

United States District Court
Southern District of Texas

ENTERED

March 11, 2019

David J. Bradley, Clerk

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
MCALLEN DIVISION

RIO HOME CARE, LLC,

Plaintiff,

VS.

ALEX M. AZAR, II,¹ *et al.*,

Defendants.

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CIVIL ACTION NO. 7:17-CV-116

REPORT AND RECOMMENDATION

Plaintiff Rio Home Care, LLC (“Rio”) seeks judicial review of a decision by Defendant Secretary of Health and Human Services (“HHS”) finding that Rio was overpaid \$4,079,073 on Medicare claims it submitted for home health care services. An HHS program integrity contractor audited a sample of 41 claims that Rio submitted during a two-year period and found that 35 of them did not qualify for Medicare coverage—an error rate of 85 percent. The total overpayment amount was determined by a statistical extrapolation from the 41 audited sample claims to the 2,197 similar claims that Rio submitted during the two-year period.

After receiving notice of the overpayment, Rio invoked the multi-level Medicare administrative review process. In addition to challenging the determination that the 35 claims were not covered by Medicare, Rio contested the statistical validity of the sampling method and the extrapolation. Rio later also claimed that its due process rights were violated by the HHS contractor’s excessive delay in providing some of the statistical data needed to test the overpayment determination.

¹ Effective January 29, 2018, Alex M. Azar II replaced Tom Price as the Secretary of the U.S. Department of Health and Human Services. Pursuant to Rule 25 of the Federal Rules of Civil Procedure, Mr. Azar “is automatically substituted as a party.” FED. R. CIV. P. 25(d).

After adverse rulings at the initial levels of administrative review, an Administrative Law Judge (“ALJ”) issued a decision that was partially favorable to Rio. Although the ALJ affirmed the determination that Medicare coverage was properly denied for the 35 individual claims that were audited, he also found that the statistical sample was invalid, that the extrapolated amount was not properly determined, and that Rio’s due process rights were violated. However, the ALJ’s decision regarding the statistical validity of the sampling and extrapolation was reviewed by the Medicare Appeals Council (“Council”), which reversed the portions of the ALJ’s decision that were favorable to Rio. The Council found that the sampling and extrapolation were statistically valid and that Rio’s due process rights had not been violated. Rio did not challenge the ALJ’s adverse rulings on the individual claims, and the Council did not address that issue.

In seeking judicial review of the Secretary’s final administrative decision, Rio asserts three principal claims: 1) that the selection of the sample deviated from applicable statistical standards; 2) that an impermissible extrapolation method was used; and 3) that Rio’s due process rights were violated as a result of the HHS contractor’s lengthy delay in providing Rio with statistical data. Rio also challenges the ALJ’s rulings on the individual claims. The parties have fully briefed the issues in cross-motions for summary judgment. (Docket Nos. 34, 39, 42.) In addition to responding to the claims asserted by Rio, the Secretary contends that Rio failed to exhaust its administrative remedies regarding the individual coverage determinations.

After carefully considering the parties’ briefing, the record, and the applicable law, the undersigned concludes that Rio’s request to set aside the Council’s decision should be denied. When considered in light of the deferential standard of review that applies, Rio has failed to show that the Council’s decision upholding the overpayment determination lacks substantial evidence, that it is arbitrary and capricious, or that it is otherwise contrary to law. Although Rio relies on

opinion evidence from its well-qualified expert statistician in challenging the sampling and extrapolation methodology, the Council's decision is supported by substantial evidence, including evidence from several qualified statisticians. And while the HHS contractor's delay in providing some of the relevant statistical data is troubling and should not be condoned, Rio has failed to show that this conduct violated its constitutional right to due process. At the end of the day, Rio received the needed data and used it in arguments before the ALJ and the Council, and both the ALJ and the Council conducted a de novo review of Rio's claims. Because Rio did not request Council review of the ALJ's decision denying the individual claims, those claims are unexhausted and not properly before the Court. Accordingly, for the reasons explained further below, it is recommended that Rio's summary judgment motion be denied and that the Secretary's motion be granted.

I. BACKGROUND²

Plaintiff Rio provides home health care services to patients in south Texas. "The Medicare program reimburses health care providers who render services to Medicare beneficiaries." *Maxmed Healthcare, Inc. v. Price*, 860 F.3d 335, 337 (5th Cir. 2017). This case is about whether and how much Rio was overpaid on claims for services to Medicare beneficiaries.

A. Medicare Reimbursement to Health Care Providers

"Medicare is a federally funded health insurance program for the elderly and disabled." *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 506 (1994); *see* 42 U.S.C. § 1395 *et seq.* (the

² The Secretary has filed the voluminous Administrative Record. (Docket No. 36.) The Record includes well over 20,000 pages, although the most relevant parts of the record are found in the first 1,649 pages. Those pages will be cited as "R." and will refer to the page numbering in the bottom right corner of each page. (*See* Docket Nos. 36-2 (R. 1-550), 36-3 (R. 551-1100), 36-4 (R. 1101-1649).) The Record has been filed under seal because it is replete with "information related to patient medical records, treatment and diagnosis, and personal identification information." (*See* Docket No. 35, at 1.)

“Medicare Act”). The Medicare program is administered by HHS. The Centers for Medicare and Medicaid Services (“CMS”) is a division of HHS and is responsible for overseeing the Medicare program. CMS, in turn, contracts with private government contractors, called Medicare Administrative Contractors, to process and make payments on Medicare claims.³ *See* 42 U.S.C. § 1395kk-1; 42 C.F.R. §§ 405.904(a)(2), 421.401.

The Medicare Act provides that “no payment may be made ... for any expenses incurred for items or services ... which... are not reasonable and necessary for the diagnosis or treatment of illness or injury. ...” 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 411.15(k)(1). Medicare providers bear the burden of maintaining and producing information to support their payment claims. *See* 42 C.F.R. § 424.5(a)(6).

Enormous numbers of Medicare claims are submitted each year.⁴ To expedite claims processing, Medicare contractors generally reimburse providers for services before reviewing the medical records relating to the claims and verifying that the claims are valid. *See John Balko & Assocs., Inc. v. Sec’y U.S. Dep’t of Health & Human Servs.*, 555 F. App’x 188, 190 (3d Cir. 2014); *see also* 42 C.F.R. § 405.922 (time frame for processing initial determinations).

³ The acronym “MAC” is sometimes used to refer to a Medicare Administrative Contractor. MAC is used this way in the regulations and by some courts as well. *See* 42 C.F.R. § 421.401 (defining a “Medicare Administrative Contractor (MAC)”); *San Bois Health Services, Inc. v. Hargan*, No. CIV-14-560-RAW, 2017 WL 5140519 at *1 n.2 (using “MAC” to refer to Medicare Administrative Contractors). However, MAC is also sometimes used to refer to the Medicare Appeals Council. *See* R. 41 n.7 (ALJ referring to “MAC decision”); *Transyd Enterprises, L.L.C. v. Sebelius*, Civil Action No. M-09-292, 2012 WL 1067561 at *1 (S.D. Tex. 2012) (referring to the Medicare Appeals Council as “MAC”). To lessen acronym confusion, in this report “MAC” will not be used to refer either to the Medicare Appeals Council or to the Medicare Administrative Contractor.

⁴ For example, during 2017, CMS and its contractors processed over *one billion* Medicare claims. *See* CMS Financial Report FY 2017 (found at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CFORreport/Downloads/2017_CMS_Financial_Report.pdf).

While this process provides faster payments to providers, it also results in huge amounts of Medicare overpayments.⁵ “Congress created the Medicare Integrity Program through which the Secretary contracts with private entities ‘for the purpose of identifying underpayments and overpayments and recouping overpayments[.]’” *Maxmed Healthcare, Inc.*, 860 F.3d at 337 (quoting 42 U.S.C. § 1395ddd(a), (h)(1)). The Medicare Integrity Program established a procedure to review payments made to providers to “increase the effectiveness of the [Medicare Program] through cost avoidance, savings, and recoupments of fraudulent, wasteful, or abusive expenditures.” 42 U.S.C. § 1395ddd(g)(1)(A)(iii). Payments initially made by Medicare contractors “may then be audited by Zone Program Integrity Contractors (‘ZPICs’). When a ZPIC identifies an overpayment, it notifies the relevant [Medicare Administrative Contractor], which then issues a demand letter to the provider.” *Family Rehab., Inc. v. Azar*, 886 F.3d 496, 499 (5th Cir. 2018) (footnote omitted); *see* 42 U.S.C. § 1395ddd(g), (h).

In a 1986 administrative ruling, CMS approved the use of statistical sampling and extrapolation in determining whether there has been an overpayment and in calculating the total amount of any overpayment. *See* Ruling 86-1 at 10.⁶ It is now well-settled that “[e]xtrapolation is one permissible method of calculating overpayments. In particular, Congress authorized Medicare contractors to ‘use extrapolation to determine overpayment amounts’ if the Secretary

⁵ For example, in a congressionally-mandated 2016 “Improper Payments Report,” CMS found that “Medicare paid an estimated \$41.1 billion incorrectly between July 1, 2014 and June 30, 2015.” *See* CMS “Medicare Fee-For-Service 2016 Improper Payments Report,” at 1-2, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/Downloads/MedicareFeeforService2016ImproperPaymentsReport.pdf>.

⁶ The predecessor of CMS was the Health Care Financing Administration (“HCFA”). Ruling 86-1 was issued by HCFA on February 20, 1986, and is available online at: <https://www.cms.gov/Medicare/Appeals-and-Grievances/OrgMedFFSAppeals/Downloads/HCFAR861v508.pdf>.

determines that “there is a sustained or high level of payment error.” *Maxmed Healthcare, Inc.*, 860 F.3d at 337 (citing 42 U.S.C. § 1395ddd(f)(3)(A)). CMS has developed guidelines for the use of statistical sampling and extrapolation in estimating overpayments, which are found in its Medicare Program Integrity Manual (“MPIM”).⁷

Health care providers can challenge a ZPIC’s overpayment determination through an elaborate five-step appeal process:

Providers who dispute an overpayment determination may challenge it in a lengthy appeal process. At the outset, a Medicare Administrative Contractor makes an “initial determination” regarding the overpayment amount. *See* 42 C.F.R. § 405.920. A provider who is displeased with the Medicare Administrative Contractor’s initial determination may then seek a “redetermination”—the first step in a five-step appeal process. *Id.* §§ 405.940–958. The redetermination is conducted by employees of the Medicare Administrative Contractor who were not involved in the initial determination. *Id.* § 405.948. Second, if the provider remains dissatisfied, the provider may request a “reconsideration.” *Id.* § 405.960. A Qualified Independent Contractor [QIC], another private contractor, conducts the “independent” reconsideration. *Id.* § 405.968. Third, if the provider still remains dissatisfied, the provider may request a hearing before an administrative law judge (ALJ). *Id.* § 405.1000(a). The ALJ reviews the case *de novo*. *Id.* § 405.1000(d). Fourth, either the provider or CMS, through its contractors, may request that the Medicare Appeals Council (Council) review the ALJ’s decision. *Id.* § 405.1100(a). The Council, like the ALJ, reviews the case *de novo*, and its decision constitutes the Secretary’s final decision. *Id.* § 405.1000(c). Fifth, if all else fails, the provider is entitled to “judicial review of the Secretary’s final decision ... as is provided in section 405(g) of this title.” 42 U.S.C. § 1395ff(b)(1)(A).

Maxmed Healthcare, Inc., 860 F.3d at 338.

B. CMS Audit of Medicare Payments Made to Rio

During the two-year period from June 1, 2007, to May 31, 2009, Rio submitted over two thousand claims for Medicare coverage of home health care services it rendered to Medicare

⁷ The MPIM may be found at: <https://www.cms.gov/regulations-and-guidance/guidance/manuals/internet-only-manuals-ioms-items/cms019033.html> (last visited March 8, 2018). A copy of Chapter 8 of the MPIM, which addresses statistical sampling for overpayment estimates, has been filed in this action. (Docket No. 39-1.)

beneficiaries.⁸ Palmetto GBA, L.L.C. (“Palmetto”) was the Medicare Administrative Contractor responsible for paying the home health care claims submitted by Rio.⁹

CMS also contracted with Health Integrity, LLC (“Health Integrity”) to conduct fraud and overpayment investigations as the Zone Program Integrity Contractor (ZPIC) in Texas. Based on an analysis of billing data, Health Integrity conducted an audit of Rio’s claims for Medicare coverage. The Council summarized Health Integrity’s review as follows:

By letter dated August 19, 2009, Health Integrity, a Zone Program Integrity Contractor (ZPIC), notified the appellate [Rio] that it was conducting a review of the appellant’s claims for Medicare coverage of home health services. The ZPIC [Health Integrity] requested records for services furnished from January 1, 2007 to August 19, 2009. *See* ALJ Master Claim File (MCF), Exh. 10 at 20-21. On November 2, 2009, the ZPIC issued a “Provider Summary of Medical Review Findings.” *See id.* at 27-33. There, the ZPIC indicated that it had reviewed forty-one claims for the period June 9, 2007 through May 12, 2009, denying coverage for thirty-five claims, an 85% error rate. *See id.* at 27. The remainder of the Summary presented claim-specific examples of the coverage issues encountered. *See id.* at 28-33.

By letter dated February 18, 2011, the ZPIC notified the appellant of its preliminary audit results. *See* MCF, Exh. 10 at 27-33. The ZPIC explained that its audit had resulted in an extrapolated overpayment totaling \$4,079,073 for claims with payment dates spanning June 1, 2007 through May 31, 2009. The ZPIC indicated that it had relied upon a “statistically valid random sample” of forty-one claims drawn from a 2,179 claim universe. The ZPIC added that it had “enclosed [an] encrypted CD” setting out the sampling methodology in greater detail. *See id.* at 34-35. The appellant’s Medicare contractor [Palmetto] provided formal notice of the disallowance by letter dated February 28, 2011. *See id.* at 49-52.

By letter dated April 19, 2011, and in reliance upon the coverage determinations emanating from its audit, the ZPIC notified the appellant that its Medicare payments had been suspended. *See* MCF, Exh. 10 at 38-41.

(R. 5-6.)

⁸ For example, the record reflects that during the two-year period at issue here, June 2007 to May 2009, the number of claims included in the audit was 2,179. But the audit did not include all the claims Rio submitted during that period.

⁹ Rio initially named Palmetto as a Defendant in its Complaint. (Docket No. 1, at 1, 4.) Palmetto was later dismissed as a party. (*See* Docket Nos. 43-46.)

Rio was paid \$5,609,692.22 for the 2,179 claims under review. (R. 434, 1220.) In auditing the 41 claims in the sample, Health Integrity personnel reviewed the medical records provided by Rio and interviewed many of the patients (sometimes with a family member also present).¹⁰ In determining that 35 of the 41 claims reviewed should not have been paid, Health Integrity found that 30 of these claims did not meet Medicare home health care coverage requirements both because the patient was not homebound and because the services were not medically reasonable or necessary. (See Docket No. 34, at 2.) Of the remaining five denied claims, three patients were found to be not homebound, and for the other two, the services were found to be not medically reasonable or necessary.

C. Rio's Request for Additional Information

Along with the February 18, 2011, letter informing Rio of the “extrapolated overpayment” amount and explaining how it was determined, Health Integrity provided Rio with a CD that contained information about the sampling methodology that was used. (R. 1304-08.) On March 21, 2011, Rio’s counsel sent a letter to Health Integrity, Palmetto, and CMS’s Freedom of Information Division, informing them that “the CD does not include the entire universe of claims and requesting “an Excel spreadsheet on a CD itemizing the 2,179 claims that comprise the ‘universe’ of claims.”¹¹ (R. 235-36.) Rio’s counsel provided specific instructions on how the spreadsheet should be formatted and what should be included (specifying 13 items). (R. 236.)

¹⁰ At least two Health Integrity representatives (including a health care professional and an investigator) were present during each interview.

¹¹ Rio’s counsel noted in the letter that Health Integrity had described the universe as follows: “According to Health Integrity, LLC, the ‘universe’ consists of 2,179 claims for codes G0151, G0152, G0154 & G0155 with dates of service 06/01/2007-05/31/2009.” (R. 236.)

The requested additional information was not forthcoming, and Rio's counsel periodically renewed the request with follow-up letters. Rio describes this effort and its unsatisfactory results as follows:

Following up on its March 21, 2011 correspondence, Plaintiff's counsel sent 8 subsequent letters requesting the relevant audit files, including all document[s] relating to statistical sampling, to CMS, ZPIC, and Palmetto on April 25, 2011, June 6, 2011, June 23, 2011, July 22, 2011, November 8, 2011, March 28, 2013, April 23, 2013 and November 12, 2013. *See* A.R. 0235-0236, A.R. 0247-0248, A.R. 0259-260, A.R. 0265-0268, A.R. 0309-0310, A.R. 0324-0326, and A.R. 0343-0345, and A.R. 0859-861.

