UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PATRICK FRATELLONE, MD,

Plaintiff,

- against -

MICHAEL O. LEAVITT,

Defendant.

REPORT AND RECOMMENDATION

08 Civ. 3100 (RMB) (RLE)

To the HONORABLE RICHARD M. BERMAN, U.S.D.J.:

I. INTRODUCTION

Plaintiff Patrick Fratellone, M.D., d/b/a Fratellone Medical Associates, LLP, brought the instant action appealing the final decision of Michael O. Leavitt, Secretary of the Department of Health & Human Services and the Centers for Medicare and Medicaid Service ("the Secretary"), denying Fratellone reimbursement for medical services he rendered to patients. Pending before the Court are the Secretary's Motion to Dismiss (Doc. No. 21) and Fratellone's Cross-Motion for Summary Judgment (Doc. No. 26). For the reasons that follow, the Court recommends that the Secretary's Motion to Dismiss be **GRANTED**, and Fratellone's Cross-Motion for Summary Judgment be **DENIED**.

II. BACKGROUND

Fratellone, a cardiologist, provided medical treatment known as Enhanced External Counterpulsation (hereinafter "EECP"), to eleven of his patients between 2002 and 2003, and sought reimbursement from Medicare's Part B carrier, Medicare contractor Empire Medicare Services ("Empire"). (Mem. of Law in Opp'n to Def.'s Mot. to Dismiss and in Supp. of Pl.'s Mot. for Summ. J. ("Pl.'s Opp'n"), Mar. 12, 2009 at 1-3.) Nearly three years after Fratellone

received the reimbursement, Empire sent him a notice on February 16, 2006, stating that the claims made for the eleven beneficiaries and the payments made by Medicare for those claims were made in error. (Administrative Record ("A.R.") at 00004.) Empire required that Fratellone repay the overpayment in the amount of $67,334.86, based upon a finding that the services provided by Fratellone were not medically necessary as required by Title 42 of The Public Health and Welfare, Social Security Act ("Medicare Act"). *See* 42 U.S.C. § 1395y(a)(1)(A); (A.R. at 00004; Mem. of Law in Supp. of Def.'s Mot. to Dismiss the Amended Compl. ("Def.'s Mem."), Jan 26, 2009 at 11.)[1]

Fratellone requested a redetermination of Empire's decision. (Def.'s Mem. at 11); *see* 42 C.F.R. §§ 405.904(a)(2); 405.948. On August 16, 2006, Empire issued a Redetermination Notice affirming the prior decision and maintaining that Fratellone was responsible for repaying the overpayment. (Def.'s Mem. at 11.) On October 11, 2006, Fratellone filed a request for reconsideration to a Qualified Independent Contractor ("QIC"). (*Id.* (citing A.R. at 00271-73)); *see* 42 U.S.C. § 1395ff(c)(2), (c)(3)(B); 42 C.F.R. §§ 405.904(a)(2); 405.960. On December 15, 2006, the QIC found that the services rendered by Fratellone were not "reasonable and necessary," thus not covered by Medicare, and affirmed Empire's decision. (A.R. at 00159 (citing Ex. 4 of the lead Beneficiary's file).) On February 13, 2007, Fratellone filed a request for a hearing before an Administrative Law Judge ("ALJ"), *see* 42 C.F.R. §§ 405.904(a)(2); 405.1000-405.1054, and on May 7, 2007, ALJ Christian J. Knapp affirmed the decision of the

[1]The total amount Fratellone was required to pay Empire was $67,334.86. However, the amount of overpayment on appeal before the MAC was $39,305.31. This is a result of three of Fratellone's patients' cases not being brought to the Secretary for review. The amount in controversy is at issue as Fratellone argues that this Court should review the payment dispute as to all eleven beneficiaries despite failure to bring the cases of three of them to the final review before the MAC. *See infra* III.B.2.

