("IME") and a "direct graduate medical education payment" ("GME"). IME payments are intended to reimburse teaching hospitals providing services to Medicare beneficiaries for their

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higher-than-average operating costs. <u>See</u> 42 U.S.C. §§ 1395f(b), 1395ww(d). Medicare makes a payment for each Medicare beneficiary discharged by a hospital. <u>See</u> 42 U.S.C. §§ 1395ww(d), 1395w-21(i)(1). The per-discharge payment increases depending on the hospital's ratio of medical residents to beds -- <u>i.e.</u>, the higher the number of residents or the higher the number of discharges, the greater the IME payment. See 42 U.S.C. § 1395ww(d)(5)(B).

The GME payment, on the other hand, is a payment intended to compensate teaching hospitals for the direct costs of graduate medical education incurred because of services provided to a Medicare beneficiary. 42 U.S.C. § 1395ww(h). The amount of the GME payment depends on the number of full-time residents and the Medicare "patient load." Hence, like the IME payment, the GME payment increases when the number of Medicare patients or the number of residents rises. See id.

Both GME and IME payments, then, depend on the number of residents and the number of Medicare patients receiving services from a hospital. A hospital may include residents training in non-hospital settings in its resident count. Under the Medicare <u>statute</u>, such residents are included if (1) their time is related to patient care and (2) the hospital incurs substantially all of the costs of their training in the non-hospital setting. <u>See</u> 42 U.S.C. §§ 1395ww(h)(4)(E), 1395ww(d)(5)(B)(iv). The <u>regulations</u> governing resident counts, however, contain a third requirement -- that the hospital have a written agreement with the non-hospital site establishing that the hospital will incur the costs of the residents' training. <u>See</u> 42 C.F.R. §§ 413.86(f) (2002), 412.105(f)(1)(ii)(C) (2002).

Before the passage of BBA '97, only services provided to Medicare part A or B beneficiaries were counted in calculating IME and GME payments. That is, the "per-discharge"

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multiplicand for IME payments did not include discharges of part C Medicare HMO enrollees, and the "patient load" multiplicand for GME payments did not include part C Medicare HMO enrollees. BBA '97, however, directed the Secretary to make additional IME and GME payments, phased in over five years, for services provided to Medicare HMO enrollees under part C. <u>See</u> BBA '97 §§ 4622, 4624 (codified at 42 U.S.C. §§ 1395ww(d)(11), 1395ww(h)(3)(D)(I)).

II. Factual Background and Administrative Proceedings

A. Factual Background

Plaintiff is a not-for-profit corporation that owns and operates Santa Barbara Cottage Hospital, a teaching hospital in Santa Barbara, California. Am. Compl. ¶ 13. From 1998 through 2001 -- the periods at issue in this case -- plaintiff operated three medical residency training programs. Id. ¶ 31. To receive IME and GME payments related to services provided to Medicare part A beneficiaries, plaintiff submitted claim forms (labeled "UB-92" forms) containing "encounter data" (i.e., the number of Medicare part A beneficiary discharges) directly to its fiscal intermediary, as required by 42 C.F.R. § 424.30, and received payment accordingly. See id. ¶ 32.

To receive the additional IME and GME payments authorized by BBA '97 for services provided to Medicare HMO enrollees, plaintiff submitted UB-92 forms containing encounter data to the Medicare HMO, not the fiscal intermediary. <u>See id.</u> ¶ 94. Plaintiff avers that it also submitted encounter data directly to the fiscal intermediary after cost periods had ended: on November 2, 2000 for the cost period ending December 31, 1998, <u>id.</u> ¶ 92; on March 27, 2002 for the cost period ending December 31, 1999, <u>id.</u> ¶ 98; and on June 10, 2003 for the cost period

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ending December 31, 2000, <u>id.</u> $102.^2$ The fiscal intermediary did not provide plaintiff with the additional payment authorized by BBA '97 for the 1998-2001 cost periods. <u>Id.</u> ¶ 103.

Plaintiff's IME and GME payments also did not account for residents providing care in non-hospital settings. In August 2002, having determined that plaintiff lacked an adequate written agreement, the fiscal intermediary excluded residents' time spent in non-hospital settings. Id. ¶¶ 129-30. In 2005, plaintiff entered into memoranda of understanding ("MOUs") with the non-hospital sites. Plaintiff alleges that the MOUs clarified and memorialized the terms of its pre-existing agreement regarding residents' training in non-hospital sites. Id. ¶ 131. The fiscal intermediary nonetheless determined that the post-dated MOUs did not satisfy the regulations.

B. PRRB's Decision

Plaintiff timely sought review of the fiscal intermediary's decision before the PRRB. The PRRB held a hearing on November 8, 2006 and issued a decision on September 28, 2007. <u>See</u> Administrative Record ("A.R.") at 25-48. Two issues were presented to the PRRB: "(1) [w]hether the Intermediary improperly disallowed [GME] and [IME] payments with respect to discharges of Medicare beneficiaries who were enrolled in [Medicare HMOs] in fiscal years ending December 31, 1998, 1999, 2000, and 2001; and (2) [w]hether the Intermediary improperly disallowed residents' time spent in non-provider settings within the scope of the Provider's approved medical residency training programs from the Provider's full-time equivalent resident counts for []GME and IME purposes." Id. at 26.

² Plaintiff's Amended Complaint does not contain the date on which it claims to have provided the fiscal intermediary with encounter data for the cost period ending December 31, 2001. Nonetheless, the parties do not dispute that plaintiff did not receive the additional IME or GME payments for that cost period.

