DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-14-2629

In the case of	**Claim for**
Sans Bois Health Services, Inc.	Hospital Insurance Benefits
(Appellant)	(Part A)
****	****
(Beneficiaries)	(HIC Numbers)
Palmetto GBA	****
(Contractor)	(ALJ Appeal Number)

The Medicare Appeals Council (Council) has decided, on its own motion, to review the Administrative Law Judge's (ALJ's) decision dated June 6, 2014, because there is an error of law material to the outcome of the claims. *See* 42 C.F.R. § 405.1110. The ALJ's decision, which was partially favorable to the appellant, addressed an extrapolated overpayment assessed against the appellant in connection with claims for Medicare coverage of home health services provided to various beneficiaries between September 1, 2007 and August 31, 2009. Before the ALJ, the question of coverage for claims involving thirty-eight beneficiaries remained unresolved. The ALJ found that some, or all, claims for six beneficiaries were covered by Medicare. *See generally* Dec. at 85. However, the ALJ found that the sampling methodology employed by the auditors in establishing the extrapolated overpayment was invalid. Thus, the ALJ limited the scope of the overpayment to the amount derived from the unfavorable coverage determinations identified in the sampled claims; that is, the beneficiary-specific claims actually reviewed. *Id*. at 81-83. The ALJ also found the appellant liable for the resulting non-covered costs and ineligible for waiver of the recoupment. *Id*. at 79.

The Council has carefully considered the record before the ALJ, as well as the memorandum from the Centers for Medicare & Medicaid Services (CMS) dated August 1, 2014, in which CMS

asserts that the ALJ's decision contains an error of law and is otherwise not supported by a preponderance of the evidence and the appellant's August 20, 2014, response. The CMS memorandum is entered into the case record as Exhibit (Exh.) MAC-1; the appellant's response as Exhibit MAC-2.

The Council finds that the extrapolated overpayment was based upon a valid sampling methodology. Consequently, the ALJ's invalidation of the sampling methodology is reversed. The Council does not otherwise disturb the ALJ's coverage findings for the sampled claims, the appellant's liability for the resulting non-covered costs or the appellant's ineligibility for waiver of recoupment.

APPLICABLE LEGAL AUTHORITIES

CMS (formerly the Health Care Financing Administration or HCFA) Ruling 86-1 describes the agency's policy on the use of statistical sampling to project overpayments to Medicare providers and suppliers. The Ruling also outlines the history and authority, both statutory and precedential, for the use of statistical sampling and extrapolation by CMS in calculating overpayments. In part, Ruling 86-1 provides -

> 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.

CMS Ruling 86-1-9 & 86-1-10.

At the time of this audit CMS' sampling guidelines were found in Chapter 3 of the Medicare Program Integrity Manual (MPIM) (IOM Pub. 100-08) (eff. 05-10-04). Effective June 28, 2011, these guidelines were relocated to Chapter 8 of the MPIM.[1] Below, the Council cites to Chapter 3 of the MPIM.

The MPIM guidelines reflect the perspective that the time and expense of drawing and reviewing the claims from large sample sizes and finding point estimates which accurately reflect the estimated overpayment with relative precision may not be administratively or economically feasible for contractors performing audits. Instead, the guidelines allow for smaller sample sizes and less precise point estimates, but offset such lack of precision with direction to the contractors to assess the overpayment at the lower level of a confidence interval-- generally, the lower level of a ninety percent one-sided confidence interval. This results in the assumption, in statistical terms, that there is a ninety percent chance that the actual overpayment is higher than the overpayment which is being assessed, thus giving the benefit of the doubt resulting from any imprecision in the estimation of the overpayment to the appellant, not the agency. *See generally* MPIM, Ch. 3, § 3.10. As a result of the above policy decision, the question becomes whether the sample size and design were sufficiently adequate to provide a meaningful measure of the overpayment and whether the provider/supplier is treated fairly despite any imprecision in the estimation.

The MPIM provides guidance to contractors in conducting statistical sampling for use in estimating overpayment amounts. The instructions are intended to ensure that a statistically valid sample is drawn and that statistically valid methods are used to project overpayments where review of claims indicates that overpayments have been made. The MPIM describes the purpose of its guidance as follows:

> These instructions are provided so that a sufficient process is followed when conducting statistical sampling to project overpayments. Failure by the PSC or the Medicare BI unit 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

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[1] Manuals issued by CMS can be found at http://www.cms.hhs.gov/manuals.

statistical validity of the sample as drawn and conducted. *Failure by the PSC or Medicare contractor BI unit or the contractor MR units to follow one or more requirements may result in review by CMS of their performance, but should not be construed as necessarily affecting the validity of the statistical sampling and/or the projection of the overpayment.*

MPIM, Ch. 3, § 3.10.1.1 (emphasis supplied).

