UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

LAWRENCE & MEMORIAL HOSPITAL, *Plaintiff*, *v.* KATHLEEN SEBELIUS, MARILYN TAVENNER, and ROBERT G. EATON, *Defendants*.	Civil No. 3:13cv1495 (JBA) December 6, 2013

RULING ON PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

On October 11, 2013, Plaintiff Lawrence & Memorial Hospital filed a Complaint [Doc. # 1] for declaratory and injunctive relief against Defendants Kathleen Sebelius, Secretary of the Department of Health and Human Services ("HHS"), Marilyn Tavenner, Administrator of the Centers for Medicare and Medicaid Services ("CMS"), and Robert G. Eaton, Chairman of the Medicare Geographic Classification Review Board ("MGCRB"), seeking a declaration that the regulatory scheme governing the MGCRB violates the Medicare Act and the Administrative Procedures Act, and a permanent injunction enjoying Defendants from applying that scheme to Plaintiff's current and future reclassification applications. That same day, Plaintiff filed a motion [Doc. # 4] for a preliminary injunction, enjoining Defendants from acting on Plaintiff's application for reclassification that is currently pending before the MGCRB until the Court can hold a hearing on the merits of this action. Defendants oppose Plaintiff's motion, arguing that the Court lacks subject matter jurisdiction to hear the case, and that Plaintiff has not shown that it is entitled to a preliminary injunction. Although the Court finds it has jurisdiction, for the following reasons, Plaintiff's motion for a preliminary injunction is denied.

I. Background

A. The Medicare Program and the Wage Index

The Medicare Program is a system of health insurance for the aged and disabled. (*See* Compl. ¶ 17); *see also* 42 C.F.R. § 400.200. Medicare Part A pertains to payment for "inpatient hospital services," (*see* Compl. ¶ 17); *see also* 42 U.S.C. § 1395d(a)(1), and Medicare Part B provides for payment of various outpatient services (*see* Compl. ¶ 17); *see also* 42 U.S.C. § 1395k. Payments to hospitals are made pursuant to the inpatient prospective payment system ("IPPS") for Medicare Part A and pursuant to the outpatient prospective payment system ("OPPS") for Medicare Part B. (*See* Compl. ¶¶ 18–19.) Under both systems, CMS sets a standardized payment rate, which is then adjusted to account for the fact that labor costs vary across the country. (*See* Compl. ¶¶ 18–22.) To effectuate this adjustment, CMS uses a "wage index," which represents the relation between the local average of hospital wages and the national average of hospital wages. (*See id.*); *see also* 42.U.S.C. § 1395ww(d)(3)(E). Thus, hospitals in areas that incur labor costs above the national average receive a higher reimbursement rate than the standardized payment rate, while hospitals that incur labor costs below the national average receive a lower reimbursement rate than the standardized payment rate. (*See* Compl. ¶ 22.)

In 1983, in order to effectuate the wage index adjustment, the Secretary of HHS established standardized hospital labor markets by grouping hospitals according to their location in Metropolitan Statistical Areas ("MSAs"). (*See id.* ¶ 23.) These MSAs are based on census data and use counties as building blocks to roughly approximate the local labor market. (*See id.*) Every hospital in a designated MSA is considered to be a part of a single labor market for the purpose of determining the wage index applicable to that

hospital. (*See id.*) After the 2000 census, the MSAs were replaced with Core Based Statistical Areas ("CBSAs") that are roughly equivalent to the previous groupings. (*See id.* ¶ 24.) The Secretary of HHS sets one wage index for each CBSA and one wage index per state for rural areas not located in any CBSA. (*See id.* ¶ 25.) Thus, urban and rural hospitals in the same state may have different wage indices, and therefore, different reimbursement rates under the IPPS and OPPS. (*See id.*) Each hospital is reimbursed according to the wage index of the CBSA in which it is physically located. (*See id.* ¶ 26.) Since the late 1980s, Congress has periodically amended the Medicare Act to permit hospitals to be reclassified from urban to rural, or to be reclassified to a CBSA other than the one in which they are physically located in order to adjust those hospitals' wage indices to reflect the fact that the CBSAs do not always accurately reflect labor market wage differences. (*See id.* ¶¶ 28–36.) More than one-third of hospitals paid under the IPPS and OPPS receive a modified wage index based on these amendments. (*See id.* ¶ 37.)

