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UNITED STATES DISTRICT COURT EASTERN DISTRICT OF NEW YORK

I O D A CEDICAL D. C.

I & R MEDICAL, P.C.,

Plaintiff,

: <u>MEMORANDUM AND</u>

-against- : <u>ORDER</u>

NORRIS COCHRAN, the Acting Secretary of the United: States Department of Health and Human Services, in his: official capacity,

17-CV-6417 (ILG)

Defendant.

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GLASSER, Senior United States District Judge:

On November 3, 2017, plaintiff I & R Medical, P.C. commenced this action pursuant to Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395, et seq., and the Administrative Procedure Act, 5 U.S.C. §§ 551, et seq., against defendant Eric D. Hargan, then Acting Secretary of the United States Department of Health and Human Services (hereinafter, "the Secretary"), ¹ in his official capacity, seeking reversal of a final decision issued by the Medicare Appeals Council that had found plaintiff was overpaid by Medicare for physical therapy and chiropractic services furnished between January 2006 and November 2008. Compl. ¶¶ 4, 5, Dkt. 1; see Dec. of Medicare Appeals Council at 2, Dkt. 1-12. Before the Court are the parties' cross motions for judgment on the pleadings pursuant to Rule 12(c) of the Federal Rules of Civil Procedure. Dkt. 24, 25. For the reasons set forth below, plaintiff's motion for judgment on the pleadings is DENIED and the Secretary's cross motion for judgment on the pleadings is GRANTED.

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¹ Acting Secretary of the Department of Health and Human Services Norris Cochran is automatically substituted as defendant for former Acting Secretary Eric D. Hargan. *See* Fed.R.Civ.P. 25(d).

BACKGROUND

I. Statutory and Regulatory Framework

Medicare is a program governed by Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395, *et seq.*, commonly known as the Medicare Act ("the Act"), that provides health insurance benefits for aged and disabled individuals. As relevant here, Medicare Part B provides supplemental medical insurance benefits that cover physicians' services and outpatient care, such as physical therapy and diagnostic tests, for beneficiaries who elect to enroll in the program and pay additional premiums. 42 U.S.C. §§ 1395j–1395w-4, 1395x(s); *see also* 42 C.F.R. Parts 407, 408, 410, 414. Part B is administered by the Centers for Medicare & Medicaid Services ("CMS"), a federal agency within the Department of Health and Human Services, in conjunction with private entities known as Medicare Administrative Contractors ("Contractors"). 42 U.S.C. § 1395kk-1.

Part B provides reimbursement for those items and 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). However, "Congress did not define the items and services that should be considered 'reasonable and necessary,' but delegated the making of this decision to the Secretary." *State of N.Y. on Behalf of Stein v. Sec'y of Health & Human Servs.*, 924 F.2d 431, 433 (2d Cir. 1991); *see Heckler v. Ringer*, 466 U.S. 602, 605 (1984). Indeed, the Secretary "has wide discretion in selecting the means" for specifying those services that are covered under the Act and "has traditionally acted through formal regulations and (informal) instructional manuals and letters." *Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 74 (2d Cir. 2006). Providers and suppliers who participate in the Medicare program have "a duty to

familiarize [themselves] with the legal requirements for cost reimbursement." *Heckler v. Cmty. Health Servs. of Crawford Cty., Inc.*, 467 U.S. 51, 64 (1984).²

The Act provides for National Coverage Determinations ("NCDs") and Local Coverage Determinations ("LCDs"). 42 U.S.C. § 1395ff(f). NCDs are "determination[s] by the Secretary with respect to whether or not a particular item or service is covered nationally." 42 U.S.C. § 1395ff(f)(1)(B); 42 C.F.R § 405.1060(a)(1). NCDs are binding on fiscal intermediaries, carriers, Quality Improvement Organizations ("QIOs"), Qualified Independent Contractors ("QICs"), Administrative Law Judges ("ALJs") and attorney adjudicators, and the Medicare Appeals Council ("the Council"). 42 C.F.R § 405.1060(a)(4). When conducting a review, an ALJ or the Council "may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD was applied correctly to the claim." 42 C.F.R § 405.1060(b)(2), (c)(2).

Local Coverage Determinations ("LCDs")³ are "determination[s] by a fiscal intermediary or a carrier under part A or part B, as applicable, respecting whether or not a particular item or service is covered on an intermediary- or carrier-wide basis under such parts, in accordance with section 1395y(a)(1)(A)." 42 U.S.C. § 1395ff(f)(2)(B). LCDs, along with CMS program guidance, such as program memoranda and manual instructions, are not binding on ALJs, attorney adjudicators, or the Council. 42 C.F.R § 405.1062(a). However, such policies must be given

² A provider is "a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, or hospice that has in effect an agreement to participate in Medicare, or clinic, rehabilitation agency, or public health agency that has in effect a similar agreement, but only to furnish outpatient physical therapy or speech pathology services, or a community mental health center that has in effect a similar agreement but only to furnish partial hospitalization services." 42 C.F.R. § 405.902. A supplier is, "unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under Medicare." *Id.*

³ LCDs were previously known as "Local Medical Review Policies" ("LMRPs"). *U.S. ex rel. Ryan v. Lederman*, No. 04-CV-2483, 2014 WL 1910096, at *1 (E.D.N.Y. May 13, 2014).

"substantial deference . . . if they are applicable in a particular case." *Id.* If an ALJ, attorney adjudicator, or the Council declines to follow a policy in a particular case, the decision "must explain the reasons why the policy was not followed." 42 C.F.R § 405.1062(b).

II. The Medicare Payment System and Appeals Process

"The Part B reimbursement system is administered by [Contractors], who 'typically authorize payment of claims immediately upon receipt of the claims, so long as the claims do not contain glaring irregularities." *Albert v. Burwell*, 118 F. Supp. 3d 505, 508 (E.D.N.Y. 2015) (quoting *Gulfcoast Med. Supply, Inc. v. Sec'y, Dep't of Health & Human Servs.*, 468 F.3d 1347, 1349 (11th Cir. 2006)). Designated contractors under the Medicare Integrity Program may then conduct post-payment audits to ensure that proper payments have been made. 42 U.S.C. § 1395ddd; 42 C.F.R. § 421.304. The post-payment audit process typically proceeds as follows:

In conducting a post-payment audit, . . . a probe sample of billings from a physician [is requested], in order to determine whether there is a likelihood of overpayment by Medicare . . .

