UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 11-23377-CIV-SEITZ/SIMONTON

COMPREHAB WELLNESS GROUP,
INC., a Florida Corporation

Plaintiff,

v.

KATHLEEN SEBELIUS,
Secretary of Health and Human Services,

Defendant.
_____/

ORDER GRANTING DEFENDANT'S CROSS-MOTION FOR SUMMARY JUDGMENT, DENYING PLAINTIFF'S MOTION FOR JUDGMENT ON THE PLEADINGS OR SUMMARY JUDGMENT, AND CLOSING CASE

THIS MATTER came before the Court upon Plaintiff's Motion for Judgment on the Pleadings or Summary Judgment [DE 20] and Defendant's Cross-Motion for Summary Judgment [DE 21]. Plaintiff, a Medicare Part B Provider, seeks judicial review of a determination by the Secretary of the Department of Health and Human Services [hereinafter the "Secretary"] that Plaintiff's Medicare billing privileges were properly revoked. The Centers for Medicare and Medicaid Services (CMS)[1] revoked Plaintiff's billing privileges after it concluded Plaintiff was improperly staffed and therefore non-operational as a Comprehensive Outpatient Rehabilitation Facility (CORF). Specifically, CMS found Plaintiff's Coordinator of Services Ms. Maria Fuentes was not licensed as a medical professional and was therefore not a "qualified professional" within the meaning of CORF regulations. CMS also found Plaintiff's physician services were inadequate because its medical director, Dr. Pedro Bosch, was only present at the facility once a month and then only to sign papers.

[1] CMS administers the Medicare program and is a division of the Department of Health and Human Services [hereinafter "HHS"] supervised by the Secretary. *Gulfcoast Med. Supply, Inc. v. Secretary, HHS*, 468 F.3d 1347,1349 (11th Cir. 2006).

In this action, Plaintiff raises three grounds why the revocation of its billing privileges is invalid. First, Plaintiff argues the revocation is invalid because CMS revoked its billing privileges under an unconstitutionally promulgated regulation. Second, Plaintiff argues the revocation is invalid because the regulation that requires a CORF to designate "qualified professional" to coordinate treatment does not define the term "qualified professional."[2] Finally, Plaintiff argues the revocation is invalid because the regulation that requires a CORF to provide physician services does not issue a "bright-line" standard for determining the sufficiency of a physician's on-site involvement.[3] The Court, having carefully considered the motions, Plaintiff's reply brief [DE 27] and the Administrative Record, must find that the Secretary based her decision to uphold the revocation of Plaintiff's Medicare billing privileges on facts supported by substantial evidence in the record, and that the decision is in accord with applicable law. Accordingly, the Court grants Defendant's motion for summary judgment.

I. BACKGROUND[4]

A. Relevant Regulatory Provisions

Medicare Part B is a federal program that pays for medical care for the elderly and disabled. 42 U.S.C. §§1395j – 1395w-4. In order to qualify as a Medicare Part B Provider a medical facility must be "operational" to "furnish Medicare . . . services. . ." 42 C.F.R. §424.510(d)(6). As the term applies here, "operational" means the provider is properly staffed to provide required services. [5] 42 C.F.R. §424.502.

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[2] 42 C.F.R. §424.58(c)

[3] 42 C.F.R. §458(a)(1)

[4] This section is derived from the administrative record in this case, which the parties have stipulated constitutes the undisputed facts. Citations to the Administrative Record follow the Bates stamped page numbers.

[5] The full definition of "operational" is as follows: the provider or supplier has a qualified physical practice location, is open to the public for the purpose of providing health care related services, is prepared to submit valid Medicare claims, and is properly staffed, equipped, and stocked (as applicable, based on the type of facility or organization, provider or supplier specialty, or the services or items being rendered), to furnish these items or services. 42 C.F.R. §502.

Whether a provider is properly staffed to provide required services depends, of course, on what the provider does. Plaintiff, CompRehab Wellness Group, Inc. [hereinafter "CompRehab"] was categorized under Medicare Part B regulations as a Comprehensive Outpatient Rehabilitation Facility ("CORF"), a non-residential rehabilitation facility operated either by a physician or under the supervision of a physician.[6] *See* 42 U.S.C. §1395x(cc)(2)(A)&(B). Congress included CORF services as a covered Medicare benefit to provide beneficiaries coordinated access to "a broad array of rehabilitation services." H.R. Rep. No. 1167, 96th Cong., 2d Sess. at 375 (1980)]. Accordingly, Congress empowered the Secretary to regulate CORFs in the interest of the health and safety of CORF patients. 42 U.S.C. §1395x(cc)(2)(J). To that end, the Secretary promulgated a series of regulations called "Conditions of Participation." A CORF must continually comply with these conditions to maintain its billing eligibility. *See* 42 C.F.R. §§485.54 – 485.66. Each Condition of Participation contains sub-regulations called Standards. These standards impose even tighter requirements on CORF operations.

