UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

LAWRENCE & MEMORIAL HOSPITAL, *Plaintiff*, *v.* SYLVIA M. BURWELL, MARILYN TAVENNER, and ROBERT G. EATON, *Defendants.*	Civil No. 3:13cv1495 (JBA) May 2, 2016

RULING ON EMERGENCY MOTION FOR PRELIMINARY INJUNCTION

Plaintiff Lawrence & Memorial Hospital ("LM") filed this suit against Defendants Sylvia Burwell, 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 preventing Defendants from applying that scheme to Plaintiff's current and future reclassification applications. This Court granted [Doc. # 41] Defendants' motion for summary judgment on December 22, 2014, finding that Defendants' regulations did not violate the Medicare and Administrative Procedures Acts. Thereafter, Plaintiff appealed that decision to the Second Circuit which, by mandate dated February 25, 2016, reversed this Court's order and invalidated the regulation at issue, holding that it contravened the unambiguous language of the Medicare Act. The Second Circuit remanded the case to this Court "so that it may impose appropriate remedies consistent" with the Second Circuit's opinion. (Mandate [Doc. # 48] at 17.)

On March 11 and 14, 2016, respectively, Plaintiff filed an Emergency Motion for Preliminary Injunction [Doc. # 50] and a supplemental declaration [Doc. # 53] in support of that motion. Defendants, at the Court's request, filed a brief summary of their opposition [Doc. # 54] to Plaintiff's motion on March 15, 2016. Following a status conference held on the record on March 17, 2016, Defendants filed a full opposition [Doc. # 61] to the motion and Plaintiff filed a reply [Doc. # 62]. For the following reasons, Plaintiff's motion is denied.

I. Background

A. The Wage Index and the Medicare Geographic Classification Review Board

As detailed in the Court's Ruling [Doc. # 25] on Plaintiff's Motion for Preliminary Injunction and Ruling on the Cross-Motions for Summary Judgment, Medicare 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. (Am. Compl. [Doc. # 28] ¶ 15.) 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 id.* ¶¶ 16–17.) 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).

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"). (Am. Compl. ¶ 21.) After the 2000 census, the MSAs were replaced with Core Based Statistical Areas ("CBSAs") that are roughly equivalent to the previous groupings. (*Id.* ¶ 22.) Each hospital is reimbursed

according to the wage index of the CBSA in which it is physically located. (*Id.* ¶ 23.) 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.* ¶¶ 29–33.)

In 1989, Congress established the Medicare Geographic Classification Review Board ("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. (*Id.* ¶ 28); *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. (Am. Compl. ¶ 37.) If a hospital has been designated as a rural referral center ("RRC"), the first and third elements of this test are waived. (*Id.* ¶ 44); *see also* 42 C.F.R. §§ 412.230(a)(3), 412.230(d)(1)(3)(C). If the MGCRB approves a hospital's application, its reclassification is valid for a period of three years. (Am. Compl. ¶ 43.)

B. 340B Drug Discount Program

Pursuant to the 340B Drug Discount Program, pharmaceutical manufacturers must, as a condition of Medicaid covering their products, enter into a Pharmaceutical Pricing Agreement with the Secretary of HHS, under which the manufacturers agree to

offer 340B "covered entities" (including RRCs) "covered outpatient drugs" at a discounted price. (*Id.* ¶¶ 57–59); 42 U.S.C. § 256b. While disproportionate share hospitals must have a disproportionate share adjustment factor of greater than 11.75% to participate, RRCs may participate as long as they have a disproportionate share adjustment factor of greater 8%. (Am. Compl. ¶ 60.) Plaintiff represents that its disproportionate share factor "based on its most recently filed cost report is greater than 8 percent but less than 11.75 percent." (Mem. Supp. Emergency Mot. Prelim. Inj. [Doc. # 51] at 6.)

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. (Am. Compl. ¶ 46); 42 U.S.C. § 1395ww(D)(8)(E). Pursuant to Section 401, HHS 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* Am. Compl. ¶ 56.) It is these regulations that the Second Circuit found invalid.

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 an RRC. (*Id.* ¶¶ 64–65.) Those requests were granted, and Plaintiff was treated as an RRC beginning October 1, 2013. (*Id.* ¶ 66.) Shortly after being reclassified as rural under Section 401, Plaintiff filed an application with the MGCRB to be reclassified to the (urban) Nassau-Suffolk, NY CBSA. (*Id.* ¶ 67.) On October 11, 2013, while Plaintiff's application was pending, Plaintiff filed this suit and sought a preliminary injunction enjoining Defendants from acting on its application for reclassification until the Court could hold a hearing on the merits of Plaintiff's claims, which the Court denied. (*See id.* ¶ 68.) In order to avoid the denial of its reclassification application (pursuant to the Secretary's regulation), Plaintiff cancelled its Section 401 status (effective October 1, 2014). (*Id.* ¶ 70.) As a result, its application for reclassification was approved but Plaintiff was no longer eligible for the 340B Program. (*Id.* ¶ 73.)

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 quotation marks omitted).

