

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
ALEXANDRIA DIVISION

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CENTRAL LOUISIANA HOME  
HEALTH CARE, L.L.C.

CIVIL ACTION 1:17-CV-00346

VERSUS

JUDGE DRELL

THOMAS E. PRICE, M.D.,  
SECRETARY OF THE  
DEPARTMENT OF HEALTH  
AND HUMAN SERVICES

MAGISTRATE JUDGE PEREZ-MONTES

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**REPORT AND RECOMMENDATION**

Before the Court are cross-motions for summary judgment (Docs. 51, 68) filed by Plaintiff Central Louisiana Home Health Care, L.L.C. (“CLHHC”) and Defendant United States Department of Health and Human Services (“DHHS”). Because substantial evidence does not support the final decision of the Secretary, Plaintiff’s Motion for Summary Judgment (Doc. 51) should be granted and defendant’s Motion for Summary Judgment (Doc. 68) should be denied.

**I. Background**

**A. Procedural Background.**

CLHHC filed this complaint<sup>1</sup> pursuant to 42 U.S.C. § 1395ff(b), seeking review of the final agency decision of the Secretary of DHHS. The DHHS administers the Medicare program through the Centers for Medicare and Medicaid Services (“CMS”). DHHS answered (Doc. 11) and filed the administrative record (Docs. 32-40).

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<sup>1</sup> The “complaint” is actually an appeal to the District Court. See 42 U.S.C. § 1395ff(b), “Appeal rights.”

CLHHC alleges that AdvanceMed Corporation (“AdvanceMed”) was employed by Medicare as a Zone Program Integrity Contractor (“ZPIC”) to audit Louisiana Medicaid providers in Louisiana. In November 2010, AdvanceMed sent CLHHC a letter requesting medical records relating to all claims for home health services billed to Part A of the Medicare program on behalf of 30 Medicare beneficiaries. CLHHC promptly complied with AdvanceMed’s records request.

CLHHC alleges that, in January 2012, AdvanceMed informed CLHHC that about 57% of the claims it had audited had been denied in whole or in part. AdvanceMed contends the claims it audited constituted a statistically valid random sample of CLHHC’s Medicare claims, and that AdvanceMed thereby extrapolated an overpayment to CLHHC of \$1,931,041.00. In its Statistical Sampling for Overpayment Estimation (“SSOE”) Memorandum, AdvanceMed stated the precision for its overpayment estimate was 40.84%, and that it had a 90% confidence level that their estimate was within 40.84% of the true overpayment amount. AdvanceMed alleged that two different statisticians had reviewed the methodology and found no instances of “non-sampling error” (examples of which involve: clerical errors; computer problems; integrity of the claims data; the sample selection process; the process of creating or rearranging the frame; and execution of the arithmetic).

CLHHC alleges that Palmetto GBA, L.L.C. (“Palmetto”), the Medicare administrative contractor employed by DHHS to process Medicare claims in Louisiana, notified CLHHC of the overpayment, and CLHHC requested a

redetermination of the alleged overpayment. Palmetto's redetermination of the overpayment was unfavorable to CLHHC.

CLHHC then requested reconsideration, which is handled by a separate contractor known as a qualified independent contractor ("QIC"), which in this case was MAXIMUS Federal Services, Inc. ("MAXIMUS"). MAXIMUS addressed CLHHC's denied claims piecemeal and rendered four unfavorable reconsideration decisions.

CLHHC filed requests for a hearing before an Administrative Law Judge ("ALJ") with the Office of Medicare Hearings and Appeals. The ALJ remanded with an order for MAXIMUS to issue one decision instead of four.

While its appeal was pending, Palmetto notified CLHHC that AdvanceMed had erred in calculating the overpayment amount. Palmetto explained that AdvanceMed's original overpayment calculation of \$1,931,041.00 only took into account the partially denied claims but omitted the fully denied claims. Palmetto revised the overpayment amount for both fully and partially denied claims to "upward of \$6,770,584.00."

After MAXIMUS re-submitted its decision, the ALJ held a hearing in May 2016 and determined that AdvanceMed's statistical method and analysis (on the recalculation of the overpayment) was flawed. The ALJ also found that claims for five of the beneficiaries at issue met Medicare criteria for coverage. The ALJ directed AdvanceMed to recalculate the alleged overpayment without extrapolation.

CLHHC appealed all aspects of the ALJ's decision that were unfavorable, and sought review of the portion of the ALJ's decision invalidating the extrapolation on its own motion. In January 2017, the Appeals Council reversed the ALJ's decision, finding: (1) the sampling methodology was valid; (2) Medicare coverage existed for approximately 15 of the 108 denied claims; and (3) CLHHC was liable for the remaining extrapolated overpayment amount. The Appeals Council's decision became the final decision of the Secretary.

CLHHC next filed an appeal for judicial review of the Secretary's final decision.<sup>2</sup> CLHHC filed a Motion for Summary Judgment (Docs. 51, 52). DHHS filed a Cross-Motion for Summary Judgment (Doc. 68), to which CLHHC replied (Doc. 77).

In its motion for summary judgment, CLHHC contends (Doc. 51-1):

- (1) The ALJ correctly determined that the statistical sampling methodology and extrapolation was invalid.
- (2) The Council erred in its rejection of Medicare coverage for home health services.
- (3) The Council erred in denying CLHHC a waiver of recoupment of the overpayment and/or its finding that CLHHC was at fault for the overpayments.

In its motion for summary judgment, DHHS asks that the decision of the Medicare Appeals Council be affirmed (Doc. 68).

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<sup>2</sup> Under 42 U.S.C. § 405(g) and (h), federal courts are vested with jurisdiction over only a "final decision" of the DHHS when dealing with claims "arising under" the Medicaid Act. See Family Rehabilitation, Inc. v. Azar, 886 F.3d 496, 500 (5th Cir. 2018). Although § 405(g) is a provision of the Social Security Act, it has been made applicable to Medicare by 42 U.S.C. § 1395ff(b)(1)(A). See Family Rehabilitation, Inc., 886 F.3d at 507, n.4.

The cross-motions for summary judgment are now before the Court for disposition.

**B. Factual Background**

The factual background of this case is set forth by the Appeals Council in its decision (Doc. 32-1, pp. 6-11/549).

CLHHC is a Medicare-certified home health agency (Doc. 32-1, p. 6/549). AdvanceMed is a ZPIC that conducts post-payment review of Medicare billing (Doc. 32-1, p. 6/549).

CLHHC submitted claims for Medicare payment for home health services furnished to multiple beneficiaries in 2008 through 2010 (Doc. 32-1, p. 6/549). Those claims were initially paid by QIC”) Palmetto GBA, the Medicare contractor (Doc. 32-1, p. 6/549). Thereafter ZPIC AdvanceMed performed a medical review of those claims for benefit integrity (Doc. 32-1, p. 6/549). According to data analysis, CLHHC ranked significantly higher than its peers nationally in average number of visits per patient and average payment per patient (Doc. 32-1, p. 6/549). CLHHC also had a significant number of patients who received home health services for more than 360 days (Doc. 32-1, p. 6/549).

AdvanceMed’s statistical sampling methodology was set forth in a letter dated January 18, 2012 (Doc. 32-1, pp. 6-7/549). AdvanceMed interviewed several beneficiaries in the sample, and found the beneficiaries received home health care far

beyond their need to services (Doc. 32-1, p. 6/549). ZPIC AdvanceMed then requested medical records for the 30 beneficiaries in the sample (Doc. 32-1, p. 6/549).

The Appeals Council found that AdvanceMed used 30 beneficiaries, who had 229 claims, out of a total of the possible 1330 beneficiaries in the sampling frame (Doc. 32-1, p. 7/549).<sup>3</sup> The universe was defined as all fully and partially paid claims submitted by the providers of interest for the period covered (January 1, 2008 through July 31, 2010) (Doc. 32-1, p. 7/549). The sampling frame was comprised of all sampling units within the universe that were: (1) non-Medicare secondary payer claims; and (2) at least one line of service on the claim was paid greater than \$ 0 to the providers of interest. AdvanceMed found that home health services should not have been covered by Medicare in whole or in part for 17 of the 30 sample beneficiaries (Doc. 32-1, p. 7/549). The lower bound of a 2-sided 90% confidence interval<sup>4</sup> was used for an increased probability that the repayment request would not exceed the amount of the actual overpayment (Doc. 32-1, p. 8/549). An overpayment amount of \$1,931,041 was calculated and requested from CLHHC (Doc. 32-1, p. 8/549).