B. The Medicare Geographic Classification Review Board

In 1989, Congress established the MGCRB to provide a mechanism by which a hospital could request to be relocated from the geographical area in which it was located to another proximate area for the purposes of determining its wage index and reimbursement rate. (*See id.* ¶ 38); *see also* 42 U.S.C. § 1395ww(d)(10). In order to have its application for reclassification approved by the MGCRB, a hospital must show that (1) its wages are higher than those of other hospitals in the area where it is physically located; (2) its wages are comparable to those of other hospitals in the area to which it seeks to be reclassified; and (3) it is proximate to the area to which it seeks to be reclassified. (*See* Compl. ¶ 39.) To satisfy the first element, the hospital's three-year average hourly wage

("AHW") must be at least 108% of the AHW of the area in which it is physically located if it is an urban hospital, and at least 106% of the AHW of the area in which it is physically located if it is a rural hospital. (*See id.* ¶ 40); *see also* 42 C.F.R. § 412.230(d)(1)(iii)(C). To satisfy the second element, the hospital's three-year AHW must be at least 84% of the AHW of the area to which it is applying to be reclassified if it is an urban hospital, and at least 82% of the AHW applicable to the area to which it is applying to be reclassified if it is a rural hospital. (*See* Compl. ¶ 41); *see also* 42 C.F.R. §412.230(d)(1)(iv)(E). To satisfy the third element, the hospital must be within 35 miles of the area to which it is applying to be reclassified if it is a rural hospital, and within 15 miles of the area to which it is applying to be reclassified if it is an urban hospital. (*See* Compl. ¶ 42); *see also* 42 C.F.R. § 412.230(b)(1). If a hospital has been designated as a rural referral center ("RRC"), the first and third elements of this test are waived. (*See* Compl. ¶ 44); *see also* 42 C.F.R. §§ 412.230(a)(3) and 412.230(d)(1)(3)(C). If the MGCRB approves a hospital's application, its reclassification is valid for a period of three years. (*See* Compl. ¶ 45.) A hospital may appeal an MGCRB decision to the Secretary of HHS's designate—the Administrator of CMS—but the ruling on the appeal "shall be final and shall not be subject to judicial review." 42 U.S.C. § 1395ww(d)(10)(C)(iii)(II); (*see also* Compl. ¶ 46.)

C. Section 401

In 1999, Congress enacted Section 401, which provides a mechanism by which hospitals in urban areas may be reclassified as rural for reimbursement purposes. (*See* Compl. ¶ 48.) Section 401 provides:

> (i) For purposes of this subsection, not later than 60 days after the receipt of an application (in a form and manner determined by the Secretary) from a subsection (d) hospital described in clause (ii), the Secretary

shall treat the hospital as being located in the rural area (as defined in paragraph (2)(D))[1] of the State in which the hospital is located.

(ii) For purposes of clause (i), a subsection (d) hospital described in this clause is a subsection (d) hospital that is located in an urban area (as defined in paragraph (2)(D)) and satisfies any of the following criteria:

(I) The hospital is located in a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725)).

(II) The hospital is located in an area designated by any law or regulation of such State as a rural area (or is designated by such State as a rural hospital).

(III) The hospital would qualify as a rural, regional, or national referral center under paragraph (5)(C) or as a sole community hospital under paragraph (5)(D) if the hospital were located in a rural area.

(IV) The hospital meets such other criteria as the Secretary may specify.

42 U.S.C. § 1395ww(D)(8)(E). A conference report accompanying the legislation enacting Section 401 explains that pursuant to Section 401:

> a hospital in an urban area may apply to the Secretary to be treated as if the hospital were located in a rural area of the State in which the hospital is located. Hospitals qualifying under this section shall be eligible to qualify for all categories and designations available to rural hospitals, including sole community, Medicare dependent, critical access, and referral centers. *Additionally, qualifying hospitals shall be eligible to apply to the Medicare Geographic Reclassification [sic] Review Board for geographic reclassification to another area. The Board shall regard such hospitals as rural and as entitled to the exceptions extended to referral centers and sole community hospitals, if such hospitals are so designated.*

H.R. Conf. Rep. No. 106-479, 512 (1999) (emphasis added).

[1] Pursuant to 42 U.S.C. § 1395ww(d)(2)(D) "the term 'urban area' means an area within a Metropolitan Statistical Area . . . [and] the term 'rural area' means any area outside such an area or similar area."

