DEPARTMENT OF HEALTH AND HUMAN SERVICES DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL

In the case of	Claim for
Transyd Enterprises, LLC	
d/b/a Transpro Medical	Supplementary Medical
Transport	Insurance Benefits (Part B)
(Appellant)	
***	****
(Beneficiaries)	(HIC Numbers)
TrailBlazer Health	
Enterprises, LLC	* * * *
(Contractor)	(AI _u I Appeal Number)

The Medicare Appeals Council has decided, on its own motion, to review the Administrative Law Judge's (ALJ's) decision dated April 21, 2009, because there is an error of law material to the outcome of the claim and because the decision is not supported by the preponderance of the evidence in the record. C.F.R. § 405.1110. The ALJ's decision concerned an overpayment assessed against the appellant based on a post-payment audit of claims for ambulance services furnished by the appellant to the beneficiaries on various dates of service from January 1, 2004 through June 20, 2006. TriCenturion, a Program Safeguard Contractor (PSC), audited a random sample of 30 of the appellant's claims and extrapolated the result of the audit to a universe of 9,982 claims. The ALJ found that the appellant had been overpaid with respect to 12 of the sampled claims, but had not been overpaid with respect to the remaining 18 claims in the sample. The ALJ further found that the sampling plan and methodology used by the PSC were unreliable and invalid. this reason, the ALJ declined to extrapolate the sample results to the universe of claims.

The Council has carefully considered the record that was before the ALJ, as well as the memorandum, with any attachments, from the Centers for Medicare & Medicaid Services (CMS) dated June 15, 2009. The CMS memorandum is hereby entered into the record in this case as Exhibit (Exh.) MAC-1. For the reasons explained

below, the Council concludes that the ALJ erred by invalidating the sampling methodology used by the PSC. Accordingly, we reverse the ALJ's decision as to this issue. CMS did not seek Council review of the ALJ's findings regarding Medicare coverage of the sampled claims at issue; therefore, we do not disturb the ALJ's findings on coverage. See Exh. MAC-1, at 6.

BACKGROUND AND PROCEDURAL HISTORY

The PSC first notified the appellant of an overpayment by letter dated January 2, 2007. ALJ Master Folder A, Exh. 1, at 99. The overpayment letter informed the appellant that the PSC had calculated an overpayment of \$2,015,903.57 by extrapolating its review of 30 sampled claims to a universe of 9,982 claims. *Id.* The Medicare carrier requested repayment of the overpayment by letter dated January 29, 2007. *Id.* at 94. The appellant requested redetermination and the carrier upheld the overpayment by letter dated June 22, 2007. *Id.* at 84. The appellant requested reconsideration and the Qualified Independent Contractor (QIC) apparently issued a partially favorable reconsideration dated September 19, 2007. The appellant filed a request to escalate the matter from the QIC to an ALJ on December 3, 2007.

The Office of Medicare Hearings and Appeals (OMHA) designated the appellant's escalation request as ALJ Appeal No. 1-224622919, and assigned it to an ALJ. By order dated February 27, 2008, the ALJ remanded the case to the QIC, with instructions to make "a new reconsideration determination, with a full explanation of the revised, extrapolated overpayment, and all supporting documentation." Id. at 18. The QIC issued a second reconsideration dated April 7, 2008. Id. at 2-9. The April 7, 2008, reconsideration reaffirmed that the PSC had correctly "followed all CMS directives to select the universe,

¹ The September 19, 2007, QIC reconsideration is not in the record before the Council. Both the appellant and the QIC, in subsequent documents, refer to the September 19, 2007, reconsideration as having been partially favorable. See Master File A, Exh. 1, at 3, 4, 52.

 $^{^2}$ The appellant apparently took the view that the September 19, 2007, reconsideration was not "final" because the QIC directed the contractor to calculate a revised extrapolated overpayment amount. See Master File A, Exh. 1, at 52.

³ The matter was initially assigned to a different ALJ than the ALJ who issued the decision presently under review.

sample, and to use statistical sampling to estimate the overpayment." *Id.* at 8.