On the first issue, the PRRB found "that this dispute is governed by the regulation, 42 C.F.R. [§] 424.30 et seq.," which sets forth "basic requirements" for filing claims, including time limits. A.R. at 36. The PRRB then found that "[t]he claims in question, for services furnished by and paid for by [Medicare HMOs], are specifically exempt from the requirements, procedures, and time limits under this section." Id. Next, the PRRB determined that BBA '97 "clearly shifted the burden for filing encounter data squarely to the [Medicare] HMOs." Id. at 37. The PRRB also concluded that no "regulation gave notice that hospitals would now be required to file a separate IME/[]GME claim with the intermediary that was virtually identical to the claim filed with the HMO." Id. The PRRB held that an "Administrative Bulletin" outlining the claims filing requirements was not the appropriate vehicle for providing notice, and even if it was, that it did not provide conclusive guidance as to billing requirements for the additional payment authorized by BBA '97. Id. at 38. Finally, the PRRB concluded that even if the UB-92 forms plaintiff provided directly to the intermediary were filed out-of-time, the intermediary improperly failed to consider those claims because they constituted the most accurate data for IME/GME reimbursement and comparison of the UB-92 forms to the intermediary's year-end cost reports revealed discrepancies. Id. at 38-39. Accordingly, the PRRB remanded the first issue to the intermediary.

As to the second issue, the PRRB identified "[t]he crux of the issue [as] whether the MOUs executed after the cost reporting periods at issue satisfy the regulation's requirements." <u>Id.</u> at 40. The PRRB found that they do not, concluding that the regulations require a contemporaneous written agreement. <u>Id.</u> The PRRB noted that its finding was consistent with the holding of Chestnut Hill Hospital v. Thompson, Civ.A.No. 04-1128, 2006 WL 2380660

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(D.D.C. Aug. 15, 2006). A.R. at 40. The PRRB found that other written agreements -- bylaws and employment agreements -- were insufficient to establish that residents' training in non-hospital settings was related to patient care and that the hospital incurred substantially all of the costs of the residents' training in the non-hospital setting. <u>Id.</u> at 40-41. Finally, the PRRB considered a letter written in 2000 by the former CMS Administrator, Thomas A. Scully, to Congressman Charles Rangel. Plaintiff had submitted the letter as evidence that CMS itself interpreted the regulation as permitting a non-contemporaneous written agreement. But the PRRB "d[id] not find the Scully letter inconsistent with its findings" that a contemporaneous written agreement was required, noting that the letter demonstrated an unwillingness to accept post-dated written agreements. <u>Id.</u> at 41. Accordingly, the PRRB affirmed the intermediary's decision to disallow residents' time spent in non-provider settings from the resident count.

C. Administrator's Decision

Both issues were timely appealed to the Administrator, and the Administrator issued a decision on November 16, 2007. <u>See</u> A.R. at 2-17. On the second issue, the Administrator "summarily affirm[ed] the Board's decision." A.R. at 2 n.1.

On the first issue, the Administrator began by describing IME and GME payments before the passage of BBA '97, A.R. at 7-8, and then described the additional payment authorized in §§ 4622 and 4624 of BBA '97, <u>id.</u> at 8-11. The Administrator next explained that the Secretary first addressed the filing requirements for the additional payment in a rule published in the May 12, 1998 Federal Register, as follows:

Under section 4622 and 4624 of the BBA, teaching hospitals may receive indirect and direct GME payments associated with [Medicare HMO enrollee] discharges. Since publication of the

final rule with comment on August 29, 1997, we have consulted with hospitals, managed care plans, and fiscal intermediaries for purposes of developing a process to implement these provisions.

We anticipate teaching hospitals will need to submit claims associated with [Medicare HMO enrollee] discharges to the fiscal intermediaries for purposes of receiving indirect and direct medical education payments. When the claims are processed, the fiscal intermediaries will make the IME payment associated with a [Medicare HMO enrollee] discharge directly to the teaching hospital. Teaching hospitals will also be required to submit bills associated with [Medicare HMO] organizations to the managed care plans. The inpatient encounter data from these bills will be submitted by the managed care plans to HCFA for purposes of implementing the risk adjustment methodology. The fiscal intermediaries should revise interim payments to reflect the Medicare direct GME payment associated with [Medicare HMO enrollee] discharges. However, until the fiscal intermediaries have more experience with paying hospitals for direct GME associated with [Medicare HMO enrollee] discharges, we believe the fiscal intermediaries will have limited data upon which to base interim payment. We are making adjustments to the Medicare cost report to allow for settlement of the cost report reflective of direct GME payment associated with [Medicare HMO enrollee] discharges.

Id. at 11 (quoting 63 Fed. Reg. 26,318, 26,342 (May 12, 1998)). The Administrator also quoted

from CMS Program Memorandum A-98-21, which was issued on July 1, 1998 and provided as

follows:

This Program Memorandum outlines intermediary and standard system changes needed to process requests for IME and []GME supplemental payments for Medicare [HMO] enrollees. Sections 4622 and 4624 of the Balanced Budget Act of 1997 state that hospitals may now request a supplemental payment for operating IME for Medicare [HMO] enrollees. During the period January 1, 1998 through December 31, 1998, providers will receive 20 percent of the fee for service []GME and operating IME payment. This amount will increase 20 percent each consecutive year until it reaches 100 percent.

PPS hospitals must submit a claim to the hospitals' regular

intermediary in UB-92 format . . .

Id. at 12 (quoting CMS Program Memorandum A-98-21). Next, the Administrator outlined the time limits for filing claims under part A, as set out in 42 C.F.R. §§ 424.30 and 424.44, A.R. at 12-13, and explained why the claim submission methodology outlined in the CMS Program Memorandum was necessary, id. at 13-14.

The Administrator then turned to the PRRB's decision. The Administrator found that the additional IME/GME payment "is within [the] framework of a pre-existing methodology[,] [which] requires that claims be made to the intermediary." <u>Id.</u> at 14. The Administrator found that the May 1998 notice in the Federal Register and the July 1, 1998 Program Memorandum, coupled with a July 13, 1998 Bulletin and an August 20, 1998 letter from the intermediary to plaintiff, provided plaintiff with notice that claims for the additional IME/GME payment were to be submitted directly to the intermediary. <u>Id.</u> at 14-15. Moreover, the Administrator found "that the APA does not require CMS to publish a new regulation under these circumstances. CMS is allowed to promulgate interpretive rules and guidance." <u>Id.</u> at 15.