In comments accompanying the adoption of regulations pursuant to Section 401, the Secretary expressed concern that Section 401 "might create an opportunity for some urban hospitals to take advantage of the MGCRB process by first seeking to be reclassified as rural under section 1886(d)(8)(E) (and receiving the benefits afforded to rural hospitals) and in turn seek reclassification through the MGCRB back to the urban area for purposes of their standardized amount and wage index and thus also receive the higher payments that might result from being treated as being located in an urban area." *Medicare Program*: *Changes to the Hosp. Inpatient Prospective Payment Sys. & Fiscal Year 2001 Rates*, 65 Fed. Reg. 47054, 47087 (Aug. 1, 2000). In other words, "some hospitals might inappropriately seek to be treated as being located in a rural area for some purposes and as being located in an urban area for other purposes." *Id.* at 47088. In the comments, the Secretary also acknowledged the language of the conference report: "We agree with the commenters that Congress contemplated that hospitals might seek to be reclassified as rural under section 1886(d)(E) [sic] of the Act in order to become RRCs so that the hospital would be exempt from the MGCRB proximity requirement and could be reclassified by the MGCRB to another urban area." *Id.* at 47089.

However, in order to address its policy concerns, the Secretary ultimately adopted regulations providing that "[a]n urban hospital that has been granted redesignation as rural under § 412.103 cannot receive an additional reclassification by the MGCRB based on this acquired rural status for a year in which such redesignation is in effect." 42 C.F.R. § 412.230(a)(5)(iii). Further, a hospital must maintain its rural status for at least one full twelve-month cost reporting period after being reclassified pursuant to Section 401 before it can cancel that status and reapply for reclassification by the MGCRB. *See* 42 C.F.R. § 412.103(g)(2). Finally, once a hospital that has been redesignated as an RCC pursuant

to Section 401 cancels its rural status, that hospital also loses its RRC designation under § 412.96. (*See* Compl. ¶ 58.)

D. Plaintiff's Reclassification Efforts

On July 2, 2013, Plaintiff requested pursuant to Section 401 to be redesignated from urban to rural status, and to be designated as a RRC. (*See id.* ¶¶ 59–60.) On August 13, 2013, the Secretary notified Plaintiff that its request was granted effective July 3, 2013. (*See id.* ¶ 61.) Plaintiff was treated as a RRC beginning October 1, 2013. (*See id.*) Beginning January 1, 2014, Plaintiff will participate in the 340B Drug Pricing Program for rural hospitals. (*See* Supp. Inzana Decl. [Doc. # 20] ¶ 2.) Participation in this program is estimated to generate between $3 million and $5 million in annual savings for Plaintiff. (*See id.* ¶ 3.) Plaintiff also filed a timely application with the MGCRB to be reclassified from the Norwich-New London, CT CBSA to the Nassau-Suffolk, NY CBSA. (*See* Compl. ¶ 62.) Plaintiff qualifies for such reclassification pursuant to the rules governing rural hospitals and RRCs. (*See id.*) The MGCRB has until March 3, 2014 to issue a decision on Plaintiff's application. Plaintiff anticipates that its application to the MGCRB will be denied pursuant to 42 C.F.R. § 412.230(a)(5)(iii), which forbids hospitals that have been redesignated as rural pursuant to Section 401 to also be reclassified to a different urban CBSA via the MGCRB for the purposes of receiving a higher wage index. (*See id.* ¶ 63.) Such a decision will not be subject to judicial review. (*See id.* ¶ 64.) Plaintiff estimates that it will lose $3 million annually in Medicare reimbursement if its reclassification application is denied. (*See* Inzana Decl. [Doc. # 4-3] ¶ 9.) Thus, Plaintiff now seeks a preliminary injunction to stay the hand of the MGCRB and enjoin it from ruling on Plaintiff's application before the Court can hold a hearing on the merits of its challenge to Defendants' regulatory scheme.

II. Legal Standard

"[A] preliminary injunction is an extraordinary remedy that should not be granted as a routine matter." *JSG Trading Corp. v. Tray-Wrap, Inc.*, 917 F.2d 75, 80 (2d Cir. 1990). Generally, a party seeking a preliminary injunction must show "(a) irreparable harm and (b) either (1) likelihood of success on the merits or (2) sufficiently serious questions going to the merits to make them a fair ground for litigation and a balance of hardships tipping decidedly toward the party requesting the preliminary relief." *Citigroup Global Markets, Inc. v. VCG Special Opportunities Master Fund Ltd.*, 598 F.3d 30, 35 (2d Cir. 2010) (internal citations and quotation marks omitted). "When, as here, the moving party seeks a preliminary injunction that will affect government action taken in the public interest pursuant to a statutory or regulatory scheme, the injunction should be granted only if the moving party meets the more rigorous likelihood-of-success standard." *Cnty. of Nassau, N.Y. v. Leavitt*, 524 F.3d 408, 414 (2d Cir. 2008) (internal citations and quotation marks omitted). "That is, [P]laintiff must establish a clear or substantial likelihood of success on the merits." *Id.* (internal citations and quotation marks omitted).

