

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

**BEACON RESPIRATORY SERVICES,
INC.,**

Plaintiff,

v.

Case No: 6:16-cv-868-Orl-41DCI

**SECRETARY, UNITED STATES
DEPARTMENT OF HEALTH AND
HUMAN SERVICES,**

Defendant.

ORDER

THIS CAUSE is before the Court on Plaintiff's Motion for Summary Judgment ("Motion," Doc. 23); Defendant's Motion for Judgment on the Pleadings, or in the Alternative, Cross Motion for Summary Judgment ("Cross-Motion," Doc. 32); and Plaintiff's Response thereto (Doc. 38). For the reasons stated herein, the Motion will be denied and the Cross Motion will be granted.

I. BACKGROUND

The following facts are undisputed. Plaintiff is an enrolled Medicare Part B supplier that provides oxygen, respiratory, and other durable medical equipment and supplies. (*See R.*, Vol. 1, at 3; Answer, Doc. 40-4, at 3).¹ In a letter dated October 16, 2008, Trust Solutions, LLC, a subcontractor for Cigna Government Services² asked Plaintiff for documentation verifying the

¹ "R." refers to the Administrative Record, which was filed with the Court, per the Court's permission, on two compact disks. (*See Notice of Filing*, Doc. 20; Nov. 2, 2016 Endorsed Order, Doc. 21). "Vol." refers to the volume in which the documents are located.

² The Centers for Medicare & Medicaid Services ("CMS") is branch of the Department of Health and Human Services ("HHS") responsible for the administration of the Medicare program in conjunction with private entities known as Medicare Administrative Contractors ("MACs"). Pursuant to 42 U.S.C. § 1395kk-1(a), the Secretary enters into contracts with MACs. Cigna

services billed for 143 Medicare beneficiaries for claims paid from January 11, 2008, to September 19, 2008.³ (Oct. 16, 2008 Letter, Doc. 1-2, at 1–6). Plaintiff provided the requested documentation, and SafeGuard Services LLC (“Safeguard”)—the Zone Program Integrity Contractor (“ZPIC”)⁴—audited the records provided by Plaintiff. (*See R.*, Vol. 3, at 1628–32). The ZPIC reviewed 149 sample claims for 143 beneficiaries. (*See id.* at 1629). The ZPIC calculated a 100% error rate, denied payment for all sampled claims, and extrapolated its findings to all claims paid for the period from January 1, 2008, through September 19, 2008. (*Id.* at 1629–30). On August 27, 2010, Plaintiff was notified that it had received Medicare overpayments in the amount of \$866, 252 (“the Overpayment Determination”). (*Id.* at 1628–30).

In a letter dated January 14, 2011, Cigna Government Services demanded repayment. (*Id.* at 1620–24). Plaintiff requested a redetermination of Cigna Government Service’s Overpayment Determination.⁵ (*Id.* at 1098–1103). The Overpayment Determination was affirmed in a letter dated July 22, 2011. (*Id.* at 1075). Plaintiff then sought reconsideration, (*R.*, Vol. 2, at 549), and the QIC affirmed the Overpayment Determination. (*Id.* at 542–44a). Thereafter, Plaintiff requested

Government Services was the MAC for durable medical equipment suppliers in the state of Florida at all times relevant for this case.

³ During that time period, Plaintiff processed approximately 8834 claims. (*See Doc.* 23 at 4); *see also* Fed. R. Civ. P. 56(e)(2) (permitting courts to consider a factual assertion undisputed when the opposing party fails to address the factual assertion).

⁴ Zone Program Integrity Contractors (“ZPICs”) are CMS contractors that have the authority to audit Medicare claims on behalf of the MACs and CMS. (*See Doc.* 32 at 5). At all relevant times, Safeguard was a ZPIC contracted by CMS. (*Id.*).

⁵ The Medicare Part B appeals process has five different stages: (1) redetermination by a MAC not involved in the initial determination, (2) reconsideration by a Qualified Independent Contractor (“QIC”), (3) a hearing with an Administrative Law Judge (“ALJ”), (4) review by the Medicare Appeals Council of the HHS Departmental Appeals Board (“the Council”), and (5) judicial review in a federal district court. *See Medicomp, Inc. v. Sec’y, U.S. Dep’t of Health & Human Servs.*, No. 6:14-cv-1848-Orl-28DAB, 2016 WL 901282, at *2 n.5 (M.D. Fla. Mar. 3, 2016) (citing *Heckler v. Ringer*, 466 U.S. 602, 606 (1984)).

review of the reconsideration by an ALJ. (*Id.* at 530). A hearing was held before an ALJ on May 20, 2014. (R., Vol. 23, at 12096). Neither CMS nor the ZPIC participated in the hearing. (*See id.* at 12097).

On October 27, 2015, the ALJ issued a ruling. (R., Vol. 1, at 247–60). The ALJ found that services provided to six beneficiaries were covered by Medicare, but the services provided to all other beneficiaries were not. (*Id.* at 255, 260). The ALJ also found that the ZPIC’s sampling methodology was invalid based on the use of disproportionate, abnormal sample sizes and the application of an incorrect confidence interval. (*Id.* at 258–60). The ALJ further held that the extrapolation could not be upheld because the ZPIC failed to timely provide information regarding the statistical sampling methodology to Plaintiff. (*Id.* at 259). The ALJ concluded that Medicare was entitled to collect only the actual overpayment on the unfavorable claims—that is, on the claims actually reviewed by the auditors—and that CMS could not correct the sampling methodology errors. (*Id.* at 259–60). On November 18, 2015, the ALJ issued an amended decision, which was substantively identical to the original decision. (*See id.* at 169–82). The amended decision was entered solely to correct a scrivener’s error. (*See id.* at 169 n.1).

