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United States District Court, M.D. Florida,
Tampa Division.
James F. PRUCHNIEWSKI, D.P.M., Plaintiff,
v.
Michael O. LEAVITT, Secretary of the United
States Department of Health and Human Services,
Defendant.
No. 8:04-CV-2200-T-23TBM.

Aug. 10, 2006.

Michael R. Lowe, P.A., Longwood, FL, for Plaintiff.

Whitney L. Schmidt, U.S. Attorney's Office,
Tampa, FL, for Defendant.

ORDER

STEVEN D. MERRYDAY, District Judge.

*1 United States Magistrate Judge Thomas B. McCoun, III, submits a report and recommendation (Doc. 23) on the plaintiff's petition for review of a final decision of the Secretary of the United States Department of Health and Human Services (the "Secretary"). Judge McCoun recommends affirming the Secretary's final decision. Neither party files an objection to the report and recommendation, and the time to file objections has expired. Accordingly, the Magistrate Judge's recommendation (Doc. 23) is **ADOPTED** and the Secretary's final decision is **AFFIRMED**. The Clerk is directed to enter judgment in favor of the Secretary and against the plaintiff.

ORDERED in Tampa, Florida, on August 9, 2006.
THOMAS B. McCOUN, III, Magistrate Judge.

REPORT AND RECOMMENDATION

The Plaintiff seeks judicial review of the final decision of the Secretary of the United States Department of Health and Human Services (hereinafter the "Secretary" or "Defendant") that Plaintiff was overpaid for podiatric services furnished to Medicare beneficiaries between January 1, 1996, and August 31, 1998.^{FN1} Because the decision of the Secretary is in accordance with the correct legal standards and is otherwise supported by substantial evidence, I recommend that the decision be affirmed.

FN1. This matter comes before the undersigned pursuant to the Standing Order of this court I dated August 28, 1987. *See also* M.D. Fla. R. 6.01(c)(21).

I.

The Secretary is the federal official responsible for administering the Medicare program, which pays for covered medical items and services provided to eligible elderly and disabled individuals. 42 U.S.C. § 1395, *et seq.* The agency component to which the Secretary has delegated authority to administer the program is known as the Centers for Medicare & Medicaid Services (hereinafter "CMS").^{FN2} The statutory scheme for the Medicare program is composed of four parts. This case involves Medicare Part B, which pays for designated "medical and other health services" rendered by physicians and certain non-physician practitioners.^{FN3} *See generally* 42 U.S.C. §§ 1395j to 1395w-4; 42 U.S.C. § 1395x(s). The statutory definition of "physician" includes doctors of podiatric medicine for certain specified purposes. 42 U.S.C. § 1395x(r)(3). To be reimbursable, medical and other health services must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the function of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A).

FN2. CMS was known as the Health Care

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Financing Administration (hereinafter "HCFA") prior to June 14, 2001. See Medicare and Medicaid Programs; Change of Agency Name: Technical Amendments, 66 Fed.Reg. 39450 (July 31, 2001).

FN3. Medicare Part A pays for care furnished by institutional providers such as hospitals, skilled nursing facilities, and home health agencies. See generally, 42 U.S.C. §§ 1395c to 1395i-5. Medicare Part C involves managed care organizations. See generally, 42 U.S.C. §§ 1395w-21 to 1395w-28. Medicare Part D delineates the Medicare prescription drug benefit. See generally, 42 U.S.C. §§ 1395w-101 to 1395w-152.

In administering the Medicare program, CMS enters into contractual agreements with private entities to perform certain statutory and regulatory responsibilities, including claims processing. See 42 U.S.C. §§ 1395h, 1395u. First Coast Service Options (hereinafter "First Coast" or the "Carrier") is the Medicare carrier involved in this case. Applicable law dictates that no payment be made to any provider of services "unless there has been furnished such information as may be necessary in order to determine the amounts due such provider..." 42 U.S.C. § 1395l(e). The Secretary is further authorized to enter into contracts to make audits of the records of providers to assure that proper payments are made. See 42 U.S.C. § 1395u(a)(1)(C). Such carrier medical review activities may occur both before and after payment of claims and may involve both reasonable costs and coverage inquiries. *Chaves County Home Health Serv., Inc. v. Sullivan*, 931 F.2d 914, 915 (D.C.Cir.1991).

*2 Plaintiff is a podiatrist licensed to practice in Florida. By letter dated November 23, 1998, First Coast notified Plaintiff that it was conducting a post-payment medical review of his claims and requested records for thirty patients ("beneficiaries"). The record request covered the period from January 1, 1996, to August 31, 1998. (R. 01287-90). In

December 1999, First Coast notified Plaintiff that it had completed its review and determined that Plaintiff had been overpaid for services that were not medically necessary and/or not properly documented. First Coast requested recovery of \$84,171.62. ^{FN4} (R. 00790).

FN4. As discussed in detail below, CMS policy authorizes carriers to utilize statistical sampling and extrapolation to estimate overpayments made to physicians and other providers, so long as such extrapolation is based upon a statistically valid random sample. In general, the Carrier's audit of Plaintiff revealed an actual overpayment for services to beneficiaries reviewed of \$5,268.03. The Carrier's extrapolation yielded an estimated total overpayment of \$105,812.87 with a standard error of \$12,737.64. According to the Carrier, to account for the margin of error revealed in the extrapolation, the Carrier revised (downward) the amount of overpayment to correspond to the lower end of the 90% confidence interval of the estimated overpayment and sought reimbursement for only this amount. (R. 00790). As set forth above, the \$84,171.62 figure was subsequently adjusted slightly upward after the fair hearing.

In January 2000, Plaintiff responded to First Coast's letter by requesting a fair hearing before a Medicare Hearing Officer. (R. 00057-8). By decision dated August 27, 2002, the hearing officer generally affirmed the carrier's determination, finding that Plaintiff had been overpaid by reason of coding errors (billing for services provided to residents of nursing homes and assisted living facilities as though they were residing in private homes), a lack of documentation that the services provided were medically necessary under Medicare, and a lack of documentation that the services were performed. (R. 673-738). The hearing officer's review of the records for the thirty beneficiaries resulted in an in-

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crease of the extrapolated overpayment amount to \$86,086.92. (R. 00130-31).

On September 4, 2002, Plaintiff requested a hearing before an Administrative Law Judge (hereinafter "ALJ"). (R. 00133).^{FN3} The hearing was conducted on March 13, 2003. Plaintiff was represented by both an attorney and a non-attorney healthcare consultant.

