

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
MCALLEN DIVISION

TRANSYD ENTERPRISES, L.L.C. DBA	§	
TRANSPRO MEDICAL TRANSPORT,	§	
	§	
Plaintiff,	§	
VS.	§	CIVIL ACTION NO. M-09-292
	§	
KATHLEEN SEBELIUS,	§	
	§	
Defendant.	§	

**ORDER AFFIRMING DECISION OF MEDICARE APPEALS COUNCIL
AND DENYING PLAINTIFF’S MOTION FOR SUMMARY JUDGMENT**

I. Introduction

Now before the Court are the appeal by Plaintiff Transyd Enterprises, L.L.C. d/b/a Transpro Medical Transport (“Transyd”), a provider of ambulance transport services to Medicare beneficiaries, of the final decision of the Medicare Appeals Council (“MAC”) that Transyd was overpaid on certain claims submitted to and paid by Medicare, and that Transyd failed to show that the statistical sampling and extrapolation methodology used to ascertain the extent of those overpayments was invalid. (Doc. 1); *see* 42 U.S.C. § 1395ff(b)(1)(A); 42 C.F.R. §§ 405.1130, 405.1136. As Secretary of the U.S. Department of Health and Human Services (“HHS”), the department that oversees the Medicare program through the Centers for Medicare and Medicaid Services (“CMS”), Defendant Sebelius is the proper adverse party to this appeal. *See* 42 C.F.R. § 405.1136(d). In addition to challenging the decision of the MAC, Transyd asserts claims that the Secretary violated its federal procedural and substantive due process rights during the administrative appeal process. (Doc. 1). Further, Transyd requests a declaratory judgment that the Secretary “may not prematurely recoup payments to reduce an alleged Medicare

overpayment in opposition to 42 U.S.C. § 1395ddd(f)(2).” *Id.* Also before the Court is Transyd’s Motion for Summary Judgment on all issues raised by the appeal. (Docs. 1, 29). Upon consideration of the pleadings, Transyd’s Motion for Summary Judgment, all briefing by the parties, and the administrative record, the Court finds that the decision of the MAC must be affirmed and Transyd’s Motion denied for the following reasons.

II. Administrative Record¹

A. Initial Overpayment Determination and Redeterminations by Contractor and QIC

In 2006, Medicare Program Safeguard Contractor (“PSC”) TriCenturion, acting on behalf of CMS, audited a random sample of 30 claims paid by CMS for ambulance transport services provided by Transyd between January 1, 2004 to June 20, 2006. AR at pp. 11415-16; *see also* p. 10890. Transyd submitted the 30 claims on behalf of 23 beneficiaries. *See id.* at p. 10853. TriCenturion determined that all of the claims did not meet Medicare coverage requirements and that Transyd had received an estimated overpayment of \$6,583.22 for those claims. *Id.* at pp. 11415-16. Since the audit was based on a statistical sample, TriCenturion extrapolated the result to the universe of 9,982 claims submitted by Transyd during the time period under examination to arrive at the total amount deemed to have been improperly paid to Transyd during that period. *Id.* The projected amount was \$2,015,903.57 “based on the lower limit of the one-sided 90 percent confidence interval.” *Id.* By letter dated January 2, 2007, TriCenturion notified Transyd of its overpayment determination. *Id.* By letter dated January 29, 2007, TrailBlazer Health Enterprises, L.L.C. (“TrailBlazer”)² requested repayment of the total amount of the overpayment minus \$70,920.62 already recovered from TrailBlazer through recoupment. *Id.* at pp. 11368-71. Transyd requested a redetermination and TrailBlazer upheld the overpayment assessment in a

¹ The Court will cite to the administrative record as “AR.”

² TrailBlazer is a CMS contracted intermediary and carrier for the state of Texas. As a CMS contractor, TrailBlazer conducts Medicare redetermination appeals. (Docs. 29, 32).

decision dated June 22, 2007. *Id.* at pp. 10890-95, 10920-21. Transyd then requested reconsideration from the Qualified Independent Contractor (“QIC”) Q2 Administrators, who apparently issued a decision partially favorable to Transyd on September 19, 2007. *Id.* at pp. 10877-88; *see also* p. 11573.³ More specifically, the QIC determined that the PSC’s overpayment determination on the sample of claims was partially incorrect, reduced the “actual” overpayment, and referred the matter to TrailBlazer to determine a “revised extrapolated” overpayment amount. *Id.* at p. 11573.

B. First Appeal to ALJ and Remand to QIC for Reconsideration

Transyd moved to escalate an appeal of the QIC decision to the Administrative Law Judge (“ALJ”) on November 26, 2007. *Id.* at pp. 11565-74. In an order dated February 27, 2008, ALJ Richard A. Opp denied Transyd’s motion for release of \$70,920.62 and an additional \$15,900.42 in funds recouped from Transyd prior to the issuance of the reconsideration decision by the QIC, finding that the recoupment was unlawful but that the ALJ lacked authority to grant the relief requested, and in any event the reconsideration decision had now been issued and the request was therefore moot. *Id.* at pp. 10846-53. The ALJ also found that TriCenturion and TrailBlazer had failed to produce documentation supporting the revised overpayment amount of \$1,517,210.69 and remanded to the QIC “for a new reconsideration determination, with a full explanation of the revised, extrapolated overpayment, and all supporting documentation.” *Id.* In a decision dated April 7, 2008, the QIC reaffirmed its decision that of the 30 claims in the sample, sufficient documentation was provided to support the ambulance transport services on four of the claims. *Id.* at pp. 11606-26. Based on this finding, TriCenturion used the random sample of 30 claims (now with an error rate of 86% instead of 100%), the universe of 9,982