On January 13, 2016, CMS referred the ALJ’s decision to the Medicare Appeals Council (the “Council”). (*Id.* at 141–65). Plaintiff filed a response in opposition to CMS’s request. (*Id.* at 30–38). Nonetheless, the Council accepted review and, on March 24, 2016, issued a final ruling reversing the ALJ’s decision. (*See generally id.* at 1–29).

Plaintiff filed this case on May 20, 2016, seeking review of the Council’s decision. The parties have filed cross motions for summary judgment.

II. LEGAL STANDARD

A. Summary Judgment

Summary judgment is appropriate when the moving party demonstrates “that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). A dispute is genuine “if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A fact is material if it may “affect the outcome of the suit under the governing law.” *Id.* “The moving party bears the initial burden of showing the court, by reference to materials on file, that there are no genuine issues of material fact that should be decided at trial.” *Allen v. Bd. of Pub. Educ.*, 495 F.3d 1306, 1313–14 (11th Cir. 2007). Stated differently, the moving party discharges its burden by showing “that there is an absence of evidence to support the nonmoving party’s case.” *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986).

However, once the moving party has discharged its burden, the nonmoving party must “go beyond the pleadings and by her own affidavits, or by the depositions, answers to interrogatories, and admissions on file, designate specific facts showing that there is a genuine issue for trial.” *Id.* at 324 (quotation omitted). The nonmoving party may not rely solely on “conclusory allegations without specific supporting facts.” *Evers v. Gen. Motors Corp.*, 770 F.2d 984, 986 (11th Cir. 1985). Nevertheless, “[i]f there is a conflict between the parties’ allegations or evidence, the [nonmoving] party’s evidence is presumed to be true and all reasonable inferences must be drawn in the [nonmoving] party’s favor.” *Allen*, 495 F.3d at 1314.

B. Judicial Review of the Secretary’s Decision

The Council’s decision constitutes the final decision of the Secretary. *See Medicomp, Inc. v. Sec’y, U.S. Dep’t of Health & Human Servs.*, No. 6:14-cv-1848-Orl-28DAB, 2016 WL 901282, at *2 (M.D. Fla. Mar. 3, 2016). “[T]his Court has jurisdiction over this appeal under 42 U.S.C. § 1395ff(b), which entitles an individual or entity to judicial review of the final decision of

the Secretary under 42 U.S.C. § 405(g).” *Chillicothe Chiropractic & Wellness Ctr. v. Sibelius*, No. 2:12-cv-330, 2014 WL 1382478, at *5 (S.D. Ohio Apr. 8, 2014), *report and recommendation adopted*, No. 2:12-cv-330, 2014 WL 6673826 (S.D. Ohio Nov. 24, 2014); *see also Heckler v. Ringer*, 466 U.S. 602, 615 (1984) (“[Section] 405(g) . . . is the sole avenue for judicial review for all claims arising under the Medicare Act.” (quotation omitted)). “Pursuant to 42 U.S.C. § 405(g), judicial review of the Secretary’s decision regarding a claim for Medicare benefits 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. v. Sec’y, Dep’t of Health & Human Servs.*, 468 F.3d 1347, 1350 n.3 (11th Cir. 2006) (quotation omitted). “Substantial evidence is more than a scintilla and is such relevant evidence as a reasonable person would accept as adequate to support a conclusion.” *Crawford v. Comm’r of Soc. Sec.*, 363 F.3d 1155, 1158 (11th Cir. 2004) (quotation omitted). “Thus, substantial evidence exists even when two inconsistent conclusions can be drawn from the same evidence.” *CompRehab Wellness Grp., Inc. v. Sebelius*, No. 11-23377-CIV, 2013 WL 1827675, at *4 (S.D. Fla. Apr. 30, 2013) (quoting *Stone & Webster Constr., Inc. v. U.S. 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.” *Id.* (citing *Adefemi v. Ashcroft*, 386 F.3d 1011, 1027 (11th Cir. 2004)). Further, “[u]nder the substantial evidence standard the reviewing court is precluded from ‘deciding the facts anew, making credibility determinations, or re-weighing the evidence.’” *Id.* (quoting *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.” *Id.*

III. ANALYSIS

“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.” *Id.* at *5. Plaintiff asks this Court to grant summary judgment in its favor and overturn the Council’s decision. Plaintiff asserts that it is entitled to this relief because CMS failed to seek review of the ALJ’s decision in a timely manner and because the Council erred in accepting review of the ALJ’s decision. Defendant opposes these arguments and further argues that it is entitled to summary judgment and that the Council’s decision should be upheld because it was supported by substantial evidence. Each of the parties’ motions will be addressed in turn.

A. Plaintiff’s Motion for Summary Judgment

1. *Whether CMS Timely Sought Review of the ALJ’s Decision*

Plaintiff asserts that summary judgment should be granted in its favor and that the Council’s decision should be overturned because CMS did not timely request for the Council to review the ALJ’s decision. Plaintiff states that 42 C.F.R. § 405.1110(b)(2) requires CMS to refer a case to the Council for review “no later than 60 calendar days after the ALJ’s . . . decision or dismissal is issued.” According to Plaintiff, because the ALJ issued his original decision on October 27, 2015, CMS was required to submit its written referral by December 28, 2015.⁶ Plaintiff argues that CMS did not submit its referral until January 13, 2016—seventy-six days after the ALJ’s original decision was issued, and thus it was untimely. Therefore, Plaintiff avers that the Council should have never reviewed the ALJ’s decision. Conversely, Defendant argues that its request for review was timely because it was submitted within sixty days of the amended ALJ decision.

