



February 2016

### 3 Takeaways from the Recent Ruling on Statistical Extrapolations in CMS Audits

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**O**n Jan. 20, 2016, a federal district court in the Western District of Texas affirmed a decision of the Medical Appeals Council (Appeals Council) affirming a CMS contractor's extrapolation methodology used to assess an overpayment of more than \$773,000 from a home health provider, Maxmed. Three key takeaways from the Court's decision that may help health care providers avoid a similar situation include:

1. Providers should be keenly aware of the rules limiting CMS's participation as a party to an appeal when devising their appeal strategies, and its subsequent ability to appeal the ALJ decision on its own. Similarly, they should be aware of the Medicare Appeals Council's ability to review any ALJ decision or dismissal on its own motion, or with referral from CMS.
2. When disputing a statistical sample and/or extrapolation, submit an expert's opinion as soon in the appeals process as practicable, preferably at the redetermination stage. When a statistical extrapolation is disputed, the Qualified Independent Contractor relies on its own statistical expert (often times an outside accounting firm). If you can overturn the extrapolation in the first two levels of appeal, and you don't seek ALJ review, CMS cannot overturn the determination.
3. CMS's rules for statistical extrapolation balance its competing interests in reaching an accurate estimate of the overpayment: limited resources vs. accuracy. CMS admits in its manuals that it does not require the most accurate estimate, and will compromise on reaching the most accurate estimate by accepting a lower bound estimation. Therefore, CMS will trade a more imprecise statistical



extrapolation for a lower overpayment estimate. Knowing this can help you and your statistical expert craft a more effective argument to try and get the statistical sampling thrown out.

## Background

The case arose out of a post-pay investigation by the Zone Program Integrity Contractor (ZPIC) Health Integrity, which denied 39 of 40 sampled Maxmed claims in a post-payment audit. Health Integrity then used a statistical extrapolation to calculate an estimated overpayment of \$773,967.00.

## Appeals

After the Medicare Administrative Contractor Palmetto GBA and Qualified Independent Contractor confirmed Health Integrity's findings, Maxmed appealed to an Administrative Law Judge (ALJ). The ALJ found one denied claim in favor of Maxmed, and also concluded that Health Integrity's extrapolation methodology was not valid because it did not conform to the Medicare Program Integrity Manual (MPIM). The ALJ also directed Health Integrity to correct the statistical sampling. The ALJ found a number of reasons why the statistical sampling methodology was deficient, including: "(1) a failure to keep a record of the random numbers used in the sample as required; (2) failure to properly define sampling units; (3) failure to demonstrate sampling units' independence; and (4) failure to demonstrate average overpayment was normally distributed." The ALJ was also persuaded by Maxmed's expert statistician, who relied on leading reference materials for the standards for precision sampling.

Maxmed then appealed the ALJ's decisions regarding the medical necessity to the Medicare Appeals Council, but did not raise the ALJ's decision on the statistical extrapolation as an issue; instead, CMS's AdQIC, on its own and over the objection of Maxmed, referred the ALJ's findings regarding the statistical methodologies for review by the Appeals Council as well. The Appeals Council reversed the ALJ's decision in part, finding that the statistical sampling and overpayment

extrapolation were valid according to CMS guidelines, and that the ALJ relied too much on Maxmed's expert who argued from statistical treatises to which CMS is not bound.

## Parties' Arguments

In the appeal, Maxmed argued that Health Integrity's sampling and extrapolation methodology was invalid because Health Integrity failed to record the random numbers it relied upon in forming the sample, its choice of sampling units based upon clusters of claim-lines resulted in a skewed distribution, and its precision level of 8 percent resulted in an unacceptably imprecise extrapolation. In response, the Department of Health and Human Services (HHS) maintained that the sampling methodology was valid, that it was not required to attain a level of statistical accuracy required in academic treatises, and that Maxmed failed to overcome CMS's presumption of statistical validity.

## Court's Decision

The court agreed with the Appeals Council, and granted summary judgment to HHS, finding that, "substantial evidence supported the Appeals Council's overall determination that the ALJ erred by invalidating the statistical sampling and overpayment extrapolation." Some factors the court found in support of the Appeals Council's determination:

1. **Probe Sample:** The MPIM does not require a probe sample before undertaking statistical sampling for overpayment estimation.
2. **Random Numbers:** Health Integrity's failure to include a list of the actual random numbers used in the sample did not render the sample invalid





because it included in its report the seed numbers and algorithm used to generate the actual random numbers, and Maxmed did not allege that it was unable to replicate Health Integrity's results.

- 3. Dependent Sampling Units:** Health Integrity's use of aggregated claim lines for a claim did not endanger the independence of the sampling units. According to the court, Health Integrity was not required to "distinguish that the probability of denying one sampling unit is independent of another sampling unit."
- 4. Precision:** The ALJ relied on an improper precision standard regarding statistical sampling, which was inapplicable to CMS's requirements when conducting medical review of claims; and, furthermore, that the MPIM does not require any specific level of precision. The court stated, "the MPIM provides that it is acceptable for a contractor to recover an amount 'that is very likely less than the true amount of

overpayment' and 'allows a reasonable recovery without requiring the tight precision that might be needed to support a demand for a point estimate.'"

- 5. Normal Distribution:** The ALJ improperly relied on Maxmed's expert's opinion that the sample as drawn was invalid because the average overpayments in the sample are not normally distributed resulting in the demand for overpayment likely being less than the actual overpayment. In reaching this conclusion, the ALJ applied a higher academic standard than is required of CMS, and that the MPIM states that it is acceptable for a contractor to recover an amount that is "very likely less than the true amount of overpayment."

The case is: *MaxMed Healthcare, Inc. v. Burwell*, 2016 BL 15612, W.D. Tex., No. 5:14-cv-00988-DAE, 1/20/16.



## For More Information

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Recognized as a leader in health care law, Polsinelli is ranked as "[Law Firm of the Year](#)" in Health Care by *U.S. News & World Report* (November 2014), no. 1 by *Modern Healthcare* (June 2015) and nationally ranked by *Chambers USA* (May 2015). Polsinelli's attorneys work as a fully integrated practice to seamlessly partner with clients on the full gamut of issues. The firm's diverse mix of attorneys enables our team to provide counsel that aligns legal strategies with our clients' unique business objectives.

One of the fastest-growing health care practices in the nation, Polsinelli has established a team that includes former in-house counsel of national health care institutions, the Office of Inspector General (OIG), and former Assistant U.S. Attorneys with direct experience in health care fraud investigations. Our group also includes current and former leaders in organizations such as the American Hospital Association. Our strong Washington, D.C., presence allows us to keep the pulse of health care policy and regulatory matters. The team's vast experience in the business and delivery of health care allows our firm to provide clients a broad spectrum of health care law services.

## About Polsinelli

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\* 2016 BTI Client Service A-Team Report

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