IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

JOHN BALKO & ASSOCIATES d/b/a
SENIOR HEALTHCARE ASSOCIATES,

Plaintiff,

12cv0572
ELECTRONICALLY FILED

v.

KATHLEEN SEBELIUS Secretary U.S.
Department of Health and Human Services,

Defendant.

Memorandum Opinion re: Parties' Cross-Motions for Summary Judgment (doc. nos. 94 and 103)

I. Introduction

Currently pending before the Court are the Cross-Motions for Summary Judgment filed by Plaintiff John Balko & Associates ("Balko") and Defendant Kathleen Sebelius, Secretary U.S. Department of Health and Human Services ("Secretary"). Doc. Nos. 94 and 103. The parties' dispute centers on the Secretary's use of extrapolation to determine Balko's liability for overbilling Medicare for routine services, such as ear wax removal. Balko argues that the determination that it had a high error rate was legally flawed. Doc. No. 97, 10-15. Balko also argues that the Medicare Appeals Council ("MAC") abused its discretion and that its decision is not supported by substantial evidence. *Id*., 15-18.

At the Initial Case Management Conference, the parties agreed that this case should be decided on Cross-Motions for Summary Judgment. After careful consideration of the Motions and Briefs in Support thereof (doc. nos. 94, 97, 103, 104), Concise Statements of Material Facts and Responses thereto (doc. nos. 98, 102, 105, 109), Briefs in Opposition (doc. nos. 101 and

108)[1], Reply Briefs (doc. nos. 108 and 443), Supplemental Letter Briefs[2] (doc. nos. 486 and 487), and Administrative Record ("AR"), Balko's Motion for Summary Judgment (doc. no. 94) will be DENIED and the Secretary's Motion for Summary Judgment (doc. no. 103) will be GRANTED.

II. Factual and Procedural Background

The parties have stipulated that the AR constitutes the facts upon which this Court must base its decision. The AR is 38,075 pages in length[3] and consists of all of the materials that were considered by the MAC in making its determination, in addition to the MAC's Opinion and transmittal letter.[4] The following is a summary of those facts necessary for the Court's disposition of this matter.

Medicare is a health care benefits program administered by the United States Department of Health and Human Services ("HHS"). It provides care for patients who are: at least 65 years of age; have certain disabilities; and/or have End-Stage Renal Disease. The Centers for Medicare and Medicaid Services ("CMS") is the agency within HHS that administers Medicare.

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[1] Pursuant to the Court's Order of December 3, 2012, Balko filed a combined Opposition/Reply Brief. Doc. No. 108.

[2] On December 17, 2012, the Court was made aware of an Opinion by Judge Spatt of the Eastern District of New York in *Anghel v. Sebelius*, 2012 WL 6212843 (E.D.N.Y. Dec. 13, 2012). On December 21, 2012, Balko filed a Letter Brief addressing *Anghel*. Doc. No. 486. The Secretary filed her Letter Brief in response thereto on December 24, 2012. Doc. No. 487.

[3] Some documents appear at multiple locations in the AR. For example, AR 2058-67 and AR 2151-60 are both a November 30, 2009, letter from SafeGuard to Balko. The Court will only cite to one instance of each document within the AR.

[4] The AR has been filed under seal on ECF. Doc. Nos. 28-91, 110-441, 444-85. This Court was provided with an electronic courtesy copy of the AR on November 9, 2012. Thus, even though the filing of the AR was not completed on ECF until December 18, 2012, the Court had already had access to the full AR for over five weeks.

Highmark Medicare Services ("Highmark") is a Medicare Contractor. *See* AR 212; 42 U.S.C. § 1395u(a)(1); *see also United States v. Erika, Inc.*, 456 U.S. 201, 208 n. 11 (1982). Balko billed Highmark for Medicare claims for service, including podiatry, audiology, vision care, and cerumen management (ear wax removal). *See* AR 212. SafeGuard Services ("SafeGuard") is a Medicare program safeguard contractor[5] ("PSC") which is responsible for "identify[ing] cases of suspected fraud, develop[ing] them thoroughly, and in a timely manner, and tak[ing] immediate action to ensure that Medicare Trust Fund monies are not inappropriately paid out and that any mistaken payments are recouped." CMS, *Medicare Program Integrity Manual* ("PIM"), § 4.2.[6]

Because SafeGuard determined that Balko "was the highest paid group rendering services at custodial care facilities in Pennsylvania from 2005 through 2007," SafeGuard reviewed a sample of Balko's claims from January 1, 2005, through January 31, 2008. AR 2059-60. SafeGuard identified a "universe of claims" to be reviewed and, using a sample size calculation, determined that a stratified random sample of 81 (out of a universe of 5,445) beneficiaries was a statistically valid random sample. AR 2060, 2166. This sample only contained claims paid for certain listed services. *Id*. SafeGuard determined that 99.85% of the claims submitted by Balko were improperly paid. *Id*. SafeGuard then extrapolated this error rate within each of the six

[5] PSC's are currently being phased out and replaced with zone program integrity contractors. PIM § 4.1. However, at all times relevant to this Opinion, SafeGuard was serving as a PSC.

