IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF OKLAHOMA

SAN BOIS HEALTH SERVICES, INC.,	
Plaintiff,	
v.	Case No. CIV-14-560-RAW
ERIC D. HARGAN, Acting Secretary and Deputy Secretary of the United States Department of Health and Human Services,[1]	
Defendants.	

ORDER[2]

San Bois Health Care Services, Inc. (hereinafter "Plaintiff") brought this Complaint for

Judicial Review pursuant to 42 U.S.C. § 1395ff(b), seeking review of the final decision of the

Secretary of the United States Department of Health and Human Services (hereinafter

"Defendant") finding that the Medicare program overpaid Plaintiff for certain claims and that the

extrapolated overpayment was based upon a valid sampling methodology. Now before the court

is Plaintiff's motion to reverse the decision of the Medicare Appeals Council (hereinafter "the

Council") [Docket No. 24]. The court has carefully considered the administrative record and the

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[1]   Eric D. Hargan is now the Acting Secretary of the United States Department of Health and Human Services. Pursuant to Federal Rule of Civil Procedure 25(d), this action survives and Eric D. Hargan is automatically substituted as Defendant.

[2]   For brevity, the following abbreviations and acronyms will be used throughout this Order:

>A.R. – administrative record
>ALJ – Administrative Law Judge
>CMS – Centers for Medicare & Medicaid Services
>MACs – Medicare Administrative Contractors
>MPIM – Medicare Program Integrity Manual
>QIC – Qualified Independent Contractor
>SAS – SAS Institute, Inc.
>ZPICs – Zone Program Integrity Contractors

briefing filed in this case, as well as the oral argument heard on September 27, 2017. The court

herein finds that the Council applied the proper legal standards and the Council's decision is

supported by substantial evidence in the administrative record. Accordingly, Plaintiff's motion

is denied, and this action is dismissed.

BACKGROUND

Medicare

Medicare is a federal health insurance program for eligible elderly and disabled persons

that is administered by CMS. 42 U.S.C. § 1395, et seq. CMS contracts with private entities to

perform administrative functions on its behalf. Medicare claims are processed by MACs. MACs

process and pay hundreds of millions of claims per year; thus it is difficult for CMS to detect and

recover improper Medicare payments. CMS, therefore, empowered its contractors to initially

authorize payment for certain claims and then later use statistical sampling in post-payment

audits to estimate overpayments.

Medical review audits are undertaken by several types of contractors, including ZPICs.

Audits are governed by Health Care Financing Administration Ruling No. 86-1[3] and the MPIM.[4]

Health Integrity, LLC is the ZPIC responsible for performing these audits in Oklahoma. Q²

Administrators, LLC is the QIC that reviews appeals of claim denials. MAXIMUS Federal

Service is the administrative qualified QIC that takes over after an ALJ issues a decision.

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[3]   Ruling 86-1 can be found at https://www.cms.gov/Medicare/Appeals-and-Grievances/OrgMedFFSAppeals/Downloads/HCFAR861v508.pdf.
[4]   At the time of the audit in this case, the relevant MPIM provisions were located in Chapter 3. Effective June 28, 2011 (one day before the original notification of overpayment), those provisions were moved to Chapter 8. The Council and Defendant cite Chapter 3. Plaintiff cites Chapter 8 and confirms that the provisions remain unchanged. The court cites Chapter 8. A copy of Chapter 8 of the MPIM may be found at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c08.pdf.

Statistical Sampling, Ruling 86-1 and the MPIM

Under Ruling 86-1, statistical sampling "creates a presumption of validity as to the amount of an overpayment which may be used as the basis for recoupment." Ruling 86-1, at 11. If a provider disagrees with the outcome, the provider may "attack the statistical validity of the sample, or it could challenge the correctness of the determination in specific cases identified by the sample." Id. The provider, however, has the burden to overcome the presumption of validity of the sampling and extrapolation methodology. Id.; Maxmed Healthcare, Inc. v. Price, 860 F.3d 335, 339 (5th Cir. 2017).

Chapter 8 of the MPIM sets out the guidelines for ZPICs "on the use of statistical sampling in their reviews to calculate and project (i.e. extrapolate) overpayment amounts to be recovered by recoupment, offset or otherwise." MPIM, Ch. 8, § 8.4.1.1. The guidelines "are provided to ensure that a statistically valid sample is drawn and that statistically valid methods are used to project an overpayment," but the failure of a ZPIC to follow one or more of the requirements "does not necessarily affect the validity of the statistical sampling that was conducted or the projection of the overpayment." Id. "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.

