

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

CORRECTED DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-14-2132

In the case of

Anthony Pagliarulo, M.D.
(Appellant)

(Beneficiaries)

Cahaba GBA

(Contractor)

Claim for

Supplementary Medical
Insurance Benefits
(Part B)

(HIC Numbers)

(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 February 25, 2014, because there is an error of law material to the outcome of the claims and because the decision is not supported by a preponderance of the evidence. See 42 C.F.R. §§ 405.1110(b)(1) and 405.1110(b)(1)(ii). The ALJ's decision, which was partially favorable to the appellant physician, addressed an extrapolated overpayment assessed against the appellant in connection with claims for Medicare coverage of various services provided to beneficiaries between March 1, 2004 and March 31, 2006. The ALJ found that certain of the sampled claims were properly reimbursed by Medicare as originally billed or could be reimbursed at a down-coded level. However, the ALJ invalidated the statistical sampling methodology employed by the auditors. Consequently, the ALJ limited the overpayment to the amount identified in claims actually reviewed by the auditors.

By memorandum dated April 24, 2014, the Centers for Medicare & Medicaid Services (CMS) alleges that the ALJ's invalidation of the sampling methodology contained both errors of law and was not supported by a preponderance of the evidence. CMS' memorandum is entered into the record as Exhibit (Exh.) MAC-1. The appellant has provided responsive briefs. The appellant's initial brief (May 13, 2014) is entered into the record as

Exhibit MAC-2 and its supplemental brief (September 3, 2014) as Exhibit MAC-3. The Council has carefully considered the record that was before the ALJ, as well as the CMS memorandum and the appellant's responsive briefs. Based upon that review, the Council reverses the ALJ's unfavorable analysis regarding the sampling methodology utilized for this overpayment. The Council neither reviews nor disturbs the findings below on the individual claims constituting the sample, as neither CMS nor the appellant has contended those findings before the Council.

BACKGROUND

On June 30, 2010, AdvanceMed, a Zone Program Integrity Contractor (ZPIC), presented the appellant with the preliminary results of its audit of the appellant's claims for Medicare coverage of physician services provided to beneficiaries from March 1, 2004 through March 31, 2006. AdvanceMed reported that, using a statistically valid random sample, it had reviewed 90 claims (drawn from a universe of 15,510 claims), involving 85 medical records (beneficiaries) and 227 claims lines. See Exh. MAC-1 at 656-666. Based on that review, AdvanceMed found that sampled claims revealed an actual overpayment totaling \$5,850.72, which was extrapolated to an assessed overpayment of \$398,737. See *id.* at 623 and 659. Addressing its sampling methodology, AdvanceMed explained that it had utilized -

RAT-STATs . . . to select a sample of claims from a list of all relevant claims paid or partially paid to you. An average overpayment per claim was then calculated and multiplied by the total number of relevant paid and partially paid claims to reach a point estimate. Using the standard statistical formulas found in RAT-STATs, a confidence interval was built around the point estimate. AdvanceMed used the lower limit of the 90% two-sided confidence interval to establish the amount of the overpayment.

Id. at 659-660.

The Medicare contractor, on redetermination, and the Qualified Independent Contractor (QIC), on reconsideration, found coverage appropriate for certain sampled claims, either as initially billed or at down-coded levels of reimbursement. Both entities found that AdvanceMed had utilized a valid statistical methodology, and the appellant was liable for the resulting non-

covered costs and ineligible for waiver of recoupment of the resulting overpayment. *Id.* at 505-526 and 28-133.

The ALJ conducted a hearing on February 6, 2014. Represented by counsel, the appellant-physician testified and provided testimony from a certified coder and two statistical experts, Drs. P.M. and H.H. AdvanceMed also participated, providing the testimony of its appeals coordinator and its statistical expert, Dr. W.C. In the decision which followed, the ALJ found that additional audited claims satisfied the pertinent coverage criteria for reimbursement either as initially billed or at down-coded levels. See generally Dec. at Beneficiary-Specific Addendum. (Neither the body of the ALJ's decision nor its addendum are paginated.)

