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Due Process: A Winning Weapon Against Extrapolated Overpayments

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Two recent federal rulings in two different districts (the Southern District of Florida and the District of South Carolina) signal an increased willingness of federal district courts to consider due process challenges to statistical sampling and extrapolation methodologies in their judicial review of assessed overpayments levied against Medicare providers.

On March 5, 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 (hereinafter, *Goose Creek* ruling).[1]

The *Goose Creek* ruling is particularly significant, as 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. Contractors for the Centers for Medicare and Medicaid Services (CMS)[2] routinely exclude these claims from their statistical analysis, which often drastically increases the extrapolated overpayment calculations assessed against providers. By acknowledging that the target universe includes zero-paid claims that must be produced to the provider and included in the administrative record of any appeal, the *Goose Creek* court implicitly acknowledged that a provider has a procedural due process right to this information.

Additionally, on March 25, 2024, in an issue of first impression in the Southern District of Florida, another district court judge vacated CMS' extrapolated overpayment demands, holding that the Department of Health and Human Services (HHS) violated the provider's due process rights by failing to provide documentation supporting the recalculated overpayment amounts (hereinafter, the *MedEnvios* ruling).[3]

This article examines the potential impact of the *Goose Creek* and *MedEnvios* rulings: (1) on the Medicare appeals process in general; and (2) more specifically on the numerous cases pending in federal district court nationwide involving due process challenges to CMS contractors' statistical sampling and extrapolation methodologies.

Appeals Process

While CMS is the agency responsible for administering the Medicare program, CMS contracts with various private entities to assist CMS in processing and auditing claims for reimbursement and in the appeals process itself.

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Unified Program Integrity Contractors (UPICs) have become the primary entity that CMS uses to investigate and data-mine for fraud in Medicare and Medicaid claims processing. UPICs perform integrity work with Medicare Parts A and B, durable medical equipment, home health and hospice, Medicaid, and the Medicare-Medicaid data match program.

UPICs are tasked with identifying both overpayments and underpayments and are also authorized to initiate appropriate administrative actions where there is reliable evidence of Medicare fraud, including, but not limited to, payment suspensions and revocations.[4] One of the primary tools that UPICs and other Medicare contracting entities use in performing their duties is statistical sampling and extrapolation, as discussed in further detail below.

If a Medicare provider wishes to appeal claims denials, they are subject to the lengthy appeals process set forth in 42 U.S.C. § 1395ff. The Medicare appeals regulations allow for five levels of appeal: (1) redetermination; (2) reconsideration; (3) administrative law judge (ALJ) hearing; (4) Medicare Appeals Council (Council) review; and (5) federal district court review.[5] Partially favorable decisions on the individual sample claims at any level of the appeals process require recalculation of the extrapolated overpayment demand. Statistical sampling and extrapolation can be invalidated at any appeal level, but appellants must assert the reasons why they disagree with how the statistical sampling and extrapolation was conducted at each appeal level to preserve such arguments.

Use of Statistical Sampling and Extrapolation in Medicare Audits to Calculate Overpayments

Scope of Improper Medicare Payments

The U.S. Government Accountability Office (GAO) estimates that CMS made approximately $51.1 billion in improper payments for Fiscal Year 2023, and $46.8 billion in improper payments for Fiscal Year 2022.[6] Improper payments include both overpayments and underpayments.[7] HHS reported the root causes of improper payments for Medicare Fee-for-Service (FFS) claims were: (1) insufficient documentation (such as support for level of care billing codes, orders for outpatient hospitals, and certification or recertification of documents); and (2) medically unnecessary errors (i.e., claims that did not meet coverage criterial for medical necessity).[8]

Although the government's focus has always been on recovering overpayments, in a CMS report entitled "Recovery Auditing in Medicare Fee For-Service for Fiscal Year 2015," Medicare FFS Recovery Audit Contractors (RACs) collectively identified and corrected 618,966 claims with improper payments that resulted in $440.69 million in payments being corrected.[9] Of these, underpayments represented 18% of total errors.[10] In 2019, underpayments represented 10% of total errors.[11]