⁶ The sixty-day deadline was December 26, 2015, which was a Saturday.

In addressing these same arguments, the Council concluded that CMS's request for review was timely. The Council reasoned that "[s]trictly from the perspective of a legal interpretation, the regulation does not distinguish between an original ALJ decision and a subsequent amending action." (R., Vol. 1, at 14–15). Additionally, the Council noted that Plaintiff had failed to cite any authority to support its argument that the sixty-day period did not restart with the filing of an amended decision, and similarly, the Council was unaware of any such authority. (*Id.* at 15).

The Court will uphold the Council's decision that CMS's request for review was timely. Title 42, part 405.1110(a) of the Code of Federal Regulations provides that "CMS or any of its contractors may refer a case to the Council for it to consider reviewing under this authority anytime within 60 calendar days after the date of an ALJ's . . . decision or dismissal." *See also* 42 C.F.R. § 405.1110(b)(2) (requiring CMS to refer a case to the Council for review "no later than 60 calendar days after the ALJ's . . . decision or dismissal is issued"). It is well established that an agency's interpretation of its own regulations is entitled to substantial deference. *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994) (collecting cases). The Court "is not to decide which among several competing interpretations best serves the regulatory purpose. Rather, the agency's interpretation must be given controlling weight unless it is plainly erroneous or inconsistent with the regulation." *Id.* (quotation omitted). "In other words, [the Court] must defer to the Secretary's interpretation unless an alternative reading is compelled by the regulation's plain language or by other indications of the Secretary's intent at the time of the regulation's promulgation." *Id.* As noted above, the Council determined that it was permissible for CMS to request review within sixty days of the ALJ's amended decision, rather than the original decision, because the regulation

does not distinguish between an original ALJ decision and a subsequently amended decision. This interpretation is supported by the plain language.⁷

To support its argument that the regulation required CMS to refer this case to the Council within sixty days of the original ALJ decision, rather than the amended decision, Plaintiff cites to several cases. These cases stand for the well-established proposition that the filing of an amended judgment extends the period for the parties to seek post-judgment review only where the amended judgment is entered to address substantive matters, rather than to make immaterial changes or to address clerical errors. *See, e.g., In Re Advanced Telecomm. Network, Inc.*, No. 6:03-bk-229-KSJ, 2016 WL 6432984, at *1 (M.D. Fla. Oct. 31, 2016) (“The U.S. Supreme Court has long held that ‘the mere fact that a judgment previously entered has been reentered or revised in an immaterial way does not toll the time within which review must be sought.’” (quoting *Fed. Trade Comm’n v. Minneapolis–Honeywell Regulator Co.*, 344 U.S. 206, 211 (1952))).

First, the Court agrees with Defendant that these cases are inapplicable here, as they involved neither the interpretation of the federal administrative regulation at issue—nor a federal administrative regulation at all—and therefore, the deferential standard of review did not apply in those cases. Second, while Plaintiff generally argued to the Council that CMS’s request for review was time-barred, Plaintiff did not provide the Council with any of the cases cited in its Motion for Summary Judgment. (*Compare R.*, Vol. 1, at 31–32, *with Doc. 23* at 8–9). This is significant because in determining that CMS had timely sought review, the Council noted that Plaintiff “ha[d] not cited any basis for its theory that an amending decision of a limited technical nature does not confer a new 60-day filing period.” (*R.*, Vol. 1, at 15). This Court cannot reverse the Council’s

⁷ Given the deferential standard this Court applies, Plaintiff’s argument that other policy implications should persuade the Court to reject the agency’s interpretation of its own regulation and adopt Plaintiff’s interpretation is not compelling.

decision based on arguments that were not presented to the Council. *See Medwin Family Medicine & Rehabilitation, P.L.L.C. v. Burwell*, No. 1:15-cv-151, 2017 WL 685696, at *15 (S.D. Tex. Jan. 31, 2017) (“A reviewing court usurps the agency’s function when it sets aside the administrative determination upon a ground not theretofore presented and deprives the [agency] of an opportunity to consider the matter, make its ruling, and state the reasons for its action.” (quoting *Unemployment Comp. Comm’n of Alaska v. Aragon*, 329 U.S. 143, 155 (1946)); *id.* at *16 (“In reviewing an administrative-agency decision, a court should not consider arguments that were not raised before the agency.”). Accordingly, this Court will uphold the Council’s interpretation of the regulation and will affirm the Council’s determination that CMS timely referred the case to the Council for review.

2. *Whether the Council Improperly Accepted Review of the ALJ’s Decision*

Alternatively, Plaintiff argues that the Council’s decision should be overturned and that the ALJ’s decision should be reinstated because the Council erred in accepting review of the case. The relevant regulation, 42 C.F.R. § 405.1110(c)(2) states that the Council “will accept review if the [ALJ’s] decision or dismissal contains an error of law material to the outcome of the case or presents a broad policy or procedural issue that may affect the general public interest.” In granting review, the Council stated that the ALJ erred as a matter of law by (1) failing to compile “a complete record of the evidence” and in issuing a decision that is not “based on evidence offered at the hearing or otherwise admitted into the record,” in accordance with 42 C.F.R. §§ 405.1042(a) and 405.1046(a); (2) “finding the sample was invalid on the basis that ZPIC used an incorrect confidence interval to determine [the] overpayment [amount]”; (3) “finding the sample invalid on the basis that the ZPIC used disproportionately sized samples from the two strata”; and (4) “limiting or waiving recoupment of an overpayment due to an alleged unexplained delay by ZPIC

in providing certain requested documentation.” (R., Vol. 1, at 7–8 (quotation omitted)). Plaintiff contends that the ALJ made no errors of law that were material to the outcome of the case, and therefore, the Council improperly granted review of the ALJ’s decision. Specifically, Plaintiff argues in its Motion for Summary Judgment that the ALJ compiled and relied upon a complete record of the evidence, that the ALJ correctly determined that the statistical methodology was flawed, and that the ALJ properly exercised deference.