The appellant requested an ALJ hearing with regard to the April 7, 2008, QIC reconsideration. In an Order dated August 26, 2008, the ALJ again remanded the case to the QIC with directions, among other things, to obtain all documentation upon which the PSC or the carrier relied in conducting the statistical sampling and calculating the extrapolated overpayment and to make that documentation available to the appellant. See ALJ Master Folder B, Exh. 1, at 55. By separate letters to the ALJ and to the appellant, both dated November 5, 2008, the QIC confirmed that it had obtained the required documentation and furnished it to the appellant. Id. at 47, 50. The QIC declined to issue a new reconsideration.

The ALJ held a hearing by telephone on March 18, 2009, which was re-convened on April 2, 2009. See Dec. at 3-4. The appellant was represented by counsel and presented the testimony of a statistical expert. Two CMS contractors, Q2 Administrators (the QIC) and Health Integrity, LLC⁴ participated in the hearing. The ALJ's decision recites additional procedural history, including his rulings on various motions of the appellant. Id. at 2-4. With the agreement of the appellant, the ALJ reviewed the issue of Medicare coverage of the sampled claims for ambulance services based on the documentary record. Id. at 3. Thus, the April 2 hearing was limited to expert testimony regarding the validity of the statistical sampling and overpayment extrapolation. Id.

The ALJ issued his decision on April 21, 2009. The ALJ found that the appellant had been overpaid with regard to 12 claims for ambulance services furnished to 10 beneficiaries, out of a sample of 30 claims furnished to 23 beneficiaries. *Id.* at 38. The ALJ further invalidated the overpayment extrapolation based on his conclusion that the PSC's sampling methodology was invalid. In this regard, the ALJ concluded:

⁴ Health Integrity, LLC, is the Zone 4 Program Integrity Contractor (ZPIC). Health Integrity assumed the work of the PSC effective February 1, 2009. See Exh. MAC-1, at 3.

⁵ It does not appear that the ALJ made his rulings (to the extent they were reduced to writing) a part of the record in this case. No ruling mentioned in the ALJ's Decision is found in the ALJ's Exhibit Lists.

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 CMS Program Integrity Manual § 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. at 39.

By a memorandum dated June 15, 2009, CMS referred this case for own-motion review by the Council. In its referral memorandum, CMS argues that the ALJ's conclusion that the statistical sampling and extrapolation were invalid is erroneous as a matter of law and is not supported by a preponderance of evidence in the record. Exh. MAC-1, at 8. We describe CMS's arguments in more detail in the Discussion section of this decision, below.

LEGAL AUTHORITY

CMS (formerly HCFA) Ruling 86-1 describes the agency's policy on the use of statistical sampling to project overpayments to Medicare providers and suppliers. The Ruling also outlines the history and authority, both statutory and precedential, for the use of statistical sampling and extrapolation by CMS in calculating overpayments. We incorporate that discussion by reference here. The Ruling provides, in part:

Sampling does not deprive a provider of its rights to challenge the sample, nor of its rights to procedural due process. Sampling only creates a presumption of validity as to the amount of an overpayment which may be used as the basis for recoupment. The burden then shifts to the provider to take the next step. The provider could attack the statistical validity of the sample, or it could challenge the correctness of the determination in specific cases identified by the sample (including waiver of liability where medical necessity or custodial care is at issue). In either case, the provider is given a full opportunity to

demonstrate that the overpayment determination is wrong. If certain individual cases within the sample are determined to be decided erroneously, the amount of overpayment projected to the universe of claims can be modified. If the statistical basis upon which the projection was based is successfully challenged, the overpayment determination can be corrected.

CMS Ruling 86-1-9 & 86-1-10.

