UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

MAXMED HEALTHCARE, INC.,	§	No. SA:14–CV–988–DAE
	§	
Plaintiff,	§	
	§	
vs.	§	
	§	
SYLVIA MATHEWS BURWELL, Secretary, United States Department of Health and Human Services,	§	
	§	
	§	
Defendant.	§	
	§	

ORDER (1) DENYING PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT; AND (2) GRANTING DEFENDANT'S CROSS-MOTION FOR SUMMARY JUDGMENT

Before the Court are (1) Plaintiff Maxmed Healthcare, Inc.'s ("Plaintiff" or "Maxmed") Motion for Summary Judgment (Dkt. # 21); and (2) Defendant Sylvia Mathews Burwell, Secretary, Health and Human Service's ("Defendant" or "HHS") Cross-Motion for Summary Judgment (Dkt. # 25). Pursuant to Local Rule 7(h), the Court finds this matter suitable for disposition without a hearing.

After careful consideration of the memoranda in support of and in opposition to the motions, and the record in the case, the Court, for the reasons that follow, (1) **AFFIRMS** the decision of the Medical Appeals Council; (2) **DENIES**

Plaintiff's Motion for Summary Judgment (Dkt. # 21); and (3) **GRANTS** Defendant's Cross-Motion for Summary Judgment (Dkt. # 25).

BACKGROUND

The present action is an appeal from the final administrative decision of the Departmental Appeals Board Medicare Appeals Council ("MAC"), which was issued on September 18, 2014. ("Compl.," Dkt. # 1 at 1.) Plaintiff is a state-licensed and Medicare-certified home health care provider located in San Antonio, Texas. (Id. at 2.)

On July 11, 2011, Medicare ("Medicare" or "CMS") Administrative Contractor Palmetto GBA, L.L.C. ("Palmetto") notified Plaintiff of a $773,967.00 Medicare overpayment based upon a post-pay investigation and statistical sampling conducted by Health Integrity in 2010. (Id. at 3–4.) Health Integrity reviewed 40 claims submitted by Plaintiff, and denied payment as to 39 of those claims. (Id. at 4.) Plaintiff appealed Health Integrity's determination as to the claims and the extrapolation of overpayment to Palmetto. (Id.) On appeal, Palmetto confirmed Health Integrity's findings, denying payment on the 39 claims and upholding the extrapolation of overpayment. (Id.)

On May 1, 2012, Plaintiff appealed Palmetto's decision to the Medicare Qualified Independent Contractor ("QIC"), Maximus Federal Services, which upheld Palmetto's decision. (Id.) On September 26, 2012, Plaintiff

appealed the QIC's decision to the Administrative Law Judge ("ALJ") at the Office of Medicare Hearings and Appeals ("OMHA"). (Id.) A pre-hearing conference was held on September 23, 2013, and the hearing was held by teleconference on January 21–22, 2014. (Dkt. # 25 at 3.) On April 24, 2014, the ALJ issued a decision finding one claim of the 39 denied claims in favor of Plaintiff, but concluding that the extrapolation methodology used by Health Integrity deviated from Medicare requirements and directed Health Integrity to correct the statistical sampling and recalculate a new overpayment extrapolation. (Dkt. # 1 at 4–5.)

On June 20, 2014, Plaintiff submitted a request for MAC review of the remaining claims found unfavorable by the ALJ. (Id. at 5.) Shortly thereafter, the Administrative Qualified Independent Contractor ("AdQIC") requested that MAC review the ALJ's decision regarding the overpayment extrapolation. (Id.) On July 7, 2014, Plaintiff submitted objections to the AdQIC's referral of the ALJ decision to the MAC. (Id. at 6.) On September 18, 2014, the MAC issued a decision reversing the ALJ's decision in part, finding that the statistical sampling and overpayment extrapolation were valid. (Dkt. #1-2 at 4.)

On November 7, 2014, Plaintiff filed its Complaint for Judicial Review in this Court, raising eight grounds for appeal and requesting that the Court set aside the MAC's final decision, prohibit HHS from prematurely recouping

payments to reduce the alleged overpayment, and issue exemplary damages and attorney's fees and costs. (Id. at 11–12.)

On July 17, 2015, Plaintiff filed a motion for summary judgment. (Dkt. # 21.) On September 3, 2015, Defendant filed a response as well as its own cross-motion for summary judgment. (Dkt. # 25.) On September 16, 2015, Plaintiff filed a response to Defendant's motion and a reply to its own motion. (Dkt. # 26.) On September 23, 2015, Defendant filed a reply to its motion. (Dkt. # 27.) These motions are discussed below.

LEGAL STANDARD

"The court shall grant summary judgment if the movant shows 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). As noted by the Fifth Circuit:

> The summary judgment procedure is particularly appropriate in cases in which the court is asked to review or enforce a decision of a federal administrative agency. The explanation for this lies in the relationship between the summary judgment standard of no genuine issue as to any material fact and the nature of judicial review of administrative decisions.... [T]he administrative agency is the fact finder. Judicial review has the function of determining whether the administrative action is consistent with the law—that and no more.

Girling Health Care, Inc. v. Shalala, 85 F.3d 211, 214–15 (5th Cir. 1996) (alterations in original) (quoting 10A Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, Federal Practice and Procedure: Civil 2d § 2733 (1983)).

The Court's review of an HHS final decision is very limited. Since the federal Medicare and Social Security programs are similar, the Court reviews a Secretary's final decision in accordance with the statute that controls review of the Commissioner of Social Security decisions, 42 U.S.C. § 405(g) (2006); 42 U.S.C. § 1395ff(b) (2006). In accordance with § 405(g), an individual may bring an action for judicial review in a district court of the United States, and

> the court shall have power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the Commissioner of Social Security, with or without remanding the cause for a rehearing. The findings of the Commissioner of Social Security as to any fact, if supported by substantial evidence, shall be conclusive . . . .

42 U.S.C. § 405(g). The Fifth Circuit has held that review of the Secretary's decision is limited to two inquiries: (1) whether the Secretary applied the proper legal standards; and (2) whether there is substantial evidence in the record to support the Secretary's decision. Estate of Morris v. Shalala, 207 F.3d 744, 745 (5th Cir. 2000).

The Court, in examining whether the Secretary applied the proper legal standards, must be mindful that Congress has charged the Secretary with the primary responsibility for interpreting the cost reimbursement provisions of the Medicare Act. Girling Health Care, 85 F.3d at 215. For this reason, the Court is required to give substantial deference to an agency's interpretation of its own

regulations. Id. The Court must defer to the Secretary's interpretation of a regulation unless it conflicts with the regulation's plain language. Id.