^{FN5}. In a pre-hearing memorandum submitted to the ALJ, Plaintiff did not challenge the hearing officer's findings related to his review of the thirty individual beneficiaries. Instead, Plaintiff identified the sole issue as the Carrier's statistical sampling and extrapolation. (R. 00922). In effect, Plaintiff concedes he owes the \$5,268.03 amount of actual overpayment but no more.

The ALJ took testimony from two experts, Michael Intrilligator, Ph.D., and Claudia Cecile Laster, Ph.D. Dr. Intrilligator, a professor of economics, political science, and policy studies at UCLA, testified on behalf of Plaintiff. Initially, the witness summarized his conclusions as set forth in a written report (R. 01180-01205). The witness testified generally that the methodology employed by First Coast for its extrapolation was seriously flawed, both in method and in execution, and that its computation of overpayment was invalid and should be rejected. Consistent with Plaintiff's argument, the witness maintained that the HCFA guidelines set forth minimum standards that Medicare carriers were obliged to follow when using statistical sampling and extrapolation to calculate overpayments and that the method employed here did not comply with those minimum standards. In this witness's view, the sample of thirty beneficiaries was inadequate under the HCFA guidelines and generally accepted statistical principles and it was demonstrably unrepresentative of the overall population. According to the HCFA guidelines, given the total population of 1,012 beneficiaries, a minimum of 320 beneficiaries was necessary for the sample, and by his own

calculations, the sample size should have included at least 260 beneficiaries.

*3 To demonstrate his point that the sample was unrepresentative, the witness pointed out that there was significant discrepancy between the average billing charge for the sample, \$403, and the average billing charge for the universe of beneficiaries, \$235. Given that the average charge for the sample was over 70% greater than the average charge in the population at large, there was likely an upward bias in the estimated overpayment by reason of this sample. The witness further criticized the lack of documentation to support that the sample was random and representative and, by his account, he should have been able to replicate the results of the Carrier's sampling but could not because of this lack of records.

According to Dr. Intrilligator, the approach used by First Coast lacked justification. In his opinion, its reliance on the commercially available MED 189 computer program to generate the sample and always numbering thirty beneficiaries regardless of the particular circumstances was arbitrary and a "one size fits all" approach inappropriate to the task. Likewise, he opined that the uniform stratification employed under the Carrier's method lacked demonstrated justification.

Dr. Intrilligator maintained that the estimated relative error, the so-called coefficient of variation (hereafter "CoV"), of 12.04% was above any acceptable tolerance level. As benchmarks, he cited the 5%-10% standard that First Coast's own expert, Dr. Donna Mohr, had cited as necessary for an acceptable or valid estimate ^{FN6} and the work of other statisticians who called for a CoV in the 5-8% range. The HCFA guidelines referenced a CoV of 12%. In his view, the high CoV for this sample was a red flag that should have prompted the Carrier to start over with a larger sample size, different type of stratification, or a different method. In his view, the adjustment made by First Coast to revise the estimated overpayment downward as a means of compensating for the imprecision of the sample was ar-

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bitrary and unacceptable. Finally, the witness criticized the Carrier for failing to consider and discuss non-sampling errors that may have contributed to an inaccurate extrapolation.

FN6. In his report, the witness describes the import of the CoV: "the [CoV] provides a measure of the inaccuracy or lack of precision of the estimates. It is a key figure of merit in evaluating a statistical study such as this on, and it is the best single measure of the precision of the estimated overpayment. It must not exceed a certain tolerance level for the study to be acceptable." (R. 01197).

In response to questioning by the ALJ, the witness conceded that he had not conducted his own computations. According to the witness, he was unable to do this because of a lack of information and documentation. By his account, this was the job of the Carrier, not the Plaintiff. In any event, the witness clarified that his opinions related to the inadequacy and unreliability of First Coast work under the HCFA guidelines and what he termed generally accepted principles. On cross-examination, he clarified that he used this term/phrase to describe what is found in the standard textbooks as opposed to any uniform standards that have been propounded in the accounting field. Reference his reliance on the HCFA guidelines, he conceded he was troubled by the fact that dollar amounts cited therein had not been adjusted over the years for inflation. *See* (R. 01819-01851, 01900-01907).

*4 The ALJ next heard from Dr. Laster, a data consultant for First Coast. Initially, she defended the sample size of thirty, noting that it had been arrived at after consideration of the HCFA guidelines, a few other studies, and cost-benefit issues significant to a program of this size. Based on language in the Appendix itself, the Carrier did not view these guidelines as binding. In Dr. Laster's view, the Carrier's sampling method was an unbiased, true probability sample that produced a valid outcome. In support of the sample size employed in this audit,

she testified that the Carrier relied on a study by Richard Leavenworth, PhD., in which it was concluded that a sample size of thirty was adequate to the task. By this study, while the use of a larger sample size might result in a slightly smaller CoV, the gain was relatively insignificant, especially in light of the additional costs inherent in using the larger sample in a program of this magnitude. *See* (R. 00603-607).

Dr. Laster also defended the method used to obtain the sample as entirely random. By her account, the Carrier employed a commercially available computer program to randomly select the sample. All the Carrier would do is specify the provider number and the dates of service it was interested in and a computer program would proceed to select beneficiaries and separate the data. Given its experience in these matters, the Carrier's statistical consultant would have determined that beneficiaries offered the best sampling unit (versus some other unit such as one based on services) because such a unit offered all the necessary cost and services information. Once generated, the data would be analyzed by the Carrier's financial services department and the overpayment and the CoV would be calculated. Here, because the CoV was high, the Carrier followed its policy and reduced the estimated overpayment to the lower limit of the 90% confidence level. The witness likewise defended the manner in which the program stratified the data and the number of stratum as having been determined by a statistical consultant in light of the Carrier's experience with such claims and providers.

On questioning by the ALJ, the witness indicated that if the CoV hit 20% or more, First Coast would not use the extrapolated amount and would instead seek to recover only the actual calculated overpayment. She could not explain the discrepancy noted by Dr. Intrilligator between the average dollar amount of the universe versus the average for the sample except to say that the Carrier had no influence over the selection of the beneficiaries, and in this case, the computer must have randomly selected

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ted beneficiaries who had received larger paid amounts. In her view, this was an inherent possibility with sampling and did not indicate that the sample was unrepresentative. As for the stratification, while she had no documentation on the matter, the witness testified that the number of stratum would have been determined by the Carrier's statistician, and here the conclusion was to use five stratum. The guidance for this selection would have come from the textbooks, the HCFA guidelines and the experience of the Carrier, as well as the Leavenworth study.