In response, Plaintiff received multiple correspondences from the Defendant over a 2-year period stating that the requested documentation was either "being reviewed," "taking longer than expected due to the voluminous amount of information requested," and — due to the length of time the request was taking — inquiring as to whether Plaintiff still wanted the requested information. *See* A.R. 0261, A.R. 366, A.R. 368-372, A.R. 375, A.R. 379, and A.R. 0858. Finally, in November 2013, Defendant provided a disc purporting to contain the universe of claim data. However, the information produced was incomplete and unusable.

(Docket No. 34, at 5.) The failure of CMS and its contractors to provide the information requested by Rio was to become a prominent issue as Rio proceeded through the administrative appeal process.

D. Rio's Administrative Appeal

1. Request for Redetermination

After receiving notice of Health Integrity's overpayment determination, Rio promptly invoked the administrative appeal process to challenge it. At the first step of that process, Rio sought a redetermination by Palmetto employees who were not involved in Health Integrity's determination. Between May 24, 2011, and June 8, 2011, Palmetto issued a series of redetermination decisions upholding the overpayment finding as to each beneficiary. Palmetto's unfavorable redetermination decisions did not address the statistical sampling methodology used

by Health Integrity to project the total overpayment from the actual overpayment found in the sample. (*See* R. 6.)

2. Qualified Independent Contractor Reconsideration

Rio then invoked the second step of the appeal process by requesting reconsideration by a Qualified Independent Contractor (QIC). Maximus Federal Services, Inc. (“Maximus”), located in Pennsylvania, was the QIC that decided Rio’s request for reconsideration. The Maximus employees and contractors who participated in the reconsideration signed conflict-of-interest statements attesting that they had no connection to or relationship with Health Integrity or Palmetto. (R. 1215-16 (health care professionals), 1225 (statistician).) Rio’s request for reconsideration argued both that Health Integrity and Palmetto were wrong in rejecting the 35 individual claims and that the sampling methodology used to determine the overpayment amount was “significantly flawed.” (R. 1228-34.) In support of the latter argument, Rio submitted a preliminary report by a statistician, Dr. Bruce Kardon. (R. 1232, 1251-71.) Rio noted that the report was incomplete due to the failure of Health Integrity and Palmetto to provide it with “the universe of claims.” (R. 1232.)

After conducting its review, Maximus sent Rio a 78-page written decision on October 21, 2011, denying Rio’s various claims. (R. 1075-1152.) As to each of the challenged individual claims, Maximus found that Rio was not entitled to payment because the claims did not meet Medicare’s criteria for home health services. Maximus’s decision included a detailed explanation as to why each claim was overpaid, with a specific discussion of each patient’s medical records and the information that had been obtained from patient interviews.¹² (R. 1082-1147.) The

¹² As to one of the individual claims, later referred to as “Beneficiary-32,” Maximus informed Rio that the claim was being dismissed because Rio had not obtained a redetermination ruling on that claim from Palmetto. (R. 1075.) Maximus pointed out that Rio “must first appeal to Palmetto

decision regarding the individual claims was supported by a lengthy (52-page) and detailed assessment performed by two licensed health care professionals, who reviewed each patient's medical records and interview responses. (R. 1155-1207.) Ultimately, both of the medical reviewers concluded that none of the services at issue were "medically reasonable and necessary." (R. 1210-14.) Both reviewers attested that, in addition to being free from any conflict of interest, they possessed the appropriate expertise to perform the medical review. (R. 1215-16.)

As to the validity of the sampling methodology and statistical extrapolation, Maximus explained the steps taken in a review performed by a qualified statistician. (R. 1148-51.) Based on that review, Maximus "determined that the methods used by Health Integrity LLC were consistent with both the Medicare guidelines and generally accepted statistical practice." (R. 1151.) The statistical review was performed by Daniel Teitelbaum, Ph.D. (R. 1218-25.) Dr. Teitelbaum "was able to fully replicate the statistical findings made by Health Integrity," and he explained the specific steps he took to do this. (R. 1223-24.) Dr. Teitelbaum opined that there were no errors or deviations from the relevant statistical extrapolation procedures. (R. 1222.)

3. Evidentiary Hearing before the ALJ

Disappointed with the unfavorable decision by the QIC, Rio took the next step in the administrative appeal process by requesting a hearing before an Administrative Law Judge (ALJ). Rio sought de novo review by the ALJ of both the adverse individual coverage determinations and the statistical sampling and extrapolation methodology. A pre-hearing conference was held, and the ALJ set an evidentiary hearing for May 19, 2015. A few days prior to the hearing, Rio's

GBA." (*Id.*) Rio was further advised that if Palmetto made an unfavorable ruling on that claim, then Rio could request that it be reconsidered by Maximus. (*Id.*) There is no indication in the record that Rio subsequently attempted to obtain a redetermination by Palmetto on this claim. This claim will be discussed further in the context of the ALJ's decision.

counsel submitted a 17-page brief, together with over 200 pages of exhibits, in support of Rio's arguments. (R. 194-212 (brief); R. 213-424 (exhibits).) Among other things, Rio's counsel described—and provided copies of—the numerous letters sent to Health Integrity, Palmetto, and CMS attempting to obtain additional information related to the statistical sampling. (R. 198-99.) As stated by Rio's counsel, on the “eve of trial,” May 14, 2015, Rio finally received from Health Integrity the additional statistical information that it had been requesting for so long.¹³ (R. 199.)

In challenging Health Integrity's statistical sampling methodology, Rio relied on the report of its expert, Dr. Harold S. Haller, who obtained a Ph.D. from Case Western Reserve University. (R. 206, 825, 1543.) Rio's initial pre-hearing submission included the initial “Declaration of Harold S. Haller, PhD.” (R. 383-86 (declaration); R. 387-424 (attachments to declaration).) Dr. Haller opined that there were multiple errors in the statistical sampling, all of which related to the failure of Health Integrity to provide complete information. (R. 384-85.) Dr. Haller's initial report was prepared on May 11, 2015, which was before Health Integrity provided additional statistical information (on May 14, 2015). (R. 386.)

After receiving the additional information from Health Integrity, Dr. Haller prepared an “Addendum” to his initial report in which he provides a detailed statistical analysis of Health Integrity's audit and extrapolation. (R. 818-48.) Including attached exhibits, Dr. Haller's addendum is a 30-page document. The Addendum is dated May 18, 2015, which was the day before the evidentiary hearing, and it was submitted to the ALJ just prior to the hearing. (R. 824, 1546.) Based on his analysis, Dr. Haller opined that the 41-claim sample was “non-representative and non-random.” (R. 823.) Dr. Haller further concluded that, because “the distribution of sample

¹³ The additional information was submitted by an attorney with Chase Consulting Group, LLC, on behalf of Health Integrity. (R. 851.)

average overpayments was not normal,” the extrapolation was “invalid” and “meaningless.” (R. 823-24.)

The ALJ conducted a telephonic evidentiary hearing on May 19, 2015. Counsel for Rio appeared, along with two witnesses for Rio, Dr. Haller and Christina Pantoja, R.N. (R. 1540-41.) Neither CMS nor any of its contractors participated in the telephonic hearing. The ALJ noted that the additional materials submitted on behalf of Rio would become part of the record. (R. 1541-42.) The ALJ also stated that he considered Dr. Haller to be an expert witness. (R. 1542.)

Dr. Haller began his testimony by explaining that Health Integrity was required by the Medicare Program Integrity Manual (MPIM) to maintain and produce information relating to its statistical extrapolation and that it had failed to do so in a timely fashion. (R. 1543-45.) In preparation for the hearing, Dr. Haller reviewed the additional statistical information submitted by Health Integrity, although it was produced just a few days before. (R. 1545-48, 1551.) Based on that review, Dr. Haller testified that Health Integrity’s statistical extrapolation was “invalid for a number of reasons.” (R. 1551.) To begin with, Dr. Haller found that “the universe [of claims] was not correctly defined” and was “contaminated.” (R. 1552.) He reached this conclusion because when he looked at the universe, he found that “it contained 2,185 claims, not 2,179” as determined by Health Integrity. (R. 1552-53.)

Another flaw identified by Dr. Haller was that Health Integrity did not provide the random numbers used to select the sample so that he was unable to test whether they had obtained a random sample. (R. 1555.) In comparing the distribution of the dollar amounts in the sample claims to the universe of claims in the frame, Dr. Haller found that “the sample was shifted to the right, with higher proportions of higher amounts paid in the claims in the sample than in the frame.” (R. 1556.) From this, Dr. Haller concluded that “there was some judgment used that was not random

in selecting the samples for the audit, namely, those samples that corresponded to the higher dollar values.” (R. 1556.) In other words, Dr. Haller believed that there was “some human intervention” in “cherry picking[ing]” the “higher paid claims rather than a random sample.” (R. 1558.) Dr. Haller agreed with Rio’s counsel that “someone manipulated the information in the so-called random sample in order to come up with a higher extrapolated amount,” although he did not “know how they did it.” (R. 1562-63.)

Dr. Haller also criticized the sampling methodology because Health Integrity did not provide the curriculum vitae (CV) for the person who apparently performed the analysis, Alan Moskowitz. (R. 1565.) This omission was contrary to the MPIM and prevented Dr. Haller from determining whether the person who performed the sampling and extrapolation was qualified to do so. (R. 1565-66.)

Dr. Haller’s other principal point was that the extrapolation was invalid. The statement by Health Integrity that they are 90 percent confident that the actual overpayment was at least \$4,079,073 “is an absolutely meaningless statement.” (R. 1573.) According to Dr. Haller, the statement is meaningless “because the distribution of the averages [of overpayments] are not normally distributed.” (R. 1573, 1575-76.)

The second part of the hearing was devoted to the testimony of Ms. Pantoja. She is a long-time registered nurse with experience in assessing whether a patient meets the Medicare criteria for home health care. (R. 1582.) Ms. Pantoja testified at length about each of the 35 patients whose Medicare claims were found to be in error, highlighting evidence about their medical condition that supported the conclusion that they were homebound and that the medical services provided to them were medically necessary. (R. 1584-1646.) As to each of these 35 claims, Ms.

Pantoja expressed her opinion that the patient was homebound and that the medical services provided by Rio were medically necessary. (*Id.*)

Following the hearing, the ALJ “left the record open for sixty (60) days to allow Appellant [Rio] the opportunity to submit a post hearing position paper and additional documents.” (R. 40.) On June 1, 2015, Health Integrity submitted a “Statistical Position Paper” regarding its audit of Rio. (R. 426-444.) The paper was authored by Aimee Mason, M.S., who was then Health Integrity’s chief statistician. (R. 444.) Ms. Mason verified and repeated each step of the statistical sampling procedure used by Health Integrity in calculating the overpayment. “The sample was randomly selected using a SAS [statistical software] program that allowed each sample of 45 claims to have an equal chance of being drawn.” (R. 428.) Ms. Mason was able to re-create and verify the original random numbers that were generated. (R. 433-38.) She confirmed that “the SAS sample selection program ran correctly selecting a simple random sample from the universe of claims.” (R. 437.)

Ms. Mason also discussed in detail the extrapolation procedure that was used and verified the extrapolation amount that was calculated (\$4,079,073) was correct—again relying on agency-approved statistical software, called “RAT-STATS.”¹⁴ (R. 439-43.) She found that the extrapolation was “in full compliance” with the MPIM, including “the conservative approach taken by Health Integrity in estimating the overpayment amount.” (R. 443.) In summarizing her review, Ms. Mason opined that the sampling and extrapolation used to determine Rio’s overpayment amount were “statistically valid” and consistent with the guidelines in the MPIM. (R. 443.)

¹⁴ The RAT-STATS software package was used for the extrapolation. It is the official software adopted by HHS’s Office of the Inspector General. (R. 429, 441-43.)

Health Integrity also submitted a post-hearing position paper regarding the medical review of the 35 individual claims that were denied. (R. 445-97.) This paper discussed the standard for Medicare coverage of home health care services and addressed in detail the medical evidence relating to each of the 35 patients. In addition, Health Integrity provided copies of the interview notes for each patient, which totaled over 300 pages. (R. 507-815.)

In a submission dated June 25, 2015, Rio filed a post-hearing paper in response to the papers filed by Health Integrity. (R. 178-86.) Rio presented arguments addressing both Health Integrity's statistical paper and its paper addressing the individual medical claims review. In support of its post-hearing paper, Rio also submitted a "Rebuttal" by Dr. Haller to Health Integrity's statistical paper.¹⁵ (R. 187-92.)

4. The ALJ's Decision

On September 7, 2016, the ALJ entered his written decision. The ALJ summarized the findings of Health Integrity, as the ZPIC:

The Zone Program Integrity Contactor (ZPIC) found Appellant [Rio] received an overpayment on 35 out of 41 claims for home health services billed for 40 beneficiaries during the examination period of June 1, 2007, through May 31, 2009. The ZPIC found an 85 percent error rate on the claims and used statistical sampling methodology to calculate an extrapolated overpayment of \$4,079,073.00 for all claims filed by Appellant during the examination period.

(R. 40.)

The ALJ conducted "a de novo review of the record." (R. 62.) After thoroughly describing the applicable legal framework (R. 41-45), the ALJ listed six issues to be decided, two of which are particularly important here: 1) "Are the remaining home health services provided by [Rio] covered by Medicare?"; and 2) "[W]as valid stistical sampling performed to extrapolate the

¹⁵ The post-hearing position papers by Health Integrity and Rio were submitted within the 60-day period during which the ALJ had left the record open. (R. 40.)

overpayment amount?” (R. 45-46.) As to the first issue, the ALJ’s ruling was unfavorable to Rio, but he ruled in Rio’s favor on the second issue.

In addressing the first issue, the ALJ made detailed findings of fact on the medical evidence in the record relating to each of the 35 patients whose claims were rejected. (R. 46-57.) As to one claim, identified as “Beneficiary-32,” the ALJ noted that the Medicare carrier (Palmetto) had “denied” this claim in its redetermination decision because no documentation was provided for the dates of service covered by the claim. (R. 56.) Based on Palmetto’s decision, the QIC (Maximus) dismissed this claim in its independent reconsideration decision. (R. 56; *see also supra* n.12.) Because there was no redetermination decision for Beneficiary-32 and because Rio “has not provided evidence or documentation demonstrating the carrier issued a redetermination decision” on this claim, the ALJ found “no error in the QIC’s dismissal of [Rio’s] reconsideration request on its claim for the services provided to Beneficiary-32.” (R. 58-59.) The ALJ thus ruled that “QIC’s dismissal is upheld and remains in effect.”¹⁶ (R. 59.)

In considering whether the remaining claims for home health services were covered by Medicare, the ALJ summarized the testimony of Ms. Pantoja on behalf of Rio at the evidentiary hearing. (R. 58.) The ALJ concluded as follows:

¹⁶ In the context of Rio’s summary judgment briefing challenging Health Integrity’s sampling and extrapolation methodology, Rio includes an argument that is apparently based on the claim relating to Beneficiary-32. (Docket No. 34, at 16.) Rio contends: “Defendant and its contractors, in reversing their decisions in denying one of the 41 claims audited, failed to recalculate the extrapolation to permit correction of the sampling errors.” (*Id.*) Rio’s argument appears to be based on the premise that there was “one claim found favorable at the ALJ hearing.” (*Id.* at 7; citing R. 62.) This is clearly wrong. The ALJ found that Maximus had properly dismissed Rio’s claim relating to Beneficiary-32 due to lack of evidence. (R. 58-59; *see also supra* n.12.) The ALJ stated that the overpayment amount Rio owed on the individual coverage claims included the “unfavorable and *dismissed* claims in Table A.” (R. 62; emphasis added.) Table A identifies Beneficiary-32 as a “DISMISSED” claim. (R. 61.) Rio did not prevail on any of the 35 individual claims that were denied, and its argument based on a contrary assumption is meritless.

Beneficiary 1-31 and 33-35: I am not persuaded by the [Rio's] argument. To qualify for Medicare coverage of home health services a beneficiary must be homebound. The record shows the beneficiaries are up as tolerated and able to complete ADLs [activities of daily living] with supervision to minimal assistance. The record does not demonstrate the beneficiaries are homebound. In addition, skilled nursing services must be needed when there are significant changes in a patient's condition, medication, or treatment plan and for services that require the skills of a nurse. During the dates of service (DOS) at issue, a nurse assessed the beneficiaries' safety, provided education, monitored compliance with medication regimens, and supervised a home health aide. The record shows the beneficiaries received general nursing, education and medical monitoring services, and there were no significant changes in their conditions, medications, or plans of care (POC). The record does not demonstrate the beneficiaries needed skilled nursing services required to qualify for Medicare home health services. Furthermore, the record shows the beneficiaries did not receive skilled nursing services on an intermittent basis but received the services for periods far exceeding the expected 2-3 week period and for chronic, ongoing conditions (FOF 2-94, 97-105). I therefore find the home health services provided to Beneficiary 1-31 and 33-35 are not covered by Medicare and enter unfavorable (UNFAV) decisions for [Rio] on these claims.

(R. 58.) The ALJ further found that, as "a Medicare provider, Appellant [Rio] knew or should have known the services are not covered." (R. 62.)