³ The MAC observed in its decision that the September 19, 2007 QIC reconsideration was not in the record, but that both Transyd and the QIC had referred to this reconsideration as “partially favorable” to Transyd. AR at p. 4 n.1.

claims, and the Minimum Sum Method (“MSM”) to arrive at the new projected overpayment amount. *Id.* The QIC explained that the MSM “involves ranking the claims in the universe in order from the lowest-paid claims to the highest paid claims. The program (SAS) identifies the number of units needed (based on the error rate in the sample) to extrapolate to, in order to attain a 90% confidence that the projected overpayment is at least as much [as] stated.” *Id.* Here, the SAS program determined that 7,499 of the 9,982 claims in the universe (the 26 claims in the sample and the next 7,469 lowest-paid claims) would be used for extrapolation, leading to a projected overpayment of \$1,517,210.69. *Id.* Based on the QIC’s review of CMS guidelines pertaining to the use of statistical sampling to estimate overpayment, and documentation from TriCenturion including an explanation of the sampling design based on the methods approved by Don Edwards, Ph.D., the QIC concluded that TriCenturion followed all CMS directives to select the sample and universe, and to use statistical sampling to recalculate the overpayment. *Id.*

C. Second Appeal to ALJ and Remand to QIC for Reconsideration

Transyd requested an ALJ hearing to challenge the QIC’s reconsideration decision. *See id.* at pp. 11631-36. In a decision dated August 26, 2008, ALJ Thomas P. McCarthy expressed concern that the documentation relied on by the QIC in its reconsideration had not been provided to Transyd. *Id.* Therefore, the ALJ again remanded the matter to the QIC with instructions that it (1) obtain all documentation from TrailBlazer and/or TriCenturion that was relied on in determining the initial and/or revised overpayment calculation; (2) make this documentation available to Transyd; (3) once the documentation has been provided, enable Transyd to rebut the revised overpayment calculation and receive, analyze, and review argument from any statistical expert Transyd uses to recreate or challenge the sampling methodology; and (4) issue a revised decision addressing Transyd’s arguments. *Id.* In a letter dated November 5, 2008, the QIC

notified the ALJ that it had satisfied the first two instructions but that the reconsideration process does not include consideration of a rebuttal/response, which may be addressed at the ALJ level, and that additional reopening could not be supported with the information available. *Id.* at p. 11630.

D. Final Appeal to ALJ

On January 9, 2009, Transyd appealed the QIC's decision declining to issue a new reconsideration. *Id.* at pp. 11586-605. ALJ McCarthy held a telephonic hearing on March 18, 2009 and reconvened the hearing on April 2, 2009 to receive competing expert testimony from Dr. Will Yancey, Ph.D. for Transyd and Dr. Greg Dobbins, Ph.D. at the ALJ's request concerning the statistical sampling method used. *Id.* at pp. 36-83; *see also* p. 14926. In a lengthy decision issued on April 21, 2009, the ALJ analyzed in detail each of the 30 claims in the sample based on the documentation provided and determined that only 12 claims submitted on behalf of 10 of the 23 sample beneficiaries were not for a Medicare covered service. *Id.* at pp. 36-83. The reasons for the denial of the 12 claims were that Transyd had failed to provide (or to timely provide) a Physician's Certification Statement for the services at issue or to submit documentation showing that the services were in fact furnished, that other means of transport would not have been unduly burdensome and were not contraindicated, or with regard to one claim, that transport from the beneficiary's home to her physician's office did not meet the origin and destination criteria for payment. *Id.* In addressing the expert testimony, the ALJ conceded that "[b]oth experts were well prepared, well-informed, and generally persuasive in advancing and explaining their respective positions." *Id.* However, after considering all of the testimony and documentation in the record, and based on his finding that the overpayment was limited to 12 of the 30 claims in the initial sample, the ALJ concluded that TriCenturion's sampling

methodology was not sufficiently reliable to sustain extrapolation in the circumstances of the case. *Id.* The ALJ rested this conclusion on the following findings. First, apart from Dr. Dobbins's testimony based on "extra-record" evidence after his review of Dr. Yancey's report, the record failed to establish that TriCenturion's statisticians who did the sample planning and evaluation using the MSM possessed a master's degree in statistics or equivalent experience as required by the CMS Medicare Program Integrity Manual ("MPIM") § 3.10.1.5. *Id.* In addition, TriCenturion failed to establish why a single random sample size limited to 30 claims was appropriate for the variable Transyd population, particularly in light of an achieved precision of 24% (using Dr. Dobbins's more favorable recalculation of Dr. Yancey's figures). *Id.* The ALJ reasoned that because the achieved precision significantly exceeded 10%, even before his decision reversing the QIC on a majority of claims in the sample, he could not conclude that the sample results should be extrapolated from the sample to the Transyd population. *Id.* Further, he agreed with Dr. Yancey that TriCenturion failed to analyze the sample results by beneficiary and to consider any need to stratify the Transyd population into high and low-frequency beneficiaries, which may impact the independence of claims in a small random sample and reveal why (as in the case of the sample beneficiaries) the overpayment rate was lower for high-frequency patients. *Id.* The ALJ stated that the lack of any analysis by TriCenturion regarding possible stratification was notable in light of MPIM § 3.10.4.1.3 and § 3.10.11.1 which encourage the use of stratified random sampling. *Id.* The ALJ summarized his findings as follows:

In sum, because the record fails to document that TriCenturion's statistician(s) possessed a master's degree in statistics or equivalent experience as required by [MPIM] § 3.10.1.5, and because the preponderance of evidence supports a finding that the sampling plan and methodology—including use of an unstratified population, a small and arbitrary sample size of 30, and a Minimum Sum Method to compute the lower bound 90% confidence

interval—was generally unexplained and insufficiently documented and thus unreliable and invalid, I find that Medicare is limited to recovering the actual 12 overpayments found in the 30 sampled claims.