The Condition of Participation relevant to this action is codified at 42 C.F.R. §485.58. This condition requires a CORF to provide at least three types of services - physician services, physical therapy services, and, at a minimum, either social or physiological services. 42 C.F.R. §485.58. The standards under the condition specify how patients are treated, by whom they are treated, and where they are treated. 42 C.F.R §§458.58 (a) – (g). Two of these standards are involved here. The first is the standard that requires the CORF to have a coordinator, 42 C.F.R. §485.58(c). The coordinator's job is to coordinate patient treatment, which is necessary given that a CORF patient might be treated

[6] CORFs are further defined in the Code of Federal Regulations as providers "established and operated exclusively for the purpose of providing diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured, disabled, or sick persons, at a single fixed location, by or under the supervision of a physician. . . " 42 C.F.R. §485.51.

by a number of medical professionals across disciplines.[7] The standard requires the coordinator be a "qualified professional," but the term "qualified professional" is not expressly defined within the standard. The standard does, however, describe the Coordinator's essential duties as follows:

> (1) Providing to all personnel associated with the facility, a schedule indicating the frequency and type of services provided at the facility;
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> (2) A procedure for communicating to all patient care personnel pertinent information concerning significant changes in the patient's status;
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> (3) Periodic clinical record entries, noting at least the patient's status in relationship to goal attainment; and
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> (4) Scheduling patient case review conferences for purposes of determining appropriateness of treatment, when indicated by the results of the initial comprehensive patient assessment, reassessment(s), the recommendation of the facility physician (or other physician who established the plan of treatment), or upon the recommendation of one of the professionals providing services.
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> *Id.*

The second standard at issue describes the physician services requirements. 42 C.F.R. 485.58(a). The standard does not specify how much time a physician must actually be at the facility, only that the physician spends sufficient time to perform the following essential duties:

> (i) Provide, in accordance with accepted principles of medical practice, medical direction, medical care services, consultation, and medical supervision of nonphysician staff;
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> (ii) Establish the plan of treatment in cases where a plan has not been established by the referring physician;
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> (iii) Assist in establishing and implementing the facility's patient care policies; and
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> (iv) Participate in plan of treatment reviews, patient case review conferences, comprehensive patient assessment and reassessments, and utilization review.
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> *Id.*

[7] The regulation describes the role of the Coordinator, in part, as follows: "Coordination of services. The facility must designate, in writing, a qualified professional to ensure that professional personnel coordinate their related activities and exchange information about each patient under their care." 42 C.F.R. §485.58(c)

B. Revocation of CompRehab's Medicare Billing Privileges

CMS assesses compliance with conditions and standards by conducting on-site reviews. On-site reviews are unannounced inspections of a Provider's premises. 42 C.F.R. §424.517(a). CMS often contracts with third-parties to conduct these reviews. *See* 42 U.S.C. §1395u. If a Provider is found non-compliant after an on-site review, CMS, or an administrative contractor, is authorized to revoke the Provider's billing privileges. 42 C.F.R. 535(a)(5)(i).

In this case, investigators from SafeGuard Services, LLC and a medical review nurse from IntegriGuard, LLC conducted an on-site review of CompRehab on March 11, 2010. [AR 001]. Investigators reviewed business records, audited patient charts, photographed CompRehab's facilities and inventoried its treatment equipment. [AR 191 – 219]. The investigators also interviewed Ms. Maria Fuentes, CompRehab's part-owner, facility administrator, and designated coordinator. [AR 193 – 195]. Ms. Fuentes was the only employee present at the facility during the on-site review. [AR 193]. The investigators discovered Ms. Fuentes did not hold any medical professional licenses. [AR 189]. Investigators also learned from Ms. Fuentes that CompRehab's Medical Director, Dr. Pedro Bosch, only visited the facility once a month and then only to sign documents. [AR 194]. On April 28, 2010, First Coast Services Options, Inc., a CMS administrative contractor, informed CompRehab that its Medicare billing number had been revoked because it was no longer operational to furnish Medicare services. Relevant to this matter, the revocation notice cited both that Ms. Fuentes was not qualified to serve as coordinator because she was unlicensed and that Dr. Bosch's monthly visits were insufficient to provide adequate physician services.[8] [AR 189]. The revocation was effective as of March 11, 2010, the date of the on-site review. *Id.* CompRehab sought reconsideration of the revocation. *See* 42 C.F.R. §§424.545(a), 498.5(l), 498.22(a). On August 5, 2010, a CMS Hearing Officer affirmed the revocation. [AR 191 – 192].

