UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNIVERSITY MEDICAL CENTER, INC.,

Plaintiff,

v.

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

Defendant.

Civil Action No. 11-260 (JDB)

MEMORANDUM OPINION

The Secretary of the Department of Health and Human Services is responsible for administering Medicare. Plaintiff is a teaching hospital in Louisville, Kentucky that seeks judicial review of the Secretary's denial of certain payments associated with services plaintiff provided to Medicare recipients in 1999. The requested payments are for the cost of training plaintiff's dental residents off-site at the University of Louisville's dental school.

According to HHS regulations, hospitals seeking payment for the cost of training residents off-site must have a written agreement with the off-site provider that the hospital will incur substantially all of the costs of that training. Plaintiff executed such an agreement with the University of Louisville on December 20, 1999. The agreement indicated that plaintiff would incur substantially all dental resident training costs retroactively to January 1, 1999. The Secretary determined, however, that the HHS regulations required written agreements between hospitals and off-site providers that are entered into prior to the occurrence of off-site training. The Secretary therefore denied plaintiff medical education payments for training costs from the

beginning of the year until the execution of the agreement on December 20, 1999. Plaintiff now argues that the regulation cannot be interpreted to require written agreements entered into prior to the occurrence of off-site training and that the Secretary failed to provide adequate notice of that requirement. Plaintiff further argues that both the written agreement requirement itself and the requirement that written agreements be in place before off-site training occurs are inconsistent with the Medicare statute.

Now before the Court are the parties' cross-motions for summary judgment. For the reasons described below, the Court concludes that plaintiff received adequate notice of the requirement to enter into written agreements prior to the occurrence of off-site training time. The Court also concludes that interpreting the regulation to contain such a requirement was reasonable and that the requirement, as well as the underlying written agreement requirement, were consistent with the statute. Accordingly, the Secretary appropriately denied plaintiff's claims, and the Court will grant the Secretary's motion for summary judgment and deny plaintiff's motion.

I. Statutory and Regulatory Background

A. Medicare and Medical Education Payments

The Secretary of the Department of Health and Human Services, through the Centers for Medicare and Medicaid Services ("CMS" or "Administrator"), administers the Medicare statute, Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. The Medicare program is divided into several parts, of which Part A is relevant here. Part A covers "inpatient hospital services" furnished to Medicare beneficiaries by participating providers, such as hospitals. 42 U.S.C. § 1395d(a)(1). CMS itself is directly responsible for the costs of Part A services. Id. To

coordinate billing by and payment to hospitals, Medicare contracts with fiscal intermediaries (usually private insurance companies) pursuant to 42 U.S.C. § 1395h.[1]

Health care providers submit claims to fiscal intermediaries for services provided to Medicare Part A patients and these claims are 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 reimbursements due. See 42 C.F.R. § 405.1803. The fiscal intermediary makes a final determination on payments due to providers, which is appealable to the Provider Reimbursement Review Board ("PRRB" or "Board"). 42 U.S.C. § 1395oo(a). The PRRB's decision is subject to further review by the CMS Administrator, and a provider may seek review of the Administrator's decision in federal district court. See 42 U.S.C. § 1395oo(f).

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 higher-than-average operating costs. See 42 U.S.C. §§ 1395f(b), 1395ww(d). Medicare makes a payment for each Medicare beneficiary discharged by a hospital. See 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 — i.e., 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 Medicare

[1] The Court will refer interchangeably to "Medicare," "the Secretary," "HHS," "CMS," and "the Administrator," since nothing hinges on the distinction between these labels.

beneficiaries. 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 enrollees 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 enrollees receiving services from a hospital.

B. Training in Non-Hospital Settings

Under revisions made to the Medicare statute in 1986, for the purpose of counting the number of residents a hospital includes in its GME payment calculation, hospitals may include residents training in non-hospital settings, such as a physician's office, clinic, or nursing home. See Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9314, 100 Stat. 1874 (codified at 42 U.S.C. §§ 1395ww(h)(4)(E)). Under the statute, the time residents spend in non-hospital settings is included if (1) their time is related to patient care and (2) the hospital incurs all or substantially all of the costs of their training in the non-hospital setting. Id. This statutory provision applied to resident training programs effective July 1, 1987. Id. In September 1989, the Secretary promulgated a regulation implementing this provision. See 54 Fed. Reg. 40,286, 40,288 (Sept. 29, 1989). In addition to the statutory requirements, the regulation imposed an additional requirement that, in order for hospitals to count resident training time at non-hospital sites, the hospital must have a written agreement with the non-hospital site establishing that the costs of the residents' training is to be paid by the hospital. See id. at 40,317 (codified at 42 C.F.R. § 413.86(f)(1)(iii)).

In 1997, Congress amended the Medicare statute to also include the time residents spend training in non-hospital settings in IME payment calculations, effective October 1, 1997. See Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4621(b)(2), 111 Stat. 251 (codified at 42

U.S.C. § 1395ww(d)(5)(B)(iv)). HHS then promulgated a regulation implementing this revision, incorporating the same requirement for a written agreement between hospitals and non-hospital sites that had previously applied with respect to counting time in non-hospital settings for GME payments. See 62 Fed. Reg. 45,966, 46,003, 46,029 (Aug. 29, 1997) (codified at 42 C.F.R. § 412.105(f)(1)(ii)(C)).

In July 1998, the Secretary revised the regulation governing the counting of time residents spend training in non-hospital sites. See 63 Fed. Reg. 40,954, 40,986-98 (July 31, 1998). The regulation, as revised, now defined the statutory requirement that a hospital incur all or substantially all of the costs of off-site resident training. Id. at 41,005. In particular, the new definition required hospitals to incur "the portion of the cost of teaching physicians' salaries and fringe benefits attributable to direct graduate medical education," in addition to the residents' salaries and fringe benefits. Id. (emphasis added). The revised regulation accordingly expanded the requirements for the written agreement between hospitals and non-hospitals sites to ensure that the written agreement specified that the hospital would pay compensation for "supervisory teaching activities," in addition to resident salaries and benefits. See id. at 40,986-97, 41,004-05 (codified at 42 C.F.R. § 413.86(f)(4) and amending cross-reference in 42 C.F.R. § 412.105(f)(1)(ii)(C)); see also Administrative Record ("A.R.") at 229. The revised regulation was made effective for portions of cost reporting periods occurring on or after January 1, 1999. Id.[2] The primary question in this case is whether hospitals and non-hospital sites were required under the regulation to have written agreements already in place when off-site training occurred

[2] The Secretary made a further, technical revision to 42 C.F.R. § 413.86(f)(4) in July 1999 to ensure that the regulation included the statutory requirement that the hospital actually incur all, or substantially all, the cost of resident training; the iteration of the rule promulgated in 1998 required hospitals to have written agreements that they "will incur" the costs of training in the non-hospital setting, but did not state that the hospitals had to actually incur the costs. See 64 Fed. Reg. 41,490, 41,517, 41,542 (July 30, 1999) (codified at 42 C.F.R. § 413.86(f)(4)(iii)). It is not contested here that plaintiff did incur the costs of training at the University, so this change is not relevant.

— that is, whether there was a requirement to have a "contemporaneous written agreement" entered into "prospectively" (before training occurred).