The MPIM further provides that a contractor may employ any sampling methodology that results in a "probability sample." The MPIM explains –

[The contractor] shall follow a procedure that results in a probability sample. For a procedure to be classified as probability sampling, the following two features must apply:

- 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

- 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.

For a procedure that satisfies these bulleted properties it is possible to develop a mathematical theory for various methods of estimation based on probability sampling and to study the features of the estimation method (i.e., bias, precision, cost) although the details of the theory may be complex. *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. In other words, a probability sample and its results are always "valid." Because of differences in the choice of a design, the level of available resources, and the method of estimation, however, some procedures lead to higher precision (smaller confidence intervals) than other methods.* A feature of probability sampling is that the level of uncertainty can be incorporated into the estimate of overpayment as is discussed below.

MPIM, Ch. 3, § 3.10.2 (emphasis supplied). The MPIM recognizes that a number of sampling designs are acceptable, including simple random sampling, systematic sampling, stratified sampling, and cluster sampling, or a combination of these. *Id.* at § 3.10.4.

The MPIM explains stratified sampling as follows -

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.

MPIM, Ch. 3, § 3.10.4.3.

As stated above, the level of uncertainty that may be part of a
sampling design can be addressed when the results of the
sampling are used to estimate the total overpayment.
The MPIM addresses this providing, in pertinent part -

In simple random or systematic sampling the total
overpayment in the frame may be estimated by
calculating the mean overpayment, net of underpayment,
in the sample and multiplying it by the number of
units in the frame. In this estimation procedure,
which is unbiased, the amount of overpayment dollars
in the sample is expanded to yield an overpayment
figure for the universe. The method is equivalent to
dividing the total sample overpayment by the selection
rate. The resulting estimated total is called the
point estimate of the overpayment, i.e., the
difference between what was paid and what should have
been paid. In stratified sampling, an estimate is
found for each stratum separately, and the weighted
stratum estimates are added together to produce an
overall point estimate.

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.* However, the PSC or Medicare contractor BI unit is not precluded from demanding the point estimate where high precision has been achieved.

MPIM, Ch. 3, § 3.10.5.1 (emphasis supplied). The MPIM further provides that –

If the decision on appeal upholds the sampling methodology but reverses one or more of the revised initial claim determinations, the estimate of overpayment shall be recomputed *and a revised projection of overpayment issued.*

MPIM, Ch. 3, § 3.10.9.2 (emphasis supplied).

With respect to component parts of a statistical sample, a statistical sample "universe and sampling frame will usually cover all relevant claims or line items for the period under review," and CMS assumes, for purposes of discussion, "that the sampling unit is the claim, although this is not required." MPIM, Ch. 3, § 3.10.3.2. The sampling frame is a list of all "possible sampling units from which the sample is selected." *Id.* at § 3.10.3.2.3. As an example, the frame can be "a list of all claims for which fully or partially favorable determinations have been issued, or a list of all the line items for specific items or services for which fully or partially favorable determinations have been issued." *Id.* CMS states that an "ideal frame is a list that covers the target universe completely" although, in some cases, duplicate sampling units must be eliminated before selecting the sample. *Id.*

A contractor must "identify the source of the random numbers used to select the individual sampling units." MPIM, Ch. 3, § 3.10.4.2. The contractor must also document "the program and its algorithm or table" and make that documentation available

for review. *Id.* The contractor must also "document the known
seed value if a computer algorithm is used." *Id.* The contractor
documents "all steps taken in the random selection process
exactly as done to ensure that the necessary information is
available for anyone attempting to replicate the sample
selection." *Id.* CMS states that SPSS, SAS, and RAT-STATS are
among the "well-known, reputable software statistical packages
. . . that may be used for generating a sample." *Id.*