CMS's sampling guidelines are found in chapter 3 of CMS's Medicare Program Integrity Manual (MPIM) (Pub. 100-08), section 3.10. The guidelines reflect the perspective that the time and expense of drawing and reviewing the claims from large sample sizes and finding point estimates which accurately reflect the estimated overpayment with relative precision may not be administratively or economically feasible for contractors performing audits. Instead, the guidelines allow for smaller sample sizes and less precise point estimates, but offset such lack of precision with direction to the carriers to assess the overpayment at the lower level of a confidence interval generally, the lower level of a ninety percent one-sided confidence interval. This results in the assumption, in statistical terms, that there is a ninety percent chance that the actual overpayment is higher than the overpayment which is being assessed, thus giving the benefit of the doubt resulting from any imprecision in the estimation of the overpayment to the appellant, not the agency. As a result of the above policy decision, the question becomes whether the sample size and design were sufficiently adequate to provide a meaningful measure of the overpayment, and whether the provider/supplier is treated fairly despite any imprecision in the estimation.

The MPIM provides guidance to contractors in conducting statistical sampling for use in estimating overpayment amounts. The instructions are intended to ensure that a statistically valid sample is drawn and that statistically valid methods are used to project overpayments where review of claims indicates that overpayments have been made. The MPIM describes the purpose of its guidance as follows:

These instructions are provided so that a sufficient process is followed when conducting statistical sampling to project overpayments. Failure by the PSC or the ZPIC BI unit or the contractor MR unit to follow one or more of the requirements contained

herein does not necessarily affect the validity of the statistical sampling that was conducted or the projection of the overpayment. An appeal challenging the validity of the sampling methodology must be predicated on the actual statistical validity of the sample as drawn and conducted. Failure by the PSC or ZPIC BI units or the contractor MR units to follow one or more requirements may result in review by CMS of their performance, but should not be construed as necessarily affecting the validity of the statistical sampling and/or the projection of the overpayment.

MPIM, Chap. 3, § 3.10.1.1 (emphasis added).

With regard to the qualifications of statisticians consulted or employed by contractors, the MPIM provides:

The sampling methodology used to project overpayments must be reviewed by a statistician, or by a person with equivalent expertise in probability sampling and estimation methods. This is done to ensure that a statistically valid sample is drawn and that statistically valid methods for projecting overpayments are followed. The PSC or ZPIC BI unit and the contractor MR unit shall obtain from the statistical expert a written approval of the methodology for the type of statistical sampling to be performed. If this sampling methodology is applied routinely and repeatedly, the original written approval is adequate for conducting subsequent reviews utilizing the same methodology. The PSC or ZPIC BI unit or the contractor MR unit shall have the statistical expert review the results of the sampling prior to releasing the overpayment demand letter. If questions or issues arise during the on-going review, the PSC or ZPIC BI unit or the contractor MR unit shall also involve the statistical expert.

At a minimum, the statistical expert (either on-staff or consultant) shall possess a master's degree in statistics or have equivalent experience. See section 3.10.10 for a list, not exhaustive, of texts that represent the minimum level of understanding that the statistical expert should have. If the PSC or ZPIC BI unit or the contractor MR unit does not have staff with sufficient statistical experience as outlined

here, it shall obtain such expert assistance prior to conducting statistical sampling.

MPIM, Chap. 3, § 3.10.1.5.

The MPIM further provides that a contractor may employ any sampling methodology that results in a "probability sample." The MPIM explains:

[The contractor] shall follow a procedure that results in a probability sample. For a procedure to be classified as probability sampling the following two features must apply:

- It must be possible, in principle, to enumerate a set of distinct samples that the procedure is capable of selecting if applied to the target universe. Although only one sample will be selected, each distinct sample of the set has a known probability of selection. It is not necessary to actually carry out the enumeration or calculate the probabilities, especially if the number of possible distinct samples is large possibly billions. It is merely meant that one could, in theory, write down the samples, the sampling units contained therein, and the probabilities if one had unlimited time; and
- Each sampling unit in each distinct possible sample must have a known probability of selection. For statistical sampling for overpayment estimation, one of the possible samples is selected by a random process according to which each sampling unit in the target population receives its appropriate chance of selection. The selection probabilities do not have to be equal but they should all be greater than zero. In fact, some designs bring gains in efficiency by not assigning equal probabilities to all of the distinct sampling units.