Id.

E. Appeal to MAC

In a memorandum dated June 15, 2009, CMS referred the case for review by the MAC on its own motion, on the bases that the ALJ's decision was erroneous as a matter of law and not supported by a preponderance of the evidence. *Id.* at pp. 19-34. Appealing to CMS rulings and various sections of the MPIM, CMS argued that the purported inconclusive documentation regarding TriCenturion's statisticians and TriCenturion's use of a relatively small, nonstratified sample did not invalidate the extrapolation, and that the remedy for the ALJ's reversal of individual claim determinations was recalculation of the extrapolated overpayment amount. *Id.* The MAC accepted review and issued its decision on September 15, 2009. *Id.* at pp. 1-17. The MAC briefly noted that CMS did not seek review of the ALJ's findings regarding coverage of the sampled claims at issue; therefore, it declined to disturb the ALJ's findings on those claims. *Id.* at p. 4. As the MAC's lengthy review and, ultimately, rejection of the contested findings by the ALJ on extrapolation form the main basis for Transyd's appeal, the Court will set forth that portion of the MAC's decision in detail.

The MAC observed that CMS Ruling 86-1 describes the agency's policy on the use of statistical sampling to project overpayments to Medicare providers, and also outlines the history and authority, both statutory and precedential, for the use of statistical sampling and extrapolation by CMS in calculating overpayments. *Id.* at p. 6. The ruling provides, in part:

Sampling does not deprive a provider of its rights to challenge the sample, nor of its rights to procedural due process. Sampling only creates a presumption of validity as to the amount of an overpayment which may be used as the basis for recoupment. The burden then shifts to the provider to take the next step. The provider could attack the

statistical validity of the sample, or it could challenge the correctness of the determination in specific cases identified by the sample (including waiver of liability where medical necessity or custodial care is at issue). In either case, the provider is given a full opportunity to demonstrate that the overpayment determination is wrong. If certain individual cases within the sample are determined to be decided erroneously, the amount of overpayment projected to the universe of claims can be modified. If the statistical basis upon which the projection was based is successfully challenged, the overpayment determination can be corrected.

Id. at pp. 6-7 (citing CMS Ruling 86-1-9 & 86-1-10). The MAC also observed that CMS's statistical sampling guidelines are found in Chapter 3 of the MPIM, § 3.10, and went on to cite and summarize in detail the provisions pertinent to the case before it. *Id.* at pp. 7-11. Based on these authorities, the MAC determined that it need not find that CMS or its contractor undertook statistical sampling and extrapolation based on the most precise methodology; rather, the test is simply whether the methodology used is statistically valid. *Id.* at p.11. Further, considering the language in Rule 86-1 that the use of statistical sampling "creates a presumption of validity" and that "the burden then shifts to the provider to take the next step," the MAC found that the ALJ erred to the extent that he concluded that TriCenturion's sampling methodology and extrapolation were invalid based on its failure to explain why it did not select a larger sample size or undertake stratified sampling. *Id.* at p. 12.

Turning to whether the evidence upon which the ALJ relied was sufficient to invalidate TriCenturion's sampling methodology, the MAC noted that the ALJ principally relied on the report and testimony of Transyd's expert, Dr. Yancey, in concluding that TriCenturion should have undertaken a different sampling methodology that may have resulted in a greater precision than that attained using the MSM and a sample size of 30 claims. *Id.* at p. 12. The MAC described Dr. Yancey's report as opining that the generally accepted statistical practice is to achieve a relative precision within 10%, that sample results should not be extrapolated if the precision is more than 10%, and therefore that TriCenturion should not have extrapolated from

the Transyd sample because its extrapolation achieved a precision of 26.17%. *Id.* at pp. 12-13. Dr. Yancey also criticized the choice of simple random sampling and the MSM because, in his view, the method was chosen for contractor convenience rather than statistical precision. *Id.* at p. 13. Finally, Dr. Yancey faulted TriCenturion's methodology because it failed to use a stratified sample. *Id.* The MAC concluded that even if it accepted Dr. Yancey's criticisms, none constituted a basis for invalidating the sampling methodology used. *Id.* First, the MPIM states that it is not improper and in fact is required that the contractor consider "real-world economic constraints," such as "the level of available resources," when choosing a sampling methodology. *Id.* (quoting MPIM §§ 3.10.2, 3.10.4.3). Therefore, even if TriCenturion chose the particular methodology because, for example, it required less staff resources than a stratified sample, this would not be a basis for concluding that the methodology was invalid. *Id.* Further, the MPIM recognizes and accepts that a smaller sample size may affect the precision of the estimated overpayment but does not prescribe a particular sample size or precision. *Id.* (citing MPIM §§ 3.10.4.3). Rather, to offset the potential lack of precision, CMS directs contractors to give the benefit of the doubt resulting from any imprecision to the provider by assessing the overpayment at the lower level of a confidence interval—generally, the lower level of a 90% confidence interval. *Id.* at pp. 13-14 n.11. This results in the assumption, in statistical terms, that there is a 90% chance that the actual overpayment is higher than the overpayment assessed. *Id.* Further, the MPIM does not prescribe any particular sampling design, but notes that any design that results in a probability sample, including simple random sampling, systematic sampling, stratified sampling, or cluster sampling is acceptable. *Id.* at pp. 13-14 (citing MPIM § 3.10.4.1). Thus, the MAC concluded that the MPIM provides no support for the ALJ's reliance on Dr. Yancey's conclusions that a sampling methodology resulting in a precision greater than 10%, or

one that is based on simple random sampling rather than stratified sampling, may not be used in calculating an extrapolated overpayment. *Id.* at p. 14.

