IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
WESTERN DIVISION

CHRISTOPHER JOHN, M.D.,	*	
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Plaintiff,	*	
	*	
vs.	*	No. 4:09CV00552 SWW
	*	
KATHLEEN SEBELIUS, in her official capacity as the SECRETARY of the UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,	* * * *	
	*	
Defendant.	*	

Memorandum Opinion and Order

This is a petition for review under 42 U.S.C. § 1395ff(b)(1) of the final decision of Kathleen Sebelius, Secretary of the United States Department of Health and Human Services ("Defendant"), upholding the use and validity of statistical sampling to determine the amount of overpayment for medical services. The parties filed briefs and the Court heard oral argument on September 17, 2010. For the reasons stated below, the Court affirms Defendant's decision.

Background

Plaintiff is a physician who, as a part of his practice, receives payments from Medicare for professional medical services rendered to Medicare beneficiaries. AdvanceMed Corp. ("AdvanceMed") is a contractor for Defendant's Centers for Medicare and Medicaid Services ("CMS"). On October 20, 2006, AdvanceMed requested medical records and supporting documentation from Plaintiff related to claims submitted by Plaintiff for medical services provided to Medicare beneficiaries between January 1, 2004, and April 30, 2006. Plaintiff supplied all requested documentation to AdvanceMed. By letter dated November 29, 2007,

AdvanceMed notified Plaintiff that it had reviewed the records and documentation and determined that it had overpaid Plaintiff for his services. The amount of alleged overpayment was estimated through the use of statistical sampling and extrapolation.

On December 11, 2007, Plaintiff received a letter from Pinnacle Business Solutions, Inc., the local Medicare carrier, that the amount of overpayment was $138,924.00. Plaintiff requested redetermination of the alleged overpayment by AdvanceMed. On February 8, 2008, AdvanceMed issued a redetermination decision, which found that its initial overpayment determination was appropriate. Following the redetermination, Plaintiff requested reconsideration by a qualified independent contractor ("QIC") for the Medicare program. Medicare recouped $15,353.50 through offset against pending Medicare claims, and Plaintiff remitted a payment of $125,017.63 to Pinnacle Medicare Services, pending appeal, and to stop the accumulation of interest charges. As of March 31, 2008, Plaintiff fully satisfied the alleged overpayment.

On June 9, 2008, the QIC issued a partially favorable decision to Plaintiff, finding that some of the overpayment determinations made by AdvanceMed were in error, and reducing the amount of the alleged overpayment to $127,211.00. Plaintiff got a refund on July 31, 2008, in the amount of $12,079.06,

Plaintiff appealed the unfavorable portions of the QIC decision to the Office of Medicare Hearing and Appeals. As a part of that appeal, Plaintiff contested AdvanceMed's use of statistical sampling and extrapolation to determine the overpayment amount, and asserted that the statistical calculations were invalid because they were so imprecise that they failed to comply with CMS requirements. The Administrative Law Judge ("ALJ") presiding over the QIC appeal held telephone hearings on October 2, 2008, and October 10, 2008, during which three

statisticians testified: Dr. Landtroop, retained by AdvanceMed; Dr. Intriligator, retained by Plaintiff; and Dr. Haller, retained by the ALJ.

On December 30, 2008, the ALJ issued her decision, which found: (a) the statistical sampling to be valid; (b) that some of the original overpayment determinations were in error; and (c) that certain other claims should have been either denied or down-coded to a lower level of payment. Plaintiff appealed the adverse decision of the ALJ to the Medicare Appeals Council. ("MAC"). In a decision dated May 26, 2009, the MAC adopted the ALJ's decision that the statistical sample was valid ("the Statistical Decision"). In a separate decision also dated May 29, 2009, the MAC reversed the ALJ's determination that some of the original overpayment determinations were in error and remanded the matter to the ALJ with instructions to issue a new decision for the relevant claims ("the Claims Decision"). On September 17, 2009, the ALJ issued an amended decision. Plaintiff appealed the amended remanded Claims Decision to the MAC on September 23, 2009, and that appeal is still pending. The case before the Court, challenging the Statistical Decision, was filed on July 24, 2009.

Plaintiff seeks relief in this Court contending that the Defendant erroneously concluded that AdvanceMed met the prerequisite for statistical extrapolation set forth in 42 U.S.C. § 1395ddd(f)(3) and that AdvanceMed complied with the CMS regulatory requirements concerning the use of statistical extrapolation.