III. Discussion

Plaintiff seeks a preliminary injunction ordering Defendants to: (1) maintain Plaintiff's current wage index classification (Nassau-Suffolk, NY); (2) order reinstatement of Plaintiff's Section 401 status; (3) order reinstatement of Plaintiff's RRC status; and (4) order Plaintiff's 340B eligibility to be immediately reinstated. (Mem. Supp. at 10.) Plaintiff explains that for the following reasons, without an injunction, it may face several hurdles and a great deal of delay in obtaining this relief.

In order to be 340B eligible, hospitals in Plaintiff's position must first obtain rural status, through for example, Section 401; then obtain RRC status; and then apply for the 340B Program. In obtaining rural status, a hospital agrees to receive a lower wage reimbursement rate, but this short-term loss is worthwhile because it enables the hospital to begin the process of obtaining large savings through the 340B Program. If Plaintiff had to begin the process of applying to the 340B Program anew, it would have to first apply for rural status and lose money for a period of time until it could get reassigned to an urban area. It argues that it should not have to go through this process and incur losses again because the only reason it gave up its 340B eligibility in the first place was the regulations, which have been invalidated. Therefore, it seeks an order classifying it nominally as rural under Section 401, solely for the purposes of being RRC-eligible, but requiring Defendants to continue to reimburse it at its current urban wage index rate.

Further, Plaintiff seeks an order requiring Defendants to reinstate its RRC status because by statute, RRC status can only be requested in the last quarter of a hospital's fiscal period, which, for Plaintiff, ends on September 30. Finally, Plaintiff seeks an order

requiring Defendants to allow it to immediately participate in the 340B program because without such an order it will not be 340B eligible until July 1, 2016.[1]

Defendants respond that with respect to Plaintiff's first request (for an order requiring them to maintain Plaintiff's current wage index classification), no order is necessary because they have stipulated that they "will not revoke the hospital's use of the Nassau-Suffolk wage index." (Opp'n Mot. Prelim. Inj. [Doc. # 61] at 1.) As to Plaintiff's other requests, Defendants contend that this Court does not have the authority to order the relief requested; the case must be remanded to the agency for "identification and implementation of the appropriate remedy"; and in any event, Plaintiff has not shown a likelihood of success on the merits or that an injunction is in the public interest. (Opp'n at 2, 5–6.) Because the Court agrees that it lacks authority to order a specific remedy, it does not address Defendants' remaining arguments.

It is long-settled law that "the function of the reviewing court ends when an error of law is laid bare. At that point the matter once more goes to the [agency] for reconsideration." *Fed. Power Comm'n v. Idaho Power Comm'n*, 344 U.S. 17, 20 (1952); *see Baptist Med. Ctr. v. Sebelius*, 855 F. Supp. 2d 1, 3 (D.D.C. 2012) ("This Court's function ended when the D.C. Circuit invalidated the rule in question. At this point, the Court must remand the issue to HHS. If the Plaintiffs take issue with the legal standard applied by HHS upon remand, relief lies with review of that final agency action, not with this Court at this time."); *Heartland Hosp. v. Thompson*, 328 F. Supp. 2d 8, 13–14 (D.D.C.

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[1] Based on HHS's timetables, an application approved during the April 1 to 15 application period is not effective until July 1, 2106. (Suppl. Musiak Decl. [Doc. # 63] ¶ 14.) The hospital applied for the 340B Program on April 1, 2016 as a disproportionate share hospital (rather than as an RRC). (*Id.*)

2004) *aff'd sub nom. Heartland Reg'l Med. Ctr. v. Leavitt*, 415 F.3d 24 (D.C. Cir. 2005) ("[A]n award to the plaintiff of its requested relief—SCH status and reimbursement plus interest—would be inappropriate under an uncontroverted line of binding cases."); *St. Bernard's Hosp., Inc. v. Thompson*, 193 F. Supp. 2d 1097, 1111 (E.D. Ark. 2002) ("Plaintiffs argue that they are entitled to the Medicare reimbursement they should have received pursuant to the RRC status . . . . The Secretary asserts that the appropriate remedy is for the Court to remand the matter to the Secretary to calculate the amounts of additional reimbursement, if any, to which the plaintiffs are entitled. The Court agrees."); *Cty. of Los Angeles v. Shalala*, 192 F.3d 1005, 1011 (D.C. Cir. 1999) ("Once . . . the district court held that the Secretary had misinterpreted § 1395ww(d)(5)(A)(iv), it should have remanded to the Secretary for further proceedings consistent with its conception of the statute. Not only was it unnecessary for the court to retain jurisdiction to devise a specific remedy for the Secretary to follow, but it was error to do so.").

