CMS Referral for Own Motion Review by DAB/MAC

Appellant at ALJ Level
Dynamic Rehabilitation Services

Beneficiary (if not the Appellant) List attached

Multiple

Health Insurance Claim Number (HICN)*

Multiple

Provider, Practitioner OR Supplier
Dynamic Rehabilitation Services

Basis for referral

Any Case

CMS as a Participant

Pre-BIPA

- Error of law material to the outcome of the claim
- Broad policy or procedural issue of public interest
- Decision not supported by the preponderance of evidence
- Abuse of discretion
- Decision not supported by substantial evidence
- Abuse of discretion

Rationale for Referral:

A Medicare zone program integrity contractor (ZPIC) conducted a postpayment audit of a sample of the Appellant’s claims for medical and chiropractic services, resulting in an overpayment decision on the sampled claims as well as an extrapolated overpayment of $2,467,432. The Appellant appealed the denied claims on the basis that the services were medically necessary, reasonable, sufficiently documented and properly paid. The overpayment was upheld at the first level of appeal and partially affirmed at the second level of appeal.

On subsequent appeal, the Administrative Law Judge (ALJ) issued a partially favorable decision upholding denials for some of the claims in the sample and allowing payment for others. In a written report and during the hearing, the Appellant’s expert statistical witness, Bruce Kardon, Ph.D., discussed various alleged flaws in the sampling methodology and design. Exh 7 at 1-7. The ALJ relied heavily on the written report and the hearing testimony to determine that “AdvanceMed’s chosen sample in this case is clearly not an accurate representation of the frame from which it was selected, thus adversely impacting the projected overpayment calculation.” ALJ decision at 11. In particular, the ALJ determined the ZPIC excluded zero-paid claims from the frame and thus failed “to look for underpayments in addition to overpayment in order to offset any estimated amount due” as required by Medicare. ALJ decision at 11. The ALJ also cited Dr. Kardon’s assertions that the ZPIC’s sample size was inadequate and the ZPIC did not sufficiently analyze why it selected the stratification scheme it did.

The ALJ erred in setting aside the extrapolated overpayment for these reasons. The Appellant’s arguments regarding the sampling method employed by the Medicare contractor are wholly speculative. Pursuant to HCFA Ruling 86-1, the provider bears the burden of demonstrating that the sample is invalid. In this case, AdvanceMed’s sampling design and methodology fully conform to CMS guidelines for conducting
statistical sampling. The Appellant has not demonstrated that the sampling in this case is invalid or that the overpayment requested is inaccurate.

Background:
This referral involves an appeal of an overpayment determination issued by a Medicare ZPIC, AdvanceMed. The background of this case is set forth in detail in AdvanceMed’s position paper submitted during the ALJ hearing proceedings. Exhibit A at 274. Briefly, the Appellant, a physical rehabilitation facility, submitted claims for physical therapy and chiropractic services for dates of service January 1, 2006 through August 31, 2008. On January 14, 2009, the ZPIC notified the Appellant that it had selected a sample of claims for review and requested records from the provider. Id. at 261.

On February 26, 2010, AdvanceMed notified the Appellant of the overpayment based on a medical review of the sampled claims. The ZPIC indicated it had conducted the review after receiving allegations regarding billing practices. Id. at 274. The overpayment notice explained:

> On October 22, 2008, AdvanceMed opened an investigation after receiving allegations regarding your billing practices. Further investigation indicated that your office billed a high level of chiropractic services on the same dates of service as physical therapy services to the same beneficiary.

Id. The ZPIC detailed a series of errors based on CMS policy and local coverage determinations (LCD) and concluded that “due to the determination that a high level of payment error existed, AdvanceMed used extrapolation to determine the overpayment amount.” Id. at 278.

At all levels of appeal, the Appellant’s Counsel argued, generally, that the services were medically necessary, reasonable, sufficiently documented and properly paid. Exh A at 313 and 266. The Appellant furnished additional explanations and, in several cases, medical records. Exh A at 330-337, 339-373 and in three boxes, individual beneficiary file folders.

Cigna Government Services, the Medicare Part B carrier, upheld the overpayment determination. Exh A at 318. Subsequently, the QIC issued a favorable reconsideration on nine of the 50 beneficiaries and a partially favorable determination on four additional beneficiaries. In its August 25, 2010 PARTIALLY FAVORABLE decision letter, the QIC decided unfavorably for several reasons:

> • Documentation provided indicates that the beneficiaries with a chronic condition and failed to meet one or more of the above noted criteria for skilled physical therapy services.
> • The documentation submitted did not support the service billed. There was no indication a re-evaluation was completed.