A contractor must keep sufficient documentation of the sampling
methodology "so that the sampling frame can be re-created,
should the methodology be challenged." MPIM, Ch. 3,
§ 3.10.4.4.1. The "total overpayment in the frame may be
estimated by calculating the mean overpayment, net of
underpayment, in the sample and multiplying it by the number of
units in the frame." MPIM, Ch. 3, § 3.10.5.1. "In this
estimation procedure, which is unbiased, the amount of
overpayment dollars in the sample is expanded to yield an
overpayment figure for the universe." *Id.*[2] This process results
in the "point estimate of the overpayment," which is "the
difference between what was paid and what should have been
paid." *Id.* CMS notes that, in cases when "actual correlation
between the original paid amount is high enough, greater
precision in estimation will be attained, i.e., the lower limit
of the one-sided 90 percent confidence interval will be closer
to the point estimate." *Id.*

Medicare regulations provide that ALJs and the Council are not
bound by CMS program guidance (such as manual authority), but
"*will* give substantial deference to these policies if they are
applicable to a particular case." 42 C.F.R. § 405.1062(a)
(emphasis added). If an ALJ or the Council "declines to follow
a policy in a particular case," the ALJ or the Council must
explain the reasons for not following the policy in that case.
42 C.F.R. § 405.1062(b). ALJs and the Council are bound by CMS
Rulings. 42 C.F.R. § 405.1063.

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[2] CMS explains that the term "bias" in statistical sampling is used in a
technical sense and does not reflect unfair treatment of a provider or
supplier. MPIM, Ch. 3, § 3.10.5.1. "A biased estimator is often used rather
than an unbiased estimate because the advantage of its greater precision
outweighs the tendency of the point estimate to be a bit high or low." *Id.*

BACKGROUND

The only issue before the Council is the validity of the underlying sampling methodology based upon the application of a single seed value across multiple sample strata. The appellant has not challenged the ALJ's findings on coverage for individual beneficiaries, and has not preserved any other basis for invalidating the sample advanced by its expert witnesses, such as the non-inclusion of zero paid claims in the sample.

On June 29, 2011, Health Integrity, the Zone Program Integrity Contractor (ZPIC; Health Integrity or HI), provided the appellant with the preliminary results of its audit of the appellant's claims for Medicare coverage of home health services provided between September 1, 2007 and August 31, 2009. There, the ZPIC identified an extrapolated overpayment totaling $5,010,148. Exh. 1, Tab B at 31-34. The Medicare contractor formally notified the appellant of the overpayment by letter dated July 7, 2011. *See* Exh. 8.

Based upon the Medicare contractor's February 2012 request, by letter dated March 5, 2012, the ZPIC notified the appellant that it had recalculated the overpayment and reduced the extrapolated overpayment to $4,131,902. Exh. 10 at 1186-1187. As had the ZPIC's preliminary report, the ZPIC's recalculation included a summary of the sampling methodology explaining -

> **Universe**
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> . . . The universe was limited to claims for beneficiaries who received 5 or more full continuous home care episodes and claims with payment amounts greater than or equal to $1,000 and had no date of death on the most current beneficiary enrollment tables. There were 2788 claims for which Sans Bois Health Services was paid a total of $6,826,174.10.
>
> **Sampling Unit/Size**
>
> The sampling unit was each claim. Health Integrity used a two-strata sample; Stratum 1 consisting of 30 claims and Stratum 2 consisting of 26 claims for a total sample size of 56 claims. Stratum 1 was for claims with payments greater than $1,000 but less than $3,000. Stratum 2 was for claims with payments

greater than $3,000. The 56 claims were randomly
selected from the 2788 claims in the universe of the
respective stratum. The selection was done using SAS,
in such a manner that each and every claim in the
universe had an equal chance of being selected.

Actual Overpayment Amount

. . . The actual overpayment for stratum 1 was
$37,501.45. The actual overpayment for stratum 2 was
$71,328.17. The actual overpayment for the sample was
$108,829.62.

Average Overpayment Amount

. . . The average overpayment for stratum 1 was
($37,501.45/30 = $1,250.05). The average overpayment
for stratum 2 was ($71,328.17/26 = $2,743.39). The
actual overpayment for the sample was $108,829.62.

Projected Overpayment Amount

. . . This amount is calculated by summing the
product of the average overpayment amount per unit by
the total number of units in the respective stratum
($1,250.05 x 2002 + $2,743.39 x 786 = $4,658,902).

Requested Overpayment

. . . We are 90% confident that the overpayment was
at least $4,131,902. The requested overpayment amount
therefore is $4,131,902.

