UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
FLORENCE DIVISION

Accident, Injury and Rehabilitation, PC, d/b/a Advantage Health and Wellness, Plaintiff, v. Alex M. Azar, II, Secretary of the United States Department of Health and Human Services; and Seema Verma, Administrator for the Centers for Medicare and Medicaid Services, Defendants.	C/A No. 4:18-cv-02173-DCC **OPINION AND ORDER**

This matter comes before the Court on Plaintiff's Motion for Temporary Restraining Order and Preliminary Injunction. ECF No. 5. On August 8, 2018, the Court directed Plaintiff to serve Defendants with the Complaint and Motion. ECF No. 8. On August 13, 2018, the Court held a telephonic status conference with the parties to discuss the pending Motion. ECF No. 14. During the conference, the Court ordered the parties to consult within ten days to discuss the possibility of settlement negotiations and directed the parties to file a joint status conference at the conclusion of the ten-day period. *Id*. On August 20, 2018, the parties filed a Joint Status Report indicating "the Parties have agreed to engage in direct settlement negotiations and, if necessary, mediation through a third party neutral." ECF No. 19. Plaintiff has requested the issuance of a Temporary Restraining Order ("TRO") during that process.

BACKGROUND

I. Overview of Medicare Appeals System

In 1965, Congress enacted Title XVIII of the Social Security Act, 42 U.S.C.

§ 1395 *et seq.*, known as the Medicare Program. Entitlement to Medicare is based on age (65 or older), disability, or affliction with end-stage renal disease. 42 U.S.C. §§ 426, 426-1. Medicare is comprised of Parts A, B, C, and D. Part B is medical insurance that authorizes payment of federal funds for health services, including physician, laboratory, outpatient, diagnostic, and radiology services. *See* 42 U.S.C. § 1395k; 42 C.F.R. § 410.10.

The Secretary of Health and Human Services ("HHS") has overall responsibility for the administration of Medicare. Within HHS, the responsibility for the administration of Medicare has been delegated to the Centers for Medicare & Medicaid Services ("CMS"). To assist in the administration of Medicare Part B, CMS initially contracted with carriers or fiscal intermediaries. Carriers, typically private insurance companies, were largely responsible for processing and paying Part B claims. 42 C.F.R. §§ 421.1–421.3.

Beginning in November 2006, Medicare Administrative Contractors ("MACs") began replacing carriers and fiscal intermediaries. *See* 42 U.S.C. § 1395kk-1; 42 C.F.R. § 421.400 *et seq.*; 71 F.R. 67960-01, at 68181 (Nov. 24, 2006). MACs generally act on behalf of CMS to process and pay Part B claims and perform administrative functions on a regional level. Since at least 2006, Palmetto GBA served as the Medicare carrier and fiscal intermediary for South Carolina until May 2010, when Palmetto GBA was awarded a contract to serve as South Carolina's MAC for Part B claims.

Medicare only covers medically necessary items or services, excluding from coverage "any expenses incurred for items or services […] which […] are not reasonable and necessary for the diagnosis or treatment of illness or injury or to

improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). After a hospital or healthcare provider performs Medicare-eligible services, it submits a claim for reimbursement to the MAC, which makes a determination of the medical necessity of the claim.

If the MAC denies a claim, a provider can engage in a four-level administrative appeal process, followed by judicial review. *Am. Hosp. Assoc. v. Burwell*, 812 F.3d 183, 185 (D.C. Cir. 2016). First, the provider presents its claim to the MAC for a "redetermination." *Id*. (citing 42 U.S.C. § 1395ff(a)(3)(A), (a)(3)(C)(ii)). If the MAC denies the "redetermination," the provider can seek "reconsideration" by a Qualified Independent Contractor ("QIC"). 42 U.S.C. § 1395ff(c). Both of these review processes are overseen by CMS. *Burwell*, 812 F.3d at 185. "If the provider remains unsatisfied, and if its claim exceeds $150, it may continue to the third stage: de novo review by an administrative law judge, including a hearing." *Id*. (citations omitted). "This stage of the process is overseen by the Office of Medicare Hearings and Appeals ["OMHA"], which houses ALJs and their support staff, and which is funded by a separate appropriation. *Id*. at 185–86 (citations omitted). The final administrative appeal stage involves de novo review by the Medicare Appeals Council, which is a division of the Departmental Appeals Board ("DAB"). *Id*. at 186. "Although the DAB has authority to hold a hearing, it does so only if there is an extraordinary question of law/policy/fact." *Id*. (quotation omitted). Only after a party exhausts these administrative appeals may it seek judicial review in federal court.