---

1 The Master File contains Exhibits 7, 6, 5, 4, and 3 followed by Exhibit A.
• We did not find that you provided authoritative medical evidence from definitive randomized clinical trials or other definitive studies supporting coverage of the pulstar device as a physical performance tool. The file also contained no scientific evidence or research studies published in peer-reviewed medical journals, consensus statements from authorities in the field, evidence-based practice guidelines, professional society position statements, or other such evidence supporting the general acceptance of the pulstar device as a physical therapy tool by the relevant medical community. Therefore there was insufficient documentation to support the service as reasonable and necessary.

• Services described in this appeal are not manual manipulation of the spine. The device Pulstar was used for the adjustments and are therefore, not covered by Medicare.

• There was no indication on the documentation submitted that the service was rendered.

• Additional services provided by the chiropractor are not covered by Medicare.

Exh A at 171-173.

On September 13, 2010, The ZPIC issued notice of the revised overpayment amount. Following the issuance of the QIC’s partially favorable decision, the overpayment had been reduced to $932,617.00 Exh A at 88.

On October 20, 2010, Appellant’s Counsel requested an in person ALJ hearing. Exh A at 3. Counsel provided an overview of events leading up to the ALJ hearing request. He noted several contentions with the overpayment at issue, including:

1. The initial findings and the findings on the Redetermination were erroneous and inadequate. Further, the findings on the Reconsideration Decision were erroneous. We also believe that the process followed was inappropriate, fails to meet the regulatory requirements, and denies to the Provider due process of law.

2. The services were rendered to each patient.

3. The physical therapy services were appropriately authorized and approved by each patient’s medical physician.

4. The services for each patient were medically necessary, reasonable, sufficiently documented and properly billed.

5. AdvanceMed failed to give to the Provider adequate notice that this was, in fact, a full blown audit, to be performed using a pre-constructed “random” sample, which was based upon a complaint and prior investigation by AdvanceMed.

6. We believe AdvanceMed may be paid based upon their findings and recoupment of alleged overpayment. This creates an incentive to create a high error rate, designed to increase their compensation.

Exh A at 8.

With regards to the overpayment extrapolation, Counsel alleged:
1. The audit was improperly conducted and reported, and fails to meet the requirements of the Medicare Modernization Act Section 935 (42 U.S.C. 1395 ddd) in that inadequate explanation were provided.

2. The provider was not given the opportunity to provide additional information that would be taken into account prior to the issuance of the determination by AdvanceMed.

3. The use of statistical sampling with extrapolation was neither warranted nor authorized in this case, the extrapolation failing to meet the basic requirements of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Public Law 108-273 (Title 421 U.S. Code Section 1395ddd) and of the CMS Manual and the Medicare Program Integrity Manual.

4. The sample selected is not representative or statistically significant.

5. The statistical extrapolation method chosen and as applied in this case is contrary to statute, and violates the Provider’s right to due process of law as guaranteed by the Fourteenth Amendment to the United States Constitution.

Id. at 9-10.

On May 19, 2011, the ALJ held an in-person hearing, wherein he addressed the following issues:

1. Whether the sampling methodology used by AdvanceMed is sufficiently reliable so as to uphold the projected overpayment and whether the overpayment assessment was based upon a statistically valid sample and subsequent extrapolation.

2. Whether the services at issue are covered and payable by Medicare under Title XVIII of the Social Security Act.

3. If the undersigned finds that the services provided are excluded from Medicare coverage, a subsidiary issue is whether the liability of the Appellant may be waived pursuant to §1879 or §1870 of the Act.