Origins of Sampling and Extrapolation in the Medicare Appeals Context

a. CMS Ruling 86-1

Given the high volume of potentially improper Medicare payments, it is not cost-efficient for the government to conduct its audits on a claim-by-claim basis. Recognizing this problem, in 1986, the Health Care Financing Administration (HCFA), the predecessor to the CMS, issued CMS Ruling 86-1, which was the first ruling that allowed a fiscal intermediary to use sampling and extrapolation in place of a claim-by-claim review.[12] CMS has since relied on this decision to justify the use of statistical sampling and extrapolation to support a demand for repayment of claims billed to federal health care programs. Notably, this ruling held that "[s]ampling does not deprive a provider of its rights to challenge the sample, nor of its rights to procedural due process[,]"[13] based on an assumption that the "provider is given a full opportunity to demonstrate that the overpayment determination is wrong."[14] "Sampling only creates a presumption of validity as to the amount of an overpayment which may be used as the basis for recoupment. The burden then shifts to the provider to take the next step."[15]

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b. Medicare Integrity Program and the Medicare Program Integrity Manual

In 1996, Congress created the "Medicare Integrity Program" to strengthen the Secretary of HHS' ability to deter fraud and abuse.[16] As part of this Medicare Integrity Program, Congress authorized the Secretary to "use extrapolation to determine overpayment amounts to be recovered."[17] Under this Program, program integrity contractors are required to identify underpayments as well as overpayments.[18]

In 2000, to carry out this congressional objective, CMS set forth guidelines for statistical sampling and overpayment estimation in the Medicare Program Integrity Manual (MPIM). Chapter 8, Section 4 of the MPIM provides detailed requirements for CMS contractors in developing an audit plan and executing the sampling and extrapolation process.[19] As explained further below, the MPIM includes guidelines regarding preservation and documentation of the universe as well as the evaluation and inclusion of zero-paid claims.[20]

Due Process Challenges to Extrapolation Currently in Federal Court

Recently, due process challenges to statistical sampling and extrapolation have gained traction in Medicare appeals at the ALJ and Council level, resulting in extrapolated overpayments being invalidated in administrative appeals. An increasing number of these due process challenges are now being raised at the district court level, with more than 20 such appeals currently pending in seven judicial districts (including, but not limited to, the Eastern District of California, Southern District of Florida, Southern District of New York, District of South Carolina, Northern and Southern Districts of Texas, and Western District of Tennessee).

These due process challenges include (but are not limited to): (1) a contractor's failure to produce the complete "target universe" of claims; (2) a contractor's failure to produce sufficient documentation to support a recalculated overpayment (after partially favorable adjudication(s) during the administrative appeals process); and (3) a contractor's failure to include zero-paid claims in the sampling frame, as discussed in greater detail below.

Constitutional Requirements Needed to Make a Procedural Due Process Claim

The U.S. Supreme Court has indicated that there are two steps to a viable claim for violation of procedural due process in the administrative context.

Step one is "to identify a property or liberty interest entitled to due process protections[.]"[21] In the Medicare claims appeal context, courts have recognized that Medicare "beneficiaries have a protected due process 'property interest' in 'receiving the medical insurance benefits for which they paid a monthly premium.'"[22] Providers and suppliers are likewise parties in interest "as assignees of the beneficiaries" and therefore have a valid property interest in receiving Medicare payments for services rendered.[23]

Step two is to show that the administrative procedures provided to the plaintiff violated mandatory procedural safeguards or were otherwise constitutionally inadequate.[24] In assessing the constitutional adequacy of existing administrative procedures, courts generally consider: (1) the private interest affected by the administrative action; (2) the risk of erroneous deprivation of that interest given the procedures used, as well as the probable value of additional or substitute safeguards; and (3) the government's interest, including the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.[25] Moreover, it is well-settled that "[t]he fundamental requirement of due process is the opportunity to be heard at a meaningful time and in a meaningful manner."[26]

The subsections below address the constitutional adequacy of several common procedures of CMS contractors in conducting their statistical sampling and extrapolation methodologies.