The MAC also found that the ALJ erred in determining that extrapolation was inappropriate in light of his finding that Medicare had overpaid Transyd on only 12 of the 30 sampled claims. *Id.* at p. 14. The MAC pointed to language in the MPIM instructing that “[i]f the decision on appeal upholds the sampling methodology but reverses one or more of the revised initial claim determinations, the estimate of overpayment shall be recomputed and a revised projection of overpayment issued.” *Id.* (citing MPIM § 3.10.9.2). Thus, the ALJ’s reversal of some of the initial claim determinations did not constitute grounds for invalidating the sampling methodology used, and the appropriate remedy was recalculation of the extrapolated overpayment. *Id.* Finally, the MAC found erroneous on several bases the ALJ’s invalidation of the sampling methodology because TriCenturion had failed to document that its statisticians possessed at least a master’s degree in statistics or equivalent experience as required by § 3.10.1.5. *Id.* First, the MAC noted the language in Ruling 86-1 establishing a presumption of regularity as to overpayments assessed via statistical sampling, and that the burden of proof is on the provider to demonstrate that the contractor’s methodology is invalid. *Id.* Further, the MPIM states that “[f]ailure by [contractors] to follow one or more MPIM requirements may result in review by CMS of their performance, but should not be construed as necessarily affecting the validity of the statistical sampling and/or the projection of the overpayment.” *Id.* at p. 15 (citing MPIM § 3.10.1.1). Thus, TriCenturion’s alleged failure to comply with § 3.10.1.5, or to document its compliance, would not necessarily invalidate its sampling methodology. *Id.* Moreover, the MAC found erroneous the ALJ’s conclusion that no documentary evidence existed to substantiate the qualifications of TriCenturion’s statisticians. *Id.* The MAC noted that

in addition to Dr. Dobbins's testimony, the record contains documents indicating that the sampling and extrapolation were prepared by Petko Kostadinov, M.S. and reviewed by Mary Alice Barth, M.I.S., and that Don Edwards, Ph.D. approved the sampling methodology used. *Id.* Thus, the ALJ's conclusion that TriCenturion failed to document that its statisticians possessed the requisite qualifications was not supported by a preponderance of the evidence in the record.

Id. The MAC concluded:

It is the decision of Medicare Appeals Council that [Transyd] failed to prove that the statistical sampling and overpayment extrapolation methodology employed by [TriCenturion] in this case was invalid. We therefore reverse that part of the ALJ's holding that no extrapolated overpayment amount may be assessed. We affirm the ALJ's coverage findings as to the sampled claims.

Id. at pp. 15-16.

III. Appeal to Federal District Court

According to Transyd, it received a letter from TrailBlazer on November 9, 2009 indicating that in light of the MAC's decision, the new overpayment amount was \$390,047.02 plus \$42,070.24 in interest. (Docs. 1, 29). On November 16, 2009, Transyd filed suit in this Court, seeking review of the MAC decision, asserting due process claims, and requesting a declaratory judgment. (Doc. 1). Transyd's Motion for Summary Judgment frames the issues presented as follows: (1) whether the Secretary properly determined the individual claims in the sample; (2) whether substantial evidence exists to support the Secretary's finding that the extrapolation methodology used by TriCenturion is statistically valid; (3) whether substantial evidence exists to support the Secretary's decision to recalculate the overpayment amount based on the new findings of the ALJ on the individual claims; (4) whether the Secretary violated Transyd's due process rights in determining that the methodology was statistically valid without making certain that the contractors followed the requirements of MPIM, Chapter 3; (5) whether

MPIM § 3.10.9.2 is invalid and violates Transyd’s due process rights because it allows the Secretary to recalculate an overpayment without giving Transyd further appeal rights to test the new calculation; and (6) whether the Secretary violated 42 U.S.C. § 1395ddd(f)(2) by recouping alleged overpayments from Transyd prior to the QIC reconsideration decision. (Doc. 29).

A. Review of MAC Decision

1. Standard of Review

The Court will address the first three issues raised by Transyd’s Motion for Summary Judgment in the context of its appeal of the MAC decision. It is well-settled that the Court “‘may overturn the Secretary’s ruling only if it is arbitrary, capricious, an abuse of discretion, not in accordance with law, or unsupported by substantial evidence on the record taken as a whole.’” *E.g., Tex. Clinical Labs, Inc. v. Sebelius*, 612 F.3d 771, 775 (5th Cir. 2010) (quoting *Sun Towers, Inc. v. Schweiker (Sun Towers I)*, 694 F.2d 1036, 1038 (5th Cir. 1983)). “Substantial evidence,” the standard of review on which Transyd’s appeal focuses, means “‘such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.’” *Girling Health Care, Inc. v. Shalala*, 85 F.3d 211, 215 (5th Cir. 1996) (quoting *Richardson v. Perales*, 402 U.S. 389, 401 (1971)). It requires “‘something less than the weight of the evidence, and the possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency’s finding from being supported by substantial evidence.’” *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1213 (5th Cir. 1991) (quoting *Consolo v. Fed. Mar. Comm’n*, 383 U.S. 607, 620 (1966)); *see also New Thoughts Finishing Co. v. Chilton*, 118 F.3d 1028, 1030 (5th Cir. 1997)) (“The substantial evidence standard is less demanding than that of preponderance of the evidence, and the [agency’s] decision need not constitute the sole inference that can be drawn from the facts.”). “If supported by substantial evidence, the decision of the Secretary is

conclusive and must be affirmed.” *Sid Peterson Mem’l Hosp. v. Thompson*, 274 F.3d 301, 311 (5th Cir. 2001) (quoting *Richardson*, 402 U.S. at 390).

