DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-10-230

In the case of	**Claim for**
Podiatric Medical Associates (Appellant)	Supplementary Medical Insurance Benefits (Part B)
**** (Beneficiaries)	**** (HIC Numbers)
Cahaba, GBA (Contractor)	**** (ALJ Appeal Number)

The Administrative Law Judge (ALJ) issued a decision dated October 1, 2009, which concerned a post-payment statistical sample of claims for Medicare coverage of podiatric and related medical services provided to various beneficiaries between September 1, 2004, and February 9, 2007. The ALJ found that the statistical sample and extrapolation of the sampled results upon which the overpayment was based were valid; that the appellant was liable for the cost of the non-covered services; and that the appellant's liability could not be waived. The appellant has asked the Medicare Appeals Council (Council) to review this action. The appellant's request for review has been entered into the record as Exhibit (Exh.) MAC-1.

The Council reviews the ALJ's decision *de novo*. 42 C.F.R. § 405.1108(a). The Council will limit its review of the ALJ's action to the exceptions raised by the party in the request for review, unless the appellant is an unrepresented beneficiary. 42 C.F.R. § 405.1112(c). As set forth below, the Council modifies the ALJ's decision. The Council finds that the statistical sampling cannot be upheld, and that the overpayment

is limited to the actual sample results on the twenty-six claims which remained at issue before the ALJ.

BACKGROUND

The appellant, in the person of Rondrick Williamson, DPM, operates a podiatric practice. On March 19, 2007, Cahaba Safeguard Administrators (Cahaba Safeguard), a Medicare Program Safeguard Contractor (PSC), notified Dr. Williamson that it would visit the appellant's facility, the next day, to review (*i.e.*, audit) claim files for seventy-four beneficiaries to ensure the propriety of the corresponding Medicare payments. Exh. 24 at Tab A. The appellant subsequently testified at the ALJ hearing, and the PSC did not dispute, that the PSC investigators copied complete medical files for seventy-four beneficiaries during this review. By letter dated May 5, 2008, the PSC notified the appellant of its preliminary audit results. Based upon a general finding of inadequately documented claims, the PSC determined that, during the period September 1, 2004, through February 9, 2007, the appellant had received a Medicare overpayment, totaling at least $625,258.84. The PSC indicated that the overpayment was projected from a sample of thirty claims, the documentation of which, "did not meet various Medicare coverage requirements." Exh. 1 at 346.

By letter dated May 27, 2008, Cahaba GBA, the appellant's Medicare carrier, formally notified the appellant of the overpayment. Exh. 1 at 99. Having retained counsel, the appellant requested a redetermination. Cahaba GBA issued a redetermination which "partially covered" some of the claims in issue. *Id.* at 321. Cahaba GBA subsequently recalculated the extrapolation based on the partially covered claims, and reduced the overpayment (including principal and interest) to $407,912.91. *Id.* at 317. The appellant requested reconsideration by a Qualified Independent Contractor (QIC).

The QIC issued a partially favorable reconsideration. Exh. 1 at 4. The QIC reconsideration found the actual overpayment on the sampled claims to be $1,481.29 and reduced the extrapolated overpayment to $362,094.63. Exh. MAC-1 at Tab G. Following the appellant's identification of errors in the post-reconsideration recalculation, the extrapolated overpayment was again recalculated and reduced to $334,428.57. *See* Exh. MAC-1 at 2 and Exh. 24 at Tab F-2.

The appellant requested a hearing before an ALJ.

The ALJ conducted a hearing by telephone on May 27, 2009. The appellant was represented by counsel and offered testimony from Dr. Williamson; Robert Weatherford, a compliance coding expert and John T. Sennetti, PhD., an expert in auditing and statistical sampling. The PSC, represented by counsel, appeared at the hearing and provided argument and testimony from a statistical expert (Mr. Casselman), an individual who participated in the medical review of the claims (Ms. Kelly), and an investigator (Mr. Carter). Cahaba GBA, offered argument/testimony from a senior statistician (Ms. Binns). Cahaba GBA's Medical Director (Dr. McKinney) also participated in the hearing. Dec. at 2-3. At this point, the overpayment was based on an extrapolation from a finding of actual overpayments in twenty-six claims for twenty-five beneficiaries. *See* Appendix to ALJ Decision.