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Failure to Produce the Target Universe

As discussed above, CMS Ruling 86-1 requires that CMS and its contractors produce to a provider sufficient documentation to recreate the sampling frame and thereby challenge the statistical validity of the sample. In order to recreate the sampling frame, a provider needs, among other things, a copy of the target universe of claims, which consists of all adjudicated claims (including zero-paid claims) submitted by the provider within the chosen time period for CMS' review.[27] Specifically, MPIM Chapter 8, Section 8.4.4.4.1 requires "[a]n explicit statement of how the universe is defined and elements included shall be made and maintained in writing . . . [and] [d]ocumentation shall be kept in sufficient detail so that the sample frame can be re-created should the methodology be challenged."

When CMS and its contractors fail to comply with the MPIM's mandate to carefully document, preserve, and produce a statistical sampling and extrapolation from start to finish, a provider is denied its due process right to recreate the process to determine if it was performed correctly and to determine if a valid challenge should be raised.[28] By extension, where a provider is denied its due process right to dispute and contest an extrapolated overpayment, the provider is not extended appeal rights in accordance with 42 U.S.C. § 1395ff(b) and the extrapolation should be invalidated.

Failure to Produce Sufficient Documentation to Support a Recalculated Overpayment

Similarly, when CMS and its contractors fail to produce sufficient documentation to support a recalculated overpayment that has been reduced after partially favorable adjudication(s) during the appeals process, a provider is denied its due process right to recreate the process to determine if the recalculation was performed correctly.[29] In these circumstances, and for the same reasons stated above, any recalculated overpayment should also be invalidated.[30]

Failure to Include Zero-Paid Claims

In order for the statistical sampling and extrapolation process to function properly and not be biased against the provider, underpayments, including zero-paid claims, must be present in the universe, sampling frame, and sample to ensure the actual net overpayment is calculated.

Auditing only paid claims is biased toward only the potential errors made by the provider. This eliminates from consideration any claims that could actually represent underpayments (which, by CMS' own findings, could constitute 10–18% of any data set of improper payments).[31] By eliminating these zero-paid claims, the audit sample is biased towards only those claims that have a higher likelihood of being overpaid rather than underpaid.

This bias renders the sample ineligible for use in any inferential statistical calculation, including extrapolation. Additionally, removal of all the unpaid claims mathematically increases the extrapolation estimate because it is working off the presumption that all the claims in the universe were paid.

The *Goose Creek* Ruling: the Government is Required to Produce the Target Universe (including Zero-Paid Claims), as well as Documentation to Support any Recalculated Overpayment in Order to "Complete" the Administrative Record

Although the district court in *Goose Creek* has not yet ruled on the merits of the provider's due process challenges, the court's ruling (requiring completion of the administrative record) is still legally significant and also signals the court's willingness to consider the due process challenges outlined above.

The Court Acknowledges the Significance of Zero-Paid Claims

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Importantly, the ruling expressly 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.[32] The court further ordered that the Secretary produce the missing "target universe" to include "zero-paid" claims data.[33]

Auditors have historically misused vague and conflicting terms regarding unpaid claims in the MPIM to argue that they are entitled to exclude zero-paid claims from the sampling frame, and also to justify their systematic failure to produce the complete target universe of adjudicated claims.[34]

Although this ruling does not go so far as to say that the exclusion of zero-paid claims from the sampling frame impermissibly biases the statistical sample and warrants invalidation of the extrapolated overpayment,[35] it does expressly acknowledge that a provider is entitled to this data, as it was information relied on by the CMS contractors, as further detailed below.