In addition to the regulation itself, the parties have focused on two contemporaneous statements from HHS about the written agreement requirement. First, the parties focus on an exchange between HHS and a commenter in the preamble accompanying the promulgation of the 1998 revision to the regulation. The preamble stated:

> One commenter noted that some arrangements between hospitals and nonhospital settings for the training of residents predate the GME base year. This commenter stated that hospitals did not compensate nonhospital sites for supervisory teaching physician costs and it would not be fair to shift these costs to teaching hospitals. The commenter also stated that teaching hospitals have already entered into written agreements with nonhospital sites under the existing rules. According to the commenter, the proposed rule would necessitate renegotiation of thousands of agreements, imposing tremendous transaction costs upon the academic medical community. The commenter noted that if the agreements are not renegotiated prior to the effective date, the hospital will be unable to count the residents for direct and indirect GME, and this will have a lasting effect because of the 3 year averaging rules.

63 Fed. Reg. at 40,994-95. HHS responded:

> The GME provisions of this final rule will be effective January 1, 1999. All other provisions of this final rule are effective October 1, 1998. By making a later effective date for the GME provisions, hospitals and nonhospital sites will have 5 months following publication of this final rule to negotiate agreements that will allow hospitals to continue counting residents training in nonhospital sites for indirect and direct GME. These agreements are related solely to financial arrangements for training in nonhospital sites. We do not believe that the agreements regarding these financial transactions will necessitate changes in the placement and training of residents.

Id. at 40,995. Second, the parties focus on a letter sent by the Administrator to the Association of American Medical Colleges ("AAMC") in February 1999. The letter first indicated that the Administrator was responding to the AAMC's request that the Administrator "delay the effective date of new criteria for graduate medical education (GME)." A.R. at 229. The letter then

summarized the change in the regulation regarding written agreements. Id. The letter concluded:

> We did not receive any comments [in the notice-and-comment process] requesting a postponement of the effective date. The provisions of the regulation other than GME were effective October 1, 1998. We specifically made the provisions affecting GME effective January 1, 1999 in order to provide hospitals and nonhospital sites with more time to make revisions to written agreements.
>
> Based on concerns brought to our attention, we issued a Program Memorandum on November 20, 1998 (enclosed) that further details our policies with regard to Medicare payment for training in nonhospital sites. While the written agreements did not need to be sent to the fiscal intermediaries prior to January 1, 1999, they must cover the period beginning January 1, 1999, and be retained as supporting documentation for residents included in hospital indirect and direct GME counts for cost reports which end in 1999 and subsequent years.

Id. at 229-30. These statements are discussed in detail below.

II. Background and Prior Proceedings

A. Plaintiff's Case

Plaintiff is a not-for-profit corporation that does business as the University of Louisville Hospital, a teaching hospital in Louisville, Kentucky. A.R. at 26. Since 1996, plaintiff and the University of Louisville ("University") have been parties to an affiliation agreement, under which plaintiff serves as the principal teaching hospital of the University. Id. Pursuant to this agreement, plaintiff works with the University's dental school to train oral surgery and dental general practice residents in the dental school's graduate medical education programs. Id. In December 1999, plaintiff and the University signed an agreement regarding the costs of training dental residents, including the costs of dental resident compensation and supervisory teaching activities. Id. Although the agreement was executed (that is, all signatures were entered) on December 20, 1999, the agreement bore an earlier effective date of January 1, 1999. See id. at 26-27.

Plaintiff incurred all or substantially all of the costs of the dental residents' training during 1999 and the dental residents were engaged in patient care activities during this time. A.R. at 27. However, plaintiff's fiscal intermediary determined that the agreement between plaintiff and the University did not go into effect until it was signed and that therefore plaintiff did not meet the written agreement requirement until the agreement was executed on December 20, 1999. Id. at 26. Accordingly, in computing GME and IME payment amounts, the intermediary counted only the time spent in training by dental residents from December 20, 1999 to December 31, 1999, the end of the cost reporting period, and not the training time for the rest of the year. This decision resulted in plaintiff receiving approximately $122,000 less in reimbursement. Id. at 27.

Plaintiff appealed the intermediary's decision to the Provider Reimbursement Review Board. Plaintiff contended that the intermediary's exclusion of the resident training time was improper for several reasons. Plaintiff argued that the written agreement requirement is inconsistent with the Medicare statute, which does not itself require a written agreement. A.R. at 28. Plaintiff disputed the intermediary's interpretation of the regulation as requiring a written agreement to be entered into before the hospital may begin to count residents training at the non-hospital site. Id. at 27-28. Plaintiff argued that in situations in which CMS required a prospectively executed written agreement, it explicitly stated the requirement in the regulations, while the regulation here did not state such a requirement. Id. at 28-29. Plaintiff noted that when CMS implemented the written agreement requirement in 1989, the rule was made effective to training occurring on or after July 1, 1987, thereby permitting retroactive agreements, and CMS did not mention the date of execution when later amending the regulations. Id. at 29. Plaintiff further contended that requiring a prospectively executed agreement was inconsistent

with the Administrator's statement in the February 1999 letter to the AAMC. Id. Plaintiff acknowledged that the Board and the Administrator had previously disallowed payments for residents training in non-provider settings when there was not an adequate written agreement between the provider and the training site, but argued that those decisions were distinguishable because the only factor at issue here is the timing of the execution of the written agreement. Id. at 29-30. Finally, plaintiff contended that the intermediary's refusal to accept the written agreement conflicts with contract law principles permitting a contract to be retroactive. Id. at 30.

The Board agreed with plaintiff that the intermediary's determination was improper because it excluded resident time that met all the statutory and regulatory requirements. A.R. at 30. The Board found that "the plain language of the regulation is silent as to the issue of the timing of execution of the written agreement and does not prohibit retroactive written agreements." Id. at 32. The Board concluded that when CMS first implemented the written agreement requirement in 1989, CMS intended to permit retroactive agreements because the rule was made effective retroactively to July 1, 1987. Id. The Board found that the purpose of the written agreement was to ensure that the hospitals actually incurred the costs of the programs in the non-provider settings and that, when CMS amended the regulations, "the focus of the regulatory revisions was on the actual payment of costs by the hospitals . . . not on the timing of the execution of the agreement." Id. The Board determined that permitting written agreements between hospitals and non-hospital sites to have retroactive effect was consistent with the Administrator's letter to the AAMC, as well as CMS policy in analogous situations, and that where CMS has required a prospectively executed written agreement, it had done so explicitly in the plain language of the regulations. Id. The Board also found that allowing parties to a contract to predate the contract was consistent with contract law. Id. at 33.