[8] CompRehab's billing privileges were revoked under 42 C.F.R. §424.535(a)(5)(i), which allows revocation on a finding a provider is non-operational following an on-site review. In addition to the two grounds discussed above, First Coast cited a third basis that is not involved in this case, missing tax records.

C. Decision of the HHS Administrative Law Judge

CompRehab appealed the revocation to an Administrative Law Judge (ALJ) of the Civil Remedies Division, HHS. [*See* AR 001 – 012]. CompRehab neither disputed that Fuentes was unlicensed nor that Dr. Bosch only came to the facility once a month to sign paperwork. Instead, CompRehab argued that CMS improperly applied the coordinator and physician services standards. CompRehab claimed it was improper for CMS to revoke CompRehab's privileges on the basis that Fuentes was unlicensed because the coordinator standard[9] only requires a "qualified professional" and not, explicitly, a licensed professional. CompRehab similarly argued it was improper for CMS to revoke its privileges on the basis that Dr. Bosch only visited the facility once a month because the physician services standard[10] only requires a physician be present for sufficient time to provide needed services and not for a prescribed amount of time. [11]

The ALJ disagreed. He noted that, first, CMS had to make a *prima facie* showing that CompRehab failed to substantially comply with federal requirements and that if CMS made that showing CompRehab had to overcome it by a preponderance of the evidence.[12] The ALJ found that CompRehab did not show by preponderance of the evidence that its billing privileges were wrongly revoked. Accordingly, the ALJ found the revocation valid. He issued the following findings of fact and conclusions of law: (1) "[CompRehab] was not operational because it had deficient staffing at the time of the inspection, and, therefore, it failed to meet all Medicare conditions of participation of

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[9] 42 C.F.R. §485.58(c)

[10] 42 C.F.R. §485.58(a)

[11] Procedurally, both parties had moved for Summary Judgment. The ALJ denied summary judgment because he found that there were material issues of fact, first, as to whether CompRehab had designated a "qualified professional" to serve as coordinator and, second, whether CompRehab had a facility physician to provide medical services as required. CompRehab and CMS submitted affidavits containing direct testimony of proposed witnesses but neither side requested cross-examination of opposing witnesses. Accordingly, the ALJ determined he would decide the case on the record without a hearing. [AR 003].

[12] Both parties submitted evidence. CMS submitted the investigators' report, including the interview notes from the interview of Maria Fuentes, affidavits of four individuals who either preformed the on-site review or were familiar with the details, and the record of the proceedings, which to that point consisted of letters to and from CMS and CompRehab's counsel. CompRehab submitted affidavits from Ms. Fuentes and Dr. Bosch in addition to other evidence not relevant to this action.

a CORF;" [AR 005]; (2) "[CompRehab] lacked a qualified professional who was coordinating services, a requirement for a CORF;" [AR 006]; and (3) "[CompRehab] lacked a facility physician on staff who was providing the required level of medical direction, medical care services, consultation, and medical supervision of nonphysician staff, a required service of a CORF."[13] [AR 008].

D. Final Decision of the Departmental Appeals Board

CompRehab appealed each of the ALJ's findings of fact and conclusions of law set out above to the HHS Departmental Appeals Board [hereinafter "DAB"] [*See* AR 013 – 025].[14] The three-judge panel affirmed, determining substantial evidence supported the ALJ's factual findings and that the ALJ's conclusions of law were not erroneous.[15] The DAB ruling is the final decision of the Secretary and is the subject of the Court's review. *See* 42 U.S.C. §405(g).

E. The Instant Case

In this lawsuit, Plaintiff seeks judicial review of the Secretarial decision and requests reversal of the revocation of its billing privileges. Plaintiff has moved for judgment on the pleadings and, in the alternative, for summary judgment. The Secretary cross-moves for summary judgment.

II. DISCUSSION

A. Judicial Review of Secretary's Decision

Judicial review of the Secretary's decision is available under the Medicare Act. *See* 42 U.S.C. §1395ff(b)(1). However, review is limited to "whether there is substantial evidence to support the findings of the . . . [Secretary], and whether the correct legal standards were applied."

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[13] The ALJ made an additional finding that CompRehab had received adequate due process, but that matter is not before the Court in this action.

[14] CompRehab did not raise the denial of due process to the DAB.

[15] While the DAB affirmed the ALJ's findings of fact and conclusions of law it noted that it did not adopt the ALJ's finding that CompRehab failed to meet the requirements of an on-site review under the enrollment regulations in 42 C.F.R. Part 424, subpart P, which the DAB recognized are different from an on-site certification survey pursuant to Parts 488 and 489 to determine compliance with an applicable conditions of participation. The DAB noted its non-concurrence with the ALJ on this point was immaterial to its affirmation of the ALJ's ultimate ruling that CMS was authorized to revoke CompRehab's Medicare billing privileges under section 424.535(a)(5)(i). [AR 020].