Exh. 10 at 1186-1187; *see also* Exh. 66 (ZPIC Sampling CD) at
Sample Design Summary.

The Medicare contractor next issued a series of beneficiary-
specific redeterminations upholding the coverage denials in
whole or part. *See generally* Exh. 1, Tab D. The contractor
issued a separate redetermination addressing, and upholding, the
ZPIC's sampling methodology. *See* Exh. 57 at 7921-7930.

On June 12, 2012, the Qualified Independent Contractor (QIC)
issued a reconsideration, partially favorable to the appellant,
providing additional claim-coverage. *See* Exh. 3. By letter
dated June 18, 2012, the appellant sought reopening, notifying

the QIC that its action had failed to address the appellant's request for reconsideration of the sampling methodology. Exh. 2 at 734-735. The QIC found good cause to reopen. *Id.* at 732. In its revised reconsideration (November 19, 2012), the QIC left unchanged the coverage findings from its June action and found the ZPIC's sampling methodology to be valid. The QIC also found the appellant liable for the associated non-covered costs. *Id.* at 690-725. The appellant timely requested an ALJ hearing. *See* Exh. 1 at 1-25.

Prior to the hearing, the ALJ received three "Expert Reports" on the sampling methodology - from Dr. R.C. (Dr. C.) for the appellant; from A.M., MS, for the ZPIC and from an independent expert retained by the ALJ, Dr. M.W. (Dr. W.). *See* Dec. at 2 and 81. The appellant also submitted an affidavit from a second statistician, Dr. B.L. (Dr. L.) for the purpose of corroborating Dr. C.'s report. *See* Exh. MAC-2 at 3; *see also* Exh. 62 at 8147-8149.

On March 24, 2014, the ALJ conducted a hearing by telephone. Represented by counsel, the appellant provided general and expert witness testimony directed at specific questions of coverage and expert testimony from Dr. C. challenging the ZPIC's sampling methodology. The ZPIC also participated through counsel and provided expert testimony relating to coverage issues. The ZPIC's statistician was unavailable to participate in the hearing. The ALJ's independent expert also participated. Dec. at. 2; *see also* ALJ Hearing CD. Following the hearing, the appellant and ZPIC submitted post-hearing briefs refining their positions on the sampling methodology. The ZPIC's post-hearing submission was written by a different statistician Dr. D.K. (Dr. K.), the appellant's by Dr. C. *Id.* at 2 and 81; *see also* Exh. 68 at 8349-8362 (ZPIC) and 8363-8381 (appellant). The decision now before the Council followed.

Of the thirty-eight beneficiary-specific claims before him, the ALJ found coverage fully warranted for four claims, partially warranted in two and precluded in the remaining thirty-two. *See* Dec. at 11-78 and 85. The ALJ held the appellant liable for the resulting non-covered costs and found it ineligible for waiver of recoupment of the overpayment. *Id.* at 79.

Having reviewed the ZPIC's sampling methodology in the context of experts' arguments and pertinent authorities, the ALJ found the methodology invalid. The ALJ explained –

A sample must be a "probability sample" in that the
sample used must be truly random and each item in a
potential sample must have a chance of being selected
in accordance with *MPIM supra*, ch. 8, § 8.4.2. The
resulting total overpayment must exhibit adequate
precision and be statistically unbiased. In this
appeal, 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 . . . [Drs. C. and W.] shows that
the sample violated *MPIM supra*, ch. 8, § 8.4.2 because
the sample was not a probability sample. Both experts
agree that the use of the same seed ultimately caused
the sample to be invalid. The ALJ agrees with those
findings. . . . . [Dr. K.'s] arguments were not
supported by sufficient documentation and were further
not supported by the earlier documentation and expert
report submitted by . . . [A.M.].

Dec. at 83 (emphasis in original).

In large part, CMS' and the appellant's arguments before the
Council refine their positions before the ALJ.