The major steps involved in conducting statistical sampling are:

(1) selecting the provider or supplier;

(2) selecting the period to be reviewed;

(3) defining the universe, the sampling unit, and the sampling time frame;

(4) designing the sampling plan and selecting the sample;

(5) reviewing each of the sampling units and determining if there was an overpayment or

an underpayment; and as applicable;

(6) estimating the overpayment.

MPIM, Ch. 8, § 8.4.1.3. The "universe" consists 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."

MPIM, Ch. 8, § 8.4.3.2.1 B. The "sampling unit" is defined by the sample design chosen by the

contractor. The most common sample designs are simple random sampling, systematic

sampling, stratified sampling, and cluster sampling, or a combination of these. MPIM, Ch. 8, §

8.4.4.1.

Regardless of the method of sample selection used, the ZPIC must follow a procedure

that results in a probability sample. MPIM, Ch.8, § 8.4.2 (emphasis added). For a procedure to

be classified as a probability sampling, the following two features must apply:

(1) It must be possible, in principle, to enumerate a set of distinct samples that the
procedure is capable of selecting if applied to the target universe. Although only one
sample will be selected, each distinct sample of the set has a known probability of
selection. It is not necessary to actually carry out the enumeration or calculate the
probabilities, especially if the number of possible distinct samples is large - possibly
billions. It is merely meant that one could, in theory, write down the samples, the
sampling units contained therein, and the probabilities if one had unlimited time; and

(2) Each sampling unit in each distinct possible sample must have a known probability of
selection. For statistical sampling for overpayment estimation, one of the possible
samples is selected by a random process according to which each sampling unit in the
target population receives its appropriate chance of selection. The selection
probabilities do not have to be equal but they should all be greater than zero. In fact,
some designs bring gains in efficiency by not assigning equal probabilities to all of
the distinct sampling units.

Id. If a particular probability sample design is properly executed, "then assertions that the

sample and its resulting estimates are 'not statistically valid' cannot legitimately be made. In

other words, a probability sample and its results are always 'valid.'" Id.

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Simple random sampling

> …involves using a random selection method to draw a fixed number of sampling units from the frame without replacement, i.e., not allowing the same sampling unit to be selected more than once. The random selection method must ensure that, given the desired sample size, each distinguishable set of sampling units has the same probability of selection as any other set - thus the method is a case of "equal probability sampling." An example of simple random sampling is that of shuffling a deck of playing cards and dealing out a certain number of cards (although for such a design to qualify as probability sampling a randomization method that is more precise than hand shuffling and dealing would be required.)

MPIM, Ch. 8, § 8.4.4.1.1.

> The MPIM explains that stratified sampling,

> > …involves classifying the sampling units in the frame into non-overlapping groups, or strata. The stratification scheme should try to ensure that a sampling unit from a particular stratum is more likely to be similar in overpayment amount to others in its stratum than to sampling units in other strata. Although the amount of an overpayment cannot be known prior to review, it may be possible to stratify on an observable variable that is correlated with the overpayment amount of the sampling unit. Given a sample in which the total frame is covered by non-overlapping strata, if independent probability samples are selected from each of the strata, the design is called stratified sampling. The independent random samples from the strata need not have the same selection rates. A common situation is one in which the overpayment amount in a frame of claims is thought to be significantly correlated with the amount of the original payment to the provider or supplier. The frame may then be stratified into a number of distinct groups by the level of the original payment and separate simple random samples are drawn from each stratum. Separate estimates of overpayment are made for each stratum and the results combined to yield an overall projected overpayment.

> > The main object of stratification is to define the strata in a way that will reduce the margin of error in the estimate below that which would be attained by other sampling methods, as well as to obtain an unbiased estimate or an estimate with an acceptable bias. The standard literature, including that referenced in Section 3.10.10, contains a number of different plans; the suitability of a particular method of stratification depends on the particular problem being reviewed, and the resources allotted to reviewing the problem.

MPIM, Ch. 8, § 8.4.4.1.3. The MPIM further provides with regard to stratified sampling:

Generally, one defines strata to make them as internally homogeneous as possible with respect to overpayment amounts, which is equivalent to making the mean overpayments for different strata as different as possible. Typically, a proportionately stratified design with a given total sample size will yield an estimate that is more precise than a simple random sample of the same size without stratifying. The one highly unusual exception is one where the variability from stratum mean to stratum mean is small relative to the average variability within each stratum. In this case, the precision would likely be reduced, but the result would be valid. It is extremely unlikely, however, that such a situation would ever occur in practice. Stratifying on a variable that is a reasonable surrogate for an overpayment can do no harm, and may greatly improve the precision of the estimated overpayment over simple random sampling. While it is a good idea to stratify whenever there is a reasonable basis for grouping the sampling units, failure to stratify does not invalidate the sample, nor does it bias the results.