Gulfcoast Med. Supply Inc. v. Sec'y, Dept. of Health and Human Svc's, 468 F. 3d 1347, 1350, fn. 4 (11th Cir. 2006) (*citing Wilson v. Barnhart*, 284 F.3d 1219, 1221 (11th Cir. 2002); 42 U.S.C. §1395ff(b)(1)(A) (incorporating into the Medicare Act the standard of review set forth in 42 U.S.C. §405(g)).[16] Substantial evidence is more than a mere scintilla, but it is less than a preponderance. *Crawford v. Comm'r of Soc. Sec.*, 363 F.3d 1155, 1158 – 59 (11th Cir. 2004). "It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion. Thus, substantial evidence exists even when two inconsistent conclusions can be drawn from the same evidence." *Stone &Webster Constr., Inc. v. United States Dep't of Labor*, 684 F.3d 1127, 1132 (11th Cir. 2012). The record evidence is viewed in the light most favorable to the agency's decision and all reasonable inferences are drawn in favor of that decision. *Adefemi v. Ashcroft*, 386 F.3d 1011, 1027 (11th Cir. 2004). Under the substantial evidence standard the reviewing court is precluded from "deciding the facts anew, making credibility determinations, or re-weighing the evidence." *Moore v. Barnhart*, 405 F.3d 1208, 1211 (11th Cir. 2005). If the Secretary's decision is supported by substantial evidence such that a reasonable mind might accept it as adequate to support her conclusion and the correct legal standards were applied, the Court must affirm the Secretary's decision.

B. Standard for Summary Judgment

Given the nature of case, there is no difference between Plaintiff's motion for judgment on the pleadings or its alternative motion for summary judgment.[17] Summary judgment is appropriate

[16]42 U.S.C. §405(g) is part of the Social Security Act and provides, with respect to the standard of review, "that the findings of the [Secretary] as to any fact, if supported by substantial evidence, shall be conclusive."

[17] Here, any distinction between judgment on the pleadings and summary judgment is a distinction without difference; the parties have filed cross-motions for summary judgment, agree that the facts contained in the record are the only material facts required for review, and Plaintiff has incorporated the entire record into its complaint [DE 1, ¶6]. "Both the summary judgment procedure and the motion for judgment on the pleadings are concerned with the substance of the parties' claims and defenses and are directed towards a final judgment on the merits. *Indeed, the standard applied by the court appears to be identical under both motions.* All factual inferences and intendments are taken against the moving party under both Rule 12(c) and Rule 56, and neither motion will be granted unless the movant is entitled to judgment as a matter of law." 5C Charles Alan Wright, Arthur R. Miller, Federal Practice and Procedure § 1369 (3d. Ed.1998) (emphasis added).

when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). Once the moving party demonstrates the absence of a genuine issue of material fact, the non-moving party must come forward with specific facts showing that there is a genuine issue for trial. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (*quoting* Fed. R. Civ. P. 56(e)). The Court must view the record and all factual inferences therefrom in the light most favorable to the non-moving party and decide whether "the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Allen v. Tyson Foods, Inc.*, 121 F.3d 642, 646 (11th Cir. 1997) (*quoting Anderson*, 477 U.S. at 251-52)).

C. Cross-Motions for Summary Judgment

By filing cross-motions for summary judgment, the parties agree that there is no issue of material fact and the sole issues are questions of law for the Court's determination. CompRehab seeks review of the Secretary's action on three grounds. CompRehab's first claim is that revocation is invalid because 42 C.F.R. §424.535, the code section authorizing CMS's revocation of CompRehab's privileges, is constitutionally defective because it was promulgated in violation of the non-delegation doctrine. Second, CompRehab claims the revocation is invalid because 42 C.F.R. §485.58(c) does not define the term "qualified professional." Finally, CompRehab argues the revocation is invalid because 42 C.F.R. §485.58(a)(1) does not establish "bright line" standards for determining the sufficiency of a physician's on-site involvement. The Secretary seeks a determination that her decision is consistent with the law and supported by substantial evidence.

1. Constitutionality of 42 CFR §424.535

Though it did not raise the issue at any stage of the administrative proceedings, CompRehab now challenges the constitutionality of 42 C.F.R. §424.535.[18] Specifically, CompRehab claims that 42 C.F.R. §424.535 is invalid because its promulgation violated the "non-delegation doctrine" – the principle that legislative authority is exclusively vested with Congress and that delegation of the authority is only proper when the statute authorizing delegation meets certain requirements. *See Wayman v. Southard*, 23 U.S. 1 (1825).