The Court Finds that the Government Must Produce the Target Universe

Most significantly, the court in *Goose Creek* held that the complete target universe of adjudicated claims must be produced by the government and included in the administrative record.[36]

Specifically, the court held that 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 ALJ—relied upon, either directly or indirectly.[37] The court then found that contractors for CMS 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.[38] Because CMS (through its contractors) relied on this missing information, the court held that the administrative record must include this missing information in order to create a complete record for the court's ultimate review.[39]

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 that a party seeks to include new evidence in the record, which requires the court, and the parties, to follow a specific statutory mechanism which governs the circumstances requiring remand to the agency."[40]

The Court Finds that the Government Must Also Produce Documentation to Support the Recalculated Overpayment

The *Goose Creek* court further held that 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).[41]

The *MedEnvios* Ruling: the Failure to Produce Sufficient Documentation to Support Recalculated Overpayments is Unconstitutional

The *MedEnvios* ruling is even more significant, as it marks the first time a federal district court has ruled on the merits of one of these constitutional challenges and invalidated an extrapolated overpayment in a Medicare appeals case on due process violation grounds.

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The Court Finds that a CMS Contractor's Failure to Produce Sufficient Documentation to Support a Recalculated Overpayment Violates a Provider's Right to Due Process

Importantly, while there has been ambiguity in Eleventh Circuit case law, the court in *MedEnvios* expressly held that a Medicare provider had a "protected property interest in the funds subject to the extrapolated overpayment demands."[42]

The court further held that the provider's procedural due process rights were violated when "Defendant failed to provide sufficient documentation to support overpayments recalculated following partially favorable appellate decisions."[43] Applying the U.S. Supreme Court's *Mathews* test, the court concluded that "[w]ithout the ability to verify the contractor's calculations, a provider does not have the information and data necessary to mount a due process challenge to the statistical validity of the sample, as is its right."[44] Because of these due process violations, the *MedEnvios* court vacated the "extrapolated overpayment demands" assessed against the provider.[45]

However, the court in *MedEnvios* also held that the CMS contractors' failure to include zero-paid claims in the sampling frames did not amount to a due process violation.[46]

Widespread Impact of These Federal Rulings on Medicare Administrative Appeals and Litigation in District Court

Impact on Medicare Administrative Appeals

The *Goose Creek* and *MedEnvios* rulings signal a shift in how some district court judges are evaluating due process challenges to extrapolated overpayments in the Medicare Appeals context. If other district court judges follow suit, it could fundamentally alter how UPICs are required to conduct their statistical analyses and calculate extrapolated overpayments, as well as how they are required to document their methodology and calculations.

While the potential impact of these rulings on pending Medicare appeals is difficult to fully quantify, at the ALJ level alone, the Office of Medicare Hearings and Appeals received approximately 20,885 new appeals in just the first two quarters of Fiscal Year 2023.[47] Consequently, a significant change in any court's interpretation of due process requirements is likely to affect thousands of Medicare appeals currently pending at the administrative level.

Although statutes and regulations require CMS contractors, including UPICs, to identify both overpayments and underpayments in their audits of Medicare reimbursements,[48] 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.

Given the deference that district courts pay to an agency's interpretation of their own regulations, to date it has been more difficult for providers to mount successful due process challenges to CMS' routine exclusion of zero-paid claims from their statistical analysis.[49] However, the more courts that order the production of this data as part of the "target universe" (as the district court ordered in *Goose Creek*), the more opportunities providers will have to independently analyze this data to effectively demonstrate the bias of these statistical samples, as well as to identify potential underpayments that need to be reimbursed to the provider. Given that CMS has previously identified an underpayment error rate of 10–18% among total improper payments identified by RACs, requiring UPICs to properly account for underpayments would mean that millions of dollars would rightfully be reimbursed or offset in future overpayment calculations to providers.

Impact on Pending and Future District Court Litigation

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The *Goose Creek* and *MedEnvios* rulings also open the floodgates for increased litigation in district courts, as providers now have both precedential and persuasive authority to rely on in mounting due process challenges to extrapolated overpayment demands issued by CMS contractors.

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."[50] 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.