In addressing whether valid statistical sampling was used to extrapolate the overpayment amount, the ALJ summarized the testimony and other evidence from Rio's expert, Dr. Haller. (R. 60.) The ALJ specifically referenced the following reasons given by Dr. Haller to show that the statistical sampling was invalid:

- the ZPIC (Health Integrity) used "incorrect formulas" for estimation and extrapolation;
- the "universe is corrupt because the frame of claims could not be recreated from the universe of claims";
- Health Integrity "used a biased sample and did not provide the random numbers used to draw the sample from the frame of claims"; and
- Health Integrity "did not provide the curriculum vitae (CV) of the statistician who designed the sampling plan."

(*Id.*)

The ALJ was persuaded by two of these points. First, the ALJ found that Health Integrity used an impermissible confidence interval in extrapolating the overpayment amount:

Confidence Level: The lower limit of a one-sided 90 percent confidence level shall be used as the amount of overpayment to be demanded for recovery from the provider or supplier (MPIM, Ch. 3, §3.1 0.5.1). Both the ZPIC’s report to the carrier and the carrier’s notice of overpayment lists an overpayment amount of \$4,079,073 (MCF, Exhibit 1, Pages 211; MCF, Exhibit 9, Page 17). The record indicates the ZPIC used an 80 percent two-sided confidence level to determine the extrapolated overpayment amount in this case (MCF, Exhibit 9, Pages 13-18). Although the ZPIC’s use of an 80 percent two-sided confidence level results in a lower overpayment amount to the benefit of [Rio], use of this type or confidence level was not allowed under the version of the applicable policy (i.e. version of the MPIM, Chapter 3) in effect on the date of the ZPIC’s decision.

(R. 60.)

The ALJ also concluded that the sampling and extrapolation was invalid because Health Integrity failed to keep the random numbers used to create the sample:

Sample: A record shall be kept of the random numbers actually used in the sample and how they were selected (MPIM, Ch. 3, §3.10.4.4). The size of the sample will have a direct bearing on the precision of the estimated overpayment, but it is not the only factor (MPIM, Ch. 3, §3.1 0.4.3). In its position paper, the ZPIC [Health Integrity] indicates the random numbers are not available because its statistical analysis software generates different random numbers with each sample re-run (Exhibit 9, Page 4).

The ZPIC’s failure to maintain the random numbers actually used in the sample and its inability to reproduce those numbers prevents Appellant from recreating the sample and independently verifying the extrapolation. The ZPIC’s failure significantly limits Appellant’s ability to both analyze and defend against the extrapolation.

(R. 60-61.)

For both of those reasons, the ALJ found that “the extrapolated amount is invalid.” (R. 61.) The ALJ also found that Health Integrity had violated Rio’s due process rights, noting the “repeated requests” by Rio “for a copy of the statistical data” used by Health Integrity in conducting the audit. (*Id.*) The ALJ explained:

It is well established that due process affords an appellant the right to mount a proper challenge during the appeals process. By not timely producing the data, the ZPIC deprived Appellant of the ability to thoroughly review the extrapolation prior to the hearing. The ZPIC also deprived Appellant of the ability to challenge the extrapolation at the lower appeal levels. I therefore also find the extrapolated amount is invalid based on the willful and deliberate actions of the ZPIC that denied Appellant due process during the appeals process.

(*Id.*)

Due to Health Integrity's "willful" delay in failing to provide documentation to Rio, the ALJ determined that CMS should not be allowed to correct the statistical sampling errors. (R. 61.) This ruling meant that Rio would be required to pay back only the actual overpayment for the 35 sample claims that did not meet Medicare coverage criteria.¹⁷ (R. 62.)

5. Council Review¹⁸

Rio was apparently satisfied with the ALJ's decision—and understandably so. Rio did not request the Medicare Appeals Council to review the ALJ's adverse rulings on the 35 individual coverage claims. CMS, however, urged the Council to review the ALJ's decision regarding the sampling and extrapolation issues, as well as the ALJ's due process ruling. (R. 4, 98-109.)

Rio filed exceptions to the referral for Council review in which it contested the statistical arguments raised by CMS. (R. 32-34.) As part of that response, Rio submitted a "Second Addendum" to Dr. Haller's declaration. (R. 78-97.) Dr. Haller noted that he had performed "additional enhanced analyses of the documents produced by [Health Integrity]." (R. 78.) Dr. Haller asserted that the ALJ was correct and that Health Integrity used "incorrect formulas" for the

¹⁷ In other words, Rio would be responsible for repaying only the \$89,765.60 overpayment on the 35 sample claims that were invalid. But Rio would not have been required to repay any additional amount based on an extrapolation from the 35 sample claims to the universe of 2,197 claims, which Health Integrity determined to be \$4,079,073.

¹⁸ As noted, *see supra* n.3, in this report the Medicare Appeals Council will be referred to as the "Council," rather than as the "MAC," which is the acronym that is also sometimes used.

extrapolation, but his reasoning for this conclusion was again that “one cannot be 90% confident that the total overpayment to the frame exceeds this calculated value if the distribution of the average overpayments is not normally distributed.” (*Id.*; emphasis in original.) Dr. Haller also offered additional analysis in support of his opinion that the 41 claims drawn from the frame (or universe) of claims was not a statistically valid random sample.¹⁹ (R. 81-85.)

The Council decided “on its own motion” to review the ALJ’s decision. (R. 4.) Like the ALJ, the Council conducted a de novo review, except that its review was limited to the statistical and due process issues raised by CMS. (R. 4-5, 27.) After considering the parties’ arguments in light of the evidence in the record, “the Council reverse[d] the ALJ’s decision as it pertains to the validity of the statistical sampling.” (R. 5.)

The Council provided a detailed summary of the case, including a description of Health Integrity’s audit and a discussion of what occurred at each prior step of the appeals process.²⁰ (R. 5-10.) In discussing the applicable law, the Council emphasized CMS’s long-standing “policy on the use of statistical sampling to project overpayments to Medicare providers and suppliers,” which

¹⁹ One possible source of confusion is that the terms “universe” and “frame” appear to be used interchangeably in the record, although their technical meanings may differ in some contexts. *See* MPIM §§ 8.4.3.2, 8.4.3.2.3 (defining universe and sampling frame). Dr. Haller consistently describes the group of claims from which Health Integrity drew the 41-claim sample as “the frame.” (*See, e.g.*, R. 82.) Dr. Haller seems to distinguish between the “universe” of “claim lines” from which the sample might have been drawn and the “frame” of “claims” that was ultimately used to select the sample. (*See* R. 820.) Dr. Teitelbaum, on the other hand, referred to the “2,179 claims in the universe.” (R. 1220, 1224.) In addressing Rio’s challenge to the sampling methodology, the ALJ also described the “universe” as the 2,179 claims from which the sample was drawn. (R. 60.) The distinction between the “universe” and the “frame”—if there is one in some statistical contexts—does not appear to be material in this case. As used in the record in this case, the “frame” and the “universe” both generally refer to the 2,179 claims from which Health Integrity selected the 41 sample claims.

²⁰ The decisions by both the ALJ and the Council were detailed, thorough, and well-written, which certainly assists the Court in fulfilling its role on judicial review.

had been justified and explained in CMS's 1986 administrative ruling, Ruling 86-1. (R. 12-13.)

The Council explained the CMS policy in effect when Health Integrity audited Rio:

CMS' guidelines in effect at the time of this audit were found in Chapter 3 of the Medicare Program Integrity Manual (MPIM) (CMS Pub. 100-08). *See* MPIM, Ch. 3, § 3.10 (eff. 5-10-4; *now* at MPIM, Ch. 8, eff. 6-28-11). Those guidelines reflect the perspective that the time and expense of drawing and reviewing the claims from large sample sizes and finding point estimates which accurately reflect the estimated overpayment with relative precision may not be administratively or economically feasible for contractors performing audits. Instead, the guidelines allow for smaller sample sizes and less precise point estimates, but offset such lack of precision with direction to the contractors to assess the overpayment at the lower level of a confidence interval - generally, the lower level of a ninety percent, one-sided confidence interval. This results in the assumption, in statistical terms, that there is a ninety percent chance that the actual overpayment is higher than the overpayment which is being assessed, thus giving the benefit of the doubt resulting from any imprecision in the estimation of the overpayment to the appellant, not the agency. As a result of the above policy decision, the question becomes whether the sample size and design were sufficiently adequate to provide a meaningful measure of the overpayment, and whether the provider/supplier is treated fairly despite any imprecision in the estimation.

(R. 13.) Ultimately, the guidance provided to contractors in the MPIM is "intended to ensure that a statistically valid sample is drawn and that statistically valid methods are used to project overpayments where review of claims indicates that overpayments have been made." (R. 14.) The Council provided a detailed discussion of the MPIM's guidance to contractors in creating a "probability sample" and in extrapolating from the sample to estimate the total overpayment. (R. 14-19.)

In its analysis of the issues, the Council first addressed the ALJ's conclusion that Health Integrity's extrapolated overpayment amount was invalid because it used an 80 percent two-sided confidence interval that was "not allowed" under the MPIM. (R. 19-22.) The Council disagreed with the ALJ's conclusion that the MPIM prohibited the confidence interval applied by Health Integrity:

The ALJ's reference point for this finding was MPIM, Chapter 3, Section 3.10.5.1. - The Point Estimate, which is set out in its entirety above. Since the audit, section 3.10.5.1 has been moved, verbatim, to Chapter 8, Section 8.4.5.1 of the MPIM. As set out above, CMS manual guidance is not binding on an ALJ or the Council. Moreover, the reference to the use of "the lower limit of a one-sided 90 percent confidence interval" in section 3.10.5.1 is qualified by the phrase "[i]n most instances." Thus, the MPIM does not establish an absolute requirement that only the lower limit of a one-sided 90 percent confidence interval is to be used in sampling. In fact, in instances where precision is obtained, the MPIM contemplates use of the point estimate for recovery rather than the lower confidence level. For reasons discussed in that section, as well as elsewhere in Chapter 3, the lower limit of a one-sided 90 percent confidence interval is the optimal confidence interval chosen by CMS to balance both the interests of CMS and suppliers and providers.

(R. 19.)

The Council also considered and found persuasive CMS's argument that in this case the lower limit of a two-sided 80 percent confidence interval was the same as the lower limit of a one-sided 90 percent confidence interval. (R. 20.) As the Council further noted, "Dr. [Haller] does not appear to dispute the basic principle that the lower limit of a one-sided 90% confidence interval is equivalent to a two-sided 80% confidence interval and frames his analysis of the ZPIC's sampling methodology around a one-sided 90% confidence interval." (R. 21.)

In addressing Dr. Haller's argument that the confidence interval analysis was meaningless because "the distribution of the average overpayments is not normally distributed," the Council concluded:

There is no support in CMS Ruling 86-1 or in the MPIM for the proposition that the non-normality of the sampling unit overpayment distribution within a sample of adequate size demonstrates that the sample is statistically invalid. In fact, in most overpayment cases involving statistical sampling and extrapolation that come before the Council, the individual sampled overpayment results are not normally distributed, yet sampling in Medicare overpayment cases has been widely upheld by the courts. The sample overpayments are extrapolated to the frame using confidence interval estimation in most all of the statistical sampling cases done by CMS contractors and reviewed by the Council.

The Council, like the MPIM guidelines, recognizes that real world constraints impose conflicting demands on limited public funds, constraints which

CMS chose to incorporate into the statistical sampling guidelines. The Council must give substantial deference to CMS guidelines including where, as here, CMS has chosen a reasonable, feasible, and well-articulated approach for collecting overpayments which, by design, offsets precision in favor of lower recovery amounts. ...

(R. 21-22.)

In summarizing its ruling on this issue, the Council explained:

Contrary to the ALJ's interpretation, the ZPIC's utilization of the lower limit of a two-sided 80 percent confidence interval was not prohibited simply because it was not specifically identified in the MPIM guidance applicable during this audit. Moreover, the Council finds CMS' argument that the lower limit of a two-sided 80 percent confidence interval is equivalent to the lower limit of one-sided 90 percent confidence interval to be fully credible. Thus, while utilization of an 80 percent confidence level is neither addressed nor precluded by the MPIM, its application did not render the ZPIC's sampling methodology invalid.

(R. 22.)

The Council also disagreed with the ALJ's ruling that the overpayment was invalid because Health Integrity failed to maintain, and was unable to reproduce, the random numbers used in selecting the sample. (R. 22-26.) The Council quoted at length from CMS's briefing on this issue, which explained that Health Integrity had maintained the random numbers and ultimately provided Rio with both the random numbers used and instructions on how Rio could reproduce and verify the random numbers, following a procedure that took into account an intervening update to the statistical software. (R. 23-26.)

The Council found CMS' explanation persuasive, concluding:

Under the appellant's theory of the case, the fact that the program for generating a random number has changed, an event outside an auditor's control, means that the sampling methodology should be invalidated. As CMS notes, even if the ZPIC had not been able to provide the random numbers to the appellant, the information otherwise provided to the appellant would enable a statistician to replicate the sample. However, the record does, in fact, contain the random numbers associated with each of the forty-one claims comprising the main sample.

(R. 26.)

In addressing whether Health Integrity violated Rio's right to due process by failing to timely produce certain data, the Council thoroughly summarized the record relating to Rio's numerous attempts to obtain additional information. (R. 26-29.) The Council also described information that was available to Rio:

Here, the appellant had a certain level of methodology information provided to it contemporaneous to the overpayment as, although the appellant did not rely on it, the record includes a March 19, 2011 "preliminary review of the documentation received from Health Integrity" produced for the appellant by the Statistician/President of a "management consulting firm specializing in statistics." See MCF, Exh. 1 at 216-227 and 229. Moreover, the appellant's initial (March 21, 2011) request for information acknowledged that with the ZPIC's February 18, 2011 notice of the preliminary audit results, it had been provided a CD with sampling information, which it considered insufficient. As recounted above, between receipt of the notice of overpayment and the hearing, the appellant, through two statisticians, produced reports analyzing the sampling methodology. Further, the methodology-based information provided by the ZPIC, just prior to the hearing, has been analyzed by the appellant's statistical expert in both his hearing testimony as well as three separate written submissions. See MCF, Exh. 8 at 2-8; MCF, Exh. 11 at 12-17 and Exh. MAC-2, Att. D.

(R. 28-29.)

Ultimately, the Council agreed with CMS that Rio's due process rights had not been violated since it had had a full and fair opportunity to present its case to both the ALJ and the Council. (R. 29.) While the Council "does not condone irresponsibility or delay tactics caused by any Medicare contractor," it also noted that if Rio had needed more time to address the statistical issues as a result of the delay, "the remedy would have been to request an extension of time to respond or a delay in the hearing date, not a blanket invalidation of the sampling." (R. 29-30.)

In sum, the Council found "that the ZPIC utilized a valid sampling methodology to arrive at the extrapolated overpayment at issue." (R. 30.) It accordingly reversed the ALJ's decision as it related to the sampling methodology and extrapolation. (*Id.*) The ALJ's findings on the 35 individual claims were "not disturb[ed]" since they were not contested. (*Id.*)

The Council's decision constitutes the final decision of the Secretary. *Maxmed Healthcare, Inc.*, 860 F.3d at 338; *see* 42 C.F.R. § 405.1136 (a party "may obtain a court review" of the Council's decision). The instant action followed in which Plaintiff seeks judicial review of the decision. (Docket No. 1.) Both Rio and the Secretary have filed motions for summary judgment, which have been fully briefed. (Docket Nos. 34, 38, 42.) The issues raised by the parties will be analyzed in light of the applicable standard of review.

II. ANALYSIS

A. Standard of Review

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). The Fifth Circuit has "consistently upheld" the use of summary judgment in judicial review of agency decisions, explaining:

The summary judgment procedure is particularly appropriate in cases in which the court is asked to review or enforce a decision of a federal administrative agency. The explanation for this lies in the relationship between the summary judgment standard of no genuine issue as to any material fact and the nature of judicial review of administrative decisions.... [T]he administrative agency is the fact finder. Judicial review has the function of determining whether the administrative action is consistent with the law—that and no more.

Girling Health Care, Inc. v. Shalala, 85 F.3d 211, 214–15 (5th Cir.1996) (alterations in original) (quoting 10A CHARLES ALAN WRIGHT, ARTHUR R. MILLER & MARY KAY KANE, FEDERAL PRACTICE AND PROCEDURE: CIVIL 2d § 2733 (1983)).

Here, the parties propose slightly different standards that should apply on judicial review of the Secretary's decision. Rio contends that the Administrative Procedure Act's ("APA's") arbitrary and capricious standard applies. (Docket No. 34, at 10.) On the other hand, the Secretary

argues that judicial review is governed by § 405(g) of the Social Security Act. (Docket No. 39, at 12.)

The Fifth Circuit addressed a similar disagreement about the standard of review in *Maxmed Healthcare, Inc. v. Price*, 860 F.3d 335 (5th Cir. 2017). That case addressed issues almost identical to those raised in the instant case: a home health care provider, Maxmed Healthcare, Inc. (Maxmed), sought judicial review of the Secretary's overpayment determination that was based on statistical sampling and extrapolation. The Fifth Circuit described the parties' standard-of-review dispute:

The Secretary contends that the appropriate standard is confined to 42 U.S.C. § 405(g): "(1) whether the [Secretary] applied the proper legal standards; and (2) whether the [Secretary's] decision is supported by substantial evidence on the record as a whole." *See Estate of Morris v. Shalala*, 207 F.3d 744, 745 (5th Cir. 2000). Maxmed argues that this court should consider, under the Administrative Procedure Act, whether the Secretary's decision is not founded on substantial evidence or is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *See* 5 U.S.C. § 706(2)(A), (E). This court recently addressed the same debate between a medical services provider and CMS and "assume[d] only for the sake of argument that the APA's arbitrary and capricious standard applies." *Baylor Cty. Hosp. Dist.*, 850 F.3d at 261. Because the standard of review "probably makes no difference," *id.*, we make the same assumption here, too.