However, it is the Court's duty to consider whether there exists substantial evidence to support the Secretary's decision. The Supreme Court has defined "substantial evidence" as more than a scintilla, or "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." Richardson v. Perales, 402 U.S. 389, 401 (1971) (quoting Consol. Edison Co. v. N.L.R.B., 305 U.S. 197, 229 (1938)). The Court "may neither reweigh the evidence in the record nor substitute [its] own judgment for the Secretary's." Hollis v. Bowen, 837 F.2d 1378, 1383 (5th Cir. 1988). In sum, the Court may not overturn the Secretary's decision if the Secretary applied the correct law and the decision is supported by more than a mere scintilla of evidence. Estate of Morris, 207 F.3d at 745.

DISCUSSION

Plaintiff contends that (1) the MAC erred in condoning CMS and its witnesses' extensive presentation of evidence and testimony at the hearing; (2) the MAC's decision on extrapolation was made in error; (3) the decision violated Medicare's "Rule of Thumb" because of the denial bases across mass numbers of claims; (4) its claims met Medicare coverage criteria, were properly presented, and fully payable; and (5) it was denied due process. (Dkt. # 21 at 8–13.)

In responding to Plaintiff's motion and in simultaneously moving for summary judgment, Defendant asserts that (1) the sampling method used by HHS provides a statistically valid basis for calculating the overpayment; (2) the record supports the presumption that the sampling and extrapolation were valid; and (3) Plaintiff has not met its burden to demonstrate the statistical sampling is invalid. (Dkt. # 25 at 13–17.) Defendant also contends that, with regard to Plaintiff's individual claims, the MAC's decision is supported by substantial evidence and Plaintiff has not demonstrated another reason for overturning the final decision. (Id. at 32.)

I. Evidence and Testimony at ALJ Hearing

Plaintiff argues that prior to the hearing before the ALJ, Health Integrity, a non-party participant at the hearing, submitted a substantive paper position which detailed new arguments on both the extrapolation method and on the denial bases for the individual claims. (Dkt. # 21 at 8.) Plaintiff contends that in addition to the paper, Health Integrity's legal counsel also directed hours of testimony from its witnesses during the hearing. (Id.) However, Plaintiff asserts that presenting both a paper and witness testimony at the hearing is contrary to 42 C.F.R. § 405.1010. Because Defendant violated this regulation, Plaintiff contends that the MAC's ultimate decision is not supported by substantial evidence.

In response, Defendant contends that Health Integrity, as a non-party participant at the hearing, could provide both a paper and testimony as evidence. (Dkt. # 25 at 32.) Defendant further asserts that the options to provide a paper or testimony at the hearing are not mutually exclusive under § 405.1010. (Id.) As such, Defendant argues that Plaintiff's ability to present its case was not compromised by the appearance and testimony of Health Integrity's witnesses, that the ALJ conducted the hearing fairly and professionally, and Plaintiff had a fair opportunity to present its case. (Id. at 33.)

42 C.F.R. § 405.1010 addresses "[w]hen CMS or its contractors may participate in an ALJ hearing." 42 U.S.C. § 405.1010. The section states, in relevant part, "[a]n ALJ may request, but may not require, CMS and/or one or more of its contractors to participate in any proceedings before the ALJ, including the oral hearing, if any. CMS and/or one or more of its contractors may also elect to participate in the hearing process." Id. § 405.1010(a). The regulation further states that "[p]articipation may include filing position papers or providing testimony to clarify factual or policy issues in a case, but it does not include calling witnesses or cross-examining the witnesses of a party to the hearing." Id. § 404.1010(c).

Health Integrity participated in the hearing as a CMS contractor, but not as a party; thus, § 405.1010 is applicable. In accordance with that section,

Health Integrity had the ability to file position papers or provide testimony to clarify factual or policy issues in the case. The record in this case demonstrates that Health Integrity submitted a position paper to the ALJ in accordance with § 405.1010. (AR Vol. 2 at 14–160.[1]) The position paper contains a chart summarizing the medical review findings in regard to the denial of Plaintiff's claims. The letter accompanying the paper states that it "was submitted to assist the Court by summarizing Health Integrity's nurse reviewer's testimony to be given at the hearing." (Id. at 14.) Health Integrity also submitted a rebuttal paper, entitled "Statistical Expert Response to the Statistical Expert Interrogatories of Harold S. Haller, PhD."[2] (Id. at 4.)

A. Health Integrity's Testimony

1. Aimee Mann

At the hearing itself, Health Integrity presented testimony from its Chief Statistician, Aimee Mason. (AR Vol. 45 at 257.) Mason's testimony at the hearing focuses on her review of "the statistical sampling and overpayment extrapolation performed on [Plaintiff]." (Id.) After testifying about her review of

[1] Citation is to the Administrative Record ("AR") filed under seal via disc. (See Dkt. # 19.)

[2] Dr. Haller submitted a paper and testified on behalf of Plaintiff at the hearing. (See AR Vol. 45.)

the sampling and extrapolation methodologies, the ALJ asked for clarification regarding some of the areas of her testimony. (Id. at 266.) After attempting to clarify her position in answer to the ALJ's question, Mason began testifying about Plaintiff's burden, as the provider, to show that each service should be covered by Medicare and that "there are many factors that may affect whether a claim is paid or denied . . . ." (Id. at 267–68.) At that point, Plaintiff's counsel objected, stating that this testimony is "outside of the witness's scope [because she was called] to participate in the hearing to clarify on factual and policy issues on the extrapolation and methodology only, not as to Medicare coverage criteria or claim." (Id. at 268.) At that point, the ALJ stated "I think I need to allow some of this . . . in order for her to be able to explain her reasoning as to whether or not the claims would be independent or not independent of each other." (Id.) However, the ALJ then stated that he believed she "explained that sufficiently," and no further testimony was elicited from Mason at that point. (Id.)

Subsequently, Mason testified again for Health Integrity after Dr. Haller testified on behalf of Plaintiff. (Id. at 280.) Mason was asked whether there was anything she "would like to add to further explain how a claim—a home health claim can be a[n] independent sampling unit." (Id.) Mason then testified in explanation to the question without any objection from Plaintiff's counsel. (Id.)

2. Judy Lerner

Health Integrity also called Registered Nurse Judy Lerner to testify. (AR Vol. 45 at 342.) Lerner's testimony explained the process by which Health Integrity conducts its medical reviews with respect to home health services. (Id.) Health Integrity's counsel then asked Lerner about her review of a denied Medicare beneficiary claim and the basis for that denial. (Id.) At that point, Plaintiff's counsel objected to the question, referencing § 405.2010 and stating that "additional testimony as to [the denied] beneficiaries and the findings are [not] necessary since . . . Health Integrity has already submitted its papers." (Id. at 346.) The ALJ overruled the objection and permitted Lerner to testify concerning the specifics of the denied beneficiary. (Id.)