Defendant argues this matter is not properly before the Court because the MAC has not issued a final decision on the claims aspect of Plaintiff's dispute. The Court finds that the Statistical Decision rendered by the MAC is the final agency action and Plaintiff has exhausted his administrative remedies as to his challenge of the use and validity of the statistical sampling.

Legal Standard

A district court reviews a final decision of the Secretary of the Department of Health and Human Services pursuant to 42 U.S.C. § 405(g). 42 U.S.C. § 1395ff(b)(1)(A). The findings of the Secretary are conclusive "if supported by substantial evidence." 42 U.S.C. § 405(g). Substantial evidence is more than a mere scintilla but is less than the weight of the evidence and refers to relevant evidence which reasonably supports a conclusion. *Richardson v. Pearles,* 402 U.S. 389, 401 (1971). It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion. *Id.* Under the substantial evidence standard, the reviewer must examine the record as a whole and take into account whatever in the record fairly detracts from the weight of the evidence below. *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 488 (1951). Federal court review is *de novo* but is limited to the administrative record. *Shalala v. St. Paul Ramsey*, 50 F.3d 522 (8th Cir. 1995).

Discussion

Plaintiff first argues that the decision that AdvanceMed complied with the statutory prerequisites for statistical extrapolation is not supported by substantial evidence.[1]

42 U.S.C. § 1395ddd(f)(3) 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.

Plaintiff argues there is no evidence that the Secretary ever made a determination that a sustained

[1] The parties agree that there is no administrative or judicial review of determinations by the Secretary of a high payment error rate.

or high level of payment error existed for him. In a Memo dated October 31, 2007, M. Suzanne Moody, Ph.D., a statistician employed by AdvanceMed, stated:

> An examination of the data analysis and/or other evidence in this case led AdvanceMed to suspect that a high level of payment error exists for this provider. AdvanceMed further determined that a full audit (i.e., an examination [of] all claims paid to the provider for the time period in question) would not be administratively feasible and would place an unwieldy burden on both AdvanceMed and the provider due to the volume of records involved. Therefore, AdvanceMed chose to draw a random sample of claims to review. The review resulted in a provider paid error rate of 17.54%. Therefore, AdvanceMed used statistical sampling to calculate and project (i.e., extrapolate) the amount of overpayment made on claims billed by this provider.

Administrative Record ("AR") at 429. Plaintiff argues that there is no statutory authority for the Secretary to delegate the function of making a finding of a sustained or high level of payment error for purposes of § 1395ddd(f)(3), and even if there were, there is no evidence showing such delegation actually occurred. In addition, Plaintiff argues that AdvanceMed unlawfully used a statistical analysis to determine whether Plaintiff had a high level of payment error and that AdvanceMed's "suspicion" is not the same as a finding of a sustained or high level of payment error.

The Court finds that the Secretary, by delegation of her authority, made a determination after examining the data analysis "and/or other evidence" that there was a high level of payment error for Plaintiff in compliance with § 1395ddd(f)(3 . Although Dr. Moody used the word "suspect" rather than "determine," the Court finds the Defendant adopted this finding as a determination under § 1395ddd(f)(3) before proceeding to statistical extrapolation to determine overpayment amounts.

Second, Plaintiff argues that the statistical sampling and extrapolation methodologies used by AdvanceMed were fundamentally flawed and should have been invalidated. AR at 281.

When statutorily authorized, it is appropriate for Medicare contractors to engage in statistical analysis to calculate projected overpayments. *Chaves County Home Health Servs., Inc. v. Sullivan*, 931 F.2d 914, 916 (D.C.Cir. 1991). For purposes of evaluating potential Medicare overpayments, Section 3.10 of the Medicare Program Integrity Manual ("the MPIM") contains the requirements that must be followed to ensure that a statistically valid sample is drawn, and that statistically valid methods are used to project an overpayment.[2] The MPIM requires that the Medicare contractor comply with the following conditions:

> The Medicare contractor must maintain complete documentation of the sampling methodology that was followed.
>
> 'An explicit statement of how the universe is defined and elements included shall be made and maintained in writing. Further, the form of the frame and specific details as to the period covered, definition of the sampling unit(s), identifiers for the sampling units (e.g. claim numbers, carrier control numbers), and dates of service and source shall be specified and recorded in your record of how the sampling was done. A record shall be kept of the random numbers actually used in the sample and how they were selected. Sufficient documentation shall be kept so the sampling frame can be re-created, should the methodology be challenged. The PSC BI units or the contractor MR units shall keep a copy of the frame.'