In order to streamline the appeals process, there are statutory time frames for each step of the process. Redetermination by the MACs shall be conducted within sixty

days. 42 U.S.C. § 1395ff(a)(3)(C)(ii). QICs shall conduct and decide reconsiderations within sixty days. *Id.* § 1395ff(c)(3)(C)(i). ALJs "shall conduct and conclude a hearing . . . and render a decision within ninety days," though the appealing provider may waive this deadline. *Id*. § 1395ff(d)(1)(A), (B). Finally, the DAB must make a decision or remand the case to the ALJ for reconsideration within ninety days. *Id*. § 1395ff(d)(2)(A). If these time periods are complied with, appeals will proceed through the administrative process within approximately a year. The statutory scheme does, however, prescribe consequences for failure to meet several of the deadlines. "In a process commonly referred to as escalation, a provider that has been waiting for longer than the statutory time limit may advance its appeal to the next stage." *Burwell*, 812 F.3d at 186 (internal quotation marks omitted).

"For years, the administrative appeal process functioned largely as anticipated, with its various stages typically completed within the statutory time frames." *Id*. (citing *Am. Hosp. Ass'n v. Burwell*, 76 F. Supp. 3d 43, 46 (D.D.C. 2014)). Then, in 2010, the Secretary of HHS implemented the Medicare Recovery Audit Program, which is designed "for the purpose of identifying underpayments and overpayments and recouping overpayments." 42 U.S.C. § 1395ddd(h)(1). In order to accomplish this task, the Secretary of HHS entered into contracts with Recovery Audit Contractors ("RACs"), who are paid on a contingency basis for collecting overpayments. *Burwell*, 812 F.3d at 186. Additionally, CMS uses Zone Program Integrity Contractors (“ZPICs”) to review post-payment claims. *San Bois Health Servs., Inc. v. Hargan*, No. CIV-14-560-RAW, 2017 WL 5140519, at *1 (E.D. Okla. Nov. 6, 2017). ZPICs frequently use statistical sampling in order to determine the total amount of a provider’s overpayments that must

be recouped. *Id.* The Recovery Audit program has been quite successful in recouping overpayments. *Burwell*, 812 F.3d at 187. "But because RAC denials are appealable through the same administrative process as initial denials, the RAC program has contributed to a drastic increase in the number of administrative appeals." *Id*. "Between RAC and non-RAC appeals, OMHA currently receives many more cases than it can process in a timely fashion." *Id*.

The backlogged administrative appeals process provides a number of inherent problems for medical providers. But during the first two levels of the appeals process, the status quo remains and the Government cannot begin recouping the money that it is allegedly owed for overpayments. Once a medical provider requests a hearing before the ALJ, however, the Government has the discretionary authority to recoup the alleged overpayments while the appeal is pending, often for several years before the provider is even afforded a hearing. 42 U.S.C. § 1395ddd(f)(2). It is precisely this issue that brings Plaintiff before the Court in this case.

II. Plaintiff's Claims

Plaintiff is a chiropractic practice that provides “medical, chiropractic and holistic care, including wellness and whole-body treatment for patients in the Florence and greater Piedmont area of South Carolina.” ECF No. 5-2 at 2. Plaintiff participates in the Medicare system and a substantial percentage of its revenue comes from Medicare reimbursements. *Id.* “Prior to 2015, [Plaintiff] earned annual gross revenues of approximately $6.8 million.” *Id.* Medicare reimbursements constituted thirty-one percent (31%) of those gross revenues. *Id.*

On or about September 4, 2012, AdvanceMed, the ZPIC for South Carolina, opened an investigation into Plaintiff's medical billing. ECF No. 1 at 2. On July 1, 2013, AdvanceMed conducted an unannounced audit of Plaintiff's facility in Florence and notified Plaintiff that it was reopening claims made within the prior four years. *Id.* The Notice of Review requested Plaintiff "provide every document and record supporting billing for 15 Medicare beneficiaries between June 2012 and April 2013." *Id.* at 2. Plaintiff provided the documentation, and, on November 3, 2014, AdvanceMed issued a Notice of Suspension of Medicare Payments to Plaintiff. *Id.* The Notice of Suspension "stated a post-payment review of 25 Medicare Part B claims result[ed] in a 97.8% denial rate." *Id.* at 3.