CLHHC asked QIC Palmetto for a redetermination as to: (1) the issue of Medicare coverage for services furnished to beneficiaries in the sample; and (2) the statistical sampling methodology (Doc. 32-1, p. 8/549). QIC Palmetto upheld the

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<sup>3</sup> The sample was 2.26% of the total pool of beneficiaries in the frame.

<sup>4</sup> The Medicare Program Integrity Manual ("MPIM") calls for the lower bound (limit) of a 1-sided 90% confidence interval (Doc. 22-1, p. 7/549).

denials of coverage of services in all but one case (beneficiary O.J., which was re-determined on a partially favorable basis) (Doc. 32-1, p. 8/549). However, QIC Palmetto failed to review the statistical sampling methodology (Doc. 32-1, p. 8/549). At CLHHC's request, Palmetto again reconsidered and issued four separate decision on reconsiderations (Doc. 32-1, p. 8/549).

The ALJ remanded the matter to QIC Palmetto for reconsideration and issuance of one decision (Doc. 32-1, p. 9/549). QIC Palmetto upheld the denials of coverage for all necessary beneficiaries in the sample and the statistical sampling and extrapolation (Doc. 32-1, p. 9/549).

CLHHC next requested a hearing before an ALJ. In January 2014, while waiting for the hearing to be held, ZPIC AdvanceMed discovered it had made errors in calculating the amount of overpayment and corrected the overpayment amount with an increase from \$1,931,041. to \$6,770,584 (Doc. 32-1, p. 9/549).<sup>5</sup>

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<sup>5</sup> 42 U.S.C. § 405.980, "Reopening of initial determinations, redeterminations, reconsiderations, decisions, and reviews," states in pertinent part:

(a) General rules.

(1) A reopening is a remedial action taken to change a binding determination or decision that resulted in either an overpayment or underpayment, even though the binding determination or decision may have been correct at the time it was made based on the evidence of record. That action may be taken by—

- (i) A contractor to revise the initial determination or redetermination;
- (ii) A QIC to revise the reconsideration;
- (iii) An ALJ or attorney adjudicator to revise his or her decision; or
- (iv) The Council to revise the ALJ or attorney adjudicator decision, or its review decision

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(3) Notwithstanding paragraph (a)(4) of this section, a contractor must process clerical errors (which includes minor errors and omissions) as reopenings, instead of as redeterminations as specified in § 405.940. If the contractor receives a request for reopening and disagrees that the issue is a clerical error, the contractor must dismiss the reopening request and advise the party of any appeal rights, provided the

1. **ALJ's Hearing**

On May 4, 2016, the ALJ held a hearing by telephone (Doc. 32-1, p. 9/549). Testimony was heard on issues relating to the validity of the statistical sampling and extrapolation, and Medicare coverage for services to individual beneficiaries in the sample (Doc. 32-1, p. 9/549).

Leeanne Dodson testified that she is a registered nurse, a certified home health coder, and the senior lead claim analyst for home health claims in the Medical Review Department at AdvanceMed (Doc. 33-1, p. 347/552). Dodson testified that the initial review of CLHHC was of 221 claims, of which 58% were denied (Doc. 33-1, p. 351/552). Most of those claims were denied as not reasonable and necessary, or due to the length of the stay (Doc. 33-1, p. 351/552). Dodson explained the national average for home health episodes per beneficiary is two, but CLHHC averaged 20 per beneficiary (Doc. 33-1, p. 352/552). The national average for home visits when nursing services are needed is 20 visits per beneficiary, but CLHHC averaged 11 per beneficiary,

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timeframe to request an appeal on the original denial has not expired. For purposes of this section, clerical error includes human or mechanical errors on the part of the party or the contractor such as—

- (i) Mathematical or computational mistakes;
- (ii) Inaccurate data entry; or
- (iii) Denials of claims as duplicates.

(4) When a party has filed a valid request for an appeal of an initial determination, redetermination, reconsideration, ALJ or attorney adjudicator decision, or Council review, no adjudicator has jurisdiction to reopen an issue on a claim that is under appeal until all appeal rights for that issue are exhausted. Once the appeal rights for the issue have been exhausted, the contractor, QIC, ALJ or attorney adjudicator, or Council may reopen as set forth in this section.

minimizing their visits and maximizing their payments (Doc. 33-1, p. 252/552).<sup>6</sup> Dodson stated that, when patients should have been discharged, CLHHC remained on service for years, and “exacerbated” diagnoses with no supporting documentation (Doc. 33-1, p. 353/552). Dodson further testified that: plans of care were not individualized for each patient; the discharge plans stated “when services were no longer needed;” non-covered lab visits were billed; patients’ vital signs were frequently noted as abnormal when they were not; and CLHHC maintained non-compliant patients on services (Doc. 33-1, p. 354/552).

The government’s expert statistician, Dr. Wes Camp (who was impliedly accepted as an expert without discussion or examination) testified that the universe of claims was composed of claims with dates of service between January 1, 2008<sup>7</sup> and July 31, 2010 (Doc. 33-1, p. 353/552). Dr. Camp explained that a sample of 30 beneficiaries was selected for review (Doc. 33-1, p. 354/552). Dr. Camp acknowledged the overpayment amount was originally miscalculated by giving the denied claims a zero-dollar overpayment (Doc. 33-1, p. 354/552). The redetermination of the overpayment showed 21 of the 30 beneficiaries had at least some error, with a “virtual actual overpayment” of \$226,000 and an extrapolated overpayment amount of \$6,700,000.

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<sup>6</sup> National statistics data regarding norms is used to identify deviations as potential claim errors that may require investigation. See MPIM Chapter 2.

<sup>7</sup> The administrative record shows the claims universe dates actually begin on November 19, 2007 (Doc. 33, p. 334/549).

Dr. Mitchell Cox, Ph.D., was accepted as an expert in statistics (Doc. 33-1, pp. 364-65). Dr. Cox testified that he found six problems with AdvanceMed's methodology (Doc. 33-1, p. 365/552). First, it was error for AdvanceMed to exclude potential underpayments from their sampling frame by excluding all unpaid claims (claims that were submitted and denied in full), resulting in a failure to estimate the net overpayment as required by the MPIM (Doc. 33-1, p. 366/552). The inspection log of AdvanceMed's "SAS software session" showed that only claims with paid amounts greater than zero were included in the sampling frame (Doc. 33-1, p. 369/552). The log showed that AdvanceMed removed the six unpaid beneficiaries (a sample unit in this case is a beneficiary) (Doc. 33-1, p. 370/552). The log also showed that unpaid claims were removed from the remaining beneficiaries whose claims were paid in part (Doc. 33-1, p. 370-552).

Dr. Cox testified that MPIM § 8.4.3.2.2 requires all potentially underpaid sampling units, including the unpaid claims, be included in the sampling frame (Doc. 33-1, p. 371/552).<sup>8</sup> MPIM § 8.4.3.2.3 states "[t]he ideal [sampling] frame is a list that covers the target universe completely" (Doc. 33-1, p. 371/552). Any unpaid claim that should have been paid is really a mis-paid claim (Doc. 33-1, p. 372/552). Dr. Cox explained the only way to estimate the "net overpayment" is to include the mis-paid

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<sup>8</sup> MPIM § 8.4.3.2.2 – The Sampling Unit, states: "Sampling units are the elements that are selected according to the design of the survey and the chosen method of statistical sampling. They may be an individual line(s) within claims, individual claims, or clusters of claims (e.g., a beneficiary). ... In principle, any type of sampling unit is permissible as long as the total aggregate of such units covers the population of potential mis-paid amounts."

amounts in the sampling frame, as set forth in MPIM § 8.4.3.2.2 and § 8.4.5.2<sup>9</sup> (Doc. 33-1, p. 371/552).

Dr. Cox testified that a ZPIC is charged with recovering overpayments from Medicare to healthcare providers, and the MPIM prescribes two ways to do that: (1) audit overpayments on a claim-by-claim basis; or (2) use statistical extrapolation (Doc. 33-1, p. 373/552). In the first method, if the ZPIC only audits overpayments, the provider can challenge underpayments and achieve full symmetry in the analysis (Doc. 33-1, pp. 373-74/552). If the ZPIC audits for overpayment by statistical analysis and extrapolation, only the ZPIC is involved in the audit (Doc. 33-1, p. 374/552). The ZPIC has a responsibility to estimate both overpaid and underpaid amounts in order to estimate the net overpayment (Doc. 33-1, p. 374/552). Therefore, the sampling universe and frame should include both underpayments and overpayments (Doc. 33-1, p. 375/552).