Similarly, CMS contractors routinely fail to provide sufficient documentation to support overpayments recalculated following partially favorable appellate decisions.

Consequently, in any Medicare appeal pending judicial review before a federal district court where CMS contractors either: (1) failed to produce the target universe (to include zero-paid claims); or (2) failed to produce sufficient documentation to support a recalculated overpayment, providers can now cite to the legal arguments outlined in the *Goose Creek* and *MedEnvios* rulings to mount a due process challenge to the government's extrapolated overpayment demand.

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[1] *Goose Creek Physical Med., LLC v. Becerra*, No. 22-cv-03932, 2024 WL 942918, at *11 (D.S.C. Mar. 5, 2024).
[2] CMS is an agency of the United States Department of Health and Human Services (HHS).
[3] *MedEnvios Healthcare, Inc. v. Becerra*, No. 23-cv-20068, 2024 WL 1252264, at *5 (S.D. Fla. Mar. 25, 2024).
[4] *See, e.g.*, 42 U.S.C. §§ 1395ddd(b) and (h), 1395g(a); 42 C.F.R. § 421.304; Medicare Program Integrity Manual (MPIM), Ch. 8, §§ 8.4.1.3, 8.4.4.4.4, 8.4.5.2, 8.4.7.1.
[5] *See* 42 U.S.C. § 1395ff. After the initial determination that an overpayment has been made, a denied claim may be submitted to a Medicare Administrative Contractor (MAC) for redetermination. *Id.* § 1395ff(a)(3)(A). If the redetermination is unfavorable, the appealing party may submit a request for reconsideration. *Id.* §§ 1395ff(b), (c). A reconsideration is a review of the MAC's redetermination conducted by a Qualified Independent Contractor (QIC). *Id.* at § 1395ff(c)(B)(i). A party that is dissatisfied with the QIC's reconsideration may request a hearing and *de novo* review before an administrative law judge (ALJ) with the Office of Medicare Hearings and Appeals, provided the amount in controversy is met. *Id.* § 1395ff(b)(1)(E). The final administrative option for appeal of an unfavorable decision occurs with the Medicare Appeals Council (Council). *Id.* § 1395ff(d)(2); 42 C.F.R. § 405.1108(a). If Council does not issue a decision, dismissal, or remand within 90 days, the appealing party may file a request to escalate the case to federal district court for judicial review. 42 C.F.R. § 405.1132(a).
[6] GAO, Improper Payments: Information on Agencies' Fiscal Year 2023 Estimates, at 3 (Mar. 26, 2024), *available at:* https://www.gao.gov/assets/d24106927.pdf; GAO, Improper Payments: Fiscal Year 2022 Estimates and Opportunities for Improvement, at 9 (Mar. 2023), *available at* https://www.gao.gov/assets/gao-23-106285.pdf [hereinafter, GAO, Improper Payments FY 2022].
[7] *See* Payment Integrity Information Act of 2019, Pub. L. No. 116-117, § 2, 134 Stat. 113, 114 (codified at 31 U.S.C. § 3351(4) (defining an "improper payment" as "any payment that should not have been made or that was made in an incorrect amount, including an overpayment or underpayment, under a statutory, contractual, administrative, or other legally applicable requirement")).
[8] GAO, Improper Payments FY 2022, at 16.
[9] CMS, Recovery Auditing in Medicare Fee-For-Service for Fiscal Year 2015, at 15, *available at:* https://www.cms.gov/research-statistics-data-and-systems/monitoring-programs/medicare-ffs-compliance-programs/recovery-audit-program/downloads/fy2015-medicare-ffs-rac-report-to-congress.pdf.
[10] *Id.*
[11] CMS, FY 2019 Medicare FFS RAC Report to Congress – Appendices, at 11, *available at:* https://www.cms.gov/files/document/fy-2019-medicare-ffs-rac-report-congress-appendices.pdf.
[12] HCFA Ruling 86-1, Use of Statistical Sampling to Project Overpayments to Medicare Providers and Suppliers, (Feb. 20, 1986), https://www.cms.gov/Medicare/Appeals-and-Grievances/OrgMedFFSAppeals/Downloads/HCFAR861v508.pdf.
[13] *Id.* at 11–12.
[14] *Id.* at 11.
[15] *Id.* at 11.
[16] *See* Health Insurance Portability and 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).
[17] *See* 42 U.S.C. § 1395ddd(f)(3)(A).
[18] *See id.* at § 1395ddd(h).
[19] *Rio Home Care, LLC v. Azar*, No. 17-cv-116, 2019 WL 1411805, at *29 (S.D. Tex. Mar. 11, 2019) (finding that MPIM guidelines on sampling and extrapolation are intended to strike a balance between precise estimates that may not be "administratively or economically feasible for contractors performing audits" and the need to ensure that "the provider/supplier is treated fairly despite any imprecision in the estimation").
[20] *See, e.g.*, MPIM, Ch. 8, §§ 8.4.7.1, 8.4.4.2, 8.4.5.2, 8.4.3.2.1.
[21] *Brock v. Roadway Exp., Inc.,* 481 U.S. 252, 260 (1987) (*citing Cleveland Bd. of Educ. v. Loudermill,* 470 U.S. 532, 538-39 (1985); *Bd. of Regents v. Roth*, 408 U.S. 564, 576–78 (1972)).
[22] *Bailey v. Mut. of Omaha Ins. Co.*, 534 F. Supp. 2d 43, 53–54 (D.D.C. 2008) (quoting *Gray Panthers v. Schweiker*, 652 F.2d 146, 148 n.2 (D.C. Cir. 1980)).
[23] *Cervoni v. Sec'y, Health, Educ. & Welfare*, 581 F.2d 1010, 1018 (1st Cir. 1978); *see also* 42 C.F.R. § 400.202 (noting payment on an assignment basis); *Med-Cert Home Care, LLC v. Azar*, 365 F. Supp. 3d 742, 751 (N.D. Tex. 2019) (stating that "[p]recedent makes clear that [the provider] has a valid property interest in receiving Medicare payments for services rendered"); *A1 Diabetes & Med. Supply v. Azar*, 937 F.3d 613, 619 (6th Cir. 2019) (finding that the provider "plainly ha[d] a significant 'private interest': payment for services rendered"). *But see In Touch Home Health Agency, Inc. v. Azar*, 414 F. Supp. 3d 1177,