The ALJ heard testimony on both the sampling process and the coverage aspects of the sampled claims. Throughout the hearing, the appellant maintained that the PSC had not provided it with information sufficient to assess the validity of the sample. The appellant also asserted that it was denied due process because it was not allowed to cross-examine the witnesses from either the PSC or Cahaba GBA.

Following the hearing, the ALJ issued an Order providing an opportunity for post-hearing briefs and responses. *See* Exh. 17 at 9. The PSC's post-hearing brief included a CD[1] with information pertinent to the sample in the case and addressed in its post-hearing brief. Upon consideration of the appellant's response to the PSC's submission, the ALJ determined that the PSC had not provided this CD to the appellant. *Sua sponte*, the ALJ provided a copy of the CD to the appellant. The ALJ gave the appellant an opportunity to respond, in writing, to its contents, as well as an opportunity for a supplementary hearing. Dec. at 3.

The appellant responded by letter dated August 28, 2009. There, the appellant recounted that it received the CD pursuant to notice from the ALJ's office that the PSC had not, of its own volition, provided the CD to the appellant. The appellant characterized this development as -

[1] Throughout the decision, the ALJ identified this disc as a DVD.

> once again a clear confirmation of what the Appellant has argued throughout this case: that Cahaba GBA and Cahaba GSA [the PSC] have both failed, despite formal requests by the Appellant, to provide the statistical documentation which they are required to maintain and produce to appellants. The Cahaba entities' lack of concern for fundamental due process continues unabated, and the Appellant wonders who will remedy this obvious breach of law and regulation.

Exh. 25 at 1.

The appellant continued, reasoning that – "[a]t this point it little matters what is on the CD-ROM." The appellant questioned the origin of the data on the CD, the time and manner of (as well as the reason for) the CD's creation, and its author. The appellant indicated that its skepticism was founded in its belief that documents "previously produced by Cahaba have been altered, modified and withheld, as discussed in prior briefing. The appellant maintained that it was not timely provided with all of the pertinent sampling information and now has "no ability to challenge it or respond to it in a meaningful way." Exh. 25 at 2.

Upon the advice of its expert, the appellant concluded, arguing that -

> the "new" documentation does <u>not</u> correct the flaws in the statistical study which were discussed at the hearing and in the Appellant's briefing:
>
> 1. The universe (sampling frame) is missing;
>
> 2. The random numbers are not connected to the universe of claims;
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> 3. The sample size is far too small;
>
> 4. The co-efficient of variation (precision) is unacceptably high;
>
> 5. There are no working papers, as required by the Program Integrity Manual; and

> 6. Cahaba failed to comply with the Medicare Modernization Act in assessing and extrapolating the overpayment.

Exh. 25 at 2 (emphasis in original).

The ALJ's decision followed.

The ALJ first addressed the question of medical necessity for the underlying "podiatric treatments, evaluation and management services, and other physician services" present in the sampled claims. The ALJ found that "the medical record for the claims at issue is clearly deficient. Some of the files do not even contain medical records at all." Dec. at 11.

Addressing the evaluation and management (E/M) services, the ALJ found the medical records to be "clearly inadequate and insufficient to support billing with a HCPCS -25 modifier.[2] Many of these records do not even indicate that any E/M services were performed." Dec. at 11. Further, "treatment notes for the podiatric services rendered are extremely sparse" either failing to indicate the need for the particular service or indicating that the service in issue was routine foot care. Thus, the ALJ concluded that "the claims for uncovered services must also remain denied." *Id.*

Turning to statistical sampling, the ALJ noted that a provider bears the burden to demonstrate the invalidity of a sample. Based on consideration of the written and testimonial evidence, the ALJ rejected the appellant's contention that the PCS "cherry-picked" the claims which compromised the sample. Dec. at 13.