Following a probe sample, . . . a statistically valid random sample ("SVRS") from the physician [is requested]. The SVRS is then extrapolated to the physician's total billing, in order to provide a reasonable approximation of the total overpayment when the quantity of billing is overly abundant. If, following an audit, [it is] determine[d] that an overpayment has been made, . . . Medicare payments from the provider [may be offset or recouped].

Art of Healing Med., P.C. v. Burwell, 91 F. Supp. 3d 400, 405 (E.D.N.Y. 2015) (quoting Anghel v. Sebelius, 912 F. Supp. 2d 4, 9 (E.D.N.Y. 2012)).

Within 120 days from the date of receipt of an initial determination, a dissatisfied party may file a request for redetermination, regardless of the amount in controversy. 42 U.S.C. § 1395ff(a)(3); see 42 C.F.R. §§ 405.940, 405.942(a). "An individual [employed by the Contractor]

who was not involved in making the initial determination must make a redetermination." 42 C.F.R. § 405.948.

Following redetermination, a dissatisfied party may then request reconsideration by a QIC within 180 days, regardless of the amount in controversy. 42 U.S.C. § 1395ff(b)(1); see 42 C.F.R. §§ 405.960, 405.962(a). Following reconsideration by a QIC, a dissatisfied party may then request a hearing before an ALJ within 60 days, if the amount remaining in controversy is at least \$100. 42 U.S.C. § 1395ff(b)(1); see 42 C.F.R. §§ 405.1000, 405.1002(a), 405.1006(b).

"CMS or any of its contractors may refer a case to the Council if, in their view, the decision or dismissal contains an error of law material to the outcome of the claim or presents a broad policy or procedural issue that may affect the public interest." 42 C.F.R. § 405.1110(b)(1). CMS may also request that the Council take its own motion review of a case if "CMS or its contractor participated in the appeal at the [Office of Medicare Hearings and Appeals ("OMHA")] level" and "[i]n CMS' view, the ALJ's or attorney adjudicator's decision or dismissal is not supported by the preponderance of evidence in the record or the ALJ or attorney adjudicator abused his or her discretion." 42 C.F.R. § 405.1110 (b)(1)(i), (ii). In a case where CMS or its contractor participated in an appeal at the OMHA level, the Council will exercise its own motion authority if there is "an error of law material to the outcome of the case, an abuse of discretion by the ALJ . . . , the decision is not consistent with the preponderance of the evidence of record, or there is a broad policy or procedural issue that may affect the general public interest." 42 C.F.R. § 405.1110(c)(1); see Dec. of Medicare Appeals Council at 21. "In deciding whether to accept review under this standard, the Council will limit its consideration of the ALJ's . . . action to those exceptions raised by CMS." 42 C.F.R. § 405.1110(c)(1).

The Council may adopt, modify, or reverse the ALJ's decision. 42 C.F.R. § 405.1128(b). A dissatisfied party may then seek review in federal court within 60 days, if the amount in controversy is at least \$1,000. 42 C.F.R. §§ 405.1006(c), 405.1130, 405.1136.

III. Facts and Procedural History

Plaintiff is a medical practice located at 112-41 Queens Blvd., Suite LLB, Forest Hills, New York 11375. Compl. ¶ 1. Isabella Bangy, M.D., a physician duly licensed by the State of New York to practice medicine, is plaintiff's sole owner. *Id.* Yakov Zilberman, D.C., a chiropractor duly licensed by the State of New York, was employed by plaintiff at all times relevant to this action. *Id.* ¶ 2.

After receiving complaints that plaintiff was improperly billing and documenting services billed to Medicare, SafeGuard Services, LLC ("SGS"), through its Eastern Benefit Integrity Support Center, performed a post-payment audit of plaintiff. Compl. ¶ 10; see Ltr. dated Aug. 7, 2012, Dkt. 1-4; Ltr. dated Aug 14, 2012, Dkt. 1-5 (correcting an administrative error). Specifically, SGS conducted two reviews, the first of which was of records of 31 patients for claims paid from February 13, 2006, through November 25, 2008, and the second of which was of records of 29 patients for claims paid from August 31, 2007, through November 24, 2008. Compl. ¶ 11. The reviews resulted in the downcoding or denial of most of the claims for services, including "physical therapy, nerve conduction, injections, chiropractic services, and Evaluation and Management services." Ltr. dated Aug. 14, 2012 at 3, 4. SGS assessed a total extrapolated overpayment of \$747,574.30. Compl. ¶ 16.

On August 28, 2012, National Government Services ("NGS"), a Medicare Contractor, sent a notice that plaintiff had been overpaid a total amount of \$747,574.30. Compl. ¶ 9; see Ltr. dated

⁴ SGS is a Zone Program Integrity Contractor. See Dec. of Medicare Appeals Council at 1, 2.

Aug. 28, 2012, Dkt. 1-3. Plaintiff timely requested a redetermination. Compl. ¶ 17. On December 7, 2012, upon a new and independent review of the disputed claims, NGS rendered an unfavorable decision affirming the underlying overpayment determination. *Id.*; *see* Redetermination dated Dec. 7, 2012, Dkt. 1-6. Plaintiff timely submitted a request for reconsideration to a QIC. Compl. ¶ 19. On July 19, 2013, the QIC issued an unfavorable decision, finding that "the services did not meet the requirements to be considered reasonable and necessary in the treatment of the patients" based on, among other things, inadequate or missing documentation and erroneous coding. QIC Ltr. dated July 19, 2013 at 15, Dkt. 1-7; *see* Compl. ¶ 19.