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1189-90 (N.D. Ill. 2019) (finding provider lacked a property interest in Medicare repayments given the contingent nature of the repayment system).
[24] *Mathews v. Eldridge*, 424 U.S. 319, 332–35 (1976).
[25] *Id.* at 335.
[26] *Id.* at 333 (internal citations and quotations omitted).
[27] *See* MPIM Ch. 8 § 8.4.3.1.
[28] *See Glob. Home Care, Inc. v. Nat'l Gov't Servs.*, No. M-11-116, 2011 WL 3668242, at *3 (HHS-DAB Jan. 11, 2011) (holding that "[w]ithout this basic documentation, a provider does not have the information and data necessary to mount a Due Process challenge to the statistical validity of the sample, as is its right under CMS Ruling 86-1").
[29] *See MedEnvios*, 2024 WL 1252264, at *4–5 (applying the *Mathews* test and determining that the plaintiff's procedural due process rights were violated).
[30] *Id.*
[31] *See supra* notes 8, 9.
[32] *Goose Creek,* 2024 WL 942918, at *2 n.2.
[33] *Id.* at *6, 11.
[34] *See, e.g., MedEnvios*, 2024 WL 1252264, at *4:

> The Department contend[s] that there is no requirement for Medicare contractors to include unpaid or "zero-paid" claims in sampling frames to avoid running afoul of procedural due process rights. Rather, the statute merely establishes a framework for performing post-payment reviews, and "left it to the Secretary to establish the methodology for selecting samples of Medicare claims for audit....[T]he relevant MPIM provision clearly instructs that "once the program integrity contractor has defined the universe for audit, the composition of that universe 'shall consist of all full and partially paid claims.' " MPIM, Ch. 8, § 8.4.3.2.1.B. This, by the Department's reading, excludes "zero-paid" claims because they are claims that "were not paid in full; they were not paid in part; they were paid $0.