[6] The Medicare Program Integrity Manual is available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019033.html (last visited Dec. 27, 2012). The PIM has been reorganized since the time of the sampling. The Court will cite to the current PIM when discussing the structure of the Medicare Act. The Court will cite to the PIM in effect at the time of the statistical sample when discussing the specifics of statistical sampling. Chapter 3 of the PIM in effect at the time of the statistical sample is available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R71PI1.pdf (last visited Dec. 27, 2012).

strata to determine that $881,414.72 had been incorrectly paid to Balko. AR 2058, 2063, 2163-64. SafeGuard calculated the lower bound of a 90% one-sided confidence interval to be $851,109.07, and demanded that amount from Balko. AR 2058, 2167.

Balko appealed this demand to the Medicare carrier, Highmark. AR 1968-85. As part of this appeal, Balko submitted additional evidence to Highmark to support the claims that it had previously submitted to Highmark. AR 1986-2029. Highmark then determined that some of the claims that SafeGuard had found to have been improperly paid, were, in fact, correctly paid. AR 1907-08. Highmark determined, however, that 81.7% of the claims submitted by Balko were incorrectly paid. *See* AR 1093.[7] After again extrapolating the respective error rates for each stratum, SafeGuard calculated the lower bound of a 90% one-sided confidence interval to be $696,347.52. AR 1907.

Balko next appealed Highmark's determination to the Medicare Qualified Independent Contractor, First Coast Service Options ("First Coast"). AR 1729-50. Balko again submitted additional evidence to support those claims that Highmark had found were improperly paid. AR 1752-1801. First Coast determined that 77% of the claims submitted by Balko were incorrectly paid. *See* AR 6726. After extrapolating the respective error rates for each stratum, SafeGuard determined the lower bound of a 90% one-sided confidence interval to be $641,437. *Id.*

[7] The Court notes that there are minor inconsistencies within the AR with respect to error rates at various points in the administrative review. For example, some locations in the AR refer to an error rate of 99.85% at the first level of review while other locations refer to an error rate of 99.6%. *Compare* AR 1093 *with* AR 2060. These minor inconsistencies are inconsequential to this Court's decision.

Balko appealed (this being the third appeal) First Coast's determination to an Administrative Law Judge ("ALJ").[8] *See* AR 60; 42 C.F.R. § 405.1014. The ALJ remanded the case to First Coast so that certain files could be included in the record to be considered by the ALJ. *See* AR 60. The ALJ bifurcated the appeal and held one hearing regarding the validity of the statistical sample. AR 6667-756. He also allowed the parties to submit written documents in support of their respective positions. *Id*. The ALJ also considered all of the evidence that had been submitted to First Coast, SafeGuard, and Highmark. *Id*. The ALJ then issued an Opinion invalidating the statistical sampling. AR 212-19.

The MAC, *sua sponte*,[9] vacated the ALJ's Opinion, holding that birfurcation was not appropriate. AR 152-54. Upon remand, the ALJ conducted two additional hearings. AR 6757-7034. He again allowed for written submissions and considered the full record before him. The ALJ then issued an Opinion on all issues. AR 59-88. The ALJ found that "the statistical sampling and associated extrapolation methodology are invalid." AR 88. The ALJ also affirmed First Coast's determinations with regard to the individual claims that had been reviewed and ordered that amount to be repaid to the government. *Id*.

The ALJ found that the statistical expert employed by Balko, Dr. Cox, "[was] qualified to provide expert testimony in this case regarding the sample of [Balko's] claims and the extrapolation of the overpayment amount." AR 69. Ms. Tracy Bendinsky, a statistician employed by SafeGuard, was questioned by the ALJ during the course of the hearing. AR 6722-26. The ALJ made no findings of fact with regard to the testimony or report of Ms. Bendinsky.

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[8] Although Balko appealed from First Coast's determination, SafeGuard, as PSC, participated in a limited capacity at the ALJ hearing. *See* 42 C.F.R. § 405.1010.

[9] Under the Regulations, CMS may refer a case to the MAC and ask that the MAC review the case *sua sponte*. *See* 42 C.F.R. § 405.1110. This occurred both times the MAC reviewed the ALJ's determinations in this case.

AR 59-88, 176-83. The ALJ found Dr. Cox's argument that SafeGuard failed to comply with 42 U.S.C. § 1395ddd(f)(3) compelling. *Id*.

The ALJ held that there was "no documentation to support that prior to their decision to do the extrapolated overpayment that [Balko] sustained a high level of payment error, nor is there any documentation to support that [Balko] was educated regarding the payment errors alleged in this matter." AR 70. The ALJ also mentioned that there were other flaws in SafeGuard's statistical sampling, but did not articulate those flaws because of his finding that SafeGuard "failed to show it met the statutory requirements for statistical sampling and extrapolation." *See* AR 6.

The MAC, *sua sponte*, reversed the ALJ's determination that the statistical sampling and extrapolation were invalid. AR 23. The MAC affirmed the ALJ's determinations regarding the sample claims that had been reviewed by First Coast. *Id*.

The MAC found that the ALJ did not have jurisdiction to consider SafeGuard's determination that there was a high level of payment error. AR 16-17. The MAC also found that the 99.85% error rate originally calculated by SafeGuard "constitute[d] a high level of payment error sufficient to trigger extrapolation of the overpayments to the universe of claims, as allowed by [statute]." AR 17. The MAC also held that the Medicare Act:

> unambiguously provides that a determination of high payment error rate (or failed educational interventions) is a condition precedent to extrapolating overpayment amounts, not a condition precedent to the contractor's decision to conduct the auditing functions, which include statistical sampling, as authorized by the Medicare Integrity Program. Nowhere does the statute require that a contractor must make any such determination before reviewing provider or supplier claims.