On August 22, 2013, plaintiff timely requested a hearing before an ALJ. Compl. ¶ 20. This ALJ request was submitted by plaintiff's prior attorney, Mathew Levy, Esq. *Id.* ¶ 21. When current counsel took over the case in 2016, they discovered that the request was never docketed, so they asked for an extension to file another request for an ALJ hearing. *Id.* ¶¶ 21–22; *see* Extension Request, Dkt. 1-8. The request for an extension was granted and the appeal was docketed and assigned to ALJ P. Arthur McAfee. Compl. ¶ 22.

The hearing took place on February 8, 2017. *Id.* ¶ 24; *see* Hr'g Tr., Administrative Record ("AR") Vol. II at 1444–1574.⁵ Jacqueline Thelian, CPC, CCS-P, an expert witness in the field of medical coding, testified on behalf of plaintiff as to the appropriate documentation for physical therapy and chiropractic services that met Medicare coverage criteria. Compl. ¶¶ 23, 26.⁶

On April 12, 2017, ALJ McAfee issued a partially favorable decision, finding, among other things, that certain claims at issue were valid and should have been paid. *Id.* ¶ 28; *see* ALJ Dec.

⁵ Counsel for defendant has provided the Court with copies of the certified administrative record. *See* Ltr. dated Oct. 22, 2018, Dkt. 33.

⁶ Harold S. Haller, Ph.D., on behalf of plaintiff, and Roumen Kozarev, on behalf of SGS, provided expert testimony related to the validity of the statistical methodology utilized in this matter. Pl.'s Mem. of Law at 8 n.4, Dkt. 24-1.

dated Apr. 12, 2017, Dkt. 1-9. Thereafter, on May 30, 2017, an Administrative Qualified Independent Contractor ("AdQIC") referred the decision to the Council for review on the basis that the decision "contain[ed] an error of law material to the outcomes of the[] claims and [wa]s otherwise unsupported by the preponderance of the evidence." AdQIC's Ltr. dated May 30, 2017 at 21, Dkt. 1-10; see Compl. ¶ 29. On June 19, 2017, plaintiff filed an exception to AdQIC's request. Compl. ¶ 30; see Ltr. dated June 19, 2017, Dkt. 1-11. On August 23, 2017, the Council reversed the ALJ's favorable findings for physical therapy and chiropractic services furnished to 50 beneficiaries and adopted the remainder of the ALJ's decision. Compl. ¶ 40; see Dec. of Medicare Appeals Council at 89.

Having exhausted the administrative remedies available to it, plaintiff brought the instant action to seek judicial review of the Secretary's final decision. On June 13, 2018, plaintiff moved for judgment on the pleadings pursuant to Rule 12(c) of the Federal Rules of Civil Procedure. Pl.'s Not. of Mot, Dkt. 24; see Pl.'s Mem. of Law in Supp. of Mot. for J. on the Pleadings ("Pl.'s Mem. of Law"), Dkt. 24-1. On August 13, 2018, the Secretary cross-moved for judgment on the pleadings. Def.'s Not. of Mot, Dkt. 25; see Def.'s Mem. of Law in Supp. of Cross-Mot. for J. on the Pleadings & in Opp. to Pl.'s Mot. ("Def.'s Mem. of Law"), Dkt. 26. On September 21, 2018, plaintiff filed a memorandum in opposition to the Secretary's cross motion and in further support of its motion. Pl.'s Mem. of Law in Opp. to Def.'s Cross-Mot. & in Further Supp. of Pl.'s Mot. ("Pl.'s Mem. in Opp."), Dkt. 29. On October 19, 2018, the Secretary filed a reply memorandum of law in further support of its cross motion. Reply Mem. of Law in Further Supp. of Def.'s Cross-Mot. ("Def.'s Reply"), Dkt. 32.

⁷ The Secretary notes in its papers that "only a portion of the total overpayment is at issue in this action. That portion of the overpayment concerns the services allegedly rendered in approximately 288 PT claims (for 26 beneficiaries) and 335 chiropractic claims (for 25 beneficiaries)." Def.'s Reply at 1 n.1, Dkt. 32; *see also* Def.'s Mem. of Law at 28 n.13, Dkt. 26.

While the motions were pending, plaintiff filed a letter advising the Court of the Supreme Court's recent decision in *Kisor v. Wilkie*, 139 S. Ct. 2400 (2019). Ltr. dated Dec. 23, 2019, Dkt. 34. In this letter, plaintiff argued that "[t]he Supreme Court's holding in *Kisor* has a meaningful impact on the determination" of the cross motions because the Secretary's position in this action failed with respect to one of the three "fundamental requirements" articulated in *Kisor*. *Id.* at 1. The Secretary filed an opposition letter, arguing that "[p]laintiff has not presented any persuasive argument demonstrating that *Kisor* has any impact, let alone a 'meaningful impact, on the determination of the outcome' of this action or that there is any basis for reversing the Secretary's final decision." Ltr. filed Mar. 2, 2020 at 1, Dkt. 36.

DISCUSSION

Plaintiff argues that this Court should find that the Council's determination to overturn those portions of the ALJ Decision that were favorable to plaintiff "was arbitrary and capricious as it relied on an incorrect and unnecessarily restrictive standard of review" and that "[t]he Council failed to consider the totality of the [p]laintiff's documentation and conveniently fixated on its own flawed interpretation of certain Medicare coverage criteria and [LCDs]." Pl.'s Mem. of Law at 2–3. The Secretary, in turn, asserts that the Council's "decision is supported by substantial evidence in the record and based upon the correct application of the legal standards and, thus, should be affirmed under 42 U.S.C. §§ 405(g) and 1395ff(b)." Def.'s Mem. of Law at 4.

I. The Council's Findings are Supported by Substantial Evidence

A. Standard of Review

"Judicial review of administrative determinations with respect to Medicare benefits is governed by 42 U.S.C. § 1395ff(b)(1)(A), which incorporates the provisions of 42 U.S.C. § 405(g)." *Estate of Landers v. Leavitt*, 545 F.3d 98, 113 (2d Cir. 2008), *as revised* (Jan. 15, 2009).

