

January 2008 through April 2010. The review was conducted by statistical sampling of 214 claims representing 445 services billed, out of a “universe” of 5,098 services billed for 154 beneficiaries. The review caused WPS to conclude that payments to Schuldt by HHS in that time frame had a 99.55 percent error rate, equating to an actual overpayment of \$11,376.13 for the 445 service claims submitted. Using that data for guidance, WPS extrapolated a projected total overpayment to Schuldt for the universe of claims in the amount of \$126,041.31.

On February 7, 2011, WPS notified Schuldt of the alleged overpayment in the amount of \$126,041.31; and on March 2, 2011, Schuldt appealed. On May 4, 2011, on redetermination pursuant to 42 C.F.R. § 405.954, WPS affirmed its earlier decision, following a review by a different examiner, using the same statistical method, who determined that more of Schuldt’s claims should be denied. Schuldt timely requested reconsideration by a qualified independent contractor (“QIC”) under 42 C.F.R. § 405.974(a), and the QIC, C2C Solutions, Inc., affirmed the WPS decision.

On September 19, 2011, Schuldt requested a hearing before an Administrative Law Judge (“ALJ”) pursuant to 42 C.F.R. § 405.1002. On April 26, 2012, ALJ William J. Cowan conducted a telephonic hearing to review the independent contractor’s decision. The record before the ALJ included WPS’s expanded post payment medical review and analysis of records of statistically selected beneficiaries, the WPS redetermination, and the QIC reconsideration. No representative, agent, or witness appeared on behalf of HHS.

Upon independent review of the 445 services billed, and considering issues of coverage, liability, and overpayment waiver, the ALJ found that 344 of the services billed were properly submitted and Schuldt should be paid for them. Considering the opinion of

Schuldt's statistical expert, Dr. Bruce Kardon, Ph.D., and the ALJ's own statistical expert, Dr. John Adams, Ph.D., the ALJ concluded that WPS's "statistical sampling method and extrapolation and results were insufficiently reliable to be used for the purpose of estimating an overpayment to a larger universe than the sample itself." *Schuldt Chiropractic Wellness Ctr.*, ALJ Appeal No. 1-828654453 (HHS June 8, 2012) ("ALJ Decision") (herein, Filing No. 1-1, at 22).

On August 6, 2012, the Center of Medicare and Medicaid Services ("CMS"), a division of HHS, filed a referral memorandum with the Medicare Appeals Counsel ("MAC"), asserting that the ALJ's decision contained an error of law material to the outcome of the claim. The MAC, on its own motion, conducted a *de novo* review of the ALJ's decision pursuant to 42 C.F.R. § 405.1100© on the single issue of whether Schuldt met its burden of proving that the statistical sampling methodology used by WPS was invalid and insufficiently reliable to be used for the purpose of estimating an overpayment to a larger universe of claims. The MAC issued its own decision on November 2, 2012, concluding that the ALJ erred in finding WPS's sampling methodology and overpayment extrapolation to be invalid. *Schuldt Chiropractic Wellness Ctr.*, ALJ Appeal No. 1-828654453, Docket No. M-12-2097, WL 10067325 (HHS Nov. 2, 2012) ("MAC Decision") (herein, Filing No. 1-4). The MAC reversed the ALJ's decision in that respect alone, not addressing or disturbing the ALJ's findings with respect to issues of coverage, liability, or overpayment waiver.

On January 4, 2013, Schuldt filed this action, requesting a review of the MAC decision. On January 31, 2013, WPS issued a "Recalculation of Projected Overpayment," applying the ALJ's findings with respect to coverage, liability, or overpayment waiver to the

sample of 445 services billed, and determined that the overpayment by HHS to Schuldt for the universe of claims was \$37,580.00. Schuldt has paid that amount to WPS.

STANDARD OF REVIEW

The Court's review is limited to determining whether HHS's action, reflected in the MAC Decision, is supported by substantial evidence in light of the record as a whole. 42 U.S.C. § 405(g) ("The findings of the Commissioner of Social Security as to any fact, if supported by substantial evidence, shall be conclusive . . .").

DISCUSSION

Statistical sampling, with extrapolation of results to the universe of all claims for recoupment purposes, may be used to determine overpayments to Medicare and Medicaid providers suspected of overbilling, "so long as the extrapolation is made from a representative sample and is statistically significant . . ." *Chaves Cty. Home Health Serv., Inc. v. Sullivan, M.D.*, 931 F.2d 914, 922 (D.C. Cir. 1991). "[E]xtrapolation based on a review of a relatively small sample is a valid audit technique in cases arising under the Social Security Act." *Illinois Physicians Union v. Miller*, 675 F.2d 151, 155 (7th Cir. 1982) (addressing alleged Medicare overpayments). 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." *Chaves*, 931 F.2d at 921 (quoting [CMS¹] Ruling 86-1, at 11) (internal quotation marks omitted). This regulatory scheme is not invalid "simply because it requires the protesting provider rather than the agency to bear the burden." *Id.* at 922.