B. MAC's Decision

Upon review of the ALJ's decision, the MAC determined that the ALJ did not err by allowing Health Integrity's statistician and medical reviewer to testify at the hearing. (Dkt. # 1-2 at 14.) The MAC stated that Plaintiff's counsel interpreted § 405.1010 too narrowly because "the regulation uses the phrase 'may include' in explaining the actions permitted a non-party participant." (Id.) The MAC indicated that, in its view, "this phrase indicates that the items 'filing position papers' and 'providing testimony' are examples of ways in which a participant may accomplish its role of clarifying factual or policy issues in a case."

(Id.) The MAC further stated that "[t]he phrase 'may include' also suggests that the two items do not represent an exclusive list of the actions permitted a non-party participant. Nor does the phrase suggest that the use of the word 'or' is intended to be read so that the selection of one option precludes the other." (Id.)

Thereafter, the MAC decided that Plaintiff's "ability to present its case was [not] in any way compromised by the appearance and testimony of [Health Integrity's] witnesses." (Id.) The MAC stated that, upon review of the audio of the ALJ hearing, "[t]he testimony of [Health Integrity's] witnesses fell squarely within the parameters defined by regulation: i.e. they provided factual or policy clarification on the issues before the ALJ." (Id.) Further, the MAC decided that "[c]onsistent with limits set in the regulation, the ALJ did not permit [Health Integrity's counsel] to call witnesses unaffiliated with [Health Integrity] or to cross-examine [Plaintiff's] witnesses." (Id.) The MAC also noted that "[t]he hearing regulations generally grant ALJ's considerable discretion in conducting hearings," and that "[t]he ALJ conducted the hearing in this case professionally and fairly," and Plaintiff "had a full and fair opportunity to present its case." (Id.)

C. Court's Review of MAC's Decision

Upon review, the Court finds that the MAC applied the proper legal standard in interpreting § 405.1010. The Court must give substantial deference to the MAC's interpretation of the regulation. See Girling Health Care, 85 F.3d at

215. The MAC's interpretation of this statute— that it is broad enough to allow a non-party participant at the hearing to both file position papers as well as provide testimony—does not conflict with the plain language of the regulation. The language of the regulation clearly states that participation "may include" such evidence as "filing position papers or providing testimony." 42 C.F.R. § 405.1010(c). The plain language of the regulation does not state that a participant must choose only one of those means to present evidence at the hearing. In such case, the Secretary's interpretation of the statute was not improper.

Additionally, substantial evidence supports the MAC's decision that Health Integrity's witnesses' testimony were within the purview of § 404.1010's requirement that such evidence is allowed only "to clarify factual or policy issues in a case." Id. Mason's testimony provided clarification on the sampling and extrapolation methodologies used by Health Integrity on Plaintiff's claims. After Plaintiff objected to her testimony concerning the factors which determine whether a claim is paid or denied, no further testimony on that subject was elicited from Mason. Lerner first testified on Health Integrity's process of paying Medicare claims; her subsequent testimony concerned the factual issues surrounding the denial of a specific Medicare beneficiary's claim. Although Plaintiff objected to the second part of Lerner's testimony, there is substantial evidence supporting the MAC's determination that this testimony "provided factual or policy clarification

on the issues before the ALJ." (See Dkt. # 1-2 at 15.) Accordingly, substantial evidence supports the MAC's determination that the ALJ properly allowed Health Integrity's witnesses to testify, in addition to filing a position paper, at the hearing.

II. MAC's Decision on Extrapolation

Plaintiff next contends that the MAC's decision on the issue of Health Integrity's sampling and extrapolation methodology was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and regulation. (Dkt. # 21 at 9.) Specifically, Plaintiff asserts that the MAC incorrectly concluded that Health Integrity met the minimum standards stated in the Medicare Program Integrity Manual ("MPIM"), reversing the ALJ's decision to reject the statistical sampling and extrapolation methodology. (Id.) Plaintiff argues that the MPIM requires Health Integrity to use statistically valid sampling methodology when extrapolating, but that it failed to do so in this case. (Id.)

In response, and in moving for summary judgment, Defendant contends that the sampling methodology used by Health Integrity provides a statistically valid basis for calculating the overpayment amount. (Dkt. # 25 at 13.) Defendant asserts that Plaintiff has not met its burden to show that the MAC's decision was erroneous. (Id.) Defendant also argues that substantial evidence supports the MAC's decision that the sampling and extrapolation were valid. (Id.)

A. Statistical Sampling Requirements

The MPIM lists the steps a Medicare contractor must follow in conducting a statistical sample for overpayment calculation. (CMS Pub. 100-08 ("MPIM"), § 8.4.1.4.)[3] The steps are: (1) select the provider or supplier, (2) select the period to be reviewed, (3) define the universe, sampling unit, and sampling frame, (4) design the sampling plan and select the sample, (5) review each of the sampling units and determine if there was an overpayment or underpayment, and, as applicable, (6) estimate the overpayment. (Id.)

The MPIM's instructions regarding statistical sampling "are provided to ensure that a statistically valid sample is drawn and that statistically valid methods are used to project an overpayment where the results of the review indicate that overpayments have been made." (Id. § 8.4.1.1.) The MPIM further states that failure by the contractor "to follow one or more of the requirements contained herein does not necessarily affect the validity of the statistical sampling that was conducted or the projection of the overpayment. An appeal challenging the validity of the sampling methodology must be predicated on the actual statistical validity of the sample as drawn and conducted." (Id.)

[3] The sampling guidelines were located in Chapter 3 of the MPIM at the time of the sampling, but they are now located in Chapter 8. (See Dkt. # 1-2 at 7 n.1.)

B. ALJ's Determination

In reviewing the statistical sampling method used by Health Integrity, the ALJ determined that it was not performed in accordance with MPIM and therefore was invalid. (AR Vol. 1 at 408.) Specifically, after considering the testimony and evidence regarding the statistical sampling and extrapolation methodologies presented by both Plaintiff and Health Integrity, the ALJ determined that "[t]here were multiple deficiencies in the statistical sampling methodology performed by Health Integrity," including (1) its "[f]ailure to keep a record of the random numbers actually used in the sample as required by the [MPIM]"; (2) "[f]ailure to properly define sampling units"; (3) [f]ailure to demonstrate sampling units' independence"; and (4) "[f]ailure to demonstrate average overpayment was normally distributed." (Id. at 419.)