III. Discussion

Defendants oppose Plaintiff's motion for a preliminary injunction, arguing that the Court lacks subject matter jurisdiction over Plaintiff's claim, and that Plaintiff cannot show, irreparable harm, a likelihood of success on the merits, or that the balance of the hardships weighs in its favor.[2]

[2] Because the Court concludes that Plaintiff has failed to show a clear likelihood of success on the merits, it will not address the parties' arguments regarding the balance of the hardships.

A. Subject Matter Jurisdiction

As a preliminary matter, Defendants argue that the Court lacks subject matter jurisdiction over this dispute because the decisions of the MGCRB are not subject to judicial review. There is a well-settled presumption of judicial review of administrative action, and the Court must give effect to that presumption absent clear and convincing evidence of congressional intent to preclude judicial review. *See Kucana v. Holder*, 558 U.S. 233, 252 (2010). "Whether and to what extent a particular statute precludes judicial review is determined not only from its express language, but also from the structure of the statutory scheme, its objectives, its legislative history, and the nature of the administrative action involved." *Block v. Cmty. Nutrition Inst.*, 467 U.S. 340, 345 (1984). Here, the Medicare Act provides that the Secretary's review of an appeal from an MGCRB decision "shall be final and shall not be subject to judicial review." 42 U.S.C. § 1395ww(d)(10)(C)(iii)(II). Defendants argue that this statute evidences a clear intent by Congress to preclude judicial review of MGCRB decisions. The principle that there is no judicial review of MGCRB decisions has been acknowledged previously, *see, e.g.*, *Parkview Med. Assocs. V. Shalala*, 158 F.3d 146, 148 (D.C. Cir. 1998) ("Judicial review of the denial itself is barred."), and Plaintiff concedes that judicial review of a denial of its reclassification application would not be reviewable by this Court (*see* Pl.'s Reply [Doc. # 19] at 7).

However, courts have recognized that where a plaintiff seeks to challenge the method by which an unreviewable determination is made, rather than the determination itself, judicial review is not precluded. *See Bowen v. Michigan Acad. of Family Physicians*, 476 U.S. 667, 677–78 (1986) (holding that although the Medicare Act precluded judicial review of individual benefits determinations, challenges to the Secretary's instructions

and regulations governing those determinations were subject to judicial review). Thus, for example, in *Parkview*, the plaintiff's reclassification application was denied by the MGCRB because the plaintiff was required to submit two cost reports for the relevant reporting period as a result of a change in ownership and the second report was excluded from consideration by the MGCRB pursuant to the regulations governing the 1994 wage index. *See* 158 F.3d at 148. The D.C. Circuit held that although judicial review of the denial of the plaintiff's application was barred, "this bar leaves the hospital free to challenge the general rules leading to denial." *Id.* The court went on to conclude that the plaintiff's suit amounted to a challenge to the Secretary's construction of the 1994 wage index, rather than to the MGCRB's decision pursuant to that construction, and that it therefore had subject matter jurisdiction over the plaintiff's claims. *Id.* Similarly, in *Universal Health Servs. v. Sullivan*, 770 F. Supp. 704 (D.D.C. 1991), prior to the MGCRB's ruling on its reclassification request, the plaintiff brought suit challenging the validity of the regulation requiring that an urban hospital be within 15 miles of the area to which it seeks to be reclassified in order to qualify. *See id.* at 709. The court, citing *Bowen*, determined that the Medicare Act "does not . . . expressly preclude judicial review of the guidelines used by the [MGCRB] and the Secretary in deciding upon reclassification requests," and held that "the [Medicare] Act's preclusion of review of individual reclassification determinations [does not] imply a congressional intent to preclude review of the underlying guidelines." *Id.* at 710. The *Universal* court similarly rejected the arguments raised by Defendants in their briefing that the strict timeline for MGCRB decisions and the requirement that the MGCRB's reclassification determinations be "budget neutral" implies a congressional intent to bar review of the regulations governing the MGCRB's decisions. *See id.* at 710–12.