If it is believed that the amount of overpayment is correlated with the amount of the original payment and the universe distribution of paid amounts is skewed to the right, i.e., with a set of extremely high values, it may be advantageous to define a "certainty stratum", selecting all of the sampling units starting with the largest value and working backward to the left of the distribution. When a stratum is sampled with certainty, i.e., auditing all of the sample units contained therein, the contribution of that stratum to the overall sampling error is zero. In that manner, extremely large overpayments in the sample are prevented from causing poor precision in estimation. In practice, the decision of whether or not to sample the right tail with certainty depends on fairly accurate prior knowledge of the distribution of overpayments, and also on the ability to totally audit one stratum while having sufficient resources left over to sample from each of the remaining strata.

Stratification works best if one has sufficient information on particular subgroups in the population to form reasonable strata. In addition to improving precision there are a number of reasons to stratify, e.g., ensuring that particular types of claims, line items or coding types are sampled, gaining information about overpayments for a particular type of service as well as an overall estimate, and assuring that certain rarely occurring types of services are represented. Not all stratifications will improve precision, but such stratifications may be advantageous and are valid.

Given the definition of a set of strata, the designer of the sample must decide how to allocate a sample of a certain total size to the individual strata. In other words, how much of the sample should be selected from Stratum 1, how much from Stratum 2, etc.? As shown in the standard textbooks, there is a method of "optimal allocation," i.e., one designed to maximize the precision of the estimated potential overpayment, assuming that one has a good idea of the values of the variances within each of the strata. Absent that kind of prior knowledge, however, a safe approach is to allocate proportionately. That is, the total sample is divided up into individual stratum samples so that, as nearly as possible, the stratum sample sizes are in a fixed proportion to the sizes of the individual stratum frames. It is emphasized, however, that even if the allocation is not optimal, using stratification with simple random sampling within each stratum does not introduce bias,

and in almost all circumstances proportionate allocation will reduce the sampling error over that for an unstratified simple random sample.

MPIM, Ch. 8, § 8.4.11.1.

While probability sampling pursuant to the MPIM results in a point estimate – the difference between what Medicare paid and what Medicare should have paid – in most situations, the lower limit of a one-sided 90 percent confidence interval is used as the amount of overpayment demanded for recovery from the provider. Id. at 8.4.5.1.

Medicare Administrative Appeals Process

Once a contractor determines that there was an overpayment, a provider may appeal. The appeals process includes five stages:

(1) Redetermination – an examination of the initial claim conducted by employees of the contractor who were not involved in the initial determination;

(2) Reconsideration – review performed by a QIC;

(3) ALJ hearing and de novo review;

(4) Council de novo review – this constitutes the Secretary's final decision; and

(5) Judicial review in a United States District Court.

Factual and Procedural Background[5]

At all times relevant hereto, Plaintiff was a Medicare-certified home health agency with its principal place of business located in Stigler, Oklahoma. Plaintiff provided home health services to elderly and homebound residents of eastern Oklahoma, many of whom were Medicare beneficiaries. In a letter dated September 21, 2009, Health Integrity, the ZPIC responsible for performing audits in Oklahoma, requested records in support of 56 claims for

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[5]   As they are not in dispute, the court adopts many of the facts as presented by both Plaintiff and Defendant. The court has integrated them and, of course, edited and corrected the citations to the administrative record where necessary.

home health services submitted by Sans Bois to the Medicare program for reimbursement between September of 2007 and August of 2009. A.R. 779-780.

Plaintiff complied with this request and produced the requested documentation to Health Integrity for review. On June 29, 2011, Health Integrity sent correspondence informing Plaintiff of the results of the post-payment medical review audit. A.R. 1740-1743. The ZPIC determined that 46 out of the 56 claims reviewed did not meet Medicare coverage criteria for home health services. Health Integrity informed Plaintiff that the claims it had reviewed constituted a statistically valid random sample of Plaintiff's Medicare claims and extrapolated an alleged overpayment in the amount of $5,010,148.00.[6] A.R. 796-798, 1740-1743.

Health Integrity stated that it utilized a stratified random sample design in this case. The sampling unit was the claim, and the claims were stratified based on the payment amounts. A.R. 797. Health Integrity's sample was comprised of two strata: stratum one consisted of claims with payment amounts between $1,000 and $3,000, and stratum two consisted of claims with payment amounts greater than $3,000.[7] A.R. 797.