Id. (citations omitted).

The MAC rejected Balko's argument that the exclusion of underpayments and zero dollar payments invalidated the sample. AR 20-21. The MAC held that PIM § 3.10.3.2 (2004 ed.),

which states "[t]he universe and sampling frame will usually be all relevant claims or line items for the period under review," justified exclusion of zero dollar payments and that underpayments were not excluded. AR 20. The MAC also rejected Balko's arguments with respect to the sample and strata size. AR 21. The MAC held that SafeGuard followed PIM guidelines, which allow for many factors, some subjective rather than objective, to be considered when determining sample and strata size. *Id*. Finally, the MAC rejected Balko's arguments with respect to non-sampling errors. AR 21-22. The MAC held that the PIM only required that SafeGuard "'adjust the extrapolation of overpayment,' not initiate a new sampling process." AR 22 (quoting PIM § 3.10.9 (2004 ed.)) (emphasis removed). Balko timely filed a Complaint with this Court challenging the MAC's decision. Doc. No. 1; 42 U.S.C. § 1395ff(b)(1)(A).

III. Standard of Review

A. Review of Medicare Appeals Council

"A district court has jurisdiction over an appeal taken from a final, reviewable decision of the Secretary made after a hearing in a Medicare case." *Tucker v. Sec'y of Health and Human Servs.*, --- F. App'x ---, 2012 WL 1704109 (3d Cir. May 16, 2012) (citing 42 U.S.C. § 405(g); 42 U.S.C. § 1395ff(b)(1)). Judicial review is limited to determining whether the Secretary's decision is "supported by substantial evidence." 42 U.S.C. § 405(g); *Hagans v. Comm'r of Soc. Sec.*, 694 F.3d 287, 292 (3d Cir. 2012). "Substantial evidence has been defined as more than a mere scintilla; it means such relevant evidence as a reasonable mind might accept as adequate." *Id*. (internal quotation marks and citation omitted). "Where the [MAC's findings] are supported by substantial evidence, [the Court is] bound by those findings, even if [the Court] would have decided the factual inquiry differently." *Id*. (quoting *Fargnoli v. Massanari*, 247 F.3d 34, 38

(3d Cir. 2001)). "Overall, the substantial evidence standard is a deferential standard of review." *Jones v. Barnhart*, 364 F.3d 501, 503 (3d Cir. 2004).

As the United States Supreme Court has held "the validity of an agency's determination must be judged on the basis of the agency's stated reasons for making that determination." *Indus. Union Dep't AFL-CIO v. Am. Petroleum Inst.*, 448 U.S. 607, 631 n.31 (1980) (citing *SEC v. Chenery Corp.*, 318 U.S. 80, 95 (1943)). The United States Court of Appeals for the Third Circuit has extended this rule to Courts that are conducting a review pursuant to § 405(g). *Fargnoli*, 247 F.3d at 44 n.7 (citing *Healtheast Bethesda Lutheran Hosp. & Rehab. Ctr. v. Shalala*, 164 F.3d 415, 418 (8th Cir. 1998)).

Balko argues that this Court also has the authority to set aside the decision of the Secretary, pursuant to the Administrative Procedures Act (5 U.S.C. § 551 *et seq.*), if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A) The United States Court of Appeals for the Third Circuit has only discussed the interaction of 5 U.S.C. § 706(2)(A) and 42 U.S.C. § 405(g) in one case, *Ginsburg v. Richardson*, 436 F.2d 1146 (3d Cir. 1971). The United States Court of Appeals for the Third Circuit noted:

> There are no reported cases holding that the Administrative Procedure Act supersedes the Social Security Act with respect to judicial review of agency actions but there are several District Court cases in other jurisdictions holding that the Administrative Procedure Act must be read in pari materia with the appropriate section of the Social Security Act on the subject of judicial review. *Couch v. Udall*, 265 F.Supp. 848 (W.D. Okla. 1967); *Miller v. Ribicoff*, 195 F.Supp. 534 (W.D. S.C. 1961); *Rafal v. Flemming*, 171 F.Supp. 490 (E.D. Va. 1959); *Julian v. Folsom*, 160 F.Supp. 747 (S.D.N.Y. 1958). We need not decide whether the Administrative Procedure Act supersedes the Social Security Act with respect to judicial review of final decisions of the Secretary for the standard of review in the Administrative Procedure Act is precisely the same standard of judicial review appearing as Section 205(g) of the Social Security Act.

Id. at 1148 n.1.

Since *Ginsburg*, other United States Courts of Appeals have split on the issue of whether § 706(2)(A) should be read *in pari materia* with § 405(g). *Compare Palomar Med. Ctr. v. Sebelius*, 693 F.3d 1151, 1159 (9th Cir. 2012) (applying the standards of review in both § 706(2)(A) and § 405(g)) *with Estate of Morris v. Shalala*, 207 F.3d 744, 745 (5th Cir. 2000) (per curiam) (holding that the two sections should not be read *in pari materia*) *with Sternberg v. Sec'y, Dep't of Health and Human Servs.*, 299 F.3d 1201, 1205 (10th Cir. 2002) (holding that the two standards of review are equivalent).

