

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

ORDER OF MEDICARE APPEALS COUNCIL
REMANDING CASE TO ADMINISTRATIVE LAW JUDGE

In the case of

John Shimko, DPM
d/b/a Lakeside Foot Clinic

(Appellant)

(Beneficiaries)

CIGNA Government Services

(Contractor)

Claim for

Supplementary Medical
Insurance Benefits (Part B)

(HIC Numbers)

(ALJ Appeal Number)

The Medicare Appeals Council has decided, on its own motion, to review the Administrative Law Judge's (ALJ's) decision dated May 28, 2009. The ALJ decision concerned a post-payment statistical sample of 60 claims, involving 58 medical records and 108 CPT line items billed for podiatry and evaluation and management (E&M) services furnished by the appellant to multiple beneficiaries from January 1, 2006, through November 30, 2007.¹ The ALJ reversed the overpayment finding of AdvanceMed, a Centers for Medicare & Medicaid Services (CMS) Program Safeguard Contractor (PSC), based upon a finding that the overpayment was not derived in accordance with Medicare law and CMS policy.

The Council will review a case on own motion review if, among other considerations, the ALJ decision contains an error of law material to the outcome of the decision. In deciding whether to accept own motion review, the Council limits its review of the ALJ's decision "to those exceptions raised by CMS." 42 C.F.R. § 405.1110(c)(1),(2).

The Council has considered the record that was before the ALJ, as well as the timely filed memorandum from CMS dated July 24, 2009, which is entered into the record as Exhibit (Exh.) MAC-1.

¹ For the list of beneficiaries at issue, the dates of service, and the beneficiaries' Health Insurance Claim (HIC) Numbers, see Appendix A.

The Council has also considered the appellant's response, bound in a binder dated August 12, 2009, which has been entered into record as Exh. MAC-2.

For the reasons set forth below, the Council finds that the ALJ decision contains an error of law material to the outcome of the claim. Therefore, the Council vacates the hearing decision and remands this case to an ALJ for further proceedings, including a new decision. See 42 C.F.R. § 405.1110(d).

BACKGROUND

The appellant provided podiatry services to multiple beneficiaries on various dates in 2006 and 2007, as listed in Appendix A to this remand order. The claims were submitted under the following HCPCS/CPT codes:

- 99307: subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least two of these three key components
 - A problem focused interval history
 - A problem focused examination
 - Straightforward medical decision making

Counseling and/or coordination of care with other providers or agencies are provided consistent with the nature of the problem(s) and the beneficiary's / family's needs. Usually the beneficiary is stable, recovering or improving.

- G0127: Trimming of dystrophic nails, any number
- 11056: Pairing or cutting of benign hyperkeratotic lesion (*i.e.* corn or callus); two to four lesions.

On August 20, 2008, the appellant received notice that Medicare had overpaid the appellant based on an audit of the appellant's claims billed for podiatry and E&M services provided between the dates of January 1, 2006, and November 30, 2007. Exh. 1 at 196. Specifically AdvanceMed, the Center for Medicare & Medicaid Services' (CMS) program safeguard contractor (PSC), selected a random sample of 60 claims, involving 58 medical records and 108 CPT line items, to represent a universe of 8,455 claims, and determined that 13% of the sample claims were not covered because they were not medically reasonable and necessary, resulting in an overpayment of \$319.02. Exh. 1 at 150, 197, see

also Exh. MAC-1 at 2. The PSC then extrapolated the sample results to the universe of claims, resulting in a total estimated overpayment of \$23,656.00 for the period at issue. *Id.*

The appellant requested redetermination of AdvanceMed's findings, and CIGNA Government Services (CIGNA) upheld the overpayment. Exh. 1 at 192. The appellant then appealed to the Qualified Independent Contractor (QIC), and the QIC subsequently issued an unfavorable decision concurring with CIGNA and AdvanceMed that all of the claims were not covered by Medicare. Exh. 1 at 149. Further, the QIC found that the record contained the prerequisite elements of statistical sampling required by Medicare. *Id.* at 158.

The appellant requested a hearing and the ALJ issued a decision on May 28, 2009, finding that "[a]lthough there was some proof that the statistical sampling methodology [employed by AdvanceMed] was invalid, Medicare contractors have not shown that the statistically derived overpayment estimation was conducted in accordance with the standards found in the Social Security Act [(the Act)] and in CMS Policy." Dec. at 1, 7.