The district court must base its judgment "upon the pleadings and transcript of the record" and can affirm, modify, or reverse the final decision of the Secretary. 42 U.S.C. § 405(g). The district court must also "accept the Secretary's findings of fact so long as they are supported by substantial evidence." *Mathews v. Weber*, 423 U.S. 261, 263 (1976). "Substantial evidence is 'more than a mere scintilla' and 'means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Murray v. Sec'y of Health & Human Servs.*, 447 F. App'x 264, 265 (2d Cir. 2012) (quoting *Richardson v. Perales*, 402 U.S. 389, 401 (1971)). "The court may not substitute its own judgment for that of the Secretary, even if it might justifiably have reached a different result upon a *de novo* review." *Jones v. Sullivan*, 949 F.2d 57, 59 (2d Cir. 1991) (quoting *Valente v. Sec'y of Health & Human Servs.*, 733 F.2d 1037, 1041 (2d Cir. 1984)).

"Although the reviewing district court must defer to the Secretary's findings of fact, it is not bound by the Secretary's conclusions or interpretations of law, or an application of an incorrect legal standard." *Anghel*, 912 F. Supp. 2d at 14 (internal quotation marks and citation omitted). The "claimant . . . has the burden of proving entitlement to Medicare benefits." *Friedman v. Sec'y of Dep't of Health & Human Servs.*, 819 F.2d 42, 45 (2d Cir. 1987).

B. Physical Therapy Services

The Council, in determining whether physical therapy services were reasonable and necessary, relied upon a variety of sources,⁸ including (1) the Medicare Benefit Policy Manual ("MBPM"), Pub. No. 100–02, Ch. 15 §§ 220–220.3 (Rev. 46, effective Jan. 1, 2006); (2) LCD L4260 "LCD for Physical Medicine and Rehabilitation" (multiple versions of which were effective

⁸ The Council noted in its decision that "[a]lthough an ALJ (or the Council) is not bound by program guidance or by the contractor's LCD, an ALJ (and the Council) is required to afford these authorities substantial deference or explain their rationale for not doing so." Dec. of Medicare Appeals Council at 15. The Council further noted that plaintiff "ha[d] not asserted that there [wa]s any reason to depart from the LCD, nor [did the Council] discern any." *Id*.

from Jan. 1, 2006, through July 18, 2008); and (3) LCD L26884 "LCD for Outpatient Physical and Occupational Therapy Services" (effective from July 18, 2008, through Nov. 13, 2008). See Dec. of Medicare Appeals Council at 15–20.9 The MBPM, effective as of January 1, 2006, and relied upon by the Council, sets forth the documentation that providers are expected to submit in response to requests involving Medicare benefits, including evaluations, any reevaluations, certified plans of care, physician certifications, progress reports, and treatment encounter notes. MBPM Ch. 15 § 220.3.5.10 The MBPM further sets forth that the records should provide a justification for treatment, including objective evidence or a clinically supportable statement of expectation that the patient's condition has the potential to improve or is improving in response to therapy, optimal improvement has not yet been attained, the anticipated improvement is attainable within a reasonable and generally predictable period of time, the patient is under the care of a physician, and services require the skills of a therapist. *Id.* For services to be considered skilled, they must be provided by a qualified professional or qualified personnel and require the expertise, knowledge, clinical judgment, decision-making and abilities of a therapist that other staff, caretakers, or the patient cannot provide independently. *Id*.

As relevant here, evaluations must include a diagnosis and the specific body part(s) evaluated, all conditions and complexities that may impact the treatment, objective measurements of the patient's functional status, clinical judgments or subjective impressions of the patient's functional status, and, if treatment is needed, a prognosis for return to premorbid condition or

⁹ Retired LCDs are located online in the CMS Medicare Coverage Database, available at https://localcoverage.cms.gov/mcd_archive/indexes/lcd_by_contractor.aspx?which=retired#l cdpos.

¹⁰ The current version of Chapter 15 of the MBPM is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf. The Court cites to the MBPM version that was in effect in 2006, as described in the Council's decision.

maximum expected condition with expected timeframe and a plan of care. *Id.* Progress reports, in turn, must provide justification for the medical necessity of treatment. *Id.* The information required in such reports should be provided at least once every 10 treatment days or once during the interval, whichever is less, and objective measures of progress should also be included whenever available. In addition, the treatment encounter notes, which are used to justify billing codes, must include the date of treatment, the specific treatment provided, the total timed code treatment minutes and total treatment time, identification of each specific intervention/modality provided and billed, signature and identification of the qualified professional who furnished or supervised the treatment, and a list of each person who contributed to treatment during the encounter. *Id.*

LCD L4260 provides more guidance pertaining to documentation requirements. Specifically, it states that the records must identify the physician or practitioner responsible for the patient's general medical care, indicate the prognosis for potential restoration of function in a reasonable and generally predictable period of time or the need to establish a safe and effective maintenance program, and provide objective measures of the patient's functional status. These objective measures must be recorded in such a way as to clearly document the patient's actual progress or lack thereof. Moreover, services must be provided in accordance with a written treatment plan and any changes to that plan must be noted in the record. LCD L26884, in turn, provides that the records should "paint a picture" of the patient's impairments and functional limitations requiring skilled intervention, describe the patient's prior functional status to assist in establishing the patient's potential and prognosis, describe the skilled nature of the treatment provided, justify the medical necessity of the type, frequency, and duration of the treatment for the

patient's condition, clearly document the timed code treatment minutes and total treatment time, and identify each specific skilled intervention.