2. Individual Claims

Having obtained a finding from the ALJ that only 12 of the claims within the original 30-claim sample, rather than all 30 of the claims as TriCenturion initially determined, were not for a Medicare covered service, Transyd now contends that the ALJ erred in determining that these 12 claims were not properly payable by Medicare. (Doc. 29). However, as the Secretary points out, neither CMS nor Transyd sought review by the MAC of the ALJ’s individual claim determinations, resulting in the MAC’s affirmance of the ALJ’s findings on the individual claims. (Doc. 32). Subject to an exception not applicable here, the Supreme Court has directed that judicial review under the Medicare Act is available only after the Secretary renders a final decision, and that “a ‘final decision’ is rendered on a Medicare claim only after the individual claimant has pressed his claim through all designated levels of administrative review.” *Heckler v. Ringer*, 466 U.S. 602, 605-06 (1984). The administrative appeal process through which a provider may challenge an overpayment determination consists of: (1) contractor redetermination; (2) QIC reconsideration; (3) ALJ hearing; and (4) MAC review. *See* 42 C.F.R. § 405.904(a)(2). As no party sought review by the MAC of the ALJ’s findings on the individual claims, exhaustion has not occurred and the Court may not review these findings on appeal.

3. Statistical Sampling Methodology

Transyd further argues that the MAC erred in finding that Transyd failed to show that the sampling methodology used by TriCenturion was statistically invalid, contending that this conclusion is not supported by substantial evidence. (Doc. 29). Transyd does not take issue with the CMS rulings and MPIM guidelines relied on by the MAC in arriving at its determination, but

simply contends that expert opinion and testimony mandate a different application of that authority. *Id.* Specifically, Transyd does not dispute that under CMS Ruling 86-1, sampling creates a presumption of validity as to the amount of an overpayment, upon which the burden shifts to the provider to attack the statistical validity of the sample. Further, Transyd does not explicitly contest the MAC's observation that the MPIM does not prescribe a particular sample size, precision, or sampling design, and requires the contractor to consider real-world economic constraints when choosing a sampling methodology. Transyd nonetheless contends that the report and testimony of its expert, Dr. Yancey, and the competing testimony of Medicare "Chief Statistician" Dr. Dobbins, establish the invalidity of the sampling methodology used, first because Dr. Dobbins agreed with Dr. Yancey that the precision did not meet the "required" 10%. *Id.*; see AR at p. 14873. Transyd further argues that Dr. Dobbins erred in relying on the paper of Dr. Edwards, the "creator" of the MSM, as support for the use of the MSM in this case because Dr. Edwards's calculations were done in the context of power wheelchair claims. (Doc. 29). According to Transyd, these are "all or nothing" claims because "you either need a wheelchair or you don't." *Id.* Transyd points to Dr. Yancey's observation that the ambulance transport claims at issue here are too complex to be compared to wheelchair claims because the former vary based on mileage, medical necessity for the transport as a whole, and the level of monitoring services rendered by staff. *Id.* Thus, Transyd maintains that Dr. Dobbins incorrectly "forced" the Transyd ambulance service claims into the same mold as wheelchair claims, further revealing that the method used is statistically invalid. *Id.* Transyd also appeals to Dr. Yancey's additional observations that the universe and the sample contain too many "variables" to justify the use of the MSM in this case. *Id.*

To resolve Transyd's argument regarding precision, the Court turns to Dr. Yancey's expert report and both experts' testimony at the ALJ hearing on April 2, 2009. First, the Court notes that the ALJ made specific findings that both experts were qualified to testify. AR at pp. 14891-92, 14931-32. In his testimony, Dr. Yancey described precision as a measure of the width of uncertainty in a sample, *i.e.*, the risk that another sample would achieve different results. *Id.* at pp. 14896-97. Dr. Yancey explains in his report that "under generally accepted statistical practice there are two distinctly different reasons to compute the precision" and then uses these two reasons as a kind of checklist for determining whether extrapolation is appropriate. *Id.* at p. 125. Dr. Yancey states that the "threshold test" requires a statistician to compare the achieved precision and the required precision. *Id.* According to Dr. Yancey, "generally accepted statistical sampling practice" sets the required precision at 10%. *Id.* If the achieved precision is worse than the required precision, "the projection cannot be made and the overpayment should be limited to the actual claims examined without extrapolation to the population." *Id.* If the achieved precision is within the required precision, the statistician then applies an "assessment at the lower bound" to determine where within the confidence interval the assessment should be made. *Id.* In the MPIM, the recommendation is to assess at the lower boundary of the confidence interval. *Id.* Applying these principles, Dr. Yancey concludes that TriCenturion failed to meet the threshold test because it achieved a precision of 26.17%, and that it cannot mitigate this flaw by assessing liability at the lower bound. *Id.* Dr. Yancey reiterated this position in his testimony. *Id.* at pp. 14982-96. As Transyd observes, Dr. Dobbins agreed that the precision achieved by TriCenturion was worse than 10%, although he set the precision at 24%. *Id.* at p. 14935. However, Dr. Dobbins countered that the MPIM makes no reference to a specific, required precision. *Id.* at pp. 14938-39. Further, he called the precision argument