Health Integrity used a software routine called SURVEYSELECT created by the SAS Institute, Inc. to generate the random numbers for the claim selection process. The SURVEYSELECT procedure, when used for this and similar purposes, requires a positive integer, commonly referred to as a "seed value," in order to initialize the routine to generate the random numbers. See A.R. 8873-8874.

In this case, Health Integrity drew its sample of claims in four steps, each of which required a separate "call" to the SURVEYSELECT routine; during each stage of its sample

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[6]   On March 5, 2012, the ZPIC notified the appellant that it had recalculated the overpayment to $4,131,902. A.R. 13. This was the lower bound of the 90% confidence level. A.R. 14.
[7]   In stratified sampling, the strata that comprise the overall sample are referred to as "subsamples." See A.R. 367-368.

selection process, Health Integrity used the same seed value, 18154, to initialize the random number generator. A.R. 805. First, it selected 33 claims for stratum one. Second, it used the same integer seed to select three claims from among the 33 claims chosen during step one to set aside as a stratum one "reserve sample."[8] Third, it used the same seed number to select 29 claims for stratum two. Finally, using the same integer seed once again, it set aside three claims from the 29 claims chosen during step three to set aside as spares.[9] See A.R. 805-848. The 56 claims selected during steps one and three of this sampling procedure comprised the sample that was ultimately used by Health Integrity for extrapolation.

Plaintiff filed an administrative appeal of Health Integrity's extrapolated overpayment determination, arguing inter alia that the statistical sampling methodology used by Health Integrity to extrapolate the alleged overpayment was irreparably flawed. A.R. 1538-1561. The first two appeal decisions were partially favorable to Plaintiff. See A.R. 1661-1691, 1745-1753. At the reconsideration stage, however, the QIC was "able to fully replicate the sample provided by Health Integrity"[10] and "determined that the methods used by Health Integrity were consistent with both the Medicare guidelines and generally accepted statistical standards of practice." A.R. 1688-1689.

On January 14, 2013, Plaintiff filed a request for a hearing before an ALJ, which included its challenge to the validity of the Health Integrity's sampling methodology. A.R.

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[8]   Statisticians often create reserve samples or set aside "spare" sampling units in the event that a problem arises with one of the units in the sample that will ultimately be used for extrapolation. See A.R. 8871.

[9]   Medicare contractors are required to identify the source of random numbers and document all steps taken during the random number selection process. MPIM, Ch. 8, § 8.4.4.2. The record in this case contains a log of the SURVEYSELECT session during which the random numbers were generated for the sample selection process. A.R. 805-848.

[10]   The MPIM requires sufficient documentation so that the sampling frame can be recreated if the methodology is challenged. MPIM, Ch. 8, § 8.4.4.4.1.

1710-1732. On March 10, 2014, Health Integrity submitted separate position papers regarding coverage and statistical sampling, as well as a copy of the CD with sampling documentation. A.R. 224-244, 257-358.

The ALJ to whom the case was assigned conducted a pre-hearing teleconference, in which Health Integrity participated on behalf of CMS. A.R. 9100-9112. At that time, the ALJ directed Plaintiff and Health Integrity to submit reports summarizing their respective positions as to the extrapolation.

Plaintiff submitted a pre-hearing report drafted by its independent statistician, Ross Mitchell Cox, Ph.D. A.R. 362-399. In his report, Dr. Cox concluded that the methodology employed by Health Integrity was statistically invalid because it did not meet the requirements for probability sampling or stratified random sampling set forth in Medicare program guidance. Id. Plaintiff also submitted to the ALJ an affidavit from a second statistician, Bruce Levin, Ph.D., wherein Dr. Levin attested that he agreed with Dr. Cox's conclusions and had independently verified the accuracy of Dr. Cox's mathematical calculations. A.R. 400-447.

Health Integrity submitted a report drafted by its chief statistician, Aimee Mason, M.S. A.R. 226-243. Ms. Mason opined that Health Integrity "used a stratified random sample with claims as the unit of analysis. The sample was randomly selected using a SAS program that allowed each claim to have a known (greater than zero) chance of being drawn." A.R. 226. She also stated: "The universe was stratified into two strata where Stratum 1 was for claims with payments greater than $1,000 and less than or equal to $3,000 and Stratum 2 was for claims with payments greater than $3,000." A.R. 234. She also notes in her report that "in regards to 'proper randomization,' Health Integrity, LLC used the SURVEYSELECT

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procedure in SAS to select the random claims and the seed value is displayed in the SAS log." A.R. 236.