The intermediary appealed to the Administrator pursuant to 42 U.S.C. § 1395oo(f). The Administrator overruled the Board, concluding that, in order to count the time that residents spend in a non-hospital setting, plaintiff must "have a contemporaneous written agreement in effect at the time the residents rotate through the clinics." A.R. at 9. The Administrator concluded that the "plain language of the regulation" required such an agreement. Id. at 10; see also id. at 7. The Administrator also determined that a "prospective requirement that a written agreement be in place" is consistent with the Secretary's response to the commenter in the preamble to the July 31, 1998 final rule. Id. at 9-10. Finally, the Administrator concluded that "[c]ontemporaneous verifiable documentation is a basic and long-standing principle in Medicare law and a policy that is consistent with the Secretary's responsibilities to ensure the proper expenditure of Trust fund monies." Id. at 10.

b. Related Cases Before This Court and the D.C. Circuit

There has been, to say the least, no shortage of cases involving Medicare payments to hospitals for medical education expenses. This Court and the D.C. Circuit considered the Secretary's denial of IME/GME payments under somewhat different cirumstances in Loma Linda Univ. Med. Ctr. v. Sebelius, 408 Fed. Appx. 383 (D.C. Cir. 2010); Cottage Health Sys. v. Sebelius, 631 F. Supp. 2d 80 (D.D.C. 2009); and Hosp. of Univ. of Penn. v. Sebelius, 2012 WL 928282 (Mar. 20, 2012) ("HUP"). Those cases pertained to supplemental IME/GME payments associated with a subset of Medicare patients to whom hospitals provided services — those to whom services were furnished under Medicare Part C. See HUP, 2012 WL 928282, at *1-3.[3] Accordingly, the regulations at issue in those three cases, 42 C.F.R. § 424.30 et seq., are not implicated in the present case. HUP and Loma Linda concluded that the Secretary could not

[3] Under Medicare Part C, beneficiaries receive Medicare benefits through private health insurance plans, which receive payment in advance from CMS for each enrollee and are then responsible for the costs of the enrollees' services. See HUP, 2012 WL 928282, at *2.

withhold supplemental medical education payments from the respective plaintiffs in those cases because CMS had not provided adequate notice of its interpretation of those regulations. See Loma Linda, 408 Fed. Appx. 383; HUP, 2012 WL 928282, at *17. This Court's determination on that issue with respect to the Cottage Health plaintiff is still pending.

In addition to the issue involving medical education payments associated with Medicare Part C patients, Cottage Health also raised an issue important here: the Secretary's denial of IME/GME payments for residents training at non-hospital sites due to the absence of a contemporaneous written agreement. Cottage Health challenged the Secretary's decision not to count its off-site resident training time on three grounds. See 631 F. Supp. 2d at 91. First, Cottage Health argued that the statute governing time spent by residents in non-hospital settings did not permit the Secretary to promulgate regulations requiring a written agreement. Id. The Court rejected this argument, concluding that "the statute itself does not speak to the precise question at issue" and that "the Secretary's interpretation of the statute to permit the promulgation of a written agreement requirement is reasonable and entitled to deference." Id. at 92-93. In reaching this determination, the Court relied substantially on Chestnut Hill Hosp. v. Thompson, 2006 WL 2380660 (D.D.C. Aug. 15, 2006), in which a judge of this district reached the same conclusion. Second, after its fiscal intermediary determined that Cottage Health had not entered into adequate written agreements with its off-site providers during the fiscal years in question, Cottage Health thereafter entered into "memoranda of understanding" with the non-hospital sites that "memorialized the terms of its pre-existing agreement." 631 F. Supp. 2d at 86-87. Cottage Health argued that the intermediary's refusal to accept these post-dated memoranda conflicted with the plain language and intent of the regulation. Id. at 91. The Court also rejected this argument, concluding that "the Secretary's interpretation requiring a contemporaneous written

agreement is reasonable and entitled to deference." Id. at 93-94. Third, Cottage Health argued that the agency's determination that Cottage Health's contemporaneous documentation — in the form of bylaws and employment agreements — did not satisfy the written agreement requirement was not supported by substantial evidence. Id. at 91, 94-95. The Court upheld the agency's determination that the contemporaneous documentation did not meet the written agreement requirement. Id. at 95.

III. Summary Judgment Standard

Under Federal Rule of Civil Procedure 56(c), 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 Procedures 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. See N.C. Fisheries Ass'n v. Gutierrez, 518 F. Supp. 2d 62, 79 (D.D.C. 2007). 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." See Occidental Eng'g Co. v. INS, 753 F.2d 766, 769-70 (9th Cir. 1985). 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. See Richards v. INS, 554 F.2d 1173, 1177 & n. 28 (D.C. Cir. 1977), cited in Bloch v. Powell, 227 F. Supp. 2d 25, 31 (D.D.C. 2002), aff'd, 348 F.3d 1060 (D.C. Cir. 2003).

Under the APA, a court may vacate an agency decision if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or if it is "unsupported by substantial evidence." 5 U.S.C. §§ 706(2)(A), (E). Agency actions are entitled to much deference, and the standard of review is narrow. See Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971). The reviewing court is not permitted to substitute its judgment for that of the agency. See id. That is, it is not enough for the agency decision to be incorrect — as long as the agency decision has some rational basis, the court is bound to uphold it. See id. The court may only review the agency action to determine "whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." Id. 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).

IV. Discussion

Plaintiff challenges the Secretary's denial of these medical education payments on three grounds. First, plaintiff argues that the written agreement requirement violates the Medicare statute. Plaintiff contends both that the underlying regulation requiring a written agreement offends the statute and that the requirement that the agreement be in place before training occurs offends the statute. The Court determines that neither requirement violates the statute. Second, plaintiff argues that the requirement that the written agreement be contemporaneous to training is contrary to the regulation that implements the written agreement requirements, 42 C.F.R. § 413.86(f)(4). The Court concludes that the Secretary's interpretation of 42 C.F.R. § 413.86(f)(4) is not plainly erroneous or inconsistent with the regulation. Third, plaintiff argues that the Secretary's denial of payment was improper because the Secretary did not provide adequate

notice of the contemporaneous written agreement requirement. The Court finds that the Secretary provided adequate notice to hospitals of this requirement.

A. The Medicare Statute and the Written Agreement Requirement

1. Parties' Arguments

Plaintiff's argument regarding the written agreement rule's consistency with the statute has evolved somewhat over the course of its briefing. Plaintiff first argued that the requirement that the written agreement be in place before training occurs violates the plain language and intent of the statute by excluding residents' training time in non-provider settings even where the two statutory conditions — that resident training time is related to patient care and that the hospital incurs substantially all of the costs — are met. See Mem. of P & A. in Supp. of Pl.'s Mot. for Summ. J. [Docket Entry 15] ("Pl.'s Mem.") at 31. Plaintiff thus initially contended that the requirement that the written agreement be contemporaneous (in place when training occurred) distinguished this case from the decision in Cottage Health, which held that the underlying written agreement requirement is consistent with the statute. See id. at 33-35. Plaintiff argued that the requirement to execute a written agreement before training occurs "is entirely divorced from the statutory requirement that a hospital must incur the cost of the training and runs precisely counter to the statutory objective to require the Secretary to reimburse hospitals for those costs when they are incurred by hospitals." Id. at 34. Likewise, plaintiff claimed that, unlike in Cottage Health, here plaintiff executed a written agreement during the fiscal year at issue, fulfilling the purpose of the written agreement requirement — assisting intermediaries in assuring that hospitals met the statutory requirements. Id. at 36-37. However, in further briefing on the matter, plaintiff now argues that the underlying written agreement requirement is itself contrary to the statute, recognizing that this argument conflicts directly with

Cottage Health. See Mem. of P. & A. in Opp'n to Def.'s Mot. for Summ. J. and Reply in Further Supp. of Pl.'s Mot. for Summ. J. [Docket Entry 18] ("Pl.'s Reply") at 21-28. Plaintiff asserts that the Secretary has authority to adopt documentation requirements that are reasonably related to the statute's purpose, but not rules that violate the text and purpose of the statute. Id. at 23-25. Plaintiff argues that the written agreement violates the text and purpose of the statute by imposing an "additional precondition" on payment not contemplated by Congress. Id. at 24, 26-28. Hence, plaintiff initially argued that the requirement that the written agreement be contemporaneous was contrary to the statute, then shifted its challenge to the written agreement requirement altogether. Since plaintiff has not explicitly abandoned either argument, the Court will consider them both.