The Court finds persuasive the reasoning of the United States Court of Appeals for the Fifth Circuit. Section 1395ff(b)(1) specifically incorporates the standard of review set forth in § 405(g). Congress decided to include that reference to § 405(g) in § 1395ff(b)(1), but not in other areas of the Medicare Act. For example, there is no such reference in § 1395oo(f)(1).[10] Instead, review under § 1395oo(f)(1) is governed by the review provisions of § 706(2)(A). *See Estate of Morris*, 207 F.3d at 745. If the Court were to adopt the approach of the United States Court of Appeals for the Ninth Circuit in *Palomar*, it would give no effect to this decision by Congress.

This is consistent with the decision of the United States Court of Appeals for the Third Circuit in *NVE, Inc. v. Dep't of Health and Human Servs.*, 439 F.3d 182 (3d Cir. 2006). In that case, the United States Court of Appeals for the Third Circuit stated it "believe[d] that the determination of the appropriate standard -- whether under [§ 706] or [a standard set forth in

[10] Balko relies on *Anghel* to bolster its argument that § 706 is the appropriate standard of review. However, *Anghel* relied upon *Visiting Nurse Ass'n of Brooklyn v. Thompson*, 378 F.Supp.2d 75, 86 (E.D.N.Y. 2004), which in turn relied upon *Huntington Hosp. v. Shalala*, 130 F.Supp.2d 376, 382 (E.D.N.Y. 2001). *Anghel*, 2012 WL 6212843 at *7. However, *Huntington* was a case brought under § 1395oo and not § 1395ff. *Huntington*, 130 F.Supp.2d at 382.

another federal law]-- [] dictate[d] the answers to the questions posed. . . ." *Id*. at 189. In *NVE*, the United States Court of Appeals for the Third Circuit held that § 706 was the appropriate standard because the action was filed pursuant to the Administrative Procedures Act. *Id*. In this case, the Complaint was filed pursuant to § 1395ff(b)(1), which specifically incorporates the standard of review set forth in § 405(g). For all of these reasons, the Court will not apply the standard of review set forth in § 706(2)(A), but instead will only apply the standard of review set forth in § 405(g).[11]

B. Summary Judgment

Summary judgment may be granted if, drawing all inferences in favor of the non-moving party, "the movant shows that there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(a).

A fact is "material" if proof of its existence or non-existence might affect the outcome of the suit under applicable law. *Anderson v. Liberty Lobby Inc.*, 477 U.S. 242, 248, (1986). "Facts that could alter the outcome are material facts." *Charlton v. Paramus Bd. of Educ.*, 25 F.3d 194, 197 (3d Cir.1994). Disputes must be both (1) material, meaning concerning facts that will affect the outcome of the issue under substantive law, and (2) genuine, meaning the evidence must be such that a reasonable jury could return a verdict for the nonmoving party. *Anderson*, 477 U.S. at 248.

A party moving for summary judgment has the initial burden of supporting its assertion that fact(s) cannot be genuinely disputed by citing to particular parts of materials in the record – *i.e.*, depositions, documents, affidavits, stipulations, or other materials – or by showing that:

[11] As in *Estate of Morris*, "[t]he outcome of this case does not depend upon the standard employed by this court to review HHS's [decision]. Appellant disputes the standard, however, so [the Court] begin[s] by articulating it." *Estate of Morris*, 207 F.3d at 445.

(1) the materials cited by the non-moving party do not establish the presence of a genuine dispute, or (2) that the non-moving party cannot produce admissible evidence to support its fact(s). Fed.R.Civ.P. 56(c)(1).

Conversely, in order to defeat a motion for summary judgment, the non-moving party must support its assertion that fact(s) are genuinely disputed by citing to particular parts of materials in the record, or by showing that: (1) the materials cited by the moving party do not establish the absence of a genuine dispute, or (2) the moving party cannot produce admissible evidence to support its fact(s). *Id*.

In reviewing a motion for summary judgment, the court "does not make credibility determinations and must view facts and inferences in the light most favorable to the party opposing the motion." *Siegel Transfer, Inc. v. Carrier Express, Inc.*, 54 F.3d 1125, 1127 (3d Cir. 1995).

IV. Discussion

The decision of the MAC is considered the final agency action of the Secretary. 42 C.F.R. § 405.1130; *Nichole Med. Equip. & Supply, Inc. v. TriCenturion, Inc.*, 694 F.3d 340, 359 (3d Cir. 2012); *John v. Sebelius*, 2010 WL 3951465, *2 (E.D. Ark. Oct. 6, 2010).

A. The Court Lacks Jurisdiction to Consider Balko's High Error Rate Arguments

The MAC found that the last sentence of § 1395ddd(f)(3) stripped the ALJ of jurisdiction to hear Balko's argument with regard to the finding of a high error rate, and the Secretary argues that this Court, too, lacks jurisdiction to adjudicate the argument. Conversely, Balko argues that this Court maintains jurisdiction to consider its argument with regard to SafeGuard's determination of a high error rate. As this case is not a review of the MAC's findings, but rather

a question of this Court's own jurisdiction to hear the case, the Court reviews the argument *de novo*.[12]

With the *de novo* standard of review in mind, the Court now turns to interpreting § 1395ddd(f)(3) to discern whether the Court has jurisdiction to review the Secretary's determination of a high error rate.