On December 3, 2014, AdvanceMed requested documents supporting billing for 80 Medicare beneficiaries between September 2010 and September 2014, which AdvanceMed claims constituted a statistically valid sample of Plaintiff's Part B claims. *Id.* Plaintiff provided the required documentation. *Id.* AdvanceMed determined that $2,507.91 of the Part B claims and $33,710.40 of the DME claims from this known data set should have been denied. ECF No. 5-5 at 2. Based on these numbers, AdvanceMed apparently extrapolated what the overpayments for the entire four-year population of Part B and DME would be. On June 8, 2015, AdvanceMed issued an Overpayment Determination, notifying Plaintiff that its overpayments totaled $5,627,263.87 for Part B claims and $1,021,614.05 for Durable Medical Equipment ("DME") claims. *Id.*

Plaintiff filed appeals with the MACs for Part B and DME claims,[1] which were denied in September 2015. *Id.* at 4. Palmetto GBA, the Medicare Part B MAC, also notified Plaintiff CMS "would seek recoupment through offsets of Plaintiff's continued provider billings" and "notified Plaintiff that $163,625.36 had been recouped on July 9, 2015." *Id.* Plaintiff appealed the MACs' findings to C2C Solutions, Inc., the QIC for South Carolina. *Id.* The QIC issued a partially favorable decision on the Part B and DME claims, overturning the denials on two of the Part B claims and eleven of the DME claims. *Id.*

On March 10, 2016, Plaintiff appealed the QIC's DME decision to OMHA and requested a full evidentiary hearing before an ALJ. *Id.* On April 4, 2016, Plaintiff appealed the QIC's Part B decision to OMHA and requested a full evidentiary hearing before an ALJ. *Id.* Plaintiff's appeals have been pending since that time, and CMS has withheld over $1.8 million in Medicare payments while Plaintiff is waiting for an ALJ hearing. *Id.* at 5. CMS has also indicated its intent to refer the overpayment collection to the United States Treasury Department. *Id.* at 6.

On August 7, 2018, Plaintiff filed a Verified Complaint for Temporary Restraining Order and Preliminary Injunction with the Court. ECF No. 1. Plaintiff alleges three causes of action: (1) denial of procedural due process; (2) ultra vires; and (3) violation of the Administrative Procedures Act. *Id.* By way of remedy, Plaintiff asks the Court to enjoin Defendants from their recoupment efforts while Plaintiff is waiting for the ALJ hearings it is entitled to by statute. On August 8, 2018, Plaintiff filed a Motion for Temporary Restraining Order and Preliminary Injunction, with numerous attachments

[1] CGS, Inc. is the MAC for DME claims in South Carolina. ECF No. 1 at 3.

and exhibits. ECF No. 5. On August 17, 2018, Plaintiff filed a Supplemental Memorandum in Support of its Motion. ECF No. 16.

LEGAL STANDARD

A TRO is designed to preserve the status quo and prevent irreparable harm so long as is necessary to hold a hearing, and no longer. *Granny Goose Foods, Inc. v. Bd. of Teamsters & Auto Truck Drivers*, 415 U.S. 423, 439 (1974). A TRO may be issued with or without notice to the adverse party. 11A Charles Allen Wright, Arthur R. Miller, & Mary Kay Kane, *Federal Practice & Procedure* § 2951 (3d ed.). To be entitled to a TRO, a party must demonstrate it meets a four-prong test: (1) that the plaintiff is likely to succeed on the merits; (2) that the plaintiff is likely to suffer irreparable harm in the absence of preliminary injunctive relief; (3) that the balance of the equities tips in the plaintiff's favor; and (4) that the injunction is in the public interest. *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). "The order expires at the time after entry—not to exceed 14 days—that the court sets, unless before that time the court, for good cause, extends it for a like period or the adverse party consents to a longer extension." Fed. R. Civ. P. 65(b)(2). "The court may issue a preliminary injunction or a temporary restraining order only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained." Fed. R. Civ. P. 65(c).

DISCUSSION

I. Likelihood of Success on the Merits

Plaintiff contends that it is likely to prevail on its underlying procedural due process claim because Defendants have failed to provide Plaintiff with an ALJ hearing

during the time period mandated by statute. Courts look at three factors when determining whether a procedural due process violation has occurred: "First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail." *Mathews v. Eldridge*, 424 U.S. 319, 335 (1976).

As to the first factor, the private interest that is affected is Plaintiff's very existence and financial stability. Plaintiff certainly has a property interest in the Medicare payments for services rendered to patients. Second, the risk of the erroneous deprivation of this private interest absent an ALJ hearing is great. Plaintiff offers evidence that the "Health and Human Services Office of Inspector General found that claim denials associated with these alleged overpayments are overturned wholly or partially at the ALJ level 60% of the time." ECF No. 16 at 5. Although Plaintiff can escalate its appeal to the DAB, it would be deprived of important procedural safeguards inherent to the ALJ hearing, namely to test the validity of Defendants' statistical sample in an evidentiary hearing before an independent arbiter. Finally, Plaintiff is not seeking any additional or substitute safeguards that would lead to administrative or financial burdens on the Government. For example, Plaintiff is not asking the Court to order Defendants to provide it with an ALJ hearing.[2] Plaintiff is simply asking that the

[2] Indeed, the Court cannot order Defendants to provide Plaintiff with an immediate hearing. *See Cumberland Cty. Hosp. Sys.v. Burwell*, 816 F.3d 48 (4th Cir. 2016)

Government not deprive it of money that it has earned when the Government cannot comply with its own procedural requirements in a timely manner. Accordingly, the Court concludes that Plaintiff has shown a substantial likelihood of success on the merits of its procedural due process claim.