Dr. Cox explained that failure to include unpaid claims increases the error rate in the sampling frame, and results in loss of the net effect of the underpayment against the whole. (Doc. 33-1, p. 376/552). One effect of removing unpaid claims was to remove six beneficiaries from the universe, because there were six beneficiaries for whom claims were denied entirely (Doc. 33-1, p. 377/562). Thus, the error rate was possibly higher than it should have been, thereby erroneously increasing the

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<sup>9</sup> MPIM § 8.4.5.2 -Calculation of the Estimated Overpayment Amount, states: "Sampling units that are found to be underpayments, in whole or in part, are recorded as negative overpayments and shall also be used in calculating the estimated overpayment."

reimbursement amount (Doc. 33-1, p. 377/562). Dr. Cox reported that, if one of the unpaid beneficiaries had been included in the sample, it would have lowered the reimbursement amount by at least \$ 229,248 (Doc. 33-1, p. 377/562). Therefore, there is a 13 % chance that at least one unpaid beneficiary would have been selected for the sample if the unpaid beneficiaries had been included in the sampling frame, so there is a 13% chance that AdvanceMed's reimbursement demand is at least \$ 229,000 too high (Doc. 33-1, p. 377/562). Moreover, if a single unpaid beneficiary had been chosen for the sample and found to be due the average payment, the reimbursement amount would have been lowered by over \$ 600,000, or almost 9 % (Doc. 33-1, p. 378/562).

Dr. Cox pointed out that Dr. Camp neither agreed nor disagreed with him regarding the exclusion of unpaid claims from the sampling universe, stating only that: "The MPIM is exceedingly clear regarding the exclusion of unpaid claims from the sampling universe." (Doc. 33-1, pp. 378-79/562). Dr. Cox further noted that AdvanceMed actually included unpaid claims in the sampling universe, and subsequently—and improperly—excluded them from the sampling frame, citing MPIM § 8.4.3.2.2 ("[A]ny type of sampling unit is permissible as long as the total aggregate of such units covers the population of potential mis-paid amounts.") and MPIM § 8.4.5.2 ("Sampling units that are found to be underpayments *in whole or* in part are recorded as negative overpayments and *shall also be used* in calculating the estimated overpayment."). (Doc. 33-1, pp. 379-80/562). Since an underpayment in whole is an unpaid claim, unpaid claims must be used in calculating the estimated

overpayment (Doc. 33-1, p. 380/562). Dr. Cox testified there are also 10 sections in the MPIM that require underpayments to be *netted* against the overpayments in determining the reimbursement amount (Doc. 33-1, p. 381/562). Thus, the MPIM is “exceedingly clear” in its prohibition against excluding unpaid claims (Doc. 33-1, p. 382/562).

Dr. Camp responded that there is no requirement that unpaid (potentially underpaid) claims be included in the sample (Doc. 33-1, p. 405/552). Dr. Camp stated that, “once a claim has been selected for review, if that claim were [*sic*] determined to be underpaid, that that [*sic*] should be included in the calculation. ...But, you know, there’s no requirement that all of those potential claims that could have been underpaid in some circumstance be included for selection in the sample.” (Doc. 33-1, p. 405/552).

Dr. Camp further explained that the point estimate was reached by taking the average overpayment per claim and multiplying it by the total number of beneficiaries in the frame (Doc. 33-1, p. 406/552). If an underpayment was determined, it would simply reduce the average overpayment per claim found in the sample (Doc. 33-1, p. 406/552).

Dr. Cox pointed out that, if the universe should not include unpaid claims, then there is no way an erroneously unpaid claim (i.e. an underpaid claim) could be included in a sample (Doc. 33-1, p. 410/552). Dr. Cox stated that interpreting the MPIM to exclude all unpaid claims from the universe was contradictory to its

provision discussing what to do with an unpaid claim in the sample (Doc. 33-1, p. 411/552). Moreover, by including unpaid claims in the universe and then excluding them from the sample frame, AdvanceMed violated its own principles and the unpaid claims could never have been selected for the sample (Doc. 33-1, p. 411/552).

Second, the precision level of AdvanceMed's overpayment estimate was 32.5%. Dr. Cox testified that precision level is one of the worst he has seen in the more than 60 Medicare extrapolations he has reviewed, and is worse than the maximum level allowed by the Office of Inspector General ("OIG") for Medicare claim reviews conducted under a corporate integrity agreement (Doc. 33-1, p. 366/552). AdvanceMed's report states it used a 90% confidence level and achieved a 32.5% precision value (Doc. 33-1, p. 383/562). Dr. Cox explained that AdvanceMed is only 90% confident (90% confidence level) that their overpayment estimate is within 32.5% of the true value of the overpayment (Doc. 33-1, pp. 366-67/552).

Dr. Cox also explained that AdvanceMed arrived at a 32.5% precision level because it bypassed an important step in its statistical study: the step of determining the sample size needed to achieve a preselected confidence level in precision (Doc. 33-1, p. 384/562). Controlling the precision level through the appropriate selection of the sample size is a step designed to protect the provider (Doc. 33-1, p. 388/562). Dr. Cox testified the ZPIC performed that step in almost every other Medicare extrapolation he had seen, but AdvanceMed did not. Instead, AdvanceMed arbitrarily decided to

use a sample size of 30 and cited nonexistent support for its decision<sup>10</sup> (Doc. 33-1, p. 384/562). Dr. Cox explained that, although the MPIM does not set specific values for precision and sample size in the audit process, an acceptable overpayment estimate must still be achieved (Doc. 33-1, p. 385/562). The MPIM lists resources to assist the ZPIC's statistician with the audit (Doc. 33-1, p. 377/562).

Dr. Cox also noted the OIG sets minimum acceptable limits to be used in a Medicare audit that is conducted against providers with whom Medicare has a corporate integrity agreement (Doc. 33-1, p. 386/562). Those limits, although not applicable to this case because there is no corporate integrity agreement, provide guidance for a ZPIC audit (Doc. 33-1, p. 386/562). The OIG limits the precision level to 25% if statistical software is not used to determine sample size (Doc. 33-1, p. 386/562). The OIG also requires a "discovery sample" in their corporate integrity agreement audits, to calculate an appropriate sample size (Doc. 33-1, p. 401/552). AdvanceMed did not use a discovery sample to determine a good sample size (Doc. 33-1, p. 401/552).

Dr. Camp responded that the MPIM does not require a specific sample size calculation or precision level (Doc. 33-1, pp. 402-03/552). Dr. Camp further stated that he did not think the OIG corporate integrity agreement requirements use the

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<sup>10</sup> Dr. Cox stated that AdvanceMed justified the selection of 30 for a sample size by stating "30 is always sufficient," and citing a journal article that actually contradicts that statement (Doc. 33-1, p. 388/562).

lower limit of a confidence interval in assessing and determining an overpayment amount (Doc. 33-1, p. 403/552).

Third, due to the poor precision of AdvanceMed's overpayment estimate, in the event CLHHC is being asked to reimburse more than they were actually overpaid, CLHHC could have to over-reimburse more than three times more than they would have to if the precision had been a more standard 10% (Doc. 33-1, p. 367/552). Usually, a high precision value may benefit the provider, but if a provider ends up having to reimburse more than it was paid, it would have to reimburse more than three times more, with a precision level of 32.5%, than it would with the customary precision level of 10% (since 32.5 is over three times higher than 10) (Doc. 33-1, p. 377/562) (Doc. 33-1, pp. 383-84/562). Dr. Cox testified there is no way to know in this case whether CLHHC is being asked to reimburse more than it was actually paid (Doc. 33-1, p. 384/562). A confidence level of 90% indicates that providers are asked to over-reimburse in 5% of Medicare cases (Doc. 33-1, p. 384/562).

Dr. Cox stated that any audit requirement that applies to a provider with a corporate integrity agreement should also apply to a ZPIC audit (Doc. 33-1, p. 387/562). A corporate integrity agreement provides for a system review to be performed on a recurring basis for the purpose of identifying problems and weaknesses in the provider's processes and preventing the problems in the future, whereas a ZPIC audit is performed only once, and is used as evidence in a legal proceeding for the purpose of recouping funds from a provider (Doc. 33-1, p. 387/562).

That is why the precision most often used in ZPIC claim review is 10% (Doc. 33-1, p. 387/562). Dr. Cox concluded that AdvanceMed's audit sample should be ruled invalid for the purpose of recouping funds from CLHHC (Doc. 33-1, p. 387/562).

Fourth, AdvanceMed did not correctly calculate the reimbursement demand because the claim line decision spreadsheet had an error of almost \$71,000 (Doc. 33-1, pp. 367, 391/552). Dr. Camp conceded that error was made (Doc. 33-1, p. 404/552).