Here, the Council, upon review of the voluminous administrative record and performing an in-depth assessment of all the patients' records at issue, reversed the ALJ's favorable findings with respect to the physical therapy services furnished to 27 beneficiaries, finding that the information provided in the records at issue was not nearly enough to meet the requirements for Medicare coverage. Dec. of Medicare Appeals Council at 28; see generally Patients' Records, AR Vol. III at 1575–2293. Specifically, the Council found that the information provided on plaintiff's pre-printed "Rehabilitation Referral & Plan of Care" form was so broad that it could not be determined, as required by the MBPM and the LCDs, "whether the beneficiary's condition ha[d] the potential to improve, whether the anticipated improvement [wa]s attainable in a reasonable and generally predictable period of time, and whether the PT services were of a level of complexity such that they require[d] the skills of a therapist." Dec. of Medicare Appeals Council at 25, 27. The Council also could not discern from the records the functional status of the condition being evaluated for each beneficiary at issue. *Id.* The Council further found that the information provided in plaintiff's "Functional Status Log," which appeared to be treatment notes,

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¹¹ The 27 beneficiaries at issue who received physical therapy services are: (1) D.A. (6 visits from Aug. 24, 2006, to Sept. 29, 2006); (2) L.A. (13 visits from Jan. 18, 2008, to July 30, 2008); (3) A.A. (16 visits from Jan. 9, 2007, to Aug. 24, 2007); (4) M.B.1 (4 visits from Nov. 30, 2006, to Dec. 27, 2006); (5) Y.B. (7 visits from May 20, 2008, to June 27, 2008); (6) M.B.2 (11 visits from Jan. 16, 2007, to June 7, 2007); (7) N.B. (5 visits from Feb. 7, 2008, to Mar. 3, 2008); (8) M.C. (9 visits from Mar. 27, 2006, to Oct. 26, 2006); (9) E.D. (15 visits from Jan. 8, 2008, to Sept. 18, 2008); (10) P.G. (2 visits from Dec. 3 and 12, 2007); (11) Z.I. (10 visits from Apr. 28, 2008, to Oct. 17, 2008); (12) S.K. (10 visits from Jan. 9, 2006, to June 12, 2006); (13) Y.K. (7 visits from Aug. 13, 2007, to Sept. 21, 2007); (14) A.K.2 (5 visits from Aug. 14, 2006, to Sept. 8, 2006); (15) M.K.1 (3 visits from Mar. 5, 2007, to Mar. 20, 2007); (16) G.L. (11 visits from May 31, 2006, to Dec. 6, 2006); (17) Z.L. (33 visits from Mar. 23, 2006, to Mar. 6, 2008); (18) S.M.1 (12 visits from Jan. 31, 2007, to June 26, 2007); (19) I.M. (6 visits from May 9, 2008, to June 13, 2008); (20) E.M. (1 visit on Feb. 19, 2008); (21) B.P. (26 visits from May 15, 2006, to Sept. 24, 2007); (22) E.S. (10 visits from Apr. 28, 2006, to Oct. 9, 2006); (23) B.S. (15 visits from Jan. 23, 2008, to Aug. 29, 2008); (24) S.S. (15 visits from June 16, 2008, to Oct. 17, 2008); (25) T.T. (10 visits from Mar. 3, 2008, to May 4, 2008); (26) Z.Y. (14 visits from Jan. 9, 2008, to Sept. 15, 2008); and (27) M.Z. (13 visits from Jan. 3, 2007, to Aug. 3, 2007).

did not "provide any information that [wa]s specific to the individual beneficiary" and was "so vague in terms of plans, goals, and treatments, that it be [came] nearly interchangeable from one beneficiary to the next, even in instances where the treatment [wa]s for very different conditions[.]" Id. at 25–26. Moreover, the "Functional Status Log" did not include, as required by the MBPM and the LCDs, information as to the specific treatment, intervention, or activity provided, timed codes and the total time spent on services and treatment, clear identification of who provided the services, and objective measures during treatment in relation to the beneficiary's condition being evaluated. Id. at 26, 28. Indeed, the Council noted, all beneficiaries were evaluated based on the same activities for either upper body or lower body, regardless of their diagnosis, and it was not evident whether the activities were performed during every visit (and, if so, how the activity or task was performed and for how long), or if the beneficiaries evaluated themselves on their own and reported the rating. *Id.* at 27. Finally, the Council found that the office notes or physicians' notes also failed to provide the requisite information and, in some cases, raised more questions about the current functional status of the beneficiary. For example, certain physicians' notes indicated that beneficiary S.M.1 "does not use an assistive device, yet the Functional Status Log provides ratings for ambulating with an assistive device," thus raising the question of whether S.M.1 did indeed require an assistive device. *Id.* at 69–70.

Contrary to plaintiff's arguments, *see* Pl.'s Mem. in Opp. at 3, a review of the patients' "Functional Status Logs" does not show that additional range of motion ("ROM") measurements were taken during each office visit to determine how the beneficiary may be improving with physical therapy. Rather, next to the activity that was evaluated, the beneficiary was given a rating out of 5 based on his or her limitations and difficulty in performance level, with no indication as to what, if any, therapies were provided and no additional information as to the beneficiary's

functional status during that particular office visit. See AR Vol. III at 1575–81 (D.A.); 1604–09 (L.A.); 1653–66 (A.A.); 1702–05 (M.B.1); 1706–08 (Y.B.); 1738–46 (M.B.2); 1747–48 (N.B.); 1749–52 (M.C.); 1753–61 (E.D.); 1805–06 (P.G.); 1888–91 (Z.I.); 1926–33 (S.K); 1934–37 (Y.K.); 1938–39 (A.K.2); 1940–41 (M.K.1); 2052–59 (G.L.); 2060–78 (Z.L.); 2079–84 (S.M.1); 2135–36 (E.M.); 2155–65 (B.P.); 2203–07 (E.S.); 2221–28 (B.S.); 2253–56 (T.T.); 2257–66 (Z.Y.); 2288–93 (M.Z.).