In making this determination, the ALJ considered the opinion evidence of Health Integrity's statistician, Aimee Mason, as well as Plaintiff's expert witness, Dr. Haller. (Id.) With regard to Mason, the ALJ stated that

> Health Integrity's expert credibly opined at the hearing that all the documentation was complete, that sufficient information was retained and provided to Appellant thereby allowing the sampling to be replicated, and that she was able to replicate the random sample. Health Integrity also opined that the actual error rate was 98% and that the Program Integrity Manual does not require any particular precision level. She summarily maintained that Health Integrity performed its statistical sampling analysis and extrapolation strictly in accordance with the Program Integrity Manual.

(Id. at 420.) The ALJ further stated that

> Health Integrity's expert opined that the sample size was 40 claims which it claimed were randomly selected from the 130 claims in the universe. The selection was done using [the statistical program] in a manner that each and every claim in the universe had an equal chance of being selected. She opined that the [the statistical program] code used to generate the random sample generated a probability sample. The [the statistical] program and [the statistical program] log contain the algorithm and seed value used to select the sample and both of these files were part of the record. She claimed that the sampling methodology report documented the source of the random numbers used to select the sampling units.

Thereafter, the ALJ considered Plaintiff's expert Dr. Haller's testimony concerning the statistical sample and extrapolation method used by Health Integrity. The ALJ determined, contrary to Mason's testimony, that

> Dr. Haller opined that no such list of random numbers was included in the documents and that the random numbers used to draw the random sample should have been included in the material reviewed. This was a flaw in failing to meet the MPIM's requirements that a mandatory "probability sample" must be based on [a] randomly selected sample. At minimum, Health Integrity failed to keep a record of the random numbers actually used in the sample as required by the MPIM § 3.10.4.1.
>
> In addition, there were concerns regarding the sampling units. Dr. Haller opined that the MPIM § 3.10.3.2.2 requires that the sampling units be defined correctly and that the sampling units be independent. Dr. Haller opined that Health Integrity chose aggregated claim lines for a claim, identified by a Claim Number (CN) as the sampling unit and that with this choice as a sampling unit, the statistical independence of the sampling units was compromised. The reason for this is that the same beneficiary as designated by a HICN could and probably had several CN's in the frame and in the sample. When this is the case, the probability of denying a CN for a HICN is not independent of denying another CN for the same HICN. The frame

> and the sampling units must be set up such that the sampling units when randomly drawn will be statistically independent. Since the sampling units in the frame are **not** statistically independent because there are multiple CNs per HICN, this rendered the sampling process invalid. He opined that the sampling units were not statistically independent, which suggests that the CLT and confidence interval methods cannot be used. He opined that the sample did not appear random because the distribution of the #CNs/HICN was significantly different for the frame and the universe and there were incorrect formulas used for estimation and extrapolation based on the CLT and confidence intervals which too rendered the [statistical sampling and overpayment extrapolation] invalid.

(Id. at 420). The ALJ further stated that

> Dr. Haller opined that Health Integrity used the method of point estimate and confidence limits in the analysis of overpayments to providers and in extrapolation the results of overpayments to providers from the sample to the entire universe of claims. However, Dr. Haller opined that the distribution of average overpayments was not normally distributed. Health Integrity failed to use correct formulas for extrapolation. Health Integrity's extrapolation of the overpayment to the universe based on a 90% confidence interval was not appropriately used given the failure to show that the distribution of average overpayments was normally distributed. In order to use the Central Limit Theorem (CLT) to compute the lower confidence limit, the random sample used to compute the average overpayment must be from a frame of "independent, identically distributed, random variables." This form of independence is completely separate from the random selection of sampling units from the frame. Since there were multiple claims associated the same Beneficiaries, this raises the question of whether the sampling units were statistically independent.

(Id.) The ALJ also stated that

> Health Integrity maintained that it was not required to perform a probe sample. I agree with Health Integrity's position and find no such requirements in the manual. Specifically, the manual provides guidance before Contractors deploy significant medical review resources to examine claims identified as potential problems from

> data analysis. This guidance includes taking the interim step of selecting a small "probe" sample of potential problem claims (prepayment or postpayment) to validate the hypothesis that such claims are being billed in error. Therefore, while it would be prudent for Contractors to use a probe sample prior to deploying significant medical review resources to examine claims identified as potential problems from data analysis, there is no such requirement that Contractors must conduct a probe sample. (Emphasis added). Therefore, Appellant's expert submission by the Contractor's failure to use a probe sample did not render the statistical sampling portion of this case invalid. Rather the deficiencies as discussed above rendered the statistical sampling fatally flawed and invalid.

(Id. at 420–21.) The ALJ then opined that "[d]eficiencies in the statistical sampling process nullify the results obtained from the statistical sampling findings." (Id. at 421.)

The ALJ further determined that "there was sufficient evidence to conclude that the statistical sampling analysis performed by Health Integrity did deviate from Medicare requirements and was fatally flawed." (Id.) The ALJ then "set aside the statistical sample as invalid" and stated that because "the sample is invalid, any results of the extrapolation are invalid as well." (Id.)

C. MAC's Review of ALJ's Decision

In issuing its determination, the MAC first observed that CMS Ruling 86-1 describes the agency's policy on the use of statistical sampling to project overpayments to Medicare providers, and outlines the statutory and precedential history and authority, for the use of statistical sampling and extrapolation by CMS

or its contractors in calculating overpayments. (Dkt. # 1-2 at 6.) The ruling provides, in relevant part:

> Sampling does not deprive a provider of its rights to challenge the sample, nor of its rights to procedural due process. Sampling only creates a presumption of validity as to the amount of an overpayment which may be used as the basis for recoupment. The burden then shifts to the provider to take the next step. The provider could attack the statistical validity of the sample, or it could challenge the correctness of the determination in specific cases identified by the sample (including waiver of liability where medical necessity or custodial care is at issue). In either case, the provider is given a full opportunity to demonstrate that the overpayment determination is wrong. If certain individual cases within the sample are determined to be decided erroneously, the amount of overpayment projected to the universe of claims can be modified. If the statistical basis upon which the projection was based is successfully challenged, the overpayment determination can be corrected.

(Id. at 6–7 (citing CMS Ruling 86-1-9 & 86-1-10)). The MAC further observed that Health Integrity's statistical sampling guidelines are found in Chapter 3 of the MIPM, § 3.10,[4] and went on to cite and summarize in detail the provisions most pertinent to the case before it. (Id. at 7–11.)

After review of these provisions, the MAC determined that the ALJ erred by invalidating the statistical sampling and overpayment extrapolation undertaken by Health Integrity. (Dkt. # 1-2 at 15.) The MAC further stated that considering the language in Rule 86-1, the use of statistical sampling "creates a

[4] As previously stated, these provisions are now located in Chapter 8 of the MIPM. (See Dkt. # 1-2 at 7 n.1.)

presumption of validity" and that "the burden then shifts to the provider to take the next step." (Id.) The MAC concluded that based on this provision, "the ALJ erred as a matter of law in her application of CMS Rule 86-1 and MPIM guidance and erred as a matter of fact by concluding that the evidence of record establishes that the statistical sampling and extrapolation were invalid. (Id.)