Fifth, AdvanceMed claimed to demonstrate a representativeness of their sample, but did not actually do so (Doc. 33-1, p. 367/552). Dr. Cox points out that Dr. Camp stated in his report that the MPIM does not require a post-hoc demonstration of sample representativeness and that it would be immaterial, despite the fact that AdvanceMed's report indicates its sample met criterion for "representative" (Doc. 33-1, pp. 389-90/562). Dr. Cox stated that representativeness is not a requirement (Doc. 33-1, p. 395/562).

And sixth, AdvanceMed's extrapolation has numerous non-sampling errors, none of which are mentioned in its statistical analysis report (Doc. 33-1, p. 368/552). A non-sampling error is an error other than those arising from the randomness of the sample selection (Doc. 33-1, p. 390/562). Dr. Cox testified that indicates AdvanceMed had no processes in place to control and correct non-sampling errors (Doc. 33-1, p. 390/562). The non-sampling errors included: (1) the failure to use the denied claims in extrapolating the overpayment in AdvanceMed's first audit attempt; (2) one of the claims in AdvanceMed's sample was entered incorrectly into the claim line decision

spreadsheet, causing the reimbursement demand to be almost \$71,000 too large (Doc. 33-1, p. 391/562). Dr. Cox points out that neither of AdvanceMed's two reviewing statisticians noticed those errors (Doc. 33-1, p. 391/562). Due to the fact that AdvanceMed missed two non-sampling errors, Dr. Cox concluded that AdvanceMed did not actually set up any internal controls for non-sampling errors and did not discuss any actual controls used, despite its inclusion in its report of boilerplate language regarding the benefits of non-sampling controls in its report (Doc. 33-1, p. 392-93, 397/562).

Dr. Camp responded in his report that errors in and revisions to the claim overpayment amount do not affect the validity of the sampling procedure (Doc. 33-1, p. 394/562). However, as Dr. Cox contends, the problem was with the *non*-sampling errors rather than the sampling procedures (Doc. 33-1, p. 394/562). Dr. Camp testified that detention and correction of non-sampling errors are not within the purview of the statisticians (Doc. 33-1, p. 404/562). However, AdvanceMed's report states: "This statistician has concluded that there are no known sources of non-sampling error to report." (Doc. 33-1, p. 395/562).

On the issue of the sample frame, the ALJ heard testimony from Dr. Cox, which showed that AdvanceMed excluded unpaid claims from the sampling frame (Doc. 32-1, p. 190/549) (which was supposed to include the universe of claims). AdvanceMed included unpaid claims in the universe of claims but excluded them from the sampling frame (Doc. 32-1, p. 190/549). AdvanceMed's expert statistician, Dr. Camp,

testified that MPIM, Ch. 8, § 8.4.3.2.1 states “the universe of claims from which the sample is selected will consist of all fully and partially paid claims submitted by the provider,” and therefore unpaid claims need not be included. The ALJ held the exclusion of zero-dollar payments was permissible (Doc. 32-1, p. 190/549).

On the issue of the precision level of AdvanceMed’s overpayment estimate (32.46%), AdvanceMed was only 90% confident (90% confidence level) that their overpayment estimate was within 32.46% of the true overpayment (Doc. 32-1, p. 192/549). The ALJ found the estimate was a highly imprecise basis for demanding \$6.7 million from CLHHC (Doc. 32-1, p. 192/549). The ALJ noted that 32.46% was the worst precision level he had seen in the more than 60 Medicare cases he had reviewed, and that, if CLHHC is actually over-reimbursing Medicare, it could have to over-reimburse over three times more than they would have to over-reimburse if the precision level had been a standard 10% (Doc. 32-1, p. 192/549). Dr. Cox testified that Medicare contractors commonly use a 10% precision level and a 90% confidence level (Doc. 32-1, p. 192/549). Dr. Cox further pointed out that the CMS OIG issued requirements for the minimum acceptable provision for Medicare claim reviews conducted against providers under a Corporate Integrity Agreement, at Office of Inspector General, Corporate Integrity Agreement FAQ, at <https://oig.hhs.gov/faqs/corporate-integrity-agreements-faq.asp> (Doc. 32-1, p. 192/549).<sup>11</sup> In this case, AdvanceMed did not use statistical software to determine

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<sup>11</sup> The ALJ noted the requirements differ in cases where RAT-STATS or equivalent software is used and those where it is not.

their sample size, and the precision was 32.46% (Doc. 32-1, p. 192/549). Therefore, as Dr. Cox further testified, the maximum value allowed by the OIG for the precision level is 25% (Doc. 32-1, p. 192/549).

Both Dr. Cox and the ALJ criticized AdvanceMed's sample size of 30, which was chosen "to limit the administrative burden associated with review," finding: it was demonstrably insufficient to reach an acceptable degree of precision; it conflicted with sample-size determination software; it conflicted with the OIG's precision requirement;<sup>12</sup> and AdvanceMed's reference source for justifying a sample size of 30 stated the opposite of what AdvanceMed asserted (Doc. 32-1, p. 193/549). However, Dr. Camp testified for AdvanceMed that MPIM sets forth no requirements for the precision of an estimate (Doc. 32-1, p. 194/549).

The ALJ found the MPIM does not require the sample to be representative, but does require that it be a "statistically valid random sample" (Doc 32-1, pp. 196-97/549). The ALJ further found CLHHC was not entitled to a waiver of recoupment of the overpayments (Doc. 32-1, pp. 228-29).

As to the individual claims, the ALJ found only one claim (for Floyd W.) had been denied in error (Doc 32-1, pp. 203/549).

The ALJ found that, although the Appeals Council and court cases had rejected arguments as to statistical principles, CLHHC had presented a new argument,

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<sup>12</sup> The OIG requires an actual precision of greater than 25% only if the sample size was determined by RAT-STATS or other statistical software to reach a 90% confidence level and a 25% precision level (Doc. 32-1, p. 193/549).

pointing to the OIG's minimal acceptable level for the precision level in sampling and extrapolation in Medicare cases (Doc. 32-1, p. 195/549). CLHHC argues that, at a minimum, the statistical sampling and extrapolation cases should satisfy the generally accepted statistical methods used by the OIG with respect to Medicare audits, sampling, and extrapolation against providers and suppliers under CIAs (Doc. 32-1, p. 195/549).

The ALJ concluded that, even if the OIG's minimal acceptable precision level for sampling and extrapolation conducted under CIAs does not *pro forma* apply in this case, the OIG's minimal acceptable precision level for sampling and extrapolation conducted under CIAs provides strong, pointed guidance and Appellants should be afforded the same protections of statistical validity as providers and suppliers audited under CIAs (Doc. 32-1, p. 196/549). The ALJ further noted the 32.46% precision level in CLHHC's case was significantly greater than the 25% precision level allowed by OIG guidelines for sampling and extrapolation performed under CIAs, and is so imprecise that it was deemed arbitrary and capricious (Doc. 32-1, p. 196/549).

The ALJ also found that AdvanceMed had no process in place to identify or control non-sampling error and inserted a pro-forma discussion of non-sampling error into their report to make it appear otherwise (Doc 32-1, p. 197/549). The ALJ noted the two non-sampling errors made in AdvanceMed's first calculation, and the non-sampling error in its second calculation (Doc. 21-1, pp. 197-98/549).

The ALJ concluded that AdvanceMed's sampling and extrapolation was sufficiently flawed so as to render the extrapolated overpayment statistically invalid and preclude recovery of the calculated overpayment amount of \$6,770,584.00.

**2. Medicare's review.**

On *de novo* review, the Appeals Council reversed the ALJ's decision as to the sampling and extrapolation on two grounds. First, the Appeals Council found the ALJ erred "as a matter of law" in holding the sampling was invalid because of non-sampling errors. The Appeals Council noted there were only two non-sampling errors, both of which were corrected (Doc. 32-1, p. 25/549). The Appeals Council overlooked the third non-sampling error, a line-item mis-entry of over \$70,000, that the government conceded to before the ALJ.

Second the Appeals Council found the ALJ erred in finding the precision level of 32.46 % was too high (Doc. 32-1, p. 25/549). The Appeals Council noted there was no case law invalidating a statistical analysis on the basis of the precision level. However, as stated by Dr. Cox and the ALJ, this case involves the highest precision level to date. There has not been any other precision level in excess of 30%.

The Appeals Council agreed with the ALJ's conclusion that the ZPIC's exclusion of zero-paid claims from the sample was permissible pursuant to the MPIM guidelines (Doc. 32-1, p. 28/549). The Appeals Council also found the ZPIC's decision to use a sample size of 30 and to not use a statistical software program to determine the sample size did not invalidate the statistical sampling (Doc. 32-1, p. 28/549).

Finally, the Appeals Council found there was no precision level limit that AdvanceMed had to meet, and that AdvanceMed's statistical analysis had complied with the MPIM (Doc. 32-1, pp. 45-46/549).