CMS' Position

Generally, CMS argues that –

The ALJ erred as a matter of law in determining the
sample was not statistically valid solely because the
same random number seed was used to select samples in
both strata and reserves. Nothing in Medicare's
sampling instructions precludes use of the same random
number seed to draw the two strata and three reserves
from each stratum or suggests that such a procedure
would result in lack of statistical independence or a
non-randomly selected sample. The ZPIC's sampling
design, including its sample selection procedures,
comport with the requirements of the *MPIM* and HCFA
Ruling 86-1. The ALJ erred in finding that the ZPIC's
sampling procedures violated *MPIM* requirements.
Furthermore, the Appellant acknowledges that it has
not demonstrated any actual or consequential
statistical dependence, but rather that the steps are
not procedurally independent, such that the ZPIC

cannot prove statistical independence or call its
sample a randomly selected probability sample. See
Exh. 68 at 8375. ("The point is not whether this
dependence can be demonstrated to exist or not; the
point is that one cannot guarantee that it doesn't
exist because HI has not taken steps to genuinely
randomize the claims . . . ."). HCFA Ruling 86-1
places the burden on the challenging party to
demonstrate the extrapolated overpayment is invalid,
not the contractor to prove its validity.
Additionally, the *MPIM* provides that challenges to
"the validity of the sampling methodology must be
predicated on the actual statistical validity of the
sample as drawn and conducted." Speculative
assertions that the ZPIC's sampling methodology does
not shield against potential and unspecified problems
do not provide a basis for invalidating the
extrapolation.

Finally because the Appellant's argument relies on
hypothetical problems that might arise from the ZPIC's
sampling procedures, and expressly avoids any
demonstration that the resulting sample "as drawn and
conducted" introduces actual statistical bias in the
sample or otherwise affects the overpayment
estimation, the ALJ's decision that the sampling
methodology is invalid is not supported by a
preponderance of evidence in the record. See Exh. 68
at 8366 ("This question [as to whether the ZPIC drew a
statistically valid random sample] can only be
answered through an a priori analysis of HI's sampling
procedure, not through an a posteriori examination of
the results of that procedure.").

Exh. MAC-1 at 1-2 (footnote omitted).

CMS summarizes the essence of the appellant's position before
the ALJ as having been that -

by using the same seed to draw the two strata and
three reserves from each stratum, a) the sample is no
longer a stratified random sample because the two
strata are not statistically independent, and b) the
resulting sample in each stratum is not a probability
sample, since "the sample selection probabilities are
unknown." . . . [The appellant's expert, Dr. C.] does

not purport to demonstrate that the two strata in this
case are in fact statistically dependent in any sense
that might affect the overpayment estimation, only
that using the same seed results in sampled claims in
both strata occupying the same relative positions
within the order of claims in the universe. . . .
Likewise, he does not attempt to show that the sample
in this case was not randomly selected, but that the
procedure of drawing three reserves from each stratum
using the same seed results in a sample that cannot be
called a probability sample. See Exh. 68 at 8366, FN 2
("Despite its grammatical form, the term 'probability
sample' or its equivalent, 'statistically valid random
sample', refers not to an individual sample but to the
procedure which produced the sample.").

Exh. MAC-1 at 12.

Appellant's Response

The appellant asserts that the ALJ's decision was fully
consistent with HCFA Ruling 86-1 and Medicare requirements for
sampling and overpayment estimation. *See generally* Exh. MAC-2
at 5-13.

The appellant states that a "probability sample is a sample
whereby each distinct sample and each of the individual sampling
units has a known probability of selection." Exh. MAC-2 at 6.
The appellant maintains that, "as a cornerstone of statistical
theory" the MPIM, at chapter 8, section 8.4.2, "unequivocally
requires "regardless of the method of sample selection" that
"each distinct sample of the [selected] set has a known
probability of selection" and that while "the selection
probabilities do not have to be equal . . . they should all be
greater than zero." *See id.* at 6-7.

The appellant contends that the ZPIC's -

sample is not a probability sample because the sample
selection probabilities are unknown. Therefore, the
first bulleted requirement [in § 8.4.2] is unknown.
Also, the selection probabilities of many of the
samples in their sampling frame are zero. Therefore
the second bulleted requirement [of § 8.4.2] is not
satisfied either.

Exh. MAC-2 at 7.

The appellant asserts its argument is borne out by the "very detailed mathematical calculations" found in the Appendix to Dr. C.'s Report. Those calculations "establish that the selection probabilities of more than 3% of the possible samples that could have been drawn from the sampling frame have a selection probability of zero . . . [additionally,] the selection probabilities of all other samples that could have been drawn from the sampling frame were unknown. Exh. MAC-2 at 7 (citing Exh. 62 at 8116 and 8134-8143). Moreover, the appellant contends that the validity of Dr. C.'s calculations have been independently verified through a review and corresponding affidavit, by a second statistician, Dr. L. *Id.* at 8 (referencing Exh. 62 at 8147-8149).