Furthermore, plaintiff's argument that a "skilled therapy" requirement was not addressed or emphasized in LCD 4260 or the guidelines that were in effect during the relevant time period is belied by the record. Pl.'s Mem. in Opp. at 3. In all the versions that were effective during the claims at issue, L4260 explicitly stated that "[s]ervices that do not require the professional skills of a physician, non-physician practitioner, or therapist to perform or supervise them are not medically necessary" and thus are not covered under Medicare. LCD 4260. The MBPM during the relevant time period also explicitly stated that "[s]ervices must not only be provided by the clinician or qualified personnel, but they must require, for example, the expertise, knowledge, clinical judgment, decision making and abilities of a therapist that other staff, caretakers or the patient cannot provide independently." MBPM Ch. 15 § 220.3.5. Moreover, although plaintiff argues that the LCDs and other Medicare rules and guidelines became more goal-oriented as time progressed, Pl.'s Mem. in Opp. at 3; Ltr. dated Dec. 23, 2019 at 2, it is apparent in L4260, L26884, and the MBPM that documenting treatment goals was important during the relevant time period. LCD 4260 ("Objective measures of function must be recorded in such a way as to clearly document the patient's actual progress or lack thereof."); L26884 ("Documentation should establish through

¹² The key on the "Functional Status Log" states: "ADL [Activity of Daily Living] scored on the limitations and the difficulty in performance level, with involved extremity, as reported by patient and evaluated by therapist: 0/5 - Unable to perform; 1/5 - Severe; 2/5 - Maximal; 3/5 - Moderate; 4/5 - Minimal; 5/5 - No difficulty or limitations to perform."

objective measurements that the patient is making progress toward goals."); MBPM Ch. 15 § 220.3.5 (Progress reports must include an "[a]ssessment of improvement, extent of progress [or lack thereof] toward each goal."). Plaintiff, as a participant in the Medicare program, had a duty to familiarize itself with the requirement to document goals for Medicare coverage purposes. *See Heckler*, 467 U.S. at 64.

Based on its review of the Council's decision, the administrative record, and the parties' pleadings, this Court concludes that the Council's determination that physical therapy services were not eligible for Medicare coverage for the 27 beneficiaries at issue—because plaintiff's records did not comport with the MBPM, LCD L4260, and/or LCD L26884—is supported by substantial evidence.

C. Chiropractic Services

The Council, in determining whether chiropractic services were reasonable and necessary, relied upon the Act, regulations, and MBPM Ch. 15 §§ 30.5, 240, et seq. These authorities provide that "Medicare Part B pays only for a chiropractor's manual manipulation of the spine to correct a subluxation if the subluxation has resulted in a neuromusculoskeletal condition for which manual manipulation is appropriate treatment." 42 C.F.R. § 410.21(b)(1); see 42 U.S.C. § 1395x(r) (Medicare coverage for chiropractic services extends only to "treatment by means of manual manipulation of the spine (to correct a subluxation) which he is legally authorized to perform by the State or jurisdiction in which such treatment is provided."); MBPM Ch. 15 § 30.5 ("Coverage extends only to treatment by means of manual manipulation of the spine to correct a subluxation provided such treatment is legal in the State where performed."). The MBPM defines "subluxation" as "a motion segment, in which alignment, movement integrity, and/or physiological function of the spine are altered although contact between joint surfaces remains

intact." MBPM Ch. 15 § 240.1.2. The MBPM provides that "subluxation may be demonstrated by an x-ray or by physical examination." *Id*.

To demonstrate a subluxation by physical examination, the MBPM provides that the documentation must contain an evaluation of the musculoskeletal/nervous system to identify at least two of the following "PART" criteria:

- a. Pain/tenderness evaluated in terms of location, quality, and intensity;
- b. Asymmetry/misalignment identified on a sectional or segmental level;
- c. Range of motion abnormality (changes in active, passive, and accessory joint movements resulting in an increase or a decrease of sectional or segmental mobility); and
- d. Tissue, tone changes in the characteristics of contiguous, or associated soft tissues, including skin, fascia, muscle, and ligament.

Id. § 240.1.2-2 (emphasis added). One of two criteria must be either asymmetry/misalignment or range of motion abnormality. *Id.* Additionally, the MBPM provides that the chiropractor must specify the level of subluxation and may do so by identifying the exact bones (i.e. C5, C6) or the area of the spine if it implies only certain bones (i.e. lumbo-sacral). *Id.* § 240.1.4.

According to the MBPM, the history recorded in the patient record should include: symptoms causing patient to seek treatment; family history if relevant; past health history (general health, prior illness, injuries, or hospitalizations; medications; surgical history); mechanism of trauma; quality and character of symptoms/problem; onset, duration, intensity, frequency, location and radiation of symptoms; aggravating or relieving factors; and prior interventions, treatments, medications, secondary complaints. *Id.* § 240.1.2-2. As for the initial visit, the documentation must include (1) the patient's history, as stated above; (2) a description of the present illness including: mechanism of trauma; quality and character of symptoms/problem; onset, duration, intensity, frequency, location, and radiation of symptoms; aggravating or relieving factors; prior

interventions, treatments, medications, secondary complaints; and symptoms causing the patient to seek treatment; (3) an evaluation of the musculoskeletal/nervous system through physical examination; (4) a diagnosis; (5) a treatment plan, which includes the recommended level of care (duration and frequency of visits), specific treatment goals, and objective measures to evaluate treatment effectiveness; and (6) the date of the initial treatment. *Id.* § 240.1.2-2.A. The symptoms causing the patient to seek treatment "must bear a direct relationship to the level of subluxation." *Id.*

As for subsequent visits, the documentation must set forth: (1) the patient's history, including review of the chief complaint, changes since last visit, and system review if relevant; (2) a physical exam, including an exam of the area of the spine involved in the diagnosis, an assessment of change in the patient's condition since the last visit, and an evaluation of treatment effectiveness; and (3) documentation of treatment given on the day of visit. *Id.* § 240.1.2-2.B. The treatment "must have a direct therapeutic relationship to the patient's condition and provide [a] reasonable expectation of recovery or improvement of function." *Id.* § 240.1.3. "Once the clinical status has remained stable for a given condition, without expectation of additional objective clinical improvements, further manipulative treatment is considered maintenance therapy and is not covered." *Id.*

