

Compliance Today - January 2020 Recent developments affecting strategies for challenging extrapolated contractor overpayments

By Stephanie F. Johnson, JD and Lauren S. Gennett, JD, MPH, CHC

Stephanie F. Johnson (<u>sfjohnson@kslaw.com</u>) is a Partner and <u>Lauren S. Gennett</u> (<u>lgennett@kslaw.com</u>) is a Senior Associate in the Atlanta offices of King & Spalding.

Healthcare providers and suppliers are subject to audits and reviews by numerous Medicare and Medicaid contractors, each with unique authority and audit scope. These myriad contractors include Recovery Audit Contractors (RACs), Quality Improvement Organizations (QIOs), Medicare Administrative Contractors (MACs), Supplemental Medicare Review Contractors (SMRCs), and Unified Program Integrity Contractors (UPICs).

In many cases, contractor audits are routine. However, in some instances, seemingly routine audits can be transformed into reviews with substantial financial implications. This is because certain contractors are authorized to review a statistically valid sample that can be extrapolated to a larger universe of claims in certain instances.

When employing statistical sampling and extrapolation, the contractor generally establishes a universe of claims at issue and then pursues statistical sampling to identify a sample of claims for review. The sample of claims is reviewed and an error rate is established. The error rate is then extrapolated, or applied, to the larger universe of claims. As such, the results of an actual review of a modest number of claims can be applied to a very large number of claims and materially increase the alleged overpayment.

Once a contractor has issued its findings, frequently the only recourse for the provider is to appeal the alleged overpayment. Appeals of extrapolated Medicare overpayments generally require providers and suppliers to navigate the backlogged Medicare appeals system. Historically, providers and suppliers have encountered challenges when appealing extrapolated overpayments, due in large part to the perceived broad authority provided by the Centers for Medicare & Medicaid Services (CMS) to contractors for sampling and extrapolation. However, CMS revised its *Medicare Program Integrity Manual* (MPIM) provisions on sampling and extrapolation, effective January 2019. CMS explains that the purpose of the MPIM update is to "help ensure that a statistically representative sample of the claim universe is drawn that yields an unbiased estimate of an overpayment." [1] Although this article does not endeavor to address all sampling and extrapolation requirements, it will address key new MPIM requirements and discuss strategies that providers and suppliers may wish to implement in their appeals of extrapolated overpayments.

Summary of updates to CMS guidance

As noted above, certain government contractors are permitted to employ statistical sampling and extrapolation during their audits of healthcare providers and suppliers. Not all government contractors have the authority to extrapolate, but those that do are required to follow CMS guidance. Historically, CMS provided general guidance regarding sampling and extrapolation, focusing primarily on the steps that contractors should take when conducting their reviews. The MPIM now provides additional detail regarding several aspects of the sampling and extrapolation process, applicable to certain contractors (i.e., UPICs, RACs, SMRCs, and MACs), that may be

useful for providers and suppliers to consider when challenging extrapolated reviews.

When sampling and extrapolation is permitted

Contractor extrapolation is permitted when there is a sustained or high level of payment error or when educational intervention has failed to correct payment errors. [2] Historically, CMS did not provide detailed guidance regarding what constitutes a sustained or high level of payment error. Accordingly, contractors were left with discretion to determine when extrapolation was appropriate. With the absence of specific authority from CMS concerning what constitutes a high error rate, some appeal adjudicators may have been reluctant to overturn a contractor's determination of a sustained or high level of payment error, even when that error rate was reduced through the appeals process.

First, the revised MPIM guidance states that statistical sampling may be used after documented educational intervention has failed to correct the payment error. This guidance is significant, because it suggests that sampling may only be permissible if documented education has not led to improvement.

Second, the new guidance provides examples of when a contractor can determine a sustained or high level of payment error, including "high error rate determinations by the contractor or by other medical reviews (i.e., greater than or equal to 50 percent from a previous pre- or post-payment review)." A 50% or greater error rate is higher than error rates that some contractors have used in the past to support extrapolation, so this new guidance may offer relief to certain providers and suppliers. However, this guidance is framed as an example, so it is possible that contractors could still pursue extrapolation with an error rate of less than 50%. Further, the MPIM provides alternative avenues for a contractor to determine a sustained or high level of error, including a prior history of noncompliance, information from law enforcement investigations, and audits conducted by the Office of Inspector General (OIG).

Statistical expert

The revised MPIM provisions also offer additional detail regarding the requirement that a statistician (either employed by the contractor or a consultant) review the sampling methodology and overpayment estimation determined by the contractor. The contractor must obtain a statistical expert review in every instance of sampling and extrapolation, and the statistician must provide written approval of the methodology. The MPIM also provides new guidance regarding the minimum qualifications of the statistician reviewing the contractor's work. As such, during appeals, providers and suppliers may wish to probe the contractor statistician's involvement in the process and their qualifications to ensure that they are appropriate.

Determination of the review universe and sample

The revised guidance also offers additional detail regarding contractor determination of the review universe. Importantly, the MPIM now states that for certain contractors, RACs and SMRCs, CMS must approve the time period of the review. The MPIM also provides new technical details regarding the claims in the review universe.

Notably, the MPIM now includes language requiring that the contractor's case file must include all documentation pertinent to the calculation of an estimated overpayment, including, but not limited to:

- the statistician-approved sampling methodology;
- the universe from which the sample was taken;

- the sample frame, including a list of all sample units in the sample frame, all the universe elements that are incorporated into those sample units, and the elements in the universe; [6] and
- the formal worksheets.

The documentation must be sufficient to allow for any future replication and/or validation by an administrative or judicial body. [7]

Findings and recovery

Once a contractor determines an alleged overpayment, the contractor generally issues a findings letter to the provider or supplier, and the MAC pursues recovery of the overpayment amount. The MPIM now states that the contractor shall obtain approval from CMS prior to issuing a findings letter 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 this approval, the contractor is required to provide CMS with a summary of its investigation, prior history, medical review results, and the extrapolated overpayment amount. It is not clear if or when CMS will deny such approval, but it is possible that CMS could elect to deny certain extrapolation requests.

Further, the new MPIM guidance states that the final review results letter sent to the provider by the reviewing contractor must include information about the review and statistical sampling methodology used for estimation. Similarly, CMS now requires that MACs must include information in the overpayment demand letter about the review and statistical sampling methodology that was followed. Previously, contractors that have pursued sampling and extrapolation have offered varying levels of detail regarding the sampling methodology in such correspondence. The new MPIM guidance does not clarify the level of detail that the contractor must use when describing the review and sampling methodology, so it is not clear how much this new requirement will affect providers and suppliers. Nevertheless, to the extent that a final review results letter or overpayment demand letter is issued without this information, providers and suppliers would have additional support to request the information.

Limitations on revised guidance

Although CMS's changes to the MPIM provisions on extrapolation offer guidance that may be helpful to providers and suppliers challenging extrapolated overpayments, CMS states that failure by contractor to follow one or more of the MPIM requirements "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 and must demonstrate actual error in the methodology that affects the overpayment amount." [10]

As such, a contractor's failure to meet the revised MPIM requirements may not be sufficient to invalidate sampling and extrapolation. As the MPIM changes are relatively new, it is not yet clear how adjudicators in the Medicare appeals process will assess the effect of a contractor's potential failure to meet the MPIM requirements.

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