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Righting an Institutional Wrong: Redefining an Overpayment Through HHS-OIG's Policy Shift on Zero-Paid Claims

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The Department of Health and Human Services Office of Inspector General (HHS-OIG) recently enacted a policy in the Corporate Integrity Agreement context that auditors must include underpayments to calculate net overpayments in setting actual overpayments owed. This development signifies an institutional shift to correct the execution and effectuation of congressional intent underlying the Medicare Integrity Program, and contract auditors' statistical sampling and extrapolation processes.

Congressional Intent Regarding Overpayments and Exclusion of Zero-Paid Claims

When Congress established the Medicare Integrity Program in 1996, the intent was to strengthen HHS' ability to deter fraud and abuse.[1] As part of the Medicare Integrity Program, codified at 42 U.S.C. § 1395ddd, Congress authorized the Centers for Medicare & Medicaid Services (CMS) to engage contract auditors to "use extrapolation to determine overpayment amounts to be recovered."[2] However, the statutory language in 42 U.S.C. § 1395ddd also evidences Congress' intent that the process be fair and objective to providers by requiring auditors to consider CMS' initial determination that a claim should be paid less than the applicable fee schedule amount, including a payment amount of zero, could be in error. In accordance with that intent, in December 2006, Congress' Tax Relief and Healthcare Act amended the statutory provisions to add a new subsection, 42 U.S.C. § 1395ddd(h), which requires contractors to identify underpayments as well as overpayments.[3] This coincides with Ruling 86-1, Use of Statistical Sampling to Project Overpayments to Medicare Providers and Suppliers (Feb. 20, 1986), in which CMS' predecessor, the Health Care Finance Administration (HCFA), originally approved the use of statistical sampling and extrapolation in determining and calculating overpayments.[4] HCFA emphasized that providers should and would have a fair opportunity to contest the overpayment amount and any adverse determinations based on statistical sampling: "Sampling does not deprive a provider of its rights to challenge the sample, nor of its rights to procedural due process."[5]

The Code of Federal Regulations[6] and the Medicare Program Integrity Manual (MPIM) demonstrate the congressional intent that auditors examine overpayments and underpayments to determine a net overpayment.[7] Despite express language requiring inclusion of potential underpayments throughout the legal hierarchy, CMS' auditors began an institutional practice over the past decade that contravened the congressional intent of auditing for underpayments and overpayments by intentionally removing fully adjudicated claims for which the final payment amount was zero. In review findings, auditors began relying on imprecise language in the MPIM that allows for the removal of "unpaid" claims from the sampling frame when filtering down from the universe of claims.[8] Factually and legally, the interpretation that an "unpaid" claim is the equivalent of an adjudicated claim with a payment amount of zero (i.e., a "zero-paid" claim) is incorrect. "Unpaid" claims are claims that have been submitted for payment but have not yet been adjudicated or processed for payment determination. Such claims are not legally ripe for reopening and should be excluded from a post-payment review. In contrast, "zero-paid" claims refers to claims that are underpayments in whole, with an amount of zero as determined for payment after adjudication.[9] Zero-paid claims are legally ripe for reopening and must be included

in the review to ensure an unbiased result.[10] An examination of the relevant MPIM sections in light of this overarching regulatory and statutory mandate reveals that the drafters of the MPIM erred by not distinguishing "unpaid" claims from "zero-paid" claims.[11]

This necessary distinction between "unpaid" and "zero-paid" claims is confirmed by multiple provisions of the MPIM that require auditors to use the sampling and extrapolation process to ultimately find the net overpayment to be asserted against the provider.[12] An intentional exclusion of zero-paid claims from the sampling frame: (i) biases the review by only examining for errors by the provider and excluding potential errors by CMS; (ii) mathematically inflates the alleged overpayment against the provider; and (iii) is in direct violation of statutory and regulatory authority, as well as the guidance provided in the MPIM. HHS-OIG recently appeared to confirm this interpretation, as set forth below.

HHS-OIG's Policy Shift Regarding Underpayments

As part of its oversight role, HHS-OIG has the "duty and responsibility" to "provide policy direction for . . . audits and investigations," including policies relevant to statistical sampling and extrapolation.[13] Given that responsibility, HHS-OIG's recent policy shift in the Corporate Integrity Agreement (CIA) context carries weight.