AR at 0329.

> In regard to sample size, the IM states the following:
>
> '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 methods of sample selection, the estimator of

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[2]Sections of the MPIM are set out in the ALJ's December 30, 2008 decision. AR at 329-30.

> 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 . . . 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.

AR at 0330.

Dr. Moody wrote a memo dated October 31, 2007, outlining the methodologies AdvanceMed used in calculating Plaintiff's overpayment. AR at 429-432. She stated that AdvanceMed used Simple Random Sampling and Stratified Random Sampling to analyze the data Plaintiff submitted. She stated that AdvanceMed used the means and standard deviations of claims paid amounts as estimates in determining the size of the sample. The total sample size estimated to achieve a precision threshold of ± 10% at the 90% confidence level and at a high error rate was 200 claims for Simple Random Sampling and 90 claims for Stratified Random Sampling. AdvanceMed determined that the Stratified Random Sampling would offer the most efficient and cost-effective approach, and the potential for a reduction in variation, and therefore, greater precision in the overpayment estimate. This resulted in an overall precision estimate of 22.48% and relative sampling error of 13.67%. Dr. Moody said there were no known non-sampling errors, the overall sample was statistically valid and replicable, and the extrapolation was carried out using DHS software in a controlled environment to minimize the potential for non-sampling risks.

According to Dr. Intriligator, AdvanceMed did not demonstrate a sample that is

statistically valid and chosen at random, provided only a cursory discussion of non-sampling error factors, provided no evidence that the computer programs it used for sampling and extrapolation have been scientifically validated, and provided no basis for the calculations that were used to calculate the overpayment. Dr. Intriligator testified that the sample AdvanceMed used was not representative of the universe and AdvanceMed failed to show that the sample attained the level of precision required for extrapolation. The statistical experts who provided opinions in this matter all agreed that in order to be statistically valid, a sample is required to have an acceptable level of confidence and precision. Dr. Intriligator noted that Dr. Moody reported a relative sampling error of 13.67 % and that something over 13 % is unacceptable as a measure of precision. He also testified that the precision percent of 22.48 % was an unacceptable level. AR at 677-703, 6067-6075; 6097-6099.

Dr. Haller testified he thought AdvanceMed based their estimates on the wrong information by using paid amounts rather than overpayment amounts. AR at 868-877; 6075-6081; 6088-6097. Dr. Haller concluded that "the sample size used for this audit was not sufficient for both the 90% confidence and 10% precision levels specified by AdvanceMed." AR 876. Dr. Haller testified that the sample could be replicated and that the computer programs used were adequate.

The ALJ asked Dr. Landtroop to address the effect of the precision in the statistical study on the validity of the extrapolation. He testified that precision in this context means the repeatability of a study, and does not imply that the results are inaccurate. AR 6082. He testified: "I can form a confidence interval around my yearly salary, so to speak. And that may be between $1,000.00 and $450,000.00. That's a very imprecise confidence interval, but it's accurate. My

salary is indeed between $1,000.00 and $450,000.00. Imprecision does not imply inaccuracy." *Id.* He further testified that a probability sample and its results are always valid. Therefore, when dealing with probability sampling, if a particular probability sample design is properly executed (i.e., defining the universe, the frame, the sampling unit, using proper randomization, accurately measuring the variables of interest, and using the correct formula for estimation) then assertions that the sample and its resulting estimates are not statistically valid, cannot be legitimately made. [3] AR 6083. As to the testimony that non-sampling errors were not adequately addressed, Dr. Landtroop testified that two independent statisticians looked at the original extrapolation and at every level internal controls were in place to ensure that there were no non-sampling errors. AR at 6084.

Upon review of the record, the Court finds that substantial evidence supports the Defendant's decision that AdvanceMed used valid statistical methodologies in calculating the overpayment and the methodology complied with the requirements set forth in the MPIM.

Conclusion

IT IS THEREFORE ORDERED that the Secretary's decision is affirmed.

DATED this 6th day of October, 2010.

/s/Susan Webber Wright

UNITED STATES DISTRICT JUDGE

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[3] There is no "statistical 'floor' which auditors must exceed in order to guarantee providers due process." *Ratanasen v. California Dept. Of Health Servs.*, 11 F.3d 1467, 1472 (9th Cir. 1993).