Turning to whether the evidence upon which the ALJ relied was sufficient to invalidate Health Integrity's sampling methodology, the MAC noted that the ALJ primarily relied on the expert opinion of Dr. Haller in concluding that Health Integrity failed to perform the statistical sampling in accordance with CMS guidelines. (Id. at 16.) The MAC disagreed with Dr. Haller's opinion that the standards for precision sampling in leading texts on the matter are incorporated by reference into the MPIM. (Id.) Instead, the MAC stated that "it is the standards found in CMS Ruling 86-1 and the MPIM that govern Medicare sampling and overpayment estimation; not those found in statistics texts and references. ALJs and Council are bound by all laws and regulations concerning the Medicare program and all CMS Rulings." (Id.) The MAC further stated that "ALJs and Council are not bound by CMS administrative authority, but are required to afford 'substantial deference' to that authority when applicable in a given case or explain the reasons for not doing so in the decision." (Id.) As such, the MAC determined that "[t]he ALJ erred in relying on Dr. [Haller's] opinion that the statistical sample

is invalid, to the extent that [the] opinion is based upon statistical sampling treatises (or industrial sampling practices) that are not binding upon Medicare adjudicators and do not adequately consider the administrative authority set forth above, which permits more flexibility and imprecision in sampling than the standard statistical texts and treatises contemplate."[5] (Id.) The MAC stated that Dr. Haller's "opinion appears to be based on a misapprehension of the role of the line items claims within the home health prospective payment system, and the requirement that a provider on medical review must demonstrate that each service independently meets Medicare coverage and payment criteria." (Id.)

In reviewing the written paper and testimony of Health Integrity's statistician, the MAC determined that the record supports Mason's conclusion that the sampling and extrapolation used in the present case satisfied MPIM requirements. (Id. at 17.) The MAC also reviewed Health Integrity's nurse reviewer Lerner's testimony at the ALJ hearing. (Id. at 18.) The MAC determined that "[b]ased on the sampling documentation and testimony of [Health Integrity's] statistician, the Council concludes that the sampling at issue resulted in a

[5] In a footnote, the MAC also stated that it reviewed the relevant sections of the treatise relied on by Dr. Haller and determined, after its review of the treatise, that it does not "support[] the position that any methodology which does not precisely follow these nine steps is, per se, not statistically valid." (Dkt. # 1-2 at 16 n.3.)

probability sample, giving rise to the presumption that the projected overpayment amount is valid, in accordance with CMS Ruling 86-1." (Id.)

Thereafter, in accordance with CMS Ruling 86-1, the MAC considered whether Plaintiff's and Dr. Haller's objections to Health Integrity's sampling and extrapolation methodology were sufficient to overcome the presumption of their validity. (Id.) The MAC determined that any "perceived shortcomings in [Health Integrity's] methodology identified by Dr. H[aller] . . . do not demonstrate that the sampling and extrapolation were invalid." (Id.) First, the MAC stated that Dr. Haller's conclusion that that sampling was invalid because Health Integrity failed to show its methodology was reviewed by a statistician with at least a Master's degree or equivalent experience is without merit. (Id.) The MAC stated "[t]he record demonstrates that two [Health Integrity] statisticians, H.P. and [Aimee Mason], reviewed [Health Integrity's] methodology." (Id. at 18–19.) The MAC found that the curriculum vitae of both statisticians indicate that each has at least a Master's degree and that Dr. Haller's observation is "factually inaccurate, perhaps because the ALJ did not furnish these exhibits to Dr. H[aller]." (Id. at 19.)

However, the MAC agreed with the ALJ's determination that the MPIM does not require a probe sample as a condition precedent to undertaking statistical sampling for overpayment estimation. (Id.) The MAC also stated that,

contrary to Plaintiff's expert's opinion, Health Integrity's failure to include a list of the actual random numbers used in the sample was not a flaw that rendered the sample invalid. (Id.) The MAC opined that "the MPIM does not require that the list of random numbers be provided"; instead, "it is sufficient if the seed number and the algorithm used are provided, so that it is possible to replicate the sample." (Id.) Therefore, the MAC determined that because Plaintiff's experts did not state that they could not "replicate the sample," Health Integrity's failure to provide a list of the actual random numbers used in the sample does not render the sample invalid. (Id.)

Next, the MAC determined that the ALJ's reliance on Dr. Haller's conclusion regarding the invalidity of the sampling and extrapolation methodologies was in error. (Id.) The MAC stated that, "[f]irst of all, the record does not establish by a preponderance of the evidence that the sampling units are not independent" because "only one of three expert witnesses opined that the sampling units are, in fact, dependent." (Id. at 21.) The MAC agreed with CMS that Dr. Haller's opinion on the issue was "speculative at best." (Id.) Further, the MAC concluded that the "selection of claims as sampling units is expressly endorsed by the MPIM" and that Dr. Haller's "contrary assertion that confidence interval extrapolation requires the sampling units be wholly independent represents another example of Dr. H[aller's] effort to incorporate by reference academic

standards that are not contemplated in CMS guidance or consistent with real-world Medicare practices." (Id. at 21–22.)

The MAC also reviewed Plaintiff's argument that the sampling and extrapolation used by Health Integrity is invalid because it resulted in a precision of eight percent, where regulations require "federal agencies conducting statistical sampling and extrapolation to attain a precision of plus or minus 2.5 percentage points with a 90 percent confidence level." (Id. at 22.) However, the MAC found that the regulation relied on by Plaintiff is inapplicable because it does not apply to sampling for Medicare overpayment estimation. (Id.) Rather "the precision standard" applies "to the Department's reporting of certain erroneous payments in the Medicare program as a whole, but it does not apply to the calculation of an overpayment to an individual provider." (Id. (emphasis in original)). Instead, the MAC determined that CMS Ruling 86-1 and the MPIM provide the appropriate standards for this purpose. (Id. at 23.)

The MAC then determined that Dr. Haller's opinion that "the sample as drawn may not validly be used to extrapolate the overpayment in this case because the average overpayments in the sample are not normally distributed is without merit." (Id.) The MAC concluded that, "once again, as is true for many of the issues discussed above, Dr. H[aller's] attempts to impose standards derived from academic texts, when such standards are not contemplated or required by

CMS." (Id.) The MAC stated that "[c]ontrary to Dr. H[aller's] opinion, the relevance of the Central Limit Theorem in this case, as in many of the overpayment cases involving statistical sampling, is that it demonstrates that a single sample of limited size is sufficient to obtain a representative sample even if the overpayments in the sample are not normally distributed. This is because the mean of a large number of repeated samples will tend to follow a normal distribution, under these circumstances." (Id.)