"The task of resolving the dispute over the meaning of § [1395ddd(f)(3)] begins where all such inquiries must begin: with the language of the statute itself." *United States v. Ron Pair Enterprises, Inc.*, 489 U.S. 235, 241 (1989) (citing *Landreth Timber Co. v. Landreth*, 471 U.S. 681, 685 (1985)). "In this case it is also where the inquiry should end, for where, as here, the statute's language is plain, 'the sole function of the court[] is to enforce it according to its terms.'" *Id*. (quoting *Caminetti v. United States*, 242 U.S. 470, 485 (1917)).[13]

Title 42 United States Code Section 1395ddd establishes the Medicare Integrity Program. There is a limitation on the use of extrapolation within that section, which reads, in relevant part:

> A medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise unless the Secretary determines that--
>
> (A) there is a sustained or high level of payment error; or
>
> (B) documented educational intervention has failed to correct the payment error.

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[12] Although the Secretary based her decision on the language of the Medicare Statute, the Court does not owe *Chevron* deference to the Secretary's conclusion that this Court lacks subject matter jurisdiction. *Cf. Leyse v. Clear Channel Broad. Inc.*, 697 F.3d 360, 372-73 (6th Cir. 2012). *Anghel* did not reach the issue as Judge Spatt found the language of § 1395ddd unambiguous. *Anghel*, 2012 WL 6212843 at *9.

[13] Where, as in this case, the language of the statute expresses Congress' intent with sufficient precision, it is unnecessary to reference the legislative history. *Ron Pair*, 471 U.S. at 685.

> **There shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise, of determinations by the Secretary of sustained or high levels of payment errors under this paragraph.**

42 U.S.C. 1395ddd(f)(3) (emphasis added); *see also* 42 C.F.R. § 405.926(p) ("[d]eterminations by the Secretary of sustained or high levels of payment errors are not initial determinations and are not appealable").

The United States Supreme Court has held that there is a "strong presumption that Congress intends judicial review of administrative action." *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 670 (1986); *St. Francis Med. Ctr. v. Shalala*, 32 F.3d 805, 811 (3d Cir. 1994). "The presumption in favor of judicial review may be overcome only upon a showing of clear and convincing evidence of a contrary legislative intent." *Traynor v. Turnage*, 485 U.S. 535, 542 (1988) (internal quotation marks omitted) (citing *Abbott Labs. v. Gardner*, 387 U.S. 136, 141 (1967)); *Rice v. U.S. Dep't of Alcohol, Tobacco and Firearms*, 68 F.3d 702, 707 (3d Cir. 1995) (*overruled on other grounds by Pontarelli v. U.S. Dep't of the Treasury*, 285 F.3d 216 (3d Cir. 2002) (en banc)). The Court looks to "specific language or specific legislative history that is a reliable indicator of congressional intent, or a specific congressional intent to preclude judicial review that is fairly discernible in the detail of the legislative scheme." *Traynor*, 485 U.S. at 542 (internal quotation marks and citation omitted).

Here, the Secretary made a determination of sustained or high levels of payment errors. AR 16-17, 2060.[14] Balko mischaracterizes the ALJ's finding. The ALJ found that the determination of a high level of payment error was not made at the appropriate time. AR 69-70. However, whether that determination was made at the appropriate time is immaterial to this

[14] In *Gentiva Healthcare Corp. v. Sebelius*, Judge Boasberg undertook a detailed *Chevron* analysis with respect to the finding of a high error rate. 857 F.Supp.2d 1, 6-14 (D.D.C. 2012). He concluded that a PSC, such as SafeGuard, could make the determination on the Secretary's behalf. *Id*. at 14. The Court adopts Judge Boasberg's well-reasoned analysis.

Court's jurisdiction to adjudicate Balko's high error rate argument. The language of the statute is unambiguous, that there "shall be no . . . judicial review . . . of determinations by the Secretary of sustained or high levels of payment errors under this paragraph." § 1395ddd(f)(3). "Indeed, it is difficult to think of anything 'Congress could have said to make the plain and unambiguous language of the statute, and its corresponding intent more clear.'" *Gentiva Healthcare Corp. v. Sebelius*, 857 F.Supp.2d 1, 14 (D.D.C. 2012) (quoting *Painter v. Shalala*, 97 F.3d 1351, 1356 (10th Cir. 1996)). Thus, even if the determination was not made at the appropriate time, the determination still may not be reviewed by this Court.

Balko argues that the legislative history of § 1395ddd(f)(3) supports a finding that the Court may review such a determination. Doc. No. 97, 12. However, the legislative history does not support Balko's argument. The language in the legislative history quoted by Balko was not a statement made by a member of Congress, but rather by witnesses who testified or submitted statements to the Committee. *See Circuit City Stores, Inc. v. Adams*, 532 U.S. 105, 120 (2001) (declining to give any weight to statements made by individuals not members of Congress); *Kelly v. Robinson*, 479 U.S. 36, 51 n.13 (1986) (same). "More important, the Supreme Court has repeatedly emphasized that courts should 'not resort to legislative history to cloud a statutory text that is clear.'" *Nat'l Assoc. of Mfrs. v. Taylor*, 582 F.3d 1, 12 (D.C. Cir. 2009) (quoting *Ratzlaf v. United States*, 510 U.S. 135, 147-48 (1994)); *United States v. Alcan Aluminum, Inc.*, 25 F.3d 1174, 1181 (3d Cir. 1994).