The Secretary argues that the written agreement requirement is valid because the Secretary has authority to require documentation from hospitals to determine compliance with the two statutory requirements. See Mem. of P. & A. in Supp. of Def.'s Mot. for Summ. J. and Opp'n to Pl.'s Mot. for Summ. J. [Docket Entry 16] ("Def.'s Mem.") at 13-15. The Secretary relies on Cottage Health and other cases that have determined that the Secretary may promulgate such rules to implement the Medicare statute. See id. at 15-18. The Secretary maintains that the requirement that the written agreement be contemporaneous with resident training is reasonable "[t]o avoid a complicated and protracted dispute after the fact about who had incurred all the costs, and to avoid situations where neither entity would actually incur all the costs," as well as "to ensure that double payment is not made." Id. at 23-24.

2. Legal Standard

A court should review an agency's interpretation of a statute under the familiar two-step analysis outlined in Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc., 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." Id. at 842-43; State of New Jersey v. EPA, 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." Chevron, 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." Pauley v. BethEnergy Mines, Inc., 501 U.S. 680, 702 (1991) (citations omitted).

3. Analysis

The Court is not persuaded by either of plaintiff's arguments regarding the written agreement requirement — that is, either that the written agreement requirement itself is contrary to the statute or that the requirement that the written agreement be in place before residents undergo off-site training is contrary to the statute. As the Secretary notes, the argument that the written agreement requirement is contrary to the statute has already been rejected by this Court, another judge in this district, the Sixth Circuit, and arguably the Eighth Circuit. See Covenant Med. Ctr. v. Sebelius, 424 Fed. Appx. 434, 438-39 (6th Cir. 2011); Cottage Health, 631 F. Supp. 2d at 92-93; Chestnut Hill, 2006 WL 2380660, at *4; see also Medcenter One Health Sys. v. Sebelius, 635 F.3d 348, 350 (8th Cir. 2011) (applying written agreement requirement because "Congress has given HHS authority to determine the adequacy of reimbursement documentation"). Plaintiff's main argument — that the written agreement requirement is an inappropriate additional condition on payment beyond the two conditions articulated in the statute — was considered and rejected by this Court in Cottage Health. The Court now rejects

the argument again for the same reasons: "the Secretary's interpretation is plainly reasonable [because] . . . 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 the training program in that setting. Moreover, . . . to disallow the written agreement requirement would foreclose the application of any of a host of requirements imposed by the Secretary to ensure the orderly administration of the Medicare program." Cottage Health, 631 F. Supp. 2d at 92 (internal marks and citation omitted).

The only new argument offered by plaintiff is that the Secretary has herself modified the written requirement in a 2004 rulemaking. See Pl.'s Reply. at 24-25. But that the Secretary chose to alter the requirement does not mean that the initial regulation was improper. The Secretary in 2004 merely concluded that it would be "less burdensome" and "more appropriate" to focus on the two statutory requirements, rather than requiring the administrative tool of a written agreement in every case. 69 Fed. Reg. 48,916, 49,179 (Aug. 11, 2004). The Secretary hardly stated that the rescinded written agreement requirement was wrong or inappropriate. Within the zone of deference afforded at the second step of the Chevron doctrine, the Secretary is entitled to change her mind about a regulatory requirement without that indicating that the old requirement was unreasonable or violated the statute. The Supreme Court "has rejected the argument that an agency's interpretation 'is not entitled to deference because it represents a sharp break with prior interpretations' of the statute in question." Rust v. Sullivan, 500 U.S. 173, 186 (1991) (quoting Chevron, 467 U.S. at 862). The reverse is also true: a decision to change a previously existing regulatory requirement does not undermine the reasonableness of the old requirement.

With respect to plaintiff's argument that the requirement that a written agreement be in place before resident training occurs violates the statute, the Court cannot see how this further requirement violates the statute when the written agreement requirement itself does not. In Cottage Health, this Court upheld the Secretary's determination that an agreement entered into after the fiscal year in question did not satisfy the written agreement requirement. See 631 F. Supp. 2d at 93-94. The "contemporaneous written agreement" requirement being enforced here is stricter — the written agreement was entered into before plaintiff submitted its cost report to its intermediary, though after residents received training — but similar reasoning applies. The statute does not mention the written agreement requirement; the conclusion reached by this Court and others was that the Secretary has authority to implement reasonable requirements that are not explicitly mentioned in the statute. If the requirement to have a written agreement is reasonable, it is difficult to see why a requirement that the written agreement be entered into before training occurs is unreasonable. Plaintiff's strongest argument is that the written agreement requirement serves the function of ensuring that the hospital is obliged to incur the cost of resident training, and that this function is fulfilled so long as the agreement is executed sometime during the cost reporting period; it isn't necessary that the agreement be entered into before training actually occurs. See Pl.'s Mem. at 36. But the Secretary has offered plausible justifications for the requirement that the written agreement be entered into before residents undergo training: to avoid disputes after the fact about who had incurred all the costs and to ensure that double payment is not made. See Def.'s Mem. at 23-24; Def.'s Reply to Pl.'s Opp'n to Def.'s Mot. for Summ. J. [Docket Entry 20] ("Def.'s Reply") at 5-6. Given the deference the Secretary is owed in administering the Medicare statute, the Court will defer to the policy determination by the Secretary that this requirement is necessary. Of course, although the requirement is consistent

with the statute, the Secretary must properly implement the requirement, with regulations where appropriate, including providing adequate notice to regulated parties.

B. Interpretation of 42 C.F.R. § 413.86(f)(4)(ii)

1. Parties' Arguments

As described above, 42 C.F.R. § 413.86(f)(4)(ii) set out the requirements for the written agreement between hospitals and non-hospital sites at which residents received training, effective for cost reporting periods occurring on or after January 1, 1999. More specifically, the regulation stated: "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." 63 Fed. Reg. at 41,005.