The MAC concluded "[i]n summary, as the MPIM emphasizes, if a particular probability sample design is properly executed, i.e., defining the universe, the frame, the sampling units, using proper randomization, accurately measuring the variables of interest, and using the correct formulas for estimation, then assertions that the sample and its resulting estimates are 'not statistically valid' cannot legitimately be made." (Id. at 24.) The MAC stated

> Suffice it to say, given MPIM provisions, the fact that [Health Integrity] selected a sampling methodology or sample size that another statistician may not prefer, or which may not result in the most precise point estimate, does not provide a basis for invalidating the sampling or the extrapolation as drawn and conducted in this case. These are simply not 'flaws' in the sampling cognizable by the guidelines which render the actual sample drawn invalid. To hold otherwise would ignore real world constraints imposed by conflicting demands on limited public funds, constraints which CMS chose to incorporate into the statistical sampling guidelines. The Council must give substantial deference to CMS guidelines including where, as here, CMS has chosen a reasonable, feasible, and well-articulated approach for collecting overpayments which, by design, offsets prevision in favor of lower recovery amounts. To the extent that Dr.

> H[aller] or other statisticians have significant concerns with the parameters of CMS's statistical sampling guidelines, those concerns should be raised by CMS, as the Council has no authority to invalidate CMS guidelines.

(Id. (emphasis in original.) Accordingly, the MAC concluded that "the ALJ erred by invalidating the sampling extrapolation in this case." (Id. at 25.)

D. Court's Review of MAC's Decision

Upon review, the Court finds that substantial evidence supports the MAC's overall determination that the ALJ erred by invalidating the statistical sampling and overpayment extrapolation undertaken by Health Integrity.

1. Statistician Qualifications

First, the MAC correctly noted that, contrary to Plaintiff's assertion, at least one of Health Integrity's statisticians had at least a Master's degree. Indeed, Health Integrity's Chief Statistician, Holly Pu, holds a Master's degree and was a Ph.D. Candidate at the time of review. (AR Vol. 2 at 340.)

2. Probe Sample

Substantial evidence likewise supports the MAC's agreement with the ALJ that the MPIM does not require a probe sample as a condition precedent to undertaking statistical sampling for overpayment estimation. As the MAC pointed out in its decision, neither CMS Ruling 86-1 nor the MPIM explicitly require that a probe sample be taken before a statistical sample for overpayment estimation is drawn. (See Dkt. # 1-2 at 18; CMR Ruling 86-1; MPIM.) The MAC's

determination relied on Health Integrity's statistician, who testified that MPIM guidance on probe samples is directed at Medicare contractors who conduct post-payment review, not on Health Integrity's review of integrity activities. (See AR Vol. 45 at 260–61.) The statistician testified that Health Integrity was "not required to select or perform a probe sample in this case." (Id. at 261.)

3. Random Numbers

Additionally, substantial evidence supports the MAC's decision to rely on MPIM guidance when determining that Health Integrity's failure to include a list of the actual random numbers used in the sample was not a flaw which rendered the sample invalid. Plaintiff's experts, Dr. Haller and Dr. Jeffrey Witmer, both opined that the failure to include the actual random numbers was a fatal flaw in the sampling methodology. (AR Vol. 2 at 316, 331.) The relevant MPIM provision states that "[a] record shall be kept of the random numbers actually used in the sample and how they were selected." (MPIM § 8.4.4.4.1.) However, the MPIM also states that it is sufficient if documentation, such as the seed number and the algorithm, is maintained so that the sample can be replicated if the methodology is challenged. (Id.)

In this case, Health Integrity's statistician testified that using HHS's statistical software package, she was able replicate the sample using the seed number and the sampling frame, and provided this information to both Plaintiff and

the ALJ. (AR Vol. 45 at 258–59, 264– 65.) Additionally, neither of Plaintiff's experts testified that they were unable to replicate the sample based on the sample documentation. In fact, Dr. Haller's written report notes the steps that could be taken to replicate the random numbers using the seed number and random number generator. (AR 2 at 325.) Accordingly, substantial evidence supports the MAC's decision that Health Integrity's failure to include the actual random numbers used in the sample does not render the sampling invalid, because the sample could still be replicated in accordance with the MPIM.

4. Dependent Sampling Units

Substantial evidence also supports the MAC's conclusion that the ALJ improperly relied on Dr. Haller's conclusions regarding the dependence of the sample units. Dr. Haller's report stated that Health Integrity's choice to use aggregated claim lines for a claim "imperiled statistical independence of the sampling units" because there are multiple claims per beneficiary in the frame and thus they cannot be statistically independent of each other. (AR Vol. 2 at 330.)

In making its determination, the MAC relied on Health Integrity's statistician who testified that although "a beneficiary may have multiple claims in the universe, . . . each are for a different date of service." (AR 45 at 267.) The statistician further stated that "essentially, each claim submission is separate from another claim submission" and that "each claim must be individually supported."

(Id.) Additionally, the MPIM provides that sampling units "may be an individual line(s) within claims, individual claims, or clusters of claims (e.g. a beneficiary)." (MPIM § 8.4.3.2.2.) Thus, the MPIM does not refer to "independent" sampling units or require Health Integrity to distinguish that the probability of denying one sampling unit is independent of another sampling unit. Accordingly, substantial evidence exists in support of the MAC's decision that Dr. Haller's opinion was "speculative at best" and that Health Integrity's use of claims as a sampling unit was not invalid.

5. Precision

Likewise, there is substantial evidence to support the MAC's conclusion that the ALJ relied on an improper standard regarding statistical sampling. The ALJ relied on a standard which requires federal agencies attain a precision of plus or minus 2.5 percentage points with a ninety percent confidence interval. The regulation, OMB Circular A-123, Appendix C, implements the requirements of the Improper Payments Information Act of 2002 ("IPIA"). Improper Payments Information Act of 2002, Pub. L. No. 107-300. The IPIA requires federal agencies to annually report to Congress their estimates of the amount of improper payments made in programs that are susceptible to "significant improper payments." Id. at 5. According to the IPIA, a "significant improper payment" is one that exceeds both "1.5 percent of program outlays and

$10,000,000 of all program or activity payments" made in a year. Id. at 9. Contrary to Plaintiff's expert's opinion, this reporting requirement does not apply to the actual calculation of Medicare overpayments to providers.