Here, the Council, upon reviewing the voluminous administrative record and performing an in-depth assessment of all the patients' records at issue, reversed the ALJ's favorable findings with respect to the chiropractic services furnished to 25 beneficiaries. Dec. of Medicare Appeals Council at 24.¹³ The Council, after noting that "the ALJ did not cite [to] or apply any of the

¹³ The 25 beneficiaries at issue who received chiropractic services are: (1) B.A. (12 visits from Sept. 7, 2007, to Oct. 15, 2007); (2) I.A. (16 visits from Jan. 9, 2008, to Feb. 12, 2008); (3) R.A. (12 visits from Nov. 14, 2007, to Dec. 7, 2007); (4) A.A. (32 visits from July 25, 2007, to Apr. 28, 2008); (5) J.B. (15 visits from May 30, 2008, to Aug. 27, 2008); (6) R.D. (7 visits from Sept. 8, 2008, to Sept. 22, 2008); (7) E.F. (18 visits from Aug. 7, 2007, to

Medicare criteria specific to coverage of [chiropractic] services," held that plaintiff's documentation was "wholly insufficient to find that Medicare coverage criteria [was] met for any of the beneficiaries at issue." *Id.* at 22. Specifically, the Council found that the records did not show that chiropractic services were provided to correct a subluxation, as there were no x-rays in the records and PART criteria were not identified. *Id.* The Council held that, although plaintiff's treatment notes provided a section where the provider could circle the joints that "were manually palpated" and another section where the provider could circle the type of chiropractic adjustment that was made and the area of adjustment, manual palpation is "not synonymous with chiropractic adjustment of a subluxation," and there was no indication in the treatment notes that a subluxation was found or that the adjustments were provided to treat a subluxation. *Id.* at 22, 23.

The Council further held that the documentation for chiropractic services lacked the requisite specificity. *Id.* at 23. The initial evaluation form, for example, included a pre-printed section for recommended level of care with three options to choose from: (1) Mild - 1–5 visits, 1 to 2 times a week; (2) Moderate - 6–10 visits, 2 to 3 times a week; and (3) Severe - 11–15 visits, 3 or more times a week. *Id.* The Council found that, "[i]n almost all of the cases at issue, 'Severe' is circled without any further information provided." *Id.* Moreover, the Council found that the initial evaluation form did not contain "individualized information with specific treatment goals for each particular beneficiary that relates to their specific condition." *Id.* Rather, the form

Dec. 24, 2007); (8) L.H. (8 visits from Oct. 2, 2007, to Oct. 23, 2007); (9) M.H. (13 visits from Jan. 7, 2008, to Sept. 8, 2008); (10) B.I. (12 visits from Jan. 9, 2008, to Mar. 12, 2008); (11) Y.I. (12 visits from Jan. 21, 2008, to Feb. 21, 2008); (12) M.I. (12 visits from Jan. 14, 2008, to Mar. 5, 2008); (13) A.K.3 (30 visits from Jan. 29, 2008, to Sept. 22, 2008); (14) M.K.2 (8 visits from May 13, 2008, to May 30, 2008); (15) Z.K. (14 visits from July 9, 2008, to Aug. 13, 2008); (16) A.L. (14 visits from Feb. 1, 2008, to Mar. 24, 2008); (17) M.L. (6 visits from Nov. 20, 2007, to Dec. 10, 2007); (18) S.M.1 (15 visits from Jan. 10, 2008, to Feb. 14, 2008, 6 visits from Sept. 10, 2008, to Sept. 22, 2008); (19) S.M.2 (11 visits from Nov. 7, 2007, to Dec. 4, 2007); (20) Z.N. (12 visits from Aug. 13, 2007, to Sept. 10, 2007); (21) F.P. (12 visits from Oct. 8, 2007, to Nov. 2, 2007); (22) S.R. (15 visits from Apr. 29, 2008, to June 9, 2008); (23) I.S. (7 visits from Aug. 27, 2007, to Sept. 26, 2007); (24) M.T. (2 visits on Aug. 16 and 20, 2007); (25) E.Z. (14 visits from May 16, 2008, to June 27, 2008).

contained pre-printed treatment goals, "two for short-term (decrease pain and increase motion) and five for long-term (pain free, motion restored, home exercise routine, correction of biomechanics to improve posture, and proper lifting and carrying instructions)." *Id.* "In most cases, all of the goals [we]re checked." *Id.*

As for subsequent visit treatment notes, the Council found that they lacked individualized objective "performance measures to demonstrate changes in the patient's condition from one visit to the next or to evaluate the treatment effectiveness." *Id.* at 24. Finally, the Council found that, based on the medical history and initial evaluation forms of the beneficiaries at issue, it appeared that chiropractic services were being used to treat chronic conditions, which are not covered by Medicare. *Id.; see generally* AR Vol. III. at 1582–1603 (B.A.); 1610–30 (I.A.); 1634–52 (R.A.); 1667–1701 (A.A.); 1709–37 (J.B.); 1762–78 (R.D.); 1779–1804 (E.F.); 1808–27 (L.H.); 1828–49 (M.H.); 1850–67 (B.I.); 1869–87 (Y.I.); 1900–25 (M.I.); 1942–83 (A.K.3); 1986–99 (M.K.2); 2000–18 (Z.K.); 2019–39 (A.L.); 2040–51 (M.L.); 2085–113 (S.M.1); 2114–32 (S.M.2); 2137–53 (Z.N.); 2166–83 (F.P.); 2184–202 (S.R.); 2208–20 (I.S.); 2244–52 (M.T.); 2267–87 (E.Z.).