860 F.3d at 340. The same assumption can be applied in the instant case as well.

Under either the APA or § 405(g), the Secretary's factual determinations must be upheld unless they are not supported by substantial evidence in the record. "Substantial evidence is that which is relevant and sufficient for a reasonable mind to accept as adequate to support a conclusion; it must be more than a scintilla, but it need not be a preponderance." *Anthony v. Sullivan*, 954 F.2d 289, 295 (5th Cir. 1992) (citing *Richardson v. Peraltes*, 402 U.S. 389, 401 (1971)); *see also* *Girling Health Care, Inc.*, 85 F.3d at 215 (citing *Richardson* and applying the

same substantial evidence standard in the context of Medicare reimbursement).²¹ In applying the substantial evidence standard, the Fifth Circuit has “consistently held that the Secretary, not the courts, has the duty to weigh the evidence, resolve material conflicts in the evidence, and decide the case.” *Johnson v. Bowen*, 864 F.2d 340, 347 (5th Cir. 1988) (citing *Chaparro v. Bowen*, 815 F.2d 1008, 1011 (5th Cir. 1987)). “If supported by substantial evidence, the decision of the Secretary is conclusive and must be affirmed.” *Sid Peterson Mem’l Hosp. v. Thompson*, 274 F.3d 301, 311 (5th Cir. 2001) (citing *Richardson*, 402 U.S. at 391).

While the substantial evidence standard is deferential, it is “not a rubber stamp for the Secretary’s decision.” *Cook v. Heckler*, 750 F.2d 391, 393 (5th Cir. 1985) (quoting *Tome v. Schweiker*, 724 F.2d 711, 713 (8th Cir. 1984)). Rather, a court “must scrutinize the record and take into account whatever fairly detracts from the substantiality of evidence supporting the Secretary’s findings.” *Id.*

In determining whether the Secretary applied the proper legal standard, “[c]ourts are required to ‘give substantial deference to an agency’s interpretation of its own regulations.’” *Girling Health Care, Inc.*, 85 F.3d at 215 (quoting *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994)). “Congress charged the Secretary with the primary responsibility for interpreting

²¹ Federal courts have often had occasion to apply the substantial evidence standard in the context of judicial review of Social Security disability decisions, which, like review of Medicare decisions, are governed by 42 U.S.C. § 405(g). *Family Rehab., Inc. v. Azar*, 886 F.3d 496, 501 n.4 (5th Cir. 2018) (noting that § 405(g) “has been made applicable to Medicare by 42 U.S.C. § 1395ff(b)(1)(A)”). The Supreme Court has “adhered to that [substantial evidence] definition in varying statutory situations.” *Richardson*, 402 U.S. at 401 (citations omitted). Consistent with this, the Fifth Circuit has applied the same substantial evidence standard in the context of judicial review governed by the APA: “Substantial evidence is more than a scintilla, less than a preponderance, and is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.” *Brown v. Napolitano*, 391 F. App’x 346, 350 (5th Cir. 2010) (quoting *Hames v. Heckler*, 707 F.2d 162, 164 (5th Cir. 1983)).

the cost reimbursement provisions of the Medicare Act, so courts accord particular deference to her interpretation of Medicare legislation.” *Id.* (citing *Batterton v. Francis*, 432 U.S. 416, 425 (1977)). Courts accord “*Skidmore* deference to ‘agency interpretations of statutes they administer that do not carry the force of law[.]’” *Baylor Cty. Hosp. Dist. v. Price*, 850 F.3d 257, 261 (5th Cir. 2017) (quoting *Luminant Gen. Co., L.L.C. v. EPA*, 675 F.3d 917, 928 (5th Cir. 2012)).²²

B. Issues

In moving for summary judgment, Rio identifies three main issues:

[1]. Whether Defendant HHS committed errors in deviating from the established statistical standards in its statistical sampling and extrapolation for overpayment.

[2]. Whether Defendant HHS violated Plaintiff’s due process right by unjustifiably withholding crucial statistical sampling and extrapolation data throughout the administrative appeal process.

[3]. Whether Defendant HHS committed errors in denying Plaintiff’s claims.

(Docket No. 34, at 10-11.) Each of these points will be considered to determine whether the Secretary’s decision is supported by substantial evidence, legally correct, and not otherwise arbitrary or capricious. The Secretary, in moving for summary judgment, addresses essentially the same issues, with one exception. (Docket No. 39, at 16-27.) As to Rio’s challenge to the individual coverage decisions, the Secretary contends that those claims are not properly before the Court because Rio did not raise them before the Council. (*Id.* at 13-14, 27-29.)

²² “The degree of deference depends on ‘the thoroughness evident in [the agency’s] consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.’” *Baylor Cty. Hosp. Dist.*, 850 F.3d at 261 (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)).

C. Statistical Validity of the Extrapolated Overpayment Amount

In its first issue, Rio challenges the statistical validity of the Secretary's overpayment determination in two principal ways. First, Rio contends that Health Integrity did not draw a statistically valid random sample in its selection of 41 claims to audit. Second, Rio argues that Health Integrity erred in applying a two-sided 80 percent confidence interval in determining the extrapolated overpayment.

In raising these points, Rio is challenging the way Health Integrity performed the statistical sampling and overpayment extrapolation. Rio does not—and cannot—challenge the Secretary's use of sampling and extrapolation in general to determine overpayments to home health care providers like Rio. Over thirty years ago, the predecessor of CMS issued its seminal ruling on the use of statistical sampling to project overpayments to Medicare providers, Ruling 86-1. *See supra* n.6. As explained in that ruling, the funds used to pay Medicare claims “belong to the public,” and CMS “has the fundamental obligation to ensure that Federal funds are spent only for those purposes permitted by law.” *Id.* at 4. CMS “has to balance the need to process billings rapidly in order that a provider's liquidity needs do not suffer and the need to verify that the claims submitted are for services covered by the Act.” Ruling 86-1, at 10. The difficulty of that balancing is greatly exacerbated by the volume of claims—which was over 330.3 million during 1985.²³ *Id.* “A case-by-case review could require a significant diversion of staff from the ongoing claims process, and the cost of determining the amount of an overpayment would be prohibitively high unless a sampling method were used. To fulfill the congressional intent, [CMS] must adopt realistic and practical auditing procedures.” *Id.* at 7.

²³ The number of Medicare claims has increased exponentially since 1985—now exceeding one billion per year. *See supra* n.4.

In response to the argument that providers would be unable to bill individual patients for services later determined to be noncovered, CMS noted “the provider had the responsibility to know and should have known that the services furnished were not medically necessary.” *Id.* at 9. CMS cited the Fifth Circuit’s decision in *Mt. Sinai Hospital of Greater Miami v. Weinberger*, 517 F.2d 329 (5th Cir. 1976), for the proposition that “the provider assumes substantial responsibility for overpayments.” *Id.*

At the same time, CMS emphasized that providers should and would have a fair opportunity to contest 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. 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. The provider could attack the statistical validity of the sample, or it could challenge the correctness of the determination in specific cases identified by the sample In either case, the provider is given a full opportunity to demonstrate that the overpayment determination is wrong. If certain individual cases within the sample are determined to be decided erroneously, the amount of overpayment projected to the universe of claims can be modified. If the statistical basis upon which the projection was based is successfully challenged, the overpayment determination can be corrected.

(*Id.* at 11.)

Since that ruling, federal courts have consistently confirmed the Secretary’s authority to calculate Medicare overpayments through sampling and extrapolation. *See Chaves County Home Health Service, Inc. v. Sullivan*, 931 F.2d 914, 923 (D.C. Cir. 1991) (holding that “[s]ample adjudication represents a judicially approved procedure” that is consistent with the Medicare Act). As noted earlier, this interpretation of the Medicare Act was further confirmed by Congress’s passage of the Medicare Integrity Program, which specifically authorizes “Medicare contractors to ‘use extrapolation to determine overpayment amounts’ if the Secretary determines that ‘there is

a sustained or high level of payment error.” *Maxmed Healthcare, Inc.*, 860 F.3d 335, 337 (5th Cir. 2017) (quoting 42 U.S.C. § 1395ddd(f)(3)(A)).

In short, CMS and its contractors had authority to use statistical sampling and extrapolation in determining whether Rio had been overpaid and in determining the amount of the overpayment. Rio contends Health Integrity’s sampling and extrapolation methodologies were statistically invalid and that the Council thus erred in failing to reject the overpayment determination. Rio’s challenges to the sample and the extrapolation will be addressed in turn.

1. Statistically Valid Random Sample

Rio argues that the 41-claim sample drawn by Health Integrity “was not a true SVRS [statistically valid random sample].” (Docket No. 34, at 12-14.) In making this argument, Rio relies on the opinion of its expert, Dr. Haller, who Rio describes as “a premier expert in the field of statistical analysis.” (*Id.* at 12.) Dr. Haller “recited the long-established standard for formulating a valid SSOE [statistical sampling for overpayment estimation], namely ‘the test is simply whether the methodology is statistically valid.’” (*Id.*; quoting from R. 80 (Dr. Haller Second Add.)) According to Rio, Dr. Haller “proved” in two ways that Health Integrity did not draw a statistically valid random sample.

First, Rio contends that the sample contains a disproportionate number of higher-amount claims:

Dr. Haller demonstrated that the average overpayments of the sample were not normally distributed within the universe of claims. *See* A.R. 0081. Comparing to the cumulative distribution of overpayments in the universe, the average overpayments of the sample bias toward the higher amount paid claims. *See* A.R. 0081-0082. In other words, the 41 claims audited consists of a disproportionate number of high paid amount claims out of the 2,197-claim universe. Because of this bias, the point estimate (average overpayment of the sample) used by CMS was improperly inflated. *See id.*

(Docket No. 34, at 13; footnote omitted.) During his hearing testimony, Dr. Haller suggested that there was some “human intervention” in the selection of the sample and that someone had “actually selectively take[n] higher paid claims rather than a random sample”; “in other words, to cherry pick, if you will.” (R. 1558.)

Second, Rio also contends that “Dr. Haller proved that there is a less than four percent (4%) probability that the sample utilized in this case, due to the bias, was an actual random sample.” (*Id.* at 14; citing R. 78-97.) According to Dr. Haller, “in the sample, 39 patients [hereafter “HICNs”] had one ICN and one HICN had exactly two (2) ICNs whereas 99.7% of the HICNs in the frame had at least four (4) ICNs each!” (R. 82 (Second Addendum).) Using mathematical formulas, Dr. Haller estimated the probability that this result occurred randomly and concluded:

I am 90% confident that the probability that a SVRS was drawn from the frame of 2,177 ICNs with at most one HICN having two ICNs and at least 41 HICNs having one ICN is at most 0.035 (3.5%), which is less than the 5% critical value. The hypothesis that a SVRS of 41 ICNs was drawn from the frame of 2,177 ICNs is rejected.

(R. 84.) Rio complains that the Council “summarily dismissed” its arguments and evidence showing that the sample was not random.²⁴ (Docket No. 34, at 14.)

²⁴ Actually, neither the Council nor the ALJ accepted these arguments. The ALJ found that the sample was invalid due to Health Integrity’s handling of the random numbers used to create the sample. (R. 60-61.) But the ALJ did not find that the sample itself was non-random, either because it was biased or because there was some “human intervention” in selecting higher-amount claims. (*See id.*) The Council rejected the ALJ’s finding regarding Health Integrity’s handling of the random numbers. (R. 22-26.) The Council concluded that “the record does, in fact, contain the random numbers associated with each of the forty-one [sample] claims,” and it further found that “the information otherwise provided to [Rio] would enable a statistician to replicate the sample.” (R. 26.) Rio does not appear to contest that part of the Council’s decision; in any event, the Council’s findings on that issue are well-supported by the record. In *Maxmed Healthcare*, the Fifth Circuit affirmed the Council’s decision rejecting an almost-identical ruling by an ALJ regarding the handling of the random numbers. 860 F.3d at 341.

The Council's decision reflects that it considered Dr. Haller's various points. (*See* R. 21 (noting that the Council reviewed "Dr. H[aller]'s various analyses" and referring to Dr. Haller's "Addendum" in which he stated that "the sample was biased toward the higher amount paid claims").) Ultimately, however, the Council did not find Dr. Haller's opinions persuasive as to the validity of the sample.

The record reflects substantial evidence to support the Council's decision. It is true that Dr. Haller appears to be a well-qualified statistician with impressive credentials. However, the record contains evidence from other qualified statisticians that support the Council's decision. In resolving evidentiary conflicts, it is the province of the Secretary "to determine the credibility of ... experts as well as lay witnesses and to weigh their opinions accordingly." *Stone v. Heckler*, 770 F.2d 482, 485 (5th Cir. 1985).

The sampling methodology used by Health Integrity was reviewed by a qualified statistician, J. Gregory Dobbins, Ph.D.²⁵ (R. 60; *see also* Docket No. 36-39 (Dr. Dobbins's CV).) Consistent with the MPIM, Health Integrity selected a universe of claims, which in this case totaled 2,179 claims submitted by Rio during the two-year period from June 1, 2007, to May 31, 2009. (R. 1304, 1306.) As Health Integrity informed Rio in its initial notice on February 18, 2011, "[a] computer-generated statistically valid random sample of claims" was drawn from this universe. (R. 1306.) This initial notice included an "enclosed encrypted CD for an explanation and details

²⁵ Based on Dr. Dobbins's CV, Dr. Haller agreed that Dr. Dobbins was a qualified statistician in accordance with MPIM § 4.1.5. (R. 190.) Dr. Haller objected that Health Integrity had failed to provide the CV of the statistician who conducted the sampling, asserting that Health Integrity's documentation showed that Alan Moskowitz, an analyst, had conducted the sampling and extrapolation. (R. 190.) However, MPIM § 8.4.1.5 requires that the sampling methodology "be reviewed by a statistician" and that this be done "prior to releasing the overpayment demand letter." As the ALJ found, Health Integrity's sampling methodology was "reviewed" by Dr. Dobbins. (R. 60.)

of the findings,” including “the Sampling Methodology.” (R. 1304.) Health Integrity advised Rio that, to insure “a statistically valid random sample,” its “statisticians select a sample whereby each element in the sample has an equal opportunity of being selected and is thus representative of the original universe.” (R. 1306.)

To select the random sample from the universe of claims, Health Integrity used the SAS statistical software.²⁶ (See R. 434, 1224.) Using such software to generate a random sample is consistent with the guidance in the MPIM. In discussing the “Random Number Selection,” the MPIM specifically notes that “[t]here are a number of well-known, reputable software statistical packages” for this purpose, including “SAS.” MPIM § 8.4.4.2. Selecting the random sample with this statistical software was also approved by Health Integrity’s statistician, Dr. Dobbins.

At Rio’s request, an independent review of Health Integrity’s statistical findings was performed by the QIC, Maximus. Dr. Teitelbaum, who has a Ph.D. from Carnegie Mellon University, performed the statistical review on behalf of Maximus. (R. 1218-25.) He attested that he had the appropriate expertise to perform the review and that he had no business or personal relationship with Health Integrity. (R. 1225.) Dr. Teitelbaum “was able to fully replicate the statistical findings made by Health Integrity,” and he described the specific steps he took to replicate the random sample:

1. I imported file frame.xlsx into SAS, version 9.1. This file included 2179 claims.
2. I selected a random sample of 45 claims using the following syntax in SAS:
PROC SURVEYSELECT DATA=_WORK.FRAME OUT=WORK.SAMPLE
SEED=18118 SAMPSIZE=45;
RUN;

²⁶ The MPIM explains that “[s]imple random sampling involves using a random selection method to draw a fixed number of sampling units from the frame without replacement.” MPIM § 8.4.4.1.1. “An example of simple random sampling is that of shuffling a deck of playing cards and dealing out a certain number of cards,” although “to qualify as probability sampling a randomization method that is more precise than hand shuffling and dealing would be required.” *Id.*

3. I then selected a random sample of 4 claims from the sample of 44 claims, using the following syntax in SAS:

```
PROC SURVEYSELECT DATA=WORK.SAMPLE OUT=WORK.RESERVE  
SEED=18118 SAMPSIZE=4;  
RUN;
```

4. I removed those 4 claims from the 45-claim sample, which resulted in a sample with 41 claims, using the syntax that follows:

```
DATA FINALSAMPLE;  
MERGE SAMPLE RESERVE (IN=res);  
BY ClaimNumber;  
IF res=0;  
RUN;
```

5. I verified that the 41 claim numbers selected in this way matched those selected by Health Integrity, as presented in file "Rio Home Care_FINANCIALSHEET_RB.xlsx". *I was thus able to replicate the random sample selected by Health Integrity.*

(R. 1224; emphasis added.) Dr. Teitelbaum's ability to recreate the same random sample using the SAS program supports the Council's decision to reject Dr. Haller's attempts to show that Health Integrity did not obtain a statistically valid random sample.