Instead, CMS guidance does not require reliance on a specified level of precision in estimating overpayments. The MPIM provides that:

> In most situations the lower limit of a one-sided 90 percent confidence interval shall be used as the amount of overpayment to be demanded for recovery from the provider or supplier. The details of the calculation of this lower limit involve subtracting some multiple of the estimated standard error from the point estimate, thus yielding a lower figure. This procedure, which, through confidence interval estimation, incorporates the uncertainty inherent in the sample design, is a conservative method that works to the financial advantage of the provider or supplier. That is, it yields a demand amount for recovery that is very likely less than the true amount of overpayment, and it allows a reasonable recovery without requiring the tight precision that might be needed to support a demand for the point estimate.

MPIM § 8.4.5.1. The MPIM therefore does not require a specific level of precision. Accordingly, there is substantial evidence to support the MAC's determination that both CMS Ruling 86-1, which presumes the validity of the sampling method, and the MPIM provide the appropriate standards for Health Integrity to apply in its statistical sampling and extrapolation of overpayments. Substantial evidence also supports the MAC's determination that Health Integrity's method was in compliance with the precision requirements in the MPIM.

6. Normal Distribution

Substantial evidence also exists to support the MAC's conclusion that the ALJ improperly relied on Dr. Haller's opinion that the sample as drawn is invalid because the average overpayments in the sample are not normally distributed. As stated earlier, according to Dr. Haller, the abnormal distribution of the average overpayments in the sample by Health Integrity undermines the applicability of the Central Limit Theory ("CLT") and therefore there is a 95% probability that the demand for overpayment in this case is for less than the amount of the actual overpayment. (AR Vol. 2 at 334.)

The MAC, however, determined that Dr. Haller was imposing standards greater than what is required in CMS Ruling 86-1 or the MPIM. Indeed, the MPIM provides that it is acceptable for a contractor to recover an amount "that is very likely less than the true amount of overpayment" and "allows a reasonable recovery without requiring the tight precision that might be needed to support a demand for a point estimate." MPIM § 8.4.5.1. On these grounds, the MAC sufficiently concluded that Plaintiff had failed to carry its burden of showing that the statistical sample was invalid, and not simply that "another statistician might construct a different or more precise sample." John Balko & Assocs., Inc. v. Sec'y U.S. Dep't of Health & Human Servs., 555 F. App'x 188, 194 (3d Cir. 2014). Here, Plaintiff fails to identify a specific part of the record that renders the MAC's

conclusion erroneous. Therefore, substantial evidence supports the MAC's determination.

III. Medicare's "Rule of Thumb"

Plaintiff next argues that the MAC erred in concluding that CMS and Health Integrity properly construed Medicare's "Rule of Thumb" in determining home-health claim denials. (Dkt. # 21 at 11.) Specifically, Plaintiff contends that Health Integrity violated the rule by reviewing only forty claims, but projecting the denial of those claims across ninety additional claims. (Id. at 11–12.) Plaintiff asserts that each claim must be reviewed independently before it is denied. (Id. at 12.)

The MAC found that applying the "Rule of Thumb" would "preclude the use of statistical sampling and extrapolation for overpayment estimation in any case involving home health services." (Dkt. # 1-2 at 24 n.7.) The MAC continued, "appellant points to no authority for such a sweeping proposition and the Council is aware of none. We therefore conclude that the asserted 'rule of thumb' prohibition is not a bar to the extrapolation of the overpayment in this case." (Id.)

The "Rule of Thumb" provision is located in the Medicare Benefit Policy Manual ("MBPM") and states "Medicare recognizes that determination of whether home health services are reasonable and necessary must be based on an assessment of each beneficiary's individual care needs. MBPM Chap. 7 § 20.3.

Therefore, denial of services based on numerical utilization screens, diagnostic screens, diagnosis or specific treatment norms is not appropriate."

As the MAC concluded in its review, Plaintiff fails to cite any authority for the proposition that Health Integrity violated Medicare's "Rule of Thumb" in denying Plaintiff's claims. Additionally, Plaintiff has not suggested any alternative means to calculate the overpayment in this case that would not violate the "Rule of Thumb." Accordingly, the Court finds that the MAC's determination regarding the "Rule of Thumb" provision in this case is based on sufficient legal reasoning and evidence.

IV. Individual Claims

Plaintiff further moves for summary judgment on the ground that the individual claims presented for payment met Medicare coverage criteria, were properly presented, and fully payable. (Dkt. # 21 at 13.) Plaintiff contends that a review of the record and witness testimony from the hearing before the ALJ demonstrates that the MAC failed to account for the evidence in support of payment on each individual claim.[6] (Id.)

[6] Plaintiff asks the Court to adopt Plaintiff's "Request for MAC Review" argument and "testimony given during the ALJ hearing" given the volume of the administrative record. (See AR Vol. 1 at 38–238; Vol. 45.) The Court will adopt this evidence for purposes of the competing summary judgment motions in this case.

Defendant also moves for summary judgment on the individual claims, arguing that the MAC's decision is supported by substantial evidence in the record. (Dkt. # 25 at 25.) Defendant asserts that Plaintiff has failed to meet its burden of establishing entitlement to Medicare payment with respect to the thirty-eight denied claims. (Id. at 26.) Defendant contends that Plaintiff's submission to the MAC and to this Court "did not specify any instances of error in the ALJ's extensive claim-by-claim analysis," but argues only that the MAC "got it wrong." (Id.)

A. Homebound Status

Plaintiff argues that while the MBPM requires a physician to certify in all cases that a patient is confined to his or her home, an individual does not have to be bedridden to be considered confined to the home. (AR Vol. 1 at 53–54.) Specifically, Plaintiff argues that "[a]ny absence of an individual from the attributable to the need to receive health care . . . shall not disqualify an individual from being considered to be confined to the home." (Id. at 54.) Plaintiff contends that claims should not have been denied on this basis. (Id.)

Defendant responds that the MAC found that the ALJ gave weight to beneficiary interviews conducted by Health Integrity investigators, and determined that the interviews were reliable in regard to homebound status. (Dkt. # 25 at 27.) The ALJ determined that "Appellant had numerous opportunities to assess the

functional abilities and homebound status of the Beneficiaries when its nurses made their home visits but it did not do so . . . . While it is true that these interviewers were conducted one to two years after the dates of service at issue, the interviews provide the strongest and most detailed available evidence of the functional abilities and homebound status of the Beneficiaries at the time the services were rendered." (AR Vol. 1 at 406.) The MAC found no error in this reasoning of the ALJ's assessment and consideration of the interviews.

The MAC also found no error with the ALJ's determination that a beneficiary, G.M., was not homebound because there was no documentation that the daycare he attended was therapeutic, rather than social. (AR Vol. 1 at 28–29.) Because the record stated only that the program was for "activities," the MAC accepted the ALJ's determination that the claim should be denied because G.M. was not homebound. (Dkt. # 1-2 at 27–28.)