QIC. (A.R. at 00008.) On June 29, 2007, Fratellone filed an appeal of the ALJ's decision to the Medicare Appeals Council ("MAC"), (Def.'s Mem. at 15); *see* 42 C.F.R. §§ 405.904(a)(2); 405.1100-405.1130, and on February 21, 2008, the MAC affirmed the ALJ's decision (A.R. at 00003-05). Having exhausted the administrative remedies available to him, Fratellone brought the instant action, seeking judicial review of the Secretary's final decision as to reimbursement for the treatment he rendered. 42 C.F.R. §§ 405.904(a)(2); 405.1136.

The principal issue before the Court is whether there is substantial evidence in the administrative record to support the Secretary's final decision that Fratellone is not entitled to Medicare reimbursement for EECP services he rendered to his patients. Two subsidiary issues are presented by the parties: (1) whether this Court may consider an affidavit submitted by Fratellone in March 2009 with his Cross-Motion for Summary Judgment, and (2) whether this Court has jurisdiction to review the claims submitted by Fratellone for the three beneficiaries that were presented to the ALJ but not to the MAC.

III. DISCUSSION

A. The Medicaid Act

Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, governs Medicare, a federally-funded health insurance plan for eligible elderly and disabled persons. Medicare "Part B" is a voluntary supplemental insurance program that covers certain outpatient services. *Goodman v. Sullivan*, 891 F.2d 449, 449 (2d Cir. 1989) (citing 42 U.S.C. §§ 1395j-1395w-3). The Secretary contracts with private insurance companies ("carriers"), to locally administer the program. 42 U.S.C. § 1395u. Under the Medicare Act, carriers may provide coverage only for services that are "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); 42 C.F.R. § 411.15(k)(1). To assist with coverage determinations, the Secretary is authorized to issue National Coverage Determinations ("NCDs"), which identify whether or not a particular item or service is covered nationally under the Medicare program. 42 U.S.C. § 1395ff(f)(1)(B); 42 C.F.R §§ 405.860; 405.1060. NCDs are binding on fiscal intermediaries, carriers, QICs, ALJs, and the MAC. 42 C.F.R § 405.1060(a)(4).

Pursuant to the Center for Medicare and Medicaid Service's National Coverage Determinations Manual, External Counterpulsation is a non-invasive procedure covered by Medicare "for patients who have been diagnosed with disabling angina (Class III or Class IV, Canadian Cardiovascular Society Classification or equivalent classification) who, in the opinion of a cardiologist or cardiothoracic surgeon, are not readily amenable to surgical intervention . . . because: 1. [t]heir condition is inoperable, or at high risk of operative complications or post-operative failure; 2. [t]heir coronary anatomy is not readily amenable to such procedures; or 3. [t]hey have co-morbid states which create excessive risk."[2] Medicare National Coverage Determinations Manual § 20.20 (Rev. 98 Dec. 24, 2008), *available at* http://www.cms.hhs.gov/manuals/downloads/ncd103c1_part1.pdf [hereinafter "NCD Manual"].

Appeal from the Secretary's final determination is properly brought to federal district court, this Court having jurisdiction to review a final decision of the Secretary. 42 U.S.C.

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[2]According to the American Heart Association, angina is chest pain or discomfort resulting from the heart not receiving enough blood and oxygen. *See* American Heart Association, What is Angina? (2007), *available at* http://www.americanheart.org/downloadable/heart/1196117004756O1%20Angina%209_07.pdf. The Canadian Cardiovascular Society ("CCS") Classification System lists four Classes of angina. The relevant classification for purposes of this case is angina Class III, which is described as "[m]arked limitations of ordinary physical activity. Angina occurs on walking one or two blocks on the level and climbing one flight of stairs in normal conditions and at a normal pace." (A.R. at 00163 (ALJ's decision).)