The ALJ thereafter retained his own statistician, Mansfield Williams, Ph.D., to review the parties' respective reports and to offer an opinion as to the validity of the ZPIC's sampling methodology. In a letter dated March 14, 2014, Dr. Williams expressed agreement with the conclusions of Drs. Cox and Levin and recommended that, "…these data not be used to extrapolate overpayments to Sans Bois Health Services." A.R. 219-221.

The ALJ conducted an evidentiary hearing by telephone on March 24, 2014. Dr. Cox offered testimony on behalf of Plaintiff elaborating on the conclusions set forth in his pre-hearing report. See A.R. 8863-8889. Dr. Williams also testified and reiterated his agreement with Dr. Cox's conclusions and opinion that the sampling methodology used by Health Integrity was invalid. See A.R. 8891-8898. Although Health Integrity did not call a statistician to offer testimony during the hearing, counsel for the ZPIC requested the opportunity to submit a post-hearing position paper in response to Dr. Cox's report. The ALJ granted this request.

Health Integrity thereafter submitted a position paper drafted by another statistician, Dana Keller, Ph.D. A.R. 185-198. In his report, Dr. Keller expressed disagreement with Dr. Cox's conclusions as to probability sampling and stratified random sampling because the ZPIC had "pre- randomized" the sampling data prior to extrapolation, which he argued guaranteed that the ZPIC's sampling methodology met the applicable requirements for probability sampling and stratified random sampling. See A.R. 186-190.

Dr. Keller noted that the primary issue Dr. Cox "raised in his evaluation of the ZPIC's sampling methodology . . . revolves around a single seed being used across multiple strata." A.R. 186. He further explained that the "case against using a single sampling seed for two or

more strata can be summarized as the potential for a lack of independence across strata when the data for each stratum are sorted by the same variable used to create the strata." Id. "A lack of independence creates a situation where the over- or under-estimated average claim value in the first sampled stratum has a greater than zero probability of being propagated to the remaining strata." Id. He explained that Health Integrity avoided this problem, however, with pre-randomization, which "results in independence of claims and claim amounts across strata, which means no eligible sampling unit has a zero probability of being selected and the method generates a true probability sample that is free of selection bias." Id. Dr. Keller further notes that "[t]wo commonly used and equally valid methods of sampling" that avoid the problem of dependence are using different sampling seeds in each stratum and the method routinely used by Health Integrity "to pre-randomize the strata entries by a variable that is unrelated to the claim amounts, such as the claim or beneficiary identification number." A.R. 188.

In his post-hearing rebuttal to Dr. Keller's report, Dr. Cox noted that the notion of "pre-randomization" did not appear in any of the ZPIC's sample design documents, Dr. Keller's conclusions contradicted statements made by the ZPIC's chief statistician, Aimee Mason, in her pre-hearing report, and that Dr. Keller had not identified an error in the calculations in the appendix to Dr. Cox's pre-hearing report. See A.R. 201-217.

The ALJ subsequently issued a decision dated June 6, 2014 wherein he found that the sampling methodology used to project the alleged overpayment was statistically invalid. A.R. 74-158. The ALJ concluded in pertinent part:

> In this appeal, the ALJ finds that the sample was not a probability sample. Specifically, the ALJ finds that the sample was not a probability sample because the claim selection in each step was not conducted independently, but rather the same seed was used. The reports and hearing testimony of Dr. Cox and Dr. Williams show that the sample violated MPIM supra, § 8.4.2 because the sample was not a probability sample. Both experts agreed that the use of the same seed ultimately caused the sample to be invalid.

> The ALJ agrees with those findings. Dr. Keller's arguments were not supported by sufficient documentation and were further not supported by the earlier documentation and expert reported submitted by Ms. Mason.
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> Based on the foregoing, the ALJ finds that the statistical sampling methodology was invalid and cannot be used to extrapolate the overpayment in this appeal.

A.R. 156. On August 1, 2014, CMS referred the ALJ's decision to the Council for own motion review, arguing that the ALJ erred as a matter of law in determining the sample was not statistically valid solely because the same random seed number was used to select samples in both strata and that the ALJ's decision was not supported by the evidence. A.R. 57-73.