The appellant asserts that, based upon these allegations of error, the ZPIC's methodology did not meet the most basic criteria for a valid sample. Thus, neither its sampling methodology, nor the resulting *extrapolated* overpayment, were compliant with the MPIM or HCFA Ruling 86-1. Exh. MAC-2 at 8.

Similarly, the appellant argues that the ZPIC's sample is not a stratified random sample. *See* Exh. MAC-2 at 9-12. Referencing the MPIM, the appellant explains –

> *. . . The random selection method <u>must</u> 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.'
>
> Stratified random 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. . . . Given a sample in which the total frame is covered by non-overlapping strata, if *independent* probability samples are selected from each strata, the design is called stratified sampling.

Exh. MAC-2 at 9 (citing MPIM, Ch. 8, § 8.4.4.1.1 and § 8.4.4.1.3; emphasis in original).

The appellant explains that, based on the MPIM's criteria, Dr. C. "concluded that Health Integrity's sample was not a stratified random sample because each and every element in the

sample did not have an equal opportunity of being selected."
Further, "due to the strong statistical interdependence between
the two strata resulting from the use of the same seed value"
Health Integrity's sample is not in accord "with any procedure
outlined in the MPIM or anywhere else. In particular it does not
satisfy the condition[s] mentioned [in the ZPIC's own sampling
materials] that 'each element in the sample has an equal
opportunity of being selected.'" Exh. MAC-2 at 9-10. The
appellant indicates that Dr. C.'s analysis demonstrates that
"the selection probabilities for each set of the sampling units
in stratum one differed from one another by a factor of at
least 5,456 and the selection probabilities for each set of the
sampling units in stratum two differed from one another by a
factor of at least 3,654." Thus the ZPIC's methodology violated
directions set out in both the MPIM and HCFA Ruling 86-1. *Id.*
at 9-10. The appellant reemphasizes that Dr. C.'s
interpretation of the failings in the ZPIC's methodology has
been corroborated by Dr. L.'s independent review. *Id.* at 11.

Responding to CMS' assertion that the appellant has effectively
conceded that its arguments are wholly "speculative" or
"hypothetical," the appellant asserts that its position is based
upon "mathematically demonstrated . . . objective conclusions."
See Exh. MAC-2 at 11-12. The appellant acknowledges that it has
the burden of demonstrating the invalidity of the sampling
methodology. The appellant insists that it has carried that
burden and maintains that CMS has added an additional burden
requiring it to "further show that the statistical invalidity of
the sample results in an inflated overpayment estimation or
involves intentional bias on the part of the contractor (Health
Integrity]." *Id*. at 12. The appellant maintains that this
additional burden is not present in either the MPIM guidance or
HCFA Ruling 86-1. Rather, the appellant notes, the relevant
legal authorities "mandate" only that it contest "the actual
validity of the sampling methodology," a requirement, which, the
appellant suggests, it has satisfied. *Id*. at 12-13.

The appellant continues, arguing that the ALJ's invalidation of
the sampling methodology is supported by the opinions of three
statisticians, its own two and the ALJ's, as well as objective
mathematical calculations which corroborate that Health
Integrity's sample is neither a probability sample nor a
stratified random sample. *See generally* Exh. MAC-2 at 13-22.
To the extent that the appellant's arguments are largely
reiterations of earlier arguments, the Council merely sets them
out in summary fashion. The appellant asserts that its

contentions as to the invalidity of the sampling methodology are supported by objective mathematical calculations, independently verified by another statistician. *See* Exh. MAC-2 at 14. The appellant also maintains that it has identified the "practical consequences of Health Integrity's failure to create a probability sample and a stratified random sample. *See* Exh. MAC-2 at 15-18.

Finally the appellant contends that the ZPIC's sampling materials and the reports submitted by its statistician are inconsistent. *See* Exh. MAC-2 at 19-22. The appellant notes that CMS' post-hearing brief suggests that the appellant's concerns regarding the use of a single seed value are baseless because the ZPIC had sufficiently pre-randomized the sampling data to overcome use of a single seed value. However, the appellant contends that CMS' position "is not supported by the ZPIC's own sampling materials and contradicted by the report from Health Integrity's other statistician," A.M. *Id*. at 19-20.