§§ 405(g); 1395ff(b); 42 C.F.R. § 405.904(a)(2); *Caremark Therapeutic Servs. v. Thompson*, 244 F. Supp. 2d 224, 227 (S.D.N.Y. 2003). Providers or other non-beneficiaries have a right to judicial review when a determination involves a denial of coverage because services were "not reasonable and necessary." 42 C.F.R. §§ 405.904(b)(1); 411.15(k)(1). A claimant seeking judicial review must obtain the Secretary's "final decision," which is rendered only after a claimant has exhausted his administrative remedies by presenting his claim at all designated levels of the administrative appeals process. *Bowen v. City of New York*, 476 U.S. 467, 482 (1986); *Heckler v. Ringer*, 466 U.S. 602, 606 (1984).

B. Collateral Issues

1. Affidavit

In support of his opposition, Fratellone submitted an affidavit on March 12, 2009, which was not presented to the Secretary or the ALJ. Fratellone contends that his affidavit, provided in support of his Cross-Motion for Summary Judgment, is not precluded by Rule 12(c) of the Federal Rules of Civil Procedure and therefore can be considered by this Court. (Reply Mem. of Law in Further Opp'n to Def.'s Mot. to Dismiss and in Further Supp. of Pl.'s Mot. for Summary J. ("Pl.'s Reply Mem."), April 6, 2009 at 6.) The Secretary argues that this Court lacks jurisdiction to consider Fratellone's affidavit because the record before this Court is closed and neither party is permitted to submit additional evidence. (Reply Mem. in Further Supp. of Def.'s Mot. to Dismiss the Amended Compl. and in Opp'n to Pl.'s Cross-Mot. ("Def.'s Reply Mem."), April 2, 2009 at 6.) The Secretary also argues that the affidavit does not introduce any new and material evidence that would justify a remand. (Def.'s Mem. at 7.)

This Court, upon reviewing the agency's determination, must base its decision "upon the pleadings and transcript of the record." 42 U.S.C. § 405(g); *Mathews v. Weber*, 423 U.S. 261, 263 (1976). Additional evidence may be taken into consideration on review, but only "upon a showing that there is new evidence which is material and that there is good cause for the failure to incorporate such evidence into the record in a prior proceeding." § 405(g). Materiality requires "'a reasonable possibility that the new evidence would have influenced the Secretary to decide [the] claimant's application differently.'" *Estate of Landers v. Leavitt*, 545 F.3d 98, 114 (2d Cir. 2008) (quoting *Jones v. Sullivan*, 949 F.2d 57, 60 (2d Cir. 1991)) (alteration in original).

Fratellone's affidavit does not present evidence or arguments that were not already reviewed by the Secretary. At best, it assists this Court in navigating through a plethora of medical terminology and files, which make up the administrative record, and helps this Court address the narrow issue of whether or not the Secretary's decision was supported by substantial evidence. Furthermore, Fratellone does not assert that the affidavit introduces new and material evidence (Pl.'s Reply Mem. at 6-7), and the Secretary apparently agrees (Def's Mem. at 7). As noted by Fratellone, the affidavit "summarizes the medical records and highlights the portions of the medical records that supported his findings that the eleven (11) patients suffered from Class III angina." (Pl.'s Reply Mem. at 6-7.)

The affidavit states that all eleven beneficiaries were diagnosed with angina and that the corresponding EECP Flow Charts, which were part of the administrative record, show that the beneficiaries had Class III angina. Fratellone maintains that on each chart there is a box checked indicating "Canadian Classification Class III." (Pl.'s Aff. in Opp'n to Def.'s Mot. to Dismiss ("Fratellone Aff."), March 12, 2009, ¶¶ 4-8; *see* A.R. at 00167.) Fratellone's affidavit lists the

eleven beneficiaries he treated with EECP therapy and summarizes their respective medical conditions present at the time of treatment. Each summary states that the individual patient was "diagnosed with angina" or "diagnosed with chest pain also known as angina," and that the Flow Charts indicate that the patient had Class III angina. (Fratellone's Aff. ¶¶ 4-13.)