*5 On cross-examination, the witness maintained that she could replicate this audit, and if she were to run the same calculations given the same data, her result would be the same. She conceded that prior to January 2001, the Appendix was the official guidance given to carriers by the HCFA for performing sampling studies and that, under the guidelines, the sample size suggested was 320. The witness denied that the Carrier had deviated from the HCFA guidelines since the guidelines were not mandatory and allowed for the Carrier to employ its own expert and method. Here, the Carrier relied on Dr. Leavenworth's study indicating that the use of thirty beneficiaries was appropriate for obtaining a reasonable level of confidence. While she conceded that a larger sample size typically results in greater precision, she referenced Dr. Leavenworth's study and noted his conclusion that the incremental difference in the CoV derived from using a sample larger than thirty did not justify the additional resources that would be necessary to review a larger sample size. From the Carrier's standpoint, this was a random and representative sample and statistically valid in spite of the slightly higher CoV. While there was no documentation from the audit showing how it generated the randomly selected numbers, the witness testified that the Carrier used the provider number as the random seed. The witness acknowledged that at the time of this review, the Carrier's position was that a CoV greater than ten was not acceptable. However, she maintained that in a program of this size, the remedy was not to throw

out the computations and start over when such occurred, but rather to make a calculated adjustment downward in the amount of overpayment sought to be recovered. She claimed that this policy was documented in a memorandum that she did not have at the hearing. (R. 01851-01900).

Subsequent to the hearing, both Plaintiff and the Carrier submitted additional exhibits. By these submissions, Plaintiff's representative contradicted Dr. Laster's testimony that the Carrier had a policy of collecting only actual overpayments when the CoV exceeded 20% by introducing a spreadsheet showing the Carrier used its extrapolation to assess overpayments in nineteen cases despite CoVs in excess of 20%. The submission also included an administrative decision that relied upon Dr. Mohr's testimony to set aside an audit, which, among other problems, reflected a CoV of thirty. (R. 00549-00569). In a follow-up letter from Dr. Laster, she indicated that the Carrier's practice at the time of this review was to seek extrapolated amounts if the CoV was less than 40%, and therefore the Carrier's pursuit of the extrapolated amount in this case was in line with its standard practice. (R. 00901-00917).

By decision dated July 25, 2003, the ALJ determined that Plaintiff was overpaid for Medicare Part B services during the period from July 1, 1998, to June 30, 1999, and the extrapolation of the overpayment to the universe resulted in a statistically valid estimate of the true overpayment.^{FN7} By this conclusion, the Carrier was entitled to recoup the full amount of the overpayment, \$86,086.42. (R. 00583-00601). Plaintiff then sought review by the Departmental Appeals Board. By letter dated August 2, 2004, Plaintiff's request for review was denied. (R. 00001-00002). The ALJ's decision thus became the Secretary's final decision for purposes of judicial review.

FN7. In the ALJ's view, the manner in which this estimate was determined was neither unfair nor unreliable and in fact favored Plaintiff. The ALJ noted that

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Plaintiff did not challenge that he had submitted claims for services he was not entitled to for the thirty beneficiaries reviewed and that Medicare therefore made unauthorized payments to him totaling \$5,268.03. The review showed that for twenty-eight of the thirty sampled beneficiaries (or 93%), there had been an overpayment. According to the Medicare hearing officer, these billings covered 310 services, only thirty-five of which were allowed to be billed. In the circumstances, Plaintiff should have known that the Carrier would review the claims and seek to recover an estimated amount of overpayment and he had a fair opportunity to demonstrate the invalidity or unreliability of the sampling method but failed to do so.

II.

*6 Applicable statutes and regulations authorize physicians who "accept assignment" ^{FN8} to appeal administratively a carrier determination that services rendered to a beneficiary are not "reasonable and necessary." 42 U.S.C. § 1395ff(b); 42 C.F.R. §§ 405.801(b)(1), 405.803(b)(5) (2000). The administrative appeal rights afforded such physicians include the right to a "fair hearing" before a carrier hearing officer, the right to a hearing before an ALJ, and the right to request review of an ALJ decision by the Department of Health and Human Services, Departmental Appeals Board (hereinafter "DAB"). 42 C.F.R. §§ 405.821-405.856 (2000). ALJ hearings in Medicare Part B cases are nonadversarial and resemble hearings in Social Security disability cases. See *Richardson v. Perales*, 402 U.S. 389, 403 (1971). The DAB's decision (or the ALJ's decision if the DAB declines review of the ALJ decision) becomes the final decision of the Secretary and is subject to judicial review in accordance with 42 U.S.C. § 405(g). 42 U.S.C. § 1395ff(b); 42 C.F.R. § 405.857(a) (2000).

FN8. A physician who "accepts assign-

ment" agrees to accept Medicare payment as payment in full for covered services, and is afforded the same appeal rights as a beneficiary. See 42 C.F.R. § 405.802.

A determination by the Secretary must be upheld if it is supported by substantial evidence and comports with applicable legal standards. See *id.* at § 405(g). Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Richardson v. Perales*, 402 U.S. 389, 401 (1971) (quoting *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938)); *Miles v. Chater*, 84 F.3d 1397, 1400 (11th Cir.1996). The Secretary must apply the correct law and demonstrate that he has done so. While the court reviews the Secretary's decision with deference to the factual findings, no such deference is given to the legal conclusions. *Keeton v. Dep't of Health & Human Servs.*, 21 F.3d 1064, 1066 (11th Cir.1994) (citing *Cornelius v. Sullivan*, 936 F.2d 1143, 1145 (11th Cir.1991)).

Medicare beneficiaries and their assigns are entitled to due process. Under Amendment V to the United States Constitution, whether procedures provided are sufficient to guarantee that a citizen is not "deprived of life, liberty, or property" in violation of the due process clause requires a balancing of competing governmental and private interests. In making this determination, the federal courts traditionally apply the test articulated by the Supreme Court in *Mathews v. Eldridge*, 424 U.S. 319 (1976). " *Mathews* dictates that the process due in any given instance is determined by weighing 'the private interest that will be affected by the official action' against the Government's asserted interest, 'including the function involved' and the burdens the Government would face in providing greater process." *Hamdi v. Rumsfeld*, 542 U.S. 507, 529 (2004); see also *United States v. Wattleton*, 296 F.3d 1184, 1198 (11th Cir.2002). Under *Mathews*, the courts must balance three factors: (1) the private interest that will be affected by the official action; (2) the risk of an erroneous deprivation of such in-

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terest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and (3) the government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail. *Mathews*, 424 U.S. at 334-35 (citing *Goldberg v. Kelly*, 397 U.S. 254 (1970)).