Recounting the pre-hearing report, by the ZPIC's chief statistician, A.M., the appellant notes that at "no point" does A.M. "even mention[] – much less explain[] – the concept of "pre-randomization" raised in Dr. K.'s report. *Id*. at 20-21. Similarly, the appellant points out, the ZPIC's explanation of its methodology does not indicate that "pre-randomization" was utilized, in spite of Dr. D.K.'s insistence that "a reviewer assessing the ZPIC's sampling data must 'explicitly accommodate' Health Integrity's 'pre-randomization' routine in order to correctly model the 'ZPIC process.'" The appellant notes that, pursuant to chapter 8, section 8.4.4.4 of the MPIM an audit agency must maintain "***complete documentation***" of the sampling methodology employed. The appellant argues that there is no physical evidence in the record suggesting that the ZPIC actually engaged in pre-randomization as CMS has alleged. *Id*. at 21-22.

In closing, the appellant suggests that the Council either provide an opportunity for a hearing, to further address the sampling methodology, or that it decline to disturb the ALJ's decision invalidating the sampling methodology. *Id*. at 22-23.

ANALYSIS

Request for Oral Argument

The Council "grants a request for oral argument if it decides that the case raises an important question of law, policy, or fact that cannot be readily decided based on written submissions alone." 42 C.F.R. § 405.1124(a). The single issue presented by this case has been extensively briefed and argued, both before the ALJ and now the Council. Accordingly, the appellant's request for oral argument is denied.

Sampling Methodology

The Council fully appreciates the effort and depth of analysis offered by Dr. C., in the appellant's challenge to the ZPIC's methodology. However, as CMS has noted, and the Council and federal courts have found, pursuant to the binding authority of HCFA Ruling 86-1 and the MPIM's guidance, an appellant is not entitled to the best possible statistical sample of its claims, but only a statistically valid random sample. *See* Exh. MAC-1 at 13 (referencing *Balko & Assocs., Inc. v. Sebelius,* 2012 W.L. 6738246 at 23 (W.D. Pa., Dec. 28, 2012)).

In essence, the appellant's position is that the ZPIC's utilization of the same seed number, across multiple strata, precludes the ZPIC's ability to have drawn a stratified sample pursuant to the above-discussed MPIM criteria. The appellant asserts that by using the same seed number for both strata, the "relative claim positions" (i.e., relationship of the claims selected in the sample to all other claims in the frame) for each stratum were the same. For example, the appellant suggests that by using a frame that selects claim 1 in stratum 2, because of this relative claim position, the same seed number would cause either claim 1, 2, or 3 to be pulled in stratum 1. Thus, if claim 1 is selected in the sample in stratum 2, any of the possible combinations of claims from stratum 1 that did not have either claim 1, 2, or 3 in it would have a 0% chance of being selected for the sample. The appellant has calculated that 3.16% of all of the possible sample combinations of claims would not have claims 1, 2, or 3 in them if 33 claims are randomly selected from 2002 claims in stratum 1. Therefore, the appellant argues that the two strata samples are not statistically independent. In the Appendix to his report,

Dr. C. advances a theoretical methodology intended to support that argument based on advanced mathematical calculations. *See* Exh. 62 at 8108-8146; *see also* Exh. 68 at 8365-8381.

As previously discussed, the burden is on the appellant to establish sample invalidity, not on the contractor to prove that a sample is valid. 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. The Council has considered, in their entirety, the arguments advanced by expert witnesses for CMS and the appellant and the briefs. The Council finds that the appellant has not met its burden of proving sample and extrapolation invalidity.

In this case, the record demonstrates that the ZPIC constructed a stratified random sample, defining the universe (2788 claims), the sampling unit (claims), the period of review (dates of service between September 1, 2007 and August 31, 2009) and the number of claims in the sample (56). *See* Exh. 66 (CD) at Sample Design Summary. The documentary record contains a printout of the universe of claims and actual payment amount, as well as a list of the sampled claims. *See generally* Exh. 66. Based on medical review findings, the ZPIC calculated the average overpayment per claim; the standard error of average overpayment; the point estimate of the total overpayment; the standard error of the point estimate; and the relative error of the total overpayment to arrive at the extrapolated overpayment at the lower limit of a one-sided 90% confidence level. Id.

The MPIM describes simple random sampling as involving "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." MPIM, Ch. 3, § 3.10.4.1.1 (emphasis supplied). The MPIM continues, stating that "[t]he 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.'" Id.