The Secretary now argues, as the Administrator concluded, that the language of the regulation itself addresses the timing of the required written agreement. Def.'s Mem. at 19-20. The Secretary notes that the regulation states that the written agreement "must indicate that the hospital will incur the cost" of resident training; the Secretary maintains that "[t]he use of the future tense verb 'will' is evidence that the agreement must be entered into prior to the commencement of the fiscal year in which residents will be rotated to non-provider settings or before the hospital can begin counting residents training at the non-hospital site." Id. The Secretary also notes that the preambles to both the 1989 and 1998 iterations of the rule similarly employed the future tense. The 1989 preamble stated that the agency was "not changing [its] original proposal that there be a written agreement between the hospital and the nonhospital

entity that the resident will spend substantially all of his or her time in patient care activities, and that the resident's compensation for the time spent in the outside entity is paid by the hospital." Id. at 20 (quoting 54 Fed. Reg. at 40,304 (alteration in original)). The 1998 preamble stated that "'a hospital may count resident training time in nonhospital sites for indirect and direct GME respectively if the resident is involved in patient care and there is a written agreement between the hospital and the nonhospital site that states that the resident's compensation for training time spent outside the hospital setting is to be paid by the hospital.'" Id. at 21 (quoting 63 Fed. Reg. at 40,986); see also id. ("CMS described the rule as requiring a 'written agreement between the hospital and nonhospital site that the hospital will provide compensation to the nonhospital site for certain types of GME costs. . . . [T]he agreements must also indicate the amounts the hospital will actually pay to the nonhospital site for GME training.'" (quoting 63 Fed. Reg. at 40,996 (alteration in original))).

HHS further argues that the Secretary's exchange with a commenter in the 1998 preamble supports her current interpretation of the regulation as requiring the execution of written agreements before residents receive training at non-hospital sites. Id. at 21-22. To reiterate, the Secretary responded to a commenter by stating that "hospitals and nonhospital sites will have 5 months following publication of this final rule to negotiate agreements that will allow hospitals to continue counting residents training in nonhospital sites for indirect and direct GME." 63 Fed. Reg. at 40,995. Finally, the Secretary asserts that her interpretation of the regulations comports with the purpose of the written agreement requirement, which is to ensure that hospitals and non-hospital sites understand their financial obligations so that Medicare can pay the appropriate entity. See id. at 23-24.

Plaintiff argues that the Secretary's disallowance of resident training time prior to the execution of the agreement on December 20, 1999 is inconsistent with this regulation. See Pl.'s Mem. at 30-31. Plaintiff relies on the Board's determination that the agency intended to allow retroactive written agreements when it first adopted the written agreement requirement in 1989. Id. at 30. Plaintiff notes that the text implementing the written agreement requirement in the original regulation was similar to the regulatory text in effect here: "There is a written agreement between the hospital and the outside entity that states that the resident's compensation for training time spent outside of the hospital setting is to be paid by the hospital." 54 Fed. Reg. at 40,317. Plaintiff observes that this language included the phrase "is to be paid," while the later regulation used "will incur," and yet the original regulation was applied retroactively (from the date of the regulation's enactment in 1989 to the 1987 effective date of the statute) without any special provision in the regulation supporting retroactivity. See Pl.'s Reply at 6-9, 10. Plaintiff argues that the use of the future tense in this context can indicate that a party to an agreement agrees to take action at some future time after executing the agreement: here, the use of the future tense could indicate that a hospital will provide payments after the execution of the agreement obligating it to take responsibility for the costs. Id. at 13. Plaintiff argues that the Secretary was free to change her original interpretation of the regulation, but was required to utilize notice-and-comment to do so. Id. at 9-10. Plaintiff also relies on the Board's determination that the "focus" of the 1998 regulation was on "the actual payment of costs by the hospitals," not on the timing of the execution of the agreement. Pl.'s Mem. at 30-31. Likewise, plaintiff contends that the purpose of the written agreement requirement was to assist intermediaries in assuring that hospitals incurred the costs of the training, which is unrelated to the timing of execution of the agreement. Id. at 31.

2. Legal Standard

Courts "must give substantial deference to an agency's interpretation of its own regulations." Thomas Jefferson Univ. v. Shalala, 512 U.S. 510, 512 (1994) (citing Martin v. Occupational Safety and Health Review Comm'n, 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." Id. Rather, the agency's interpretation is "controlling unless 'plainly erroneous or inconsistent with the regulation.'" Auer v. Robbins, 519 U.S. 452, 461 (1997) (quoting Bowles v. Seminole Rock & Sand Co., 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 other indications of the Secretary's intent at the time of the regulation's promulgation.'" Thomas Jefferson Univ., 512 U.S. at 512 (quoting Gardebring v. Jenkins, 485 U.S. 415, 430 (1988)).

3. Analysis

The Court is not persuaded by either side's argument that a contemporaneous written agreement is either compelled or proscribed by 42 C.F.R. § 413.86(f)(4). Beginning with the text of the regulation, the language uses the present and future tenses to describe the agreement: "The written agreement . . . must indicate that the hospital will incur the cost . . . . The agreement must indicate the compensation the hospital is providing to the nonhospital site for supervisory teaching activities." The Court understands the Secretary's argument to be that this "will incur" phrasing suggests that the agreement is in effect before the payment obligation occurs. There is some intuitive appeal to the notion that the statement that the hospital "will incur" the cost means that the cost will happen in the future (that is, after the agreement is made). But there may be less to this argument than initially meets the eye.

As plaintiff accurately points out, it is not an especially unusual use of language to state that a party to an agreement "will incur" the cost of an event that has already transpired. The phrasing may indicate that the party will make payment in the future for the costs indicated in the agreement. For example, consider a hypothetical situation in which the president of a hospital and the Secretary of Health and Human Services go out to a business lunch. The hospital president pays for the meal and the Secretary initially does not object. On further consideration later that day, the Secretary decides that accepting a free lunch is inappropriate and informs the president, who agrees to reimbursement. It may be most accurate to say that the conversation was "an agreement that the Secretary will pay the cost that was incurred for lunch," because the agreement was made after the lunch was eaten and paid for. But would it be clearly incorrect to describe the conversation as "an agreement that the Secretary will incur the cost of her lunch"? The Court thinks not. It is not clearly wrong for a party to an agreement to say that she "will incur" the cost of an expense that really occurred previously, even if it is technically more accurate to say that the party "will pay" in the future for a cost "incurred" in the past. Hence, while the Secretary may be correct that the regulation mildly favors her reading that the written agreement must be in place before residents undergo training, that conclusion is not compelled by the text.

On the other hand, plaintiff has not mustered any argument that the text of the regulation precludes the Secretary's reading. The language itself simply does not support plaintiff's view. Instead, plaintiff relies primarily on the fact that the Secretary allowed retroactive agreements under the similar predecessor regulation, and argues that therefore the current interpretation is contrary to the Secretary's original regulatory intent and can only be changed by the notice-and-comment process. This argument is not frivolous; it is noteworthy that the Administrator

allowed retroactive agreements under the original regulation (at least with respect to the "gap" between the statute's enactment and the promulgation of the regulation), but has concluded here that similar language in the successor regulation clearly excludes retroactive agreements.