Having found that the claims filing requirement was valid and that plaintiff had notice of it, the Administrator found that plaintiff had not filed its claims within the time limits set forth in 42 C.F.R. § 424.44. <u>Id.</u> Finally, the Administrator rejected the argument that those time limits did not apply:

The only exception to the claims processing requirements at 42 C.F.R. § 424.30 is for services furnished on a prepaid capitation basis to the beneficiary by a managed care plan, which is not at issue here. The claims in the instant case were claims for an established reimbursement methodology for hospitals' costs associated with being a teaching hospital and not for the services furnished to a managed care enrollees [sic].

<u>Id.</u> at 15-16. Hence, the Administrator concluded "that the Intermediary properly disallowed []GME and IME payments with respect to discharges of Medicare beneficiaries who were enrolled in [Medicare HMOs]. Thus, the Administrator reverses the Board's decision" <u>Id.</u> at 16.

Plaintiff timely filed suit in this Court on January 17, 2008 under 42 U.S.C. § 139500(f) and amended its complaint on February 13, 2008. Plaintiff filed a motion for summary judgment on July 11, 2008, and the Secretary filed a cross-motion for summary judgment on September 22, 2008. The motions are now fully briefed and ripe for resolution.

STANDARD

Under Rule 56(c) of the Federal Rules of Civil Procedure, summary judgment is appropriate when the pleadings and the evidence demonstrate that "there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." In a case involving review of a final agency action under the Administrative Procedure Act, 5 U.S.C. § 706, however, the standard set forth in Rule 56(c) does not apply because of the limited role of a court in reviewing the administrative record. <u>See North Carolina Fisheries Ass'n v. Gutierrez</u>, 518 F. Supp. 2d 62, 79 (D.D.C. 2007); <u>Fund for Animals v. Babbitt</u>, 903 F. Supp. 96, 105 (D.D.C. 1995), <u>amended on other grounds</u>, 967 F. Supp. 6 (D.D.C. 1997). Under the APA, it is the role of the agency to resolve factual issues to arrive at a decision that is supported by the administrative record, whereas "the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." <u>See Occidental Eng'g Co. v. INS</u>, 753 F.2d 766, 769-70 (9th Cir. 1985); <u>see also</u> Northwest Motorcycle Ass'n v. U.S. Dep't of Agriculture, 18 F.3d 1468, 1472 (9th Cir. 1994)

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("[T]his case involves review of a final agency determination under the [APA]; therefore, resolution of th[e] matter does not require fact finding on behalf of this court. Rather, the court's review is limited to the administrative record."). Summary judgment thus serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review. <u>See Richards v.</u> INS, 554 F.2d 1173, 1177 & n.28 (D.C. Cir. 1977).

Under the APA, the Administrator's decision can be set aside only if it is "unsupported by substantial evidence," or "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A) and (E); see 42 U.S.C. § 139500(f)(1) (providing that judicial review of Medicare reimbursement decisions shall be made under APA standards); St. Elizabeth's Med. Ctr. of Boston v. Thompson, 396 F.3d 1228, 1233 (D.C. Cir. 2005). The "scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency." Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). The court must be satisfied that the agency has "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made." Id.; Alpharma, Inc. v. Leavitt, 460 F.3d 1, 6 (D.C. Cir. 2006). The agency's decisions are entitled to a "presumption of regularity," Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 415 (1971), and although "inquiry into the facts is to be searching and careful, the ultimate standard of review is a narrow one." Id. at 416. The court's review is confined to the administrative record, subject to limited exceptions not applicable here. See Camp v. Pitts, 411 U.S. 138, 142 (1973) ("[T]he focal point for judicial review should be the administrative record already in

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existence, not some new record made initially in the reviewing court.").

A court should review an agency's interpretation of a statute under the familiar two-step analysis outlined in <u>Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.</u>, 467 U.S. 837 (1984). The first step is determining whether Congress has spoken directly to the "precise question at issue," for if it has, "the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." <u>Id.</u> at 842-43; <u>State of New Jersey v. EPA</u>, 517 F.3d 574, 581 (D.C. Cir. 2008). If, however, the statute is silent or ambiguous on the specific issue, "the question for the court is whether the agency's answer is based on a permissible construction of the statute." <u>Chevron</u>, 467 U.S. at 843. When the agency's construction of a statute is challenged, its "interpretation need not be the best or most natural one by grammatical or other standards Rather [it] need be only reasonable to warrant deference." <u>Pauley v.</u> BethEnergy Mines, Inc., 501 U.S. 680, 702 (1991) (citations omitted).

ANALYSIS

I. Written Agreement Requirement

Plaintiff takes issue with three aspects of the Secretary's decision not to count residents training in non-hospital settings in calculating IME and GME payments. See Am. Compl. ¶ 136. First, plaintiff argues that the written agreement requirement is "inconsistent with the plain meaning and manifest intent of the statut[e]." Id. ¶ 136(A). Next, plaintiff contends that the intermediary's "refusal to accept the Hospital's post-dated memoranda of understanding . . . conflicts with the plain language and intent of the regulations." Id. ¶ 136(B). Finally, plaintiff contends that refusal to accept the post-dated memoranda is not based on substantial evidence "because contemporaneous Hospital records reflect that the Hospital had a commitment to incur

all or substantially all of the costs of the residents' training in non-hospital settings." Id. ¶ 136(C).