On October 30, 2014, the Council reversed the portion of the ALJ's decision invalidating the statistical extrapolation. The Council was not convinced "that the entire sample is invalidated by the use of the same seed" and opined that this "is simply not a 'flaw' in the sampling process cognizable by current CMS guidelines which would render the actual sample invalid." A.R. 26. The Council noted that the claims selection within each stratum was "the result of parallel process of selection, and there was no direct causation of one stratum on the other." Id. The Council further noted that there was "no evidence that the seed number was selected in a way so as to influence that selection of particular claims in each or both stratum sample." A.R. 25. The Council highlighted the manner in which the ZPIC's constructed sample mapped the provisions of the MPIM and found that the ZPIC's "sampling methodology, based, in part, upon the application of a single seed value across two strata, was compliant with the MPIM guidance." A.R. 24-26.

The Council's action constitutes the final agency decision as to this matter. Plaintiff filed a Complaint in this court on December 23, 2014 seeking judicial review of the Council's decision.

STANDARD OF REVIEW

The court's review of the Secretary's final decision is very limited. Maxmed Healthcare, Inc. v. Burwell, 152 F.Supp.3d 619, 624 (W.D. Tex. 2016). The court reviews the final agency decision to determine: (1) whether it is supported by substantial evidence in the administrative record; and (2) whether the Council applied the proper legal standards. Hackett v. Barnhart, 395 F.3d 1168 (10th Cir. 2005). "The Medicare Act provides that 'the findings of the Secretary as to any fact, if supported by substantial evidence, shall be conclusive.'" Anghel v. Sebelius, 912 F.Supp.2d 4, 13-14 (E.D. N.Y. 2012) (citing 42 U.S.C. §§ 405(g) and 1395ff(b)).

Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'" Andrade v. Secretary of Health and Human Srvcs., 985 F.2d 1045, 1047 (10th Cir. 1993) (citation omitted). Substantial evidence requires "more than a scintilla, but less than a preponderance." Lax v. Astrue, 489 F.3d 1080, 1084 (10th Cir. 2007).

"The possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's findings from being supported by substantial evidence." Curtis, Inc. v. I.C.C., 662 F.2d 680, 685 (10th Cir. 1981). The court "may not 'displace the agency's choice between two fairly conflicting views, even though the court would justifiably have made a different choice had the matter been before it de novo." Zoltanski v. F.A.A., 372 F.3d 1195, 1200 (10th Cir. 2004) (citation and brackets omitted). The court does not reweigh the evidence or substitute its own judgment for the Secretary's decision. Hackett, 395 F.3d at 1172.

Evidence, however, "is not substantial if it is overwhelmed by other evidence in the record or constitutes mere conclusion." Musgrave v. Sullivan, 966 F.2d 1371, 1374 (10th Cir. 1992). To determine whether a decision is supported by substantial evidence, the reviewing court must "engage in substantial inquiry of the relevant facts as developed in the administrative

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record and then . . . define, specifically, those facts which it deems supportive of the agency decision if that is the court's resolution of the matter." Hill v. Morton, 525 F.2d 327, 328 (10th Cir. 1975).

The court reviews questions of law de novo, yet gives substantial deference to an agency's reasonable interpretation of its own regulations. Sta-Home Home Health Agency, Inc. v. Shalala, 34 F.3d 305, 308 (5th Cir. 1994); Maxmed Healthcare v. Burwell, 152 F.Supp.3d at 625 (noting that Congress has charged the Secretary with the primary responsibility for interpreting the provisions of the Medicare Act). The court defers to "the Secretary's interpretation of the regulation unless it conflicts with the regulation's plain language." Maxmed Healthcare v. Burwell, 152 F.Supp.3d at 625.

ANALYSIS

Plaintiff argues that this court should reverse the final agency decision because it does not correctly apply the relevant legal standards and is not supported by substantial evidence. Specifically, Plaintiff argues that Dr. Cox's mathematical calculations demonstrate objectively that the ZPIC's use of the same seed during each of the four steps in its sampling procedure resulted in a sample that did not meet the MPIM requirements for probability sampling and stratified random sampling.

Emphasizing Dr. Cox's calculations and findings and the agreement therewith by Drs. Levin and Williams, Plaintiff argues that there is no evidence in the record corroborating that it is possible to calculate the selection probabilities of the distinct samples from the universe or the individual sampling units, as required by MPIM, Ch. 8, § 8.4.2. Plaintiff further argues that there is no evidence that the sampling methodology satisfied the MPIM requirements for

stratified random sampling because the selection probabilities of the stratum subsamples were unequal and the strata were not statistically independent.