Nonetheless, the Court cannot conclude that the policy the Secretary adopted when the written agreement requirement was first adopted precludes her current interpretation. As far as the Court can tell from the record, allowing retroactive agreements upon the initial adoption of the policy was a one-time decision; the Court has not been presented with any evidence that the Administrator ever accepted other retroactive agreements from a hospital during the decade that followed. The Court is wary of finding the Secretary precluded from reading a regulation in a particular way because a one-time policy adopted approximately ten years earlier suggested a contrary interpretation. See NetworkIP, LLC v. FCC, 548 F.3d 116, 125 (D.C. Cir. 2008) ("[I]t was unreasonable for [plaintiffs] to assume that an idiosyncratic exception should define the rule."). That is especially so where the earlier policy was at the initiation of the written agreement requirement when the unique circumstance of addressing training pre-dating the effective date of the requirement was posed. Furthermore, the policy of allowing retroactive agreements was adopted under a different iteration of the rule, which was replaced by the new regulation in 1998 through the notice-and-comment process. Plaintiff is actually arguing that the Secretary is bound by her interpretation of a different (though admittedly similar) predecessor regulation, and that the Secretary must undergo a separate notice-and-comment process to "change" her interpretation of a new regulation that was itself promulgated with notice-and-comment. This cannot be right.

The Court is persuaded by the various statements in the record that more clearly support the Secretary's reading of the regulation than does the text of the regulation itself. The most

significant of these was the exchange in the preamble to the 1998 rule, in which the Secretary stated on July 31, 1998 that "hospitals and nonhospital sites will have 5 months following publication of this final rule to negotiate agreements that will allow hospitals to continue counting residents training in nonhospital sites for indirect and direct GME." 63 Fed. Reg. at 40,995. Plaintiffs may argue, as discussed below, that this statement was insufficiently specific to put them on notice of the requirement, but in any case the statement is certainly quite consistent with the notion that hospitals would need to have agreements in place by the first of the year. It is also notable that this exchange appears in the published preamble accompanying the regulation's promulgation. To the degree that plaintiff complains the Secretary is changing her interpretation of the regulation without employing the notice-and-comment process, this exchange actually suggests that the Secretary did, in fact, engage directly with the public in notice-and-comment regarding the timing of agreements. Additionally, the other preamble statements from the Secretary in the future tense confirm, albeit implicitly, that the agreement was intended to be in place before residents underwent off-site training. In particular, the Court notes HHS's statement that it is "not changing [its] original proposal that there be a written agreement between the hospital and the nonhospital entity that the resident will spend substantially all of his or her time in patient care activities, and that the resident's compensation for the time spent in the outside entity is paid by the hospital." 54 Fed. Reg. at 40,304. The language of this statement — in particular, the phrase "will spend" — suggests more clearly than the text of the regulation itself that off-site training will occur after the agreement is made.

In sum, the Secretary's interpretation of the regulation's text is plausible and the preamble accompanying the regulation confirms her interpretation, both implicitly and more directly. Hence, this is a setting where the Secretary's interpretation of her regulation must receive

substantial deference under Thomas Jefferson University. To be sure, the predecessor regulation may have been read differently on one particular occasion — to cover the initial "gap" between the statute's enactment and promulgation of the rule — but this sole exception is not enough to override the strong deference the Secretary is owed in this situation, especially considering that the interpretation seems to be confirmed in statements accompanying the promulgation of the rule.

Plaintiff also contends that the timing of the execution of the written agreement is not relevant to the purpose of the written agreement requirement. The purpose of the requirement was to ensure that hospitals were actually paying for the training for which they are being compensated, which plaintiff contends is not served by the requirement that the agreement be in effect prior to training. Plaintiff also contends that retroactive agreements are accepted by the Secretary in other contexts. The Secretary counters that her interpretation of the regulation properly ensures that hospitals and training sites understand their financial obligations prior to training occurring.

In the Court's view, entering into a debate about whether an interpretation of this regulation serves the purpose of the regulation is exactly the type of policy determination that the deference doctrine seeks to avoid. The Secretary has offered plausible justifications for the rule. Given that the Secretary's interpretation of the regulation is otherwise quite reasonable, the Court will defer to the Secretary's judgment that her interpretation serves the underlying policy interest behind the regulation. Hence, the Court concludes that the Secretary's interpretation is not "plainly erroneous or inconsistent with the regulation," Auer, 519 U.S. at 461 (quoting Bowles, 325 U.S. at 414), and therefore will defer to that interpretation.

C. Notice

1. Parties' Arguments

Plaintiff argues that the Secretary cannot deny the hospital payment for the 1999 fiscal year on the basis of a requirement of a contemporaneous written agreement because plaintiff did not have adequate notice of the requirement. See Pl.'s Mem. at 21-29. Plaintiff again notes that the Secretary accepted agreements executed after the July 1, 1987 effective date of the statute when HHS first promulgated the original regulation in 1989. See id. at 24-25. Plaintiff acknowledges that the preamble to the 1998 iteration of the rule, issued on July 31, stated that hospitals would have five months to negotiate new agreements, but nonetheless argues that "that preambulatory statement did not say what the Administrator construed it [to] mean in his decision in this case. It did not say that the new written agreements had to be negotiated and finally executed prior to January 1, 1999 or any later start of a subsequent cost reporting period. . . . All the agency said is that hospitals would have not less than five months to negotiate." Id. at 25; see also Pl.'s Reply at 17. Plaintiff also contends that the Administrator's response to the AAMC in February 2012 "was incompatible with any notion that the agency intended to require hospitals to execute final agreements for 1999 by the January 1st effective date." Pl.'s Mem. at 26. Medicare in analogous contexts, it is noted, accepts agreements that are not prospective. See id. at 26-27. Plaintiff emphasizes that the PRRB determined that the regulations did not require contemporaneous written agreements, arguing that plaintiff cannot have had notice of a requirement that even the Board did not think was present. See id. at 27-28. Finally, plaintiff argues that "[e]ven now, the Secretary still struggles to define the required timing of execution of the written agreements," noting that the Secretary's current briefing uses differing language to describe the requirement. See Pl.'s Reply at 13-16.[4]

[4] Plaintiff argues that a 2006 report from the Department of Health and Human Services' Office of Inspector General supports its position that the December 1999 agreement was sufficient. See Pl.'s Mem. at 27; A.R. at 243-55.

The Secretary responds that plaintiff waived the notice argument by not previously presenting it to the Board or the Administrator. Def.'s Mem. at 28-29. The Secretary also argues that plaintiff received notice of the Secretary's view of the regulation either from the plain text of the regulation itself or from the Secretary's statement in the preamble to the 1998 regulation. Id. at 29-32. The Secretary maintains that, the initial exception aside, HHS never intended the regulation to permit retroactive agreements, id. at 32-33, and that the agency materials issued after January 1999 could not have misled plaintiff about the requirements in effect at the beginning of the year, id. at 33-35. Finally, the Secretary's reply brief argues that the "fair notice" doctrine does not apply here because the Medicare disallowance at issue is not a "penalty or grave sanction." Def.'s Reply at 8-11.