With respect to the first and second issues, the PRRB found that the regulations were a valid exercise of the Secretary's rule-making authority and that the regulations called for a contemporaneous written agreement. A.R. at 40. As to the third issue, the PRRB determined that plaintiff's contemporaneous bylaws and employment agreements were insufficient to establish that residents' training in non-hospital settings was related to patient care and that the hospital incurred substantially all of the costs of the residents' training in the non-hospital setting. <u>Id.</u> at 40-41. In reviewing the PRRB's decision, the Administrator "summarily affirm[ed]" the PRRB on these issues. Id. at 2 n.1.

A. Reasonableness of Written Agreement Requirement

Plaintiff argues that the statute governing time spent by residents in non-hospital settings did not permit the Secretary to promulgate regulations requiring a written agreement. <u>See Pl.</u> Mem. at 35-38.³ The relevant statute provides as follows:

> <u>Counting Time in Outpatient Settings</u>. Such rules shall provide that only time spent in activities relating to patient care shall be counted and that all the time so spent by a resident under an approved medical residency training program shall be counted towards the determination of full-time equivalency, without regard to the setting in which the activities are performed, if the hospital incurs all, or substantially all, of the costs for the training program in that setting.

³ The briefing in this case consists of the following: Plaintiff's Memorandum in Support of its Motion for Summary Judgment ("Pl. Mem."); Defendant's Opposition and Memorandum in Support of its Cross-Motion for Summary Judgment ("Def. Opp."); Plaintiff's Reply and Opposition Memorandum ("Pl. Rep."); Defendant's Reply Memorandum ("Def. Rep."); and Plaintiff's Sur-Reply Memorandum ("Pl. Sur.").

42 U.S.C. § 1395ww(h)(4)(E). The challenged regulation is as follows:

For portions of cost reporting periods occurring on or after January 1, 1999, the time residents spend in nonprovider settings such as freestanding clinics, nursing homes, and physicians' offices in connection with approved programs may be included in determining the number of [full-time equivalent] residents in the calculation of a hospital's resident count if the following conditions are met--

- (i) The resident spends his or her time in patient care activities.
- (ii) The written agreement between the hospital and the nonhospital site must indicate that the hospital will incur the cost of the resident's salary and fringe benefits while the resident is training in the nonhospital site and the hospital is providing reasonable compensation to the nonhospital site for supervisory teaching activities. The agreement must indicate the compensation the hospital is providing to the nonhospital site for supervisory teaching activities.
- (iii) The hospital must incur all or substantially all of the costs for the training program in the nonhospital setting

42 C.F.R. § 413.86(f)(4) (2002).

The statute, then, sets forth two requirements: that only time spent in activities relating to patient care may be counted and that time is only counted if the hospital incurs all or substantially all of the costs in the non-hospital setting. <u>See Pl. Mem. at 35-38</u>. As plaintiff would have it, the statute's use of the word "shall" bars the Secretary from promulgating regulations requiring anything other than the two requirements set forth in the statutory text itself.

The Court must apply the familiar two-step Chevron analysis to determine whether the

Secretary's interpretation of the statute to permit a written agreement requirement was arbitrary or capricious. The first step is determining whether Congress has spoken directly to the "precise question at issue," because if it has, "the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." <u>Chevron</u>, 467 U.S. at 842-43. Here, the statute itself does not speak to the precise question at issue: whether the Secretary may require a written agreement before counting time spent by residents in non-hospital settings. Although a different portion of the statutory provision requires the Secretary to "establish rules consistent with this paragraph," <u>see 42 U.S.C. § 1395ww(h)(4)(E)</u>, that language does not unambiguously state what rules the Secretary may promulgate to ensure that the statutory requirements are satisfied. This ambiguity is underscored by a different statutory provision that grants the Secretary broad authority to promulgate rules. <u>See 42 U.S.C. § 1395hh(a)(1)</u> (providing that the Secretary "shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs"). Hence, the Court must proceed to the second step of the <u>Chevron</u> analysis to determine whether the Secretary's requirement of a written agreement is entitled to deference.

Under the second step of <u>Chevron</u>, the Court must assess whether the Secretary's interpretation of the statute is "reasonable to warrant deference." <u>See Pauley</u>, 501 U.S. at 702. Here, the Secretary's interpretation is plainly reasonable. The reasonableness of the written agreement requirement was specifically addressed in <u>Chestnut Hill</u>, where the court concluded that the "shall . . . allow" language in the statute did not eliminate the Secretary's discretion and "[a]ccordingly, the Secretary possessed the authority to impose a 'written agreement' requirement to ensure that reimbursement flowed only to those entities meeting, for example, the requirement that reimbursement be limited to hospitals that 'incurred all, or substantially all, of the costs for

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the training program in that setting." 2006 WL 2380660 at *4. Moreover, as <u>Chestnut Hill</u> pointed out, to disallow the written agreement requirement would "foreclos[e] . . . the application of any of a host of requirements imposed by the Secretary to ensure the orderly administration of the Medicare program." <u>Id.</u> This Court agrees with the reasoning of <u>Chestnut Hill</u>, as did the PRRB, which noted the decision in determining that the written agreement requirement was reasonable. A.R. at 40. Under <u>Chevron</u> step two, then, the Secretary's interpretation of the statute to permit the promulgation of a written agreement requirement is reasonable and entitled to deference.

B. Interpretation of Regulation as Requiring Contemporaneous Written Agreement

The next question is whether the Secretary reasonably interpreted the regulation as requiring a <u>contemporaneous</u> written agreement, which was the fiscal intermediary's basis for rejecting the retroactive MOUs. Plaintiff argues that interpreting the regulation to require a contemporaneous agreement is contrary to the regulation's plain language and intent. <u>See</u> Pl. Mem. at 38-44.