Defendants attempt to distinguish these cases by arguing that Plaintiff's request for relief is actually a request for a review of the underlying MGCRB ruling on its application, and thus judicial review is barred under the Medicare Act. In *Skagit Cnty. Pub. Hosp. Dist. No. 2 v. Shalala*, 80 F.3d 379 (9th Cir. 1996), the plaintiff brought suit to challenge the Secretary's failure to properly correct the wage data upon which the MGCRB relied in denying its application for reclassification. The plaintiff argued that it was challenging the process by which its application was denied, rather than the denial itself. However, the Ninth Circuit distinguishing *Universal* and *Bowen*, found that the plaintiff's request for injunctive relief was moot, and that the plaintiff's challenge to the intermediary wage correction process was raised only in order to reverse the individual MGCRB ruling on the plaintiff's reclassification application, and thus the suit was barred under the Medicare Act. *See id.* at 386 ("Accordingly, if a procedure is challenged only in order to reverse the individual reclassification decision, judicial review is not permitted."). Similarly, in *Palisades Gen. Hosp., Inc. v. Leavitt*, 426 F.3d 400 (D.C. Cir. 2005), the plaintiff also brought a challenge to the denial of its MGCRB reclassification application, claiming that the Secretary had erred in denying its wage data correction requests. Distinguishing *Parkview* and citing *Skagit*, the D.C. Circuit found that the plaintiff's challenge was inextricably intertwined with its challenge to the reclassification denial, and was a challenge to a general rule. *Id.* at 405. The court therefore concluded that the Medicare Act therefore barred judicial review of the case. *Id.*

Contrary to Defendants' characterization of Plaintiff's suit, Plaintiff here, like the plaintiffs in *Universal* and *Parkview*, is challenging a general rule governing the consideration of MGCRB applications, rather than the denial of its individual application. To begin with, unlike *Palisades* and *Skagit*, Plaintiff's application has not yet been denied

and thus there is no individual determination to be challenged. Further, in both *Palisades* and *Skagit*, the plaintiffs were challenging an intermediary determination of a wage correction application that bore only on their individual reclassification applications. Unlike those cases, and similar to the plaintiffs in *Universal* and *Parkview*, Plaintiff is challenging the validity of one of the general regulations governing the MGCRB application process—to wit, the ineligibility of hospitals that have been reclassified under Section 401. Plaintiff does not seek to undo any individual determinations with regard to its own wage data, and rather seeks to bar the application of a general regulation that is broadly applicable to many reclassification applicants. Therefore, this Court has subject matter jurisdiction over Plaintiff's claims.

B. Irreparable Harm

Plaintiff argues that it will suffer irreparable harm if the requested injunctive relief does not issue because its reclassification application will be denied and it will lose millions of dollars in Medicare reimbursements that it cannot recoup in a legal action challenging the denial of its application by the MGCRB.[3] Defendants argue that Plaintiff cannot show irreparable harm because the harm of which it complains can be readily avoided by canceling its rural status under Section 401. Defendants argue that pursuant to the regulations governing Section 401 and the MGCRB, Plaintiff can cancel its rural and RRC status effective at the beginning of fiscal year 2015 such that it regains its eligibility for reclassification under 42 C.F.R. 412.230(a)(5)(iii), but it will still maintain

[3] Although the harm Plaintiff complains of is monetary—i.e., the loss of an estimated $3 million in Medicare reimbursements—such harm cannot be adequately compensated with a monetary award because a monetary award is not available. *Cf. United States v. State of New York*, 708 F.2d 92, 93 (2d Cir. 1983) (holding that because an action to recover damages would be barred by the Eleventh Amendment, irreparable harm was established). Once its reclassification application is denied Plaintiff can never bring suit to recoup the loss via a legal challenge to the denial of its application.

that status at the time of the MGCRB's decision such that the lower rural standards will apply to its application. (*See* Def.'s Opp'n [Doc. # 18] at 14–16.) Therefore, Defendant argues, the harm of which Plaintiff complains is actually self-inflicted and easily avoidable, and thus cannot constitute "irreparable harm" for the purposes of establishing that Plaintiff is entitled to a preliminary injunction. *See, e.g.*, *Bristol Technology, Inc. v. Microsoft Corp.*, 42 F. Supp. 2d 153, 162 (D. Conn. 1998) ("The court agrees that either delay or self-inflicted harm can be fatal to a motion for a preliminary injunction.").