As a preliminary matter, the overarching theme of Plaintiff’s argument—that the Council erred in deciding to review the ALJ’s decision because the ALJ made no errors of law material to the outcome of the case—is not persuasive. Under the relevant regulation, after CMS refers a case to the Council, “[t]he Council will accept review if the decision or dismissal contains an error of law material to the outcome of the case or presents a broad policy or procedural issue that may affect the general public interest.” 42 C.F.R. § 405.1110(c)(2). In its decision, the Council noted that it had decided, “on its own motion, to review the [ALJ’s] decision dated November 18, 2015, because it contains an error of law material to the outcome of the claim.” (R., Vol. 1, at 4). Consistently, the Council concluded that the ALJ did commit material errors of law. (*Id.* at 7–8). The Court finds this sufficient to support the Council’s decision to review the ALJ’s decision pursuant to 42 C.F.R. § 405.110. *See Chillicothe Chiropractic & Wellness Ctr.*, 2014 WL 1382478, at *7 (determining that the Medicare Appeals Council had properly granted review under similar circumstances); *see also Doctors Testing Ctr., LLC II v. U.S. Dep’t of Health & Human Servs.*, No. 4-11-cv-857, 2014 WL 112119, at *4 (E.D. Ark. Jan. 10, 2014) (concluding that the Council did not exceed its authority in deciding to review the ALJ’s decision based on errors of

law where the CMS referred the ALJ's decision to the Council because CMS believed the ALJ erred as a matter of law and the Council agreed).⁸

Also problematic is the fact that portions of Plaintiff's argument focus on the propriety of the ALJ's conclusions. (*See, e.g.*, Doc. 23 at 14 (arguing that the ALJ's finding that "valid statistical sampling methodology was not used to extrapolate the overpayment amount and the extrapolated amount is invalid should have remained undisturbed" (quotation omitted)); *id.* at 15 (asserting that the ALJ's findings were supported by a complete record); *id.* (contending that the ALJ properly exercised deference and that the ALJ's decision comported with applicable legal standards and guidelines and was supported by substantial evidence)). However, "inasmuch as [this Court is] concerned on this appeal . . . with a review of [the Council's] decision, [the Court does] not review the ALJ's findings, and [the plaintiff's] arguments addressing those findings are irrelevant." *John Balko & Assocs., Inc. v. Sec'y U.S. Dep't of Health & Human Servs.*, 555 F. App'x 188, 193–94 (3d Cir. 2014) (citing *Int'l Rehab. Scis. Inc. v. Sebelius*, 688 F.3d 994, 1001–02 (9th Cir. 2012) (stating that appellate review is limited to whether "the agency decision on direct review is supported by substantial evidence" and that the court is not to compare that "decision . . . with other agency decisions not on review")); *see also Simms v. Sec'y of Health & Human Servs.*, No. 1:13cv1873, 2014 WL 1761953, at *6 (N.D. Ohio Apr. 30, 2014) (explaining that in the context of a Medicare appeal, the district court's "exercise of judicial review is not without significant restraint" and that in determining whether the Secretary's decision is supported by substantial evidence or whether the Secretary applied the correct legal standards, the court is

⁸ Moreover, the Court stresses that its inquiry is limited to determining whether the Council applied the proper legal standards and whether the Council's decision is supported by substantial evidence. Plaintiff's argument that the Council improperly granted review does not demonstrate that the Council erred by applying an incorrect legal standard or by rendering a decision that is not supported by substantial evidence.

not permitted “to review the merits of the ALJ’s decision, pass on its correctness or even enforce the ALJ’s order”). Accordingly, the Court rejects the portions of Plaintiff’s arguments that ask the Court to overturn the Council’s decision because the ALJ’s decision was correct. Bearing this in mind, the Court will address Plaintiff’s specific arguments.

a. Completeness of the Record

Assuming Plaintiff’s argument as to the completeness of the record is otherwise proper, Plaintiff’s argument still fails. Title 42 of the Code of Federal Regulations, part 405.1042(a)(1) requires the ALJ to make a “complete record of the evidence and administrative proceedings on the appealed matter.” The record is to include “the appealed determinations, and documents and other evidence used in making the appealed determinations and the ALJ’s . . . decision, including, but not limited to, claims, medical records, written statements, certificates, reports, affidavits, and any other evidence the ALJ . . . admits.” *Id.* § 405.1042(a)(2). Additionally, 42 C.F.R. § 405.1046(a)(1) requires an ALJ’s decision to “be based on evidence offered at the hearing or otherwise admitted into the record.”

In determining that the ALJ erred as a matter of law by failing to compile a complete record, the Council explained that Plaintiff had received a compact disk with sampling-related documentation from the ZPIC. (R., Vol. 1, at 7). The Council further explained that when the case was before the ALJ, Plaintiff’s statistician submitted a report to the ALJ based on her review of the ZPIC’s sampling documentation. (*Id.*). The Council noted that some of the relevant sampling documentation relied upon by Plaintiff’s statistician might have been on the compact disk the ZPIC provided to Plaintiff. (*Id.*). But the disk was not a part of the record. (*Id.*). Moreover, the ALJ relied on Plaintiff’s statistician’s written report and hearing testimony in making his decision. (*Id.*). Accordingly, the Council concluded that the ALJ erred by failing to compile a complete record

and issuing a decision that was not based on evidence offered at the hearing or otherwise admitted into the record, in violation of 42 C.F.R. §§ 405.1042(a) and 405.1046(a). (*Id.* at 7).