The Court rejects plaintiff's argument that it had insufficient opportunity to respond to the issue of subluxation because subluxation was never raised as a basis for denial of its claims "in any of the stages of the underlying appeals process." Pl.'s Mem. in Opp. at 12. In its reconsideration decision, the QIC identified inadequate documentation of subluxation as a basis for denial for numerous beneficiaries. AR Vol. II at 343–76 ("Exact site of treated subluxation not described" was a specific denial for many of claims for chiropractic services). Moreover, the AdQIC, in its referral to the Council, discussed subluxation as a requirement for Medicare coverage, AdQIC's Ltr. dated May 30, 2017 at 15, and argued that the ALJ's decision failed to address whether I.A.—the exemplar beneficiary—suffered a subluxation, *id.* at 19–21. Thus,

because plaintiff was notified during the administrative review process that its documentation with respect to subluxation was insufficient, it had ample opportunity to produce additional documentation and refute such findings of insufficiency. In any event, as stated above, plaintiff, as a participant in the Medicare program, had a duty to familiarize itself with the requirement to demonstrate subluxation for Medicare coverage of chiropractic services. *Heckler*, 467 U.S. at 64.

This Court concludes that the Council's determination that chiropractic services were not eligible for Medicare coverage for the 25 beneficiaries at issue—because the records did not show any evidence of subluxation and the information provided lacked the requisite specificity—is supported by substantial evidence.

II. The Council Applied the Correct Legal Standards

Plaintiff argues that the Council "arbitrarily substitute[d] the thoroughly reasoned ALJ Decision with its own hyper-technical and restrictive interpretation of certain Medicare coverage criteria and [LCDs]." Pl.'s Mem. of Law at 1–2. Plaintiff points out that the MBPM and LCDs are not binding, *id.* at 13, and asserts that "[t]he fact that [the ALJ] did not interpret these guidelines in a manner Defendant would like is not an error of law," *id.* at 15.

The Council applied the correct legal standards. As stated above, the Council set forth in exacting detail all applicable authorities and guidelines, including provisions from the Act, regulations, MBPM, and LCDs, and then applied those authorities and guidelines to the disputed claims. Although plaintiff is correct that the MBPM and LCDs are not binding, the Council appropriately gave them "substantial deference," as required by 42 C.F.R § 405.1062(a). Indeed, had the Council declined to follow the MBPM or the LCDs, it would have had to explain the reasons why the policy was not followed. 42 C.F.R § 405.1062(b). In contrast, as the Secretary points out, the ALJ failed to cite all applicable LCDs or any of the MBPM provisions concerning

chiropractic services and did not explain why he was declining to follow them. Def.'s Mem. of Law at 50–51. Additionally, the ALJ did not address whether the records showed that the beneficiaries who received chiropractic services had a diagnosis of subluxation, as required by the Act and regulations. *See* 42 U.S.C. § 1395x(r); 42 C.F.R. § 410.21(b)(1).

In a letter filed December 23, 2019, plaintiff advised the Court of the Supreme Court's recent decision in *Kisor v. Wilkie*, 139 S. Ct. 2400 (2019), claiming that it has a "meaningful impact" on the determination of the pending motions in this case. Ltr. dated Dec. 23, 2019 at 1. In that case, "the only question" before the Supreme Court was whether it should overrule *Auer v. Robbins*, 519 U.S. 452 (1997) and *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410 (1945) and discard the deference those cases give to agency interpretations of ambiguous regulations. *Kisor*, 139 S. Ct. at 2408. The Supreme Court "answer[ed] that question no," holding that "*Auer* deference retains an important role in construing agency regulations." *Id.* However, the Supreme Court took the opportunity in *Kisor* to "reinforc[e] some of the limits inherent in the *Auer* doctrine." *Id.* at 2415.

"First and foremost," the Court held, "a court should not afford *Auer* deference unless the regulation is genuinely ambiguous." *Id.* In making the determination on whether a regulation is ambiguous, "a court must exhaust all the traditional tools of construction" and "carefully consider the text, structure, history, and purpose of a regulation, in all the ways it would if it had no agency to fall back on." *Id.* (internal quotation marks, alteration, and citations omitted). The Court held that, "[i]f genuine ambiguity remains, the agency's reading must still be 'reasonable." *Id.* (quoting *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 515 (1994)). However, the Court stressed, "not every reasonable agency reading of a genuinely ambiguous rule should receive *Auer* deference." *Id.* at 2416. "[T]he regulatory interpretation must be one actually made by the agency.

In other words, it must be the agency's authoritative or official position, rather than any more ad hoc statement not reflecting the agency's views." *Id.* (internal quotation marks and citation omitted). Next, "the agency's interpretation must in some way implicate its substantive expertise." *Id.* at 2417. "Finally, an agency's reading of a rule must reflect 'fair and considered judgment." *Id.* (quoting *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 155 (2012)). This means "that a court should decline to defer to a merely 'convenient litigating position' or 'post hoc rationalizatio[n] advanced' to 'defend past agency action against attack." *Id.* (quoting *Christopher*, 567 U.S. at 155).

Here, plaintiff asserts that "[t]he Secretary's reliance on the Council's decision is precisely the type of 'post hoc rationalization' and 'convenient litigation strategy' that was proscribed by the Supreme Court in *Kisor*." Ltr. dated Dec. 23, 2019 at 2. Plaintiff reasons that, because "the Council adopted arguments that not only had never been raised in the prior proceedings, but were inconsistent with the then-applicable Medicare guidelines," the Court should grant its motion for judgment on the pleadings. *Id.* However, as the Secretary argues, plaintiff has failed to point to any "genuinely ambiguous" regulatory term at issue in this case that would require a *Kisor* analysis. *See* Ltr. filed Mar. 8, 2020 at 3. Moreover, as already stated above, the Council applied the correct standards and requirements set forth in the statute, regulations, MBPM, and LCDs that were effective at the time. All of plaintiff's arguments lack force in this regard.

CONCLUSION

For the foregoing reasons, plaintiff's motion for judgment on the pleadings is DENIED and the Secretary's cross motion for judgment on the pleadings dismissing the Complaint is GRANTED. The Clerk of the Court is directed to mark this case as closed.

SO ORDERED.

/s/ I. Leo Glasser, U.S.D.J.

Brooklyn, New York February 18, 2021