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LAWFLASH

CMS MAKES SIGNIFICANT CHANGES IN STATISTICAL SAMPLING METHODOLOGY FOR OVERPAYMENT ESTIMATION

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A new update to the Medicare Program Integrity Manual offers healthcare providers and suppliers more details on how Medicare contractors should perform statistical sampling and when extrapolation of overpayment determinations is permitted. The guidance also gives providers facing overpayment determinations that include extrapolations greater opportunities to determine the appropriateness of the Medicare contractor's methodology.

The Centers for Medicare & Medicaid Services (CMS) recently updated its guidance, effective January 2, 2019, to Medicare contractors, i.e., Medicare Administrative Contractors (MACs), Recovery Audit Contractors (RACs), Supplemental Medical Review Contractors (SMRCs), and Unified Program Integrity Contractors (UPICs). The Program Integrity Manual (PIM) provides clarifying details on performing statistical sampling and when extrapolating overpayment determinations is permitted, and provides accountability mechanisms for contractors' calculations throughout the overpayment identification and appeal process.

BACKGROUND

Medicare contractors frequently audit healthcare providers and suppliers (together, providers) to determine whether overpayments exist. While contractors may analyze only a small number of a provider's claims, historically they have often extrapolated the sample review results to a broader Medicare claim universe. In order to extrapolate an error rate, contractors must use a "statistically valid random sample," and then apply that error rate on a broader "universe" of claims using "statistically valid methods."

As noted in the CMS Change Request, the PIM previously provided little guidance to Medicare contractors on what standards to follow when extrapolating overpayment findings. Its guidance was limited to generally identifying the steps contractors should take: "(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, (6) Estimating the overpayment.”[1] The lack of specificity around sampling methodologies sometimes afforded providers the opportunity to successfully challenge extrapolations during administrative appeals of contractor overpayment determinations. This success, though more limited over time, was in part due to the lack of clarity from CMS as to what constituted an appropriate extrapolation methodology. This lack of clarity also led to frustration among many providers about the inconsistent application of extrapolation by Medicare contractors, when its use can have enormous negative financial consequences for the provider.

CHANGES TO THE PIM

The PIM now provides greater guidance regarding contractors’ extrapolation methodology, and provides accountability mechanisms for contractors’ calculations throughout the overpayment identification and appeal process. However, while the revised PIM aims for greater process transparency and clarifies many existing ambiguities, the PIM continues to state that “[f]ailure by the contractor to follow one or more of the requirements contained herein 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.” Accordingly, providers should be cognizant that, while this update does provide new evidence and arguments for appeals challenging poorly performed extrapolations, a Medicare contractor’s failure to comply strictly with these guidelines may not always yield a successful challenge to the extrapolation.

The following key updates have been made to the PIM.

Determining When a Statistical Sampling May Be Used. Under the new guidance, a contractor “shall use statistical sampling when it has been determined that a sustained or high level of payment error exists. The use of statistical sampling may be used after documented educational intervention has failed to correct the payment error.”[2] This guidance now creates a three-tier structure:

1. Extrapolation *shall* be used when a sustained or high level of payment error exists.
2. Extrapolation *may* be used after documented educational intervention (such as in the Targeted Probe and Educate (TPE) program).
3. It follows that extrapolation should *not* be used if there is not a sustained or high level of payment error or evidence that documented educational intervention has failed.

What is a “sustained or high level of payment error?” The PIM now specifies this can be when the sample review error rate is “greater than or equal to 50[%].”[3] This is a significant difference from error rates Medicare auditors have previously used to justify a high error rate and may provide some relief as to the punitive effects of extrapolation. However, the “50% or greater” test is not the only method CMS permits to determine a sustained or high level of payment error. The PIM also states that the contractor may look to the provider’s history of noncompliance for the same or similar billing issues, or a historical pattern of noncompliant billing practice.[4]