Balko's argument that such a construction would deprive § 1395ddd(f)(3) of any effect, is also without merit. Although there may not be administrative or judicial review of such determinations, CMS is free to consider any factor, including the use of extrapolation, when deciding whether to renew a company's Medicare contract. *See Anghel v. Sebelius*, 2012 WL

6212843, *15 (E.D.N.Y. Dec. 13, 2012) (citation omitted). The unambiguous language of the statute evinces that Congress made a conscious decision to strip ALJ's and Courts of jurisdiction to review such determinations. To hold otherwise would render the last sentence of § 1395ddd(f)(3) without effect. Furthermore, Congress' decision not to allow judicial review is logical. *Id*. at *9; *Gentiva*, 857 F.Supp.2d at 14. "No sanction attaches to this initial determination; it merely permits a contractor to use a particular method of calculation in determining an overpayment amount." *Id*. (citing 74 Fed. Reg. 65303-04).

Other District Courts outside this Circuit that have considered the matter have also found that § 1395ddd(f)(3) precludes judicial review of such a determination. *Anghel*, 2012 WL 6212843 at *9 ("the Court agrees that the determination of a sustained or high level of payment error is not subject to administrative or judicial review"); *Miniet v. Sebelius*, 2012 WL 2930746, *5 (S.D. Fla. July 18, 2012) ("the determination of a sustained or high level of payment error . . . is not subject to administrative or judicial review . . . . As such, the Secretary is entitled to summary judgment on the issue of whether the extrapolation should have been conducted."); *Morgan v. Sebelius*, 2012 WL 1231960, *2 (S.D. W.Va. Apr. 12, 2012) ("[§ 1395ddd(f)(3)] clearly and unequivocally prohibits judicial or administrative review of a determination of a high level of payment error"); *Gentiva*, 857 F.Supp.2d at 2 ("Congress expressly precluded judicial review of 'sustained or high level of payment error' determinations, [thus] the Court lacks jurisdiction to consider Gentiva's challenge to the contractor's finding that such a level of payment error existed here.").

A finding that this Court lacks jurisdiction to review Balko's claim is also consistent with how United States Courts of Appeals have construed parallel language in the Medicare statute, finding that the language precludes judicial review. *See Paladin Cmty. Mental Health Ctr. v.*

Sebelius, 684 F.3d 527, 530 (5th Cir. 2012) (construing 42 U.S.C. § 1395l (t)(12)(E)); *Tex. Alliance for Home Care Servs. v. Sebelius*, 681 F.3d 402, 411 (D.C. Cir. 2012) (construing 42 U.S.C. § 1395w–3(b)(11)); *Am. Soc'y of Cataract and Refractive Surgery v. Thompson*, 279 F.3d 447, 456 (7th Cir. 2002) (construing 42 U.S.C. § 1395w–4(i)(1)).

There is "clear and convincing evidence" that Congress intended to preclude judicial review of the determination of a high error rate. *Traynor*, 485 U.S. at 542. Accordingly, this Court will not address the merits of Balko's claim (that the Secretary's determination of a high error rate was flawed) due to a lack of jurisdiction. To the extent that the arguments raised in Balko's briefs may be considered an attack on the sufficiency of a determination made by the Secretary over which this Court has jurisdiction, said arguments will be addressed *infra*.

B. The MAC's Determinations Are Supported by Substantial Evidence[15]

Balko argues that there is no substantial evidence to support the MAC's credibility determinations. Doc. No. 97, 15-16. Balko does not cite a single portion of the MAC's decision wherein the MAC overturned any credibility determination made by the ALJ. Balko only makes generalized statements that the MAC must have made credibility determinations because the MAC reversed the ALJ's decision. *Id*. The Court finds the opposite to be the case. In fact, the MAC acknowledged the credibility determination of the ALJ, or at the minimum did not overturn any of these determinations. However, Balko seems to be impliedly challenging the MAC's determination regarding the finding of a high error rate. *Id*. at 17. As rehearsed, because the Court has found herein above, that it does not have jurisdiction to adjudicate the merits of the finding of a high error rate, the Court cannot adjudicate Balko's claims.

[15] As discussed in the Standard of Review Section, *supra*, the appropriate standard of review is § 405(g) and not § 706. Thus, the Court will group Balko's arguments relating to the MAC's alleged abuse of discretion and the alleged lack of substantial evidence to support the MAC's decision.

The MAC found that the ALJ made a determination with respect to the validity of the statistical sample. Substantial evidence exists in the record to support this interpretation by the MAC. Indeed, the ALJ stated (after remand) that "[the MAC] did not find that the ALJ was incorrect in its determination that the statistical sampling and extrapolation were invalid." AR 65. Because CMS raised the issue in its referral to the MAC for action on its own motion, AR 134-48, the MAC was able to review this determination. 42 C.F.R. § 405.1110(c)(1). Like this Court's review of its own jurisdiction, the MAC reviews determinations of the ALJ *de novo*. 42 C.F.R. § 405.1100(c); *Int'l Rehabilitative Scis. Inc. v. Sebelius*, 688 F.3d 994, 997 (9th Cir. 2012).