HHS-OIG recently affirmed the requirement that zero-paid claims be included in the statistical sampling and extrapolation process. Specifically, HHS-OIG has enacted a policy in the context of CIAs that Independent Review Organizations (IROs) performing audit work must include underpayments to calculate the net overpayment in setting the actual overpayment owed under a CIA. HHS-OIG counsel announced that shift in a September 2022 public presentation, but the shift had first begun appearing in some CIAs as early as June 2022.[14]

This change is reflected in the definition of "Error Rate" utilized in CIAs. Previously, HHS-OIG had instructed IROs to calculate an Error Rate for CIA purposes "by dividing the Overpayment in the Claims Review Sample by the total dollar amount associated with the Paid Claims in the Claims Review Sample."[15] Now, HHS-OIG has updated its policy to expressly require the inclusion of underpayments—including zero-paid claims—re-defining "Error Rate" as "the percentage of net Overpayments identified in the Claims Review Sample. The net Overpayment shall be calculated by *subtracting all underpayments* identified in the Claims Review Sample from all Overpayments identified in the Claims Review Sample."[16]

Conclusion and Practical Guidance

Although this new policy by HHS-OIG may not seem like a major change, it signifies an institutional shift that corrects the execution and effectuation of the congressional intent for auditors who examine overpayments and underpayments to determine a net overpayment. Nevertheless, the HHS-OIG policy is a recommendation and guidance to CMS, and CMS still has not publicly responded to this change in HHS-OIG policy.

When faced with CMS and other government audits, providers should carefully examine alleged overpayments to ensure that there was no improper removal of fully adjudicated claims for which the final payment amount was zero. If zero-paid claims were removed, providers should challenge the validity of the statistical sampling and extrapolation and the denial of their due process rights during the appeal process. Providers should continue to monitor HHS-OIG, CMS, and other legislative developments, as the legal framework for statistical sampling and extrapolation continues to rapidly evolve.

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[1] Health Insurance Portability & Accountability Act of 1996, Pub. L. No. 104–191, §§ 201–02, 110 Stat. 1936, 1992–98 (codified at 42 U.S.C. §§ 1395i(k)(4), 1395ddd).

[2] *See* 42 U.S.C. § 1395ddd(f)(3)(A).

[3] *See* Tax Relief and Health Care Act of 2006, Pub. L. No. 109-432, Div. B, Title III, § 302(a), 120 Stat. 2991 (codified at 42 U.S.C. §1395ddd(h)); "Underpayments" refers to non-payments where an applicable law requires payment by CMS to a provider or supplier; or to payments of less than the amount owed by CMS to a provider or supplier according to applicable law.

[4] HCFA Ruling 86-1, Use of Statistical Sampling to Project Overpayments to Medicare Providers and Suppliers (Feb. 20, 1986).

[5] *Id.* at p. 11.

[6] 42 C.F.R. § 455.504.

[7] In 2000, to carry out the congressional objective on using extrapolation, CMS set forth its Medicare guidelines for statistical sampling and overpayment estimation in the MPIM.

[8] *See, e.g.*, MPIM Ch. 8, §§ 8.4.3.2, 8.4.3.2.1, 8.4.3.2.3.

[9] *See Id.* at Ch. 3, §§ 3.5.2, 3.6.1, 3.7.1.1; MPIM Ch. 8, §§ 8.4.1.3, 8.4.3.2.1, 8.4.4.4.3, 8.4.4.4.4, 8.4.5.2, 8.4.6., 8.4.7.1.

[10] *See* 42 U.S.C. §1395ddd(h).

[11] *See, e.g.*, MPIM Ch. 8, §§ 8.4.3.2, 8.4.3.2.1, 8.4.3.2.3, 8.4.4.4.3, 8.4.5.2.

[12] *See id.* at §§ 8.4.3.2.2, 8.4.4.4.3, 8.4.4.4.4, 8.4.5.1, 8.4.5.2, 8.4.6.3, 8.4.7.1, 3.5.2, 3.6.1, 3.7.1.1.

[13] 5a U.S.C. § 4(a)(1).

[14] *See, e.g.*, OIG, *Corporate Integrity Agreement Between [OIG of the Department of Health and Human Services] and Citadel Consulting Group LLC [D/B/A Citadel Care Centers LLC and TCPRNC, LLC D/B/A The Plaza Rehab and Nursing Center]*, App'x B, at 1 (June 17, 2022), https://www.oig.hhs.gov/fraud/cia/agreements/Citadel_Consulting_Group_LLC_dba_Citadel_Care_Cent [hereinafter, Updated OIG CIA]; *see also* Laura Ellis, *CIA Changes on the Horizon: What They Are and What They May Mean For You*, Speech at Am. Health L. Ass'n Fraud and Compliance Forum (Sept. 29, 2022) (discussing the policy shift in her capacity as Senior Counsel in OIG's Office of Counsel).

[15] *See, e.g.*, HHS-OIG, *Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and VirtuOx, Inc.*, App'x B, at 5 (May 11, 2022), https://www.oig.hhs.gov/fraud/cia/agreements/VirtuOx_Inc_05112022.pdf.

[16] *See, e.g.*, Updated OIG CIA, App'x B, at 1 (emphasis added).

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