The Council's conclusion is further supported by the post-hearing position paper submitted by Health Integrity's chief statistician, Aimee Mason, M.S. (R. 426-44.) Ms. Mason also confirmed that the "sample was randomly selected using a SAS program that allowed each sample of 45 claims to have an equal chance of being drawn with 4 spares (the Reserve) not being used resulting in a valid random sample of 41 claims." (R. 428.) "Probability sampling was followed because the SAS code used to generate the random sample generates a probability sample, whereby all sampling units have a known probability of being selected, as does the entire sample." (R. 436.) Ms. Mason was able to confirm that "the SAS sample selection program ran correctly selecting a simple random sample from the universe of claims." (R. 437.)

Based on two “histogram” graphs showing the frequency of claims at different payment amounts for the universe and the sample, Ms. Mason suggested that “the sample is representative of the universe at various levels of claims payments.”²⁷ (R. 434-35.) More importantly, though, the sample was entirely “random,” which is the guiding standard under the MPIM. (R. 434.) Ms. Mason opined that the “sample was randomly drawn as a statistically valid random sample (SVRS).” (R. 435.)

As Ms. Mason explained, the sample was originally selected using a prior version of the SAS software. (R. 430.) She described the precise steps and computer commands that Rio and its expert (or anyone else) could follow in order “to replicate the original sample.” (*Id.*) The random number selection was “documented to maintain the integrity of the random number selection

²⁷ The histogram graphs are Figures 1 and 2 in Ms. Mason’s paper. Figure 1 shows a graph of the frequency of claim amounts for the universe of 2,179 claim payments, with the numbers of claims on the vertical y-axis and the amount per claim on the horizontal x-axis. (R. 434.) The histogram in Figure 2 shows the same information for the 41 claims that were in the sample. (R. 435.) Consistent with Ms. Mason’s point, the two histograms show a similar grouping of payment amounts. However, Dr. Haller took issue with this point in his “rebuttal” paper, arguing that the histogram in Figure 2 demonstrates a bias for higher amount claims. (R. 188-89.) To show this, Dr. Haller reproduces Figure 2 in his paper and circles claim amounts in the sample that were at the \$7,000 and \$8,000 level. (R. 189.) The claims circled by Dr. Haller represent three claims out of the 41-claim sample. (*See* R. 435 (Figure 2).) It hardly seems surprising that in a random sample drawing, several claims were selected that were outside the main grouping of claim amounts, particularly since there were a number of claims in the 2,179-claim universe that ranged from \$4,000 up to \$10,000. (*See* R. 434 (Figure 1).) Similarly, Dr. Haller states that “the average amounts paid to the sample ICNs is almost \$600 more than the frame *for amounts paid greater than \$3,000.*” (R. 189; emphasis added.) But this observation applies to only eight of the 41 sample claims. (*See* R. 435.) Although Dr. Haller focuses on the higher-paid sample claims, one could also conclude from the histograms that for claim amounts less than \$2,000 (the bar for the lowest amount), there are a higher percentage of claims in the sample as compared to the universe—and the number of claims at this level is higher in both the sample (10 claims) and the universe (about 350 claims). (*See* R. 434-35.) In “scrutinize[ing]” this evidence, Dr. Haller’s attempt to show higher-claim bias is not so compelling that it “fairly detracts from the substantiality of evidence supporting the Secretary’s findings.” *Cook*, 750 F.2d at 393. As discussed above, there is substantial evidence to support the conclusion that the sample was randomly drawn.

process and to be able to reproduce the results at any time in the future.” (R. 436.) Although Dr. Haller had the means available to test whether he could likewise replicate the sample using the SAS software, he does not indicate whether he attempted to do so.²⁸

To the extent that Rio continues to contend—based on Dr. Haller’s hearing testimony—that someone interfered with the sample by “cherry picking” higher-amount claims, the record contains substantial evidence to support the Council’s rejection of that notion. Dr. Teitelbaum and Ms. Mason replicated the original random sample using the MPIM-approved SAS statistical software, which strongly suggests that there was no “human intervention.”

Other than the “human intervention” theory, Dr. Haller does not suggest why the methodology used by Health Integrity resulted in a sample that he claims was not statistically valid. Dr. Haller does not attempt to challenge the proposition that Health Integrity’s sample can be replicated using the SAS statistical software (and following the provided instructions), nor does he suggest that there is a flaw in the SAS software.²⁹ Instead, he attempts to “prove” that the sample that was drawn was not a valid random sample.

²⁸ The Council reviewed the evidence in the record showing that Health Integrity provided Rio with the seed number used to create the original sample, as well as instructions describing the steps to take using the current version of the SAS software to replicate the sample (which was drawn using an earlier version of SAS). (R. 20-26.) The Council agreed with CMS that “the information . . . provided to [Rio] would enable a statistician to replicate the sample.” (R. 26.) Contrary to that finding, Rio asserts in its reply brief (in addressing its due process claim) that “[a]t no point was Plaintiff supplied with the sampling data necessary to replicate the statistical study.” (Docket No. 42, at 7.) The record contains more than enough evidence to support the Council’s contrary conclusion.

²⁹ In his declaration submitted to the Council (Second Addendum), Dr. Haller continued to urge that the sample was invalid because, contrary to the MPIM, Health Integrity failed to “supply” the actual random numbers used. (R. 81.) Dr. Haller may have been referring at that point to Health Integrity’s failure to supply the random numbers sooner since, as the Council found, the actual random numbers were part of the record by that point. (R. 23-26.) In any event, Dr. Haller’s Second Addendum shows that he had access to the instructions that would have enabled him to replicate the sample using the current version of the SAS software. (R. 81 (referring to “Quality Addendum to Explain Need to Add RANUNI.DOC”).)

The circumstances here reflect a classic example of an evidentiary conflict that the factfinder must resolve. On the one hand, there is evidence tending to show that Health Integrity used a well-accepted statistical software program designed to draw a random sample, that the program ran properly, that the resulting sample can be replicated, and that the selected sample claims are representative of the universe. On the other hand, there is evidence that sample is biased toward higher amount claims and that it can be mathematically proved (based on the number of patients in the sample with multiple claims) that the sample was not randomly drawn. Such “conflicts in the evidence are for the Secretary to resolve.” *Anthony*, 954 F.2d at 295 (citing *Patton v. Schweiker*, 697 F.2d 590, 592 (5th Cir. 1983)). “This Court may not reweigh the evidence or try the issues *de novo*.” *Anthony*, 954 F.2d at 295 (citing *Cook v. Heckler*, 750 F.2d 391, 392 (5th Cir. 1985)).

In challenging the Council’s decision, Rio argues that the Council “failed to consider the substantial evidence in Plaintiff’s administrative appeal” supporting the ALJ’s ruling that the sampling methodology was invalid. (Docket No. 1, at 14.) It is true that the record contains substantial evidence from which the Council could have ruled in Rio’s favor, including Dr. Haller’s expert opinion. But that is not the standard. The question is not whether there is evidence from which the Council could have ruled in favor of Rio, but rather it is whether the Council’s decision against Rio is supported by substantial evidence. *See Hammond v. Barnhart*, 124 F. App’x 847, 853 (5th Cir. 2005) (although there may be “some evidence that points to a conclusion that differs from that adopted by the [Secretary],” reversal is not appropriate where the Secretary’s finding is supported by “more than a scintilla of evidence”). As to that question, the record includes ample evidence—far more than a scintilla—to support the Council’s decision, including (as discussed above) evidence from several qualified statisticians. *See Richardson*, 402 U.S. at

401 (“supported by substantial evidence” means “more than a mere scintilla”); *see also San Bois Health Servs., Inc. v. Hargan*, No. CIV-14-560-RAW, 2017 WL 5140519, at *6 (E.D. Okla. Nov. 6, 2017) (finding substantial evidence in support of the Council’s decision reversing the ALJ’s ruling that the sample was not a probability sample in a case where “Health Integrity, LLC used the SURVEYSELECT procedure in SAS to select the random claims”).

2. Confidence Interval Formula

Rio also challenges the Council’s decision to overturn the ALJ’s ruling that Health Integrity did not use valid formulas in extrapolating the overpayment amount. The ALJ ruled that Health Integrity was “not allowed” to use an 80 percent two-sided confidence interval, even though it “results in a lower overpayment amount to the benefit of [Rio].” (R. 61.) Rio argues that the ALJ was correct in concluding that Health Integrity erred in failing to use the “mandatorily required” 90 percent one-sided confidence interval in estimating Rio’s overpayment from the sample. (Docket No. 42, at 3-4.) In addition to this argument, or—perhaps more accurately—in the alternative, Rio relies on Dr. Haller’s opinion that “one cannot be 90% confident that the total overpayment to the frame exceeds this calculated value if the distribution of the average overpayments is not normally distributed.” (Docket No. 34, at 15.)

a. *80 Percent Two-Sided Confidence Interval*

The MPIM provides guidance on estimating the total overpayment owed by a provider based on the audit results from a random sample. A simple way to do this, called a “point estimate,” is to calculate the average overpayment from the sample and simply multiply this amount by the number of units in the universe.³⁰ *See* MPIM § 8.4.5.1. However, recognizing that

³⁰ In one of the early federal cases addressing audit procedures for determining overpayments, the Seventh Circuit held that the use of “sampling and extrapolation is proper” to determine Medicaid overpayments to doctors. *Illinois Physicians Union v. Miller*, 675 F.2d 151, 156 (7th Cir. 1982).

this approach may sometimes be imprecise, possibly resulting in an overpayment amount that is too high, the MPIM adopts a methodology called “confidence interval estimation.” This approach takes into account the uncertainty in statistical sampling methodology and results in the calculation of a conservative overpayment amount “that is very likely less than the true amount of the overpayment”—to the benefit of the provider. *Id.* The MPIM explains the interaction between the point estimate and confidence interval estimation as follows:

In simple random or systematic sampling the total overpayment in the frame may be estimated by calculating the mean overpayment, net of underpayment, in the sample and multiplying it by the number of units in the frame. In this estimation procedure, which is unbiased, the amount of overpayment dollars in the sample is expanded to yield an overpayment figure for the universe. The method is equivalent to dividing the total sample overpayment by the selection rate. The resulting estimated total is called the point estimate of the overpayment, i.e., the difference between what was paid and what should have been paid. . . .

In most situations the lower limit of a one-sided 90 percent confidence interval shall be used as the amount of overpayment to be demanded for recovery from the provider or supplier. The details of the calculation of this lower limit involve subtracting some multiple of the estimated standard error from the point estimate, thus yielding a lower figure. This procedure, which, through confidence interval estimation, incorporates the uncertainty inherent in the sample design, is a conservative method that works to the financial advantage of the provider or supplier. That is, it yields a demand amount for recovery that is very likely less than the true amount of overpayment, and it allows a reasonable recovery without requiring the tight precision that might be needed to support a demand for the point estimate. However, the . . . ZPIC . . . is not precluded from demanding the point estimate where high precision has been achieved.

In that case, the extrapolation was performed by simply calculating the “average overpayment” from the sample and then multiplying that by “the total number of cases for which the physician received Medicaid payments during the audit period” (i.e., the number of claims in the universe). *Id.* at 153 n.2. The Seventh Circuit thus approved what the MPIM calls the “point estimate” in extrapolating the overpayment. While acknowledging that providers had a substantial interest in receiving their full statutorily-allotted compensation for services rendered, the court found that, “in balancing the interests of the parties, the balance is heavily weighted in favor of the [agency].” *Id.* at 157. The agency “processes an enormous number of claims and must adopt realistic and practical auditing procedures.” *Id.* “[I]n view of the enormous logistical problems of Medicaid enforcement, statistical sampling is the only feasible method available.” *Id.* (citation omitted).

MPIM § 8.4.5.1 (reprinted in Docket 39-1, at 43-44.)

In addressing the ALJ's finding that the confidence interval used by Health Integrity was "not allowed," the Council observed that "the reference to the use of 'the lower limit of a one-sided 90 percent confidence interval' in section 3.10.5.1 is qualified by the phrase '[i]n most instances.'" (R. 19.) From this, the Council concluded:

Thus, the MPIM does not establish an absolute requirement that only the lower limit of a one-sided 90 percent confidence interval is to be used in sampling. In fact, in instances where precision is obtained, the MPIM contemplates use of the point estimate for recovery rather than the lower confidence level.

(R. 19.)

In arguing that the Council failed to follow MPIM guidelines, Rio emphasizes the language in former § 3.10.5.1 (now § 8.4.5.1) stating that "a one-sided 90 percent confidence interval *shall be used*." (Docket No. 42, at 3 (emphasis in original) (quoting MPIM § 3.10.5.1).)³¹ Rio reasons that if CMS "is free to pick any confidence interval limit on a given case, the 90% Limit requirement (as it is expressly referenced in § 3.10.5.1) will be entirely unnecessary and a pure textual and functional surplusage." (Docket No. 42, at 3 (citations omitted).)

Rio's argument is not persuasive. While it is of course true as a matter of statutory construction that provisions should be interpreted in a way that does not render language superfluous, Rio's interpretation requiring that that a 90 one-side interval be used in every case violates the principle it espouses by rendering the language "in most cases" superfluous.

³¹ At the time of Health Integrity's audit, the MPIM guidelines addressing statistical sampling were found in Chapter 3. Subsequently, the sampling guidelines were moved to MPIM Chapter 8. As the Council noted, the sampling guidelines at issue here are identical for both the version of the MPIM in effect at the time of Health Integrity's audit and the version now in effect. (R. 19.) Both parties refer to MPIM Chapter 8 throughout their briefing. Because there is no difference in the language of the two MPIM versions that is relevant to the issues here, this report generally refers to the current MPIM (Chapter 8).

Moreover, as the Council emphasized, this is not a case where CMS willy-nilly chose a different confidence interval, which brings us to another key point made by the Council in its decision.

Evidence in the record, which the Council found persuasive, shows that in this case there is no difference between the lower limit of one-sided 90 percent confidence interval and the lower limit of a two-sided 80 percent interval. (R. 22.) In calculating Rio's overpayment from the sample, Health Integrity used the RAT-STATS statistical software.³² (See R. 441-43.) Dr. Teitelbaum, in performing his independent statistical review, likewise used the RAT-STATS software to verify and replicate the extrapolation of the overpayments. (R. 1224.) Dr. Teitelbaum found:

The output produced by RAT-STATS showed that the point estimate was \$4,770,713. It also showed that the lower limit of the two-sided 80% confidence interval (*which is equivalent to the lower limit of one-sided 90% confidence interval*) was \$4,079,073.

(R. 1224; emphasis added.) Thus, Dr. Teitelbaum opined that the extrapolated amount calculated by Health Integrity using the lower limit of a two-side 80 percent confidence level was the same as the lower limit of a one-sided 90 percent confidence interval.

The Council quoted from CMS's briefing to explain how this can be so:

An 80 percent two-sided confidence interval has an upper and lower limit with the understanding that the true overpayment amount is 80 percent likely to be within the upper and lower limits. That is, the true overpayment amount will be above the lower limit 90 percent of the time and below the upper limit 90 percent of the time. RAT-STATS output files include both upper and lower confidence intervals. However, the upper limit is inconsequential for purposes of overpayment estimation in Medicare cases, which is why the MPIM requires the lower limit of a one-sided 90 percent confidence interval. Whether expressed as the lower limit of a one-sided 90 percent confidence interval or a two-sided 80 percent confidence interval, the contractor is 90 percent confident that the overpayment estimate is

³² In the context of sample creation, the MPIM notes "reputable software statistical packages" that may be used. MPIM § 8.4.4.2. Specific mention is made of "RAT-STATS, available (at time of release of these instructions) through the Department of Health and Human Services, Office of Inspector General Web Site." *Id.*

greater than the lower limit. Both descriptions are consistent with the standard set forth in the MPIM, currently and on the dates of service.

(R. 20 (quoting CMS brief, R. 104).)

This conclusion is further supported by Ms. Mason's statistical analysis in which she also replicated and confirmed the overpayment amount calculated by Health Integrity. She reported:

I verified the extrapolated overpayment amount of \$4,079,073 using the Unrestricted Variable Appraisal program in the Department of Health & Human Services Office of Inspector General (OIG) RAT-STATS software. *See* RAT-STATS output below (emphasis added) which matches the results in the overpayment extrapolation Excel spreadsheet. Note that *the lower limit of the 90% one-sided confidence interval is the same as the lower limit of the 80% two-sided confidence interval* for the estimated overpayment (difference) amount.

(R. 441; emphasis added.)

