UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
CASE NO. 10-24127-CIV-SEITZ/SIMONTON

RALPH MINIET, M.D.,

Plaintiff,

vs.

KATHLEEN SEBELIUS, as
Secretary of the Department of
Health and Human Services,

Defendant.
_____/

ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT, DENYING PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT, AND CLOSING CASE

THIS MATTER came before the Court upon the parties' cross-motions for summary judgment. [DE 20, DE 21]. Plaintiff, a physician, seeks judicial review of a determination by the Secretary of the U.S. Department of Health and Human Services ("the Secretary"), that Plaintiff was erroneously paid $2,372,181.23 in Medicare reimbursements for certain injections he administered to his patients. Following an audit of a sample of Plaintiff's patient files, a contractor for the Center for Medicare & Medicaid Services ("CMS")[1] determined that Plaintiff billed Medicare for "medically unbelievable doses" of the injections and that 100 percent of the 60 claims in the sample should have been denied payment. Based on this determination, the CMS contractor extrapolated the overpayment for the 60 sample claims to a universe of 569 claims that Plaintiff submitted to Medicare for reimbursement from January 1, 2003 through December 31, 2004. The results of the

[1]CMS administers the Medicare program and is a division of HHS supervised by the Secretary. *Gulfcoast Med. Supply, Inc. v. Secretary, HHS*, 468 F.3d 1347, 1349 (11th Cir. 2006). Contractors, called "carriers," have the authority to conduct audits to determine whether overpayments were made and if so, to take action to recover overpayments. 42 C.F.R. § 421.200.

extrapolation revealed an overpayment of over $2.3 million for the injections, which the Secretary seeks to recoup. In this lawsuit, Plaintiff raises two issues. First, he contends that the extrapolation should not been conducted because the CMS contractor failed to determine that there was a "sustained or high level of payment error" with respect to its audit of the 60 sample claims, which is required by the Medicare Act. Second, Plaintiff maintains that even if the extrapolation was permitted, the statistical methodology the contractor used to conduct it is invalid. Having reviewed the administrative record, the Court must conclude that the record establishes that the Secretary's findings that the extrapolation was conducted in accord with the Act and that the methodology used was statistically valid are supported by substantial evidence. As such, the Court will deny Plaintiff's Motion for Summary Judgment and grant the Secretary's Motion for Summary Judgment.

I. BACKGROUND[2]

This case is an appeal from a decision by the Secretary that Plaintiff was overpaid $2,372,181.23 in Medicare reimbursements for intravenous injections of Rho D immune globulin ("the injections") he provided to beneficiaries in 2003 and 2004. In October 2004, a CMS contractor tasked with performing medical review functions identified Plaintiff as a high billing physician with respect to the injections and other items. At the time, Medicare had already paid Plaintiff $1,229,975.62 in 2003 and $1,715,649.41, as of December 2004, with an additional $957,365.00 in payments pending.

A. Audit of Plaintiff's Patient Records and Determination of Overpayment

As a result of Plaintiff's designation as a high billing physician and after a number of

[2]This section is derived from the administrative record filed in this case, which the parties have stipulated constitutes the undisputed facts.

unsuccessful attempts to contact Plaintiff, a CMS contractor requested that Plaintiff provide medical records for 23 Medicare beneficiaries, who were Plaintiff's patients, in order to conduct an audit to determine if the claims Plaintiff previously submitted for payment met Medicare requirements. All of beneficiaries for whom records were requested were diagnosed with Primary Thrombocytopenia, were treated with the Rho D immune globulin injections by Plaintiff from January 1, 2003 through December 31, 2004, and Medicare reimbursed Plaintiff for the injections.

Plaintiff provided medical records for only 18 of the 23 requested beneficiaries. These18 patient files contained 60 Medicare claims for the injections.[3] These 60 claims formed the sample for the audit. The 60 sample claims came from a much larger group (known as a universe or sampling frame) of 569 claims that Plaintiff submitted to Medicare from January 1, 2003 through December 31, 2004 for reimbursement for the injections.