III.

*7 The Plaintiff broadly maintains that "[t]he carrier should not be allowed to extrapolate its overpayment determination because of its failure to perform a statistically valid random sample." Within this broad assertion, he makes six specific claims of error: (1) the statistical extrapolation should be overturned because the carrier failed to follow federal due process requirements; (2) the sampling process was fundamentally unfair because the carrier failed to select an adequate sample size; (3) the carrier's lack of documentation renders the statistical extrapolation invalid; (4) the carrier's sample was not representative; (5) the carrier failed to use appropriate stratification of the sample; and (6) the carrier's extrapolation fails to meet acceptable tolerance levels for error. Plaintiff concludes that, at best, the Carrier may recover the actual overpayments associated with the beneficiaries actually reviewed and nothing more. Because the ALJ's decision is supported by substantial evidence and otherwise comports with applicable law, I recommend that the decision be affirmed.

Plaintiff initially maintains that the sampling method employed in his case failed to follow federal due process requirements.^{FN9} In particular, he urges that the sampling was arbitrary, capricious and unreliable because it did not comport with HCFA's minimum due process requirements or with generally accepted standards for statistical analysis. Fundamental to this argument is his contention that the HCFA guidelines established a minimal due process standard applicable to all carriers who calculated overpayments through the use of statistical

sampling and extrapolation. By Plaintiff's contention, the record indisputably demonstrates that the sampling method employed by the Carrier fell well below several minimum standards set forth in the Appendix. While Plaintiff acknowledges that carriers can employ alternative sampling techniques consistent with the Appendix, he maintains that carriers are prohibited from using methods that are less rigorous than that called for by the Appendix. Given that the record establishes the method employed here was much less rigorous than that called for by the Appendix, Plaintiff contends that his rights to fundamental fairness and due process were denied.^{FN10} Within this claim, Plaintiff also urges that the Carrier's sampling technique failed to comport with generally accepted standards for statistical analysis. In support of this contention, Plaintiff offers the testimony of his expert, Dr. Intrilligator, who claims to have coined this phrase to refer to a variety of general standards referenced in statistical textbooks. Rather than a formal body of generally accepted principles or practices such as those compiled in the accounting profession, the phrase references matters the witness believes are generally accepted in the textbooks and published material. In Dr. Intrilligator's opinion, the sampling method employed here fell below these generally accepted standards and the HCFA guidelines.

FN9. As Plaintiff must acknowledge, numerous courts have rejected due process challenges to the use of statistical sampling as a method of determining overpayments in government programs. See, e.g., *Mich. Dep't. of Educ. v. U.S. Dep't. of Educ.*, 875 F.2d 1196, 1204-06 (6th Cir.1989) (approving the use of a random sampling technique used to support a determination of misused federal funds in the Michigan vocational rehabilitation program); *Ill. Physicians Union v. Miller*, 675 F.2d 151, 155-56 (7th Cir.1982) (providing that the use of statistical sampling was not arbitrary, capricious or invidiously discriminatory); *Ratanasen v. Cal. Dep't. of Health*

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Servs., 11 F.3d 1467, 1471 (9th Cir.1993) (joining those circuits approving "the use of sampling and extrapolation as part of audits in connection with Medicare ..., provided the aggrieved party has an opportunity to rebut such evidence."); *Chaves*, 931 F.2d 914, 923 (D.C.Cir.1991) (finding no general constitutional defect with sample adjudication).

FN10. Throughout his memorandum, Plaintiff cites to administrative decisions as legal support for his contentions. Those decisions, however, are not binding on the Secretary's interpretation of the guidelines at issue. *See, e. g., Community Care Found. v. Thompson*, 318 F.3d 219, 226-27 (D.C.Cir.2003); *Amor Family Broad. Group. v. F.C.C.*, 918 F.2d 960, 962 (D.C. Cir1990); *Homemakers North Shore, Inc. v. Bowen*, 832 F.2d 408, 413 (7th Cir.1987).

*8 As the decision reflects, the ALJ rejected Plaintiff's contentions, finding initially that he offered no legal support for his position that the Appendix embodied federal law or established a due process minimum. Looking to the Appendix itself and the testimony of Dr. Laster, the ALJ concluded that the Appendix lacked the force and effect of federal law or regulation and did not establish a minimum due process standard. Going further, he found the Carrier's reading of the Appendix, as testified to by Dr. Laster, consistent with his reading of the Appendix insofar as it allowed a carrier such as First Coast to consult with its own statistical consultant to formulate a different sampling method if it chose to do so. As for the argument that the sampling method also failed to comport with generally accepted principles, the ALJ concluded that since the statistical community had not actually promulgated such standards, there was no basis for concluding the Carrier erred in not following them. In any event, the ALJ concluded that "... there is no basis for finding that a failure to

adhere to these standards violated the Appellant's right to due process."

With respect to the binding effect of the Appendix, both parties recite from the introductory language of the Appendix in support of their respective positions:

1.0 GENERAL

The purpose of these guidelines is to provide carriers with the minimal elements of interest to SSA concerning sample design and control if the carrier decides to use sampling techniques to estimate the amount of overpayment to a physician. As such, these guidelines are one instrument for assuring that the goals of proper statistical techniques, fairness to the debtor and the government, and proper control of process are achieved.

1.1 GUIDELINES AS MINIMUM STANDARD

The sections below provide carriers which do not have access to competent sampling guidance,* an explicit step-by-step minimum procedure as guidance to their immediate staff. Where carriers have access to persons with the necessary statistical training and experience, these Guidelines are intended to serve as an indication of the minimum approach suggested for all carriers.

(R. 00144). In the footnote *, "[i]t is recognized that persons with competence in statistical sampling can provide effective guidance in using more sophisticated techniques which might ensure a better result for the same degree of effort...." *Id.* While Plaintiff emphasizes the phrase "minimum procedure" to argue that the Appendix establishes a due process minimum that carriers were required to follow, the Secretary asserts that this and other language makes clear that the purpose of the guidelines was to educate those carriers without access to their own sampling guidance and to set forth a suggested approach for those that had such access.