Turning to the sampling methodology, the ALJ first noted that the Medicare contractor had encountered difficulties reproducing the sample because "AdvanceMed had not specified which version of Rat-Stats software it used." The ALJ then struck from the record a portion of AdvanceMed's prehearing brief [page 7 of Exhibit 9]. The ALJ took this action because "AdvanceMed [had] engaged in *ad hominem* attacks on . . . [Dr. P.M.'s] credentials. As a non-party participant AdvanceMed has no standing to address the acceptance of . . . [Dr. P.M.] as an expert. To compound this offense AdvanceMed proffered hearsay criticism of . . . [Dr. P.M.] from another tribunal in an unrelated case"

Addressing the methodology itself, the ALJ explained that he had -

considered in detail the contentious arguments of the statistical witnesses, and is persuaded that the sampling methodology utilized by AdvanceMed did not comply with Medicare requirements. Generally . . . the AdvanceMed sampling was conducted with little regard for the integrity of the process, and it has failed to supply many of the missing details. In particular, the ALJ adopts the summary of flaws contained on pages 17-18 of the report of Dr. . . . [H.H.]. Therefore the extrapolated overpayment calculation was invalid.

The ALJ then found the appellant liable for the remaining non-covered costs and ineligible for waiver of the recoupment of the overpayment.

The Council notes here, that the ALJ effectively incorporated by reference the sampling deficiencies raised by one of the appellant's experts, Dr. H.H. Thus, where CMS challenges certain of the ALJ's "findings," those findings are specifically detailed in Dr. H.H.'s Declaration. See Exh. 11 at 36-53.

CMS' Position

CMS first questions the ALJ's determination that the sampling frame is "impossible to replicate because the record includes an additional data file with a broader date range than the one used for the actual universe." CMS argues that this finding is not supported by a preponderance of the record. Exh. MAC-1 at 9. Rather, CMS asserts, AdvanceMed's identification of the sampling frame and the supporting elements of record has been consistent "from the outset." CMS notes that the appellant's first formal challenge to the sampling methodology arose at the reconsideration level, through a document identified as the Barraclough Report (found at Exhibit 1 at 550-590). This report contained a review of AdvanceMed's methodology by an audit group retained by the appellant. *Id.* at 9. CMS maintains that while the Barraclough Report did enumerate "stock challenges to the sampling methodology," at no point did it "cite inconsistent or excessive data regarding the universe." Rather, it alleged a lack of information sufficient to justify the audit analysis. *Id.* at 9-10.

CMS recounts the appellant's pre-hearing argument that, in response to the appellant's requests for additional supporting information, AdvanceMed had "revealed the existence of *at least two different universe data files, both of which AdvanceMed has contended were the basis for the statistical sampling and extrapolation.*" *Id.* at 10 (citing Exh. 7 at 9-10) (emphasis in original). CMS notes that, in a written response to the concerns expressed by one of the appellant's statistical experts, AdvanceMed's expert explained that the "second data set in the record was a broader set of claims that represented 'all the claim line information for the . . . [appellant] at the time [of the audit]' . . . by removing the unpaid claims and any claims with line items having dates prior to March 1, 2004 or after March 31, 2006 one would end up with the universe actually used." *Id.* (referencing *AdvanceMed Supplemental Brief: Statistical Sampling Methodology* found at Exh. 9).

CMS further maintains that AdvanceMed has been responsive to the appellant's requests for explanation of the methodology at every

turn. Given the amount of post-audit information provided, CMS admits that the particular descriptions of certain supporting submissions could have been more precise, if only to enable a lay appellant to distinguish between such submissions. However, from a professional perspective, CMS reiterates that the sampling methodology is fully compliant with the applicable program guidelines and that the record is replete with documentation supporting that methodology. CMS also notes that, throughout this process, the appellant had engaged at least three statistical experts to review the audit. While not challenging the appellant's right to such assistance, CMS intimates that many of the issues now raised by the appellant result from the confusion to be expected by the cross-pollination of professional opinions. *Id.* at 10-11.

CMS next argues that the ALJ "erred as a matter of law in invalidating the sample on the basis that the claims were used as sampling units." Exh. MAC-1 at 11. CMS argues that, contrary to the ALJ's finding, AdvanceMed's use of claims as sample units was fully compliant with Medicare's sampling guidelines as established by chapter 8, sections 8.4.1.3, 8.4.3.2.2 and 8.4.3.2.3 of the Medicare Program Integrity Manual (MPIM) (CMS Pub. 100-08).¹ Exh. MAC-1 at 11-12.