Plaintiff has failed to demonstrate that the Council's determination that the ALJ failed to compile a complete record is not supported by substantial evidence. Plaintiff's statement that the ALJ relied on a variety of documents in rendering his decision fails to demonstrate that the Council improperly concluded that the ALJ erred as a matter of law by failing to compile a complete record. Additionally, the Court disagrees with Plaintiff's argument that despite the Council's conclusion otherwise, the Council actually believed that the record was complete, as evidenced by its statement that "the current case record provides an *adequate basis* to resolve the sampling issues presented." (*Id.* at 16 (emphasis added)). This statement does not amount to a decision that the ALJ created and relied upon a complete evidentiary record in accordance with the relevant regulations. Finally, even if this Court agreed with Plaintiff that the Council incorrectly determined that the ALJ erred as a matter of law by failing to compile a complete record, it still does not follow that the Council's grant of review was improper. In granting review, the Council explained that review was appropriate because the ALJ had erred as a matter of law on several different grounds. Because the Court agrees with the Council that there were other errors that supported review, Plaintiff's argument regarding the completeness of the record does not carry the day.

*b. Statistical Sampling Methodology—Disproportionate Sampling
from Two Strata*

Plaintiff also challenges the Council's conclusion that the statistical sampling and extrapolation conducted in this case were valid. By way of background, the sampling methodology was as follows: the ZPIC divided the universe of 8834 claims into two strata. (*Id.* at 21). Strata 1 consisted of 4074 claims, which ranged in amount from \$.01 to \$80.00, and Strata 2 consisted of

4760 claims which ranged in amount from \$80.01 to the maximum amount. (*Id.*). The ZPIC sampled 30 claims from Strata 1, which constitutes .736% of the stratum. (*Id.*). In contrast, the ZPIC sampled 119 claims from Strata 2, which constitutes 2.5% of the stratum. (*Id.*). The ALJ held that “[b]y disproportionately allocating the stratum samples, the ZPIC ensured that four . . . times as many claims would be selected from Strata-2, which greatly increased the likelihood of claims with higher overpayment amounts being denied on review, resulting in a significantly higher total/extrapolated overpayment amount.” (*Id.* at 181). This, plus his findings regarding the confidence interval that the ZPIC applied—which the Court discusses below—caused the ALJ to conclude that an invalid statistical sampling methodology was used to extrapolate the overpayment amount, rendering the extrapolated amount invalid. (*Id.*).

The Council reversed the ALJ’s decision. (*Id.* at 25). In its decision, the Council acknowledged that it was “unclear why [the ZPIC] sampled 30 claims from stratum 1 and 119 from stratum 2.” (*Id.* at 23). The Council noted, however, that “the statistical sampling guidelines do not require that either strict proportionate or disproportionate sampling . . . be applied.” (*Id.*). The Council concluded that while the ZPIC may have employed “an unusual sample selection methodology for which the rationale is not apparent from the record, . . . having vastly different sample sizes from each of the two strata did not inflate the overpayment.” (*Id.*). The Council explained:

In each stratum, the overpayment found from adding up the individual sampled claim overpayments in that stratum were divided by the number of sampled claims from that stratum, thus yielding an average claim overpayment amount for that stratum. That average overpayment was then multiplied by the number of claims in the frame for that stratum only, thus effectively “weighting” the findings, as is routinely done in cases involving strata of different frame sizes. Separate standard deviations were then calculated and separate T-values were applied before the results were added

together to calculate the total overpayment amount. Thus, the Council finds no bias in the results of the ultimate calculation.

(*Id.*). Further, the Council cited CMS Ruling 86-1, which establishes that a presumption of validity attaches to the statistical sampling and extrapolation undertaken by a Medicare contractor. (*Id.* at 24). Council reasoned that the “burden of proof is therefore on [the claimant] to demonstrate that the methodology used by the contractor is invalid” and that Plaintiff failed to rebut that presumption. (*Id.*).

In arguing that it is entitled to summary judgment and a reversal of the Council’s decision, Plaintiff takes issue with the sampling methodology, arguing—*inter alia*—that it likely increased the overpayment amount because more samples were taken from the stratum with higher values. Plaintiff specifically argues that the Council should not have granted review because the ALJ did not err as a matter of law but, rather, properly determined that the use of disproportionate strata and abnormal sample sizes invalidated the sampling methodology. In its Cross-Motion, Defendant argues that the Council’s decision to reverse the ALJ’s decision on this basis was supported by substantial evidence, an assertion with which Plaintiff disagrees.

Plaintiff attempts to call into question the Council’s determination that no bias resulted from the ZPIC’s calculation. Plaintiff argues that the Council was incapable of making this determination given the Council’s acknowledgement that it was unclear why the ZPIC employed the sampling methodology that it did and that the methodology was “unusual.” But the Council’s decision makes clear that although it was unsure of the particular sample selection methodology used, or why that particular sample selection methodology was used, it was aware of the method by which the overpayment amount was calculated within each stratum as well as the total overpayment amount. Based on these calculations, the Council determined that the results of the ultimate calculation were not biased. (*Id.* at 23).