The Appeals Council reversed the ALJ's decision that the statistical analysis was invalid. The Appeals Council concluded that CLHHC had not identified any specific, uncorrected defect in the sampling method or the sampling itself (as corrected), including the extrapolation (Doc. 32-1, pp. 44-45/549).

The Appeals Council then reviewed the ALJ's decisions as to the individual beneficiary claims, reversed in part to award some benefits as to some individual claimants, affirmed the denial of the remainder (Doc. 32-1, pp. 50-109/549), and ordered recalculation of the extrapolated overpayment (Doc. 32-1, p. 111/549). The Appeals Council also affirmed the ALJ's denial of a waiver of recoupment (Doc. 32-1, p. 109/549).

## **II. Law and Analysis**

### **A. Motion for Summary Judgment**

Under Rule 56 of the Federal Rules of Civil Procedure, a court must grant summary judgment "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." Paragraph (e) of Rule 56 also provides the following:

If a party fails to properly support an assertion of fact or fails to properly address another party's assertion of fact as required by Rule 56(c), the court may:

(1) give an opportunity to properly support or address the fact;

- (2) consider the fact undisputed for purposes of the motion;
- (3) grant summary judgment if the motion and supporting materials-- including the facts considered undisputed--show that the movant is entitled to it; or
- (4) issue any other appropriate order.<sup>13</sup>

“A genuine dispute of material fact exists ‘if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.’” Hefren v. McDermott, Inc., 820 F.3d 767, 771 (5th Cir. 2016) (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986)). In deciding a motion for summary judgment, a court must construe all facts and draw all inferences in the light most favorable to the non-movant. See Dillon v. Rogers, 596 F.3d 260, 266 (5th Cir. 2010). However, a mere scintilla of evidence is insufficient to defeat a motion for summary judgment. See Stewart v. Murphy, 174 F.3d 530, 533 (5th Cir. 1999).

#### **B. Scope of Review**

Title XVIII of the Social Security Act, 79 Stat. 291, as amended, 42 U.S.C. § 1395 et seq., commonly known as the Medicare Act, establishes a federally subsidized health insurance program to be administered by the Secretary. See Heckler v. Ringer, 466 U.S. 602, 605 (1984). The Medicare Act authorizes the Secretary to determine what claims are covered by the Act “in accordance with the regulations prescribed by him.” § 1395ff(a); see also Ringer, 466 U.S. at 605.

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<sup>13</sup> Local Rule 56.2W (formerly 2.10W) also provides that all material facts set forth in a statement of undisputed facts submitted by the moving party will be deemed admitted unless the opposing party controverts those facts.

Pursuant to 42 U.S.C. § 405(h), federal courts are stripped “of primary federal-question subject matter jurisdiction’ over claims that arise under that Act.” Instead, “the Act provides for an administrative hearing before the Secretary of [DHHS] ... [and] ‘judicial review of the Secretary's final decision’ in the form of a civil action in federal district court against the Secretary.” See White v. Blue Cross & Blue Shield of Alabama, 450 Fed. Appx. 818, 820 (11th Cir. 2011) (citing Dial v. Healthspring of Ala., Inc., 541 F.3d 1044, 1047–48 (11th Cir. 2008)); 42 U.S.C. §§ 405(g), 1395w–22(g)(5). Federal courts have jurisdiction over only those cases that are properly appealed from a final administrative decision, and that are filed against the Secretary of DHHS. See id.

The Court’s review of the Secretary's decision on reimbursement matters is governed by 42 U.S.C. § 1395o(f)(1), which incorporates the standard of review from the APA.<sup>14</sup> See Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 512 (1994). Section 1395o(f)(1), “Provider Reimbursement Review Board– Finality of decision; judicial review; determinations of Board authority; jurisdiction; venue; interest on amount in controversy,” states in pertinent part: “Such action shall be brought in the district court of the United States for the judicial district in which the provider is

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<sup>14</sup> The DHHS argues that the scope of review set forth in 42 U.S.C. § 405(g) applies to Medicare cases. However, 42 U.S.C. 1395ii specifically adopts *only* § 405(a), (d), (e), (h), (i), (k), and (l) for application to the Medicare Act. It does *not* adopt and incorporate the standard for judicial review set forth in § 405(g).

located...and shall be tried pursuant to the applicable provisions under chapter 7 of Title 5 notwithstanding any other provisions in section 405 of this title.

The APA commands reviewing courts to “hold unlawful and set aside” agency action that is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” See Thomas Jefferson University, 512 U.S. at 512 (issue as to Medicare reimbursement of hospital’s educational expenses); see also Community Care, L.L.C. v. Leavitt, 537 F.3d 546, 548 (5th Cir. 2008) (reviewing Medicare reimbursement to skilled nursing facility under the arbitrary and capricious standard of the APA); Sierra Medical Center v. Sullivan, 902 F.2d 388, 390–91 (5th Cir. 1990) (court applied APA to review of denial of “new provider” designation for Medicare provider, pursuant to § 1395, stating the district court will reverse the DHHS's decision only if it acted arbitrarily, capriciously, not in accordance with law, or abused its discretion, citing 5 U.S.C. § 706(2)); Southwest Ambulatory Behavioral Services, Inc. v. Burwell, 2016 WL 1306749, at \*2 (W.D. La. 2016) (applying arbitrary and capricious standard in reviewing Secretary’s method of calculating cost to charge ratios for reimbursement to Medicare outpatient rehabilitation provider); Canon Hospice, L.L.C. v. Burwell, 2015 WL 5125544 (S.D. Miss. 2015) (applying APA to review of denial of Medicare reimbursement to Medicare hospice provider).<sup>15</sup>

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<sup>15</sup> The United States Court of Appeals for the Fifth Circuit recently addressed the issues of the standard for judicial review of Medicare claims in Maxmed Healthcare, Inc. v. Price, 860 F.3d 335, 340 (5th Cir. 2017), and Baylor Cty. Hospital District v. Price, 850 F.3d 257, 261 (5th Cir. 2017). The parties disagreed to as whether the standard of judicial review is governed by 42 U.S.C. § 405(g) or the Administrative Procedure Act (“APA”). In both cases, the Fifth Circuit left the issue open, stating it “assume[d] only for the sake of argument that the APA's arbitrary and capricious standard applies,” finding that the standard of review probably made no difference in those cases. Maxmed Healthcare,

The standard of judicial review under the APA is set forth in 5 U.S.C. § 706(2)(A) & (E):

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall: ...

(2) hold unlawful and set aside agency action, findings, and conclusions found to be-

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; ...

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; ...

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

See also Trans-American Van Service, Inc. v. U.S., 421 F. Supp. 308, 316 (N.D. Tex. 1976). These two provisions of the Administrative Procedure Act are separate standards of review. See Trans-American Van Service, Inc. v. U.S., 421 F. Supp. at 316 (citing Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 413 (1971)). An agency's finding, therefore, may reflect arbitrary and capricious action even though it is supported by substantial evidence. See Trans-American Van Service, Inc., 421 F. Supp. at 316 (citing Bowman

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Inc., 860 F.3d at 340 (quoting Baylor Cty. Hospital District, 850 F.3d at 261); see also Superior Home Health Services, L.L.C. v. Azar, 2018 WL 3717121, at \*3 (W.D. Tex. 2018).

Transportation, Inc. v. Arkansas-Best Freight System, Inc., 419 U.S. 281, 284 (1974)).

“Substantial evidence” on the record taken as a whole is more than a mere scintilla. It is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion. See Acadian Homecare, L.L.C. v. Leavitt, 513 F. Supp. 2d 684, 691 (W.D. La. 2007) (citing Richardson v. Perales, 402 U.S. 389, 401 (1971); Girling Health Care, Inc. v. Shalala, 85 F.3d 211, 215 (5th Cir. 1996)). In determining whether substantial evidence exists, a court does not re-weigh the evidence, retry the issues, or substitute its own judgment. See Acadian Homecare, L.L.C., 513 F. Supp. 2d at 691 (citing Greenspan v. Shalala, 38 F.3d 232, 236 (5th Cir. 1994)). “The Agency decision must be upheld as long as there is a rational basis for the Secretary's interpretation of the statute and the regulations.” Acadian Homecare, L.L.C., 513 F. Supp. 2d at 691 (citing Sun Towers, Inc. v. Heckler, 725 F.2d 315, 325–326 (5th Cir. 1984)).

