NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NATIONWIDE AMBULANCE SERVICES, INC.,	
Plaintiff,	**Hon. Dennis M. Cavanaugh**
v.	**OPINION**
SAFEGUARD SERVICES, LLC,	Civil Action No. 11-cv-5213 (DMC)(MF)
Defendants.	

DENNIS M. CAVANAUGH, U.S.D.J.:

Nationwide Ambulance Services, Inc.'s ("Plaintiff," alternatively "Nationwide") commenced this cause of action for a preliminary injunction by way of an Application for Emergency Relief ("Application") against SafeGuard Services, LLC ("Defendant," alternatively "SafeGuard") under L.Civ.R. 65.1. In response, Defendant filed a Motion Opposing the preliminary injunction and further Cross-moved for Summary Judgment and to Dismiss Plaintiff's Complaint. Arguments for and opposing the Application were heard in this Court on October 6th, 2011 at nine o'clock A.M. After considering all of the arguments and based upon the following reasons, it is the decision of this Court, for the reasons herein expressed, that Plaintiff's Application is **denied**. Defendant is hereby granted leave to renew and resubmit the cross-motion to dismiss and for summary judgment.

I. BACKGROUND

1. Relationship between Nationwide and SafeGuard

Nationwide is a New Jersey ambulance service provider headquartered in Cranford, New

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Jersey. (Pl.'s V. Compl. 1, Sept. 9, 2011, ECF No. 1). SafeGuard is a Delaware Limited Liability Company and Medicare contractor headquartered in Miramar, Florida. Id. Nationwide renders non-emergency, scheduled, repetitive ambulance services to dialysis patients for transportation between their residences and the nearest dialysis center for dialysis therapy. Initial payments for services under Medicare are ordinarily made as long as the claim contains no irregularities on its face. SafeGuard is a designated Program Safeguard Contractor ("PSC") specifically contracted to review and investigate claims with a focus on preventing fraudulent claims or claims resulting from errors in processing. (Def.'s Mot. Opp. 10, Sept. 26, 2011, ECF No. 12). SafeGuard serves as an intermediary between a service provider, such as Nationwide, and a Medicare Administrative Contractor ("MAC") such as Highmark Medicare Services ("Highmark"). Id. at 16. Highmark determines overpayments and underpayments to suppliers and is the party who actually makes payments on claims. Id. at 11. Nationwide argues that SafeGuard interfered with their right to receive Medicare payments from Highmark. (Pl.'s V. Compl. at 10).

2. Pre-payment audits by SafeGuard

Nationwide had, at points, been receiving reimbursement payments regularly from Highmark under the Medicare program. On January 13th, 2011, CMS notified Nationwide that "the PSC for New York and New Jersey" would be conducting a "pre-payment process. . . to ensure that all payments made by the Medicare program are appropriate and consistent with Medicare policy" (the "pre-payment audit"). (Pl.'s V. Compl. Ex. A). As of September 20, 2011, 950 claims had been reviewed by SafeGuard as part of the pre-payment audit. (Ilg Cert. ¶ 15, Sept.13, 2011; Baldwin Cert. ¶ 35, Sept. 26, 2011). Of 950 claims, 875 had been denied (92.1%) by Highmark based on SafeGuard's recommendation. Id.

Previously, in 2008, Nationwide underwent a pre-payment audit resulting in denial of claims for want of evidence beyond a physician's Certificate of Medical Necessity ("CMN").

3. Engagement in the Appeals Process

The appeals process for denial of Medicare claims involves four levels: (1) a request for "redetermination" of an initial determination by a Medicare carrier; (2) "reconsideration" by another Medicare contractor called a "Qualified Independent Contractor" ("QIC"); (3) hearing before an Administrative Law Judge ("ALJ"); and, (4) appeal to the Medicare Appeals Council ("Council") for a final decision. Once the fourth level is reached, review of the Council's final decision may be sought in Federal District Court. Determinations; appeals, 42 U.S.C. § 1395ff(b)(1) (1997).

Plaintiff has appealed the instant claims through the QIC level. (Pl.'s App. 8, Sept. 13, 2011, ECF No. 5-1). Plaintiff has received decisions from an ALJ in some, but not all, cases. Id. Plaintiff conceded during oral argument on October 6th, 2011 that the matter has not reached the final level of appeal before the Medical Appeals Council. Plaintiff noted that the ALJ has handed down several decisions in its favor.

Plaintiff concedes that administrative remedies have not been exhausted while simultaneously contending that this Court need not "interpret Medicare law." (Pl.'s App. 21). Plaintiff characterizes the emergent nature of this Application as "simply a [potential inability] to survive the long and winding road imposed on it to obtain an adjudication by...[the Medicare appeals process]." (Pl.'s App. 26). During oral argument, Plaintiff contended that SafeGuard's interference arose to the level of a long, unreasonable and unfounded delay in their receipt of payment due.