Plaintiff also argues that the Council did not adequately explain its decision. Under 42 C.F.R. 405.1062(a), “ALJs and attorney adjudicators and the Council are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case.” Additionally, pursuant to 42. C.F.R. § 405.1062(b), “[i]f . . . [the Council] declines to follow a policy in a particular case, the . . . [Council’s] decision must explain the reasons why the policy was not followed.” Plaintiff argues that despite this requirement, the Council provided “no explanation . . . as to why the particular sampling method in this case was employed.” (Doc. 38 at 6). But under the plain language of the regulation, the Council is not required to explain why a particular decision is made, but rather, why it declined to follow a particular policy. To the extent Plaintiff argues that the Council erred by failing to explain why it declined to follow the policy of utilizing proportionate sampling, this Court disagrees. In its decision, Council noted that there was no particular sampling policy that applied in this case, citing the Medicare Program Integrity Manual (“MPIM”) for support. (*See R.*, Vol. 1, at 23 (“[T]he statistical sampling guidelines do not require that either strict proportionate or disproportionate sampling . . . be applied.”); *id.* at 8 (finding that the ALJ erred in invalidating the sample based on the use of disproportionate samples because “CMS does not require proportionate sampling” and citing MPIM § 8.4.11.1)). Additionally, in as much as the MPIM’s chapter on administrative actions and statistical sampling for overpayment estimates discusses proportionate sampling, it merely states that “[t]ypically, a proportionately stratified design with a given total sample size will yield an estimate that is more precise than a simple random sample of the same size without stratifying,” MPIM § 8.4.11.1,⁹ that

⁹ The MPIM can be found at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html>.

“in almost all circumstances proportionate allocation will reduce the sampling error over that for an unstratified simple random sample,” *id.*, and that absent certain circumstances, “a safe approach is to allocate proportionately,” *id.* Moreover, various sampling methods are permitted under the MPIM. Because proportionate sampling is not a policy under the MPIM, the Council was not required to explain why it declined to require that proportionate sampling be used.

More importantly, the Court concludes that the Council’s determination that the sampling methodology was presumptively valid and that Plaintiff failed to rebut that presumption is supported by substantial evidence. As the Council explained, “CMS Ruling 86-1 establishes a presumption of validity that attaches to the statistical sampling and extrapolation undertaken by a Medicare contractor.” (R., Vol. 1, at 24). Thus, Plaintiff had the burden of proving that the sampling methodology used was invalid. Further, “[a]n appeal challenging the validity of the sampling methodology must be predicated on the actual statistical validity of the sample as drawn and conducted.” MPIM § 8.4.1.1. The arguments Plaintiff presented to the Council—and that Plaintiff now presents to this Court—focus on how *CMS failed* to address Plaintiff’s contention that the sampling method may have increased the overpayment amount and how *CMS failed* to offer evidence to support its own contention that the sampling methodology may have increased the accuracy of the Overpayment Determination. (*See* R., Vol. 1, at 36; Doc. 38 at 6–7). Such arguments attempt to improperly transfer the burden of proof to CMS. Plaintiff “failed to offer any affirmative evidence demonstrating that [CMS’s] sampling methodology did not comport with the guidelines established by CMS Ruling 86-1 and the MPIM.” *Maxxim Care EMS, Inc. v. Sebelius*, No. CIV.A. H-10-1408, 2011 WL 5977666, at *3 (S.D. Tex. Nov. 29, 2011). Additionally, to the extent Plaintiff argues that the ZPIC, CMS, or the Council failed to comply with the MPIM, “[f]ailure to follow [M]PIM guidelines is not a basis for setting aside a statistical sample or

extrapolation.” *Id.* Accordingly, the Court concludes that the Council’s decision that the use of disproportionate strata sizes did not invalidate the sampling methodology is supported by substantial evidence in the record. Plaintiff’s request to overturn Council’s decision on this basis will be rejected.

*c. Deference*¹⁰

In its Motion for Summary Judgment, Plaintiff also argues that the Council erred in granting review of this case because the ALJ properly exercised his discretion. Plaintiff argues that the ALJ decision should stand because the ALJ’s decision “comported with applicable legal standards and guidelines, and was supported by substantial evidence.” (Doc. 23 at 15). As the Court previously discussed, the Court’s inquiry is limited to whether the Council applied the correct legal standard and whether the Council’s decision was supported by substantial evidence. The findings or the correctness of the ALJ’s decision are irrelevant for purposes of this appeal. *See John Balko & Assocs., Inc.*, 555 F. App’x at 193–94. Therefore, the Court rejects Plaintiff’s argument that it is entitled to summary judgment because the ALJ properly exercised his discretion.

In sum, the Court rejects Plaintiff’s arguments, and Plaintiff’s Motion for Summary Judgment will be denied.

B. Defendant’s Cross-Motion for Summary Judgment

Defendant asks this Court to grant summary judgment in its favor and uphold the Council’s decision because (1) the Council’s decision that the government’s statistician selected and applied the appropriate confidence interval is supported by substantial evidence, (2) the Council’s decision

¹⁰ Although Plaintiff argues that the ALJ properly exercised deference, a more accurate characterization of Plaintiff’s argument is that the ALJ properly exercised his discretion.

that the disproportionate sampling methodology did not invalidate the sampling methodology is supported by substantial evidence, (3) CMS timely provided Plaintiff with the sampling data and methodology, and (4) CMS timely referred this case to the Council for review. The Court has already addressed Defendant's arguments regarding the use of disproportionate sampling and whether CMS's request for review was timely and has decided both issues in Defendant's favor. Accordingly, the Court will address Defendant's arguments with regard to the confidence interval the government's statistician applied and whether CMS timely provided Plaintiff with the sampling data and methodology.