In response to the ALJ's May 28, 2009, decision, CMS referred this matter to the Medicare Appeals Council. See Exh. MAC-1. CMS argued that

- 1) the ALJ erred in evaluating whether there was sufficient evidence of a sustained or high level of payment error,
- 2) the ALJ erred in the interpretation of the Program Integrity Manual (PIM) regarding statistical sampling requirements, and
- 3) the ALJ erred in that the ALJ shifted the burden to Medicare to prove that the statistical sample was valid.

Id. at 7-11.

In response, the appellant asserts that the ALJ's decision was supported by the evidence and was not erroneous. Specifically, the appellant argues that AdvanceMed failed to show the prerequisite sustained or high level of payment error or that documented education intervention has failed to correct the

payment error. Exh. 2 at 2. Further, the appellant contends that that statistical analysis undertaken to calculate the overpayment was erroneous and that the appellant's due process rights were violated because AdvanceMed's failure to provide timely documentation hindered the appellant's ability to challenge the validity of the statistical sample. *Id.* at 7.

DISCUSSION

CMS' Basis for Extrapolation by Statistical Sampling

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and Section 1893(f)(3) of the Act both require that before extrapolating an overpayment amount, "there must be a determination of sustained or high level of payment error, or documentation that educational intervention has failed to correct the payment error." See MPIM Ch. 3, § 3.10.1.2.

The ALJ found that

the undersigned feels constrained to reverse the statistical sampling on the grounds that the carrier had failed to determine that the appellant had a sustained or high level of payment error, or that although there was some evidence of educational intervention, it failed to correct the appellant's alleged payment errors, prior to engaging in this procedure.

Dec. at 6.

CMS states that the ALJ lacks authority to evaluate whether CMS met the burden identified in the Act and MPIM. In response, the appellant argues that

Here, there is no evidence of "educational efforts" by AdvanceMed. Further, there is no evidence that AdvanceMed made a finding of sustained or high level of payment error. As a result the extrapolated overpayment should be struck down.

Exh. MAC-2 at 2.

The Act states that "there shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of determinations by the Secretary of sustained or high levels

of payment errors." See Act, § 1893(f)(3). Thus, neither the ALJ nor the Council have jurisdiction to review the Secretary's decision to undertake statistical sampling in this instance. Accordingly, the Council finds that the ALJ erred as a matter of law in invalidating the statistical sample based on a finding of failure of the PSC to establish a sustained or high level of payment error.

Principles of Probability Sampling and Extrapolation

CMS Ruling 86-1 provides CMS's policy on the use of statistical sampling to project overpayments to Medicare providers and suppliers.² Exh. 3. CMS Ruling 86-1 also outlines the history and authority, both statutory and precedential, for the use of statistical sampling and extrapolation by CMS through its claims payment and program safeguard contractors in calculating overpayments.

The relevant criteria and principles for probability sampling are set forth in greater detail in the Medicare Program Integrity Manual (MPIM), Pub. 100-08, Ch. 3. The relevant criteria in section 3.10.2 provide as follows:

Regardless of the method of sample selection used, the PSC or ZPIC BI unit or the contractor MR unit 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

² By regulation, CMS Rulings are binding on ALJs and the Council. 42 C.F.R. §§ 401.108, 405.1063.

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 [indented] 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.

With respect to the sample size, section 3.10.4.3. provides:

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. 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 or ZPIC BI unit or the contractor MR unit 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.

Section 3.10.5.1 of the MPIM explains that variable precision in sampling design may be accounted for through the use of the lower limit of a one-sided ninety percent confidence interval, which is a conservative method that works to the financial advantage of the supplier, as follows:

In simple random or systematic sampling the total overpayment in the frame may be estimated by calculating the mean overpayment, net of underpayment, in the sample and multiplying it by the number of units in the frame. In this estimation procedure, which is unbiased, the amount of overpayment dollars in the sample is expanded to yield an overpayment figure for the universe. The method is equivalent to dividing the total sample overpayment by the selection rate. The resulting estimated total is called the point estimate of the overpayment, i.e., the difference between what was paid and what should have

been paid. In stratified sampling, an estimate is found for each stratum separately, and the weighted stratum estimates are added together to produce an overall point estimate.