2. Legal Standard

"Traditional concepts of due process incorporated into administrative law preclude an agency from penalizing a private party for violating a rule without first providing adequate notice of the substance of the rule." Satellite Broad. Co., Inc. v. FCC, 824 F.2d 1, 3 (D.C. Cir. 1987). Although courts normally defer to an agency's reasonable interpretation of its own rules, an agency through its regulatory power cannot, in effect, punish a member of the regulated class for reasonably interpreting agency rules. Id. at 3-4. "The agency's interpretation is entitled to deference, but if it wishes to use that interpretation to cut off a party's right, it must give full notice of its interpretation." Id. at 4. The D.C. Circuit has endorsed the "ascertainable certainty" standard for providing fair notice of regulatory requirements: "If, by reviewing the regulations and other public statements issued by the agency, a regulated party acting in good faith would be able to identify, with 'ascertainable certainty,' the standards with which the agency expects

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However, this report seems to have examined plaintiff's dental resident count in fiscal years 2000 through 2002, not fiscal year 1999, which is the subject of this suit. A.R. at 250.

parties to conform, then the agency has fairly notified a petitioner of the agency's interpretation." Gen. Elec. Co. v. EPA, 53 F.3d 1324, 1329 (D.C. Cir. 1995) (quoting Diamond Roofing Co. v. OSHRC, 528 F.2d 645, 649 (5th Cir. 1976)).

There is a relationship between the need for agencies to notify regulated parties of regulatory requirements and the text of the regulations that set out those requirements. When the text of a regulation is clear, the agency need not provide other notice to regulated entities because the regulation itself provides notice. See Gen. Elec., 53 F.3d at 1329 ("[W]e must ask whether the regulated party received, or should have received, notice of the agency's interpretation in the most obvious way of all: by reading the regulations."); see also NetworkIP, 548 F.3d at 123 ("We have never applied the fair notice doctrine in a case where the agency's interpretation is the most natural one."). On the other hand, this Court has concluded that when "the agency's interpretation of its regulation may actually contradict the regulatory text," then "the obligation on the agency to provide adequate notice is at its peak." HUP, 2012 WL 928282, at *11.

3. Analysis

A threshold question is whether plaintiff waived its argument regarding adequate notice by failing to raise the argument at the agency level. If plaintiff "could have called a question of law or fact to the agency's attention, but did not, the issue is waived." NetworkIP, 548 F.3d at 122. In order to prevent waiver, however, "an issue need not be raised explicitly; it is sufficient if the issue was 'necessarily implicated' in agency proceedings." Id. (quoting Time Warner Entm't Co. v. FCC, 144 F.3d 75, 79-80 (D.C. Cir. 1998)). Here, the Court finds that plaintiff did not waive the issue of notice. It is true that plaintiff appears not to have explicitly used the word "notice" in presenting its arguments at the agency level. Nonetheless, the deliberation at HHS

revolved around whether the Secretary's interpretation of the regulation, 42 C.F.R. § 413.86(f)(4), was clear from its plain text and whether the Secretary's contemporaneous statements regarding the policy supported or contradicted the Secretary's current interpretation of the regulation. The Administrator ultimately concluded that the "plain language of the regulation" indicated a "prospective requirement that a written agreement be in place" and found that this requirement was "consistent with the Secretary's response to commenters" in the preamble to the rule's promulgation. A.R. at 10. This consideration of the plain meaning of the regulation in relation to what the Secretary contemporaneously articulated about the rule is sufficiently related to the notice determination that the Court finds the notice issue was not waived. Since plaintiff raised the issue of what it understood the regulation to mean in relation to the Secretary's contemporaneous statements about the rule, the issue of notice was "necessarily implicated" in the arguments plaintiff presented to the Board and to the Administrator upon review of the Board's decision. Cf. NetworkIP, 548 F.3d at 122.

The Secretary has also raised two additional reasons why the notice issue might not be appropriate for the Court's consideration. First, the Secretary argues that the fair notice doctrine does not apply here because her interpretation of the regulation is "the most natural one." The Secretary contends that her "interpretation is the most logical given the future tense of the verb 'to be' that is used in the regulations." Def.'s Mem. at 29. This argument that the notice doctrine does not apply is essentially indistinguishable from the argument that the plain meaning of the regulation provides adequate notice; the idea is that the Secretary need say nothing more when the regulation's meaning is clear. That view has already been rejected by the Court in deciding that the language of the regulation is not clear and unequivocal. Second, the Secretary argues

(albeit only in her reply brief) that the notice doctrine does not apply here because the Medicare disallowance at issue is not a "penalty or grave sanction."

The Court agrees with the Secretary that the notice doctrine should not be permitted to engulf the ordinarily deferential standard under which a court assesses an agency's interpretation of its own regulation. The Court shares the concern, articulated by a judge of this district, that "[i]f an agency were prevented on notice grounds from enforcing its interpretation of a regulation against any party who proffered a reasonable alternative interpretation and suffered monetary loss, the practice of deferring to an agency's reasonable interpretation of its regulations would be rendered essentially meaningless." Ar. Dept. of Human Servs. v. Sebelius, 2011 WL 4826983, at *15 (D.D.C. Oct. 12, 2011) (internal citation omitted). In the administration of a program of Medicare's size, it would not be fair to require the Secretary to anticipate any possible ambiguity in her regulations on every issue, no matter how small, and provide crystalline interpretative guidance in advance eliminating all ambiguity. On the other hand, it is difficult to conclude that the fair notice standard does not apply here when the D.C. Circuit, as well as this Court, recently concluded that CMS had to provide fair notice of its interpretation of a related regulation before denying hospitals IME/GME payments. See Loma Linda, 408 Fed. Appx. 383; HUP, 2012 WL 928282. The hospitals in those cases were claiming IME/GME payments under slightly different circumstances,[5] but even so the Secretary's argument that "the disallowance of GME/IME Medicare funding" is not a penalty or sanction, see Def's Reply at 8-10, would seem to apply with equal force to the denials in those cases, in which the notice doctrine was, in fact, applied against the Secretary. Furthermore, as discussed above, the Court does not believe that the plain text of the regulation unequivocally supports the Secretary's reading, although the Court does

[5] As explained above, Loma Linda and HUP involved supplemental medical education payments for services furnished by hospitals to patients under Medicare Part C. See HUP, 2012 WL 928282, at *1-3.

agree that the Secretary's interpretation may be somewhat more natural than plaintiff's. Cf. HUP, 2012 WL 928282, at *11 (finding, by contrast, that the Secretary's interpretation of the regulation in question was "quite strained").

Under these circumstances, rather than concluding that the fair notice doctrine does not apply (in "all or nothing" fashion), the Court believes the most appropriate tact is to apply the fair notice doctrine with an appropriately deferential posture toward the Secretary. To prevent the notice doctrine from overwhelming the rule of deference to an agency's interpretation of its own regulations, the Court will approach the Secretary's statements in the record about the regulation mindful of the interpretive flexibility that courts ordinarily use in giving deference to an agency's interpretation of its regulations.

Upon examination of the record, the Court finds that there was adequate notice to hospitals that written agreements would need to be entered into by hospitals and off-site training providers before residents undertook off-site training. In particular, the Secretary's statement in the preamble accompanying the rule provided adequate notice that the Secretary interpreted the regulation in this manner. The Secretary noted that a commenter stated that "teaching hospitals have already entered into written agreements with nonhospital sites under the existing rules" and that "if the agreements are not renegotiated prior to the effective date, the hospital will be unable to count the residents for direct and indirect GME." 63 Fed. Reg. at 40,994. The Secretary responded that "[b]y making a later effective date for the GME provisions, hospitals and nonhospital sites will have 5 months following publication of this final rule to negotiate agreements that will allow hospitals to continue counting residents training in nonhospital sites for indirect and direct GME." Id. at 40,995. It is difficult to see how this statement can be interpreted in any way other than as an indication that hospitals and off-site providers would

need to have agreements in place by January 1, 1999 in order for training time to be counted from that date. The Secretary's response to the commenter would actually be inaccurate under plaintiff's reading of the regulation; hospitals and off-site providers would have many more than five months to negotiate agreements if they could execute the agreements as late as December 20, 1999.