APA’s “arbitrary and capricious” review is narrow and deferential, requiring only that the agency articulate a rational relationship between the facts found and the choice made. See Acadian Homecare, L.L.C., 513 F. Supp. 2d at 691 (citing City of Abilene v. EPA, 325 F.3d 657, 664 (5th Cir. 2003)). Under this deferential standard, the Court may not substitute its own judgment for that of the agency. See Acadian Homecare, L.L.C., 513 F. Supp. 2d at 691 (citing City of Abilene, 325 F.3d at 664). If the agency's reasons and policy choices conform to minimal standards of rationality,

then its actions are reasonable and upheld. See Acadian Homecare, L.L.C., 513 F. Supp. 2d at 691 (citing City of Abilene, 325 F.3d at 664).

Moreover, it is well established that an agency's interpretation and construction of its own regulations “must be given ‘controlling weight unless it is plainly erroneous or inconsistent with the regulation’” itself. See Acadian Homecare, L.L.C., 513 F. Supp. 2d at 691 (citing Thomas Jefferson Univ., 512 U.S. at 512). However, agency interpretations such as those in opinion letters, policy statements, agency manuals, and enforcement guidelines all lack the force of law and do not warrant Chevron-style<sup>16</sup> deference. See Christensen v. Harris Cty., 529 U.S. 576, 587 (2000) (citing Reno v. Koray, 515 U.S. 50, 61 (1995)). Interpretations contained in such formats are entitled to respect, but only to the extent that those interpretations have the power to persuade. See Christensen, 529 U.S. at 587.

A court must begin with the presumption that the agency's decision is valid; it is plaintiff's burden to overcome that presumption by showing the agency's decision was erroneous. See Memorial Hermann Hosp. v. Sebelius, 728 F.3d 400, 405 (5th Cir. 2013). A court must review an agency's factual findings only for substantial evidence, i.e., that which is relevant and sufficient for a reasonable mind to accept as adequate to support a conclusion. Memorial Hermann Hosp. v. Sebelius, 728 F.3d at 405 (citing Spellman v. Shalala, 1 F.3d 357, 360 (5th Cir. 1993)). The reviewing court must be

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<sup>16</sup> In Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842-44 (1984), the United States Supreme Court held that a court must give effect to an agency's regulation containing a reasonable interpretation of an ambiguous statute. See Christensen v. Harris County, 529 U.S. 576, 586-87 (2000).

highly deferential to the administrative agency whose final decision is being reviewed. See Memorial Hermann Hosp. v. Sebelius, 728 F.3d at 405 (citing Board of Mississippi Levee Com'rs, 674 F.3d 409, 417 (5th Cir. 2012)).

**C. Substantial evidence does not support the Appeals Council's conclusion that AdvanceMed's statistical sampling methodology and extrapolation were valid.**

CLHHC contends “the [Appeals] Council’s decision does not correctly apply the relevant legal standards and is unsupported by substantial evidence because it upholds the use of extrapolation where the methodology does not satisfy Medicare requirements for statistical sampling” (Doc. 1). CLHHC argues the Appeals Council erred in reversing the ALJ’s determination that AdvanceMed’s statistical sampling and extrapolation methodology were erroneous and invalid. CLHHC argues the Council’s decision erroneously upholds AdvanceMed’s use of extrapolation where the methodology does not satisfy Medicare’s requirements for statistical sampling.

CLHHC is a health care provider that receives Medicare payments from HHS for home health services they provide to eligible individuals under Part A of the Medicare program, 42 U.S.C. §§ 1395c-1395i. Medicare Part A provides insurance for hospital and related post-hospital services. See Mount Sinai Hospital v. Weinberger, 517 F.2d 329, 334 (5th Cir. 1975), modified in part, 522 F.2d 179 (5th Cir.1975), cert. denied, 425 U.S. 935 (1976). Issues in Medicare Part A arise as to “coverage” determinations and “reasonable cost” determinations. See Mount Sinai Hospital, 517 F.2d at 334. Coverage determinations involve issues about whether

specific items or services are covered by § 1395d and not excluded § 1395y. See id. at 335.

The Medicare program does not entitle providers to dollar-for-dollar reimbursement for all costs incurred. Rather, utilization of the prospective payment system provides for hospitals to “receive a standard reimbursement amount per inpatient ... regardless of the actual costs of caring for that patient.” See Trinity Reg'l Med. Ctr. v. Azar, 2018 WL 4295290, at \*7 (N.D. Iowa 2018). Claims for reimbursement by Medicare providers are typically paid without substantive inquiry, but the payments remain subject to subsequent review by a third-party auditor, known as a recovery audit contractor. See D & G Holdings, L.L.C. v. Price, 2018 WL 3715748, \*2 (W.D. La. 2018).

Congress created the audit program to serve “the purpose of ... recouping overpayments,” and it incentivized the recovery audit contractors by paying them “on a contingent basis for collecting overpayments.” See id.; 42 U.S.C. § 1395ddd(h)(1). Healthcare providers wishing to challenge these initial claim determinations by the Medicare administrative contractor or the recovery audit contractor must pursue a comprehensive, four-step administrative review process before seeking review in court. See D & G Holdings, L.L.C., 2018 WL 3715748, \*2.

The four-part administrative review process begins with a request for redetermination to the original audit contractor, then proceeds to a request for reconsideration by a qualified independent contractor (“QIC”). The third step is a

hearing before an ALJ, and the review culminates with a decision by the Appeals Council. See 42 U.S.C. § 1395ff(a)-(d); 42 C.F.R. §§ 405.940; 405.960; 405.1000; 405.1100. The Medicare Act also provides timing deadlines for the review process and requires that the ALJ's decision be issued within ninety days of the provider's request for review. See 42 U.S.C. § 1395ff(d)(1)(A). A provider may also escalate the review process by proceeding to the next step of review if the timing deadlines are not met. See D & G Holdings, L.L.C., 2018 WL 3715748, \*2. After the issues the final administrative decision of the Secretary, the provider may seek judicial review of that decision in the appropriate United States District Court. See 42 U.S.C. §§ 1395ff(b)(2)(C); 405(g).

The Medicare program reimburses health care providers who render services to Medicare beneficiaries. See Maxmed Healthcare, Inc. v. Price, 860 F.3d 335, 337–38 (5th Cir. 2017). 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.” See 42 U.S.C. § 1395ddd(a), (h)(1); Maxmed Healthcare, Inc., 860 F.3d at 337–38. Extrapolation is one permissible method of calculating overpayments. See Maxmed Healthcare, Inc., 860 F.3d at 337–38. Congress authorized Medicare contractors to “use extrapolation to determine overpayment amounts” if the Secretary determines that “there is a sustained or high level of payment error.” § 1395ddd(f)(3)(A); Maxmed Healthcare, Inc., 860 F.3d at 337–38.

CMS, the agency responsible for administering Medicare, has issued two key documents that govern the use of extrapolation. CMS Ruling 86–1<sup>17</sup> provides that sampling for extrapolation purposes “only creates a presumption of validity as to the amount of an overpayment which may be used as the basis for recoupment.” See Maxmed Healthcare, Inc., 860 F.3d at 337–38. Following an overpayment determination based on extrapolation, the burden shifts to the Medicare provider, who “could attack the statistical validity of the sample or could challenge the correctness of the determination in specific cases identified by the sample.” See Maxmed Healthcare, Inc., 860 F.3d at 337–38.

The second document is the Medicare Program Integrity Manual (“MPIM”),<sup>18</sup> which sets out “[t]he major steps in conducting statistical sampling,” and articulates a number of criteria that govern the specifics of each step in the extrapolation process in Chapter 8 (formerly Chapter 3). See MPIM § 8.4.1.3; see also id. §§ 8.4.3.1 (Period for Review), 8.4.3.2.1 (Composition of the Universe), 8.4.3.2.2 (Sample Unit), 8.4.4.3 (Sample Size); Maxmed Healthcare, Inc., 860 F.3d at 337–38. The MACs, Recovery Auditors, and ZPICs, among others, are required to follow all sections of the MPIM. See MPIM § 1.3.3. The purpose of requiring contractors to comply with the MPIM is

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<sup>17</sup> Also (formerly) known as HCFA Ruling 86-1.

<sup>18</sup> Agency interpretations such as those in opinion letters, policy statements, agency manuals, and enforcement guidelines all lack the force of law and do not warrant Chevron-style deference. See Christensen v. Harris Cty., 529 U.S. 576, 587 (2000) (citing Reno v. Koray, 515 U.S. 50, 61 (1995)); see also Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842-44 (1984). Interpretations contained in such formats are entitled to respect, but only to the extent that those interpretations have the power to persuade. See Christensen, 529 U.S. at 587.

to “identify and verify potential errors to produce the greatest protection to the Medicare program,” MPIM § 2.1, and to calculate a valid projected overpayment, MPIM § 8.2.2.