In most situations the lower limit of a one-sided 90 percent confidence interval shall be used as the amount of overpayment to be demanded for recovery from the provider or supplier. The details of the calculation of this lower limit involve subtracting some multiple of the estimated standard error from the point estimate, thus yielding a lower figure. This procedure, which, through confidence interval estimation, incorporates the uncertainty inherent in the sample design, is a conservative method that works to the financial advantage of the provider or supplier. That is, it yields a demand amount for recovery that is very likely less than the true amount of overpayment, and it allows a reasonable recovery without requiring the tight precision that might be needed to support a demand for the point estimate. However, the PSC or ZPIC BI unit or the contractor MR unit is not precluded from demanding the point estimate where high precision has been achieved.

An appeal challenging the validity of the sampling methodology must be predicated on the actual statistical validity of the sample as drawn and conducted. MPIM, Ch. 3, § 3.10.1.1:

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 in successfully challenged, the overpayment determination can be corrected.

See also Ruling 86-1.

In the decision, the ALJ states

AdvanceMed was not present [at the hearing] to defend the statistical sampling, although there do appear to be flaws in the sampling methodology in this case to make the sampling invalid. The undersigned [ALJ] is barred from reviewing the determination.

Dec. at 6.

The Council disagrees and finds that the ALJ is not barred from making a ruling on whether the statistical sampling methodology was valid. Ruling 86-1 and the MPIM make clear that an appellant must be given an opportunity to challenge both the findings on the individual services reviewed in the sample and the sampling methodology and extrapolation. Thus, the Council finds that the ALJ erred in finding that he was "barred" from reviewing the QIC's reconsideration that the statistical sampling was valid.

For these reasons, the Council accordingly vacates the ALJ's decision and remands the case to an ALJ for further proceedings.

INSTRUCTIONS UPON REMAND

When the case was previously before the ALJ, the PSC waived, in writing, its opportunity to participate in the ALJ hearing. However, following the scheduled hearing, the PSC alleged that it was supposed to be included in the hearing, per a scheduler's change, but never received the phone call to participate in the hearing. Because the Council is remanding this case for another hearing, the PSC should again be notified of the hearing and afforded an opportunity to participate. Moreover, because of his holding on the PSC's foundation for statistical sampling, the ALJ did not reach the merits of the individual claims in his previous decision. Even in instances where a statistical sample is held invalid, the PSC is entitled to collect the actual overpayment found on the sampled claims, and the appellant has a right to challenge the individual findings with regard to each claim.

On remand:

- The ALJ shall schedule a supplemental *de novo* hearing, notifying all parties and the PSC of the scheduled hearing and offering them an opportunity to participate. In lieu of the hearing, the ALJ may obtain a written waiver of the right to appear pursuant to 42 C.F.R. § 405.1020(c)(1) from all parties. The ALJ shall incorporate into the record the full supplemental hearing.
- The ALJ shall give the appellant the opportunity to provide testimony challenging the statistical sample and extrapolation, and shall provide PSC an opportunity to respond. The ALJ shall also provide the parties an opportunity to address the coverage issues with regard to each sampled claim.
- The ALJ may secure the services of an independent medical expert familiar with HCPCS/CPT coding and Medicare coverage for E&M and podiatry services, as warranted, to fully address the merits of this case.
- The ALJ shall issue a new decision addressing whether the services furnished to each sampled beneficiary were medically reasonable and necessary, met other coverage criteria, and are thus covered by Medicare. In doing so, the ALJ shall consider the contractor's coverage policies in effect during the dates of service at issue. 42 C.F.R. § 405.1062. The ALJ should discuss the reasons for adopting or rejecting the opinions of the appellant's witnesses and shall provide a reasoned explanation of the weight afforded the testimony of the witnesses. The ALJ shall also issue a determination on whether the statistical sample was valid.
- After resolving the question of Medicare coverage, the ALJ will, if necessary, consider whether the overpayment, if any, may be limited or waived pursuant to section 1879 and/or section 1870(b) of the Act.

The ALJ may take further action not inconsistent with this order.

MEDICARE APPEALS COUNCIL

/s/ Gilde Morrisson
Administrative Appeals Judge

/s/ M. Susan Wiley
Administrative Appeals Judge

Date: October 15, 2009