Plaintiff counters that Defendants' claim that Plaintiff can easily qualify for reclassification by canceling its rural status is disingenuous. Plaintiff cites two recent attempts by hospitals to navigate the process outlined by Defendants in their opposition. In both cases, the hospital's reclassification applications were denied despite their timely attempts to cancel their rural status because the hospitals had not received confirmation of their cancellations from CMS prior to the issuance of the MGCRB decisions denying their reclassification applications. *See Laredo Medical Center (Provider No. 45-0029)*, MGCRB Case No. 13C0103, Decision of the Administrator (Mar. 14, 2012), 2012 WL 3060847; *Northwest Medical Center (Provider No. 03-0085)*, MGCRB Case No. 13C0119, Decision of the Administrator (Mar. 14, 2012), 2012 WL 3060848. Thus, as Plaintiff argues, there is no guarantee that Plaintiff can avoid the harm of which it complains by acting to cancel its rural redesignation.[4] Further, Plaintiff also claims that if it were to cancel its status as an RRC, it would stand to lose between $3 and $5 million because it

[4] At oral argument, counsel for Defendants represented that Plaintiff's cancelation would be acted on within several days of its receipt by CMS. On December 5, 2013, Plaintiff submitted a letter notifying the Court that it had been informed by the MGCRB that Plaintiff needed to submit notice of its cancellation by December 10, 2013 for the purposes of its application for geographic reclassification. (*See* Not. of Supp. Authority [Doc. # 23] at 1.)

will no longer qualify for the 340B Drug Pricing Program. (*See* Pl.'s Reply [Doc. # 19] at 4–5.) Thus, absent a preliminary injunction, Plaintiff would be forced to choose between losses, and even then, it would not be guaranteed to avoid the application of the regulation it challenges in this suit. Therefore, Plaintiff has established that it will suffer irreparable injury if the requested injunctive relief is not granted.

C. Likelihood of Success on the Merits

Plaintiff argues that it is likely to succeed on the merits of its challenge to 42 C.F.R. § 412.230 because the terms of that regulation directly conflict with the clear language of Section 401. Challenges to an agency's interpretation of the statute that it administers are governed by the two-pronged analysis laid out in *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984). A court must first determine whether "Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* at 842–43. Next, "if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Id.* at 843. At the second step, an agency's interpretation will be given controlling weight unless it is arbitrary and capricious. *Id.* at 844; *see also Natural Resources Defense Council, Inc. v. Muszynski*, 268 F. 3d 91, 98 (2d Cir. 2001) ("[C]onsiderable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer." (internal citations and quotation marks omitted)).

1. Chevron *Step One*

At *Chevron* step one, the Court considers whether Congress has clearly spoken in Section 401 as to whether the Secretary is required to treat hospitals with acquired rural

status as "rural" for the purposes of an application to the MGCRB for geographic reclassification. *See Cohen v. JP Morgan Chase & Co.*, 498 F.3d 111, 116 (2d Cir. 2007). "If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* (internal citations and quotation marks omitted). "To ascertain Congress's intent, we begin with the statutory text because if its language is unambiguous, no further inquiry is necessary. If the statutory language is ambiguous, however, we will resort first to canons of statutory construction, and, if the statutory meaning remains ambiguous, to legislative history." *Id.* (internal citations and quotation marks omitted).

Plaintiff argues that the regulation barring a hospital that has been redesignated as rural pursuant to Section 401 from the additional benefit of reclassification to a different urban CBSA under the MGCRB application process is in direct conflict with the clear terms of Section 401. Section 401 provides that if a hospital qualifies for redesignation, "the Secretary shall treat the hospital as being located in the rural area (as defined in paragraph (2)(D)) of the State in which the hospital is located." As Plaintiff argues, the Supreme Court has recognized that "shall" indicates mandatory language. *See, e.g.*, *United States v. Monsanto*, 491 U.S. 600, 607 (1989). Thus, Plaintiff argues, because there is only one definition of "rural" in the Medicare Act, *see* 42 U.S.C. § 1395ww(d)(2)(D), and because Section 401 does not qualify the purposes for which the Secretary must treat a hospital as being located in a rural area, the clear terms of Section 401 mandate that the Secretary treat redesignated hospitals as rural for all purposes, including for the purpose of evaluating their reclassification applications before the MGCRB.

However, Section 401 does not explicitly require by its terms that redesignated hospitals be treated the same as hospitals physically located in rural areas for all purposes.