1. Confidence Interval

Defendant argues that it is entitled to summary judgment because, among other things, the Council's determination that the appropriate confidence interval was applied is supported by substantial evidence. "In most situations the lower limit of a one-sided 90[%] confidence interval shall be used as the amount of overpayment to be demanded for recovery from the provider or supplier." MPM § 8.4.5.1. In this case, the ZPIC used the lower limit of a two-sided eighty percent confidence interval. The ALJ concluded that "the ZPIC incorrectly used the lower limit of the 80[%] confidence level to determine the overpayment amount." (R., Vol. 1, at 180). Based on this finding and the use of disproportionate strata and abnormal sample sizes discussed above, the ALJ concluded that a "valid statistical sampling methodology was not used to extrapolate the overpayment amount." (*Id.* at 181).

In referring this case to the Council, CMS argued that the ALJ's decision should be reversed because the ZPIC's use of the two-sided 80% confidence interval and resulting calculation were consistent with MPIM guidelines. (*Id.* at 142). Plaintiff, on the other hand, explained that in an e-mail from the ZPIC statistician to the ZPIC fraud investigator, the statistician

indicated that they were “using the lower bound of the 90% Confidence Interval” to calculate the overpayment, which resulted in a total overpayment projection of \$866,252. (*Id.* at 34 (emphasis omitted)). Plaintiff objected to the statistician’s ambiguous statement, arguing that she failed to specify that the ZPIC was utilizing the lower limit of a 90% *one-sided* confidence interval. (*Id.*). Additionally, Plaintiff argued that the statement regarding the confidence interval used contradicted the actual confidence interval that was used: despite the statistician’s statement that they were using a 90% confidence interval, the total overpayment calculation equaled \$866,252, which corresponded to the use of an 80% two-sided confidence interval. (*Id.*). Plaintiff explained that the contradiction between the confidence interval that the statistician said they used versus the confidence interval actually used and the resulting calculation formed the basis for the argument Plaintiff presented to the ALJ and that the ALJ relied, in part, upon this contradiction in concluding that the incorrect confidence interval had been used. (*Id.* at 35). Notably, the ALJ’s conclusion led to the invalidation of the sampling methodology. (*See id.* at 181).

After evaluating both parties’ arguments, the Council reversed the ALJ’s decision as to the confidence interval. (*Id.* at 7). First, the Council explained that it was inappropriate for the ALJ to invalidate the sampling methodology based on his conclusion that an improper confidence interval was applied because according to CMS Ruling 86-1-10, where the confidence interval is successfully challenged, “the overpayment determination can be simply and immediately corrected” by recalculating “a new lower confidence level corresponding to a different confidence interval by applying a different multiplier . . . without requiring any revisiting of the sampling process itself.” (*Id.* at 20). Next, the Council pointed out that Plaintiff had conceded that “whether expressed as the lower limit of the 80% two-sided confidence interval or the lower limit of the

90% one-sided confidence interval, the contractor is 90[%] confident that the overpayment estimate is greater than the lower confidence limit.” (*Id.* (emphasis omitted); *see id.* at 34).

Next, the Council addressed Plaintiff’s argument about the contradictory nature of the statistician’s e-mails. In doing so, it reviewed the sampling methodology work papers accompanying the e-mail between the ZPIC statistician and the fraud investigator. (*Id.* at 20). The Council rejected Plaintiff’s suggestion that it was unclear whether the statistician used a one or two-sided confidence interval because she failed to specify as much, stating “the T-values used by the ZPIC in its calculations of the 80%, 90% and 95% confidence intervals for each of the two strata correspond to 80%, 90%, and 95% two-sided confidence intervals.” (*Id.* (emphasis omitted)). The Council also noted that the RAT-STATS¹¹ print-out identified both lower and upper confidence limits, indicating that the ZPIC used two-sided confidence intervals. (*Id.* at 20–21). Moreover, the Council explained that “the 80% two-sided lower confidence level produces overpayment results equivalent to the lower limit of the 90% one-sided confidence interval.” (*Id.* at 20).

Arguing that it is entitled to summary judgment, Defendant summarizes the Council’s reasoning and asserts that its decision was supported by substantial evidence. Plaintiff again argues that the statistician’s e-mails were ambiguous and caused confusion as to the actual confidence interval used. But this argument was sufficiently addressed by the Council. The Court finds that the Council’s decision as to the confidence interval is well-reasoned and supported by the administrative record. Notably, Plaintiff still concedes that “[u]sing the lower bound of a one-sided 90% confidence interval is theoretically the same as the lower bound of a two-sided 80%

¹¹ RAT-STATS is a statistical software package that is approved by Medicare and used by HHS for compliance and auditing purposes. The ZPIC used RAT-STATS to calculate the overpayment in this case. (*See* Doc. 32 at 12 & n.11).

confidence interval.” (Doc. 38 at 5). Therefore, the Court concludes that the Council’s determination that the ALJ erred¹² in finding that the sample was invalid because the ZPIC used the incorrect confidence interval is supported by substantial evidence. The Council’s decision with regard to the confidence interval will be upheld.

2. *Unexplained Delay in Providing Sampling Documentation*

Defendant argues that it is entitled to summary judgment because the Council properly determined that the ALJ erred in finding that the extrapolated overpayment could not be recouped due to an unexplained delay by the ZPIC in providing Plaintiff with sampling documentation. The relevant underlying facts are as follows: Plaintiff received the Overpayment Determination on August 27, 2010, as well as a compact disk which included a portion of the statistical methodology used to calculate the extrapolated overpayment amount. (*See R.*, Vol. 3, at 1628–32; *id.* Vol. 1, at 7; *see also* Doc. 23 at 4–5). On March 22, 2011, Plaintiff submitted a Freedom of Information Act (“FOIA”) request to the ZPIC for documentation concerning the sampling methodology. (*R.*, Vol. 1, at 332–34). On April 20, 2011, Plaintiff requested a redetermination of the Overpayment Determination. (*Id.* Vol. 3, at 1098–1103). The redetermination decision affirmed the initial Overpayment Determination and was communicated to Plaintiff via a letter dated July 22, 2011. (*Id.* at 1075–87). On September 23, 2011, Plaintiff sought reconsideration, (*R.*, Vol. 2, at 549), and in a letter dated November 14, 2011, the Overpayment Determination was affirmed yet again. (*Id.*