See also Cent. La. Home Health Care, LLC v. Price, No. 17-cv-00346, 2018 WL 7888523, at *16 (W.D. La. Dec. 28, 2018) ("The DHHS contends that all unpaid claims were properly excluded from the sampling frame and sample in this case, as found by both the ALJ and the Appeals Council.").
[35] Two recent district court rulings have expressly rejected this due process argument as a basis for invalidating an extrapolated overpayment. *See, e.g., MedEnvios*, 2024 WL 1252264, at *3–4 (finding that the Department did not violate MedEnvios' "procedural due process rights by excluding 'zero-paid' claims from the sampling universe in the two relevant post-payment audits[,]" but ultimately vacating the recalculated extrapolated overpayments on other due process grounds); s*ee also Compass Lab'y Servs, LLC v. Becerra*, No. 23-cv-02018, *Order*, at *8–13 (ECF No.52) (W.D. Tenn. Mar. 26, 2024) [hereinafter, "*Compass* Ruling"] (granting in part the defendant-Secretary's motion for summary judgment and holding that zero-paid claims need not be included in the sampling process).
[36] *Goose Creek,* 2024 WL 942918, at *6, 11.
[37] *Id.* at *11.
[38] *Id.*
[39] *Id.*
[40] *Id.* at *5 n.7 (citations and internal quotations omitted).
[41] *Id.* at *7, 9 n.12, 11.
[42] *See, e.g., MedEnvios*, 2024 WL 1252264, at *3.
[43] *Id.* at *4.
[44] *Id.* at *5 (quoting *Glob. Home Care*, at *3 (internal quotations omitted)).
[45] *MedEnvios*, 2024 WL 1252264, at *5.
[46] *Id.* at *3–4; *see also Compass* Ruling, at *8–13 (granting in part the defendant-Secretary's motion for summary judgment and holding that zero-paid claims need not be included in the sampling process).
[47] *See Am. Hosp. Ass'n v. Becerra*, No. 14-cv-00851, *Joint Status Report*, at *3 (ECF No. 117), *available at:* https://www.aha.org/system/files/media/file/2023/04/alj-delay-april-2023-status-report-filed-4-7-23-re-aha-hospitals-sue-to-require-hhs-to-meet-deadlines-for-deciding-appeals.pdf?mkt_tok=NzEwLVpMTC02NTEAAAGLDCr1KfyVVSh6-ew4oFaCNahtkWNq-f1558B93RRiwag6IZ_Vh-QKcSYoO3mV2AGaXDiCnQy0zJbvTJaYJ2v7ZiQn30PnawMZW3BNfVKVgMmeZA.
[48] *See, e.g.,* 42 U.S.C. §§ 1395ddd(b), 1395g(a); 42 C.F.R. § 421.304; *see also* MPIM, Ch. 8, §§ 8.4.1.3, 8.4.6.3, 8.4.5.2, 8.4.7.1.
[49] *See, e.g., Cent. La. Home Health Care*, 2018 WL 7888523, at *16:

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The DHHS interpretation of the MPIM regulations to exclude all unpaid claims clearly results in a substantially higher overpayment calculation. In this case, that amount was recalculated to about $5,000,000 higher. However, the exclusion of all unpaid claims was recently accepted by a sister court (it was noted as an option, but not discussed). *See Cypress Home Care, Inc.*, 326 F. Supp. 3d at 324. Although it is not the only possible interpretation of that provision, the DHHS' interpretation appears reasonable and, therefore, is afforded deference.

[50] MPIM, Ch. 8, § 8.4.4.4.1.

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