Because the question before this Court requires a review of the record as it was presented to the Secretary, and because Fratellone's affidavit does not introduce new and material evidence, the Court will consider it as an aid to understand and highlight Fratellone's position with respect to the medical records and his interpretation of their contents.

2. Three Beneficiaries Not Included in the MAC's Appeal

Fratellone alleges he provided EECP treatment therapy to eleven beneficiaries between January 1, 2002, and December 31, 2003. (Am. Compl., Dec. 3, 2008 at 2; Fratellone's Aff. ¶ 4.) The Secretary argues that although Fratellone may have provided EECP therapy to eleven patients, only eight of the beneficiaries that Fratellone seeks recovery for are properly before this Court because Fratellone has not exhausted his administrative remedies for the remaining three patients (Dress, Peller, and Petruzzelli), as their claims were not included in the appeal before the MAC. (Def.'s Mem. at 1.) Fratellone argues that the three cases were inadvertently excluded from the appeal to the MAC and that the Secretary's determination pertaining to the eight beneficiaries should be construed as dispositive for *all* the beneficiaries. (Pl.'s Reply Mem. at 8.) Fratellone contends that the MAC would have rendered the same decision for the three missing beneficiaries because the medical evidence the ALJ relied on was the same for all eleven patients and therefore, the outcome for all the beneficiaries would not be dissimilar. (*Id.* at 7-8.) Fratellone further maintains that exhaustion issues are applied for fairness and that in this

context, the remaining three beneficiaries' claims were fairly exhausted. Finally, he asserts that the Secretary would not be prejudiced as a result of the Court considering all eleven beneficiaries claims exhausted.

The Secretary argues that there is no evidence that the omission of the three beneficiaries from appeal to the MAC was inadvertent. In addition to noting that Fratellone failed to include the three beneficiaries in the appeal letter, the Secretary notes that Fratellone "had good reason to not pursue his arguments as to the three additional beneficiaries, as the ALJ raised particular concerns about the documentation for these beneficiaries." (Def.'s Mem. at 8.)

The Medicare Act statutorily proscribes the course of action a claimant must take in order to appeal the agency's decision to a district court. 42 U.S.C §§ 1395ff(b)(1)(A); 405(g); 42 C.F.R. § 405.904(a)(2). The claimant must obtain a "final decision" from the Secretary, 42 U.S.C §§ 1395ff(b)(1)(A); 405(g), and in order to obtain a "final decision," the claimant must exhaust the administrative appeals process by presenting his or her claim at every possible appeal level. *Heckler*, 466 U.S. at 606; *Mathews v. Eldridge*, 424 U.S. 319, 328-29 (1976). To do so, the claimant must seek review all the way through the process to the MAC, which is the final step in the appeals process and represents the Secretary's final and binding decision. 42 C.F.R. § 405.1130.

The exhaustion requirement can be waived for futility. *See Pavano v. Shalala*, 95 F.3d 147 (2d Cir. 1996). The MAC's review of the ALJ's decision is *de novo*. 42 C.F.R. § 405.1108(a); (*see* A.R. at 00003 (MAC decision)). Here, the MAC explicitly states that "[s]ave for each beneficiary's specific medical history, the claims in issue contained common issues of law and fact." (A.R. at 00003.) Despite the fact that the materials presented to the MAC did not

address the medical records or include any supplemental materials from Fratellone as to the three excluded beneficiaries, it seems no different outcome would result had the MAC considered their files. Indeed, having reviewed the records of these three beneficiaries, the Court concludes that they contain weaker evidence of the presence or diagnosis of disabling angina. Dress's medical records lack any mention of chest pain (A.R. at 00161); Petruzzelli's medical records indicate inconsistencies as the "officer and treatment records on file do not correspond with the dates of service at issue" (A.R. at 00161); and Peller's medical records don't indicate any symptoms of chest pain or evidence that he was provided with EECP therapy (A.R. at 00160). Compared to the files of the eight patients actually covered by the appeal, these patients have less evidence to justify EECP treatments. Therefore, this Court finds that appeal would have been futile, and the decision rendered by the ALJ as to these three beneficiaries would have been upheld, as the MAC upheld the ALJ's decision on the other eight beneficiaries. Thus, this Court deems Fratellone's instant case to include his claims as to all eleven beneficiaries.