¹² Plaintiff argues that the ALJ’s decision about the confidence interval was not a material error of law because “if the identified confidence interval or lower confidence level upon which a projected overpayment is based is successfully challenged, the overpayment determination can be simply and immediately corrected.” (*See R.*, Vol. 1, at 20 (citing CMS Ruling 86-1-10)). This argument misses the mark. Rather, this demonstrates that the ALJ committed a material error of law when he invalidated the ZPIC’s sampling methodology based on, *inter alia*, his finding that the ZPIC applied the incorrect confidence interval. Applying the abovementioned principle, the ALJ’s determination about the confidence interval did not warrant invalidation but, instead, correction of the Overpayment Determination.

542–44a). In the interim, on September 30, 2011, the ZPIC responded to Plaintiff’s FOIA request. (R., Vol. 1, at 330). After receiving the reconsideration decision, on December 8, 2011, Plaintiff appealed the Overpayment Determination to the HHS and requested a hearing before an ALJ. (R., Vol. 2, at 530–41). The ALJ issued a Notice of Hearing on March 10, 2014, for a hearing on May 20, 2014. (Doc. 23 at 5; Doc. 32 at 16; *see* R., Vol. 23, at 12096).

The ALJ concluded that Plaintiff had been prejudiced by an “unexplained delay by ZPIC in providing records and sampling methodology documentation to [Plaintiff] during the lower level appeals process” and because “records and documentation were only provided following [Plaintiff’s] FOIA request.” (R., Vol. 1, at 181). The ALJ determined that ZPIC’s actions “violate[d] Medicare policy and the principals of fundamental fairness and due process.” (*Id.*). Therefore, the ALJ held that Defendant was not permitted to correct the sampling errors, but instead, the overpayment amount needed to be recalculated. (*Id.*). Specifically, the ALJ stated that “Medicare is . . . limited to recalculating the overpayment using only the claims for the non-covered services provided to the remaining beneficiaries . . . and may not correct the sampling methodology errors to extrapolate the overpayment amount of the remaining claims or extrapolate the overpayment amount using any other methodology.” (*Id.* at 181–82).

The Council, however, held that it was undisputed that Plaintiff received all available sampling information via the compact disk and the FOIA request well before the hearing before the ALJ. (*Id.* at 25). Accordingly, the Council reasoned that Plaintiff’s statistician had adequate time to prepare her report prior to the hearing, and therefore, Plaintiff was not prejudiced. (*See id.*). Plaintiff had argued to the Council that based on Defendant’s delay in turning over information, it had been deprived of the opportunity to challenge the validity of the sampling methodology prior to the proceedings before the ALJ—i.e., at the redetermination and reconsideration levels. (*Id.* at

37). But the Council concluded that because Plaintiff had the opportunity to raise this challenge before the ALJ and before the Council and because review at both levels is *de novo*, Plaintiff's inability to challenge the statistical methodology in earlier proceedings was a moot point. (*Id.* at 25).

Defendant urges this Court to uphold the Council's decision, arguing that Plaintiff received the information it requested from the government more than two years prior to the ALJ hearing, and therefore, Plaintiff had sufficient to time to hire an expert and challenge the statistical methodology in the proceeding before the ALJ. In its Response, Plaintiff merely reiterates that it was deprived of the right to challenge the sampling methodology at the redetermination and reconsideration levels. This is insufficient to persuade the Court that the Council applied the wrong legal standard or that the Council's decision with regard to the alleged delay in providing information to Plaintiff is not supported by substantial evidence. Given the highly deferential nature of the standard of review that the Court must apply in this case, the Court will uphold the Council's determination that the ALJ erred in finding that the extrapolated overpayment could not be recouped due to an unexplained delay by the ZPIC in providing Plaintiff with sampling documentation.

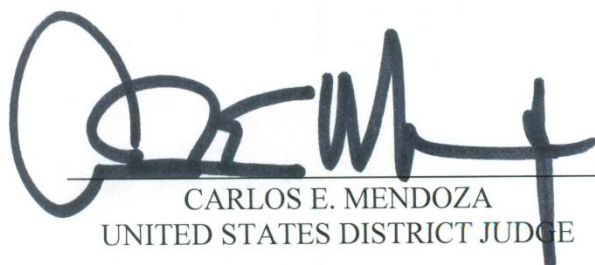
IV. CONCLUSION

After reviewing the parties' cross-motions for summary judgment, the Court concludes that Plaintiff has failed to demonstrate that the Council committed any legal errors or that that the Council's decision is not supported by substantial evidence. Accordingly, it is **ORDERED** and **ADJUDGED** as follows:

1. Plaintiff's Motion for Summary Judgment (Doc. 23) is **DENIED**.

2. Defendant's Motion for Judgment on the Pleadings, or in the Alternative, Cross Motion for Summary Judgment (Doc. 32) is **GRANTED**.
3. The Clerk is directed to enter judgment in favor of Defendant and against Plaintiff, providing that Plaintiff shall take nothing on its claims against Defendant. Thereafter, the Clerk is directed to close this case.

DONE and ORDERED in Orlando, Florida on March 30, 2018.



CARLOS E. MENDOZA
UNITED STATES DISTRICT JUDGE

Copies furnished to:

Counsel of Record