The ALJ recognized that the appellant had not received "the entire file in a timely manner." However, the ALJ reasoned that "the appellant's attempts in requesting all the necessary

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[2] Providers and suppliers utilize the Healthcare Common Procedure Coding System (HCPCS) in filing claims for Medicare reimbursement. HCPCS is comprised of two coding levels. HCPCS Level I consists of the American Medical Association's *Current Procedural Terminology* (CPT). CPT codes identify medical services and procedures furnished by physicians and other health care professionals. HCPCS Level II is an alphanumeric standardized coding system used primarily to identify products, supplies and services not included in the CPT codes. The HCPCS "-25" modifier identifies a "significant, separately identifiable evaluation and management service by the same physician on the day of a procedure."

documentation were fairly minimal" having been made to "the Medicare carrier [Cahaba GBA] and to the ALJ's office, neither of which are directly connected to the PSC." Dec. at 14. Further, the ALJ noted that once the PSC "finally submitted" the requested information to the ALJ, the appellant elected not to respond to it "even though the fact that [the] information was missing was fairly obvious from the PSC's brief itself and even noted by the appellant in its response." *Id.* (citation omitted). The ALJ found no merit in the appellant's position, as framed in its August 28, 2009, letter (Exhibit 25), that there was no point in responding to the late-supplied sampling information because the hearing was long-passed and it had been precluded from cross-examining the PSC's witnesses. The ALJ recounted that he had provided the appellant an opportunity for a supplementary hearing and questioned how the appellant could elect to not avail itself of every opportunity to make its case given the concerns it had expressed throughout the history of the case before the ALJ. While noting that he "sympathizes with the appellant's situation" the ALJ nevertheless found that -

> the late submission of part of the PSC's overpayment calculation file does not invalidate the overpayment itself. Given the extent to which the ALJ provided the appellant with an opportunity to challenge and voice any concern with any and all contents of the study . . . the appellant's due process rights were not violated.

Dec. at 14-15.

The ALJ rejected the appellant's argument that the lack of a probe study and/or validation review invalidated the sample, finding that as neither of those techniques was required by the guidance enunciated in the Medicare Program Integrity Manual (MPIM) (Pub. No. 100-08). Dec. at 15. Further, the ALJ did not accept the appellant's argument that the extrapolation was invalid because the coefficient of variation was too high and the sample size too small. The ALJ noted the PSC's argument that "the lack of precision rendered by the study is incorporated in the extrapolation, actually working to the financial advantage of the appellant." The ALJ distinguished between precision and accuracy pointing out that a greater coefficient of variation "without a larger sample size will necessarily increase the confidence interval." The ALJ reasoned that this method actually works in the appellant's favor because CMS, routinely, "only charges an overpayment of the *lower bound*

of the confidence interval." *Id.* at 15-16 (emphasis in original).

Responding to another facet of the appellant's "due process" argument, the ALJ then found that use of a one-sided 90% confidence interval was appropriate. The ALJ noted that while a 95% interval is generally "used for such extrapolations," the 90% methodology reflects the guidance in the MPIM and is supported by case law. Dec. at 16.

The ALJ also found no merit in the appellant's argument that the sample design was flawed because PSC was required to produce separate samples for each claim year under review. Again relying upon the MPIM, the ALJ noted that separate claim year samples are required for claims paid under "the Medicare cost report," that is Medicare Part A claims. The claims under review in the appellant's case involved Medicare Part B. Thus, the ALJ determined, the sample design was correct. Dec. at 16-17.

Regarding liability, the ALJ found no evidence in the record that the beneficiaries had received Advance Beneficiary Notices explaining possible non-coverage for the services provided. Thus, the ALJ determined, under section 1879 of the Act, the appellants could not be held liable for any of the resulting non-covered costs. However, as a provider whose knowledge of possible non-coverage was presumed, the appellant could be held liable for such non-covered costs. Further, the ALJ determined that the appellant's liability for the overpayment could not be waived under section 1870 of the Act. Dec. 11-12.

With modification to encompass issues arising during the ALJ hearing and subsequent decision, the appellant's arguments in its request for review otherwise consistently reflect those raised during the hearing as well as in its pre- and post-hearing briefs. Summarized here, the appellant argues that its due process rights were violated at the ALJ hearing because the ALJ denied it the opportunity to cross-examine witnesses afforded to parties to ALJ hearings by 42 C.F.R. §§ 405.1000(b) and 405.1036(g). Exh. MAC-1 at 4. The appellant asserts that it performed podiatric, as well as related E/M or physician services authorized for Medicare reimbursement under applicable federal law, regulations and program guidance. Exh. MAC-1 at 5-22. The appellant reiterates that - the PSC failed to follow the applicable laws and CMS program memoranda prior to

issuing an extrapolated overpayment; the extrapolated overpayment should be overturned because the PSC failed to follow basic due process requirements; the lack of documentation renders the extrapolation invalid; the PSC statistical study was flawed in design; and the ALJ accepted "inadmissible and improper evidence" from the PSC. Exh. MAC-1 at 22-38. For these reasons, the appellant maintains that if an overpayment is appropriate, it should be limited in amount to those Medicare funds associated with the claims actually review by the PSC, rather than to an extrapolated overpayment. Exh. MAC-1 at 38.