C. Standard of Review

Judicial review of administrative decisions under the Social Security Act are governed by 42 U.S.C. § 1395ff(b)(1), which incorporates provisions of 42 U.S.C. § 405(g). The ALJ's determination creates the entire and complete record of the case. 42 C.F.R. § 405.1042(a)(1). The MAC's decision represents the final decision of the Secretary and "is binding on all parties unless a Federal district court issues a decision modifying the MAC's decision . . . ." 42 C.F.R. § 405.1130. The Court must base its judgment on the pleadings and transcript of the record, and can affirm, modify, or reverse the decision of the Secretary. 42 U.S.C. § 405(g); *Mathews v. Weber*, 423 U.S. at 263. The Secretary's decision is afforded considerable deference. *Kaplan ex*

rel. Estate of Kaplan v. Leavitt, 503 F. Supp. 2d 718, 722 (S.D.N.Y. 2007) (citing *Jones*, 949 F.2d at 59). The MAC's decision represents the Secretary's final decision and, ". . . if supported by substantial evidence, shall be conclusive[,]" 42 U.S.C. § 405(g); 42 C.F.R. § 405.1136(f); *Friedman v. Sec'y of Health & Human Servs.*, 819 F.2d 42, 44 (2d Cir. 1987), even if there is substantial evidence that would support a contrary conclusion. *Murphy v. Sec'y of Health & Human Servs.*, 62 F. Supp. 2d 1104, 1106 (S.D.N.Y. 1999) (referencing *Schauer v. Schweiker*, 675 F.2d 55, 57 (2d Cir. 1982); *Rutherford v. Schweiker*, 685 F.2d 60, 62 (2d Cir. 1982)). The Secretary's final decision may be set aside only upon the Court's finding of legal error or that the decision was made absent substantial evidence. *Berry v. Schweiker*, 675 F.2d 464, 467 (2d Cir. 1982). "Substantial evidence" means "'such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'" *Murphy*, 62 F. Supp. 2d at 1104 (quoting *Richardson v. Perales*, 402 U.S. 389, 401 (1971) (quoting *Consolidated Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938))).

In assessing whether substantial evidence supports a decision by the Secretary, a court is to review the record as a whole, looking at the evidence supporting the Secretary's position, as well as other evidence that detracts from it. *Alston v. Sullivan*, 904 F.2d 122, 126 (2d Cir. 1990). In determining whether substantial evidence exists, the court should not "reevaluate the facts, reweigh the evidence, or substitute [its] own judgment for that of the [Secretary]." *Luna v. Shalala*, 22 F.3d 687, 689 (7th Cir. 1994). Furthermore the claimant has the burden of proving entitlement to Medicare benefits. *Kaplan*, 503 F. Supp. 2d at 724 (citing *Friedman*, 819 F.2d at 45).

D. The Secretary's Finding

1. Substantial Evidence

The question before the Court is whether the Secretary's conclusion that the services rendered were not reasonable and necessary is supported by substantial evidence. In order to determine what constitutes reasonable and necessary for the purposes of obtaining Medicare coverage for EECP therapy, Medicare publishes the National Coverage Determinations ("NCDs"), which are binding on ALJs and the MAC. 42 C.F.R. § 405.860(a)(4); (A.R. at 00004). According to the NCD for EECP for Severe Angina, EECP therapy is only covered for patients with *disabling* angina (Class III or IV), and are not readily amenable to surgery in the opinion of a cardiologist or cardiothoracic surgeon. NCD Manual § 20.20.