Significantly, Rio's expert, Dr. Haller, does not challenge the assertion that the 80 percent two-sided confidence interval used by Health Integrity produced the same result as a 90 percent one-sided confidence interval. To the contrary, in commenting on Ms. Mason's statement that she verified the extrapolation, Dr. Haller states that: "Given that the overpayment data satisfy the assumptions of RAT-STATS, the algebra programmed into this software will calculate the correct lower one-sided 90% confidence interval based on an average and standard deviation of overpayments from a sample of n sampling units." (R. 191.) Dr. Haller thus confirms that the software program used by Health Integrity to calculate the extrapolation will yield a "correct lower one-sided 90% confidence interval." (*Id.*) Nowhere in Dr. Haller's multiple declarations (or in his hearing testimony) does he contend, as does Rio here, that Health Integrity's calculation was invalid because it used the lower end of a two-sided 80 percent confidence interval.³³

After considering these issues, the Council concluded:

³³ To be sure, Dr. Haller does take strong exception to the extrapolation, but he does so on different grounds. That argument will be addressed separately.

Contrary to the ALJ's interpretation, the ZPIC's [Health Integrity's] utilization of the lower limit of a two-sided 80 percent confidence interval was not prohibited simply because it was not specifically identified in the MPIM guidance applicable during this audit. Moreover, the Council finds CMS' argument that the lower limit of a two-sided 80 percent confidence interval is equivalent to the lower limit of one-sided 90 percent confidence interval to be fully credible. Thus, while utilization of an 80 percent confidence level is neither addressed nor precluded by the MPIM, its application did not render the ZPIC's sampling methodology invalid.

(R. 22.) The Council's ruling reflects a reasonable interpretation of the MPIM and is supported by substantial evidence in the record from qualified statisticians.

b. *Distribution of Average Overpayments*

The Council also addressed and rejected Dr. Haller's different rationale for faulting Health Integrity's extrapolation calculation. Rather than challenging Health Integrity's use of a two-sided 80 percent confidence interval, Dr. Haller asserts that the entire calculation was "meaningless because the distribution of the average overpayments of the sample is not normal," as he had "tested and proved." (R. 81.)

The Council "reviewed the sampling methodology work papers supporting the ZPIC's methodology and Dr. H[aller]'s various analyses." (R. 21.) After noting that "Dr. H[aller] does not appear to dispute the basic principle that the lower limit of a one-sided 90% confidence interval is equivalent to a two-sided 80% confidence interval," the Council addressed Dr. Haller's argument "that 'one cannot be 90% confident that the total overpayment to the frame exceeds this calculated value if the distribution of the average overpayments is not normally distributed.'" (R. 21; quoting from R. 81 (Haller Second Addendum (emphasis in original).) The Council concluded:

There is no support in CMS Ruling 86-1 or in the MPIM for the proposition that the non-normality of the sampling unit overpayment distribution within a sample of adequate size demonstrates that the sample is statistically invalid. In fact, in most overpayment cases involving statistical sampling and extrapolation that come before the Council, the individual sampled overpayment results are not normally

distributed, yet sampling in Medicare overpayment cases has been widely upheld by the courts. The sample overpayments are extrapolated to the frame using confidence interval estimation in most all of the statistical sampling cases done by CMS contractors and reviewed by the Council. The Council, like the MPIM guidelines, recognizes that real world constraints impose conflicting demands on limited public funds, constraints which CMS chose to incorporate into the statistical sampling guidelines. The Council must give substantial deference to CMS guidelines including where, as here, CMS has chosen a reasonable, feasible, and well-articulated approach for collecting overpayments which, by design, offsets precision in favor of lower recovery amounts. To the extent that Dr. H[aller] has significant concerns with the parameters of CMS's statistical sampling guidelines, those concerns should be raised with CMS, as the Council has no authority to invalidate CMS guidelines.

(R. 21-22.)

The sampling and extrapolation guidelines set out in the MPIM are entitled to *Skidmore* deference. *See Baylor Cty. Hosp. Dist.*, 850 F.3d at 261-64 (applying “*Skidmore* deference” to CMS’s State Operations Manual). Rio does not contest this. (Docket No. 42, at 6.) Rio nevertheless asserts that CMS “is required to observe all fundamental laws and principles of probability and statistical theory.” (Docket No. 34, at 12; citing MPIM § 8.4.10.) According to Rio, “§ 8.4.10 of the MPIM expressly references and incorporates numerous authoritative texts and treatises in the field of statistical analysis to serve as guideposts for CMS’ utilizations of SSOE [statistical sampling for overpayment estimation].” (*Id.*) One of the texts listed in § 8.4.10 is “Sampling Techniques,” by William G. Cochran. Dr. Haller “heavily relied” on the Cochran text in forming his opinion that the extrapolation was meaningless and invalid. (Docket No. 42, at 5.) Rio argues that the Council’s decision was wrong because Health Integrity’s sampling and extrapolation methodology “fails to observe the fundamental principles of statistical sampling.” (Docket No. 42, at 431.)

Rio’s position is supported neither by statute nor by the MPIM. As part of the “Medicare Integrity Program,” Congress authorized the Secretary to “use extrapolation to determine

overpayment amounts to be recovered” if the Secretary determines that “there is a sustained or high level of payment error.” 42 U.S.C. § 1395ddd(f)(3)(A). But in approving the Secretary’s use of “extrapolation” in determining Medicare overpayments, Congress provided no guidance on how the extrapolation was to be performed. While the statute uses the word “extrapolation,” the words “statistics” or “statistical” do not appear. To carry out the congressional objective on using extrapolation, CMS (on behalf of the Secretary) issued Ruling 86-1 and developed the guidelines in the MPIM.

The MPIM’s guidelines “are provided to ensure that a statistically valid sample is drawn and that statistically valid methods are used to project an overpayment where the results of the review indicate that overpayments have been made.” MPIM § 8.4.1.1. Thus, the MPIM itself adopts the “statistical validity” standard. Importantly, though, the MPIM also provides specific guidance on how that “statistical validity” is to be achieved. In other words, the MPIM appears to assume that following its guidelines will result in a statistically valid extrapolation.

Rio’s reliance on MPIM § 8.4.10 is misplaced. Section 8.4.10 is entitled “Resources,” and it merely lists ten statistical books and texts. Nowhere in the MPIM does it suggest that these “Resources” trump the guidance in the manual.

In any event, here it is unnecessary to decide whether and to what extent “generally accepted principles for statistical sampling” (as Rio puts it) must be superimposed on the MPIM guidelines. Even assuming such a standard must be considered, it would not change the result here. The Council found that Health Integrity satisfied the “statistically valid” standard: “The Council finds that the ZPIC utilized a valid sampling methodology to arrive at the extrapolated overpayment at issue.” (R. 30.) To the extent this finding rested on the “statistically valid” standard reflected by the MPIM guidelines, Rio has failed to show that the Council erred in

interpreting the MPIM provisions at issue. As the Council noted, the MPIM does not support Dr. Haller's opinion that the extrapolation was meaningless because the distribution of average overpayments was not normally distributed. (R. 21-22.)

To the extent that the proper standard looks outside the MPIM to "generally accepted" statistical principles, the Council's decision is supported by substantial evidence. As discussed in the context of Dr. Haller's challenge to the randomness of the sample, the record reflects three qualified statisticians who have reviewed and approved the accuracy and statistical validity of Health Integrity's extrapolation methodology: Dr. Dobbins; Dr. Teitelbaum, and Ms. Mason. Dr. Dobbins approved the extrapolation method used by Health Integrity. Dr. Teitelbaum and Ms. Mason replicated the extrapolation using the RAT-STATS statistical software and confirmed that the results were statistically valid. (R. 439-443, 1150-51, 1224-25.) Here again, "conflicts in the evidence are for the Secretary to resolve." *Anthony*, 954 F.2d at 295 (citing *Patton v. Schweiker*, 697 F.2d 590, 592 (5th Cir. 1983)).

The Council is also correct that federal courts have upheld the sampling and extrapolation method used in this case. Most significantly, another Texas federal court rejected almost exactly the same argument that Rio is making in this case; in fact, in that case Health Integrity had likewise performed the sampling and extrapolation, and the provider, Maxmed Healthcare, Inc. (Maxmed), was also relying on expert opinion by Dr. Haller.³⁴ *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 630 (W.D. Tex. 2016), *aff'd*, *Maxmed Healthcare, Inc. v. Price*, 860 F.3d 335 (5th

³⁴ To add to the similarity, Ms. Mason was also the expert statistician who presented evidence for Health Integrity, and Palmetto was the Medicare Administrative Contractor. 152 F.Supp.3d at 623, 626. In that case, Dr. Haller was an independent expert retained to assist the ALJ (not an expert hired by the provider, Maxmed). See *Maxmed*, 860 F.3d at 341-42. Nonetheless, Maxmed, like Rio here, relied principally upon Dr. Haller's opinions both before the Council and on judicial review. Perhaps due to Maxmed's heavy reliance on Dr. Haller's opinion evidence, the district court referred to Dr. Haller as "Plaintiff's expert witness." 152 F.Supp.3d at 629.

Cir. 2017). Based on Dr. Haller's testimony, the ALJ had ruled in favor of the provider on statistical issues, finding (among other things) that Health Integrity had not used correct extrapolation methodology. *Id.* at 624. There, like here, Dr. Haller made multiple arguments against the statistical validity of the sampling and extrapolation, including "opin[ing] that the sampling units were not statistically independent, which suggests that . . . confidence interval methods cannot be used." *Id.* at 630. As he does here, Dr. Haller also opined that the extrapolation was invalid because "the distribution of average overpayments was not normally distributed." 152 F.Supp.3d at 630 (quoting from the ALJ's decision). Finding Dr. Haller's opinions unpersuasive, the Council in *Maxmed* had reversed the ALJ and concluded that the sampling and overpayment extrapolation were "valid." *Id.* at 624. On judicial review, the district court held that "[s]ubstantial evidence ... exists to support the [Council's] conclusion that the ALJ improperly relied on Dr. Haller's opinion that the sample as drawn is invalid because the average overpayments in the sample are not normally distributed." *Id.* at 636-37. The court likewise rejected Maxmed's various other challenges to the validity of the sample and the extrapolation. *Id.* at 628-39.

On appeal, the Fifth Circuit affirmed. 860 F.3d at 345. In affirming the district court's rejection of one of Maxmed's challenges to the statistical validity of the sample, the Fifth Circuit endorsed the Council's reasoning in rejecting Dr. Haller's opinions:

The conclusion of the Council's reasoning in rejecting Maxmed's challenge to the sampling and extrapolation methodology is worth repeating:

Suffice it to say, given MPIM provisions, the fact that [Health Integrity] selected a sampling methodology or sample size that another statistician may not prefer, or which may not result in the most precise point estimate, does not provide a basis for invalidating the sampling or the extrapolation as drawn and conducted in this case.... The Council must give substantial deference to CMS guidelines including where, as here, CMS has chosen a reasonable, feasible, and well-articulated approach for collecting overpayments which, by design, offsets precision in favor

of lower recovery amounts. To the extent that [Dr. Haller] or other statisticians have significant concerns with the parameters of CMS's statistical sampling guidelines, those concerns should be raised with CMS, as the Council has no authority to invalidate CMS guidelines.

860 F.3d at 342 (omission in original).³⁵

Similarly, in another recent decision, a different federal judge in the Western District of Texas affirmed the Secretary's overpayment decision in the context of Medicare claims for home health services. *Superior Home Health Servs., L.L.C. v. Azar*, No. 5:15-CV-00636-RCL, 2018 WL 3717121, at *1 (W.D. Tex. Aug. 3, 2018). In that case, again like here, Health Integrity was the ZPIC and Palmetto was the Medicare Administrative Contractor. Health Integrity used the RAT-STATS software to calculate the overpayment and applied "an 80% two-sided confidence interval." *Id.* at *7. The provider, Superior Home Health Services, L.L.C. ("Superior"), disputed Health Integrity's sampling and extrapolation procedure. After considering those issues, the court concluded:

Four reviewing entities have determined that the sampling and extrapolation methodologies employed by the ZPIC in this case resulted in a probability sample, and that the sample was therefore entitled to a presumption of validity. The Secretary has demonstrated with substantial evidence that the procedure used to extrapolate the overpayment value is compliant with Medicare standards as set forth in 42 U.S.C. § 1395ddd and the MPIM. Superior has made clear in its submissions to this Court that its expert witnesses would have employed a different methodology, perhaps even one that would have yielded a significantly more accurate result—but it is not the function of this Court on judicial review to dictate

³⁵ Here, in an apparent response to the Council's *Maxmed* ruling, Dr. Haller provided the Council with some legal analysis on the proper standard for statistical sampling and extrapolation. (R. 79-80 (Second Addendum).) Dr. Haller calls "absurd" what he characterizes as the Council's attempt "to require that the methodology be statistically valid without meeting the standards upon which statistical validity is based." (R. 80.) He further criticizes the Council's ruling in *Maxmed* as being "diametrically opposed" to other legal opinions "regarding sampling and extrapolation, which makes the [Council's] opinion irrelevant." (R. 79-80 (Second Addendum).) Of course, Dr. Haller's legal opinions are not particularly helpful or persuasive, given that his expertise—while considerable—lies in the field of statistics. In the *Maxmed* case, both the District Court for the Western District of Texas and the Fifth Circuit found that the Council's decision was legally correct.

which sampling and extrapolation methodologies must be used in administrative proceedings. What matters for the purpose of this appeal is the substantial evidence in the record supporting the Secretary's finding that the methodologies used by the ZPIC satisfied all relevant legal and administrative requirements. His decision pursuant to those findings was neither arbitrary nor capricious.

Id. at *8. That analysis applies with equal force to the instant case.³⁶

Finally, as the Council explained in its decision, the 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.” (R. 13.) Rio has failed to show that the Council erred in striking that balance in this case. Dr. Haller insisted in each of his papers and in his hearing testimony that he “made no attempt to suggest or recommend improved, alternative, or more precise methods of estimation and extrapolation.” (R. 78 (Second Addendum); *see also* R. 383 (Declaration), R. 187 (Rebuttal), R. 1567-68 (ALJ hearing).) Dr. Haller is merely stating his opinion on the statistical validity of Health Integrity’s

³⁶ Federal courts have affirmed the Council’s decisions regarding the statistical validity of overpayment determinations in many—but not all—other cases. *See, e.g., San Bois Health Servs., Inc. v. Hargan*, No. 14-cv-560, 2017 WL 5140519, at *8-11 (E.D. Okla. Nov. 6, 2017) (affirming the Council’s decision that an overpayment determination by Health Integrity was statistically valid); *Dominion Ambulance, L.L.C. v. Burwell*, No. 16-cv-146, 2017 WL 5507724, at *2, *5-6 (W.D. Tex. Aug. 30, 2017) (affirming the Council’s decision that an overpayment determination by Health Integrity was statistically “sound”); *Schuldt Chiropractic Wellness Ctr. v. Sebelius*, No. 13-cv-4, 2014 WL 247972, *3-4 (D. Neb. Jan. 22, 2014) (affirming the Council’s decision that an overpayment determination was based on valid sampling and extrapolation); *Transyd Enters. v. Sebelius*, No. 09-cv-292, 2012 WL 1067561, at *8-10 (S.D. Tex. Mar. 27, 2012) (affirming the Council’s decision that an overpayment determination was statistically valid); *Maxxim Care EMS, Inc. v. Sebelius*, No. 10-cv-1408, 2011 WL 5977666, at *2-4 (S.D. Tex. Nov. 29, 2011) (affirming the Council’s decision that an overpayment determination was based on valid sampling methodology). *But see Cypress Home Care, Inc. v. Azar*, No. 16-cv-80, 326 F. Supp. 3d 307 (E.D. Tex. June 11, 2018) (reversing the Council’s decision that an overpayment determination by Health Integrity was statistically valid).

sampling and extrapolation without “offering or proposing a better way to do the audit.”³⁷ (R. 1568.) In other words, Rio has taken an all-or-nothing approach in arguing that the sampling and extrapolation methodology is invalid and should be disregarded entirely.³⁸

Significantly, Rio provides no reason to believe that the extrapolated amount determined by Health Integrity is unfair in the sense that it is likely higher than it should be, given the 85 percent error rate found in Rio’s audited Medicare claims.³⁹ Nowhere does Dr. Haller suggest that the extrapolated overpayment amount was higher than the actual overpayment that Rio received, nor does it appear that he could have done so. To the contrary, the record suggests that the extrapolated overpayment reflected “a demand amount for recovery that is very likely less than

³⁷ Perhaps this approach was taken in response to the Council’s position (as reflected by its ruling in *Maxmed*) that the ZPIC did not err by selecting “a sampling methodology or sample size that another statistician may not prefer, or which may not result in the most precise point estimate.” *Maxmed Healthcare, Inc.*, 860 F.3d at 342 (quoting the Council’s reasoning in rejecting the provider’s challenge to the sampling and extrapolation methodology).

³⁸ Both Ruling 86-1 and the MPIM contemplate that “[i]f the statistical basis upon which the projection was based is successfully challenged, the overpayment determination can be corrected.” Ruling 86-1, at 11; *see also* MPIM §§ 8.4.9, 8.4.9.1 (directing that after an appeal decision invalidating the sampling methodology, CMS “shall take appropriate action to adjust the extrapolation,” including “correction of errors” in the methodology or “conduct[ing] a new review”). Rio’s evidence provides no guidance on how Health Integrity’s extrapolation could have been “corrected.” Nor is there any evidence in the record to suggest whether there is a more precise sampling and estimation approach that would have been administratively feasible.

