WHAT'S BEEN MISSING: DISTRICT COURT ORDERS THE GOVERNMENT TO PRODUCE COMPLETE UNIVERSE OF CLAIMS IN PROVIDER'S DUE PROCESS CHALLENGE TO EXTRAPOLATED OVERPAYMENT

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US Policy and Regulatory Alert

On 5 March 2024, in an issue of first impression in the District of South Carolina, a district court judge overseeing judicial review of a final agency decision in a Medicare claims appeal ordered the Government to complete the administrative record. Specifically, the judge ordered the Government to produce the missing target universe of claims, including adjudicated claims issued zero payment (zero-paid claims) that were excluded by a Medicare auditor in calculating an extrapolated overpayment levied against a health care provider. The provider in this case had fought through the labyrinth of the Medicare appeals process for over a decade and finally received a measure of vindication for arguments raised throughout.

WHAT IS REQUIRED TO "COMPLETE" THE ADMINISTRATIVE RECORD

This ruling is significant for a number of reasons: namely, it represents the first time a federal district court has held that:

1. A provider was entitled to zero-paid claims data, the routine exclusion of which often drastically increases an auditor's extrapolated overpayment assessment;
2. The administrative record for a Medicare Act claims appeal brought under 42 U.S.C. § 405(g) must include anything that any agency decision-maker—not just the Administrative Law Judge—relied upon, either directly or indirectly;
3. The administrative record for a Medicare Act claims appeal must include all information supporting any recalculation of an extrapolated overpayment demand, even if not reviewed by the final agency decision-maker, because such recalculations are "effectuations" and properly reviewable under 42 U.S.C. § 405(g);
4. Contractors for the Centers for Medicare and Medicaid Services (CMS)[1] acted on behalf of the agency and relied on information missing from the administrative record (i.e., zero-paid claims data) in performing their statistical sampling and extrapolation; and
5. Because CMS (through its contractors) relied on this missing information, the administrative record before the court must include this missing information in order to create a complete record for the court's ultimate review.

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The court also recognized and set forth a helpful delineation between "completing" the administrative record and "supplementing" the administrative record. "[C]ompleting the administrative record means including existing evidence initially omitted from the administrative record to make that record whole," whereas supplementing the administrative record means seeking to include new evidence in the record, which requires a more rigorous showing for a movant.[2]

Of note, the ruling also explicitly acknowledges the difference between zero-paid claims (that is, fully adjudicated claims that have been assigned zero payment) and unpaid claims that have been submitted for payment but have not yet been adjudicated or processed. As discussed further below and in a prior publication on due process challenges to statistical sampling and extrapolation in Medicare claims appeals, this acknowledgement is crucial to cases in the Medicare claims appeal arena.

WHAT THIS RULING MEANS MOVING FORWARD

The implications of this ruling are far-reaching.

Although statutes and regulations require CMS contractors, including Unified Program Integrity Contractors (UPICs), to identify both overpayments and underpayments in their audits of Medicare reimbursements,[3] historically, UPICs and other CMS contractors have only focused their audits on identifying overpayments, and routinely have excluded zero-paid claims (which could, in fact, represent underpayments) from their audit review.

When UPICs audit a provider and assess an extrapolated overpayment, they also are required to produce "sufficient" documentation "so that the sampling frame can be recreated should the methodology be challenged."[4] Sufficient documentation includes producing the actual universe of claims (that is, the target universe of all claims submitted by the provider for Medicare reimbursement within the chosen time period). An auditor's failure to produce the target universe is an independently sufficient basis to invalidate an extrapolated overpayment, as this failure deprives a provider a due process right to recreate and challenge the statistical sampling and extrapolation methodology.

Despite these requirements, UPICs and other CMS post-payment auditors, with rare exception, only provide a filtered "universe" that excludes zero-paid claims when they produce documentation to the provider in support of their statistical sampling methodology and extrapolated overpayment assessments.

By acknowledging that the actual universe includes zero-paid claims that must be produced to the provider and included in the administrative record of any appeal, the court implicitly acknowledges that the provider has a procedural due process right to this information. Consequently, this ruling opens the floodgates for federal litigation on this issue and provides an opportunity to challenge the statistical validity of any extrapolated overpayment where the CMS contractor has failed to produce this missing universe.

A copy of the court's order can be accessed here.

FOOTNOTES

[1] CMS is an agency of the United States Department of Health and Human Services.

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[2] *Goose Creek Physical Med., LLC v. Becerra*, No. 22-cv-03932, 2024 WL 942918, at *5 n.7 (D.S.C. Mar. 5, 2024) (citations and quotations omitted).

[3] *See*, e.g., 42 U.S.C. §§ 1395ddd(b), 1395g(a); 42 C.F.R. § 421.304; *see also* Medicare Program Integrity Manual ("MPIM") (Pub. 100-08), Chapter 8, §§ 8.4.1.3, 8.4.6.3, 8.4.5.2, 8.4.7.1.

[4] MPIM, Ch. 8, § 8.4.4.4.1.

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