APPLICABLE LEGAL STANDARDS

Statistical Sampling

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. We incorporate that discussion by reference here. The Ruling provides, in part:

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

CMS Ruling 86-1 at 9 and 10.

CMS's sampling guidelines are found in chapter 3, section 3.10 of the MPIM. Those 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 carriers 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 ZPIC BI unit or the contractor MR 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 ZPIC BI units 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. MPIM, ch. 3, at § 3.10.4.1. Stratified sampling is a design that "involves classifying the sampling units in the frame into non-overlapping groups or strata." The objectives are 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, § 3.10.4.1.3. This section continues providing that "the independent random samples from the strata need not have the same selection rates." *Id.*

The MPIM provides the following guidance with respect to selecting the sample size:

> The size of the sample (i.e., the number of sampling units) will have a direct bearing on the precision of the estimated overpayment, but it is not the only factor that influences precision. The standard error of the estimator also depends on (1) the underlying variation in the target population, (2) the particular sampling method that is employed (such as simple random, stratified, or cluster sampling), and (3) the particular form of the estimator that is used (e.g., simple expansion of the sample total by dividing by

> the selection rate, or more complicated methods such as ratio estimation). It is neither possible nor desirable to specify a minimum sample size that applies to all situations. A determination of sample size may take into account many things, including the method of sample selection, the estimator of overpayment, and prior knowledge (based on experience) of the variability of the possible overpayments that may be contained in the total population of sampling units.
>
> **In addition to the above considerations, real-world economic constraints shall be taken into account.** As stated earlier, sampling is used when it is not administratively feasible to review every sampling unit in the target population. In determining the sample size to be used, the PSC or ZPIC BI unit or the contractor MR unit shall also consider their available resources. That does not mean, however, that the resulting estimate of overpayment is not valid, so long as proper procedures for the execution of probability sampling have been followed. **A challenge to the validity of the sample that is sometimes made is that the particular sample size is too small to yield meaningful results. Such a challenge is without merit as it fails to take into account all of the other factors that are involved in the sample design**.

MPIM, ch. 3, § 3.10.4.3 (emphasis added).

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, at § 3.10.9.2 (emphasis added).

Medically Reasonable and Necessary

Medicare covers “medical and other health services” under Part B, which is defined in the Social Security Act (Act) to include physician services. Act § 1861(s); *see also* 42 C.F.R.

§ 410.10(a). Physician services "are the professional services performed by a physician or physicians for a patient including diagnosis, therapy, surgery, consultation and care plan oversight." Medicare Benefit Policy Manual (MBPM), Pub. 100-02, ch. 15, § 30.A. Section 1862(a)(1)(A) of the Act provides that only items and services that are "reasonable and necessary" for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member are covered under the Medicare program. *See, also,* 42 C.F.R. § 411.15(k).

Section 1833(e) of the Act prohibits payment "to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due." It is the responsibility of the provider or supplier to furnish sufficient information to enable the contractor to determine whether payment is due and the amount of the payment. 42 C.F.R. § 424.5(a)(6).

The Medicare Claims Processing Manual (MCPM), Pub. 100-04, chapter 12, section 30.6 addresses the use of E/M service codes. Section 30.6.1.A provides, in part, that medical necessity is the overarching criterion for payment, in addition to the individual requirements necessary to support the level of service represented by the CPT code(s) billed.

DISCUSSION

Due Process

Contrary to its arguments during the hearing and in its post-hearing submissions, the appellant's due process rights were not compromised by its inability to cross-examine the Cahaba GBA or Cahaba Safeguard witnesses in the ALJ hearing.

The appellant contends that its right to cross-examine those witnesses is preserved by regulation. Specifically, the appellant relies upon 42 C.F.R. § 405.1000(b) which provides that parties to an ALJ hearing may "present and/or question witnesses," and 42 C.F.R. § 405.1036(g) which provides that an ALJ "may" allow a party or its representative to question witnesses. However, the appellant's right to cross-examine only extends to a "party" to an ALJ hearing.