1. **The DHHS interpretation of “fully and partially paid claims” is afforded deference.**

The parties dispute the composition of the universe of claims, the sampling frame, and the claim sample in this case. The dispute concerns the meaning of “fully and partially paid claims,” and whether unpaid claims should be included in the sampling frame and sample.

MPIM § 8.4.3.2.1, “Composition of the Universe,” provides as to Medicare Part

A claims:

A. Part A Claims: For providers reimbursed through cost report, the universe of claims from which the sample is selected shall consist of fully and partially adjudicated claims obtained from the shared systems. For such claims, use the service date to match findings to the cost report.

For providers reimbursed under PPS, the universe of claims from which the sample is selected will consist of all fully and partially paid claims submitted by the provider for the period under review.

See also Cypress Home Care, Inc. v. Azar, 326 F. Supp. 3d 307, 324 (E.D. Tex. 2018).

This case involves the second paragraph, relating to PPS, or pre-paid services.

A sampling frame was drawn from the universe of claims. MPIM § 8.4.3.2.3,

“The Sampling Frame,” provides:

The sampling frame is the “listing” of all the possible sampling units from which the sample is selected. The frame may be, for example, a list of all beneficiaries receiving items from a selected supplier, a list of all claims for which fully or partially favorable determinations have

been issued, or a list of all the line items for specific items or services for which fully or partially favorable determinations have been issued.

The ideal frame is a list that covers the target universe completely. In some cases the frame must be constructed by combining lists from several sources and duplication of sampling units may result. Although duplicate listings can be handled in various ways that do not invalidate the sample, it is recommended that duplicates be eliminated before selecting the sample.

Depending on the nature and scope of a given audit, various limiting criteria are then applied to the universe to filter out certain sampling units. An example of a limiting criterion would be all claims with payment amounts greater than \$0. See Cypress Home Care, Inc., 326 F. Supp. 3d at 324. The group of sampling units that remain following the application of the limiting criteria to the universe is referred to as the sampling frame. See Cypress Home Care, Inc., 326 F. Supp. 3d at 324.

Dr. Camp testified that, initially, unpaid claims were included in the sampling frame and sample and assigned a zero-dollar overpayment (Doc. 33-1, p. 354/552). In the recalculation, only paid claims were included, resulting in a substantially higher overpayment amount (Doc. 33-1, p. 354/552). Dr. Cox testified that AdvanceMed removed the six wholly unpaid beneficiaries from the sampling frame (Doc. 33-1, p. 370/552), and removed all unpaid claims from the remaining beneficiaries whose claims were paid in part (Doc. 33-1, p. 370-552).

Once the sampling frame has been created, the contractor's statisticians select a particular sample design to be used. According to the MPIM, the most common sample designs include simple random sampling, stratified sampling, systematic

sampling, and cluster sampling. See MPIM § 8.4.4.1; Cypress Home Care, Inc., 326 F. Supp. 3d at 325. Based on the sample design to be implemented, the contractor’s statisticians use a computer program to generate a sequence of random numbers, which are, in turn, matched with the position numbers of the sampling units in the frame. See Cypress Home Care, Inc., 326 F. Supp. 3d at 325. The sampling units that are paired with the random numbers are then selected as the sample to be audited and used for extrapolation. See MPIM § 8.4.4.2; Cypress Home Care, Inc., 326 F. Supp. 3d at 325. The contractor requests medical records from the provider related to each of the units in the statistical sample, and medical review staff renders a determination as to whether each unit in the sample was correctly paid, overpaid, or underpaid. See MPIM § 8.4.6.3; Cypress Home Care, Inc., 326 F. Supp. 3d at 325. Based on the results of the medical review process, any overpayment that is identified is then projected, or “extrapolated,” to the provider’s universe of claims. See MPIM § 8.4.5; Cypress Home Care, Inc., 326 F. Supp. 3d at 325.

AdvanceMed used a simple random sampling method and chose a sample size of 30 because it was an “acceptable” number. MPIM § 8.4.4.3, Determining Sample Size, states:

The size of the sample (i.e., the number of sampling units) will have a direct bearing on the precision of the estimated overpayment, but it is not the only factor that influences precision. The standard error of the estimator also depends on (1) the underlying variation in the target population, (2) the particular sampling method that is employed (such as simple random, stratified, or cluster sampling), and (3) the particular form of the estimator that is used (e.g., simple expansion of the sample total by dividing by the selection rate, or more complicated methods such

as ratio estimation). It is neither possible nor desirable to specify a minimum sample size that applies to all situations. A determination of sample size may take into account many things, including the method of sample selection, the estimator of overpayment, and prior knowledge (based on experience) of the variability of the possible overpayments that may be contained in the total population of sampling units.

In addition to the above considerations, real-world economic constraints shall be taken into account. As stated earlier, sampling is used when it is not administratively feasible to review every sampling unit in the target population. In determining the sample size to be used, the PSC or ZPIC BI unit or the contractor MR unit shall also consider their available resources. That does not mean, however, that the resulting estimate of overpayment is not valid, so long as proper procedures for the execution of probability sampling have been followed. A challenge to the validity of the sample that is sometimes made is that the particular sample size is too small to yield meaningful results. Such a challenge is without merit as it fails to take into account all of the other factors that are involved in the sample design.

Therefore, the sample in this case consisted of the paid claims for 30 beneficiaries.

CLHHC contends the phrase “all fully and partially paid claims” should include unpaid claims because they are potentially underpaid claims. CLHHC points to other provisions in the MPIM that refer to the offset of underpaid claims against overpaid claims to achieve the “net” balance owed.

The DHHS contends that all unpaid claims were properly excluded from the sampling frame and sample in this case, as found by both the ALJ and the Appeals Council.

The DHHS interpretation of the MPIM regulations to exclude all unpaid claims clearly results in a substantially higher overpayment calculation. In this case, that amount was recalculated to about \$5,000,000 higher. However, the exclusion of all

unpaid claims was recently accepted by a sister court (it was noted as an option, but not discussed). See Cypress Home Care, Inc., 326 F. Supp. 3d at 324. Although it is not the only possible interpretation of that provision, the DHHS's interpretation appears reasonable and, therefore, is afforded deference.

**2. Substantial evidence does not support the Appeals Council's conclusion that the statistical analysis is valid.**

Next, CLHHC contends the overpayment calculation is based on an invalid statistical analysis.

As argued by the DHHS, there are no requirements or specific standards for each step of the statistical analysis. There is no specific sample size to be used, and neither the precision level nor the confidence level need to meet specific minimum levels or standards. The DHHS cites CMS Ruling 86-1:

Sampling does not deprive a provider of its right 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 (including waiver of liability where medical necessity or custodial care is at issue). In either case, the provider is given a full opportunity to demonstrate that the overpayment determination is wrong.

The DHHS also refers repeatedly to the rules for statistical analysis set forth in Chapter 8 of the MPIM. However, the contractors in this case have not adhered to those rules. The DHHS argues there are no specific standards its [non-corporate integrity agreement] contractors must meet in their statistical analyses in order to

prove a Medicare provider was overpaid, and that failure to adhere to the rules does not necessarily invalidate an analysis.

However, there is one mandatory requirement that the DHHS has overlooked.

There must be a *statistically valid* analysis. MPIM 8.4.1.1 states:

The purpose of this section is to provide instructions for PSC and ZPIC BI units and contractor MR units on the use of statistical sampling in their reviews to calculate and project (i.e., extrapolate) overpayment amounts to be recovered by recoupment, offset or otherwise. *These instructions 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. These guidelines are for reviews performed by the PSC or ZPIC BI units or contractor MR units. (Emphasis added.)

Thus, the MPIM rules attempt to ensure the statistical analysis is valid, despite the inherently fluid nature of statistics, by setting forth specific factors, the combination of which should ensure validity in the analysis. Those rules safeguard both the validity of the analysis and the rights of the provider.

The “MPIM section 8.4.1.1 makes clear that a contractor’s failure ‘to follow one or more of the requirements contained herein does not necessarily affect the validity of the statistical sampling that was conducted or the projection of the overpayment.’” Galindo v. Burwell, 2018 WL 4689610 (S.D. Tex. 2018) (citing Maxmed Healthcare, Inc., 860 F.3d at 341 (failure to record the random numbers does not actually render a sampling invalid)). “Instead, [a]n appeal challenging the validity of the sampling methodology must be predicated on the actual statistical validity of the sample as drawn and conducted.” Maxmed Healthcare, Inc., 860 F.3d at 341 (citing MPIM § 8.4.1.1).