Plaintiff's argument that this statement did not provide notice of the requirement is quite unpersuasive. Plaintiff asserts that the statement "did not say that the new written agreements had to be negotiated and finally executed" and that "[a]ll the agency said is that hospitals would have not less than five months to negotiate." Pl.'s Mem. at 25; see also Pl.'s Reply at 17. But that is not what the Secretary said and, moreover, it makes no sense to draw a distinction between "negotiating" agreements and "finally executing" them. The Secretary's statement indicates that agreements had to be negotiated by the first of the year; the statement would be meaningless if agreements could, in fact, be executed months later. It would be unfair to the Secretary to conjure up, after the fact, a distinction between the negotiation and execution of agreements in order to find ambiguity where there was none. This statement provided notice with "ascertainable certainty," Gen. Elec., 53 F.3d at 1329, of the requirement to have written agreements in place before resident off-site training time would count for IME/GME payments.

Plaintiff's other arguments regarding notice are equally unavailing. That the Secretary once allowed retroactive agreements upon promulgation of the predecessor regulation may suggest that the regulation is susceptible to both meanings, but, as explained above, it is unreasonable for plaintiff "to assume that an idiosyncratic exception should define the rule." NetworkIP, 548 F.3d at 125. But see United States v. Chrysler Corp., 158 F.3d 1350, 1356 (D.C. Cir. 1998) ("[A]n agency is hard pressed to show fair notice when the agency itself has taken

action in the past that conflicts with its current interpretation of a regulation."). If the Secretary had said nothing when revising the rule, plaintiff's argument regarding the predecessor rule might carry more weight, but here the Secretary was prompted by the commenter to address the issue when implementing the revised rule.

Furthermore, even if the Administrator's February 2012 response to the AAMC had contradicted the language in the preamble, "[c]ourts 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." Cottage Health, 631 F. Supp. 2d at 94 (citing Thomas Jefferson Univ., 512 U.S. at 515-16). Given that the Secretary gave a clear indication of the requirement in a preamble published in the Federal Register accompanying the new regulation, a letter sent to a private party more than a month into the time period in question cannot have deprived plaintiff of notice. In any case, the letter to the AAMC does not actually contradict the Secretary's reading of the regulation. In fact, the letter explicitly confirmed that "[w]e specifically made the provisions affecting GME effective January 1, 1999, in order to provide hospitals and nonhospital sites with more time to make revisions to written agreements." A.R. at 229. Again, it is difficult to see how this statement can be read to comport with plaintiff's reading of the regulation. The statement would be simply incorrect if hospitals and off-site providers did, in fact, have until December 20 "to make revisions to written agreements." And the later statement in the letter, characterized as a "further detail[]," is not to the contrary; the Administrator merely states that "written agreements did need to be sent to the fiscal intermediaries prior to January 1, 1999." A.R. at 229-30. When agreements had to be sent to fiscal intermediaries does not obviously bear on when the written agreements had to be executed. Sending written agreements to fiscal intermediaries is a distinct action from making the

agreements, in a way that "negotiating" agreements or "making revisions" to agreements is not distinct from "executing" new agreements. Hence, plaintiff's reading is inconsistent with the letter read as a whole, which confirms, rather than undermines, the Secretary's reading of the regulation.

The Board's determination about the fiscal intermediary's denial of payment does not change the Court's determination about the notice plaintiff received prior to or during 1999. Indeed, that the Board concluded that plaintiff was entitled to these payments may well suggest that the regulation is not as clear as the Secretary suggests, as the Court has already concluded. But the Board merely concluded that "the regulations do not address the timing of execution of the agreement," not that the regulatory text foreclosed the Secretary's reading. And for whatever reason, the Board seems not to have considered (or, at least, did not discuss) the preamble language. See A.R. at 30-33. The Secretary's interpretation, not the Board's, is the final decision of the agency. See, e.g., Am. Med. Int'l, Inc. v. Sec'y of Health, Educ. and Welfare, 466 F. Supp. 605, 611 (D.D.C. 1979), aff'd, 677 F.2d 118 (D.C. Cir. 1981). Given the substantial deference the Court believes the agency is owed here, the Court finds that the preamble language gave sufficient notice even though the regulation's meaning was not plain.

Likewise, plaintiff's contention that the Secretary's counsel has himself inconsistently characterized the written agreement over the course of the current litigation warrants little attention. Plaintiff seizes on the fact that counsel characterized the rule as requiring "prospective" written agreements, whereas previously the rule had been described as requiring "contemporaneous" agreements. See Def.'s Mem. at 9 n.5. But whether the Secretary is requiring a "contemporaneous" written agreement or a "prospective" one is pure semantics; the agreement needs to be in place when the residents undergo training (contemporaneously), which

requires that the agreement be entered into beforehand (that is, prospectively). There is no inconsistency in describing the agreement requirement either way. Furthermore, in addition to stating accurately that the written agreement must be "signed before the time the residents begin training at the nonhospital site," Def.'s Mem. at 23, the Secretary's counsel variously described the requirement as being "that a written agreement be in place before a hospital may begin counting residents' time spent in non-hospital settings," id. at 12, and "that the agreement must be entered into prior to the commencement of the fiscal year," id. at 23. Although it is technically true that the hospital "counts" resident time at the end of the year (that is, when it does its accounting in the cost report), counsel's intent was obviously that training time does not "count" until the written agreement is in place. Similarly, the statement that "the agreement must be entered into prior to the commencement of the fiscal year" is not necessarily true, since it assumes that, as was the case here, the hospital sought to count resident training time that coincided with the commencement of the fiscal year. Although arguably somewhat imprecise, these statements do not reflect a different characterization of the policy, which is abundantly clear by this point in the proceedings.

In sum, the Court approaches the issue of notice with a fairly deferential posture toward the Secretary, and concludes that the Secretary's statements in the preamble accompanying the regulation provided adequate notice to hospitals of the Secretary's reading. Plaintiff's arguments to the contrary cannot overcome the notice provided by this statement.

V. Conclusion

The Medicare statute did not preclude HHS from requiring hospitals to have written agreements with off-site providers of training to hospital dental residents in order for hospitals to receive medical education payments associated with that training. Furthermore, while HHS

regulations did not unequivocally require hospitals to have the written agreement with off-site providers already in place when residents underwent training, reading the regulation in that manner was well within the deference properly afforded to the Secretary in interpreting her own regulations. Moreover, the Secretary provided adequate notice to hospitals of this requirement for a contemporaneous written agreement. Accordingly, the Secretary's decision denying plaintiff the disputed payments was reasonable and not arbitrary, capricious or in violation of law, and the Court will grant the Secretary's motion for summary judgment. A separate order has been issued.

/s/
JOHN D. BATES
United States District Judge

Dated: April 17, 2012