The text of Section 401 itself makes no mention of the MGCRB reclassification process and does not discuss the intersection of redesignation and geographic reclassification under the Medicare Act. Section 401 also does not address the standards by which the MGCRB should evaluate a hospital's eligibility for geographic classification. Thus, Section 401 is effectively silent as to whether hospitals that have been redesignated as rural must be eligible for geographic reclassification. Further, 42 C.F.R. § 412.230 does not purport to treat hospitals that have been redesignated pursuant to Section 401 as non-rural or urban for the purposes of MGCRB reclassification. The regulation does not direct the MGCRB to apply the standards for urban hospitals to hospitals that were redesignated as rural pursuant to Section 401, which arguably would violate the plain meaning of the text of Section 401. Rather it directs the MGCRB to reject all reclassification applications by hospitals that have been redesignated as rural, regardless of whether they would meet the rural, the urban, or the RRC guidelines for reclassification.

Elsewhere in the Medicare Act, Congress gave the Secretary broad discretion to develop the guidelines for considering MGCRB applications. *See* 42 U.S.C. § 1395ww(d)(10)(D)(i) ("The Secretary shall publish guidelines to be utilized by the Board in rendering decisions on applications submitted under this paragraph . . . "); *see also Athens Community Hosp., Inc. v. Shalala*, 21 F.3d 1176, 1179 (D.C. Cir. 1994) (holding that "Congress delegated to the Secretary the authority to determine the degree to which the [MGCRB's] discretion should be limited."). The Secretary exercised her discretion in enacting 42 C.F.R. § 412.230, and Section 401 does not purport to cabin that discretion. In light of Section 401's silence regarding the geographic reclassification process, and in light of the delegation of authority to the Secretary to develop the

standards by which hospitals are evaluated before the MGCRB, Plaintiff cannot make the requisite "clear or substantial showing" that 42 C.F.R. § 412.230 violates the plain meaning of Section 401.

To support its proposed construction of Section 401, Plaintiff relies on the text of a conference report published in conjunction with the adoption of the legislation enacting Section 401:

> a hospital in an urban area may apply to the Secretary to be treated as if the hospital were located in a rural area of the State in which the hospital is located. Hospitals qualifying under this section shall be eligible to qualify for all categories and designations available to rural hospitals, including sole community, Medicare dependent, critical access, and referral centers. *Additionally, qualifying hospitals shall be eligible to apply to the Medicare Geographic Reclassification Review Board for geographic reclassification to another area. The Board shall regard such hospitals as rural and as entitled to the exceptions extended to referral centers and sole community hospitals, if such hospitals are so designated.*

H.R. Conf. Rep. No. 106-479, 512 (1999) (emphasis added). Defendants argue that it is inappropriate to rely on legislative history at *Chevron* step one to defeat an exercise of agency discretion. While the Second Circuit has considered legislative history at step one of *Chevron*, *see Cohen*, 498 F.3d at 116, it has also noted that "the Supreme Court has issued mixed messages[5] as to whether a court may consider legislative history at . . . step one of *Chevron*," *Coke v. Long Island Care At Home, Ltd.*, 376 F.3d 118, 137 (2004) *vacated and remanded on other grounds by* 546 U.S. 1147 (2006); *see also id.* at 137 n.3 (collecting and comparing cases). Here, adopting Plaintiff's analysis would require the Court to rely on the conference report to expand on the clear terms of Section 401 and create a conflict with the challenged regulation where none exists on the face of the

[5] Mixed messages undermine Plaintiff's efforts to make the "clear or substantial" showing required for Plaintiff to succeed on its motion.

statute. Other courts have rejected such attempts by plaintiffs to create statutory ambiguity via legislative history when confronted with an otherwise permissible agency interpretation. *See, e.g.*, *San Bernardino Mountains Cmty. Hosp. v. Sec'y*, 63 F.3d 882, 887 (9th Cir. 1995) ("[B]ecause the Secretary's interpretations fall squarely within her statutorily granted discretion, legislative history such as the Senate committee report cannot defeat the regulation."); *Clinton Mem. Hosp. v. Shalala*, 10 F.3d 854, 858 (D.C. Cir. 1993) ("It is far from clear to us that anything in a Senate committee report . . . could condemn as impermissible an interpretation fitting squarely within statutory language."); *Macon Cnty. Samaritan Mem. Hosp. v. Shalala*, 7 F.3d 762, 767 (8th Cir. 1993) (suggesting that an attempt to create an ambiguity via legislative history "puts the car before the horse.")