CMS also asserts that the ALJ "erred as a matter of law in invalidating the sample on the basis that distribution of the stratified average overpayments is not normally distributed." Exh. MAC-1 at 12. CMS notes that-

After determining the stratified average in the sample was not normally distributed . . . [Dr. H.H.] asserted that the ZPIC could no longer use the confidence interval to calculate the overpayment, because there was no longer a 90% probability that the overpayment demand was "equal to the lower limit of a 90% one-sided confidence interval." . . . [Exh. 11 at 51. Dr. [H.H.] . . . cites no relevant authority to support the proposition that non-normality of the average within individual strata or of sampling units within a single sample demonstrate that the sample is statistically invalid. . . . The assumptions underlying Medicare overpayments are that the sample

¹ Manuals issued by CMS can be found at <http://www.cms.hhs.gov/manuals>. Because, at the time of this audit, the sampling guidelines were located in Chapter 3 of the MPIM, **the Council's citations** will be to Chapter 3 of the MPIM.

is an unbiased estimate of the overpayment for all claims in the universe. Although the projection of the sample overpayment to the amount demanded by the contractor relies on the normality of the distribution of sample means, it is at the sample level - not within each stratum. AdvanceMed's demand of the lower bound of the two-sided 90 percent confidence interval as the overpayment amount allows for the lower precision of the study and potential non-normality of the strata.

Id.

CMS explains that, pursuant to HCFA Ruling 86-1, "sampling creates a presumption that the established overpayment amount is valid. From there, an appellant has the obligation of demonstrating how that estimate is wrong. Assertions that the distribution of the average within an individual stratum is not normally distributed do not demonstrate that the sample is invalid." Exh. MAC-1 at 13.

Appellant's Exceptions to CMS' Position

The appellant argues that CMS failed to demonstrate that the ALJ's decision was not supported by a preponderance of evidence or that it contained errors of law. Rather, the appellant contends that the ALJ correctly applied the applicable program regulations and policy to find that AdvanceMed's sampling methodology was intrinsically flawed. Exh. MAC-2 at 2-3. The appellant maintains that both HCFA Ruling 86-1 and chapter 8 of the MPIM provide an inherent "due process right" to challenge the sampling methodology upon which an overpayment is based. The appellant recounts that he retained the services of four "highly experienced experts in the field of statistical studies" (two of whom were involved in development of the Barraclough Report) whose examinations of the audit revealed numerous flaws in AdvanceMed's sampling methodology, which are documented in the record. *Id.* at 3-6.

The appellant reasserts that the sample was based upon multiple universes plainly invalidates its methodology; that CMS has continually ignored the fatal flaws in the sampling methodology; that AdvanceMed's universe also included claims outside the defined audit universe; and that CMS failed to maintain data necessary to replicate and verify that the claims in the universe were within its definition, as required by chapter 8,

section 8.4.4.4.1 of the MPIM. See Exh. MAC-2 at 6-15. Before the Council, the appellant revisits his arguments before the ALJ that the sampling methodology was flawed because AdvanceMed's definition of sampling units were not statistically independent, which is necessary in order to use the Central Limit Theorem (CLT) and confidence intervals, and that "because the stratified average overpayments were not normally distributed, the confidence intervals alleged to apply to the statistical projection were rendered meaningless." *Id.* at 15-17.

The appellant argues that pursuant to 42 C.F.R. § 405.1110, the Council's standard of review here should be limited to simply whether the ALJ's decision contained errors of law, rather than whether the decision is supported by a preponderance of the evidence, because "Q2 Administrators [the QIC] did not participate in the ALJ hearing as a party or non-party participant." Exh. MAC-2 at 17 (footnote omitted).