The MAC determined that there was also no error in the ALJ's decision that beneficiaries B.G. and A.P. were not homebound because the record demonstrated that B.G. could vote, attend birthday parties, exercise on her own, and walk to the back gate of her house. (AR 1 at 378.) Additionally, the record demonstrated that A.P. was not homebound because she could go out of town and do yard work. (Id. at 386.)

The MAC concluded that Plaintiff had failed to identify any error in the ALJ's determination that seventeen claims did not qualify for home health care on the dates of service at issue because the beneficiaries were not homebound. (Dkt. # 1-2 at 28.) Likewise, in its motion for summary judgment, Plaintiff has failed to produce any evidence of error in the ALJ's, and ultimately, the MAC's decision that the seventeen claims were properly denied on the basis that they were not homebound. Therefore, substantial evidence exists in support of the MAC's determination that the beneficiaries at issue were not homebound.

B. Medical Necessity for Skilled Nursing Services

Plaintiff contends that the ALJ failed to consider section 40.1.1 of the MBPM, which concerns "General Principles Governing Reasonable and Necessary Skilled Nursing Care." (AR 1 at 55.) The relevant provision states that "the determination of whether services are reasonable and necessary should be made in consideration that a physician has determined that the services ordered are reasonable and necessary." (MPIM, Chap. 7 at § 40.1.1.) In reviewing Plaintiff's objection, the MAC determined that Plaintiff was essentially arguing the "treating physician rule," which means that the opinion of the treating physician is entitled to greater weight in such proceedings. (Dkt. # 1-2 at 29.) The MAC nonetheless concluded that the treating physician rule was inappropriate in this case and that

Plaintiff had failed to provide a sufficient basis for reconsideration of the ALJ's determination. (Id.)

Contrary to Plaintiff's contention, "if the medical evidence is inconsistent with the physician's certification, the medical review entity considers the attending physician's certification only on a par with the other pertinent medical evidence." CMS Ruling 93-1. There is no presumption that a treating physician's determination is subject to any greater weight in the Medicare context. Therefore, there is substantial evidence in the record to support the MAC's determination the ALJ properly reviewed the record and concluded that, in most instances, the physician's certification for the relevant beneficiary was either unsupported or contradicted by the document in Plaintiff's notes.

C. Insulin Injections

Plaintiff also asserts that the MBPM, Chapter 7, section 40.1.2.4, entitled "Administration of Medications, Insulin Injections," creates an exception to the general rule that home health services must be needed and provided on an intermittent basis. (AR 1 at 56.) This provision states that "[i]nsulin is customarily self-injected by the patients or is injected by their families. However, where the patient is either physically or mentally unable to self-inject insulin and there is no other person who is able and willing to inject the patient, the injections

would be considered a reasonable and necessary skilled nursing service." (MPBM, Chap. 7 at § 40.1.2.4.)

The MAC determined that Plaintiff had failed to offer evidence that would allow a medical reviewer or adjudicator to determine whether nursing services, such as administering insulin, were reasonable and necessary, and therefore payable claims by Medicare. (Dkt. # 1-2 at 31.) The MAC stated that Plaintiff had provided only conclusory documentation in support for its claims that diabetic beneficiaries were physically and/or mentally incapable of self-administering their medication and that no other person could help them. (Id.) The MAC ultimately agreed with the ALJ that the lack of detailed evidence in Plaintiff's documentation resulted in Plaintiff's inability to meet its burden that the claim was payable. (Id. at 32.)

The extensive record in this case indicates that home health claims involved skilled nursing visits to provide insulin injections for at least ten beneficiaries. (AR 1 at 318–56.) The documentation for each of these beneficiaries indicates that they are not capable of self-administering their medication and that no one else could help them; however, there is no further documentation beyond that generic statement. (See id.) For instance, there was no documentation regarding any assessments of the beneficiary's inability to perform the diabetic care, nor is there documentation concerning any attempts to locate and

instruct an alternative caregiver. Accordingly, there is substantial evidence in the record to support the MAC's decision that Plaintiff's claims were properly denied on the basis of a lack of documentation for these claims.

V. Due Process

Finally, Plaintiff moves for summary judgment on the basis that it was denied due process when Health Integrity failed to provide it with the statistical sampling and extrapolation information, as well as the beneficiary interview records, during the course of the appeal and prior to the ALJ hearing in 2014. (Dkt. # 21 at 13.) Plaintiff contends that it did not receive this pertinent information until the hearing was set before the ALJ and that it failed to have a "meaningful dialogue" with Health Integrity. (Id.)

Defendant responds that Plaintiff was provided an encrypted CD with an explanation of findings on June 29, 2011, well before the hearing before the ALJ. (Dkt. # 25 at 34.) Defendant contends that Plaintiff had a full and fair opportunity to present its case before the ALJ and that a "meaningful dialogue" is not the standard governing the preliminary stages of this appeal. (Id.)

After a party has "channeled" an action arising under the Medicare Act through the administrative process, a court reviewing an agency determination has the authority to resolve "any statutory or constitutional contention that the agency does not, or cannot, decide." Shalala v. Ill. Council on Long Term Care,

Inc., 529 U.S. 1, 23 (2000). Because this action has been "channeled" through all levels of appeal, the Court may consider Plaintiff's due process claim. See Transyd Enters., L.L.C. v. Sebelius, No. M-09-292, 2012 WL 1067561, at *10 (S.D. Tex. Mar. 27, 2012).

The record in this case indicates that on June 29, 2011, Plaintiff was sent a letter stating that Plaintiff had received Medicare payments in error. (AR 3 at 447.) The letter tells Plaintiff to "refer to the enclosed encrypted CD for an explanation and details of the findings, which include the Provider Summary of Medical Review Findings and the Sampling Methodology." (Id.) Thus, in 2011, well before the hearing before the ALJ, Plaintiff received pertinent information used by Health Integrity. Additionally, the record indicates that Plaintiff was provided relevant information and documentation prior to the hearing before the ALJ. Likewise, Plaintiff provides no evidence that it specifically requested certain documentation and was denied access to it prior to the hearing. In such case, Plaintiff has failed to produce sufficient evidence to survive summary judgment that it was deprived of "notice and opportunity for hearing appropriate to the nature of the case," which is the hallmark of a due process claim. See Transyd, 2012 WL 1067561, at *10 (quoting Mullane v. Cent. Hanover Bank & Tr., 339 U.S. 306, 313 (1950)).

CONCLUSION

For the reasons stated above, the Court (1) **AFFIRMS** the decision of the Medical Appeals Council; (2) **DENIES** Plaintiff's Motion for Summary Judgment (Dkt. # 21); and (3) **GRANTS** Defendant's Cross-Motion for Summary Judgment (Dkt. # 25).

IT IS SO ORDERED.

DATED: San Antonio, Texas, January 20, 2016.

David Alan Ezra
Senior United States Distict Judge