Defining the Universe, the Sampling Unit, and the Sampling Frame. The revised PIM puts a finer point on the identification of the claims universe. Specifically, “[t]he sampling frame is the listing of sample units, derived from the universe, from which the sample is selected.”[5] On occasion, “the universe may include items that are not utilized in the construction of the sample frame. This can happen for a number of reasons,

including, but not limited to: (1) Some claims/claim lines are discovered to have been subject to a prior review, (2) The definitions of the sample unit necessitate[] eliminating some claims/claim lines, or (3) Some claims/claim lines are attributed to sample units for which there was no payment.”[6] The revised PIM also requires the contractor to include a list of all sample units, all universe elements incorporated in the sample units, and the elements of the universe such that the sample units may be reassembled during the replication process. This additional information will help providers assess the accuracy of the audit results, and also provides an additional means to attack the validity of extrapolation.

Maintenance of Documentation of Universe and Sample Frame. To facilitate the replication process, the revised PIM requires contractors to “maintain all documentation pertinent to the calculation of an estimated overpayment including but not limited to the statistician-approved sampling methodology, universe, sample frame and formal worksheets.”[7] Although the stated purpose of the documentation is to assist administrative and judicial bodies in validating the audit results, this requirement may provide an additional inroad to providers challenging the validity of extrapolation if supporting documentation on the universe and sample frame is not produced.

Recovery from Provider. Under the revised PIM, a Medicare contractor must now seek additional approval from CMS to issue a finding letter when the extrapolated overpayment exceeds a certain threshold. A contractor must now obtain approval from CMS before “issuing a findings letter to the provider/supplier when the estimated overpayment exceeds \$500,000 or is an amount that is greater than 25% of the provider’s Medicare revenue received within the previous 12 months.”[8] In seeking approval, the contractor must provide CMS with a summary of its investigation, prior history, medical review results, and the extrapolated overpayment amount for CMS’s review. For providers without a history of noncompliance, this may provide another opportunity to avoid extrapolated overpayment determinations that they are not financially capable of repaying.

Changes Resulting from Appeals. Finally, if claims are reversed from the initial claim determination during the administrative appeals process, Medicare contractors are now required to “adjust the estimation of the overpayment with the revised input of the statistical expert who created the initial methodology or the revised input of another statistical expert supplied by the contractor should the creator of the initial methodology no longer be available.”[9] This update should prevent providers from continuing to be penalized for contractor mistakes that have been overturned earlier in the appeals process.

TAKEAWAYS

Providers facing overpayment determinations that include extrapolations are now provided with greater opportunities to confirm whether the Medicare contractor’s methodology was appropriate. From the revised PIM, it is unclear whether providers may gain access to the supporting documentation of the underlying audits as part of the redetermination or reconsideration process, but such information must be made available during administrative and judicial reviews. Providers should analyze determination letters from contractors describing the statistical sampling methodology to ensure compliance with the new PIM guidance.

This guidance should also provide some relief to providers, in that CMS appears to put the brakes on the unfettered discretion of Medicare contractors to determine when extrapolation will be used for a high or sustained error rate, and now contemplates that extrapolation may be used only when documented education has not led to improvement. High-volume providers should face lower risk of extrapolation if

their audited error rate is less than 50% and they do not have a history of noncompliance for the same or similar billing issues or a historical pattern of noncompliant billing practice. The PIM's requirement that very large overpayment determinations be approved by CMS should also reduce contractor abuse of discretion. However, it is not yet known how Medicare tribunals and CMS will enforce this new update, as CMS has created a broad exception for itself and its contractors that their failure to follow the guidance will not necessarily be viewed as affecting the validity of the extrapolation.

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[1] *See* PIM (Pub. 100-08), Chapter 8, § 8.4.1.3.

[2] *Id.* § 8.4.1.4.

[3] PIM (Pub. 100-08, Transmittal 828), Chapter 8, § 8.4.1.4.

[4] *Id.*

[5] *Id.* § 8.4.3.2.

[6] *Id.*

[7] *Id.* § 8.4.4.5.

[8] *Id.* § 8.4.7.1.

[9] *Id.* § 8.4.9.

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