Courts "must give substantial deference to an agency's interpretation of its own regulations." <u>Thomas Jefferson Univ. v. Shalala</u>, 512 U.S. 510, 512 (1994) (citing <u>Martin v.</u> <u>Occupational Safety and Health Review Comm'n</u>, 499 U.S. 144, 150-51 (1991)). The court's "task is not to decide which among several competing interpretations best serves the regulatory purpose. Rather, the agency's interpretation must be given 'controlling weight unless it is plainly erroneous or inconsistent with the regulation.'" <u>Id.</u> (quoting <u>Bowles v. Seminole Rock & Sand</u> <u>Co.</u>, 325 U.S. 410, 414 (1945)). "In other words, [courts] must defer to the Secretary's interpretation unless 'an alternative reading is compelled by the regulation's plain language or by

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other indications of the Secretary's intent at the time of the regulation's promulgation." <u>Id.</u> (quoting <u>Gardebring v. Jenkins</u>, 485 U.S. 415, 430 (1988)).

The Secretary points out that its interpretation of the regulations (set out in full at § I.A above) as demanding a contemporaneous written agreement is reasonable because the regulation consistently uses the present or future tense, and never the past tense. See 42 C.F.R. § 413.86(f)(4)(ii) (2002) ("The written agreement . . . must indicate that the hospital will incur [costs] while the resident is training in the nonhospital site and the hospital is providing reasonable compensation The agreement must indicate the compensation the hospital is providing to the nonhospital site.") (emphasis added). The Secretary again cites to Chestnut Hill, where the court considered this precise question and held that "[t]he Secretary's interpretation of the relevant regulations to require a contemporaneous written agreement . . . is reasonable and entitled to deference." 2006 WL 2380660, at *5. Plaintiff argues that the Chestnut Hill court did not have the benefit of a letter written in 2000 by Thomas Scully, then the Administrator of CMS, to Representative Charles Rangel. According to plaintiff, the Scully-Rangel letter demonstrates that the Secretary at one point interpreted the regulation to permit retroactive written agreements, but now appears to have modified his interpretation. Pl. Mem. at 40-42. The PRRB rejected that argument, finding that the letter did not demonstrate a prior, different interpretation by the Secretary. A.R. at 41.

To determine whether the PRRB's assessment of the Scully-Rangel letter is unreasonable requires an examination of the letter itself, which states in pertinent part:

A written agreement signed before the time the residents begin training at the non-hospital site indicates the hospital's ongoing commitment to incur the costs of training at that site. Written agreements that are retroactive for the time the residents began training at the non-hospital site do not demonstrate an ongoing commitment by that hospital to incur the training costs. The retroactive application of this provision would appear to be solely a vehicle to increase GME payments to the hospital for a period when training at the non-hospital location was already occurring without the hospital's facilitation or commitment to pay for the costs of that training. However, if [a] hospital can document that there was a commitment to incur the training costs before the time that the residents began training in the [non-hospital site], we would allow [the] hospital to count the training time of the . . . residents training in the [non-hospital site].

A.R. at 1926.

The Scully-Rangel letter cannot bear the weight plaintiff assigns it. Courts are rarely persuaded by isolated letters offered to demonstrate that an agency's actual interpretation of its regulations contradicts its publicly-stated interpretation of those regulations. <u>See Thomas</u> <u>Jefferson Univ.</u>, 512 U.S. at 515-16. Skepticism is warranted here as well. The Scully-Rangel letter appears to involve parties not now before this Court, and plaintiff has not argued that it relied on the letter in electing to submit a retroactive written agreement rather than a contemporaneous one. Plaintiff has not submitted other evidence showing that the Secretary has in fact permitted retroactive written agreements.⁴ And even if the final sentence of the above-quoted portion of the letter could be read as allowing retroactive written agreements in some narrow circumstances, the three preceding sentences amply demonstrate -- as the PRRB found, <u>see</u> A.R. at 41 -- that the Secretary interprets the regulations to require contemporaneous written

⁴ The administrative decisions in <u>Barnes Hospital v. Mutual of Omaha</u>, HCFA Adm'r Dec., Medicare & Medicaid Guide (CCH) ¶ 42,592 (July 5, 1994), and <u>Washington Hospital</u> <u>Center v. Mutual of Omaha</u>, HCFA Adm'r Dec., Medicare & Medicaid Guide (CCH) ¶ 36,850 (Feb. 4, 1988), are of little help to plaintiff. Those cases do not show a contrary agency practice with regard to the regulation at issue here. Rather, they involved different regulations requiring different kinds of written agreements for different aspects of Medicare reimbursement.

agreements.

In sum, the Secretary is entitled to substantial deference in construing his own regulations. <u>See Thomas Jefferson Univ.</u>, 512 U.S. at 512. Interpreting the regulations to require a contemporaneous agreement is consistent with the language of the regulation itself, as the <u>Chestnut Hill</u> court found as well. The Scully-Rangel letter does not demonstrate that the Secretary has changed his interpretation of the regulations because the letter does not establish that the Secretary did, in fact, previously interpret the regulations differently. Under <u>Thomas</u> <u>Jefferson University</u>, then, the Secretary's interpretation requiring a contemporaneous written agreement is reasonable and entitled to deference.

C. Contemporaneous Bylaws and Employment Agreements

Plaintiff also challenges the PRRB's determination that contemporaneous bylaws and employment agreements did not satisfy the written agreement requirement. See Am. Compl. ¶ 136(C). The PRRB found that the bylaws and employment agreements were insufficient to establish that residents' training in non-hospital settings was related to patient care and that the hospital incurred substantially all of the costs of the residents' training in the non-hospital setting. A.R. at 40-41. Plaintiff has provided no reason why the PRRB's decision was arbitrary or capricious, and indeed devotes but a single paragraph of its memorandum in support of its motion to this issue. See Pl. Mem. at 43-44. This Court, then, sees no reason to disturb the PRRB's decision on this point. This conclusion is underscored by the holding of <u>Chestnut Hill</u> that bylaws and employment agreements in that case were insufficient to satisfy the written agreement requirement as well. 2006 WL 2380660, at *5.