For a procedure that satisfies these bulleted properties it is possible to develop a mathematical theory for various methods of estimation based on probability sampling and to study the features of the estimation method (i.e., bias, precision, cost) although the details of the theory may be complex. If

a particular probability sample design is properly executed, i.e., defining the universe, the frame, the sampling units, using proper randomization, accurately measuring the variables of interest, and using the correct formulas for estimation, then assertions that the sample and its resulting estimates are "not statistically valid" cannot legitimately be made. In other words, a probability sample and its results are always "valid." Because of differences in the choice of a design, the level of available resources, and the method of estimation, however, some procedures lead to higher precision (smaller confidence intervals) than other methods. A feature of probability sampling is that the level of uncertainty can be incorporated into the estimate of overpayment as is discussed below.

MPIM, Chap. 3, § 3.10.2 (emphasis added). The MPIM recognizes that a number of sampling designs are acceptable, including: simple random sampling, systematic sampling, stratified sampling, and cluster sampling, or a combination of these. *Id.* at § 3.10.4.1.

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

The size of the sample (i.e., the number of sampling units) will have a direct bearing on the precision of the estimated overpayment, but it is not the only factor that influences precision. The standard error of the estimator also depends on (1) the underlying variation in the target population, (2) the particular sampling method that is employed (such as simple random, stratified, or cluster sampling), and (3) the particular form of the estimator that is used (e.g., simple expansion of the sample total by dividing by the selection rate, or more complicated methods such as ratio estimation). It is neither possible nor desirable to specify a minimum sample size that applies to all situations. A determination of sample size may take into account many things, including the method of sample selection, the estimator of overpayment, and prior knowledge (based on experience) of the variability of the possible overpayments that may be contained in the total population of sampling units.

In addition to the above considerations, real-world economic constraints shall be taken into account. stated earlier, sampling is used when it is not administratively feasible to review every sampling unit in the target population. In determining the sample size to be used, the PSC or ZPIC BI unit or the contractor MR unit shall also consider their available That does not mean, however, that the resources. resulting estimate of overpayment is not valid, so long as proper procedures for the execution of probability sampling have been followed. A challenge to the validity of the sample that is sometimes made is that the particular sample size is too small to yield meaningful results. Such a challenge is without merit as it fails to take into account all of the other factors that are involved in the sample design.

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

The MPIM further provides that:

If the decision on appeal upholds the sampling methodology but reverses one or more of the revised initial claim determinations, the estimate of overpayment shall be recomputed and a revised projection of overpayment issued.

MPIM, Chap. 3, § 3.10.9.2 (emphasis added).

DISCUSSION

The Council notes at the outset that we need not find that CMS or its contractor undertook statistical sampling and extrapolation based on the most precise methodology that might be devised in order to uphold an overpayment extrapolation based on that methodology. Rather, as the above-quoted authorities make clear, the test is simply whether the methodology is statistically valid. The ALJ found that the statistical sample was invalid because he concluded that the sample size of 30 claims was too small and that the PSC should have used a stratified sample. Dec. at 38-39. The ALJ further found the sampling methodology unreliable because the PSC did not establish that the statisticians who conducted the sampling and extrapolation had at least a master's degree in statistics or equivalent experience. *Id.* at 4, 39. In its referral memorandum, CMS argues that applicable guidance, including CMS

Ruling 86-1 and the MPIM, establishes that the reasons cited by the ALJ in support of his decision to invalidate the sampling methodology in this case do not, in fact, demonstrate that the methodology was invalid. See Exh. MAC-1, at 8. CMS further argues that the ALJ erred in placing the burden on the contractor to demonstrate that the sampling methodology was appropriate, rather than on the appellant to demonstrate that the methodology was invalid. Id. at 12. The Council finds CMS's arguments well-founded. We first address the burden of proof.