In her cross-motion and response, the Secretary contends CompRehab's constitutional claim is unexhausted and waived because CompRehab failed to bring the claim to the agency's review process first. The Court shares that view. The Secretary points to *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1 (2000) to support her contention that CompRehab's constitutional claim is barred.

In *Illinois Council*, the plaintiff, an association of nursing homes, sued the Secretary, *inter alia*, on grounds that certain Medicare Part A provisions related to post-inspection sanctions were constitutionally defective - they denied the nursing homes due process, they were vague, and they were promulgated in excess of the Medicare Act's legislative mandate. Instead of bringing the claims to the agency and then seeking judicial review pursuant to 42 U.S.C. §405(g), the plaintiff filed suit directly in district court under federal question jurisdiction pursuant to 28 U.S.C. §1331.[19] The District Court dismissed for lack of jurisdiction citing the Medicare Act's "virtually exclusive, system of administrative and judicial review for Medicare claims. . ." *Id.* at 5. Though the Court of Appeals reversed, the Supreme Court affirmed the District Court's dismissal for lack of jurisdiction.

The Medicare Act's "virtually exclusive" system as set out in 42 U.S.C. §405(g) is made exclusive by 42 U.S.C. §405(h), which bars federal courts from reviewing Medicare cases under

[18] As discussed above CompRehab's privileges were revoked pursuant to 42 C.F.R. §424.535(a)(5)(i), which authorizes revocation where CMS finds a CORF is non-operational after an on-site review.

[19] Plaintiff was a group that represented more than 200 nursing homes that "need[ed] advance knowledge [of whether the regulations were constitutional] for planning purposes." *Illinois Council*, 529 at 10.

federal question jurisdiction. Under the Medicare review system, district courts may only review claims that are part of the Secretary's final decision. Accordingly, plaintiffs seeking to preserve claims for judicial review must have those claims considered by the agency and therefore must exhaust all agency-level recourse. The claim's nature is irrelevant; the exhaustion requirement applies to "evidentiary, rule-related, statutory, constitutional, or [claims on] other legal grounds." *Illinois Council*, 529 U.S. at 10; *cf. Lifestar Ambulance Servs., Inc. v. United States*, 365 F.3d 1293, 1297 (11th Cir. 2004) ("In *Illinois Council,* the Court held that, despite the fact that some claims, such as constitutional or statutory challenges, cannot be resolved administratively, they must still proceed first through the administrative process. Such claims are subject to plenary judicial review under the Medicare remedial scheme only *after* the administrative review process has been exhausted.") (internal citation omitted) (emphasis original).

CompRehab points to *Califano v. Sanders*, 430 U.S. 99, 109 (1977) for the proposition that constitutional claims are "obviously unsuited to resolution in administrative hearing proceedings, and therefore access to the courts is essential to the decision of such questions." [DE-27 at p. 1 - 2]. This language from *Sanders* refers to the Supreme Court's decisions in *Weinberger v. Salfi*, 422 U.S. 749 (1975), and *Mathews v. Eldridge*, 424 U.S. 319 (1976), two cases where the Supreme Court did allow judicial review of unexhausted constitutional claims. However, these cases turned on facts not present here and contrary to Plaintiff's suggestion, they do not stand for the principle that constitutional claims are exempted from the exhaustion requirement.

In *Salfi*, the Court allowed the plaintiff's unexhausted claims to proceed because the Court found that the Secretary did not object to their going forward. The Court construed the Secretary's non-objection as an incorporation of the constitutional claim into the Secretary's final decision. *Salfi*, 422 U.S. at 769. In *Eldridge*, the non-exhausted claim was a constitutional due process challenge to the general procedures the Social Security Administration used to deny benefits, a claim the Court found collateral to the Secretary's decision on the termination of Plaintiff's benefits. *Id.* at

330. Neither exception applies here. The Secretary objects to CompRehab raising unexhausted claims here [DE 21 at pp. 12 – 14] and the claims CompRehab raises (see discussion *infra*) concern the substance of the regulations at issue, not the collateral matter of general administrative procedure. Accordingly, the Court finds Plaintiff's non-delegation claim is barred.

Even if the claim were before the Court, it would be denied. CompRehab's argument is that the revocation under 42 CFR §424.535, the section that allows revocation where a Provider has been found non-operational after an on-site review, is invalid because the rule is the product of an enabling statute that violates the non-delegation principle. Part 424 of the Code of Federal Regulations, the part containing the rule, cites as its statutory authority both of the Medicare law's enabling provisions, 42 U.S.C. §§1302 and 1395hh. The authorizing language of §1302 states:

> (a) the Secretary . . . of Health and Human Services . . . shall make and publish such rules and regulations, not inconsistent with this chapter, as may be necessary to the efficient administration of the functions with which [he or she] is charged under [Chapter 7 of Title 42 (dealing with Social Security programs and Medicare)].