The program regulations, addressing ALJ hearings provide, in pertinent part,

> (c) In some circumstances, a representative of CMS or its contractor, including the QIC, QIO, fiscal intermediary or carrier, may participate in or join the hearing as a party. (*see* § 405.1010 and § 405.1012).

42 C.F.R. § 405.1000.

The regulation at 42 C.F.R. § 405.1010 addresses CMS's role in an ALJ hearing as a **participant**, providing:

> (b) If CMS or one of its contractors elects to participate, it advises the ALJ, the appellant and all other parties identified in the notice of hearing of its intent to participate no later than 10 days after receiving the notice of hearing.
>
> (c) Participation may include filing position papers or providing testimony to clarify factual or policy issues in a case, but does not include calling witnesses or cross-examining the witnesses of a party to the hearing.
>
> (d) When CMS or its contractor participates in an ALJ hearing, the agency or its contractor may not be called as a witness during the hearing.

The regulation at 42 C.F.R. § 405.1012 address CMS's role in an ALJ hearing as a **party**, providing:

> (b) CMS and/or its contractor(s) advise the ALJ, appellant and all other parties identified in the notice of hearing that it intends to participate as a party no later than 10 days after receiving the notice of hearing.
>
> (c) When CMS or one or more of its contractors participate in a hearing as a party, it may file position papers, provide testimony to clarify factual or policy issues, call witnesses or cross examine the witnesses of other parties. CMS or its contractor(s) will submit any position papers within the time frame specified by the ALJ. CMS or one or more of its contractor(s), when acting as parties, may also submit

> evidence to the ALJ within the timeframe designated by the ALJ.

The preamble to the Final Rule, implementing the regulations governing the Medicare Claims Appeal Procedures (42 C.F.R. Part 405), clarifies that participation by CMS or its contractor(s) at the ALJ hearing level, while optional, is consistent with the statute and intended to serve to develop information for both ALJs and beneficiaries. In response to comments raising concerns about the possible adversarial nature of an ALJ hearing in which CMS or its contractors participate, the regulatory authors noted that "the scope of a participant's rights under § 405.1010 is limited" so as to deny a participant the "cornerstone elements . . . [of] an adversarial proceeding." 74 Fed. Reg. 65,316 - 65,317 (Dec. 9, 2005).

The preamble then notes that -

> the policy prohibiting CMS or its contractors from being called as a witness when it has chosen to participate as a non-party . . . is consistent with the Department's Touhy regulations at 45 CFR Part 2, which leaves to agency discretion the decision whether to permit agency officials or certain contractors to testify or produce evidence in proceedings in which the agency is not a party.

74 Fed. Reg. at 65,318.

The preamble continues reiterating both that CMS and its contractors have the discretion to determine the manner and extent of their participation in an ALJ hearing and that, under 42 C.F.R. § 405.1010, the limits of that participation can extend to a refusal to be cross-examined. 74 Fed. Reg. 65,318.

Having examined the pertinent pre-hearing documentation and correspondence in the record (generally, Exhibits 4-16), the Council finds no clear statement of intent from either Cahaba GSB or Cahaba Safeguard, delineating the manner of their participation in the ALJ hearing.[3] The lack of clarity in the regulations, and the contractors' failure to identify their manner of participation prior to the start of the hearing,

[3] The Council recognizes that the words "participant" or "participate" appear in numerous pre-hearing documents, mostly those emanating from the ALJ's office. However, the usage of these words there is in the common grammatical sense, rather than in the more specific sense anticipated by the regulations.

undoubtedly left their status unclear to the appellant, as contended. The Council finds no clear characterization of the nature of the contractors' participation until an objection at the ALJ hearing, by counsel for Cahaba Safeguard (Attorney Wood), when counsel for the appellant (Attorney West) attempted to cross-examine Mr. Casselman. However, this lack of clarity did not rise to the level of a due process violation.

The Sample and Extrapolation

As noted in the legal authority discussed above, CMS retains a wide degree of latitude in the use of sampling and extrapolation to recoup overpayments to providers. That latitude aside, however, the Council finds that not all relevant and material information relating to the sampling methodology, to which the appellant is entitled, has been provided to the appellant or submitted for the appeals record in this case. Thus, we are reluctant to uphold the extrapolation from the sample to the universe in this case.