In finding the extrapolated overpayment invalid, the ALJ stated that the PSC failed to establish that its methodology was appropriate to the population of the appellant's claims, specifically because the PSC did not explain why it had not undertaken stratified sampling. Dec. at 38. CMS argues that the ALJ erred in this analysis by placing the burden of proof on the PSC to explain why it did not use a different sampling methodology. See Exh. MAC-1, at 8. We agree with CMS that this was error. As stated in CMS Ruling 86-1, the use of statistical sampling "creates a presumption of validity as to the amount of an overpayment which may be used as the basis for recoupment." The Ruling goes on to state that "the burden then shifts to the provider to take the next step." Thus, the provisions of CMS Ruling 86-1 establish that the burden is on the appellant to prove that the statistical sampling methodology was invalid, and not on the contractor to establish that it chose the most precise methodology. Therefore, the ALJ erred to the extent that he concluded that the PSC's sampling methodology and extrapolation were invalid based on the PSC's failure to explain why it did not select a larger sample size or undertake stratified sampling.

We next consider whether the evidence upon which the ALJ relied was sufficient to establish that the PSC's sampling methodology and overpayment extrapolation were invalid. In reaching this conclusion, the ALJ relied principally on the report and testimony of the appellant's expert, Will Yancey, Ph.D., CPA. See Dec. at 38. Based on Dr. Yancey's report and testimony, the ALJ concluded that the PSC should have undertaken a different sampling methodology that may have resulted in an extrapolation with greater precision than that attained using the minimum sum method and a sample size of 30 claims. Id. In his report, Dr.

 $^{^{\}rm 6}$ Dr. Yancey's curriculum vita (CV) is in the record as an attachment to ALJ Master Folder A, Exh. 5.

Yancey opined that it is "[q]enerally accepted statistical practice . . . to achieve a relative precision percentage within 10%." ALJ Master Folder A, Exh. 5, at page 3 of 9. He further opined: "If the achieved precision [percentage] is more than 10 percent, the sample results should not be extrapolated from the sample to the population in a Medicare overpayment demand." Id. Dr. Yancey opined that the PSC should not have extrapolated from the sample in this case because, by Dr. Yancey's calculation, the PSC's extrapolation of the overpayment achieved a precision percentage of 26.17%. Id. Dr. Yancey also criticized the choice of simple random sampling and the minimum sum method because, in his view, the method was chosen for contractor convenience, rather than statistical precision. Id. at pages 3-5 of 9. Finally, Dr. Yancey faulted the PSC's methodology because it failed to use a stratified sample. Id. at pages 5-7 of 9.

Even if we accept Dr. Yancey's criticisms, however, none is a basis for concluding that the sampling methodology employed here was invalid, under the applicable program guidance. As quoted above, the MPIM states explicitly 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. See MPIM, Chap. 3, §§ 3.10.2, 3.10.4.3. Therefore, even if the PSC chose the particular sampling methodology because, for example, it required less staff resources than a stratified sample, that would not be a basis to conclude that the methodology is invalid. Further, the MPIM recognizes and accepts that a smaller sample size may affect the precision of the estimated overpayment. Id. at § 3.10.4.3. The MPIM does not prescribe a particular sample size¹⁰ or precision. Similarly, the MPIM does

 $^{^7}$ Dr. Yancey defined the term "precision percentage" as the ratio of precision amount to point estimate. ALJ Master Folder A, Exh. 5, at page 2 of 9.

 $^{^8}$ Significantly, Dr. Yancey did not opine that the PSC's methodology was invalid. Rather, he concluded that the results of the sampling should not be extrapolated to the population. ALJ Master Folder A, Exh. 5, at page 8 of 9.

⁹ The Council notes that there is no evidence in the record regarding the PSC's reasons for selecting the sampling methodology it did. Moreover, as we stated above, it is not the PSC's burden to document why it chose one acceptable sampling methodology over another.

¹⁰ J. Gregory Dobbins, Ph.D., Chief Statistician for Health Integrity, who offered expert testimony in support of the PSC's methodology, confirmed that the MPIM does not require the use of a methodology resulting in a specific

not prescribe any particular sampling design, but notes that any sample design that results in a probability sample, including simple random sampling, systematic sampling, stratified sampling, or cluster sampling is acceptable. MPIM, Chap. 3, § 3.10.4.1. Thus, there is no support in Medicare's statistical sampling authorities for the ALJ's reliance on Dr. Yancey's conclusions that a sampling methodology that results in a relative precision percentage greater than 10%, or one that is based on simple random sampling, rather than a stratified sample, may not be used in calculating an extrapolated overpayment.