The hospital's assertion that it should be restored to the position it would have occupied had the Secretary not issued an invalid regulation has been squarely rejected by the D.C. Circuit. As that court explained in *Palisades Gen'l Hosp. v. Leavitt*,

> [T]he hospital's contention [that it is entitled to make-whole relief that puts it in the position it would have been in had the agency acted correctly] is based on a flawed premise. The district court had no jurisdiction to order specific relief. Unlike a district court managing a garden variety civil suit, a district court reviewing a final agency action does not perform its normal role but instead sits as an appellate tribunal. Thus, under settled principles of administrative law, when a court reviewing agency action determines that an agency made an error of law, the court's inquiry is at an end: the case must be remanded to the agency for further action consistent with the correct legal standards. Accordingly, the district court had jurisdiction only to vacate the Secretary's decision

> rejecting the hospital's revised wage data and to remand for further action consistent with its opinion. It did not, as the hospital contends, have jurisdiction to order either reclassification based upon those adjusted wage data or an adjusted reimbursement payment that would reflect such a reclassification.

426 F.3d 400, 403 (D.C. Cir. 2005) (internal quotation marks and citations omitted); *see Alegent Health-Immanuel Med. Ctr. v. Sebelius*, 917 F. Supp. 2d 1, 3 (D.D.C. 2012) ("Although the Court sympathizes with Plaintiffs' desire for clear directions to, and prompt attention from, the agency, under settled principles of administrative law, when a court reviewing agency action determines that an agency made an error of law, the court's inquiry is at an end: the case must be remanded to the agency for further action consistent with the corrected legal standards. Only in extraordinary circumstances do courts issue detailed remedial orders." (internal quotation marks, alterations, and citations omitted)). Remand is particularly appropriate here, where the statutory scheme at issue is highly complex, and its administration has been specifically committed by Congress to the expertise of the Secretary.

Plaintiff's arguments to the contrary—that (1) if the Court of Appeals had "wanted the matter to be remanded to the agency, it would have said so and done so" (Reply Interim Opp'n [Doc. # 55] at 1); (2) "*Chevron* indicates that if the agency's interpretation is rejected at Step 1 of the two-step analysis," as it was here, "there is no reason to remand to the agency because the statutory provision at issue i[s] clear and unambiguous and there is no discretion for the agency to exercise" (*id.* at 2 (citing *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984))); (3) remand is unnecessary because it would be futile (Reply Opp'n [Doc. # 62] at 3–4); and

(4) the Declaratory Judgment Act gives the Court the authority to issue the requested remedial order (*id.* at 2)—are unavailing for the reasons that follow.

A. The Remand Order

Plaintiff contends that "[i]f the Court of Appeals believed that the courts were without authority to remedy the damage suffered by Lawrence + Memorial, there would had been no need for a remand of any kind. The Second Circuit could have just declared the regulation unlawful and left it at that. If the Court of Appeals wanted the matter to be remanded to the agency, it would have done so." (Reply Opp'n at 2.) This argument, is however, unpersuasive, as appellate courts routinely remand cases to district courts to be remanded back to an agency.

B. *Chevron*

Plaintiff's *Chevron* argument fares no better. The Court is not persuaded that *Chevron* dictates that this Court may order the remedy Plaintiff seeks. *Chevron* requires that both the reviewing court and the agency give effect to the unambiguously expressed intent of Congress. The Second Circuit here found that the statute at issue unambiguously expresses Congress' intent, and therefore *in construing that statute*, it did not defer to the agency. Nowhere does *Chevron* state that once a court, as here, has determined that a particular regulation is invalid as inconsistent with Congress's intent, the agency is stripped of any role in implementing that decision.

C. Futility

Plaintiff next claims that remand is unnecessary here because "[c]ourts do not remand matters when it would be an 'idle and useless formality' and 'convert judicial review of agency action into a ping-pong game.'" (*Id.* at 3 (quoting *Morgan Stanley*

Capital Grp. Inc. v. Pub. Util. Dis. No. 1 of Snohomish Cnty., Wash., 554 U.S. 527, 545 (2008)). Although this is undoubtedly an accurate statement of the law, the Court has no reason to believe that remanding this case would be an exercise in futility. Contrary to Plaintiff's contention that the Secretary "has already advised the court what the Secretary will do if the matter is remanded to the agency — nothing, except for the promise not to violate the law [in the future]" (*id.*), the Secretary in fact represented that she "stands ready and willing to address the implications of the Second Circuit's decision and implement changed regulations and policy, as appropriate," including considering Plaintiff's applications for Section 401 status, RRC status, and the 340B drug discount program (Opp'n at 7). That Defendants have not promised to immediately reinstate Plaintiff into the 340B program, regardless of the implications of such an action for the agency's administration of the complex Medicare program, does not mean that remand to the agency would be futile.

D. Declaratory Judgment Act

The Court likewise rejects Plaintiff's claim, unsupported by citation to caselaw, that the Declaratory Judgment Act grants this Court the authority to issue the order sought, because as Defendants note, the Act "is not an independent source of jurisdiction." (Opp'n at 8 (citing *Schilling v. Rogers*, 363 U.S. 666, 677 (1960)).)

IV. Conclusion

For the foregoing reasons, Plaintiff's motion for preliminary injunction is DENIED, and this case is remanded to the agency for identification and implementation of an appropriate remedy in light of the Second Circuit's decision. The Clerk is requested to close this case.

IT IS SO ORDERED.

/s/

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

Dated at New Haven, Connecticut this 2nd day of May, 2016.