The Appellant, his Counsel, and Bruce Kardon, Ph.D., statistical expert for the Appellant, were in attendance. On August 12, 2011, the ALJ issued a bifurcated partially favorable decision, first addressing the statistical sampling and extrapolation and next addressing medical necessity of the services in question and liability for any remaining overpayment. With regard to the statistical sampling and subsequent extrapolation, the ALJ found the statistical sample and extrapolation invalid, explaining:

Presumably, any type of sampling unit is permissible under Medicare rules “as long as the total aggregate of such units covers the population of mis-paid [sic] amounts.” However, AdvanceMed’s chosen sample in this case is clearly not an accurate representation of the gram from which it was selected, thus adversely impacting the projected overpayment calculation. Therefore, the present statistical sample is invariably flawed. Additionally, the MPIM requires ZPIC and PSC contractors to look for underpayments in addition to overpayment in order to offset any estimated amount due. This was not done as such claims were in fact excluded by AdvanceMed from the frame. Thus, it is the conclusion of the undersigned that due to the above-mentioned misrepresentation, the statistical sample and subsequent extrapolated estimated overpayment is invalid in toto.
With regard to the medical necessity of services in question, the ALJ determined that submitted documentation supported some of the services in question so favorable determinations were rendered for those services, but when documentation did not support coverage, the services remained denied. *Id.* at 11-13; see also individual determinations in Attachment A to the ALJ’s decision. For services that remained denied, the ALJ held the Appellant financially liable under § 1879 of the Act. Regarding waiver of recoupment under § 1870 of the Act, the ALJ noted that “Medicare may not recoup an overpayment amount when the provider of services or individual is ‘without fault.’” He summarily concluded that “Medicare recoupment is prohibited for payments made to the Appellant with respect to the medical services provided to beneficiaries during the dates of service prior to January 1, 2006.” *Id.* at 13.

**Applicable Law, Regulation, and Medicare Policy:**

*Statistical Sampling and Use of Extrapolation*

Section 1893(f)(3) of the Act establishes that contractors may only use extrapolation to determine overpayment amounts if the Secretary determines that either there is a sustained or high level of payment error or documented educational intervention has failed to correct the payment error. Section 1893(f)(3) also provides, “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 under this paragraph.” The Secretary has delegated to contractor benefit integrity units and medical review units the task of determining whether a sustained or high level of payment error exists. Medicare Program Integrity Manual (MPIM) (CMS Pub 100-08), § 8.4.1.4. (formerly 3.10.1.4). The MPIM states that a sustained or high level of payment error may be determined in several ways, including:

- error rate determinations by MR unit, ZPIC, ZPIC or other area
- probe samples
- data analysis

2 The ALJ erred in relying on time restrictions as a basis for waiving recoupment. Section 1870(b) creates a rebuttable presumption that a provider is without fault, absent evidence to the contrary, when the overpayment is discovered “subsequent to the third year following the year in which” payment was made. The Medicare Financial Management Manual states that a provider is not “without fault” if it billed for services it should have known were not covered. Chapter 3, § 80 and § 90.1(H). Regardless of when an overpayment is assessed, § 1870 requires an analysis as to whether a provider was without fault in causing the overpayment based on application of pertinent Medicare guidelines.

However, none of the services in this case predate January 1, 2006, so the ALJ’s decision regarding waiver under § 1870 is without effect.
• provider/supplier history
• information from law enforcement investigations
• allegations of wrongdoing by current or former employees of a provider or supplier
• audits or evaluations conducted by the OIG

*Id.*

HCFA Ruling 86-1 sets forth CMS’s policy regarding use of statistical sampling, including its authority and rationale for conducting sampling as well as certain rights and remedies afforded providers when sampling is used. Ruling 86-1 also maintains the providers right to challenge the sampling methodology, noting that the burden is on the provider to demonstrate that the sample is not statistically valid:

> Sampling does not deprive a provider of its right 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.

Chapter 8, § 8.4.1.1 (formerly Chapter 3, §§ 3.10-3.10.11.2) of the MPIM set forth CMS’ instructions to contractors regarding statistical sampling for overpayment estimation. According to the manual, the purpose of the instructions is “to ensure that a statistically valid sample is drawn and that statistically valid methods are used to project an overpayment where the results of the review indicate that overpayments have been made.”

Section 8.4.1.1 explains that the manual instructions provide a “sufficient process” for “conducting statistical sampling to project overpayments,” such that “an appeal challenging the validity of the sampling methodology must be predicated on the actual statistical validity of the sample as drawn and conducted.” While failure to follow one of more of the manual’s requirements may result in CMS’s review of a contractor’s performance, it “should not be construed as necessarily affecting the validity of the statistical sampling and/or the projection of the overpayment.”