“facetious” in the context of the MSM, which is “extremely conservative and favorable” to the provider. *Id.* at pp. 14936, 14938. Dr. Dobbins explained that using the MSM, TriCenturion estimated based on the sample that of the population of 9,982 claims, 7,499 constituted medically unnecessary ambulance trips. *Id.* at p. 14937. Then, TriCenturion sorted the unsampled, medically unnecessary claims from lowest to highest and added only the lowest claims to achieve the overpayment total. *Id.* Dr. Dobbins stated that if TriCenturion had used the Central Limit Theorem (“CLT”), the method to which Dr. Edwards’s paper proposes the MSM as an alternative, it would have achieved a better precision of 12% but the lower limit of the one-sided 90% confidence interval would have resulted in a *larger* overpayment calculation. *Id.* at pp. 14937-38. Addressing Dr. Yancey’s “checklist,” Dr. Dobbins further observed that “[t]here’s no such list to check off in statistics.” *Id.* at pp. 14953-54. As set forth *supra*, the Court’s role is not to determine which expert was more persuasive on this point, but whether substantial evidence, *i.e.*, less than a preponderance, exists to support the MAC’s determination that Dr. Yancey’s opinion on precision does not invalidate TriCenturion’s sampling methodology. It is worthwhile to again note that the ALJ who heard the experts’ testimony found both experts to be “well-prepared, well-informed, and generally persuasive.” Not surprisingly, therefore, the MAC implicitly accepted Dr. Dobbins’s explanation that the lack of precision did not invalidate the use of the MSM in this case. The Court finds that in doing so, the MAC rested its decision on substantial evidence.

The Court next turns to Transyd’s arguments regarding “variability” and whether substantial evidence exists from which the MAC could conclude that the variables identified by Dr. Yancey did not invalidate the sampling method used. Both experts recognized that Dr. Edwards, who authored the paper proposing the MSM as an alternative to the CST in Medicare

fraud investigations, did so in the context of power wheelchair claims. *See id.* at pp. 155-77. Dr. Yancey found this significant, in that “[m]otorized wheel chairs are a homogenous population and each beneficiary receives one,” whereas in the Transyd population the claims vary widely in dollar amount based on factors such as mileage and whether the service is for basic or advanced life support. *Id.* at pp. 126-27, 14902. Dr. Dobbins, on the other hand, described the Transyd population as homogeneous, in that the question on each claim is whether a particular ambulance trip was medically necessary or not. *Id.* at p. 14936-37. Further, he opined that the MSM “sidesteps” the issue of variability by adding only the smallest of the unsampled, medically unnecessary claims to the sampled claims to arrive at the overpayment amount. *Id.* at p. 14951. Again, the Court need not decide which opinion better persuades, and finds that substantial evidence supports the MAC’s implicit conclusion that the MSM could be validly applied to ambulance transport claims.

In his report, Dr. Yancey also concludes that variability between high and low-frequency beneficiaries invalidates the use of the MSM in this case. *Id.* at pp. 128-29. He explains that of the 337 beneficiaries in the Transyd universe, the seven beneficiaries with payments over \$100,000 represent 38% of the total dollars paid and the 39 beneficiaries with payments over \$10,000 represent 93% of the total dollars paid. *Id.* at p. 128. Dr. Yancey observes that TriCenturion’s sampling plan ignores this distinction by failing to analyze or discuss how multiple claims of a beneficiary may or may not be independent of other claims of that beneficiary. *Id.* According to Dr. Yancey, a key assumption of random sampling is that claims are independent of each other. *Id.* In the sample, Dr. Yancey found that the six claims for the two highest-frequency beneficiaries had an error rate of 53% whereas the error rate for beneficiaries with one or two sampled claims was at or near 100%, further demonstrating a

systematic difference between high and low-frequency beneficiaries and a need to stratify the population accordingly. *Id.* at pp. 128-29. Dr. Yancey provided similar testimony at the hearing. *Id.* at pp. 14908-16. Again, Dr. Dobbins's counter to this argument was that the "key issue" is the medical necessity of ambulance transportation per trip, and that the MSM sidesteps any variability among beneficiaries by always making a conservative projection of the overpayment amount. *Id.* at 14950-51. The Court finds that this testimony constitutes substantial evidence from which the MAC could conclude that TriCenturion's methodology based on random sampling rather than stratified sampling was not statistically invalid.

In a related argument, Transyd questions whether substantial evidence exists to support the Secretary's decision to recalculate the overpayment based on the ALJ's findings that only 12 of the 30 sample claims were not for a Medicare covered service. (Doc. 29). Transyd argues that any recalculation "will miss the mark so to speak by the same amount ([24%] precision rather than [10%]) because the same sample is being extrapolated." *Id.* However, as the Court explained *supra*, the MAC's implicit determination that the achieved precision did not invalidate the use of the MSM is supported by substantial evidence. Further, the Court found no testimony by either expert that a reduction in the number of non-payable sample claims would itself invalidate the use of the MSM. Finally, as the MAC observed, the MPIM provides that if the decision on appeal upholds the sampling methodology but reverses one or more individual claim determinations, the estimate of overpayment shall be recomputed and a revised projection of overpayment issued. Therefore, both substantial evidence and applicable Medicare guidelines support the Secretary's recalculation of the extrapolated overpayment.

B. Due Process Claims

After a party has “channeled” an action arising under the Medicare Act through the administrative process, a court reviewing an agency determination has the authority to resolve “any statutory or constitutional contention that the agency does not, or cannot, decide.” *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 23 (2000). Although the Secretary generally contends that Transyd did not properly “preserve” the issues raised through its due process claims, it fails to point to the source of the Secretary’s authority to consider these claims during Transyd’s administrative appeal. (Doc. 32). The Court recognizes that Transyd itself did not appeal the ALJ’s final decision to the MAC; yet, the MAC reviewed the ALJ’s decision on its own motion. Therefore, as the action has been “channeled” through all designated levels of appeal, it appears that the Court may now undertake review of Transyd’s due process claims.