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D. Conclusion

The Court does not disturb the PRRB's conclusion that the Secretary was permitted to promulgate a written agreement requirement, that the Secretary's interpretation of the requirement to demand a contemporaneous agreement was reasonable, and that plaintiff's bylaws and employment agreements did not satisfy the written agreement requirement. On this issue, then, plaintiff's motion for summary judgment will be denied and the Secretary's motion for summary judgment will be granted.

II. Supplemental IME/GME Payments

Plaintiff contends that the Administrator's decision disallowing the additional IME and GME payment authorized by BBA '97 should be set aside for five reasons. See Am. Compl. ¶ 135(A)-(E). The Court will address each reason, albeit under a different organizational framework than the one proposed by plaintiff. First, the Court will examine whether plaintiff received adequate notice of the claims filing requirements for receiving the additional IME/GME payments. This inquiry requires an assessment both of the Secretary's method of providing notice and of whether plaintiff received notice as to the specific time frame within which submission of claims was required. Next, the Court will assess plaintiff's challenge under the Paperwork Reduction Act, 44 U.S.C. § 3501 et seq. As described above, the Court must apply the standard set forth in the APA, under which the Administrator's decision can be set aside only if it is "unsupported by substantial evidence," or "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A) and (E).

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A. Notice

1. Whether Plaintiff Received Notice That Claims for the Supplemental IME/GME Payments Were to be Submitted to the Fiscal Intermediary

Plaintiff asserts that it did not receive adequate notice that claims for the additional IME and GME payments authorized by BBA '97 were to be submitted directly to the fiscal intermediary. <u>See</u> Pl. Mem. at 20-24, 27-31. The statute itself did not set forth the claims filing requirement and the Secretary did not promulgate a final rule setting forth the filing requirement. Nonetheless, the Administrator determined that plaintiff received adequate notice through anticipatory language in a May 12, 1998 rule published in the Federal Register, a July 1, 1998 Program Memorandum, a July 13, 1998 Bulletin, and an August 20, 1998 letter from the fiscal intermediary to plaintiff. <u>See</u> A.R. at 11-12, 14-15. Upon review of those documents, the Court concludes that the Administrator's decision that plaintiff received notice of the claims filing requirement was supported by substantial evidence.

The May 12, 1998 rule stated the Secretary's "anticipation" that "teaching hospitals will need to submit claims associated with [Medicare HMO] discharges to the fiscal intermediaries for purposes of receiving [IME] and [GME] payments." 63 Fed. Reg. 26,318, 26,342. The rule went on to make clear that such claims were to be submitted twice -- once to the fiscal intermediary for reimbursement and once to the Medicare HMO for tracking purposes. <u>See id.</u> ("When the claims are processed, the fiscal intermediaries will make the IME payment associated with a [Medicare HMO] discharge directly to the teaching hospital. Teaching hospitals will also be required to submit bills associated with [Medicare HMOs] to the managed care plans. The inpatient encounter data from these bills will be submitted ... for purposes of implementing the

risk adjustment methodology."). Hence, the May 12 rule put plaintiff on notice that the Secretary intended to implement the filing requirements now at issue here.

Less than two months later, on July 1, 1998, the Secretary implemented the filing requirement through a Program Memorandum. See A.R. at 569-70. The Program Memorandum specifically addressed the additional payments for IME and GME authorized by BBA '97 and clearly stated that "hospitals must submit a claim to the hospitals' regular intermediary in UB-92 format." Id. at 569. On July 13, 1998, the Secretary issued Medicare Bulletin 416, which further addressed filing requirements for the additional IME payments. See id. at 521. The Bulletin did not address the filing requirement in the same, plain terms as the Program Memorandum and the May 12 rule. Rather, the Bulletin presumed the reader's familiarity with other terms used in the highly-specialized world of Medicare reimbursement. In any event, the Bulletin does not provide guidance conflicting with that clearly set forth in the Program Memorandum and the May 12 rule.

Finally, on August 20, 1998, the fiscal intermediary wrote to plaintiff in response to plaintiff's request for information about how the additional payment authorized by BBA '97 would be implemented. See A.R. at 517 (plaintiff's request for information); 519 (intermediary's response). The fiscal intermediary wrote that "[t]o bill for the IME supplemental payment, . . . hospitals must submit a claim to the hospital's regular intermediary in UB-92 format." Id. at 519. As for the GME payment, the fiscal intermediary wrote that it would "eventually be included with the interim payment currently employed" but that "a needed system enhancement is pending that would accumulate separately the inpatient days attributable to Medicare [HMOs]." Id.

Read together, these four documents -- the May 12 rule, the Program Memorandum, the

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Medicare Bulletin, and the August 20 letter -- support the Administrator's decision that plaintiff had notice that claims for the additional IME and GME payments authorized by BBA '97 were to be submitted directly to the fiscal intermediary, not to the Medicare HMO. The Program Memorandum clearly explains that "hospitals must submit a claim" for the additional IME/GME payments "to the hospitals' regular intermediary in UB-92 format." <u>See</u> A.R. at 569. Even though plaintiff can validly find some fault in the remaining three documents -- the language in the May 12 rule is merely anticipatory, the Medicare Bulletin is not explicit, and the August 20 letter only squarely addresses claims for IME payments -- those documents are consistent with the requirement plainly set forth in the Program Memorandum.

Plaintiff argues that a fifth document, a regulation issued on June 26, 1998, outlined a filing requirement that contradicted the guidance set forth in these four documents. <u>See</u> Pl. Mem. at 13. The regulation cited by plaintiff, 63 Fed. Reg. 34,968, dealt with the establishment of Medicare HMOs as part of BBA '97 and required Medicare HMOs to submit encounter data to CMS (through fiscal intermediaries). <u>Id.</u> at 35,006, 35,092. But the June 26 regulation does not address the additional IME or GME payments authorized by BBA '97. In the face of the clear guidance in the Program Memorandum specifically addressing the filing requirements for those payments, the Secretary reasonably concluded that the June 26 rule was not contradictory as to billing for the additional IME/GME payments.