This Court will adjudicate, on the merits, Balko's argument that no substantial evidence exists to support the MAC's conclusions that the extrapolation and statistical analysis were valid. After sampling, the burden shifts to Balko to show that the sampling is invalid. *Chaves Cnty. Home Health Serv., Inc. v. Sullivan*, 931 F.2d 914, 921 (D.C. Cir. 1991) (citing HCFA[16] Ruling 86-1); *Transyd Enters., L.L.C. v. Sebelius*, 2012 WL 1067561 (S.D. Tex. Mar. 27, 2012) (same). The MAC determined that the statistical sample taken by SafeGuard was valid. AR 17-19. The MAC stated that SafeGuard "constructed a probability sample, defining the universe as the set of claims for services provided between January 6, 2006, through January 31, 2008; for all procedures codes; and with 'paid amount: >0.'" AR 18 (quoting the record). The frame consisted of 5,445 beneficiaries and 23,148 claims. *See id*. (citing the record). The MAC found that SafeGuard used stratified random sampling, with optimal allocation, and a sample size of 81. The sampling unit utilized by SafeGuard was the beneficiary instead of the claim. *Id*. "Sampling units were placed into six strata according to the total provider paid amount and a

[16] HCFA was the predecessor to CMS. HCFA Ruling 86-1 was filed at doc. no. 487-2.

random sample was then chosen from each group using the survey select procedure in SAS . . . ." *Id*. (citing the record) (quotation marks and alterations omitted).

The resulting sample contained 581 claims totaling $21,503.60. *Id*. at 18-19 (citing the record). SafeGuard then reviewed all 581 claims and determined that 580 of the 581 claims, for a total of $21,420.04, had been incorrectly paid. AR 19 (citing the record). SafeGuard then extrapolated the error rate for each of the six strata, summed the total to get a point estimate, and calculated a 90% one-sided confidence interval. *Id*. (citing the record). A list of formulas used to calculate the sample size, point estimate, and confidence interval was provided by SafeGuard. *Id*. (citing the record). The MAC found that this method was "both contemplated and approved by CMS." AR 19 n. 13. The extrapolation method was repeated after each level of review.

The Court has carefully reviewed all of the citations to the record that the MAC made when it set forth the factual background of the statistical methodology used by SafeGuard in calculating the overpayment. There were no errors made by the MAC in this regard, and all of the citations support the factual background as set forth in the MAC's Opinion and summarized above.

The MAC addressed, in detail, many of Dr. Cox's arguments for invalidating the sample. AR 20. The MAC also noted that it reviewed the remaining arguments raised by Dr. Cox and found "them insufficient bases for invalidating the statistical sample and overpayment extrapolation in this case." AR 20 n. 14. The MAC first addressed "[Balko's] argument that [SafeGuard] excluded underpayments or zero dollar payments from the universe." AR 20.

Balko erroneously asserts that underpayments were automatically excluded from the sampling frame. As the MAC correctly held, with a citation to the relevant part of the record, all claims that had a payment greater than zero were included in the sampling frame. AR 20. This

allows for an overpayment to be offset by an underpayment when calculating the point estimate (and thus the confidence interval). *Id*. (citing PIM § 3.10.5.1 (2004 ed.)).

Turning to Balko's argument that zero dollar "payments" were excluded from the sampling frame, the MAC quoted the PIM, which states that the sampling frame "shall consist of all fully and partially paid claims submitted by the supplier for the period selected for review and for the sampling units to be reviewed." AR 20 (quoting PIM § 3.10.3.2.1.B. (2004 ed.)). Furthermore, the sampling frame shall include claims "for which fully or partially favorable determinations have been issued." AR 20 (quoting PIM § 3.10.3.2.3 (2004 ed.)). Finally, the sampling frame chosen by SafeGuard complied with the PIM's statement that "any type of sampling unit is permissible as long as the total aggregate of such units covers the population of potential mis-paid amounts." AR 21 (quoting PIM § 3.10.3.2.2 (2004 ed.)). Thus, the MAC's decision, that the exclusion of zero dollar payments was permissible, is supported by substantial evidence.

The MAC next addressed Balko's argument that the sample and strata sizes were too small. The MAC noted that, "a determination of sample size may take into account many things, including the method of sample selection, the estimator of overpayment, and prior knowledge (based on experience) of the variability of the possible overpayments that may be contained in the total population of sampling units." AR 21 (citing PIM § 3.10.4.3 (2004 ed.)). SafeGuard was also permitted to consider "real-world economic constraints" when determining the sample size. *Id*. (citing PIM § 3.10.4.3 (2004 ed.)). The MAC held that SafeGuard's determination of sample size, after considering all of these factors, was reasonable. AR 21.

In *Transyd*, the United States District Court for the Southern District of Texas considered a similar argument to that being made by Balko. In *Transyd*, the PSC used a sample size of only

30 claims. *Transyd*, 2012 WL 1067561 at *2. This represented a smaller proportion of the universe of claims than sampled in this case.[17] Originally, the error rate was calculated to be 100%, similar to this case. *Id*. This figure was later reduced to 40% but the sample size remained the same. *Id*. at *6. Like in the case at bar, the MAC overturned the ALJ's determination, and held the statistical sample to be valid. *Id*. at *8. The MAC's reasoning in *Tyansyd* was remarkably similar to the reasoning given by the MAC in the case at bar. *Id*. The MAC cited the same portions of the PIM and made the same determinations. *Id*. The District Court found that the MAC's decision was supported by substantial evidence despite Transyd's expert report. *Id*. The Court noted that a more precise estimate could have been drawn with a larger sample size but that this is not required by the PIM. *Id*.

Other District Courts that have considered similar arguments regarding sample size have likewise declined to overturn the MAC's determinations with respect to the minimum sample size needed. *Maxxim Care EMS, Inc. v. Sebelius*, 2011 WL 5977666, *1 (S.D. Tex. Nov. 29, 2011) (upholding a sample size of 30 claims); *Pruchniewski v. Leavitt*, 2006 WL 2331071, *10 (M.D. Fla. Aug. 10, 2006) (upholding a sample size of 30 claims). These three cases show that 30 claims is a routinely used sample employed by PSC's. In the case at bar, 581 claims, or almost 20 times as many claims, were included in the sample.