In his supplemental brief, the appellant argues that the CMS' arguments fail to address "the validity of the conclusion" by Dr. H.H. and other statisticians that "the distribution of the data used was sufficiently 'not normal' to invalidate the 'confidence interval' that [was] based upon that data." Exh. MAC-3 at 2. Rather, the appellant asserts that "CMS sets up a 'straw man' argument," based upon the absence of citation to "relevant authority," to challenge Dr. H.H.'s "proposition that non-normality of the average within an individual strat[um] or of sampling units within a sample demonstrate that the sample is statistically invalid." The appellant maintains that CMS' general argument "implicitly acknowledges" that projection of an overpayment requires normal data distribution and such a distribution is absent here. *Id.* at 2-4 (footnotes omitted).

The appellant emphasized that the auditors' failure to define independent sampling units invalidates the sampling methodology generally and the AdvanceMed's use of the CLT specifically. Exh. MAC-3 at 4-6. The appellant characterizes, as little more than superficial, CMS' reliance upon chapter 8, section 8.4.3.2.2 of the MPIM for the proposition "that various types of sampling units are acceptable." The appellant explains that, per Dr. H.H.'s analysis, the "problem identified is not the sampling unit that was used, it was that the methodology was not designed so that each sampling unit was independent of other sampling units." *Id.* at 7.

Finally, the appellant argues that the AdvanceMed's use of the lower limit of a 90% one-sided confidence interval does not correct a sampling methodology too statistically flawed to form the basis of a confidence interval. The appellant maintains that his position is fully consistent with chapter 8, section 8.4.1.1 of the MPIM which directs that "an appeal challenging the validity of the sampling methodology must be predicated on the *actual statistical validity* of the sample as drawn and conducted." Exh. MAC-3 at 8-9 (emphasis in original).

APPLICABLE LEGAL AUTHORITIES

CMS (formerly 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, the Ruling 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.

CMS's sampling guidelines in effect at the time of the sample are found in Chapter 3 of the Medicare Program Integrity Manual. See MPIM, Ch. 3, § 3.10 (eff. 05-10-04, now at MPIM Ch. 8, § 8.4 eff. 06-28-11). The 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. 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 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 added).

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 added). 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.

As stated just 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. Section 3.10.5.1 addresses this, 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.² 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.

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.*

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 added).

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. Relative to Part B claims, CMS states that "[t]he universe shall consist of all *fully and partially paid claims*" *Id.* at § 3.10.3.2.1.B (emphasis added). 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.*

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 added).

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.

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.

ANALYSIS

CMS' Allegation of an Error of Law

The appellant's assertion that CMS could not allege a basis for requesting own motion review by the Council based on a preponderance of the evidence standard because it did not participate in the ALJ hearing is incorrect. In pertinent part, the regulation establishing the Council's standard for own motion review provides:

(c) *Referral of cases.* (1) Referral by CMS after participation at the ALJ level. If CMS or its contractor participated in an appeal at the ALJ level, the [Council] exercises its own motion authority if there is an error of law material to the outcome of the case, an abuse of discretion by the ALJ, the decision is not consistent with the preponderance of the evidence of record, or there is a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review under this standard, the [Council] will limit its consideration of the ALJ's action to those exceptions raised by CMS.

42 C.F.R. § 405.1110(c)(1).

CMS' contractor, AdvanceMed, participated in the ALJ hearing. See Dec. at 1; see also ALJ Hearing CD. Thus, the appellant's argument is unsupported in the context of the record and applicable regulatory standards. The Council may take own motion review here based on either an error of law or an ALJ decision not based on a preponderance of the evidence of record.

Sampling Methodology

As noted above, CMS Ruling 86-1 establishes a presumption of validity that attaches to the statistical sampling and extrapolation undertaken by a Medicare contractor. CMS Ruling 86-1 at 86-1-9 and 86-1-10. The burden of proof is therefore on the appellant to demonstrate that the methodology used by the contractor is invalid. *Id.* In the present case, the ALJ erred as a matter of law in his application of CMS Ruling 86-1 and MPIM guidance. Moreover, a preponderance of the factual evidence leads the Council to conclude that the statistical sampling and extrapolation conducted in this case were presumptively valid, and that such presumption has not been rebutted.

The issues surrounding the sampling methodology underlying this overpayment have been extensively argued and briefed. From a substantive perspective, the ALJ essentially adopted Dr. H.H.'s four-point summary of purported flaws in the sampling methodology. See ALJ Dec. at "**Sampling and extrapolation;**" see also Exh. 11 at 52-53. However, the Council notes that the ALJ did not discuss those points in any detail nor indicate why he

found them sufficiently convincing to invalidate the statistical sampling conducted in this case.