The APA standard of review only permits the Administrator's decision to be reversed if it is "unsupported by substantial evidence," or is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A) and (E). Here, the Administrator determined that the Program Memorandum and other guidance outlined above provided plaintiff

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with notice of the filing requirement for the additional IME and GME payments authorized by BBA '97. <u>See</u> A.R. at 11-12, 14-15. That determination is supported by substantial evidence and hence the Administrator's conclusion that plaintiff had notice of the filing requirement must stand.

2. Whether the Method of Providing Notice Was Adequate

The next question is whether the Administrator acted arbitrarily or capriciously in deciding that the Secretary's method of providing notice was adequate. The Administrator determined "that the APA does not require CMS to publish a new regulation under these circumstances. CMS is allowed to promulgate interpretive rules and guidance." A.R. at 15. The general proposition underlying the Administrator's conclusion is straightforward -- the Secretary is not required to promulgate interpretive rules through notice and comment rulemaking. See Monmouth Medical Ctr. v. Thompson, 257 F.3d 807, 814 & n.2 (D.C. Cir. 2001). But the parties dispute whether notice and comment rulemaking is required for an interpretive rule replacing a previous interpretive rule. Plaintiff argues that it is, relying on cases like Monmouth. See Pl. Mem. at 23. As the Secretary points out, however, a recent case has clarified that a change to a prior interpretive rule only requires notice and comment rulemaking when parties relied on the prior interpretation substantially and justifiably. See MetWest Inc. v. Sec'y of Labor, 560 F.3d 506, 510-11 (D.C. Cir. 2009). Resolution of this legal issue is unnecessary here because plaintiff has failed to make an adequate showing as to a threshold matter: that the filing requirement (as set forth in the Program Memorandum) is a change to a prior interpretive rule.

As discussed in greater detail in § II.A.3 below, the Administrator determined that the filing requirements set out in the Program Memorandum also required plaintiff to comply with

time limits for filing claims set forth in 42 C.F.R. § 424.30 <u>et seq.</u> See A.R. at 15-16. To establish that the Secretary previously interpreted the applicable regulations differently, plaintiff points to <u>Saint Anthony's Health Center v. BlueCross BlueShield Ass'n/AdminaStar Federal</u> <u>Illinois</u>, CMS Adm'r Dec., Medicare & Medicaid Guide (CCH) ¶ 81,547 (July 19, 2006). <u>See</u> Pl. Mem. at 23. In <u>Saint Anthony's</u>, the Administrator determined that § 424.30 did not apply to services for which "an HMO company is responsible for paying the claim." <u>Id.</u> But that interpretation is not inconsistent with the one applied by the Administrator here. HMO companies are not "responsible for paying" the additional IME/GME payments authorized by BBA '97. As discussed earlier, §§ 4622 and 4624 of BBA '97 directed the <u>Secretary</u>, not the HMO, to make those payments.

Without a prior contrary interpretation, the general proposition that interpretive rules may be promulgated informally applies. <u>See Monmouth</u>, 257 F.3d at 814. The Administrator's decision that the Program Memorandum was a validly-issued interpretive rule, then, was not arbitrary or capricious.

3. Whether Plaintiff Received Notice of Time Limits

The final issue regarding notice is whether plaintiff had notice that it was required to file claims for the additional IME/GME payments within a specific time frame. If plaintiff did have notice of the deadline for filing, then certain other arguments it raises -- like its argument that the fiscal intermediary disregarded the best available evidence in denying plaintiff the additional IME/GME payments -- may fall flat. On the other hand, those arguments carry greater weight if plaintiff did <u>not</u> have notice of the time frames for filing claims directly with the intermediary.

The Administrator determined that the time limits set out in 42 C.F.R. §§ 424.30 and

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424.44 applied. A.R. at 15-16. The Administrator did not point to any rule or informal notice that explicitly incorporated the time limits from that regulation. Rather, the Administrator explained that:

The only exception to the claims processing requirements at 42 C.F.R. § 424.30 is for services furnished on a prepaid capitation basis to the beneficiary by a managed care plan, which is not at issue here. The claims in the instant case were claims for an established reimbursement methodology for hospitals' costs associated with being a teaching hospital and not for the services furnished to a managed care enrollees [sic].

A.R. at 15-16. Plaintiff does not contend (nor can it) that it met the § 424.44 time limits, which require claims to be filed "(1) [o]n or before December 31 of the following year for services that were furnished during the first 9 months of a calendar year; and (2) [o]n or before December 31 of the second following year for services that were furnished during the last 3 months of the calendar year." 42 C.F.R. § 424.44. Nonetheless, plaintiff avers that it did submit encounter data directly to the fiscal intermediary, albeit it well beyond the § 424.44 time limits. <u>See</u> Am. Compl. ¶ 92, 98, 102.

To determine whether the Administrator's decision was arbitrary or capricious, the Court may assess "solely . . . the grounds invoked by the agency," and may not consider counsel's post hoc explanations. <u>Clark County, Nevada v. FAA</u>, 522 F.3d 437, 448 (D.C. Cir. 2008) (quoting <u>SEC v. Chenery</u>, 332 U.S. 194, 196 (1947)). Here, in deciding that the time limits from 42 C.F.R. § 424.44 apply to claims for the additional IME/GME payment, the Administrator did not explain his reasoning in sufficient detail to permit the Court to test his conclusion.