Plaintiff seeks a preliminary injunction restraining SafeGuard from continuing its pre-payment

audit of Nationwide's Medicare, Part B claims that are based on the provision of scheduled, repetitive, non-emergency ambulance transportation to patients for continuing dialysis treatments. (Order to Show Cause 2, Sept. 16, 2011, ECF No. 9). Further, Plaintiff seeks restraints against SafeGuard's recommendation that any claims be denied for processing and reimbursement once Nationwide has provided a valid and timely CMN within sixty days preceding the transportation. Id.

II. ISSUE

Plaintiff attempts to isolate the issue to SafeGuard's interference with the orderly and timely processing of its Medicare claims. SafeGuard interferes in the processing of claims to investigate whether or not payments are reimbursing services actually covered under the statute. To confront the issue of whether SafeGuard's interference was reasonable or, as Plaintiff argues, "far outside any legitimate purpose of its contract with [the Centers for Medicare & Medicaid Services]," this Court would have to interpret the requirements for coverage under the Medicare statute, including particularly the evidentiary requirement for proving "medical necessity" under 42 C.F.R. § 410.40 (2000). (Pl.'s Reply 15, Sept. 30, 2011). Moreover, this Court would have to weigh evidence as to the condition of beneficiaries provided with such services. This Court is precluded from reaching that issue for want of subject matter jurisdiction.

III. ANALYSIS

This Court has allowed the parties to submit and oppose Plaintiff's Application for a preliminary injunction on the basis of Plaintiff's contention that emergency relief is needed. Considering those arguments here, this Court finds that issuance of a preliminary injunction is not appropriate in this case.

Defendant states that this Court is without jurisdiction to interpret the statute because this Court lacks the power of judicial review until administrative remedies are exhausted. The inquiry into SafeGuard's alleged interference hinges on the evidentiary requirement for coverage, if any, beyond a physician's CMN. Plaintiff seeks a determination from this Court that a physician's CMN is sufficient to prove coverage under the Medicare statute. Defendant, counters that a physician's CMN is necessary but not sufficient. Indeed, discerning the evidentiary standard for coverage requires an interpretation of the Medicare statute, a task which this Court has the authority to undertake only in certain, limited circumstances. The power of judicial review over a matter arising under the Medicare statute is conferred upon this Court once Plaintiff exhausts the available administrative remedies pursuant to 42 U.S.C. § 405(g). Determinations; appeals, 42 U.S.C. 1395ff(f)(3) (2003). The Medicare program involves numerous regulations and a robust administrative system established by Congress to carry out the intended purpose. Without a final judgment of the Medicare Appeals Council, Plaintiff has not exhausted the administrative remedies Congress has made available. Consequently, this Court lacks the authority to review.

1. Application for Emergency Relief in the form of a Preliminary Injunction

To issue a preliminary injunction this Court must consider the following four factors: (1) the likelihood that the moving party will succeed on the merits; (2) the extent to which the moving party will suffer irreparable harm without injunctive relief; (3) the extent to which the nonmoving party will suffer irreparable harm if the injunction is issued; and, (4) the public interest in the matter. Liberty Lincoln-Mercury, Inc. v. Ford Motor Co., 562 F.3d 553, 556 (3d Cir. 2009). A preliminary injunction is an "extraordinary remedy that may only be awarded upon a clear showing that plaintiff is entitled to

such relief." Winter v. Natural Res. Def. Council, Inc., 129 S.Ct. 365, 375 (2008) (citing Mazurek v. Armstrong, 520 U.S. 968, 972 (2008)). Further, in the Third Circuit, the irreparable harm requirement is not met if a Plaintiff demonstrates a significant risk that he or she will experience harm, but that harm can adequately be compensated after the fact by monetary damages. Adams v. Freedom Forge Corp., 204 F.3d 475, 484-5 (3d Cir. 2000).

Plaintiff here is seeking a preliminary injunction against SafeGuard's investigation of claims and recommendation that claims be denied. The first factor of the preliminary injunction analysis involves a determination of the Plaintiff's likelihood of success on the merits. Plaintiff seeks to enjoin SafeGuard from investigating the basis Plaintiff sets out for the coverage entitlement because it unduly delays payment of allegedly rightful claims. It is clear that success on the merits depends on whether or not beneficiaries of Nationwide's services are covered by the Medicare statute. For the reasons discussed herein, his Court does not have the authority to reach the merits that underlie this claim.

Investigating the basis Plaintiff sets out for coverage is the exact function of a PSC. See, Medicare Integrity Program, 42 U.S.C. § 1395ddd (2010). As a PSC, SafeGuard is specifically designated to investigate, for example, whether evidence of a beneficiary's condition proves that ambulance transport is a medical necessity. The regulations clearly grant this specific authority at 42 U.S.C. § 1395ddd(f)(7) (2010), the provision which guides and explains "payment audits," and at 42 C.F.R. § 421.500 (2008), the provision which explains the contractual relationship between a CMS and a PSC. In fact, it is clear from the pleadings that the initiation of the pre-payment audit came directly from CMS. See, Pl.'s V. Compl. Ex. A. Plaintiff has not pleaded sufficient evidence before

this Court to show either that SafeGuard wrongfully initiated or carried out its pre-payment process beyond its entitlement as a PSC.