However, considering the text of the conference report in interpreting the statute, and construing Section 401 as requiring the Secretary to permit redesignated hospitals to receive MGCRB reclassification under the rural guidelines, it still remains far from clear that the challenged regulation would violate the statute under the circumstances in the present case. As outlined in Defendants' brief, if a hospital that has been redesignated as rural and a RRC, like Plaintiff, cancels its rural status for the next fiscal year, that hospital nonetheless will be eligible for reclassification by the MGCRB and its application will be evaluated as if it were an RRC.[6] Thus, Plaintiff's application would be evaluated under rural standards if it canceled its rural status going forward. (*See* Gov't's Supp. Mem.

[6] In supplemental briefing to the Court, the parties have clarified that a hospital that has acquired rural status pursuant to Section 401, but is not an RRC, would be treated as urban by the MGCRB even if it canceled its rural status going forward. (*See* Not. of Supp. Authority at 2; Gov't's Supp. Mem. [Doc. # 24] at 2–3.) Thus, in some circumstances, other than those present in this case, 42 C.F.R. § 412.230 may conflict with Plaintiff's proposed construction of Section 401.

[Doc. # 24] at 2–3.) Neither the text of Section 401 nor the language of the conference report requires that hospitals be permitted to maintain their rural status indefinitely in order to be eligible for MGCRB reclassification. Therefore, even under Plaintiff's construction of Section 401, Plaintiff fails to make the requisite clear or substantial showing of a likelihood of success on the merits of its claims at step one of *Chevron*.

2. Chevron *Step Two*

Plaintiff argues that even if 42 C.F.R. § 412.230 did not clearly conflict with the plain meaning of Section 401, the Secretary's interpretation of Section 401 to permit the exclusion of redesignated hospitals from the MGCRB reclassification process is arbitrary and capricious. Plaintiff bases this argument on the Secretary's comments in adopting regulations pursuant to Section 401, in which the Secretary acknowledged the language of the conference report, and stated that "[w]e agree with the commenters that Congress contemplated that hospitals might seek to be reclassified as rural under section 1886(d)(E) [sic] of the Act in order to become RRCs so that the hospital would be exempt from the MGCRB proximity requirement and could be reclassified by the MGCRB to another urban area." 65 Fed. Reg. 47054, 47089.

However, Plaintiff's argument ignores the rest of the Secretary's comments explaining the decision to disqualify redesignated rural hospitals from the MGCRB process. The Secretary expressed concern "that some hospitals might inappropriately seek to be treated as being located in a rural area for some purposes and as being located in an urban area for other purposes," *id.* at 47088, and that such a scenario could have unintended consequences permitting some hospitals to receive inappropriate reimbursements, *see id.* at 47089. As the Secretary explained:

> This policy is consistent not only with the statutory language but also with the policy considerations underlying the MGCRB process. The MGCRB

> process permits a hospital to be reclassified from one geographic area to another if it is significantly disadvantaged by its geographic location and would be paid more appropriately if it were reclassified to another area. We believe that it would be illogical to permit a hospital that applied to be reclassified from urban to rural under section 1886(d)(8)(E) of the Act because it was disadvantaged as an urban hospital to then utilize a process that was established to enable hospitals significantly disadvantaged by their rural or small urban location to reclassify to another urban location. If an urban hospital applies under section 1886(d)(8)(E) of the Act in order to be treated as being located in a rural area, then it would be anomalous at best for the urban hospital to subsequently claim that it is significantly disadvantaged by the rural status for which it applied and should be reclassified to an urban area.

Id. at 47088. Further, the Secretary considered alternative proposals to limit the potential for inappropriate payments and concluded that the proposed regulation would best address its concerns regarding the interplay of Section 401 and the MGCRB reclassification process. *Id.* at 47089. Thus, the Secretary's interpretation of Section 401 is meant to avoid permitting a hospital to be treated as rural for some purposes and as urban for others, thereby receiving inappropriate Medicare reimbursements. Such an interpretation is hardly arbitrary or capricious. *See Bellevue Hosp. Ctr. v. Leavitt*, 443 F.3d 163, 174 (2d Cir. 2006) (a finding that agency action is arbitrary and capricious can be made only where the agency "has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." (internal citations and quotation mark omitted)). Therefore, Plaintiff cannot establish a clear likelihood of success on the merits at the second step of *Chevron*.

IV. Conclusion

For the foregoing reasons, Plaintiff's Motion [Doc. # 4] for a Preliminary Injunction is DENIED.

IT IS SO ORDERED.

/s/
Janet Bond Arterton, U.S.D.J.

Dated at New Haven, Connecticut this 6th day of December, 2013.