Dr. H.H.'s expert opinion, in large part, is based on principles drawn from several of the references, including W.G. Cochran's *Sampling Techniques*, 3rd Edition; William Feller's *An Introduction to Probability Theory and Its Application* and W.E. Deming's *Sample Design in Business Research*, utilized in drafting the instructions found in MPIM Chapter 3, section 10. See Exh. 11 at 6-7 and 46-47. In Dr. H.H.'s opinion, the principles derived from these texts should be read as essentially incorporated by reference into the MPIM, because the MPIM cites them as "**Resources.**" See *id.* at 41-42, 46-48. While the Council fully recognizes the degree of expertise reflected in the Cochran, Feller and Deming treatises, as well as in those of other leading statisticians, the totality of the standards for precision sampling in those texts are not incorporated into the MPIM, as suggested by Dr. H.H. Rather, the MPIM's sampling guidance is derived from a variety of resource texts reflective of the variety of sampling theories available. The standards found in CMS Ruling 86-1 and the MPIM that govern Medicare sampling and overpayment estimation confer great latitude to CMS in conducting sampling beyond the strict precision sampling guidance found in the listed statistics texts and references.

ALJs and the Council are bound by all laws and regulations concerning the Medicare program and all CMS Rulings. 42 C.F.R. § 405.1063. ALJs and the Council are not bound by CMS administrative authority, but are required to afford "substantial deference" to that authority when applicable in a given case or explain the reasons for not doing so in the decision. 42 C.F.R. § 405.1062. The ALJ erred in relying upon Dr. H.H.'s opinion that the statistical sample is invalid, as that opinion is based upon statistical sampling treatises that are not binding upon Medicare adjudicators and do not adequately consider the administrative authority set forth above, which permits more flexibility and imprecision in sampling than the standard statistical texts and treatises contemplate but offset such imprecision by reducing the assessed overpayment to a lower confidence bound.

The MPIM requires that a Medicare contractor follow six steps in conducting a statistical sample for overpayment estimation:

1. Select the provider or supplier.
2. Select the period to be reviewed.

3. Define the universe, sampling unit, and sampling frame.
4. Design the sampling plan and select the sample.
5. Review each of the claims or line(s) on the claim and determining if there was an overpayment, or, for administrative reviews, an underpayment; and, as applicable,
6. Estimate the overpayment.

MPIM Ch. 3, § 3.10.1.3.

AdvanceMed's sampling methodology was initially set out in its preliminary report of the audit results and the accompanying memorandum detailing the methodology. See Exh. 1 at 656-687. From a frame consisting of 15,510 claims, AdvanceMed drew a sample consisting of "90 claims, 85 medical records and 330 CPT [claim] lines." *Id.* at 657 and 666. The methodology memorandum indicated that AdvanceMed designed a stratified random sample, with sampling units consisting of "at least one line of service Paid > 0 to the provider." *Id.* at 662 (emphasis added). The claims fell within the March 1, 2004 through March 31, 2006 (as processed through March 31, 2006) period. See *id.* AdvanceMed utilized RAT-STATS (Version 1.0) to create two sample size estimation procedures, stratified variable sample size determination and unrestricted variable sample size determination. These two methods were used in order to compare the theoretical differences in sample size estimates derived from using simple random sampling versus stratified random sampling. *Id.* at 663. AdvanceMed continues to explain the methods by which it arrived at other sampling elements. *Id.* at 663-665. AdvanceMed then specifically identifies, both on an overall and strata-specific level, the frame size, sample size, claims in error, claim error rate, provider error rate, point estimate, standard error and relative to the two-sided 90% confidence interval, the upper and lower limits, precision amount and percent, relative sampling error, and t- and z-values used. *Id.* at 675-678.

The material accompanying AdvanceMed's explanation of its audit methodology identifies the claims divided among three audit strata. Exh. 1 at 693-694. Also included here are beneficiary-specific comment screens and evaluation and management review sheets which identify the beneficiary-specific dates of service, each of which falls within the date range identified in the audit. *Id.* at 696-834.