Regarding the second factor of the preliminary injunction analysis, in oral argument before this Court on October 6th, 2011, it became clear that Plaintiff's claim of irreparable harm boils down to the loss of business to competitors and an "extremely perilous financial...situation." (Pl.'s App. 2). The Supreme Court's holding in Samson v. Murray particularly guides this Court's consideration of irreparable harm in the instant matter:

> The key word in this consideration is *irreparable*. Mere injuries, however substantial, in terms of money, time and energy necessarily expended in the absence of a stay, are not enough. The possibility that adequate compensatory or other corrective relief will be available at a later date, in the ordinary course of litigation, weighs heavily against a claim of irreparable harm. Samson v. Murray, 94, S.Ct. 937, 953 (1974) (citing Virginia Petroleum Jobbers Ass'n v. Fed. Power Comm'n, 259 F.2d 921, 925 (D.C. Cir. 1958)) (emphasis added).

This thinking has echoed through Third Circuit jurisprudence. See, Instant Air Freight, Co. v. C.F. Air Freight, Inc., 882 F.2d 797 (3d Cir. 1989) (finding loss of business, employees, jobs, goodwill and reputation to be compensable with money damages rather than equitable relief); Caplan v. Fellheimer, 68 F.3d 828 (3d Cir. 1995) (finding the harm to be self-inflicted and therefore not qualifying as irreparable harm under preliminary injunction analysis). Though this Court is sympathetic to Nationwide's financial dependence on Medicare payments, it cannot properly grant an extraordinary remedy in this case where it is plain that the harm resulting from Defendant's alleged interference cannot be construed as anything other than monetary.

The public interest factor weighs heavily in favor of Defendant. SafeGuard is a contractor of the government entrusted to perform anti-fraud duties to assure that Medicare payments are properly determined and paid out. Further, public interest weighs against having this Court interpret the

Medicare statute before administrative remedies have been exhausted. This Court must heed the advice of the Supreme Court in looking out for the particular contexts where the "contribution to effective government" could outweigh the "potential harm to individual citizens." Westfall v. Erwin, 108 S.Ct. 580, 585 (1988) (superseded by statute on other grounds) (citing Doe v. McMillan, 412 U.S. 306, 320 (1973)). Congress intended that the discretion to determine Medicare coverage lie with the Secretary of HHS. See, Heckler v. Ringer, 466 U.S. 602 (1984). Plaintiff must adhere to the administrative procedure which Congress has established for adjudicating their Medicare claims. Heckler, 466 U.S. at 619. This Court finds that in this particular context, Congress has a significant interest in ensuring that the Medicare program carry out its own interpretation of its regulations.

The irreparable harm and public interest factors weigh overwhelmingly in favor of the Defendant. Further, without reaching the merits that underlie Plaintiff's claim regarding coverage under an interpretation of the Medicare statute, it is clear that SafeGuard has the authority to initiate a pre-payment audit and Plaintiff is not likely to succeed on the merits. The Court finds that the final factor, considering harm to the nonmoving party, has nominal effect on weighting the preliminary injunction analysis and is rather inapplicable here since SafeGuard is a government contractor carrying out a program integrity system rather than the payor itself.

2. Subject Matter Jurisdiction

Congress put into place an exhaustive set of regulations to guide the Medicare program, coverage and payment process. The appeals process consists of four levels: (1) redetermination; (2) reconsideration; (3) hearing before an ALJ; and finally, (4) judgment of the Medicare Appeals

Council ("Council"). Plaintiff has reached, and has not completed, the third level of this process.[1] The Council was formed as part of the administrative fabric set up to interpret the Medicare statutes Congress enacted. The Council provides the appropriate place for Plaintiff's grievance with SafeGuard. This Court will defer to that administrative process in the instant case.

For the foregoing reasons, this Court does not have jurisdiction to reach the merits of this matter and will defer to the appeals process that Congress put into place for grievances related to Medicare coverage issues.

IV. CONCLUSION

Plaintiff's Application for a preliminary injunction is **denied**.

s/ Dennis M. Cavanaugh
Dennis M. Cavanaugh, U.S.D.J.

Date: October 7, 2011
Orig.: Clerk
cc: All Counsel of Record
Mark Falk, U.S.M.J.

[1]This Court is aware that an ALJ has handed down decisions favorable to the Plaintiff, however, the Medicare Appeals Council is the appropriate place to raise the ultimate issue in the instant matter which requires interpretation of the Medicare statute. Prohibition against any Federal interference, 42 U.S.C. § 1395 (1965); see also, Determinations, appeals, 42 U.S.C. § 1395ff (2003).