In reaching its decision, the MAC reviewed the voluminous administrative record, which consists of forty to sixty pages of medical records for each beneficiary and the additional evidence submitted by Fratellone.[3] The Secretary affirmed the findings of the ALJ who had determined that the medical records did not support the medical necessity of the EECP therapy. (A.R. at 00004.) Specifically, the Secretary found that the record was bereft of evidence that the beneficiaries suffered from disabling angina and, despite some evidence that the beneficiaries had signs and symptoms of chest pain or angina, none of the medical records contained a "diagnosis" of angina Class III or IV. Therefore, the Secretary concluded that the medical necessity of EECP therapy was not established. (*Id.*) The Secretary upheld the ALJ's conclusion

[3]With permission of the ALJ, Fratellone submitted letters written at the time his appeal was under consideration, which was more than three years after the services were rendered to the patients. These letters highlighted and summarized the medical conclusions based upon the information contained in the medical records. (Pl.'s Opp'n at 11.)

that the EECP Flow Charts, which were associated with the beneficiaries' medical records and contained an angina "Class III" box checked-off, were insufficient evidence to support a diagnosis of angina Class III. (*See id.* at 00167.) The Secretary also affirmed the ALJ's finding that Fratellone failed to establish that the patients were not amenable to surgery because they had at least one of the medical conditions listed in the NCD. (Def.'s Mem. at 23.) The Secretary found that the assertions and conclusions contained in the letters provided to the ALJ were effectively inconsistent with the beneficiaries' contemporaneous medical records. (*See* A.R. at 00004 (MAC decision); A.R. at 00167-68 (ALJ decision); *see also* Def.'s Mem. at 21.)

Fratellone argues that the medical treatments rendered to the eight patients were "reasonable and necessary" as required by 42 U.S.C. § 1395y(a)(1)(A), (Pl.'s Mem. at 9); *see* 42 C.F.R. § 411.15(k)(1), because all the beneficiaries suffered from disabling angina and co-morbidities as demonstrated by the medical records (*id.* at 8). He contends that the fact that the patient's medical records do not contain the language, "disabling angina," should not be dispositive for the Court. (*Id.*) Fratellone argues that the Secretary's decision was not supported by substantial evidence and that the record contained evidence that all the patients suffered from disabling angina (Class III angina), which was "clearly stated in the EECP Therapy Flow Charts for each beneficiary." (*Id.* at 9.) Further, Fratellone argues that the Secretary failed to make a determination on substantial evidence as the decision relied on only about forty of the 700 pages of medical records to rule against him. (Pl.'s Reply Mem. at 1.)

Fratellone asserts that he diagnosed each beneficiary with an "abnormal stress test [and] chest pain[,] which is angina." (Pl.'s Opp'n at 9.) In his appeal of the ALJ's decision, he argued that all the at issue patients suffered from ischemia and chest pain. (A.R. at 00029.) To support

the proposition that they had angina, he cited *New York v. Sullivan*, 906 F.2d 910, 913 (2d Cir. 1990), where the court found that, "[i]ndividuals with ischemic heart disease typically suffer chest pain ('angina') upon exertion." (*See* A.R. at 00029, 00043, 00057, 00073, 00092, 00115, 00134.) Additionally, Fratellone argues that the medical records supported the conclusion that the beneficiaries were not amenable to surgery because they all had documented co-morbidities, which rendered surgical intervention very risky, and therefore EECP therapy was medically necessary. (Pl.'s Opp'n at 12-13.)