By my consideration, the HCFA guidelines are

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what they claim to be, guidelines. Even if they were intended to demonstrate some type of minimal process for sampling methods, they did not carry the weight or authority of federal law or regulation and were not binding on carriers who otherwise established a reliable sampling methodology of their own. First, the ALJ's conclusion that the language of the Appendix itself nowhere claimed any greater authority or binding effect than such internal guidelines would ordinarily carry is supported by the substantial evidence. Ordinarily, such internal guidelines lack the force and effect of law. As the Secretary correctly notes, the Appendix was not promulgated pursuant to the notice and comment rule-making procedures of the Administrative Procedure Act, 5 U.S.C. § 553; it was not a regulation; and, under applicable authority, it was not binding on the Secretary. Case law supports this position. See *Schweiker v. Hansen*, 450 U.S. 785, 789 (1981) (providing that the SSA's Claims Manual, a handbook for use internally by SSA employees, was without legal force and not binding on the SSA); *Pub. Citizen, Inc. v. U.S. Dep't of Health & Human Servs.*, 332 F.3d 654, 660 (D.C. Cir.2003) (providing that HCFA's Peer Review Organization Manual was mere guidelines lacking the force of law and not entitled even to *Chevron*-style deference); see also *Christensen v. Harris County*, 529 U.S. 576, 587 (2000) ("Interpretations such as those in opinion letters-like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law do not warrant *Chevron*-style deference.").

*9 A fair reading of various passages from the Appendix suggests that its purpose was to encourage, if not insure, fair and reliable results to the providers and the government in instances of Medicare overpayment. In cases where sampling was used, the Appendix provided one acceptable model to achieve this goal. However, the guidelines both acknowledged and anticipated that other acceptable sampling techniques were available or could be developed consistent with this goal. Surely this undermines any contention that these guidelines were to

be accorded binding effect such that any deviation from them rendered the sampling method invalid. Thus, I find that the ALJ did not err in concluding that the HCFA guidelines were without binding effect.

As for the argument that the Carrier's sampling technique failed to comport with generally accepted standards for statistical analysis, the ALJ's conclusion that since the statistical community had not promulgated such standards there was no basis for according them binding effect or for concluding that they established a due process minimum, is also supported by substantial evidence. Dr. Intrilligator's own testimony establishes that the term (generally accepted standards) was his and that there was no discrete body of generally accepted statistical principles at which to look as establishing minimum standards. While there is no reason to doubt his testimony that textbooks include any number of generally accepted principles, the fact remains that there is no authority for the proposition that they establish an enforceable due process standard. I find that it is also significant that the expert did not apply these principles to demonstrate empirically that the Carrier's method truly was unreliable. The fact that Plaintiff had the fair opportunity to demonstrate the invalidity of the Carrier's statistical sampling substantially undermines his due process argument.

Furthermore, a review of pertinent case law refutes the contention that the Appendix established a due process "floor" above which auditors were required to operate in conducting statistical sampling in overpayment cases. As noted above, many courts that have considered due process challenges to the use of sampling techniques in a variety of overpayment cases have generally upheld the use of sampling. In *Ratanasen*, the Ninth Circuit expressly rejected the concept of a statistical "floor," stating that "the cases addressing sampling cited above make no mention of a statistical 'floor' which auditors must exceed in order to guarantee providers due process." *Ratanasen*, 11 F.3d at 1472. Plaintiff

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provides no authority to the contrary. Indeed, a medical provider such as the Plaintiff is faced with a difficult burden when seeking to assert a due process claim in such circumstances:

To sustain such a [due process] contention [providers] have a very difficult burden of persuasion in light of the three-factor analysis adopted in *Mathews v. Eldridge*, Absent an explicit provision in the statute that requires individualized claims adjudications for overpayment assessments against providers, the private interest at stake is easily outweighed by the government interest in minimizing administrative burdens; in light of the fairly low risk of error so long as the extrapolation is made from a representative sample and is statistically significant, the government interest predominates.

*10 *Chaves*. 931 F.2d at 922. Further, at the time of this overpayment review, the Medicare statute did not require individualized claims adjudication. On the contrary, the Appendix itself was issued in 1975 by the Social Security Administration, and HCFA Ruling 86-1 was promulgated in 1986, expressly approving a policy regarding the use of statistical sampling techniques in overpayment audits.^{FN11} *Id.* at 915. As such, as noted in *Chaves*, there is no general constitutional defect with sample adjudication, and as long as the overpayment extrapolation was made from a representative sample and was statistically significant, a challenge on due process grounds will not likely prevail. Thus, I conclude that the ALJ correctly determined that, while the Appendix and Dr. Intrilligator's generally accepted principles offered guidance for an acceptable method of statistical sampling in overpayment cases, neither established a legal or constitutional minimum above which this Carrier had to operate.

FN11. Consistent with due process considerations, the ruling also permits the provider to challenge the statistical validity of the sample as well as the correctness of the determination in specific cases.

Consistent with *Chaves*, Plaintiff next urges that the sampling process employed in his review was fundamentally unfair because it was based on an inadequate sample size and was unrepresentative. Again citing to the Appendix, the decisions of other ALJs, and the opinions of his expert as authority, Plaintiff urges that the Carrier was obliged to sample a minimum of 320 beneficiaries^{FN12} and that the selection of only thirty beneficiaries for the sampling study was arbitrary and insufficient to permit an accurate extrapolation. As part of this claim, Plaintiff argues that the evidence does not establish that the beneficiaries were randomly selected. Additionally, he maintains that this sample was not a representative sample of the universe of patients or claims. In support thereof, he relies on Dr. Intrilligator's calculations, which revealed a distortion or upward bias in the sample that would likely affect the accuracy of the extrapolation. By this "simple test," Dr. Intrilligator concluded that because the average payment in the sample was 70% higher than the payment in the universe, the sample could not have been representative.

FN12. Plaintiff also references an OAS Audit Policies and Procedures Manual indicating that usually 200 sampling units are necessary. *See* (Doc 15 at 8). As noted above, Plaintiff's expert indicated that, in his opinion, the sample size should have included at least 260 beneficiaries.

As the decision reflects, the ALJ rejected these arguments, again finding that the Appendix was not binding on the Carrier and did not direct the conclusion that the sampling size was inadequate or unrepresentative. Further, by his review, federal courts had affirmed and found reliable sample sizes as small as the sample used here and, as noted in *Ratanasen*, had declined to establish any statistical "floor" that must be exceeded to guarantee due process. The ALJ discounted Dr. Intrilligator's testimony that the sample size of thirty was without justification, the sample size was too small in light of generally accepted statistical principles, and a much

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larger sample was required. In doing so, the ALJ noted that the method employed by the Carrier was based on a study by Dr. Leavenworth, in which it was determined that a sample size of thirty beneficiaries, stratified six per stratum, was sufficient to render reliable results regardless of the universe of beneficiaries given the lack of significant gain in relation to the higher administrative costs that flowed from a technique that maintained a constant percentage of the population in the sample when measured against a 10% CoV criterion. Significant to the ALJ was the fact that Dr. Intrilligator did not introduce any empirical findings to support his opinions that the sample size of thirty was too small to be reliable or that a sample of 320 would have produced an estimated overpayment that was below the lower limit of the 90% confidence level calculated by the Carrier. By the ALJ's conclusion, the witness's testimony did not support a conclusion that the sample size of thirty violated Plaintiff's due process rights. Similarly, the ALJ discounted Dr. Intrilligator's "simple test" as proof that the sample was unrepresentative based on a lack of legal or statistical authority dictating that the average sample payments must approximate the average universe payments in order to be considered representative.