The appellant asserted during the hearing, and in post-hearing briefing, that neither CMS nor its contractors provided documented educational intervention prior to the extrapolation in issue. *See* Exh. 19 at 3 (**Supplemental Brief of the Appellant** (June 8, 2009)). Further, in its **Second Supplemental Brief** (June 25, 2009), the appellant argues that the PSC's finding that the appellant had a high level of payment error rate resulted from the audit sample itself and was not a preexisting condition, providing a basis for the audit, as required by the Medicare Modernization Act and applicable Program Memorandum. Exh. 22 at 4. As explained below, these specific arguments do not invalidate the extrapolation.

Section 1893(f)(3) of the Act provides:

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

There is no judicial or administrative review of a determination of a sustained or high payment error rate by the Secretary, and, by extension, the contractors. Section 1893(f)(3) of the Act further provides that "[t]here shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of determinations by the Secretary of sustained or high levels of payment errors under this paragraph." Therefore, neither the ALJ, nor the Council, has jurisdiction to consider any aspect of a contractor's determination that a high payment error rate exists, which extends to the contractor's decision to perform extrapolation.

However, the appellant has argued persuasively that it has not, at any point of the appeal process, been supplied with certain portions of the "data and documentation needed to replicate the statistical study." Exh. 22 at 5. Referencing Cahaba Safeguard's June 5, 2009, post-hearing submission (Exhibit 23), the appellant, in its Second Supplemental Brief, asserts that the PSC's –

> submission states that information is being provided on a CD or DVD. However, no such CD or DVD was provided to Appellant with their [the PSC's] submission. Nor were Appendices C, D, or E provided to counsel. If, as appears likely, the CD contains the same materials contained in a CD previously given to the Appellant, such does not contain the following:
>
> - The random numbers used in the study
> - How the random numbers were selected
> - The sampling frame
> - The working papers and all calculations of the statistician.

Exh. 22 at 5.

In its post-hearing submission, the PSC reiterated its position that it –

> fully documents its sampling and overpayment extrapolations, meeting all requirements for Medicare contractors when conducting a statistical study. Along with this document, all . . . [PSC] sampling and projection documentation is being provided once again including the universe, the sampling frame including the random number

> seed and the random numbers, and the method of randomization (these are included in the appendices on the CD accompanying this document). This documentation meets all guidelines for Medicare contractors and guarantees that the entire process is being replicated. The documentation files are listed below with descriptions of the information contained in the files. [A description of the contents of CD Appendices B-E followed.]

Exh. 23, Tab - **Statistician's Response to Post Hearing Orders**, at 2.

The CD referenced by the PSC is formally labeled as **Cahaba Safeguard's Post Hearing Submission for ALJ Appeal Number 1-373708584.** The post-hearing CD's Table of Contents, which the Council has printed and entered into the record as Exhibit MAC-2, indicates that the CD's contents would replicate that of Exhibit 23. However, the CD is otherwise password protected. That password is not specifically available in the record before the Council.

The case file also contains another CD with the following identification, handwritten, in black indelible marker: "**1-350874561 CAHABA GBA**." That CD's table of contents contains a file/folder titled "Dr. Rondric Williamson CSA Case Encryption." However, this "first" CD is also otherwise password protected. An e-mail, originating from an individual identified as a Cahaba GBA, Part A/B Appeals Manager, dated December 10, 2008, with a subject line title: "Passcode" to another individual of unknown address is folded and taped to this "first" CD. The passcode referenced in the e-mail is also printed, in blue indelible marker, on the "first" CD.

The passcode opens neither the "first" CD, nor the "post-hearing" CD submitted by Cahaba PSC.

In its second supplemental brief, the appellant, by way of comparison, vaguely references the contents of "a CD previously given to the Appellant." Exh. 22 at 5. It is not clear if this is a reference to the "first" CD or if the appellant was able to actually access the substantive information contained in that or the "post-hearing" CD. There is no indication from the decision whether the ALJ had access to the information on either CD. Certainly the fact that the PSC alleges that the necessary audit-related information is on these CDs, and that the

appellant has continually asserted that is has not been provided that information (rather than arguing that the information is incorrect or substantively inadequate), lends support to a conclusion that the PSC has not provided all of the relevant and material sampling information to the appellant despite repeated requests. If provided at all, that information has not been provided in a timely manner despite repeated requests, or has not been provided in usable or accessible form.