II. Irreparable Harm

Plaintiff has complied with the administrative appeals process and has been waiting more than two years for a hearing before an ALJ. During that time, Plaintiff has lost an estimated $6,000,000 in gross revenue, and its owner, Dr. Steven McKay, has contributed more than $1,300,000 in capital contributions in order to keep the business operational. ECF No. 5-2 at 4. Additionally, Plaintiff has been forced to terminate twenty four employees in light of its dwindling gross revenue.[3] Plaintiff's share of the applicable healthcare market has "shrunk precipitously." *Id.* at 3. Plaintiff's Chief Financial Officer attested that, "[i]f such recoupment continues, it will irreparably harm [Plaintiff], and [it] will be forced to close [its] doors and declare bankruptcy imminently." *Id.* at 4. Accordingly, the Court concludes that Plaintiff has established a substantial threat of immediate and irreparable harm for which no adequate remedy at law exists.

III. Balance of the Equities

The balance of the equities weighs in favor of granting the TRO. Absent relief, Plaintiff alleges that it will go bankrupt, employees will lose their jobs, and patients will lose access to much needed healthcare. Conversely, Defendants will suffer no harm

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(affirming a district court's denial of a petition for a writ of mandamus to order the Government to immediately provide an ALJ hearing).

[3] In 2017, Plaintiff's gross revenue was down 63% compared to 2014. ECF No. 5-2 at 3.

from granting the TRO because they will have the ability to resume recoupment of any overpayments if the ALJ rules in their favor. Under the facts of this case, the Court finds that the harm to Defendants is substantially outweighed by the harm that Plaintiff will suffer if recoupment continues while it is deprived of a hearing before an ALJ.

IV. Public Interest

The quality of the healthcare services Plaintiff provides to an underserved community is not at issue in this case, only the reimbursement for those services. The public interest will be served by granting the TRO in order to allow Plaintiff to continue to provide these much needed services.

V. Bond Requirement

In its discretion, the Court waives the bond requirement for Plaintiff. *See Pashby v. Delia*, 709 F.3d 307, 332 (4th Cir. 2013) ("[T]he district court retains the discretion to set the bond amount as it sees fit or waive the security requirement." (citations omitted)). Under the circumstances of this case, the Court finds that the Defendants will suffer no meaningful harm, as they can continue their ongoing recoupment efforts immediately if this Order is dissolved. *See Hoechst Diafoil Co. v. Nan Ya Plastics Corp.*, 174 F.3d 411, 421 n.3 (4th Cir. 1999) ("In fixing the amount of an injunction bond, the district court should be guided by the purpose underlying Rule 65(c), which is to provide a mechanism for reimbursing an enjoined party for harm it suffers as a result of an improvidently issued injunction or restraining order.").

CONCLUSION

For the reasons detailed above, the Court **GRANTS** Plaintiff's Motion for Temporary Restraining Order, ECF No. 5, and **ORDERS** that Defendants are hereby

restrained and enjoined from withholding Medicare payments to Plaintiff to effectuate the recoupment of any alleged overpayments. The Court **FURTHER ORDERS** that Defendants are hereby restrained and enjoined from attempting or initiating any other collection efforts, such as referral through the Department of the Treasure or a third-party collection agency. This TRO shall expire fourteen days after the date and hour of its issuance, unless otherwise extended by the Court.

The Court directs Defendants to file a response to Plaintiff's Motion for Preliminary Injunction by Monday, August 27, 2018, and Defendant shall file a reply, if necessary, by Wednesday, August 29, 2018. A hearing on the Motion for Preliminary Injunction will be held on Friday, August 31, 2018, at 1:00 p.m., at the Donald S. Russell Courthouse, 201 Magnolia Street, Spartanburg, South Carolina 29306.

The Court encourages the parties to seek a beneficial resolution of the underlying Medicare appeals. Therefore, the parties may notify the Court by Wednesday, August 29, 2018, if they consent to an extension of the TRO so that settlement negotiations may continue.

IT IS SO ORDERED.

s/ Donald C. Coggins, Jr.
United States District Judge

4:19 P.M., August 21, 2018
Spartanburg, South Carolina