The ALJ also concluded that it was inappropriate to extrapolate from the sample to the universe because he had found only 12 claims out of the sample of 30 were overpaid. Dec. at 38. contends that this conclusion was error because it conflicts with quidance in the MPIM. The Council agrees. 3.10.9.2 of the MPIM instructs 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." As this provision makes clear, a finding that one or more claims identified in a sample were not overpaid has no bearing on the question of whether or not the sampling methodology was valid. Therefore, the fact that the ALJ found that only 12 of 30 sampled claims were overpaid is not a basis for invalidating the sampling methodology. As stated in the MPIM, the appropriate remedy is to recalculate the overpayment extrapolation based on the revised sample overpayment amount.

The ALJ also concluded that the PSC's sampling methodology was invalid because the PSC failed to document that its statisticians possessed at least a master's degree in statistics or equivalent experience, as the ALJ said was required by MPIM Chap. 3, § 3.10.1.5. Dec. at 38-39. The ALJ's conclusion is

precision percentage. April 2, 2009, Hearing CD 2, at 11:51. Dr. Dobbins' CV is in the record as ALJ Master Folder A, Exh. 6.

As noted above, it is CMS's policy to allow for smaller sample sizes and less precise point estimates, but to offset such lack of precision by directing the contractors to give the benefit of the doubt resulting from any imprecision in the estimation of the overpayment to the appellant, not the agency. This is done by assessing the overpayment at the lower level of a confidence interval – generally, the lower level of a ninety percent one-sided confidence interval. This results in the assumption, in statistical terms, that there is a ninety percent chance that the actual overpayment is higher than the overpayment which is being assessed.

erroneous for several reasons. First, as discussed above, CMS Ruling 86-1 establishes a presumption of regularity as to overpayments assessed via statistical sampling, and the burden of proof is on the appellant to demonstrate that the PSC's methodology is invalid. Thus, even if the credentials of the contractor's statisticians failed to comply with § 3.10.1.5 of the MPIM (a fact which the appellant did not establish, as discussed below) that would not necessarily prove that the contractor's sampling methodology was invalid. In this regard, the MPIM states: "Failure 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." MPIM, Chap. 3, § 3.10.1.1. Similarly, a contractor's failure to document that a qualified statistician had reviewed the sampling methodology would not necessarily prove that the methodology was invalid. 12

Moreover, the ALJ incorrectly asserted that there was no documentary evidence to substantiate the qualifications of the PSC's statisticians. As CMS points out, in addition to Dr. Dobbins' testimony, there are documents in the record indicating that the sampling and extrapolation in the appellant's case were prepared by Petko Kostadinov, M.S., and reviewed by Mary Alice Barth, M.I.S. See ALJ Master Folder A, Exh. 4 (CD file "Reopenings 1-2553896720006" at page 418). Further, the record indicates that the sample methodology was approved by Don Edwards, Ph.D. See ALJ Master Folder A, Exh. 3 (CD file, Sample Folder, Transyd Enterprises Technical Document). Thus, the ALJ's conclusion that the PSC failed to document that its statisticians had the requisite credentials is not supported by a preponderance of the evidence in the record.

For all the reasons enumerated above, we conclude that the ALJ erred in finding the PSC's sampling methodology and overpayment extrapolation invalid.

Section 3.10.4.4.1 of the MPIM requires contractors to keep "sufficient documentation . . . so that the sampling frame can be re-created, should the methodology be challenged." There is no allegation that the PSC failed to satisfy this standard. See ALJ Master Folder A, Exhs. 3 and 4.

As the ALJ acknowledged, Dr. Dobbins testified that he had verified that the PSC's statisticians had a master's degree in statistics. See Dec. at 4. The ALJ discounted Dr. Dobbins' testimony, however, because he found that it was based on extra-record evidence and was not substantiated by documents in the record. Id.

DECISION

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

MEDICARE APPEALS COUNCIL

/s/ Susan S. Yim Administrative Appeals Judge

/s/ M. Susan Wiley Administrative Appeals Judge

Date: September 15, 2009