Section 8.4.1.3 (formerly Section 3.10.1.3) outlines the major steps involved in statistical sampling:

1. Selecting the provider or supplier;
2. Selecting the period to be reviewed;
3. Defining the universe, the sampling unit, and the sampling frame;
4. Designing the sampling plan and selecting the sample;
5. Reviewing each of the sampling units and determining if there was an overpayment or an underpayment; and, as applicable,
Section 8.4.3.2.1 (formerly Section 3.10.3.2.1) instructs contractors on how to define the universe. For Part B claims:

*The universe shall consist of all fully and partially paid claims* submitted by the supplier for the period selected for review and for the sampling units to be reviewed. For example, if the review is of Physician X for the period January 1, 2002 through March 31, 2002, and laboratory and other diagnostic tests have been selected for review, *the universe would include all fully and partially paid claims* for laboratory and diagnostic tests billed by that physician for the selected time period. For some reviews, the period of review may best be defined in terms of the date(s) of service because changes in coverage policy may have occurred.

Emphasis added. Section 8.4.3.2.3 states, similarly, the "sampling frame" is the list of all possible sampling units in the universe. “The frame may be, for example, a list of all beneficiaries receiving items from a selected supplier, a list of all claims for which fully or partially favorable determinations have been issued, or a list of all the line items for specific items or services for which fully or partially favorable determinations have been issued.” Emphasis added. Sampling units may include, among other things, individual claims, individual claim lines, or clusters of claim (e.g., a beneficiary). *Id.* at § 8.4.3.2.2 (formerly § 3.10.3.2.2).

The total overpayment in the frame is estimated “by calculating the mean overpayment, net of underpayment, in the sample and multiplying it by the number of units in the frame.” *MPIM*, § 8.4.5.1 (formerly § 3.10.5.1). “Sampling units that are found to be underpayments, in whole or in part, are recorded as negative overpayments and shall also be used in calculating the estimated overpayment.” *MPIM*, § 8.4.5.2. (formerly § 3.10.5.2).

CMS sampling instructions provide a method for determining an overpayment amount that is not dependent on the size of the sample or the precision of the sampling methodology. While there were early efforts to develop statistically valid random samples upon which to base precise overpayment projections, CMS revised its procedures in 2001 to allow valid projections of overpayments without requiring the large sample sizes of the earlier methods. Transmittal B-01-01, January 8, 2001, “Use of Statistical Sampling for Overpayment Estimation When Performing Administrative Reviews of Part B Claims,” at *www.cms.hhs.gov/transmittals/downloads/B0101.pdf*. CMS recognized that smaller sample sizes and less precise point estimates would result in less precision and, therefore, instructed contractors to assess the overpayment at the lower limit of a one-sided 90 percent confidence interval. As CMS explained, “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.” *MPIM* § 8.4.5.1.

Where a sampling procedure results in a properly executed probability sample:
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.

MPIM, §8.4.2 (formerly § 3.10.2). While different sample designs and sizes may lead to a higher precision than others, a properly executed “probability sample and its results are always ‘valid.’” Id.

Section 8.4.4.1 and succeeding subsections discuss common sampling designs that Medicare contractors may use, including “simple random sampling, systematic sampling, stratified sampling, and cluster sampling, or a combination of these.” Stratified sampling is a design that “involves classifying the sampling units in the frame into nonoverlapping groups, or strata.” MPIM § 8.4.4.1.3 (formerly § 3.10.4.1.3). The objectives are “to define the strata in a way that will reduce the margin of error in the estimate below that which would be attained by other sampling methods, as well as to obtain an unbiased estimate or an estimate with an acceptable bias.” Id. The MPIM indicates that “the independent random samples from the strata need not have the same selection rates.” Id. Stratified sampling is discussed further in § 8.4.11.1 of the MPIM.

Section 8.4.4.3 (formerly § 3.10.4.3) discusses considerations specific to selecting the sample size:

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 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 8.4.4.4.1 (formerly § 3.10.4.4.1) of the MPIM sets forth documentation requirements for Medicare contractors regarding the sampling methodology and universe and frame used by the contractor. In particular, contractors must keep:

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

According to § 8.4.7.1. (formerly § 3.10.7.1) of the MPIM, when a contractor sends an overpayment demand letter to the provider, it must include “information about the review and statistical sampling methodology that was followed.” The explanation must include:

- a description of the universe, the frame, and the sample design;
- a definition of the sampling unit,
- the sample selection procedure followed, and the numbers and definitions of the strata and size of the sample, including allocations, if stratified;
- the time period under review;
- the sample results, including the overpayment estimation methodology and the calculated sampling error as estimated from the sample results; and
- the amount of the actual overpayment/underpayment from each of the claims reviewed.