*11 Plaintiff's complaint regarding the sampling size is problematic, and if the standard of review was different and a better showing had been made, perhaps I would recommend a different result. Here, the sampling method employed was indeed a "one size fits all" approach insofar as it always employed a sample size of thirty regardless of the size of the sampling universe. In addition, the testimony of Dr. Intrilligator and references to a number of sources that called for a sample pool much larger than thirty for this size sampling population would support a conclusion that a larger sample might be more appropriate. However, given the conclusion that neither the HCFA guidelines nor Dr. Intrilligator's generally accepted principles were binding on the Carrier or established a due process minimum, and given the case law rejecting the statistical

"floor" argument in relation to sample size, I must conclude that the ALJ's decision in this regard was not contrary to applicable standards. As the ALJ's review reflects, courts have approved a variety of sampling sizes against due process challenges. Furthermore, despite the contrary views, the ALJ's conclusion that the approach used by the Carrier was statistically valid is also supported by substantial evidence.

In the face of Plaintiff's contention that sample size was arbitrary and without justification, the Secretary has adequately demonstrated that the sampling method employed by the Carrier was the considered product of Dr. Leavenworth's 1991 study (which found that a sampling size of thirty beneficiaries, six per stratum, regardless of the population size, was a cost efficient and reasonably reliable sampling method for use in overpayment reviews). Significantly, as noted by the ALJ, Plaintiff failed to contradict Dr. Leavenworth's conclusions with empirical evidence of his own demonstrating that a sample size of thirty was too small to allow for a reliable estimate of overpayment or evidence that a sample size of 320 (or any other number) would produce an estimated overpayment that was outside the range of overpayments calculated by the Carrier. On this issue, I am left to conclude that, while others would employ a larger sample on the belief that it would provide more reliable results, and perhaps this is so, Plaintiff failed to demonstrate before the ALJ or on this appeal that the results achieved from the sampling of only thirty beneficiaries were unreliable or that the ALJ's conclusion in this regard should be overturned.^{FN13}

FN13. At oral arguments, counsel receded somewhat from the argument that the sample was not randomly selected. A fair reading of the testimony at the administrative hearing and the record as a whole provide substantial evidence to support a conclusion that the sample was randomly selected. The record also supports the ALJ's acceptance of the testimony on why

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the Carrier did not perform precision estimates before auditing the claims.

Dr. Intrilligator's simple test for the representativeness of this sample is also interesting, but Plaintiff does not demonstrate that it dictates a conclusion that the sample was unrepresentative. As before the ALJ, Plaintiff offers no legal or statistical authority to the court on what is "representative." Here, while Dr. Intrilligator's testimony suggested his test revealed an upward bias in the sample, this was contradicted by the testimony of Dr. Laster who found a close correlation between the respective averages. In her view, the sample was clearly randomly selected and representative of the universe when the strata were considered. In these cases, it is for the ALJ, rather than this court, to weigh the evidence and resolve conflicts therein. Here, I am obliged to conclude that there is substantial evidence to support the ALJ's conclusions. Further, there was no showing that the ALJ's conclusions violated any applicable standard.

*12 Plaintiff next urges that the Carrier's failure to document its audit procedures in a manner permitting his own post-audit review and to provide documentation to establish the validity of the statistical extrapolation renders the extrapolation invalid. Citing again to express provisions in the Appendix and the expert testimony, Plaintiff argues that the Carrier has failed to document the random selection process and failed to produce documents sufficient to permit his recreation of its sampling process in violation of the HCFA guidelines and due process.^{FN14} On the basis of case law supporting the general proposition that due process is violated when the government fails to follow its own rules or regulations, Plaintiff urges that his rights were violated because of the lack of documentation for this audit and because he was precluded from performing an independent audit of his own. As a remedy for this violation, he urges that the Carrier's audit should be determined to be invalid. Plaintiff also argues that the Carrier failed to use an appropriate stratification, and because it provides no documentation,

analysis or support for its decision to use five stratum, the study should be stricken.

FN14. In particular, Plaintiff complains of the lack of documents in the record supporting: the Carrier's decision for a sample size of thirty; its reason/justification for the manner of its stratification of the sample; the composition of the sampling frame; the representativeness of its sample; the random numbers used to generate the sample/ the random seed; and the alleged standard for accepting a CoV of 20%. The record indicates that Plaintiff made demand on the Carrier for a variety of these matters in January 2000 (R. 00579-580) and October 2002 (R. 00300-302). Defendant responded in some fashion in November 2002. (R. 00303). The Secretary maintains that the Plaintiff has been provided or otherwise had a full complement of documentation. (Doc. 18 at 15-19). Dr. Intrilligator's report gives an overview of what he reviewed. (R. 01183-01187).

In rejecting these claims, the ALJ relied primarily on the testimony of Dr. Laster. While she could not physically document some aspects of the sampling method, she explained in some detail the Carrier's justification for its sampling methodology and why she believed it was random, representative and reliable. This, together with a lack of showing of prejudice by the Plaintiff in his not having the actual documentation, was enough to satisfy the ALJ that this was no basis to reject the sampling method.