The authorizing language of §1395hh is as follows:

> (a) The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under [the Medicare program].

An enabling statute that gives the agency an "intelligible principle" with which to regulate does not violate the principle of non-delegation. *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 472 (2001). Here, Congress authorized the Secretary to make regulations for Medicare programs that are necessary to carry out the administration of the Medicare programs or to make regulations necessary to carry out the efficient administration of such programs. By comparison, the Supreme Court has found the broader language of other enabling statutes to provide an "intelligible principle." See, *e.g., Nat'l Broad. Co. v. United States,* 319 U.S. 190, 225–226 (1943) (upholding Federal Communications Commission's power to regulate airwaves "as the public convenience, interest and necessity requires"); *New York Cent. Sec. Corp. v. United States,* 287 U.S. 12, 24–25 (1932)

(upholding Interstate Commerce Commission's power to approve railroad consolidations "in the public interest"). Moreover, from a historical perspective, the Supreme Court has been extraordinarily deferential to Congress in judging Congress's delegation of its legislative power. "In the history of the Court [it has] found the requisite "intelligible principle" lacking in only two statutes, one of which provided literally no guidance for the exercise of discretion, and the other of which conferred authority to regulate the entire economy on the basis of no more precise a standard than stimulating the economy by assuring "fair competition." *Whitman*, 531 U.S. at 473 (citations omitted). Essentially, what CompRehab seeks is the invalidation of a statute granting authority to a named agency to regulate an identified federal program using statutory language well within the bounds of what has already been deemed constitutional. Under these circumstances and in light of the Supreme Court's prior rulings, had the claim been before the Court, it would have been denied.

2. Determination that Plaintiff's designated Coordinator was not a "Qualified Professional"

Plaintiff argues revocation of its billing privileges is invalid because 42 C.F.R. §485.58(c) does not define the term "qualified professional." The Secretary acknowledges the regulation does not define the term, but her cross-motion for summary judgment points to an absence of evidence in the record that CompRehab's coordinator was, in fact, a "qualified professional." The Secretary argues that under the regulation as interpreted by the ALJ, CompRehab could have proven Fuentes was qualified by virtue of experience and training as opposed to licensure, but, as CompRehab failed to make this showing, the ALJ made the appropriate finding that Fuentes was unqualified.[20]

[20] Other than its First and Fifth arguments, which are address in sections 1 and 3 of this order respectively, Plaintiff's response to the Secretary's cross-motion/reply brief [DE 27] is largely non-responsive. Its second argument is that the ALJ improperly shifted the burden to Plaintiff to show that its designated coordinator was qualified without first requiring CMS to first make a *prima facie* showing that the revocation was justified. Its third argument is that 42 C.F.R. §485.58(c) is unconstitutionally vague. The Court does not reach the merits of either claim advanced in CompRehab's response to the Secretary's cross-motion. First, CompRehab did not raise these claims to the DAB and, accordingly, the Court finds they are unexhausted. Second, to the extent that CompRehab seeks affirmative relief by raising statutory and constitutional arguments in a response, the Court notes that a response to a motion is not a motion. *See* Fed. R. Civ. P. 7.

Turning to Plaintiff's argument, insofar as CompRehab argues as a purely legal matter that revocation was invalid because the coordinator regulation does not define the term "qualified professional," the Court does not agree. The ALJ did not find Ms. Fuentes' non-licensure to be dispositive. Instead, the ALJ construed the non-defined term "qualified professional" to mean an individual qualified on the basis of licensure in rehabilitative services or education and training in rehabilitative services. Agencies are entitled to construe ambiguities in their regulations provided the construction is both "reasonable," *Ehlert v. United States*, 402 U.S. 99, 105 (1971), and "sensibly conforms to the purpose and wording of the regulations," *N. Indiana Pub. Serv. Co. v. Porter Cnty. Chapter of Izaak Walton League of Am., Inc.*, 423 U.S. 12, 15 (1975). Where an agency has met these prerequisites the agency's construction "is entitled to substantial deference." *Lyng v. Payne*, 476 U.S. 926, 939 (1986).