Transyd acknowledges that the use of sampling and extrapolation in determining publicly funded overpayments to medical providers comports with due process, but as reflected by two of the issues identified in its Motion for Summary Judgment, argues that the Secretary deprived it of property without due process in the following respects: by failing to follow MPIM guidelines on what renders a sampling method statistically invalid, and by complying with MPIM § 3.10.9.2 and thus failing to give Transyd further opportunity to rebut the Secretary’s revised overpayment amount following the MAC’s decision. (Doc. 29). In essence, the first due process challenge reiterates the arguments advanced by Transyd in the context of its request for review of the MAC decision—that is, what Transyd actually challenges is the Secretary’s application of MPIM guidelines in light of the evidence presented, not its failure to follow the guidelines at all. *See* (Docs. 29, 36). Although Transyd disagrees with the Secretary’s findings, it has not been deprived of “notice and opportunity for hearing appropriate to the nature of the case,” the

hallmarks of due process. *Mullane v. Cent. Hanover Bank & Trust Co.*, 339 U.S. 306, 313 (1950). Rather, upon notification of the Secretary's initial overpayment determination, Transyd pressed its challenge to that determination through three designated levels of administrative review, achieving a significant reduction in the number of sample claims found to have been paid in error. Further, the ALJ twice remanded the case to the QIC in part for the purpose of ensuring that Transyd received all documentation upon which TriCenturion relied in arriving at its overpayment estimation. At the time the MAC rendered its decision, Transyd had received adequate notice of the bases for the Secretary's initial assessment and had been afforded a reasonable opportunity to be heard on its positions that the individual claim determinations were in error and that the sampling methodology used to project the total overpayment amount was invalid. That Transyd achieved only a partially favorable result, and that the Secretary did not apply MPIM guidelines in the manner urged by Transyd, does not show a deprivation of fundamental fairness. *See Mich. Dep't of Educ. V. U.S. Dep't of Educ.*, 875 F.2d 1196, 1206 (6th Cir. 1989) (where state challenging projected overpayment determination was given "every opportunity" to challenge each disallowance in sample as well as audit technique itself, and where consideration of state's objections resulted in reduction in total disallowance by over one-third, state had been treated "as fairly as is practicable under the circumstances"); *see also Ratanasen v. State of Cal., Dep't of Health Servs.*, 11 F.3d 1467, 1472-73 (9th Cir. 1993) (no violation of due process where appellant given reasonable opportunity to rebut initial, extrapolated overpayment determination); *Ill. Physicians Union v. Miller*, 675 F.2d 151, 156-57 (7th Cir. 1982) (same).

Transyd's second due process challenge takes issue not with the Secretary's alleged failure to follow the MPIM, but with its express compliance with MPIM § 3.10.9.2. (Doc. 29).

As reflected in the MAC's decision, that provision states that "[i]f the decision on appeal upholds the sampling methodology but reverses one or more of the revised initial claim determinations, the estimate of overpayment shall be recomputed and a revised projection of overpayment issued." Transyd takes the position that the Secretary's application of § 3.10.9.2 in this case is "doubly harmful" to Transyd, and a violation of due process, because the extrapolation methodology is in fact invalid and Transyd has no opportunity to challenge the recalculated overpayment on appeal. (Doc. 29). The Court finds this argument unpersuasive. Again, Transyd was afforded the protections of due process when it was given a reasonable opportunity to challenge the sampling method used to arrive at the initial, extrapolated overpayment. *See Ratanasen*, 11 F.3d at 1472-73; *Miller*, 675 F.2d at 156-57. Ultimately, upon consideration of the ALJ's revised findings on the individual claims, the MPIM, and the record evidence, the MAC did not invalidate that method. The Court has already concluded that substantial evidence supports the MAC's decision. Therefore, the Secretary did not deprive Transyd of due process by using the same sampling method to recalculate the extrapolated overpayment amount. Moreover, Transyd still has recourse to a reopening of the matter for the purpose of correcting any mathematical or computational mistakes. *See* 42 C.F.R. § 405.980. For all of these reasons, the Court must deny Transyd's request for summary judgment on its due process claims.

C. Request for Declaratory Judgment

The final issue raised by Transyd's Motion for Summary Judgment relates to its request for a declaratory judgment that the Secretary "may not prematurely recoup payments to reduce an alleged Medicare overpayment in opposition to 42 U.S.C. § 1395ddd(f)(2)." (Docs. 1, 29). That provision states in relevant part as follows:

(f) Recovery of overpayments

(2) Limitation on recoupment

(A) In general

In the case of a provider of services or supplier that is determined to have received an overpayment under this subchapter and that seeks a reconsideration by a qualified independent contractor on such determination under section 1395ff(b)(1) of this title, the Secretary may not take any action (or authorize any other person, including any medicare contractor, as defined in subparagraph (C)) to recoup the overpayment until the date the decision on the reconsideration has been rendered.

42 U.S.C. § 1395ddd(f)(2)(A). Transyd interprets this language as prohibiting the Secretary from *beginning* recoupment until the date a QIC reconsideration decision has been rendered, and argues the Secretary violated this prohibition both in Transyd's case and through promulgation of a regulation requiring the Secretary to *cease* recoupment upon receipt of a timely and valid request for reconsideration by the QIC until issuance of the QIC's decision. (Doc. 29); *see* 42 C.F.R. § 405.379(d), (e). At the time TrailBlazer recouped funds from Transyd in 2007, the Secretary operated under an interim rule that largely mirrors the current one. 71 Fed. Reg. 55,404, 55,414 (September 22, 2006) (to be codified at 42 C.F.R. § 405.379). As set forth *supra*, Transyd raised its opposition to the alleged premature recoupment before ALJ Opp, who concluded in part that he lacked authority to order a CMS contractor to release even unlawfully recouped funds. Therefore, it appears that the Court may consider Transyd's request for declaratory judgment under *Ill. Council, supra*.