The CMS contractor audited the sample and determined that 100 percent of the 60 sample claims should have been denied payment because Plaintiff billed Medicare for "medically unbelievable doses" of the injections. [DE 14 at 601-603].[4] The contractor then determined that Plaintiff had been overpaid $255,719.76 for the 60 claims in the sample. [*Id.* at 142-143]. Because the contractor determined that 100 percent of the sample claims should have been denied payment, the contractor extrapolated the overpayment for the 60 sample claims to the universe of 569 claims and found that Medicare overpaid Plaintiff a total of $2,372,181.23. [*Id.* at 143, 146-152]. On December 19, 2007, the contractor sent Plaintiff a letter demanding the extrapolated overpayment

[3]Some of the patient files contained multiple claims for the injections thereby accounting for the fact that there were more claims than beneficiaries in the sample group. The Medicare procedure code for the injections is J2792.

[4]The parties have Bates stamped the administrative record. The page numbers cited here refer to the Bates stamped page numbers.

amount of $2,372,181.23. [*Id.* at 565-569].

B. Appeal Process

Thereafter, Plaintiff sought reconsideration of the overpayment determination, which was denied. Plaintiff then requested a hearing before an Administrative Law Judge ("ALJ") at the U.S. Department of Health and Human Services Office of Medicare Hearings and Appeals for the Southern Region. Plaintiff raised two issues before the ALJ. First, Plaintiff contended that the extrapolation should not have been conducted because the Secretary did not first make a determination of a sustained or high degree of payment error, which is required prior to utilizing extrapolation. Second, Plaintiff asserted that the statistical methodology used for the extrapolation was unreliable and flawed.[5]

1.Administrative Law Judge's Decision

Following a hearing, the ALJ sustained the determination of overpayment for the 60 sample claims, but found that the statistical extrapolation must be set aside because the Secretary (through the CMS contractor) did not make a determination of a sustained or high degree of error as statutorily required. The ALJ further found that Plaintiff's challenges to the sampling and extrapolation "call into question the reliability and validity of the statistical sampling and extrapolation." The ALJ summarized the method used to select the sample of 60 claims as follows:

> [The contractor] randomly selected 60 claims from the 569 claims in the universe. This was done by stratifying the [universe] into five groups. According to Ms. Moya,[6] these 5 strata were created by first taking the total amount paid for all claims in the universe

[5]Plaintiff did not dispute that he was liable for the overpayment of $255,719.76 on the 60 sample claims, but instead solely disputed the use of extrapolation to increase the overpayment to over $2.3 million.

[6]Ms. Moya is a statistician for the Medicare contractor who reviewed Plaintiff's patient files in the sample and made the determination of overpayment.

> ($2,373,678.22) and dividing it by 5 ($474,735.64). Then, the claims in the [universe] were sorted in ascending order by the amount paid. Using this order, the first stratum was created by totaling claims in ascending order until the claims added up to the closest possible amount to $474,735.64 (one-fifth of the total amount paid for all claims in the universe). The remaining [four] strata were purportedly created in the same fashion. Stratum 1 consists of 134 claims, Stratum 2 has 117 claims, Stratum 3 has 115 claims, Stratum 4 has 108 claims, and Stratum 5 has 95 claims. Using equal allocation, [the contractor] randomly selected 12 claims from each stratum, which produced the 60 claims needed for the sample group . . .

The ALJ determined that there were fundamental problems with the sampling design because there were identical claim amounts in multiple strata. This was problematic because it indicated overlapping strata, which the ALJ concluded are contrary to the methodology provided for in the Medicare Program Integrity Manual ("MPIM").[7] The MPIM states that "Stratified sampling involves classifying the sampling units in the [universe] into non-overlapping groups, or strata." The MPIM further states that "The stratification scheme should try to ensure that a sampling unit from a particular stratum is more likely to be similar in overpayment amount to others in its stratum than to sampling units in other strata." The ALJ concluded that the problems with the sampling design in terms of overlap undercut the reliability of the sample.