Regarding the lack of documentation supporting the randomness of this sample, the ALJ noted Dr. Laster's testimony describing how the Carrier generated its sample and the fact that Dr. Intrilligator was familiar with the commercially available software used to create the random sample. Significantly, there was no testimony that it was an unreliable means for selecting a random sample. Concerning the sampling frame from which this sample was drawn, the ALJ noted it too was fully available

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to Plaintiff given that it had been clearly defined from the outset and derived from his patient records. On the Plaintiff's claim that there was no rhyme or reason to the sample size or the stratification method and no documentary support for either, the ALJ opted to accept the testimony and opinions of Dr. Laster, namely, that the Carrier looked to the Appendix, the work of Dr. Leavenworth and the experience of its statisticians in fashioning its method. Citing expressly to her testimony and the Leavenworth study, the ALJ found ample justification for the sample size and stratification chosen here and the decision not to perform a probe sample. Again, it was significant to the ALJ that the Plaintiff had failed to present any empirical support for his suggestion that a different stratification would have made a material difference in the overpayment calculation or that the method chosen violated due process or resulted in an unreliable overpayment estimate. Citing to the HCFA Ruling 86-1, the ALJ noted that the Carrier's sampling methods carried a presumption of validity, and contrary to the Plaintiff's position, the Carrier was not required to produce documentation supporting the validity of the sampling study. Given that Plaintiff possessed the records for each beneficiary as well as their claims, the ALJ rejected that it was impossible for his expert to independently test the reliability of the audit. By his conclusion, had Plaintiff chosen to audit this review, he had an adequate basis to do so.

*13 After much consideration, I find that the ALJ's conclusions that the Plaintiff did not suffer a due process violation or otherwise demonstrate grounds to discard this sample audit by reason of a lack of documentation are supported by substantial evidence and consistent with applicable standards. By my consideration, the Appendix did not establish a due process "floor" and cannot alone be relied upon to prove the alleged violation of due process. Thus, the mere failure of the Carrier to have all the documents Plaintiff inquired about does not equate to a due process violation; nor is it grounds to invalidate this sampling method or its conclusions. And, while I cannot agree with the ALJ to the extent he would

find no obligation in the Carrier to document its sampling methods and to produce adequate documentation to allow it to be tested,^{FN15} I conclude that there was adequate documentation and information available to the Plaintiff to permit him to test the reliability of this audit had he chosen to do so. Although Dr. Intrilligator generally decried the lack of documentation, he acknowledged that he never attempted to recreate this audit or otherwise validate or invalidate it through his own methods, deeming that to be the job of the Carrier. However, as the ALJ noted, under Ruling 86-1, sampling creates a presumption of validity as to the amount of overpayment and the burden of attacking the statistical validity of the sample is shifted to the provider. As before the ALJ, Plaintiff fails to demonstrate the lack of any particular documentation that deprived him of a fair opportunity to independently assess the reliability of the sampling method or attack it in this instance. As determined by the ALJ, the sampling frame was well-defined and composed of beneficiaries who were Plaintiff's own patients. The methodology was based on Dr. Leavenworth's study, with which Dr. Intrilligator was familiar. Similarly, the software used to generate the random sample was commercially available and also known to Plaintiff's expert. The correspondence between the Carrier and the Plaintiff related to the audit revealed a great deal about the methodology, and Dr. Intrilligator's testimony reveals that he fully understood the methodology. Thus, the ALJ's conclusion with respect to Plaintiff's claim that it was impossible for an independent person to determine the reliability of the audit appears correct.^{FN16} Here, even if Plaintiff could not recreate this sample audit, he had the services of a highly qualified expert and all the data necessary to construct his own audit, had he chosen to do so.

FN15. Clearly, there are due process implications in a carrier's failure to adequately document its sampling methodology. As *Chaves* instructs, while statistical sampling as a means of estimating overpayments of this sort may withstand a due

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process attack, it does so upon a showing that the extrapolation is made from a representative sample and is statistically significant, and only after the provider has been given a fair opportunity to demonstrate otherwise. Even if the HCFA guidelines are viewed as aspirational rather than binding, the suggestions therein that the carrier document its methodology in case the sampling is challenged or must be reviewed are highly prudent. Because the burden is on the provider to demonstrate the unreliability of the sampling method, the carrier cannot be permitted to impede the provider, through a lack of documentation or otherwise, from a fair opportunity to make such a showing.

FN16. By my consideration, the only information of significance to Plaintiff's ability to replicate this study that Dr. Intrilligator may not have had was the random seed. It appears that this information may first have been revealed at the administrative hearing. While Plaintiff also complains that he had no information about this Carrier's CoV policy until after the hearing, I find this of little consequence to the claim of prejudice in not being able to replicate this test. In the final analysis, nothing prevented Dr. Intrilligator from attempting to validate or invalidate this audit by his own sampling method except that this was not what he was hired to do.

As for the stratification issue, the ALJ could properly conclude on this record that the Carrier's method was justified on the basis of the Leavenworth study, as well as the HCFA guidelines and the experience of the Carrier and its statisticians. While Dr. Laster may not have been able to produce documentation in support of the decision to use five stratum in this instance, and she could only assume why this was done, the ALJ could clearly find on this record that the selection was not arbitrarily

made. Indeed, the selection of five stratum was consistent with the Leavenworth study. Furthermore, as Plaintiff must concede, the Appendix permits carriers to use either a simple random sample or a stratified random sample and the guidelines themselves approve the use of a stratum of five or six. Thus, the selection of five stratum was neither arbitrary nor without justification. Significantly, there was again no demonstration by Plaintiff that a different stratification would have made a significant difference in the overpayment estimation. For these reasons, the ALJ's ultimate conclusion that there was no due process violation by reason of the alleged lack of documentation is supported by substantial evidence and is not inconsistent with an applicable standard.

*14 Finally, Plaintiff argues that the Carrier's extrapolation failed to meet an acceptable tolerance level of error. More particularly, he urges that the best measure of the precision of an estimated overpayment is its CoV, and that here, the CoV of 12.04% was unacceptably high under provisions of the Appendix and according to the opinions of Dr. Intrilligator and Dr. Mohr, as well as other recognized experts. By Plaintiff's argument, a sampling technique that tolerates such a high level of statistical error is unreliable and fundamentally unfair.

In addressing this argument, the ALJ first noted that the CoV in this audit was ultimately calculated to be 11.38%, a figure below the 12% figure cited in the Appendix as acceptable for a stratified sample of 100.^{FN17} As for Dr. Intrilligator's testimony that the CoV exceeded the 8% tolerance level recommended by other statisticians and Dr. Mohr's opinion that a CoV above 10% was not acceptable, the ALJ attempted to discount Dr. Mohr's opinions.^{FN18} Thus, the ALJ ultimately determined that, even though the CoV was higher than some experts would consider optimal, the Carrier's method for compensating for the higher than expected relative error by seeking to recoup an amount at the lower limit of the 90% confidence level for the estimated overpayment was adequate to satisfy due process

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concerns.

FN17. In any event, the ALJ again concluded that the Appendix did not set a due process minimum in this regard.

