UPCOMING CHANGES REGARDING THE USE OF STATISTICAL SAMPLING FOR OVERPAYMENT ESTIMATION

Date: 5 December 2018

Health Care Alert

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In a September 28, 2018 Change Request to Medicare's Program Integrity Manual ("PIM"), the Centers for Medicare & Medicaid Services ("CMS") updated its instructions to Medicare contractors regarding the use of statistical sampling and extrapolation in their review and estimation of overpayments. [1] CMS indicated that this update was designed to "ensure that a statistically representative sample of the claim universe is drawn that yields an unbiased estimation of an overpayment." [2] This Alert summarizes CMS's new approach to statistical sampling, key changes in that approach, and the potential impact for health care providers.

INTRODUCTION

Currently, when a Medicare contractor, such as Medicare Administrative Contractor ("MAC"), Recovery Audit Contractor ("RAC"), or Unified Program Integrity Contractor ("UPIC"), conducts an audit and determines an overpayment exists, the contractor may elect to extrapolate that overpayment to a broader sample of claims. In order to extrapolate an error rate from a smaller set of sampled claims, the contractor must first obtain a proper statistical sample and, thereafter, project the error rate to a broader "universe" of claims using "statistically valid methods." The PIM currently provides minimal guidance to contractors on what standards must be observed when extrapolating overpayment amounts. [3]

As such, when providers and suppliers appeal these often substantial, extrapolated overpayments, a strategy is to argue the propriety of each claim reviewed in the sample while also attacking the validity of the statistical sampling and extrapolation. However, because the PIM has little guidance regarding valid sampling and extrapolation methodologies, arguments regarding whether the contractor has failed to meet the PIM requirements rely primarily on expert review without clear standards set by CMS.

NOTABLE CHANGES

The changes, which take effect on January 2, 2019, articulate clearer guidance for contractors to consider when extrapolating an overpayment amount. Below is a brief summary of some of the major changes to take effect next year.

1. Steps for Conducting Statistical Sampling

Previously, the PIM only outlined the major steps in conducting statistical sampling — limiting its guidance within each step to:

> (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. [4]

The revisions break these steps out and provide additional direction for their application. Specifically, there is a new step that requires contractors to utilize appropriate sampling methodologies to accommodate "non-normal" distributions. [5] Additionally, the PIM now requires contractors to perform "appropriate assessment(s) to determine whether the sample size is appropriate for the statistical analyses used, and identify[], relative to the sample size used, the corresponding confidence interval." [6]

2. Determining When Statistical Sampling May Be Used

Currently, the PIM states, "[Contractors] shall use statistical sampling when it has been determined that a **sustained or high level of payment error** exists, or where documented educational intervention has failed to correct the payment error." [7] However, "sustained or high level of payment error" is not defined. This, again, presents roadblocks in arguing against the sufficiency of an extrapolation, particularly when the error rate is reduced based on favorable findings on specific claims reviewed at various stages of appeal.

The revisions specifically state, "For purposes of extrapolation, a sustained or high level of payment error shall be determined to exist through a variety of means, including, but not limited to:

- high error rate determinations by the contractor or other medical reviews (i.e., **greater than or equal to 50 percent** from a previous pre- or post-payment review)." [8]

This new error rate standard gives providers and suppliers a clear standard against which to measure their own error rate. If, after the first few stages of appeal, the error rate drops to below 50%, the provider or supplier can argue the audit should not be extrapolated because there is not a high level of payment error.

3. Defining the Universe, the Sampling Unit, and the Sampling Frame

In the past, suppliers have argued that some of the claims, or claim lines, included in the universe are improperly included for purposes of extrapolation. However, the current PIM provides little to no additional guidance regarding the inclusion or exclusion of claims when conducting the statistical analysis. [9] By contrast, the revised PIM specifically states:

> The universe includes all claim lines that meet the selection criteria. The sampling frame is the listing of sample units, derived from the universe, from which the sample is selected. However, in some cases, 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.
    a. Some claims/claim lines are discovered to have been subject to a prior review,
    b. The definitions of the sample unit necessitates eliminating some claims/claim lines, or
    c. Some claims/claim lines are attributed to sample units for which there was no payment. [10]

By providing detailed criteria by which contractors should exclude certain claims from the universe or sample frame, the revised PIM will also provide suppliers another means to argue against the validity of the extrapolation.