The ALJ's construction of the term "qualified professional," as affirmed by the DAB, was reasonable and in conformity with the purpose and wording of CORF regulations. The ALJ construed the regulation in a manner that he believed "responsible," given that pursuant to the regulation the coordinator must (1) provide the facilities personnel a schedule of treatments and available services; (2) provide a procedure to communicate significant changes in a patient's status to all personnel; (3) provide periodic clinical entries noting at least the patient's status in relationship to goal attainment; and (4) schedule review conferences to consider the appropriateness of a given patient's treatment on assessment, reassessment, or professional provider recommendation. [AR 008]. The ALJ looked to published administrative guidance, specifically the State Operations Manual (SOM), CMS's guidance to surveyors and contractors. After reviewing the SOM, the ALJ concluded the coordinator's role was not administrative but medical. [AR 007]. The DAB affirmed the ALJ's interpretation of the regulation stating that "the ALJ correctly noted that the issue was not whether the Administrator was qualified to administer the facility but whether she was qualified to coordinate the provision of professional rehabilitative services." [AR 020] (record citation omitted).

The DAB also found that within the framework of CORF regulations the terms "qualified professional" and "professional" relate to providing professional comprehensive rehabilitative services to CORF patients as opposed to the administrative tasks of running the CORF practice.[21] [AR 021]. Accordingly, the construction of the term "qualified professional" conforms to how the term is used within CORF regulations. The Court finds the ALJ's construction of the term "qualified professional," and the DAB's affirmance of the construction to be within the limits of an agency's inherent authority and disagrees with CompRehab's argument that revocation under the regulation was invalid as a legal matter.

Turning to the ALJ's application of the facts to the regulation as interpreted, the Court finds the ALJ's factual findings are supported by substantial evidence in the record. The key evidence on this point, the affidavit of Ms. Fuentes, is largely non-responsive to CMS's allegation that Ms. Fuentes was unqualified. The ALJ found Ms. Fuentes' affidavit did not support that Ms. Fuentes was qualified to be coordinator. Ms. Fuentes served as CompRehab's administrator from May 11, 2006. Her duties as administrator included "insuring that the professional personnel contracted with CompRehab coordinate their related activities and exchange information about each patient under their care." [AR 280]. The ALJ notes that the affidavit makes no mention of Ms. Fuentes' education and experience, nor does it provide any information which would support the conclusion that Ms. Fuentes was qualified to conduct patient care according to the enumerated duties set out in 42 C.F.R. §485.58(c). In light of these facts, the Court finds that the ALJ's conclusion that Ms. Fuentes was not qualified to serve as CompRehab's coordinator, and the DAB's affirmation of the same, is supported by substantial evidence in the record.

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[21] The Secretary directs the Court to 42 C.F.R. §485.70, which sets out the qualifications for various CORF professionals including physicians, licensed practical nurses, registered nurses, occupational therapists, orthotists, physical therapists, physical therapist assistants, prosthetists, psychologists, rehabilitation counselors, respiratory therapists, respiratory therapist technicians, social workers, and speech/language pathologists. [DE 21]. The ALJs construction of the term "qualified professional" is in accord with how this section of the regulation describes the qualifications of other CORF medical professionals. The DAB also references this section of the regulation in its affirmance. [AR 021].

3. Determination that Plaintiff was not properly staffed to provide an adequate level of physician services

CompRehab does not dispute Dr. Bosch was only at the facility once a month to sign documents. Rather, CompRehab argues that revocation under 42 C.F.R. §485.58(a) is invalid because the regulation lends itself to "arbitrary and capricious" administration given that it lacks a "bright-line" standard for how much time a facility physician must spend at the facility. CompRehab also argues that Dr. Bosch's monthly visit in conjunction with his availability by telephone, his periodic review of medical records, and his consultation with facility providers amounted to CompRehab providing an adequate level of physician services.[22] The Secretary submits that CompRehab's arguments as to the adequacy of its physician services are conclusory and, that on review, CMS's revocation was appropriate given the lack of evidence in Dr. Bosch's affidavit. The Court does not reach the merits of CompRehab's non-responsive, unexhausted, counter-arguments.[23] *See Shalala v. Illinois Council on Long Term Care, Inc.* 529, U.S. 1 (2000).

CompRehab's argument that the revocation is invalid because 42 C.F.R. §485.58(a) lacks a "bright-line" is unavailing. The Court finds that despite the lack of a "bright-line," the regulation's other requirements coupled with the availability of agency guidance provides administrators with a sufficient framework to administer the regulation in a non-arbitrary, non-capricious manner. On its face, the regulation requires more than just that a physician spend a "sufficient amount of time at a facility." Rather, it requires a physician spend a sufficient time doing a number of delineated tasks. Consequently, the regulation provides administrators a metric by which to determine if a physician is spending a sufficient amount of time at the facility and administrators may look to whether or not the

[22] The Court notes again that its review of factual determinations is not *de novo*. Rather the Court's review is limited to "whether there is substantial evidence to support the findings of the . . . [Secretary], and whether the correct legal standards were applied." *Gulfcoast Med. Supply Inc.*, 468 F. 3d at 1350, fn. 4 (11th Cir. 2006).