Discussion:

This request for own motion review concerns the ALJ’s decision to invalidate the extrapolation. The ALJ found the “the statistical sample and subsequent extrapolated estimated overpayment is invalid in toto,” specifically because AdvanceMed excluded zero-paid claims from the frame and thus failed “to look for underpayments in addition to overpayment in order to offset any estimated amount due.” ALJ decision at 11. The ALJ also cited Dr. Kardon’s report and hearing testimony in which he asserted:

- “there was no clear analysis as to why the strata were defined [as less than $65 and greater than or equal to $65] or why 2 strata were utilized”; and
- The sample size was inadequate.

Id. at 10-11.

ALJ decision at 11.

The ALJ erred in determining that the sampling methodology was invalid because the ZPIC improperly excluded certain claims from the sampling frame. Section 3.10.3.2.1 of the MPIM provides that the sampling universe for Part B claims is to “consist of all fully and partially paid claims submitted by the supplier for the period selected for review and for the sampling units to be reviewed.” Consistent with the MPIM, AdvanceMed defined its sampling universe as non-Medicare secondary payer claims “with at least on line of service paid > 0 to provider” within the selected timeframe. Furthermore, the Appellant has not identified any underpaid claims that were excluded from the sampling frame. Allegations that the sampling frame excluded underpayments are wholly speculative.
To the extent the ALJ relied on assertion that the stratification scheme was insufficiently analyzed as a basis for finding the sample statistically invalid, his decision is in error. The MPIM states:

The stratification scheme should try to ensure that a sampling unit from a particular stratum is more likely to be similar in overpayment amount to others in its stratum than to sampling units in other strata. … A common situation is one in which the overpayment amount in a frame of claims is thought to be significantly correlated with the amount of the original payment to the provider or supplier. The frame may then be stratified into a number of distinct groups by the level of the original payment and separate simple random samples are drawn from each stratum.

Section 8.4.4.1.3 (formerly § 10.3.4.1.3) (emphasis added). AdvanceMed defined the strata according to level of original payment, in accordance with the MPIM.

HCFA Ruling 86-1 explains that sampling creates a presumption of the validity of the projected overpayment amount. From there, the provider has the burden of establishing that the sample is not statistically valid. “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, § 8.4.1.1 (formerly § 3.10.1.1). The contractor does not bear the burden of proving why it did not stratify differently. Furthermore, speculation that a different method of stratification might have produced more precise results does not demonstrate the invalidity “of the sample as drawn and conducted.”

To the extent the ALJ relied on documentation and testimony that the sample size was too small as a basis for finding the sample statistically invalid, his decision is in error. CMS program guidance provides a method for determining an overpayment amount that is not dependent on the size of the sample or the precision of the sampling methodology. While there were early efforts to develop statistically valid random samples upon which to base precise overpayment projections, CMS revised its procedures in 2001 to allow valid projections of overpayments without requiring the large sample sizes of the earlier methods. Transmittal B-01-01, January 8, 2001, "Use of Statistical Sampling for Overpayment Estimation When Performing Administrative Reviews of Part B Claims," at www.cms.hhs.gov/transmittals/downloads/B0101.pdf. CMS recognized that smaller sample sizes and less precise point estimates would result in less precision and, therefore, instructed contractors to assess the overpayment at the lower limit of a one-sided 90 percent confidence interval. As CMS explained, “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.” MPIM § 8.4.5.1 (formerly § 3.10.5.1).

Section 8.4.4.3 (formerly § 3.10.4.3) of the MPIM addresses considerations specific to selecting the sample size:

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 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. [Italics added.]

Prior to instructions in the PIM, both federal and administrative courts have held that arguments that the sample is too small do not render the sample invalid. See Chaves County Home Health Services, Inc. v. Sullivan, 931 F.2d 914 (D.C.Cir. 1991), cert. denied, 502 U.S. 1091 (1992), citing Illinois Physicians Union v. Miller, 675 F.2d 151, 155 (7th Cir.1982), “extrapolation based on review of a relatively small sample is a valid audit technique in cases arising under the Social Security Act”; see also In the Case of Samuel Nigro, M.D., Medicare Appeals Council, (April 30, 2001), http://www.hhs.gov/dab/macdecision/Nigro.html.