The only issue before the Council was "the validity of the underlying sampling methodology based upon the application of a single seed value across multiple sample strata." A.R. 13. The Council's decision is thorough and well-reasoned. The Council fully considered Dr. Cox's analysis, but found pursuant to the binding authority of Ruling 86-1 and the MPIM's guidance, that "an appellant is not entitled to the best possible statistical sample of its claims, but only a statistically valid random sample." A.R. 22. "A difference in statistical sampling approach or preference in methodology is no basis for finding that a statistical sample is not randomly selected and thus invalid." A.R. 23. The Council considered the arguments advanced by the expert witnesses and found that Plaintiff had not met its burden of proving the invalidity of the sample and extrapolation. Id.

The administrative record shows that the ZPIC took each of the six steps outlined by the MPIM in constructing its probability sample.

(1) Health Integrity selected Plaintiff for an audit of claims for Medicare coverage of home health services. A.R. 849.

(2) Health Integrity selected the period to be to be reviewed: September 1, 2007 through August 31, 2009. A.R. 849, 1688.

(3) Health Integrity defined the universe as all claims by Plaintiff during the relevant time period for beneficiaries who received five or more full continuous home care episodes and claims with payment amounts greater than $1000. A.R. 849, 1688. The ZPIC defined the sampling unit as the claim, and constructed the sampling frame of 2,788 claims based on the time period, universe, and sampling unit. Id.

(4) Health Integrity designed a two-strata sample, with the first stratum consisting of 30 claims with payments greater than $1,000 and less than $3000, and the second stratum consisting of 26 claims with the payments greater than $3,000. A.R. 849-850, 1688.

(5) Health Integrity reviewed each of the sampling units and determined there was an overpayment. A.R. 1207.

(6) Health Integrity estimated the overpayment. A.R. 796-798, 1740-1743.

As the Council noted, the record also demonstrates that the ZPIC constructed a stratified random sample. A.R. 23. The Council explained,

> Stratified sampling, as used here, involves classification of "the sampling units in the frame into non-overlapping groups, or strata." MPIM, Ch. 3, § 3.10.4.3. Independent probability samples, or simple random samples, are then selected from each stratum. When stratified sampling is used, not all sampling units across the frame have the same probability of being selected for the sample, although the units in each stratum have the same probability of selection.

A.R. 23-24. The Council recognized that: "The sample for each strata was a probability sample." A.R. 24. The only question, then, was whether the use of a single seed number for drawing multiple strata rendered the entire sample invalid because the strata would not be statistically independent. Id.

The Council considered Dr. Cox's mathematical explanation "that using the same seed number in a certain sample (**that was not actually used here**) consisting of the first thirty (stratum 1) or twenty six (stratum 2) claims in each stratum will narrow the range of possible samples drawn from strata, by eliminating 3.16 percent of all possible sample combinations." A.R. 25 (emphasis added). The Council also considered Dr. Keller's assertion, however, "that the potential for positive correlation across strata sorted by the stratification variable is mathematically minimized, **although not reduced to zero**, to the extent that the strata contain different numbers of eligible cases." Id. (emphasis added). The Council found that Health

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Integrity's "pre-randomization" procedure "eliminates the correlation between particular claim (paid) values across strata before applying the sampling seed." Id. Additionally, "because no threat to the resulting probability sample exists, no mathematical proof of the absence of a problem is readily available." Id. Ultimately, the Council found:

> Even accepting the appellant's argument that the use of the same seed in both strata theoretically eliminates certain combinations of claims in each stratum, this does not necessarily indicate that the entire sample was impermissible. There is no evidence that the seed number was selected in a way so as to influence that selection of particular claims in each or both stratum sample. The claims in each stratum were drawn independently by random means using a frame that was not ordered by the variable of interest. Within each stratum each claim in the stratified frame had a known equal probability of selection. And the contribution of each stratum to the overpayment is independent.
>
> For these reasons, we agree with CMS that the two strata samples are independent probability samples, as contemplated in the MPIM.

Id.

The Council explained that "the MPIM is primarily concerned with the probability of selection of any particular claim, not the probability of selection of any particular combination of claims resulting from stratified sampling. In any stratified sample, all combinations are possible until a seed number is chosen, regardless of whether a single seed is chosen or two seeds, one for each stratum." Id. The Council rejected Plaintiff's argument that some combinations of claims were ruled out once certain claims were selected in the first stratum and the implication that "one stratum's outcome affected the other when, in fact, they were simply the result of parallel processes of selection, and there was no direct causation of one stratum on the other." A.R. 25-26.

The only questions now before this court are whether the Council applied the proper legal standards and whether its decision is supported by substantial evidence in the administrative record. The court finds that the Council applied the proper legal standards in interpreting the

MPIM and that its decision – that "in the context of this audit and upon the specific facts presented, the ZPIC's sampling methodology, based, in part, upon the application of a single seed value across two strata, was compliant with the MPIM guidance" – is supported by substantial evidence in the administrative record. A.R. 26.