[23] CompRehab's fourth and sixth arguments in its response/reply brief [DE 27] are unexhausted. CompRehab's fourth argument is that the Secretary unconstitutionally promulgating a regulation that sets requirements for physician presence in excess of those set by Congress in 42 U.S.C. §1861(cc)(2) which, CompRehab contends, requires only that a physician be available at the facility on a full-or part-time basis, not actually present. CompRehab's sixth argument is in the alternative to its first statutory/constitutional argument. For the reasons set forth in note 20, *supra*, the Court does not reach the merits of these.

physician, while at the facility, is preforming the required tasks in accordance with accepted principles of medical practice to determine if physician services are adequate. These tasks include providing medical direction, medical care services, consultation, and medical supervision of nonphysician staff; establishing the plan of treatment in cases where a plan has not been established by the referring physician; assisting in establishing and implementing the facility's patient care policies; and participating in plan of treatment reviews, patient case review conferences, comprehensive patient assessment and reassessments, and utilization review. 42 C.F.R. §485.58(a).

Moreover, the frontline administrators of Medicare regulations, the CMS contractors that do the inspections, are specifically directed to evaluate if a physician is preforming these tasks when assessing if the CORF is providing adequate physician services. SOM §485.58(a) instructs investigators assessing physician presence to ". . .Review the activities of the group of professional personnel, utilization review process, patient records and reports of case review conferences to ascertain the extent of physician participation in patient care activities. The extent of physician participation can be determined, in part, by the type and volume of patients, scope of services and need for consultation and medical care services." Despite the lack of a "bright-line," the regulation, on its face, provides administrators a principle by which to non-arbitrarily and non-capriciously enforce its provisions, and because the associated guidance directs administrators how to enforce them in practice, the Court finds that 41 C.F.R. §485.58(a) is not invalid on the grounds stated by Plaintiff.

Turning to CompRehab's argument that Dr. Bosch spent sufficient time at the facility and the Secretary's counter-argument that the record does not support such a conclusion, the Court concludes the Secretary is correct. The ALJ looked to the SOM which directs investigators to ensure that where a physician is serving part-time as a facility physician, as was the case at CompRehab, to pay attention to whether the physician is effectively performing required responsibilities. SOM §485.58(a). Accordingly, the ALJ looked to evidence in the record that showed Dr. Bosch was

actively directing rehabilitative services. Despite Dr. Bosch's telephonic availability, periodic review of medical records, and his consultation with facility providers, the ALJ could not conclude that Dr. Bosch was actively directing rehabilitative services.

Dr. Bosch's affidavit, considered along with the other evidence in the record, does not support CompRehab's assertion that its level of physician services were adequate. First, Dr. Bosch's affidavit describes his engaging in some, but not all, of the duties required by a facility physician in accordance with 42 C.F.R. §485.58(a). Specifically, the affidavit does not mention that Dr. Bosch participated in plan of treatment reviews, patient case review conferences, comprehensive patient assessments and reassessments, or utilization reviews. 42 C.F.R. §485.58(a)(iv). Moreover, Dr. Bosch does not provide any information about how much time he actually spent at the facility, much less any of his purported activities. While he does assert in a conclusory statement that the physician services he provides are in accordance with accepted principles of medical practice, he offers no evidence about how he directs, consults, or supervises non-medical staff. This lack of evidence, coupled with practice administrator/coordinator Maria Fuentes' lack of knowledge about Dr. Bosch's availability at the facility during a given month [AR 194] substantiates the ALJ's conclusion that CompRehab's physician services were inadequate. This conclusion and the ALJ's application of the regulations was affirmed by the DAB. On review, this Court finds the Secretarial decision as rendered in the DAB's affirmance of the ALJ's findings of fact is supported by substantial evidence in the record insofar as a reasonable mind might accept it as adequate to support the Secretary's conclusion. *See Stone &Webster Constr., Inc. v. United States Dep't of Labor*, 684 F.3d 1127, 1132 (11th Cir. 2012) (discussing substantial evidence standard). The Court also finds that the Secretary's decision is in accord with applicable laws and regulations.

III. CONCLUSION

For the reasons set forth above, it is

ORDERED THAT

(1) Plaintiff's Motion for Judgment on the Pleadings or Summary Judgment is DENIED. [DE 20].

(2) Defendant's Cross-Motion for Summary Judgment is GRANTED. [DE 21].

(3) The CASE is CLOSED.

DONE AND ORDERED in Miami, Florida, this 30th day of April, 2013.

PATRICIA A. SEITZ
UNITED STATES DISTRICT JUDGE

cc: Honorable Andrea M. Simonton
All counsel of record