4. Maintenance of Documentation

The PIM currently states that the overpayment demand letter should include information about the review and statistical sampling methodology that was followed. In particular, the explanation of the sampling methodology 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 and the calculated sampling error as estimated form the sample results; and

The amount of the actual overpayment/underpayment from each of the claims reviewed. [11]

In this regard, Medicare contractors did not routinely provide the above-listed information. Instead, affirmative requests to these contractors for the additional information were often rejected or ignored by Medicare contractors. The revised PIM will add a section on the maintenance of documentation — a section that previously did not exist in the PIM — that will specifically require:

> The contractor shall 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. The documentation must be sufficient to allow for any future replication and/or validation by an administrative or judicial body. [12]

It is unclear if this change to the PIM will further encourage Medicare contractors to provide documentation they were already required to provide. Regardless, it will offer providers and suppliers with an additional argument against a statistical extrapolation if documentation is not maintained.

5. Recovery From Provider or Supplier

Under the revised PIM, a Medicare contractor must obtain additional approval from CMS before it can proceed with recovery on certain extrapolated overpayments. Currently, once an overpayment has been determined and extrapolated, the contractor is permitted to proceed with recoupment without any additional required approval. [13] However, the revised PIM will require the Medicare contractor to obtain approval from CMS if the extrapolated amount is large enough or accounts for a certain percentage of a provider or suppliers gross Medicare revenue. [14] In particular, the contractor "shall obtain approval from CMS prior to 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/supplier's Medicare revenue received within the previous 12 months." [15]

6. Changes Resulting From Appeals

As a challenge to an extrapolated overpayment determination works its way through the administrative appeals process, often a certain number of claims may be reversed from the initial claim determination. When this happens, the statistical extrapolation must be revised, and the extrapolated overpayment amount must be adjusted. [16] This requirement remains unchanged in the revised PIM; however, the Medicare contractors will now be required to consult with a statistical expert in reviewing the methodology and adjusting the extrapolated overpayment amount. [17]

CONCLUSION

The Change Request contains additional revisions to the PIM; but the above-discussed changes are among the most practical changes applicable to challenging the validity of the statistical extrapolations conducted by Medicare contractors. However, even considering all the above changes, it is important to note that 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." [18] Thus, it remains unclear exactly the effect these revisions to the PIM will have moving forward in contesting a contractor's extrapolation decisions.

In this regard, K&L Gates' health care practice group routinely advises providers and suppliers through the post-payment audit administrative appeals process. We recognize these appeals can be time consuming, costly, and place significant burden on providers and suppliers as they await resolution. K&L Gates works closely with clients to argue the propriety of claims on a claim-by-claim basis and with expert statisticians to argue the invalidity of any extrapolation — all with the goal of presenting appeals in as clear and concise a manner as possible in order to obtain the best possible result for clients.

NOTES:

[1] *See* PIM (Pub. 100-08, Transmittal 828), Chapter 8, §§ 8.4 *et seq*., https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R828PI.pdf.

[2] *See* PIM (Pub. 100-08, Transmittal 828), Summary of Changes, https://www.cms.gov/Regulations-and-

Guidance/Guidance/Transmittals/2018Downloads/R828PI.pdf.
[3] *See* PIM (Pub. 100-08), Chapter 8, §§ 8.4 *et seq*., https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c08.pdf.
[4] PIM (Pub. 100-08), Chapter 8, § 8.4.1.3.
[5] PIM (Pub. 100-08, Transmittal 828), Chapter 8, § 8.4.1.3(4).
[6] PIM (Pub. 100-08, Transmittal 828), Chapter 8, § 8.4.1.3(5).
[7] PIM (Pub. 100-08), Chapter 8, § 8.4.1.4 (emphasis added).
[8] PIM (Pub. 100-08, Transmittal 828), Chapter 8, § 8.4.1.4 (emphasis added).
[9] PIM (Pub. 100-08), Chapter 8, § 8.4.3.2.
[10] PIM (Pub. 100-08, Transmittal 828), Chapter 8, § 8.4.3.2.
[11] *See* PIM (Pub. 100-08), Chapter 4, § 4.8.2; *see also* PIM (Pub. 100-08), Chapter 8, § 8.4.4.4.1 (requiring information to accurately recreate the study).
[12] PIM (Pub. 100-08, Transmittal 828), Chapter 8, § 8.4.4.5.
[13] PIM (Pub. 100-08), Chapter 8, § 8.4.7.1.
[14] PIM (Pub. 100-08, Transmittal 828), Chapter 8, § 8.4.7.1.
[15] *Id.*
[16] PIM (Pub. 100-08), Chapter 8, § 8.4.9.
[17] PIM (Pub. 100-08, Transmittal 828), Chapter 8, § 8.4.9.
[18] PIM (Pub. 100-08, Transmittal 828), Chapter 8, § 8.4.1.1.; *see also* PIM (Pub. 100-08), Chapter 8, § 8.4.1.1 (containing former, but similar, language).

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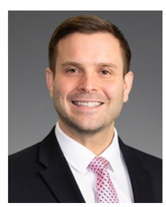

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