At least three aspects of the Administrator's decision were too conclusory to permit the review this Court must undertake. First, the Administrator did not explain why the exception to

§ 424.30 was inapplicable. The PRRB had determined that §§ 424.30 and 424.44 did not apply to claims for the additional IME/GME payments, see A.R. at 36-37, because those time limits do not apply "when services are furnished on a prepaid capitation basis by a [Medicare HMO]," see § 424.30. In reversing the PRRB, the Administrator stated simply that the exception "is not at issue here." A.R. at 15. Next, the Administrator characterized the claims -- without explanation -- as being "for an established reimbursement methodology for hospitals' costs associated with being a teaching hospital and not for the services furnished to a managed care enrollees [sic]." But this characterization is debatable and merits at least some discussion. Indeed, the additional IME/GME payment authorized by BBA '97 was designed to reimburse teaching hospitals for the costs of graduate medical education incurred while furnishing services to managed care enrollees. Finally, the Administrator appears to have assumed that the claims for the additional IME/GME payments fell under Medicare part A. See A.R. at 12-13. But, as the briefing demonstrates, there is a legitimate debate as to whether these payments fall under Medicare part A or part C. Compare Def. Opp. at 38-40 (arguing that the payments fall under Medicare part A) and Def. Rep. at 14-18 (same), with Pl. Rep. at 23-26 (arguing that the payments fall under Medicare part C) and Pl. Sur. at 1-5 (same).

On this record, the Court cannot determine whether the Administrator's decision that the time limits from 42 C.F.R. §§ 424.30 and 424.44 applied should be left undisturbed. The appropriate remedy in this situation is a remand for further explanation. <u>See Florida Power & Light Co. v. Lorion</u>, 470 U.S. 729, 744 (1985) (holding that "if the reviewing court simply cannot evaluate the challenged agency action on the basis of the record before it, the proper course . . . is to remand to the agency for additional . . . explanation"); <u>Tourus Records, Inc. v. DEA</u>, 259 F.3d

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731, 737 (D.C. Cir. 2001) (same). Accordingly, this issue will be remanded to the Secretary for further explanation as to whether the time limits from 42 C.F.R. §§ 424.30 and 424.44 apply, and if so, why.

B. Plaintiff's Claims Under the Paperwork Reduction Act

The final issue concerns plaintiff's claims under the Paperwork Reduction Act, 44 U.S.C. § 3501 <u>et seq.</u> ("PRA"). Although raised before the Administrator, <u>see</u> A.R. at 104-06, the Administrator did not address these claims in his written decision. Nonetheless, in their crossmotions for summary judgment, the parties devote considerable attention to the issue. When the Administrator fails to address a potentially meritorious claim, the appropriate remedy is remand for further explanation. <u>See Florida Power</u>, 470 U.S. at 744. Therefore, the Court does not decide this issue in the first instance here. The discussion below, then, is only intended to demonstrate that plaintiff's claims under the PRA are sufficiently colorable to have warranted examination by the Administrator.

The public protection provision of the PRA provides that "no person shall be subject to any penalty for failing to comply with a collection of information . . . if the collection of information does not display a valid control number assigned by the Director in accordance with this subchapter." 44 U.S.C. § 3512(a). A "penalty" is defined to include the denial of a benefit, § 3502(14), and a "collection of information" includes "obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public, of facts or opinions by or for an agency," § 3502(3). Denying reimbursement for failure to provide claims information to the fiscal intermediary would seem to fall within the scope of the public protection provision.

The Secretary argues that the collection of information at issue here is valid. The UB-92

claims forms bear a control number indicating approval by the Office of Management and Budget, the argument goes, so the public protection provision of the PRA does not apply. <u>See</u> Def. Rep. at 21-22. But this conclusion is not inescapable because the claims filing requirement at issue here was a <u>new</u> use of the UB-92 form. Issuance of control numbers is governed by § 3507, and § 3507(h) applies when an agency "decides to seek extension of the Director's approval granted for a currently approved collection of information." Under § 3507(h), the agency must conduct an extensive review, which includes seeking public comment, to extend the use of a previously-approved collection of information. Indeed, that is the practice the Secretary appears to have followed when seeking to extend the use of the UB-92 forms to other collections of information. <u>See, e.g.</u>, 63 Fed. Reg. 34,903 (June 26, 1998) (seeking public comment for extension of UB-92 to a new collection of information).

The Secretary opposes plaintiff's PRA claims on two other grounds. First, the Secretary argues that he has general authority to require the filing of paperwork under 42 U.S.C. § 1395g(a), so he is not required to follow the strictures of the PRA in issuing the claims filing requirement at issue here. See Def. Opp. at 41-44. But that argument may prove too much -- if the Secretary may ignore the requirements of the PRA, then the PRA may be quite toothless. Second, the Secretary contends that the PRA does not apply when information is collected pursuant to an investigation or audit. See Def. Opp. at 42 (citing § 3518(c)). But here the filing requirement is not a collection of information assembled pursuant to an investigation or audit. Rather, it is generally applicable -- any teaching hospital seeking the additional IME/GME payments authorized by BBA '97 is required to comply with it.

These arguments merit further development and should have been addressed in the first

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instance by the Administrator. Hence, plaintiff's claims under the PRA will be remanded to the Secretary for further explanation and decision.

CONCLUSION

In sum, with respect to the Administrator's decision that plaintiff did not comply with the validly-issued written agreement requirement, the Secretary's motion for summary judgment will be granted and plaintiff's motion for summary judgment will be denied. As to the Administrator's decision that plaintiff did not comply with claims filing requirements in order to receive the supplemental IME and GME payments authorized by BBA '97, each party's motion will be granted in part and denied in part. The Administrator's decision that plaintiff had notice that claims were to be submitted to the fiscal intermediary, and that notice and comment rulemaking was unnecessary for this kind of interpretive rule, was supported by substantial evidence and was not arbitrary or capricious. But the Administrator did not provide an adequate explanation as to why plaintiff had sufficient notice as to the <u>time limits</u> for filing claims. Nor did the Administrator address plaintiff's claims under the PRA, which are sufficiently colorable to have warranted explanation. Accordingly, this case shall be remanded to the Secretary for resolution of these issues. A separate Order accompanies this opinion.

SO ORDERED.

/s/ John D. Bates JOHN D. BATES United States District Judge

Date: July 7, 2009