³⁹ This error rate is based on Health Integrity’s finding that 35 out of the 41 sample claims did not meet the Medicare criteria for payment. Apart from Health Integrity’s well-documented audit, its findings on the individual claims were independently reviewed and confirmed by Palmetto, Maximus, and the ALJ. Dr. Haller does not—and could not—challenge the 85 percent error rate since it results from a medical review of the claim submitted on behalf of each patient, which is outside his area of expertise. Given that Rio’s medical evidence addressed only the 35 sample claims that were denied, there is no evidence in the record to show any likelihood that the error rate for the universe of claims would have been any different than the error rate found in the sample. *See Chaves Cty. Home Health Serv., Inc. v. Sullivan*, 931 F.2d 914, 921 (D.C. Cir. 1991) (noting that “in an effort to challenge the accuracy of the extrapolation, a provider could separately present evidence of a different random sample from the universe of claims that yields a lower rate of denials or prove that the projection is not a true estimate of the rate of denials in the non-sample universe”).

the true amount of overpayment,” as contemplated by the MPIM’s overpayment estimation guidelines in order to ensure that providers are treated fairly.⁴⁰ *See* MPIM § 8.4.5.1.

In sum, substantial evidence supports the Council’s decision that the sampling and extrapolation methodology used by Health Integrity to determine the overpayment amount was statistically valid and complied with the MPIM. Rio has failed to show that the Council’s decision was either arbitrary and capricious or otherwise contrary to law. As such, “the decision of the Secretary is conclusive and must be affirmed.” *Sid Peterson Mem’l Hosp. v. Thompson*, 274 F.3d 301, 311 (5th Cir. 2001) (quoting *Richardson*, 402 U.S. at 391).

D. Due Process Claim

Rio argues that CMS violated its “due process rights by unjustifiably withholding crucial sampling and extrapolation data until the eve of the ALJ hearing.” (Docket No. 34, at 16-22.)

⁴⁰ Rio was paid \$5,609,692.22 for the 2,179 claims in the universe for the two-year period from June 2007 to May 2009. (R. 434, 1220.) With an 85 percent error rate (*see supra* n.39), Rio was overpaid approximately \$4,768,238.39 on the 2,179 claims. (By applying the error rate to the entire amount Rio was paid for the claims in the universe, it sidesteps Dr. Haller’s assertion that the sample claims were biased towards higher amounts; in any event, the point estimate, based on the average overpayment in the sample, was \$4,770,713.23 (R. 440), which is a difference of only about \$2,500.) But the overpayment amount determined by Health Integrity using confidence interval estimation was \$4,079,073. (R. 40, 1306.) Thus, the overpayment demand amount is \$689,165.39 *less* than the amount one might assume based on the error rate. As noted in the MPIM, the procedure followed by Health Integrity, “which, through confidence interval estimation, incorporates the uncertainty inherent in the sample design, is a conservative method that works to the financial advantage of the provider or supplier.” MPIM § 8.4.5.1. Somewhat ironically, it also seems likely that the overpayment amount would have *increased* had Dr. Haller suggested a more precise method to determine the overpayment amount and had such a procedure been followed. As recognized in the MPIM, using “confidence interval estimation,” as Health Integrity did, “allows a reasonable recovery without requiring the tight precision that might be needed to support a demand for the point estimate.” *Id.* “However, the ... ZPIC ... is not precluded from demanding the point estimate where higher precision has been achieved.” *Id.* In other words, had Health Integrity employed a more precise estimation method, such as Dr. Haller apparently could have recommended, it may well have resulted in an overpayment demand that was higher than the one determined using the more conservative (and less administratively burdensome) confidence interval estimation.

“From Plaintiff’s initial written request on March 21, 2011 until the disc containing the ‘complete’ data was finally produced on May 14, 2015, Defendant has deliberately withheld the crucial statistical sampling data for no apparent reason.” (*Id.* at 18.) Rio contends that the “last-minute production is functionally equivalent to a complete withholding of the sampling data.” (*Id.* at 19.) According to Rio, it is “disingenuous and incredible for the [Council] to claim that Plaintiff was afforded a ‘full and fair opportunity to present its case.’” (*Id.*) Because CMS’s “deliberate withholding of the statistical sampling and extrapolation data infringes upon [Rio’s] due process right and is offensive to the general notion of fairness,” Rio urges that the Court must “reverse the [Council’s] decision *and invalidate the statistical sampling and extrapolation.*” (*Id.* at 22; emphasis added.)

“Procedural due process imposes constraints on governmental decisions which deprive individuals of ‘liberty’ or ‘property’ interests within the meaning of the Due Process Clause of the Fifth or Fourteenth Amendment.” *Mathews v. Eldridge*, 424 U.S. 319, 332 (1976). “Procedural due process promotes fairness in government decisions ‘[b]y requiring the government to follow appropriate procedures when its agents decide to deprive any person of life, liberty, or property.’” *John Corp. v. City of Houston*, 214 F.3d 573, 577 (5th Cir. 2000) (quoting *Daniels v. Williams*, 474 U.S. 327, 331 (1986)). As the Fifth Circuit has explained, “[d]ue process requires only ‘that there is at some stage an opportunity for a hearing.’” *United States v. Batson*, 782 F.2d 1307, 1315 (5th Cir. 1986) (quoting *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594, 599 (1950)) (internal quote marks omitted).

In *Brock v. Roadway Express, Inc.*, 481 U.S. 252, 261 (1987), the Supreme Court described the requirements for procedural due process in the administrative context:

[T]he first step is to identify a property or liberty interest entitled to due process protections, *Cleveland Board of Education v. Loudermill*, 470 U.S. 532, 538–539,

105 S.Ct. 1487, 1491–92, 84 L.Ed.2d 494 (1985); *Board of Regents v. Roth*, 408 U.S. 564, 576–578, 92 S.Ct. 2701, 2708–09, 33 L.Ed.2d 548 (1972)

“Once it is determined that due process applies, the question remains what process is due.” *Morrissey v. Brewer*, 408 U.S. 471, 481, 92 S.Ct. 2593, 2600, 33 L.Ed.2d 484 (1972). Though the required procedures may vary according to the interests at stake in particular contexts, *Boddie v. Connecticut*, 401 U.S. 371, 378, 91 S.Ct. 780, 786, 28 L.Ed.2d 113 (1971), “[t]he fundamental requirement of due process is the opportunity to be heard ‘at a meaningful time and in a meaningful manner.’” *Mathews v. Eldridge*, 424 U.S. 319, 333, 96 S.Ct. 893, 902, 47 L.Ed.2d 18 (1976), quoting *Armstrong v. Manzo*, 380 U.S. 545, 552, 85 S.Ct. 1187, 1191, 14 L.Ed.2d 62 (1965); see also *Mullane v. Central Hanover Bank & Trust Co.*, 339 U.S. 306, 313, 70 S.Ct. 652, 656, 94 L.Ed. 865 (1950).

Roadway Express, Inc., 481 U.S. at 261.

While due process requires an opportunity for a hearing “at a meaningful time and in a meaningful manner,” it does not require multiple hearings. As the Fifth Circuit has explained:

Due process requires only “that there is at some stage an opportunity for a hearing.” *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594, 599, 70 S.Ct. 870, 873, 94 L.Ed. 1088 (1950). The Supreme Court has “repeatedly held that no hearing at the preliminary stage is required by due process so long as the requisite hearing is held before the final administrative order becomes effective.” *Id.* at 598, 70 S.Ct. at 872. *Cf. Hilburn v. Butz*, 463 F.2d 1207, 1209 (5th Cir.1972) (due process does not require the ASCS to give notice and hearing before withholding legitimately earned subsidies pending resolution of a disputed overpayment in a previous year).

Batson, 782 F.2d at 1315 (addressing administrative determinations ordering refund overpayments of cotton subsidies) (footnote omitted).

The Supreme Court has also long-recognized that to prevail on a due process claim prejudice generally must be shown. See *United States v. Lovasco*, 431 U.S. 783, 789–90 (1977) (holding that “proof of prejudice is generally a necessary but not sufficient element of a due process claim”) (discussing *United States v. Marion*, 404 U.S. 307, 324-26 (1971)). The Fifth Circuit has likewise long held that “[t]o establish a denial of procedural due process, a party must show substantial prejudice.” *Keough v. Tate Cty. Bd. of Educ.*, 748 F.2d 1077, 1083 (5th Cir. 1984) (citations omitted). Of course, the prejudice requirement applies with equal force to due

process challenges made in the context of administrative proceedings. *Ka Fung Chan v. INS*, 634 F.2d 248, 258 (5th Cir. 1981) (rejecting due process challenges “because proof of a denial of due process in an administrative proceeding requires a showing of substantial prejudice”); *see also Achola v. Sessions*, 707 F. App’x 830, 831 (5th Cir. 2018) (“[T]his circuit requires a showing of substantial prejudice to prevail on a due process claim.”)

Similarly, it is well-settled that other types of procedural errors occurring during administrative proceedings require a showing of prejudice to be actionable. *See American Airlines, Inc. v. Department of Transp.*, 202 F.3d 788, 797 (5th Cir. 2000) (declining to remand based on alleged violations of the Administrative Procedures Act where appellant’s “continued failure to identify the evidence it would have submitted indicates that [it] was not prejudiced” by any inadequacy in the agency’s notice); *see also Jones v. Astrue*, 691 F.3d 730, 734–35 (5th Cir. 2012) (“The party seeking to overturn the Commissioner’s decision has the burden to show that prejudice resulted from an error.”); *Carey v. Apfel*, 230 F.3d 131, 142 (5th Cir. 2000) (“This Court will not reverse the decision of an ALJ for failure to fully and fairly develop the record unless the claimant shows that he or she was prejudiced by the ALJ’s failure.”); *Audler v. Astrue*, 501 F.3d 446, 448 (5th Cir. 2007) (“‘Procedural perfection in administrative proceedings is not required’ as long as ‘the substantial rights of a party have not been affected.’”) (quoting *Mays v. Bowen*, 837 F.2d 1362, 1364 (5th Cir. 1988)). The Fifth Circuit “will not set aside agency action for mere harmless error.” *Murtaza Mussaji, D.O., P.A. v. United States Dep’t of Health & Human Servs.*, 741 F. App’x 222, 225 (5th Cir. 2018) (citing *Graves v. Colvin*, 837 F.3d 589, 592–93 (5th Cir. 2016)).

As noted, Rio claims its due process rights were violated as a result of the inexcusable delay by CMS and its contractors in providing complete information regarding Health Integrity’s statistical sampling. It cannot be disputed that, in an initial notice dated February 18, 2011, Health

Integrity provided Rio with an encrypted CD containing “an explanation and details of the findings,” including “the Sampling Methodology.” (R. 1304.) It also cannot be disputed that, in a letter dated March 21, 2011, Rio acknowledged receiving the CD with information about the sampling methodology, but Rio advised that it did “not include the entire universe of claims.” (R. 1300.) Rio requested an Excel spreadsheet and provided detailed instructions on how the spreadsheet should be set up (including 13 items that should be included). (R. 1301.)

It is likewise undisputed that Rio’s repeated demands for this information over the next several years went essentially unheeded until a few days before the ALJ hearing, which was held May 19, 2015. Prior to the hearing, Rio requested the ALJ to order CMS to produce additional information. (R. 380.) After learning of this request, Health Integrity finally sent Rio and the ALJ another encrypted CD with additional information on May 13, 2015.⁴¹ (R. 380-82.)

In response to Rio’s due process claim, the Secretary takes exception to Rio’s suggestion that CMS withheld from the beginning data that it was required to disclose by the MPIM. (Docket No. 39, at 26-27.) The MPIM requires CMS contractors to send overpayment demands letters that include the following “information about the review and statistical sampling methodology”:

- a description of the universe, the frame, and the sample design;
- a definition of the sampling unit;
- the sample selection procedure followed, and the numbers and definitions of the strata and size of the sample, including allocations, if stratified;
- the time period under review;
- the sample results, including the overpayment estimation methodology and the calculated sampling error as estimated from the sample results; and

⁴¹ At the time Health Integrity produced the additional information, it does not appear that the ALJ had yet ordered it to do so.

- the amount of the actual overpayment/underpayment from each of the claims reviewed.

MPIM § 8.4.7.1. The Secretary points out that “Rio received this information with the overpayment determination.” (Docket No. 39, at 27.) From this, the Secretary concludes that “while Rio did experience a delay in receiving the information that it requested, it promptly received the information that the contractor was required, by the MPIM, to produce.” (*Id.*)

The Secretary may be correct that Rio received the MPIM-required information with the demand letter, but it is unnecessary to decide that issue. The failure of CMS and its contractors to provide additional information in response to Rio’s repeated requests is inexcusable and must not be condoned. Particularly given CMS’s overpayment determination, Rio’s request for additional information about the universe was reasonable, and the additional information should have been promptly provided so that Rio could better challenge Health Integrity’s findings.⁴² Instead, Rio was left in administrative limbo for years while its requests were apparently shuttled from one government office/contractor to another, resulting in inadequate responses that the Council generously described as “compartmentalized.” (R. 28.) The failure of CMS and its contractors to respond to Rio’s request in an appropriate and timely manner caused unnecessary expenditure of time and resources by Rio, the ALJ, the Council, and now this Court. The delay in responding to Rio’s request was unfair not just to Rio, but also to the various decisionmakers who have had to address this issue and—perhaps most importantly—to the public.⁴³

⁴² It is also unnecessary to decide whether it was reasonable for Rio to demand that the additional information to be provided in the particular format and detail described in its letters. If CMS or its contractors had found this to be unduly burdensome, the proper response would have been to provide the basic information in a different format—not to ignore the request altogether.

⁴³ The MPIM provides that the failure by a contractor “to follow one or more requirements may result in review by CMS of their performance, but should not be construed as necessarily affecting the validity of the statistical sampling and/or the projection of the overpayment.” MPIM § 8.4.1.1. It is hoped that CMS will review its own performance and that of any contractor involved in the

While the unacceptable delay by CMS and its contractors in responding to Rio's requests amounted to egregious conduct, this does not mean that Rio's constitutional right to due process was violated in the context of the elaborate administrative appeal process that Rio invoked. As discussed above, the touchstone of due process "is the opportunity to be heard 'at a meaningful time and in a meaningful manner.'" *Mathews*, 424 U.S. at 333. "In assessing what process is due ... substantial weight must be given to the good-faith judgments' of those who provide the procedures." *Burciaga v. Deutsche Bank Nat'l Tr. Co.*, 871 F.3d 380, 390 (5th Cir. 2017) (quoting *Mathews*, 424 U.S. at 349).

The Council's decision appropriately applied these principles:

However compartmentalized the various contractors' responses to the appellant's requests may have been, these events do not amount to a violation of the appellant'[s] [Rio's] due process. Even if, as the appellant suggests, its ability to develop and present sampling methodology arguments at earlier levels of review had been compromised, both the ALJ and the Council engage in de novo review. See 42 C.F.R. §§ 405.1000(d) and 405.1100(c). Thus, neither an ALJ nor the Council would have been bound by the findings at earlier levels of review.

(R. 28.) The Council is correct. CMS provides a multi-level appeal process, which satisfies the requirements of due process in that providers have the opportunity to present evidence and arguments at multiple stages, including de novo review before both an ALJ and the Council.

failure to timely respond to Rio's request for information. This case illustrates why such review is so important. The ALJ was understandably concerned by the "significant, willful, and unexplained delay" in responding to Rio's requests. (R. 61.) As a result of that conduct, he found not only that the extrapolated amount was "invalid," but also that CMS should not be permitted to correct any sampling errors. (*Id.*) Apparently intending to penalize CMS, the result of the ALJ's ruling would have also penalized the public and arguably provided a windfall to Rio. Had the ALJ's ruling stood, Rio would not have been required to repay about \$4 million in Medicare overpayments it was found to have received; instead, Rio would have repaid only the \$89,765 overpayment it received on the 35 individual claims that were audited. (R. 61-62.) Such a result would have run counter to the purposes of the Medicare Integrity Program, in which Congress approved contractors' use of extrapolation in an attempt to recoup rampant Medicare overpayments. 42 U.S.C. § 1395ddd(a), (f), (h); see generally *supra* Part I.A..

Substantial evidence supports the Councils finding that Rio received sufficient information to fully challenge Health Integrity's sampling and extrapolation. Although Rio did not receive all of the information until the "eve of trial" (as Rio accurately describes it), Rio's expert was able to review the additional information just prior to the hearing and addressed it at length both in his hearing testimony and in his first "Addendum" to his initial written declaration. (R. 818-48, 1551-77.) Significantly, the difficulty Rio faced in addressing the new information was alleviated by the ALJ, who "left the record open for sixty (60) days to allow [Rio] the opportunity to submit a post hearing position paper and additional documents." (R. 40.) Rio appropriately took advantage of this opportunity, filing a "Rebuttal" by Dr. Haller that was submitted several weeks after the hearing. (R. 187-92.)