The ALJ also determined that the sampling method was invalid because the stratification was done by claim rather than by beneficiary. The ALJ posited a hypothetical in which one beneficiary could have all of the claims in the sample, and if this beneficiary's medical records were lost, the result would be a 100 percent error rate extrapolated to the universe of claims. While the ALJ acknowledged that this hypothetical was not illustrative of the sample in the instant case, he also

[7]The MPIM provides guidance to contractors in conducting statistical sampling for use in estimating overpayments.

found that the sample was suspect because it did not include any of the claims that were in the lowest amount paid ($1,956.70), yet included two claims in the highest amount paid ($5,517.00). Thus, the ALJ set aside the statistical sampling and extrapolation.

2. Medicare Appeals Council Decision

After the ALJ rendered his decision, the Medicare Appeals Council (the Council"), on its own motion, decided to review the ALJ's decision because it found there was an error of law material to the outcome of the claim. The Council reversed the ALJ's decision and found that (1) the Secretary, through the CMS contractor, determined that there was a sustained or high level of payment error and the ALJ did not have authority to review this determination; and (2) the ALJ erred in finding the sampling methodology invalid.

Specifically, as to the ALJ's finding that there was no determination of a sustained or high level of payment error, the Council disagreed and found that based on the determination by the CMS contractor that 100 percent of the sample claims reviewed should have been denied payment, the error rate of the sample was 100 percent. The Council stated "implicit in the determination to engage in extrapolation of the overpayment is the determination that a 100 percent error rate was a 'sustained or high level of payment error(s).'" The Council declined to review the determination because such a review is prohibited by the Medicare Act and found that the ALJ also lacked authority under the Act to review the determination.

Additionally, in determining that the ALJ erred in finding the contractor's sampling methodology and overpayment extrapolation invalid, the Council opined that the contractor is not required to use the most precise methodology, only a methodology that is statistically valid. The Council reviewed Plaintiff's expert's report and concluded that the expert argued only that he would

have conducted the sampling in a different manner than that utilized by the CMS contractor. The Council determined that the methodology utilized is valid under the MPIM. Additionally, the Council reviewed the sampling frame and the stratified sample and found that in extrapolating the results of its sample claims, the CMS contractor assessed the overpayment using the lower limit of a ninety-five percent confidence interval, as opposed to a ninety-percent confidence interval, as required by CMS guidelines. As such, the CMS contractor made an assumption more favorable to Plaintiff than required, namely that the estimated overpayment is based on a ninety five percent chance that the actual overpayment is higher as opposed to a ninety percent chance that the actual overpayment is higher. Finally, the Council found that because the use of sampling creates a presumption of validity as to the amount of an overpayment, it is Plaintiff's burden to prove that the statistical sampling methodology is invalid. The Council concluded that Plaintiff had not met his burden. As such, the Council reversed the ALJ's decision.

C. The Instant Case

In this lawsuit, Plaintiff seeks judicial review and reversal of the Secretary decision, as rendered by the Council. Both parties have moved for summary judgment. The Secretary seeks summary judgment on the ground that her decision is supported by substantial evidence. Plaintiff maintains that he is entitled to summary judgment and that the Court should reverse the Secretary's decision and reinstate the ALJ's decision based on the record evidence.

II. DISCUSSION

A. Judicial Review of Secretary's Decision

Judicial review of the Secretary's decision is available under the Medicare Act. *See* 42 U.S.C. § 1395ff(b)(1). However, review is limited to "whether there is substantial evidence to

support the findings of the . . . [Secretary], and whether the correct legal standards were applied." *Gulfcoast Med. Supply*, 468 F. 3d at 1350, n. 4 (*citing Wilson v. Barnhart*, 284 F.3d 1219, 1221 (11th Cir. 2002); 42 U.S.C. § 1395ff(b)(1)(A) (incorporating into the Medicare Act the standard of review set forth in 42 U.S.C. § 405(g)).[8] "Substantial evidence is more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion. Thus, substantial evidence exists when two inconsistent conclusions can be drawn from the same evidence." *Stone &Webster Constr., Inc. v. United States Dep't of Labor*, 2012 U.S. App. LEXIS 12490, at *10 (11th Cir. June 19, 2012) (citations and quotations omitted).