The court notes that at the reconsideration stage, the QIC was "able to fully replicate the sample provided by Health Integrity" and "determined that the methods used by Health Integrity were consistent with both the Medicare guidelines and generally accepted statistical standards of practice." A.R. 1688-1689. Dr. Keller also opined that the ZPIC's sampling methodology met the applicable requirements for probability sampling and stratified random sampling. See A.R. 186-190.

Dr. Keller explained that the ZPIC had "pre- randomized" the sampling data prior to extrapolation, which resulted "in **independence of claims and claim amounts across strata, which means no eligible sampling unit has a zero probability of being selected** and the method generates a true probability sample that is free of selection bias."   A.R. 186 (emphasis added). Dr. Keller further explained that "[t]wo **commonly used and equally valid methods of sampling**" **that avoid the problem of dependence** are using different sampling seeds in each stratum and the method routinely used by Health Integrity "to pre-randomize the strata entries by a variable that is unrelated to the claim amounts, such as the claim or beneficiary identification number." A.R. 188 (emphasis added).

The Council fully considered Dr. Cox's mathematical analysis, but found it unpersuasive. As Dr. Keller explained, the ZPIC used one of two commonly used and equally valid methods of sampling, and it complied with the MPIM. The sampling methodology "need not be based on the most precise methodology, just a valid methodology." Anghel, 912 F.Supp.2d at 18 (citation

omitted). A sample is not invalid merely because "another statistician might construct a different or more precise sample." Balko & Assocs., Inc. v. Department of Health and Human Servs., 555 Fed.Appx. 188, 194 (3d Cir. 2014). Also, a district court may not displace an agency's choice between two fairly conflicting views, even if "the court would justifiably have made a different choice had the matter been before it de novo." Zoltanski, 372 F.3d at 1200. Moreover, under Ruling 86-1, "there is a presumption of validity when statistical sampling is used by the CMS contractor, and, as such, the burden is on Plaintiff to establish the invalidity of the methodology during the administrative review." Id.

Notably, as Defendant argues, the MPIM does not prohibit the use of the same seed number in a multi-step sampling methodology process. Additionally, "the MPIM does not actually have a strict 'independence' requirement that conforms to authoritative statistical standards and texts." Maxmed Healthcare, Inc. v. Price, 860 F.3d at 342. Even if a ZPIC fails to follow one or more of the requirements, such a failure "does not necessarily affect the validity of the statistical sampling that was conducted or the projection of the overpayment." MPIM, Ch. 8, § 8.4.1.1. In this case, however, Plaintiff has not shown that the ZPIC failed to follow any of the MPIM requirements. As Defendant argues, Dr. Cox's analysis focused on hypothetical scenarios rather than on whether the ZPIC's methodology complied with the MPIM.

After agreement by the parties, the court also appointed its own technical advisor. As explained at the hearing on September 27, 2017, the court does not and cannot adopt her report. The court notes, however, that she found that the sample constructed in this case was a probability sample. Docket No. 84. A probability sample and its results are always valid. MPIM, Ch.8, § 8.4.2.

There is substantial evidence – undoubtedly more than a scintilla – in the administrative record that the ZPIC satisfied the MPIM requirements for a probability sample and a stratified random sample. The court, therefore, finds that the Council applied the proper legal standards and that its decision – that "in the context of this audit and upon the specific facts presented, the ZPIC's sampling methodology, based, in part, upon the application of a single seed value across two strata, was compliant with the MPIM guidance" – is supported by substantial evidence in the administrative record.[11]

CONCLUSION

For the foregoing reasons, the court finds that the Council applied the proper legal standards, and its decision is supported by substantial evidence in the administrative record. It is, therefore, ordered that the Secretary's decision is AFFIRMED. Accordingly, Plaintiff's motion [Docket No. 24] is DENIED, and this case is hereby DISMISSED.

IT IS SO ORDERED this 6th day of November, 2017.

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THE HONORABLE RONALD A. WHITE
UNITED STATES DISTRICT JUDGE
EASTERN DISTRICT OF OKLAHOMA

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[11]   The court further finds that the Secretary's decision was not arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and regulation. See Maxmed Healthcare, Inc. v. Price, 860 F.3d at 340; Transyd Enters., LLC v. Sebelius, No. M-09-292, 2012 WL 1067561, at *7 (March 27, 2012 S.D. Tex).