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.

Here, each stratum was ordered by the claim number, which is a variable unrelated to the claim amount paid. Dr. K referred to this ordering as "pre-randomization," although the appellant notes that the order within each stratum was not "randomized" in the sense that no mathematically random program was used. Nevertheless, any selection of random claims from similar positions in both strata would have no direct correlation to either paid amount or, by extension, overpaid amount. Thus, ultimately it would make no predictable difference on outcomes if the claims were pulled from similar relative positions from each stratum, based on the same seed number, when there would be no way based on claim number organization to predetermine the outcome by having particular claims in the same relative positions.

A probability sample was then drawn from each stratum, using random numbers supplied by the SAS program based on the selected seed number. There were 2002 claims in the frame for stratum 1, and 786 claims in the frame for stratum 2. Thirty claims were selected for the stratum 1 sample, and twenty six claims for the stratum 2 sample. The appellant has not challenged the randomness of the SAS program used to select the seed number used for the stratum samples nor the randomness of the sequence of claims selected by that algorithm. It is possible, in principle, to enumerate a set of distinct samples for each stratum that the SAS procedure is capable of selecting, with a known probability of selection, as required by chapter 3, section 3.10.2 of the MPIM (now MPIM, Ch. 8, § 8.4.2).

There appears to be no real dispute that either or both strata were correctly drawn in and of themselves once the seed number was applied. The sample for each strata was a probability sample. The question before us then, is whether the use of the same seed number for drawing strata 2, after that seed number was randomly selected by the SAS program for stratum 1, renders the entire sample invalid, because the strata are then considered not statistically independent.[3]

The appellant, through Dr. C., has explained mathematically that using the same seed number in a certain sample (that was not actually used here) consisting of the first thirty (stratum 1)

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[3] There does not appear to be any present dispute regarding the subselection of the reserve in each stratum. *See* Exh. 68 at 8374.

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. Exh. 68 at 8116 and 8119. In his post-hearing submission, Dr. C. contended that his conclusions that the ZPIC's sample was neither a valid probability nor stratified random sample "follow the model of mathematical proof." Exh. 68 at 8376. Dr. K. asserts 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. The ZPIC's "pre-randomization" procedure of ordering the frame by claim number also eliminates the correlation between particular claim (paid) values across strata before applying the sampling seed. However, because no threat to the resulting probability sample exists, no mathematical proof of the absence of a problem is readily available. *See* Exh. 68 at 3350-3352.

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. In any event, we believe 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. No claims were ruled out specifically until the seed number was run to select the actual sample. But once a seed is assigned, again whether one seed or multiple seeds, the probabilities change based on that seed's particular algorithm. To the extent there were not equal probabilities once the seed was selected, that is always the case whether a single seed number or multiple seed numbers are

chosen as the seed number then determines which claims may actually be selected in each stratum. The appellant's argument that some combinations of claims were ruled out once certain claims were selected in one stratum implies 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.

In sum, we are not convinced that the appellant has presented a compelling case that the entire sample is invalidated by the use of the same seed, even if appellant would prefer a sample drawn using a different new seed for each stratum. As the MPIM states, 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. MPIM, Ch. 3, § 3.10.2. Suffice it to say that, given the MPIM provisions, the fact that a contractor may have selected sample claims by a process that another statistician may not prefer, does not provide a basis for invalidating the sampling or the extrapolation as actually drawn and conducted. This is simply not a "flaw" in the sampling process cognizable by current CMS guidelines which would render the actual sample invalid. To hold otherwise would ignore real world constraints imposed by conflicting demands on limited public funds, constraints that CMS chose to incorporate into the 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.

Accordingly the Council finds 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. Accordingly the ALJ's decision invalidating the ZPIC's sampling methodology is reversed. The Council offers no opinion on any other aspect of the ALJ's decision.

DECISION

It is the decision of the Medicare Appeals Council that the ZPIC's sampling methodology was compliant with the MPIM guidance. Accordingly, the ALJ's decision invalidating the ZPIC's sampling methodology is reversed.

This extrapolated overpayment will be recalculated to reflect the ALJ's individual coverage findings for the beneficiaries identified below.

MEDICARE APPEALS COUNCIL

/s/ Clausen J. Krzywicki
Administrative Appeals Judge

/s/ Gilde Morrisson
Administrative Appeals Judge

Date: October 30, 2014