Based on the sampling documentation and accompanying evidence of record, the Council concludes that the sampling at issue resulted in a probability sample, giving rise to the presumption that the projected overpayment amount is valid, in accordance with CMS Ruling 86-1.

In the reports and opinions of the statisticians below, there were many (quite contentious) objections and rebuttals raised to the manner in which the statistical sampling was conducted in this case. Many of those objections were addressed below and were not raised before the Council. Basically, the objections raised in the CMS referral memorandum and in the appellant's responsive briefs, and which will be addressed here, involved three statistical issues:

1. The reliability of the universe and frame data sets furnished by AdvanceMed;
2. The independence of the sampling units; and
3. The non-normality of distribution of the sampled overpayments and the Central Limit Theorem (CLT).

Each of these will be addressed below.

1. The Reliability of the Universe and Frame Data Sets furnished by AdvanceMed.

Dr. H.H. first asserts that (1) several non-identical universe files were made available for his review; (2) thus, he could not reproduce a "frame file." Dr. H.H. asserted that, either individually or collectively, these issues violated MPIM, chapter 8, sections 8.4.2 and 8.4.4.4.1 (during the audit chapter 3, sections 3.10.2 and 3.10.4.4.1, respectively). See Exh. 11 at 52.

Other than to reassert that the purported presence of multiple data sets made replication of the sampling methodology impossible, neither Dr. H.H. nor the appellant has directly responded to the CMS' argument, which had been advanced by AdvanceMed's expert in the ZPIC's supplemental brief to the ALJ, that the "second data set," upon which the appellant's argument was based, was a broader set of claims that represented all the

appellant's claim line information at the time of the audit. See Exh. 9.

Dr. W.C. of AdvanceMed indicated in his January 21, 2014 supplemental brief (Exhibit 9) that the first set of claim lines data supplied to the appellant, consisting of a frame size of 15,510 claims and a total paid frame amount of \$1,399,105.78, so clearly aligned with the identified frame size and paid amount in the extrapolated overpayment that "any reasonable person could discern" that this was the frame data. The Council finds that this was the frame used for the overpayment and that it was timely made available to the appellant. The Council further agrees with CMS that the appellant's consultants should have been able to identify that this data constituted the overpayment frame based on the identified frame size and total paid amount.

In any event, the Council has reviewed the record and notes that while multiple CDs containing frame and universe data were furnished to the appellant, they were furnished at the appellant's request in each instance either due to additional information the appellant was requesting or due to password and accessibility problems the appellant reported with previous CDs. In each of these instances, the CDs were accompanied with an explanation of what they contained and how they were responsive to the appellant's requests. There does not appear to have been any reluctance on the part of either Cahaba or AdvanceMed to be forthcoming and transparent in response to any request of either the appellant's counsel or former counsel, and the responsive materials were identified by the contractors in each instance.

The appellant argued that even with the correct data set identified, there were still discrepancies between the universe description and the listed claims in the frame. The appellant pointed out that some of the claims in the frame listed in the identified data set had paid dates that were, in fact, after March 31, 2006, and thus outside of the defined universe. The Council notes that the contractor has offered the explanation that the "claim paid" dates identified on the line items in the frame are not necessarily the "claim processed" dates. The Council finds this explanation plausible, and the Council notes that the contractor is in the unique position to understand the contractor's claims processing procedures. In any event, given that all of the dates of service in both the data set identified as the frame and the sampled claims are within the dates defined as the universe, the Council finds that an extrapolation from the sample at issue to the identified frame was reasonable.

2. The Independence of the Sampling Units.

Dr. H.H. also opined that AdvanceMed's methodology is invalid based on an assertion that the sampling units are not independent. Exh. 11 at 43-45 and 46-48. According to Dr. H.H., confidence interval extrapolation is valid only in instances where the variables at issue are statistically and mathematically independent. *Id.* at 47. In Dr. H.H.'s view, it was improper for AdvanceMed to base the extrapolation in this case on a sample in which the sampling unit was defined as a claim because there are multiple claims per beneficiary in the frame. In turn, this resulted in a few instances of multiple claims for the same beneficiary being selected for the sample. It is Dr. H.H.'s position that different claims for the same beneficiary cannot be statistically independent of one another. See *id.* at 47-48. Dr. H.H. asserts that the sampling methodology is invalid because AdvanceMed's definition of the sampling units did not result in statistically independent sample units, which precluded using the Central Limit Theorem and confidence interval estimation. *Id.* at 52.