¹ Formerly Health Care Financing Administration ("HCFA").

A provider may (1) dispute denials in the sample, as Schuldt successfully did before the ALJ whose findings in this respect the MAC left undisturbed, or (2) challenge the statistical validity of the extrapolation from the sample, as Schuldt also did to the satisfaction of the ALJ, but not to the satisfaction of the MAC. See *Chaves*, 931 F.2d at 922.

“[T]o challenge the accuracy of the extrapolation, a provider could separately present evidence of a different random sample from the universe of claims that yields a lower rate of denials or prove that the projection is not a true estimate of the rate of denials in the non-sample universe.” *Id.* at 921. A provider may also “establish the validity of all or a sufficient number of its actual claims to demonstrate that the HHS projection is factually impossible of correctness.” *Id.*

Here the Administrative Record includes the opinions of two statistical experts, Dr. Kardon and Dr. Adams, who both concluded that the methodology used by WPS was not reliable and should not be used for purposes of extrapolating the findings to a larger universe beyond the samples. The central area of agreement between the experts was the principle that “correlation” could have skewed the WPS sample, because individual beneficiaries in the sample may have had multiple claims for similar services. To avoid that problem, the experts suggested that a larger sample of claims should have been used, or samples should have been selected from a larger number of beneficiaries.²

² Although Dr. Kardon criticized WPS’s use of stratified random sampling, Dr. Adams found it to be a sensible approach and the ALJ agreed, citing the Medicare Program Integrity Manual (MPIM), ch. 8 (Eff. May 1, 2008). (ALJ Decision at 18.)

The experts' concern, upon which the ALJ relied, relates to the precision of the methodology used by WPS, *i.e.*, if a larger number of claims had been sampled, or if the claims had been selected from a larger number of beneficiaries, the potential for skewing due to correlation of multiple claims for similar services provided to individual beneficiaries would have been reduced. While the experts' observation is no doubt true, the HHS Medicare Program Integrity Manual (MPIM) allows for smaller statistical samples with less precise results, offset by the direction that overpayments be assessed at the lower level of confidence intervals, giving the benefit of the doubt regarding the range of overpayment to the Medicare provider. MPIM, Ch. 3, § 3.10 (Eff. May 1, 2008). The MAC notes that 42 C.F.R. § 405.1062 requires that ALJs and the MAC give "substantial deference" to manual instructions.

Here, the question before the Court is whether the MAC's conclusion, that Schuldt failed to meet its burden of demonstrating that WPS's sampling methodology and overpayment extrapolation were invalid, is supported by substantial evidence in light of the record as a whole. While the ALJ's Decision is thorough and well-reasoned, and this Court might reach a different conclusion were this matter before it *de novo*, there is substantial evidence in the record as a whole to support the MAC's conclusion that Schuldt failed to meet its burden of demonstrating that WPS's sampling methodology and overpayment extrapolation were invalid.

The sampling methodology was based on a stratified random sample design, consistent with MPIM guidance. Schuldt presented no "evidence of a different random sample from the universe of claims that yield[ed] a lower rate of denials or prove[d] that the projection [was] not a true estimate of the rate of denials in the non-sample universe." See

Chaves, 931 F.2d at 921. Neither did Schuldt “establish[] the validity of all or a sufficient number of its actual claims [in the non-sample universe of claims] to demonstrate that the HHS projection [was] factually impossible of correctness.” *Id.* Neither of those tasks should have been onerous in this case, where WPS’s sampling methodology indicated that between 99.55 percent and 100 percent of services for which Schuldt claimed reimbursement through Medicare had been paid in error.

“A court reviewing an agency's adjudicative action should accept the agency's factual findings if those findings are supported by substantial evidence on the record as a whole.” *Arkansas v. Oklahoma*, 503 U.S. 91, 113 (1992). Viewing the Administrative Record as a whole, including the WPS Statistical Sampling Worksheet, Calculation of Projected Overpayment, Sampling Design and Methodology, Sampling Results and Overpayment Estimates, and Formulas and Calculations (Administrative Record, at Filing No. 17-4), the record contains substantial evidence to support the MAC’s finding that WPS’s expanded post-payment medical review of claims was made from a representative sample of claims that was statistically significant to the universe of claims, and that Schuldt did not meet its burden of proving otherwise.

Accordingly,

IT IS ORDERED:

1. The Motion for Summary Judgment submitted by Plaintiff Schuldt Chiropractic Wellness Center (“Schuldt”) (Filing No. 38), is denied;
2. The Motion for Summary Judgment submitted by Defendant Kathleen Sebelius, in her capacity as Secretary of the U.S. Department of Health and Human Services (“HHS”) (Filing No. 36), is granted;

3. The Plaintiff's Complaint (Filing No. 1) is dismissed, with prejudice; and
4. A separate Judgment will be entered.

DATED this 22nd day of January, 2014.

BY THE COURT:

s/Laurie Smith Camp
Chief United States District Judge