B. Standard for Summary Judgment

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

[8]42 U.S.C. § 405(g) is part of the Social Security Act and provides, with respect to the standard of review, that the "findings of the [Secretary] as to any fact, if supported by substantial evidence, shall be conclusive."

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C. Cross-Motions for Summary Judgment

By filing cross-motions for summary judgment, the parties agree that there is no issue of material fact and the sole issues are questions of law for the Court's determination. Plaintiff seeks review of the Secretary's decision that (1) the ALJ did not have authority to review the determination of a sustained or high level of payment error; and (2) the ALJ erred in finding the sampling methodology and extrapolation invalid. The Secretary seeks a determination that her decision is consistent with the law and supported by substantial evidence.

1. **Determination of a Sustained or High Level of Payment Error**

The Medicare Act provides that "a medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise *unless the Secretary determinates that there is a sustained or high level of payment error . . .*" 42 U.S.C. §1395ddd (f)(3)(A) (emphasis added). Additionally, the Act specifies that "there shall be no administrative or judicial review . . . of determinations by the Secretary of sustained or high levels of payment errors . . ." 42 U.S.C. §1395ddd (f)(3). In her Motion for Summary Judgment, the Secretary maintains that administrative and judicial review are statutorily foreclosed with respect to whether the extrapolation should have been conducted because the Secretary, through the CMS contractor, found that the sample had a 100 percent payment error rate. The Secretary maintains that this constitutes an implicit determination that there was a sustained or high level of payment error and, as such, extrapolation was proper. [DE 21 at 12]. However, Plaintiff argues that the Secretary did not make an explicit determination of a sustained or high level of payment error, which is a condition precedent to using extrapolation, and, thus, administrative and judicial review are

permitted. [DE 24 at 2].

Here, the Council's finding that the Secretary determined a sustained or high level of payment error is supported by substantial evidence. The CMS contractor concluded that 100 percent of the sixty claims they reviewed during the audit should have been denied payment. [DE 14 at 9, 601-602]. Clearly, a finding of a 100 percent error rate constitutes a "sustained or high level of payment error" as contemplated by the Medicare Act. Plaintiff provides no legal authority to support his contention that the Secretary must expressly state that a determination of a sustained or high level of payment error was made in a case like this one where 100 percent of the sample claims should have been denied payment. Thus, substantial evidence in the record supports that the Secretary, through the CMS contractor, made the required determination of a sustained or high level of payment error thereby allowing the extrapolation to be conducted. Further, the determination of a sustained or high level of payment error (here, 100 percent) is not subject to administrative or judicial review. 42 U.S.C. §1395ddd (f)(3). As such, the Secretary is entitled to summary judgment on the issue of whether the extrapolation should have been conducted.

***2.* Validity of the Statistical Methodology for Extrapolation**

Plaintiff maintains that the Council's finding concerning the validity of the statistical methodology used to conduct the extrapolation is not supported by substantial evidence. Specifically, Plaintiff asserts that the methodology is flawed for two reasons: (1) there were identical claim amounts in multiple strata, which indicates overlapping strata; and (2) stratification was done by claim rather than by beneficiary. [DE 20 at 11-13]. The Secretary argues that Plaintiff's contentions concerning invalidity are not supported by the record. [DE 21 at 14-19].

First, it is undisputed that the Secretary may utilize statistical extrapolation to determine the

amount of overpayment and that the MPIM permits the use of stratified sampling. As such, the question is whether the Council's finding that the sampling was valid is supported by substantial evidence in the record. Importantly, the sampling utilized need not be based on the most precise methodology, just a valid methodology. [DE 14 at 10]. Moreover, there is a presumption of validity when statistical sampling is used by the CMS contractor and, as such, the burden is on Plaintiff to establish the invalidity of the methodology during the administrative review. [*Id.* at 15].