Fratellone argues that the letters he submitted to the ALJ provided further support that the beneficiaries suffered from Class III angina and that the Seeretary erroneously afforded less evidentiary weight to them. (*Id.*) He contends that these letters summarized the medical conclusion and highlighted the medical conditions for each beneficiary that rendered them eligible recipients for EECP therapy. (*Id.*)

The ALJ stated that although the letters submitted by Fratellone mentioned the beneficiaries suffering from chest pain, he afforded them less weight because they did not include an actual diagnosis of angina Class Ill or IV. (A.R. at 00167.) The ALJ also found that some of the letters, submitted three years after the treatments were provided, conflicted with the contemporaneous medical records and considered these inconsistencies indicative of insufficient diagnosis. For example, the ALJ mentioned the case file of one patient who had no reported chest pain at the time of treatment, but Fratellone indicated in his March 2006 letters that the patient developed chest pain during a stress test. (A.R. at 00167.) Similarly, for another patient Fratellone noted that there was a positive stress test upon exertion conducted on October 24,

2001, but the record listed no complaints of chest pain before, during, or after the test. (A.R. at 00168.)

"[T]he Secretary is entitled to give more weight to contemporaneous medical evidence than to medical opinions [after-the-fact affidavits] that are based on hindsight." *Tsoutsouris v. Shalala*, 977 F. Supp. 899, 905 (N.D. Ind. 1997) (summarizing *Anderson v. Sullivan*, 925 F.2d 220, 222 (7th Cir. 1991)). Furthermore, the evidence Fratellone cites in support of his position fails to satisfy the explicit requirements of the NCD. It is not enough that the beneficiaries had angina or ischemia. In order for Fratellone to be eligible for reimbursement under Medicare, he has the burden of proving that the beneficiaries had been diagnosed with *disabling* angina (Class III or IV) *and* that the beneficiaries were not amenable to surgery either because (1) their condition was inoperable; (2) their coronary anatomy was not amenable to a surgical procedure; or (3) they had co-morbidities that create an excessive risk. NCD Manual § 20.20; (A.R. at 00166-67). While Fratellone may be correct in asserting that "the NCD does not state that the record must state in bold letters 'CLASS III ANGINA' as a precondition to payment for the use of EECP" (Pl.'s Reply Mem. at 6), the NCD Manuel is clear in requiring that patients be diagnosed with Class III or Class IV angina in order for EECP treatments to be covered by Medicare. Moreover, the law is clear that the burden of proof is on Fratellone. Consequently, while Fratellone has submitted some evidence in support of his position, this Court concludes that the Secretary's review of the voluminous administrative record, and finding that the treatment was not eligible for Medicare coverage because the record did not evidence the requisite preconditions, the medical necessity of the treatment, is supported by substantial evidence. (*See* A.R. at 00168); 42 U.S.C. §405(g); *Keefe on Behalf of Keefe v. Shalala*, 71 F.3d

1060, 1062 (2d Cir. 1995); *Alston*, 904 F.2d at 126. Because of this conclusion, the Court does not further explore the Parties' dispute about the proof of the beneficiaries respective co-morbidities.

2. Treating Physician Rule

Fratellone argues that the Secretary erroneously denied application of the treating physician rule. (A.R. at 00031-32.) The treating physician rule was originally a common law rule that gave substantial deference to the opinions of treating physicians in disability benefit cases. *Kaplan*, 503 F. Supp. 2d at 723. Eventually, the treating physician rule was modified and codified in the *Standards for Consultative Examinations and Existing Medical Evidence*, 56 Fed. Reg. 36, 932 (1991). *Id.* The newly codified regulation afforded less weight to the opinions of treating physicians. *Id.* (referencing *Schisler v. Sullivan*, 3 F.3d 563, 567 (2d Cir. 1993), wherein the Second Circuit upheld the regulation).