FN18. I find that the ALJ's efforts to discount Dr. Mohr's opinion were quite strained and ignored Dr. Laster's testimony that it was Dr. Mohr's view that a CoV above ten was unacceptable and that this was the standard for this Carrier at the time. Thus, his decision to discount Dr. Mohr's standard is not supported by substantial evidence. Nonetheless, as set forth above, I find that the ultimate conclusions by the ALJ on this issue are supportable.

As with the argument related to the sample size, this claim is problematic in light of the authority cited by the Plaintiff that a CoV above 8% or 10% is unacceptable. On the basis of these opinions, Plaintiff's sampling results were unacceptable, and according to Dr. Intrilligator, should not have been used to calculate the estimated overpayment. In contrast, the Carrier argues that considerations of cost-benefit dictate that it not reject the results and start over when this occurs but instead it should make adjustments favorable to the provider to compensate for the higher than ideal CoV. By Dr. Laster's account, the Carrier was willing to pursue this approach even when the CoV was as high as 40%.^{FN19} This too is troubling. While case law supports considerations of costs and benefits in these matters, the Carrier offers no expert support that such a seemingly high degree of imprecision is nonetheless reliable and will satisfy due process considerations. Were this a case with that degree of imprecision, perhaps Plaintiff might prevail on his claim. However, such is not the case here where the CoV was much closer to the Carrier's then target goal of 10%. While I cannot agree with all the reasons relied upon by the ALJ to deny this claim, I do conclude that his decision, that Plaintiff has failed to demonstrate that the CoV of 11.38% reveals the extrapolation to be fundamentally unfair, unreliable

and below basic minimum standards, is supported by substantial evidence and consistent with applicable standards.

FN19. Dr. Laster testified that at the time of the hearing, the Carrier viewed a CoV above 20% as unacceptable. In a post-hearing submission, she indicated that the Carrier would proceed to collect overpayments (rather than disregard the results and seek only actual overpayment) as long as the CoV was under 40%. In light of this testimony, Plaintiff asserts that Dr. Laster's misrepresentation of the Carrier's policy before the ALJ is further proof of the arbitrary and capricious attitude of the Carrier. While it is not apparent that the witness sought to mislead the ALJ, this policy, if it is one, certainly opens the door to future claims in which it is employed in cases with such high degree of imprecision.

First, Plaintiff cannot prevail on this argument because there is no basic minimum standard as he would urge. Just as courts have rejected imposing a statistical "floor" above which auditors must operate in order to assure due process in these type cases, there appears no legal authority that prescribes a tolerance level above which a carrier cannot operate in estimating overpayments of this sort without violating due process. Nor does it appear that there is an established standard acceptable to statisticians either. All agree that the lower the CoV, the more likely it is that the estimated overpayment approximates the actual overpayment, and conversely, the higher the CoV, the less likely this is so. However, as the evidence suggests, what constitutes an acceptable level of tolerance for statisticians appears a subjective matter. While Plaintiff's CoV was above the 8% and 10% standards approved by certain statisticians, it was slightly less than the 12% CoV suggested by the Appendix and thus arguably within an acceptable range. Due process is a flexible concept and dependent on the circumstances of the given case. *Arrington v. Helms*,

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438 F.3d 1336, 1350 (11th Cir.2006). Courts have recognized that, at best, these sampling audits can never provide more than an estimate of the overpayment in any event. *See generally, Chaves*, 931 F.2d at 921. To satisfy due process, that estimate must be reliable such that it is not an arbitrary or capricious result. *See generally, Ill. Physicians Union*, 675 F.2d at 155-56. This is not determined merely by citing to a variety of professional opinions on acceptability, but instead by a demonstration of unreliability. I find the ALJ's conclusion that no such minimum standard was violated in this case is supported by the evidence and consistent with applicable standards.

*15 Because there is no established standard of precision for this type sampling, it appears clear to me that the ALJ was also correct in concluding that providers such as Plaintiff must go further and establish that the degree of imprecision is such that the extrapolation does not reasonably approach the actual overpayment, that is, it is so imprecise as to be arbitrary and capricious. As the ALJ concluded, Plaintiff did not do that in this case. At best, his expert proved that a different method could be constructed to arrive at a more precise estimate of the Plaintiff's overpayment. But this alone does not establish the due process violation.

Further, as the Secretary urges, there appears no legal or statistical standard which requires that a sampling result with a CoV above a target goal must be discarded and the sampling redone for that reason alone. While Dr. Intrilligator would urge that the Carrier disregard the results and start over, the Carrier here sought to remedy the imprecision in the audit by making a favorable adjustment for the provider. If due process required a carrier to achieve the highest degree of precision regardless of the cost in resources, then Plaintiff's remedy might be called for. However, if the goal of due process is to achieve an acceptable and reasonable degree of precision in an efficient manner, Dr. Leavenworth's study indicates that the Carrier's approach is an appropriate one. By my consideration,

because absolute precision is not required to satisfy due process and because cost-benefit analysis is an appropriate factor in the due process calculus, absent a showing of unreliability in the extrapolation, a carrier need not entirely disregard its audit and start over and may seek to remedy the imprecision by some other means. Stated otherwise, absent a showing of unreliability in the extrapolation, that is, a result which is demonstrably inaccurate and unfair such that it is arbitrary and capricious, a carrier is not required to disregard the audit and start over in the name of due process.

Here, as noted by the ALJ, while the CoV was higher than some experts might consider optimal, the Carrier compensated for this by adjusting the estimated overpayment downward according to a formula and in a manner favorable to the Plaintiff. Although the Plaintiff had a fair opportunity to demonstrate his claim that this correction was arbitrary and ineffective in addressing the imprecision inherent in the result, he chose not to do so.^{FN20}

FN20. For example, nothing prevented Plaintiff from showing an error in the Carrier's calculations or demonstrating through his own, more reliable, sampling method an estimated overpayment that was less than the lower limit of the 90% confidence interval calculated by the Carrier.

IV.

In the end, the ALJ was persuaded by the undisputed fact that Plaintiff had billed for and received Medicare reimbursement to which he was not entitled. Given the nature of the program, sampling was appropriate and consistent with due process principles. While Plaintiff had a fair opportunity to demonstrate the unreliability and unfairness of the process, he failed to do so. Finding the approach taken to be consistent with that approved in *Chaves*, the ALJ concluded that the method employed in this case was sufficiently reliable to comport with due process. I agree. For the foregoing reasons, the

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decision of the Secretary of the United States Department of Health and Human Services is in accordance with the correct legal standards and is otherwise supported by substantial evidence, and I recommend that the court affirm the decision. I further recommend that the court direct the Clerk to enter Judgment in favor of the Defendant and to close the file.

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