Thus, regardless of the possible substantive merit to the PSC's extrapolated overpayment determination, the above-discussed circumstances appear to give credibility to the appellant's allegations that it has encountered significant impediments in obtaining the information to which it is entitled from the Carrier and the PSC in this case.

Given the inability to access the CDs, specifically the "post-hearing" CD, the record before the Council does not, in spite of the PSC's contentions to the contrary, contain the documentation referenced in Appendices C-E of the PSC's post-hearing submission. Specifically, that documentation is identified, by the PSC as – (Appendix C) the "Sample," the "Sample Frame" and the "Universe;" (Appendix D) the *Overpayment Projection – CSA [PSC] Review*; and (Appendix E) *Overpayment Projection – After Latest Appeals*. Exh. 23, Tab - **Statistician's Response to Post Hearing Orders,** at 2.

The regulation at 42 C.F.R. § 405.1000(b) provides that "the parties may submit evidence . . . [and] examine the evidence used in making the determination under review . . . ." This would, to a reasonable degree, presuppose that the evidence to be reviewed would generally be available to an appellant prior to the hearing. As noted above, the "first" CD with purported audit-related information, apparently provided to the appellant in December 2008 was inaccessible. Thus, not only was the audit-related evidence sought by the appellant not provided prior to the hearing, it was not present at the hearing and not voluntarily forthcoming post-hearing. Even when finally provided, *sua sponte,* by the ALJ following the first round of post-hearing submissions, the "post-hearing" CD then purporting to contain audit-related information was inaccessible. The Council remains unable to access some of the statistical sampling data (including the frame) because of access restrictions on the CDs in the record.

It is well-established that due process affords an appellant provider the right to examine audit results in order to mount a proper challenge in the appeals process. Not only was pertinent audit-related information withheld from the appellant, the inaccessibility of the CDs in the record forwarded to the Council by the ALJ leads to the conclusion that the record upon which the ALJ relied in upholding audit extrapolation was incomplete. An ALJ decision must be based on evidence offered at the hearing or otherwise admitted into the record. 42 C.F.R. § 405.1046(a). Absent supporting evidence, the appellant is deprived of its ability to review the extrapolation in question.

For these reasons, the Council reverses the extrapolation of the audit results at issue here. The Council further notes that this reversal may have been wholly avoidable had the PSC been both attentive and timely in providing the information in usable form to both the appellant and the ALJ.

The remaining questions before the Council go to coverage for the allegedly overpaid claims actually reviewed by the PSC and the appellant's liability for any such overpayment.

Claims Coverage

Basically, in order to receive Medicare Part B coverage for the claims at issue, the appellant must show that the provided services were medically reasonable and necessary pursuant to section 1862(a)(1)(A) of the Act. Pursuant to section 1833(e) of the Act, the appellant bears the burden of properly documenting that medical necessity.

The Council has reviewed the claims for the twenty-five beneficiaries addressed in the ALJ decision. As the ALJ found, the documentation in many of those files ranges from nonexistent to, at best, minimal. Six files have no documentation at all. An additional six files contain only a one-page document titled "Podiatry Progress Note" (PPN). Another file contains two, one-page PPNs. Even in the remaining twelve case files which contain more than one or two pages of documentation, that additional documentation does not support a determination that that the services provided to the associated beneficiary constituted anything more than routine foot care. Accordingly, the Council finds that the twenty-six claims associated with the

twenty-five beneficiaries identified in the Attachment to this decision are not covered by Medicare.

Liability

Other than to assert that the overpayment should be limited to the claims actually reviewed by the PSC, the appellant did not challenge the ALJ's determination that, pursuant to section 1879 of the Act, the appellant was liable for the non-covered services and that the appellant's liability could not be waived under section 1870(b) of the Act. *See* Exh. MAC-1 at 38. Accordingly, the Council upholds the appellant's liability for the cost of the non-covered services resulting from those claims actually reviewed by the PSC.

DECISION

It is the decision of the Medicare Appeals Council that the evidence of record does not support the extrapolated overpayment at issue. However, the overpayment resulting from the claims associated with the beneficiaries identified in the Attachment to this decision is supported by the record before the Council. The appellant is liable for the cost of those non-covered services.

MEDICARE APPEALS COUNCIL

/s/ Gilde Morrisson
Administrative Appeals Judge

/s/ Clausen J. Krzywicki
Administrative Appeals Judge

Date: June 22, 2010