As reflected in ALJ Opp's decision and the record, TrailBlazer issued its initial overpayment demand on January 29, 2007, in which it revealed that it had already recouped \$70,920.62 from Transyd to satisfy the total overpayment amount of \$2,015,903.57. On February 13, 2007, TrailBlazer received Transyd's request for a redetermination and upheld the overpayment assessment in a decision dated June 22, 2007. AR at p. 10851 n.3. On July 3,

2007, Transyd filed a request for reconsideration with the QIC but the QIC did not receive the request until August 2, 2007. AR at p. 10850 n.2. Between July 3, 2007 and July 26, 2007, TrailBlazer recouped an additional \$15,900.42 from Transyd. *Id.* at p. 10850. On September 19, 2007, the QIC issued a decision partially favorable to Transyd, in that it reduced the total overpayment amount to \$1,517,210.69. ALJ Opp concluded that TrailBlazer “did not adhere to [§ 1395ddd(f)(2)], regulations, or Medicare policies and procedures” in recouping funds prior to the issuance of the reconsideration decision by the QIC. *Id.* at p. 10851. The ALJ focused on TrailBlazer’s January 29, 2007 demand letter, in which it notified Transyd of “the right under 42 C.F.R. § 405.374 to submit a rebuttal statement within 15 days of the date of this letter, giving the reason(s) why you feel this action should not be taken. Within 15 days of receipt of your rebuttal statement...we will determine whether the facts justify termination or adjustment of this request.” *Id.* at pp. 10850-51. Transyd’s counsel, within 15 days, requested both a redetermination from TrailBlazer and a stay on all collection of the alleged overpayment, including recoupment, pending final decision on the appeal. *Id.* at p. 10851. Noting the language in § 1395ddd(f)(2) prohibiting recoupment until after the QIC decision has been rendered, the ALJ then concluded that TrailBlazer’s recoupment prior to that time was without authority. *Id.* Again, the ALJ also found that he had no authority to order the release of recouped funds, but in any event concluded that “a reconsideration decision has now been issued; therefore, the matter is moot.” *Id.* The ALJ thus denied Transyd’s motion for release of the funds held by TrailBlazer. *Id.*

The Court first notes that in this case, Transyd does not assert any violation by TrailBlazer of the language in its demand letter, or the regulation to which that letter referred, or the interim rule that would eventually become 42 C.F.R. § 405.379. Rather, Transyd challenges

TrailBlazer's recoupment, and the now-enacted § 405.379, as a violation of § 1395ddd(f)(2). (Doc. 29). When reviewing an agency's construction of a statute, courts apply the two-step analysis of *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984). *E.g.*, *Tex. Coal. Of Cities for Util. Issues v. Fed. Commc'ns Comm'n*, 324 F.3d 802, 806 (5th Cir. 2003). Under step one, where "Congress has directly spoken to the precise question at issue," the court must "give effect to the unambiguously expressed intent of Congress" and reverse an agency interpretation that does not conform to the plain meaning of the statute. *Id.* at 806-07 (quoting *Chevron*, 467 U.S. at 842-43). If the statute is silent or ambiguous as to the question at issue, the court proceeds to the second step to determine "whether the agency's answer is based upon a permissible construction of the statute." *Id.* at 807 (quoting *Chevron*, 467 U.S. at 843). Under this second step, the court can reverse the agency's decision only if it was "arbitrary, capricious, or manifestly contrary to the statute." *Id.* (quoting *Chevron*, 467 U.S. at 844). If the agency's construction of the statute is a reasonable one, the court must defer to the agency's interpretation. *Id.*

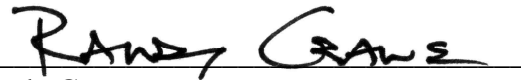
The Court first notes that TrailBlazer in fact ceased recoupment when the QIC received Transyd's request for reconsideration, which is what both the interim rule and § 405.379 require. Although Transyd takes the position that a contractor may not *begin* recoupment until a decision from the QIC, § 1395ddd(f)(2) only expressly prohibits the Secretary from taking any action to recoup any overpayment until the date the QIC decision has been rendered; it contains no language regarding when recoupment may first be initiated. The Court can comfortably assume that a provider will not, in every case, appeal an overpayment determination, under which circumstances Transyd's reading of the statute would leave open the question of when recoupment may begin. Thus, it stands to reason that before a contractor can be held to have

violated § 1395ddd(f)(2), it must receive notice that the provider is seeking redetermination from the QIC. The Court therefore finds that the Secretary's interpretation of the statute in Transyd's case, and through promulgation of § 405.379, was a reasonable one, and must give it the deference required.

IV. Conclusion

For the foregoing reasons, it is hereby **ORDERED** that the decision of the Medicare Appeals Council is **AFFIRMED** and Transyd's Motion for Summary Judgment (Doc. 29) is **DENIED**. It is further **ORDERED** that the Secretary shall submit, within 14 days of the date of this Order, a proposed final judgment in accordance with the Court's findings.

SO ORDERED this 27th day of March, 2012, at McAllen, Texas.

A handwritten signature in black ink that reads "Randy Crane". The signature is written in a cursive, slightly slanted style. Below the signature is a horizontal line.

Randy Crane
United States District Judge