It is unsettled law whether the treating physician rule applies to Medicare cases. *Keefe*, 71 F.3d 1060; *Kaplan*, 503 F. Supp. 2d at 723. "The codified version of the treating physician rule does not by its terms apply in Medicare cases." *Kaplan*, 503 F. Supp. 2d at 723. While the Second Circuit has not explicitly decided whether the rule applies in Medicare cases, *id.* (citing *Keefe*, 71 F.3d at 1064; *State of N.Y. v. Sec'y of Health & Human Servs.*, 924 F.2d 431, 433-34 (2d Cir. 1991)), it has indicated that it is possible that some version of the treating physician rule could apply in that context. *See Keefe*, 71 F.3d at 1064 (referencing *Klementowski v. Secretary, Dep't of Health & Human Servs.*, 801 F. Supp. 1022, 1025-26 (W.D.N.Y. 1992)).

The treating physician rule is based on the premise that the opinion of a treating physician should be accorded more weight because the physician has intimate and first hand knowledge

about a patient's specific medical condition. *Id.* The federal regulatory scheme permits giving a treating physician's opinion special weight only if it is "'well-supported by medically acceptable clinical and laboratory diagnostic techniques and . . . [is] not inconsistent with the other substantial evidence in the record . . . ." *Arruejo v. Thompson*, 2001 WL 1563699, at *14 (E.D.N.Y. July 3, 2001) (court denied application of treating physician rule because the treating physicians failed to submit medical records or other patient-specific evidence showing reasons for treatments or medical necessity) (quoting 56 Fed. Reg. 36,932, 36,936; referencing *Friedman*, 819 F.2d at 46). Therefore, even were the treating physician rule broadly applicable in Medicare cases, Fratellone failed to submit well-documented evidence to support his medical conclusions, and therefore, his medical opinion is not entitled to more evidentiary weight. (*See* A.R. at 00004, 00168.) Fratellone maintains that the unsigned Flow Charts constitute a diagnosis. (Pl.'s Reply at 12.) He fails, however, to substantiate this assertion. Fratellone also argues that practitioners use "Class III Angina" and "disabling angina" interchangeably, presumably to suggest that references to disabling angina in the record support his assertion that all beneficiaries were diagnosed. This argument is unavailing as the record lacks even significant mention of disabling angina. The Secretary concluded that despite the fact that Fratellone was given the opportunity to provide additional evidence to the ALJ, "the assertions of medical necessity contained in the summaries prepared by [Fratellone], three years after the treatment dates were effectively at odds with the beneficiaries' more contemporaneous medical records." (A.R. at 00004.)

Under the Medicare program, EECP therapy is only covered where the patient has been diagnosed with disabling angina (Class III or IV). Fratellone failed to document such a diagnosis as to these eleven beneficiaries. Therefore, the Secretary's decision should be upheld.

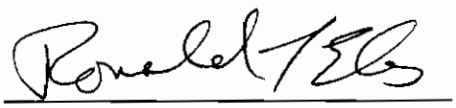
IV. CONCLUSION

For the foregoing reasons, I recommend that the Secretary's Motion to Dismiss be **GRANTED**, and Fratellone's Cross-Motion for Summary Judgment be **DENIED**.

Pursuant to Rule 72, Federal Rules of Civil Procedure, the parties shall have ten (10) days after being served with a copy of the recommended disposition to file written objections to this Report and Recommendation. Such objections shall be filed with the Clerk of the Court and served on all adversaries, with extra copies delivered to the chambers of the Honorable Richard M. Berman, 500 Pearl Street, Room 650, and to the chambers of the undersigned, Room 1970. Failure to file timely objections shall constitute a waiver of those objections both in the District Court and on later appeal to the United States Court of Appeals. *See Thomas v. Arn*, 474 U.S. 140, 150 (1985); *Small v. Sec'y of Health & Human Servs.*, 892 F.2d 15, 16 (2d Cir. 1989) (*per curiam*); 28 U.S.C. § 636(b)(1) (West Supp. 1995); FED. R. CIV. P. 72, 6(a), 6(d).

DATED: August 7, 2009
New York, New York

Respectfully Submitted,



The Honorable Ronald L. Ellis
United States Magistrate Judge

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