Armed with the additional information received prior to the hearing before the ALJ, Dr. Haller also prepared and submitted to the Council a detailed analysis and critique of Health Integrity's sampling and extrapolation. (R. 78-97.) Dr. Haller's "Second Addendum" was dated November 15, 2016, which was over a year after Health Integrity had provided the additional information. The Council considered this, as well as all of the other evidence in the record, in conducting its de novo review.

Rio argues that the Council "conveniently ignored that the Social Security Act, in comporting with the [requirements of] due process, grants a provider a multi-level appeal process." (Docket No. 34, at 20 (citing 42 C.F.R. § 1395ff).) According to Rio, "[a] provider is, therefore, entitled to a fair opportunity to be heard at each level of the administrative appeal." (*Id.*) Rio is essentially arguing that in the Medicare context, a provider is constitutionally entitled to four separate due process hearings, each of which must satisfy the requirements of *Mathews*. Not surprisingly, Rio cites no legal authority for this novel argument. Rio's due process right to be

heard “at a meaningful time and in a meaningful manner” was clearly satisfied by its de novo hearing before the ALJ and the de novo review by the Council.⁴⁴

This conclusion is confirmed by the Fifth Circuit’s rejection of an identical due process claim in *Maxmed*. As noted, that case also involved judicial review of a Medicare overpayment determination regarding home health care services; Health Integrity was the ZPIC and Palmetto was the Medicare Administrative Contractor. The Fifth Circuit described the due process issue there as follows:

Maxmed asserts that CMS and its contractors “deprived Maxmed of a meaningful opportunity to dispute and contest the overpayment by withholding critical evidence such as the statistical sampling and extrapolation data and information.” Maxmed concedes that it obtained all of this information at least shortly before the ALJ hearing, and the Secretary disputes the untimeliness. Moreover, the information was thoroughly tested before the ALJ and the Council. The company nevertheless complains that the information was “withheld for years and through two appeal stages” (presumably referring to the redetermination and reconsideration stages).

Maxmed Healthcare, Inc., 860 F.3d at 344. But the Fifth Circuit found that the “district court properly rejected” Maxmed’s similar due process argument, explaining: “We are unaware of any authority holding that agency processes become fundamentally unfair under the circumstances

⁴⁴ Rio argues that receiving de novo review before the ALJ did not remedy the effects of due process violations earlier in the appeals process. (Docket No. 34, at 20.) In support, Rio cites the ALJ’s statement in a footnote that in “reality and as a practicality, an ALJ rarely exercises full de novo review in deciding a case but looks only at the unfavorable issues remaining at the ALJ hearing level.” (R. 61 n.15.) The ALJ’s attempt to rationalize the finding that Rio’s due process rights were violated despite having received a full evidentiary hearing is unpersuasive for at least two reasons. First, the ALJ was obviously aware of the issues raised by the belatedly-provided information, and he did in fact address those issues de novo, as reflected by his thorough decision. Second, the not-really-de novo-review rationale is contrary to the ALJ’s description of his review in the last paragraph of his decision, in which he states: “This decision is partially favorable and based on a de novo review of the record.” (R. 62.) The ALJ’s concluding statement is consistent with his duty, as mandated by the regulations, to “conduct[] a de novo review.” 42 C.F.R. § 405.1000(d).

before us, where Maxmed never denies having received the information before the ALJ conducted a *de novo* hearing.” *Id.*

Rio’s due process claim also fails because it has not—and under the circumstances here cannot—show that it was prejudiced. Such prejudice requires a showing that the result of the proceeding would have likely been different but for the procedural error. *See Ka Fung Chan*, 634 F.2d at 258 (“proof of a denial of due process in an administrative proceeding requires a showing of substantial prejudice”); *Achola*, 707 F. App’x at 831 (“[T]his circuit requires a showing of substantial prejudice to prevail on a due process claim.”); *see also Gonzalez v. Holder*, 488 F. App’x 795, 796 (5th Cir. 2012) (substantial prejudice requires “show[ing] the results of the proceeding would have differed”); *Morris v. Bowen*, 864 F.2d 333, 335 (5th Cir. 1988) (“procedural improprieties ... will therefore constitute a basis for remand only if such improprieties would cast into doubt the existence of substantial evidence to support the ALJ’s decision”). Here, Rio had a full—if belated—opportunity to challenge Health Integrity’s sampling and extrapolation methodology before both the ALJ and the Council. There is no reason to believe that the result of Rio’s administrative appeal process would have been any different had it received the missing information earlier. *See Maxmed Healthcare, Inc.*, 860 F.3d at 344 (noting that “Maxmed alleges in only conclusory terms that it was prejudiced by late disclosure”).

For all these reasons, Rio’s challenge to the Council’s due process ruling should be rejected. The Council applied the correct legal standard, and its decision is supported by substantial evidence.

E. Exhaustion: Individual Sample Claims Denials

In moving for summary judgment, Rio claims that the Secretary erred in denying the individual claims that were audited by Health Integrity. Rio argues that the Secretary erred in

three ways: failing “to comprehensively assess these patients”; “applying a retrospective informal and unlawful stability presumption in evaluating the beneficiaries’ need for skilled services”; and “undermining the certifying physicians’ medical judgment.” (Docket No. 34, at 22-25.) Rio does not address the specific evidence in the record as to any of the individual patients and does not refer to the ALJ’s decision.

In responding to this claim, the Secretary moves for summary judgment on the basis that the individual claim denials are not properly before the Court because “Rio did not fully exhaust its administrative rights by challenging the individual, beneficiary-specific claims denial[s] before the Council.” (Docket No. 39, at 27-29.) Although Rio responded to the Secretary’s summary judgment motion, Rio did not address the Secretary’s argument that the individual claims were unexhausted and should not be considered on judicial review. (*See* Docket No. 42.) Because the Secretary’s position is correct, it is unnecessary to address Rio’s arguments regarding the individual coverage denials.

The judicial review provisions of the Social Security Act, including 42 U.S.C. § 405(g), (h), have been incorporated into the Medicare Act for purposes of judicial review of Medicare administrative decisions. *See* 42 U.S.C. § 1395ff(b)(1)(A) (individuals dissatisfied with HHS Secretary’s “final decision” are entitled to judicial review as provided in § 405(g)); 42 U.S.C. § 1395ii (§ 405(h) made applicable to Medicare determinations). Section 405(g) provides that only a “final decision” of the Secretary is subject to judicial review, and § 405(h) states that “[n]o findings of fact or decision” can be subject to judicial review except as specifically authorized.

The Supreme Court has explained that where the basis of a claim is the Medicare Act, “all aspects” of any such claims “must be ‘channeled’ through the administrative process.” *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 12, 120 (2000) (quoting *Heckler v. Ringer*, 466

U.S. 602, 614 (1984)). This prohibition “reaches beyond ordinary administrative law principles of ‘ripeness’ and ‘exhaustion of administrative remedies,’” which “in any event normally require channeling a legal challenge through the agency.” *Id.* (quoting *Weinberger v. Salfi*, 422 U.S. 749, 757 (1975)).

In applying § 405(g) in the context of the denial of Social Security disability benefits, the Supreme Court explained that a claimant seeking judicial review must have first completely exhausted his administrative remedies by seeking review from the Appeals Council:

SSA regulations provide that, if the Appeals Council grants review of a claim, then the decision that the Council issues is the Commissioner’s final decision. But if, as here, the Council denies the request for review, the ALJ’s opinion becomes the final decision. *See* 20 CFR §§ 404.900(a)(4)-(5), 404.955, 404.981, 422.210(a) (1999). If a claimant fails to request review from the Council, there is no final decision and, as a result, no judicial review in most cases. *See* § 404.900(b); *Bowen v. City of New York*, 476 U.S. 467, 482–483, 106 S.Ct. 2022, 90 L.Ed.2d 462 (1986). In administrative-law parlance, such a claimant may not obtain judicial review because he has failed to exhaust administrative remedies. *See Salfi, supra*, at 765–766, 95 S.Ct. 2457.

Sims v. Apfel, 530 U.S. 103, 106–07 (2000) (footnote omitted).⁴⁵

⁴⁵ In *Sims v. Apfel*, the Supreme Court held that judicially-imposed issue exhaustion did not apply in Social Security disability cases due to the non-adversarial nature of those proceedings. 530 U.S. at 110-12. In *Cypress Home Care, Inc. v. Azar*, 326 F.Supp.3d 307 (E.D. Tex. 2018), the court held that issue exhaustion should likewise not be applied in Medicare cases because “the rules of the Medicare appeal process are not sufficiently adversarial to trigger a strict issue exhaustion requirement.” *Id.* at 324. Whether the holding in *Sims* should be extended to Medicare cases need not be addressed here since the instant case does not involve mere issue exhaustion. In *Cypress Home Care, Inc.*, the ALJ had, like here, invalidated the statistical sampling methodology, and CMS had referred for Council review that part of the ALJ’s ruling. *Id.* at 312. But unlike the present case, the provider had also “filed an appeal with the Council seeking review of all unfavorable aspects of the ALJ’s ruling,” including the ALJ’s affirmance of some of the claim denials. *Id.* As a result of the provider’s appeal to the Council, the Council reviewed and issued decisions on the individual coverage claims. *Id.* In seeking judicial review, the provider challenged the Council’s ruling on the individual claims but raised a new legal argument regarding those claims. *Id.* at 323. The Secretary argued that the provider had waived that legal issue by failing to raise it before the Council, which prompted the court’s holding that issue exhaustion should not apply in Medicare cases. *Id.* at 323-24. Here, in contrast, Rio did not appeal the ALJ’s

Similarly, Medicare regulations provide for ultimate de novo review by the Council. 42 C.F.R. § 405.1100. The regulations also specify that “a party to a Council decision” may obtain judicial review of that decision if the \$1,000 administrative amount-in-controversy requirement is met. 42 C.F.R. § 405.1136(a)(1) (referring to § 405.1006(c)). In the context of claims brought by individual Medicare beneficiaries, the Supreme Court observed that “the Secretary has provided that a ‘final decision’ is rendered on a Medicare claim only after the individual claimant has pressed his claim through all designated levels of administrative review.” *Heckler v. Ringer*, 466 U.S. 602, 606 (1984) (footnote omitted). “If the Appeals Council also denies the claim and if the claim exceeds \$1,000, only then may the claimant seek judicial review in federal district court of the ‘Secretary’s final decision.’” *Id.* at 607 (citing 42 U.S.C. §§ 1395ff(b)(1)(C), (b)(2)).

The Supreme Court explained that the exhaustion requirement serves the purpose of “preventing premature interference with agency processes, so that the agency may function efficiently and so that it may have an opportunity to correct its own errors, to afford the parties and the courts the benefit of its experience and expertise, and to compile a record which is adequate for judicial review.” *Salfi*, 422 U.S. at 765. By “‘channeling’ of virtually all legal attacks through the agency, it assures the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes without possibly premature interference by different individual courts.” *Ill. Council on Long Term Care, Inc.*, 529 U.S. at 13.

The Fifth Circuit and other federal courts have applied this exhaustion principle in the context of providers challenging Medicare overpayment determinations. *See RenCare, Ltd. v. Humana Health Plan of Texas, Inc.*, 395 F.3d 555, 557 (5th Cir. 2004) (stating that “[r]egulations

denial of coverage on the individual claims, and the Council thus did not address at all the individual claim determinations.

promulgated by the Secretary ... indicate that a final decision is issued only after a case has progressed through all the levels of administrative review provided for each Part of the Medicare Act”) (citations omitted); *see also Am. Hosp. Ass’n v. Azar*, 895 F.3d 822, 828 (D.C. Cir. 2018) (stating that, as a precondition of obtaining judicial review of Medicare-related claims, “the plaintiff must fully exhaust all available administrative remedies,” though this type of exhaustion is “waivable”) (citing *Mathews v. Eldridge*, 424 U.S. 319, 328 (1976)); *Prime Healthcare Servs. - Montclair, LLC v. Hargan*, No. CV 17-659 PA (JCX), 2018 WL 333862, at *1–2 (C.D. Cal. Jan. 9, 2018) (describing the Medicare appeal process and stating that “[o]nce this administrative process is exhausted, the claimant may then seek judicial review”); *Moller v. CMS-Centers for Medicare & Medicaid Servs.*, 959 F. Supp. 2d 1031, 1034 (E.D. Mich. 2013) (stating that the Medicare Act “requires that claims be pursued all the way to the end of an administrative review process before the Court is able to exercise its jurisdiction”). As simply stated by another court in this District: “Under the Medicare Act, a party dissatisfied with a contractor’s overpayment calculation must go through four levels of administrative review before seeking judicial review,” including review by the Council. *Maxxim Care EMS, Inc. v. Sebelius*, Civil Action No. H-10-1408, 2011 WL 5977666 at *2 (S.D. Tex. Nov. 29, 2011) (citing *Rencare, Ltd.*, 395 F.3d at 557; 42 C.F.R. § 405.1136).

Here, Rio had the right to request review by the Council of the ALJ’s adverse rulings on the individual coverage claims. 42 C.F.R. § 405.1100(a). It did not do so. Rio thus did not exhaust its administrative remedies regarding the individual claim determinations. The Secretary has not waived exhaustion as to those claims, and there is no basis to judicially override the refusal to

waive that requirement.⁴⁶ While Rio's decision not to request Council review of the individual claims is understandable (given the ALJ's otherwise very favorable ruling), it does not alter the conclusion that Rio thereby waived judicial review of those non-exhausted individual coverage claims. *See Maxxim Care EMS, Inc.*, 2011 WL 5977666 at *2; *see also Transyd Enterprises, L.L.C. v. Sebelius*, Civil Action No. M-09-292, 2012 WL 1067561 at *1 (S.D. Tex. 2012) (holding that since neither CMS nor the provider "sought review by the [Council] of the ALJ's finding on the individual claims, exhaustion has not occurred and the Court may not review these findings on appeal").⁴⁷ Accordingly, the Secretary's summary judgment motion should be granted as to Rio's individual coverage claims.

⁴⁶ In *Ringer*, the Supreme Court described the two requirements that must be met for judicial review of this type of administrative decision: "We have previously explained that the exhaustion requirement of § 405(g) consists of a nonwaivable requirement that a 'claim for benefits shall have been presented to the Secretary,' *Mathews v. Eldridge*, 424 U.S., at 328, 96 S.Ct., at 899, and a waivable requirement that the administrative remedies prescribed by the Secretary be pursued fully by the claimant. *Ibid.*" *Ringer*, 466 U.S. at 617. As applied here, there can be no dispute that Rio satisfied the presentment requirement; Rio clearly presented its claims as to the individual coverage determinations to the ALJ. But there can also be no legitimate dispute that Rio did not satisfy the second requirement in that it did not "pursue[] fully" its administrative remedies as to the individual claims. Rio did not request Council review of those claims. While there are "certain special cases" in which a court may judicially override the Secretary's reliance on the exhaustion requirement, such as where the claimant is asserting "a claim that was wholly 'collateral' to his claim for benefits," there has been no showing that any such exception applies here. *See id.* at 618 (citing *Mathews*, 424 U.S. at 330-32).

⁴⁷ The circumstances in *Maxxim Care EMS* were almost identical to those here. There, the ALJ had found that 25 out of the 30 audited Medicare claims were not covered and were properly denied, but the ALJ also ruled that the sample was not "sufficiently reliable." *Id.* at *1. Although CMS sought Council review of the ALJ's decision regarding the statistical sampling, the provider "did not seek review of the ALJ decision." *Id.* In granting summary judgment for the Secretary on this issue, the court stated: "The record is clear that [the provider] did not exhaust its administrative remedies regarding coverage of the 25 denied claims affirmed by the ALJ." *Id.* at *2. Likewise, the procedural posture in the *Transyd* case was very similar to this case. There, a provider of ambulance services, *Transyd*, was found to have been overpaid on claims for transport services to Medicare beneficiaries. The ALJ ruled in *Transyd*'s favor on some, but not all, of the individual coverage claims and ruled that the statistical sampling and extrapolation were invalid. 2012 WL 0167561 at *3. There, as here, CMS requested Council review on the statistical sampling and extrapolation issues, and neither party sought review of the ALJ's rulings on the individual


III. CONCLUSION

For the foregoing reasons, the undersigned respectfully recommends that Plaintiff Rio's motion for summary judgment (Docket No. 34) be DENIED, that the Secretary's cross-motion for summary judgment (Docket No. 39), and the decision of the Secretary be AFFIRMED, and that this action be DISMISSED.

NOTICE TO THE PARTIES

The Clerk shall send copies of this Report and Recommendation to the parties who have fourteen (14) days after receipt thereof to file written objections pursuant to 28 U.S.C. § 636(b)(1)(C) and Rule 72(b) of the Federal Rules of Civil Procedure. Failure to file timely written objections shall bar an aggrieved party from receiving a de novo review by the District Court on an issue covered in this Report and, except upon grounds of plain error, from attacking on appeal the unobjected-to proposed factual findings and legal conclusions accepted by the District Court.

DONE at McAllen, Texas on March 11, 2019.


Peter E. Ormsby
United States Magistrate Judge

claims. *Id.* at *4. Transyd sought judicial review of the ALJ's adverse rulings on some of the individual claims, but the court granted the Secretary's motion for summary judgment because "exhaustion ha[d] not occurred" as to those claims. *Id.* at *7.