The Court finds that the MAC's determination is supported by substantial evidence. As the MAC acknowledged, Dr. Cox's report details how a more precise statistical sample could be drawn. However, that is not the question before the Court. It is always possible to draw a sample that is more precise than that used by the PSC, unless 100% of the sampling frame is included in the sample. Instead, the question is whether the sample size was sufficient to be

[17] In this case 581/23,148 claims, or 2.51% of the universe, were sampled. In *Transyd*, 30/9,982 claims, or 0.30% of the universe, were sampled.

statistically valid. *Anghel*, 2012 WL 6212843 at *11 ("Importantly, the sampling utilized need not be based on the most precise methodology, just a valid methodology.") (quoting *Miniet*, 2012 WL 2930746 at *6). The AR contains substantial evidence to support the MAC's conclusion that the statistical sample size, including strata size, was large enough to be valid, which is all that is required. Thus, the Court rejects Balko's argument that the sample size and strata size were too small.

The MAC then rejected Balko's arguments that non-sampling error invalidated the sample. Two of these arguments relate to individual determinations. Specifically, Balko argues that failure to consider all of the documentation and failure to consider the physician's judgment, were non-sampling errors. AR 22. However, Balko had the opportunity to appeal the ALJ's decision relating to individual claim determinations, however chose not to. 42 C.F.R. § 405.1108(a). Balko cannot now collaterally attack those determinations by arguing that they invalidate the sampling method.

Balko next argues that because the error rate dropped at each level of review, new samples should have been drawn at each level of review. However, this is contrary to the PIM which states that if the "appeals process 'reverses the revised initial [sample] claim determination,' the contractor 'shall . . . adjust the *extrapolation* of overpayment,' not initiate a new sampling process." AR 22 (quoting PIM § 3.10.9 (2004 ed.)) (alteration and emphasis in original). As mentioned above, the Court in *Transyd* upheld a similar sampling method where the error rate decreased at each level of appellate review. *Transyd*, 2012 WL 1067561 at *8; *see also Morgan*, 2012 WL 1231960 at *2 (upholding a similar sampling method where the error rate decreased from 100% to under 37%). Thus, the MAC's determination that new samples did not need to be drawn is supported by substantial evidence.

The MAC rejected Balko's argument that a probe sample is required prior to a statistically valid random sample being conducted. AR 8 n.7 (citing PIM § 3.6.1 (2004 ed.)). Section 3.6.1 provides guidance on which providers should be selected for post-payment review. Section 3.6.1 does not state that a probe sample is a requirement prior to a statistically valid sample. Instead, it lists probe samples as one of three types of post-payment reviews. *Id*. Balko now argues that *Anghel* supports its argument that a probe sample is required. However, that is not what *Anghel* states. Although a probe sample was used in *Anghel*, the Court implicitly recognized that use of a probe sample is only an option for a PSC, and not a requirement. *Anghel*, 2012 WL 6212843 at *2 ("In conducting a post-payment audit, the Carriers *may* first request a probe sample.") (emphasis added). Thus, the MAC's determination, that such a probe sample was not required, is supported by substantial evidence.

Finally, the MAC held that Balko's other arguments were without merit. Dr. Cox raised ten objections in his report. AR 1516-37. The MAC discussed, and rejected, conclusions 1, 2, 3, 4, 5, 6, 8, and 10. The only two arguments that the MAC did not address explicitly were objections 7 and 9.

In Objection 7, Dr. Cox opined that SafeGuard did not adequately disclose its randomization technique. AR 1527. However, after Dr. Cox's report was filed, SafeGuard disclosed the precise randomization methodology that it used. In particular, SafeGuard disclosed the seed values used in SAS. Balko has not pursued that argument since the precise randomization methodology was disclosed. Thus, the MAC was not required to explicitly address this objection.

In Objection 9, Dr. Cox opined that SafeGuard failed to verify the amount paid to the provider. However, even if this is true, it is not a reason to invalidate the statistical sample.

Balko has (or should have) records of all payments that it received from Highmark for services provided under Medicare but failed to produce any records that the payment amounts were incorrect. Furthermore, this is another collateral attack on the individual determinations that Balko chose not to appeal from the ALJ to the MAC. Thus, the MAC was not required to explicitly address this argument.

In sum, Balko seeks to have this Court invalidate the sample drawn by SafeGuard because Dr. Cox, a qualified statistician, showed how a more precise point estimate could have been calculated using a different sampling method. However, Balko is not entitled to the best possible statistical sample of claims that it submitted to Highmark under Medicare. Instead, Balko is only entitled to a statistically valid random sample. The MAC's decision, that the statistical sample was valid, is supported by substantial evidence in the AR. Therefore, the Court declines to overturn the MAC's determination.

V. Conclusion

For the reasons explained herein above, the Court does not have jurisdiction to hear Balko's challenge to the Secretary's finding of a high error rate. Furthermore, there is substantial evidence to support the decision of the Secretary in the matters over which this Court maintains jurisdiction. Accordingly, Balko's Motion for Summary Judgment (doc. no. 94) will be DENIED and the Secretary's Motion for Summary Judgment (doc. no. 103) will be GRANTED.

An appropriate Order follows.

s/ Arthur J. Schwab
Arthur J. Schwab
United States District Judge

cc: All ECF counsel of record