As to the first issue concerning identical claim amounts in multiple strata, Plaintiff's expert, Dr. Bruce Kardon, stated in his report that multiple similar claims in a sample should be counted as one claim instead of as independent claims. [DE 14 at 45, 207]. Ms. Moya, the CMS contractor's statistician, explained in her report that five strata were created by first taking the total amount paid for all of the claims in the universe ($2,373,678.22) and dividing by five ($474,735.64). The claims in the frame were then sorted in ascending order by the amount paid. The strata were created such that the claims in each stratum totaled the closest possible amount to $474,735.64. Thereafter, twelve claims from each stratum were randomly selected to equal the sixty claims needed for the sample group. [DE 14 at 42-43, 75]. Ms. Moya stated that this methodology "established a well defined limit between strata so no overlapping would be possible." [*Id.* at 75].

In reviewing the record, Plaintiff has not come forward with evidence to refute Ms. Moya's assertion that the strata were non-overlapping. As set forth above, Ms. Moya explained that the sample design establishes that the strata are non-overlapping. Plaintiff fails to point to record evidence to support his assertion that the fact that there were identical claim amounts in multiple strata demonstrates that the strata were overlapping, particularly given the fact that CMS asserted during the administrative review that it is not unusual to have multiple claims with the same dollar

value because the injections at issue are priced and billed by units provided and therefore, several claims would have the same paid amount. [DE 14 at 10]. The MPIM states that "[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." *See* MPIM Section 8.4.1.1[9] (emphasis added). Thus, upon a review of the record, the finding that the strata are non-overlapping is supported by substantial evidence as Plaintiff has not come forward with actual evidence of the invalidity of the sampling design.

Plaintiff also maintains that the methodology is invalid because the stratification was done by claim rather than by beneficiary. The ALJ found this methodology invalid based on a hypothetical he posed, specifically that:

> [If] a beneficiary had 60 separate services each with its own claim number, then the services for his one beneficiary could constitute the entire sample group. Now, let's say [Plaintiff] lost the medical records for this one beneficiary. This would result in a 100% error rate for lack of documentation. Then, this result would be extrapolated to the frame to produce the substantial overpayment amount, despite the fact that it may be the only beneficiary in the frame with lost records.

[DE 14 at 46]. However, there is no evidence in the record to suggest that the scenario posited by the ALJ occurred in this case. Further, the MPIM specifically permits sampling units comprised of individual claims. *See* MPIM, Section 8.4.3.2.[10] Additionally, Plaintiff does not explain in his Motion for Summary Judgment why stratifying by claim instead of by beneficiary is statistically invalid. Instead, he refers generally to Dr. Krandon's report and the testimony at the hearing before

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[9]Chapter 8, "Administrative Actions and Statistical Sampling for Overpayment Estimates," of the MPIM is publicly available on the internet at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c08.pdf. Prior to May 27, 2011, Chapter 8 of the MPIM was found in Chapter 3 and section 8.4.1.1 was section 3.10.1.1.

[10]Section 8.4.3.2 was formerly section 3.10.3.2.2.

the ALJ. [DE 20 at 17]. However, as the Council recognized, Dr. Kardon asserts only that he would have conducted the sampling in a different manner than the CMS contractor did. [DE 14 at 14]. This is insufficient to reverse the Council's decision because the relevant inquiry is not whether the most precise sampling method was used, but rather whether a valid methodology was used. Lastly, to the extent that the statistical methodology used in this case was not optimal, the CMS contractor accounted for this by using a ninety-five percent confidence interval and reducing its overpayment estimate to the lower bound of the confidence interval. As such, the contractor assumed that there was a ninety-five percent chance that the actual overpayment is higher than the assessed overpayment. [DE 14 at 15]. Thus, there is substantial evidence to support the Secretary's finding that the methodology used is valid.

III. CONCLUSION

For the reasons set forth above, it is

ORDERED THAT

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

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

(3) This CASE is CLOSED.

DONE AND ORDERED in Miami, Florida, this 18th day of July, 2012.

PATRICIA A. SEITZ
UNITED STATES DISTRICT JUDGE

cc: Honorable Andrea M. Simonton
All counsel of record