The Council disagrees and finds that the opinion of Dr. H.H. on this point is insufficient to overcome the presumption that the sampling and extrapolation were valid.

The MPIM, at chapter 3, section 3.10, sets out the general "**Steps for Conducting Statistical Sampling.**" Pertinent here, chapter 3, section 10.3.2.1 provides that the universe for sampling involving Part B claims shall "consist of all full and partially paid claims submitted . . . for the period selected for review and for the sampling units to be reviewed." Chapter 3, section 3.10.3.2.2 provides that -

Sampling units are the elements that are selected according to the design of the survey and the chosen method of statistical sampling. They may be an individual line(s) within claims, individual claims, or clusters of claims (e.g., a beneficiary). For example, possible sampling units may include specific beneficiaries seen by a physician during the time period under review; or, claims for a specific item or service. In certain circumstances, e.g., multi-stage sample designs, other types of clusters of payments may be used. In principle, any type of sampling unit is permissible as long as the total aggregate of such

units covers the population of potential mis-paid amounts.

Addressing the sampling frame, section the MPIM at chapter 3, section 3.10.3.2.3 provides that the -

sampling frame is the "listing" of all the possible sampling units from which the sample is selected. The frame may be, for example, a list of all beneficiaries receiving items from a selected supplier, 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.

The ideal frame is a list that covers the target universe completely. In some cases the frame must be constructed by combining lists from several sources and duplication of sampling units may result. Although duplicate listings can be handled in various ways that do not invalidate the sample, it is recommended that duplicates be eliminated before selecting the sample.

The record does not establish by a preponderance of the evidence that the sampling units are not independent. Responding to the appellant's argument (originally presented by appellant's statistician Dr. M. and adopted by Dr. H.H.) explained:

[Dr. M.'s] conclusion would mean that every CLT-based extrapolation ever performed to determine a Medicare overpayment was invalid. This is obviously false. The statistical notion of independence, in sampling for overpayment estimation, means that the amount of overpayment for a claim does not depend on which claims are reviewed alongside it. In other words, *observations* are what must be independent; the observed overpayment on one claim should not change based on which other claims are observed in the sample. A statement that the data must be independent is . . . [illogical]; the overpayment amounts for any provider are of course related, given that they will

naturally be for similar types of procedures, all billed to Medicare, within a similar time frame.

Exh. 9 at 9 (emphasis in original).

Further, as CMS argues in its referral memorandum -

The fact that a single beneficiary may have been represented by more than one claim in the sample does not mean the claims are not independent or the sampling units were not randomly selected from the universe of claims. Each claim for services must be independently supported. Pursuant to § 1833(e) of the Act, the Appellant has the burden to show that each service should be covered by Medicare. Consistent with MPIM instructions, there is no reason why the individual claims cannot serve as independent sampling units as long as each claim has an equal probability of being selected.

Exh. MAC-1 at 12.

CMS' position reflects the MPIM guidance, which expressly authorizes the use of "claims, individual claims, or clusters of claims (e.g. a beneficiary)" as the sampling units. MPIM, Ch. 3, § 3.10.3.2.2.

Because selection of claims as sampling units is expressly endorsed by the MPIM, the Council does not find that their use in the present case renders the sampling invalid. The Council finds no inherent problem with having a sample containing multiple claims pertaining to the same beneficiary, as would be expected when using claims rather than beneficiaries as the sample unit, so long as the claims do not contain duplicate billings for the same services and the findings with regard to each claim were assessed separately.

