

## **Challenges to Statistical Extrapolation in the Evolving Audit Landscape**

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The RAC Statement of Work authorizes the RACs to extrapolate or project audit findings to a provider's universe of claims, so long as the RAC complies with the limitations set forth in Section 935 of the Medicare Modernization Act (MMA) and Section 3.10 of the Medicare Program Integrity Manual. A successful challenge to the use of extrapolation can significantly reduce the overpayment demand from the projected amount to the "actual" amount. In the past, the use of statistical sampling and extrapolation has been successfully challenged to the extent that the contractor did not properly follow the guidelines set forth in the Medicare Program Integrity Manual. A statistical expert has always been essential to this type of defense. While contractors are expected to follow the Medicare guidelines, a recent Medicare Appeals Council (MAC) decision suggests that the MAC (and potentially other appellate decision makers) may not be as receptive to expert criticism of the methodology employed by the contractor for purposes of invalidating statistical extrapolation.

The use of statistical extrapolation in audits is subject to statutory limitations. Section 935 of the MMA limits the use of extrapolation to situations in which "the Secretary determines that there is a sustained or high level of payment error" or in which the Secretary determines that "documented educational intervention has failed to correct the payment error." Although the Secretary's determination regarding a "sustained or high level of payment error" cannot be challenged on appeal, the issue of whether such a determination was made by the Secretary is appealable. In the case of

*Cabarrus Podiatry Clinic*, issued December 14, 2007, the MAC declined to review the Administrative Law Judge's (ALJ) decision regarding the use of statistical sampling where neither CMS nor the Medicare contractor made the requisite determination that there was a sustained or high level of payment error or that documented educational intervention failed to correct the payment error. In *Cabarrus*, CMS attempted to point to an internal memorandum from Thad Perry, Ph.D. to a representative at the Program Safeguard Contractor (PSC) in order to satisfy the determination required under section 1893(f)(3). However, the MAC found that the memorandum failed to state any of the requisite conclusions and declined further review.

Yet the ability to successfully mount a statistical challenge may be growing more difficult in the evolving audit landscape. In deciding whether to appeal the contractor's use of statistical sampling based on a failure to follow Medicare guidelines, providers and suppliers should be aware of a recent MAC case, *Transyd Enterprises, LLC d/b/a Transpro Medical Transport*. In *Transyd*, issued September 15, 2009, the MAC critically evaluated and ultimately reversed a successful challenge to the statistical projection. The MAC decided, on its own motion, to review the ALJ's decision that the sampling plan and methodology used by the PSC were unreliable and invalid. Specifically, the ALJ found that the record failed to demonstrate that the PSC's statistician possessed a master's degree in statistics or equivalent experience, as required by the Program Integrity Manual. The ALJ also concluded that the use of an unstratified population, a "small and arbitrary sample size of 30," and the Minimum Sum Method to compute the lower bound 90 percent confidence interval were generally unexplained and insufficiently documented, thereby warranting a finding that the sampling plan and

methodology were unreliable and invalid. The MAC found the ALJ's decision erroneous as a matter of law. In reaching this conclusion, the MAC emphasized a provision of the Program Integrity Manual which states that failure by the PSC or Zone Program Integrity Contractor (ZPIC) Benefit Integrity units or the contractor Medical Review units to follow one or more Program Integrity Manual requirements may result in review of their performance by CMS, but should not be construed as necessarily affecting the validity of the sampling or projection. According to the MAC, the test was not whether the PSC used the most precise methodology for statistical extrapolation – it was simply whether the methodology was statistically valid.

In reversing the ALJ's decision, the MAC noted that the ALJ erroneously placed the burden on the PSC to explain why it did not select a larger sample size or utilize stratified sampling. In contrast, the MAC determined that statistical sampling creates a presumption of validity as to the amount of the overpayment; the burden is then on the provider to demonstrate that the sampling methodology was invalid.

The MAC found that the challenges to the sampling methodology and overpayment extrapolation by the provider's statistical expert did not provide a basis for concluding that the sampling method employed was invalid. Further, the PSC's failure to *document* that a qualified statistician reviewed the methodology did not necessarily invalidate the methodology in light of the language of the Program Integrity Manual. The MAC concluded that the provider failed to prove that the statistical sampling and overpayment extrapolation methodology was invalid and reversed the findings of the ALJ.

While the *Cabarrus* decision suggests that Medicare contractors will be expected to strictly adhere to statutory requirements in order to use extrapolation, the MAC's recent decision in *Transyd* may be a "warning shot" to providers that some MACs may also take a more deferential approach to contractor compliance with Manual guidelines.