3. The Non-Normality of Distribution of the Sampled Overpayments and the Central Limit Theorem (CLT).

Dr. H.H. also opined that the sample as drawn may not validly be used to extrapolate the overpayment in this case because the overpayments in the sample are not normally distributed. According to Dr. H.H., the non-normal distribution of the overpayments within the sample undermines the applicability of

the Central Limit Theorem in the present case. Exh. 11 at 48-52. As a result, Dr. H.H. opines that "the lower 90% two sided confidence interval does **not** provide a 95% probability that the population mean exceeds the value computed." *Id.* at 50 (emphasis in original). In other words, Dr. H.H. is not persuaded that there is a 95% probability that the overpayment demand in this case is for less than the amount of the actual overpayment. The ALJ also accepted this reasoning as a basis for invalidating the sampling and extrapolation

As CMS argues in the referral memorandum, there is no support in CMS Ruling 86-1 or in the MPIM for the proposition that "non-normality of the average of sampling units *within a single sample* demonstrate[s] that the sample is statistically invalid." Exh. MAC-1, at 13 (emphasis in original). Contrary to Dr. H.H.'s opinion, the relevance of the Central Limit Theorem (CLT) in this case, as in many of the overpayment cases before the Council involving statistical sampling, is that it demonstrates that a single sample of an adequate (but finite) size is sufficient to obtain a representative sample *even if* the overpayments in the sample are not normally distributed. This is because, under the theory of the CLT, the resulting means of a large number of independent samples from the same frame could be expected to follow a normal distribution when samples of sufficient size are repeatedly taken; thus, there is a strong probability of the mean of the actual sample taken, regardless of normality of distribution within the particular sample, being near the mean that would be found had a large number of samples been drawn.

The Council notes that in most overpayment cases involving statistical sampling and extrapolation that come before the Council, the individual sampled overpayment results are *not* normally distributed. Certainly, they are rarely if ever normally distributed within each individual stratum, and this is the first time the Council can recall an argument being made that intra-strata results must be normally distributed in order to apply confidence level estimation. Nonetheless, the sample overpayments are extrapolated to the frame using confidence interval estimation in most all of the statistical sampling cases done by CMS contractors and reviewed by the Council. In addressing the CLT arguments, the Council emphasizes that it is *not* taking the position, as suggested by Dr. H.H., that the CLT "guarantees that the sample average is normally distributed because the sample is large." See Exh. 11, at 50. Rather, we are finding that while the sample overpayments may not be

normally distributed in the actual sample, the probability of the actual sample's mean being near the average mean that would be calculated from a large number of samples from the same frame (which means would be normally distributed) is significant, based on the theory behind the CLT.

In summary, as the MPIM emphasizes, if a particular probability sample design is properly executed, *i.e.*, defining the universe, the frame, the sampling units, using proper randomization, accurately measuring the variables of interest, and using the correct formulas for estimation, then assertions that the sample and its resulting estimates are "not statistically valid" cannot legitimately be made. MPIM, Ch. 3, § 3.10.2. Suffice it to say that, given MPIM provisions, the fact that AdvanceMed selected a sampling methodology or sample size that another statistician may not prefer, or which may not result in the most precise point estimate, does not provide a basis for invalidating the sampling or the extrapolation as drawn and conducted *in this case*. These are simply not "flaws" in the sampling cognizable by the guidelines which render the actual sample drawn invalid. To hold otherwise would ignore real world constraints imposed by conflicting demands on limited public funds, constraints which CMS chose to incorporate into the statistical sampling guidelines. The Council must give substantial deference to CMS guidelines including where, as here, CMS has chosen a reasonable, feasible, and well-articulated approach for collecting overpayments which, by design, offsets precision in favor of lower recovery amounts. To the extent that Dr. H.H. or other statisticians have significant concerns with the parameters of CMS's statistical sampling guidelines, those concerns should be raised with CMS, as the Council has no authority to invalidate CMS guidelines.

As evident from the supporting documentation and explanation of the sampling methodology documented in the record, from the outset of the review process, AdvanceMed's sampling methodology was compliant with the MPIM guidance.

DECISION

It is the decision of the Medicare Appeals Council that that ALJ's invalidation of the sampling methodology underlying the extrapolated overpayment in this case should be reversed. The extrapolated overpayment will be recalculated to be consistent with the coverage decisions on the individual sampled claims

following the ALJ's decision. The appellant remains liable for the resulting non-covered costs and ineligible for waiver of the final overpayment, as this has not been contested before the Council.

MEDICARE APPEALS COUNCIL

/s/ Gilde Morrisson
Administrative Appeals Judge

/s/ Constance B. Tobias, Chair
Departmental Appeals Board

Date: September 26, 2014