In scientific and statistical studies, the term “reliability” refers to reproducibility of results. The term “valid” refers to accuracy. “Reliability is necessary, but not sufficient, to ensure accuracy. In addition to reliability, ‘validity’ is needed.” D.H. Kaye, D.E. Bernstein, J.L. Mnookin, The New Wigmore: A Treatise on Evidence—Expert Evidence, § 11.7, p. 405 (2004). “Some gaps or mistakes are present in almost any major study. The crucial question as regards admissibility is whether they are so numerous or substantial as to distort the results to the point at which the evidence would not be useful or not worth the time and effort it would take to explain its limitations. Measurement error usually affects the weight of the evidence but does not render it inadmissible.” The New Wigmore: A Treatise on Evidence—Expert Evidence, § 11.7, pp. 407-408.

The DHHS contends and explains there are no specific requirements as to sample size, confidence level, or precision level. The MPIM does not specify mandatory requirements for the statistical methodology and extrapolation. However, there is a requirement that contractors use “statistically valid random sampling and extrapolation.” The parties agree (without source citation) that the DHHS OIG has set specific standards for statistical analysis and extrapolation of overpayments in an attempt to ensure validity. However, those requirements apply only to Medicare providers that are working with Medicare pursuant to a corporate integrity agreement. The DHHS contends there are no standards that apply to the statistical

analysis and extrapolation of overpayments to Medicare providers who do not have a CIA with Medicare.

The MPIM attempts to set forth procedures designed to ensure the integrity of the statistical analysis. MPIM § 8.4.1.5 directs that the sampling methodology used to project overpayments must be reviewed by a statistician, or by a person with equivalent expertise in probability sampling and estimation methods to ensure that a statistically valid sample is drawn and that statistically valid methods for projecting overpayments are followed.<sup>19</sup> For instance, “[t]he PSC or ZPIC BI unit and the contractor MR unit shall obtain from the statistical expert a written approval of the methodology for the type of statistical sampling to be performed. If this sampling methodology is applied routinely and repeatedly, the original written approval is adequate for conducting subsequent reviews utilizing the same methodology. The PSC or ZPIC BI unit or the contractor MR unit shall have the statistical expert review the results of the sampling prior to releasing the overpayment demand letter. If questions or issues arise during the on-going review, the PSC or ZPIC BI unit or the contractor MR unit shall also involve the statistical expert.” MPIM § 8.4.1.5, Consultation With a Statistical Expert.

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<sup>19</sup> “At a minimum, the statistical expert (either on-staff or consultant) shall possess a master’s degree in statistics or have equivalent experience. See section 3.10.10 for a list, not exhaustive, of texts that represent the minimum level of understanding that the statistical expert should have. If the PSC or ZPIC BI unit or the contractor MR unit does not have staff with sufficient statistical experience as outlined here, it shall obtain such expert assistance prior to conducting statistical sampling.” MPIM 8.4.1.5 - Consultation With a Statistical Expert.

Although AdvanceMed states in its report that a “statistician” reviewed its sampling design and processes, there is no written approval by an expert statistician in the record, as required by MPIM §8.4.1.5, nor does the report include the name and qualifications of its statistician (Doc. 32-2, p. 513/550).<sup>20</sup>

Moreover, MPIM § 8.4.1.2-Probability Sampling, states: “Regardless of the method of sample selection used, the ZPIC or other contractor shall follow a procedure that results in a probability sample. For a procedure to be classified as probability sampling the following two features must apply: [i]t must be possible, in principle, to enumerate a set of distinct samples that the procedure is capable of selecting if applied to the target universe.... [and] [e]ach sampling unit in each distinct possible sample must have a known probability of selection.” In this case, the rules as to sampling and probability samples are set forth, but the probability sample for this case was not discussed in AdvanceMed’s report (Doc. 32-2, pp. 515/550).

MPIM Rule 8.4.2 assumes there is a “properly executed” probability sample design: “If a particular probability sample design is properly executed, i.e., defining the universe, the frame, the sampling units, using proper randomization, accurately measuring the variables of interest, and using the correct formulas for estimation, then assertions that the sample and its resulting estimates are ‘not statistically valid’ cannot legitimately be made.” CLHHC argues that AdvanceMed failed to properly execute its

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<sup>20</sup> AdvanceMed’s report was written by Brad Landtroop (Doc 32-2, p. 512/550). It is not clear whether Landtroop was the statistician, or was simply the report-writer.

sample design and failed to properly analyze the data in accordance with MPIM requirements, resulting in a very poor precision level.

The MPIM requirements are the safeguards that ensure the validity of a statistical analysis. While noncompliance with one, or possibly two, of those factors may not affect the validity of the analysis, failure to adhere to several or all of these safeguards should eliminate the presumption that the statistical analysis is valid. See MPIM § 2.1.1.

Those safeguards are particularly important when a claim of overpayment reaches the federal courts. Courts do not generally have the expertise to conduct an in-depth review of a statistical analysis and determine whether errors were made. Therefore, adherence to the safeguard procedures in the MPIM becomes of particular importance in according a presumption of correctness and validity to the statistical analysis. Failure to follow those procedures is indicative that the statistical analysis may not be valid.

CLHHC has generally complained of many aspects of AdvanceMed's methodology, but appears to rest its argument as to statistical invalidity on AdvanceMed's poor precision level. CLHHC complains the 32.4% precision level of AdvanceMed's statistical analysis far exceeds the outside precision level limit of 25% that is imposed by the OIG on ZPICs operating under a corporate integrity agreement. AdvanceMed contends only that, since it does not have a corporate integrity agreement, the 25% precision level does not apply to it.

Precision is the most important factor for determining the sample size. It reflects how far away the upper and lower limits are expected to be from the point estimate. “Statistical Sampling: A Toolkit for MFCUs” (OIG-12-18-1) (September 2018), p. 18, a publication of the U.S. Dept. of Health and Human Services, Office of Inspector General.<sup>21</sup> The worse the precision, the less meaningful the point estimate will be. “Statistical Sampling: A Toolkit for MFCUs”, p. 18. “The precision is sometimes referenced in terms of the margin of error. The margin of error is often expressed as the distance of the upper and lower limit from the point estimate.”<sup>22</sup> “Statistical Sampling: A Toolkit for MFCUs”, p. 18.

“Specifying the precision needed for sample estimates is an important part of sample design. The desired precision is the amount of sampling error that can be tolerated but that will still permit the results to be useful. This is sometimes called tolerable error or the bound on error. Because precision is a way of expressing the amount of error that can be tolerated, it is related to the accounting concept of materiality or the evaluative concept of importance.” United States General

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<sup>21</sup> Available at <https://webcache.googleusercontent.com/search?q=cache:FUSI81wks-wJ:https://oig.hhs.gov/fraud/medicaid-fraud-control-units-mfcu/files/MFCU%2520Sampling%2520Guidance%2520Final.pdf+&cd=1&hl=en&ct=clnk&gl=us&client=firefox-b-1>.

<sup>22</sup> For example, suppose the estimated total overpayment is \$100,000 with a 90-percent confidence interval that ranges from \$85,000 to \$115,000. In this case the margin of error could be expressed as plus or minus \$15,000 or equivalently as plus or minus 15 percent. “Statistical Sampling: A Toolkit for MFCUs”, p. 18.

Accounting Office, Using Statistical Sampling § 10.1.6 (1992),<sup>23</sup> at p. 48. “Materiality, or importance, is linked to precision in the following way. To develop a reasonable specification of precision, evaluators must gauge the materiality or importance of the estimates to be made and use this information to decide how much the statistical estimates can vary from the true but unknown population value and yet provide useful information.” Using Statistical Sampling § 10.1.6 at p. 48.

“In addition to specifying the precision of the estimate, evaluators must specify the degree of confidence that they want placed in the estimate. Referred to as confidence level, this is expressed as a percentage. It is the complement of the chance that [the] estimate and its precision will not contain the true but unknown population value.” Using Statistical Sampling § 10.1.6 at p. 49. Therefore, “[p]recision refers to the maximum amount, stated at a certain confidence level, that we can expect the estimate from a single sample to deviate from the results obtained by applying the same measuring procedures to all the items in the population.” Using Statistical Sampling § 10.1.6 at p. 67.

Other courts that have considered the precision level of statistical methodologies have found a margin of error of 43.3% to be too high while a margin of error of 20% to be sufficiently reliable. See Duran v. U.S. Bank Nat. Assn., 59 Cal.4th 1, 46, 172 Cal.Rptr.3d 371, 325 P.3d 916 (2014) (describing a precision level of 43.3%

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<sup>23</sup> The 1992 GAO Statistical Sampling Guide, available at [222.gao.gov/assets/80/76112.pdf](https://www.gao.gov/assets/80/76112.pdf), is referred to by the OIG in his 2018 “Statistical Sampling: A Toolkit for MFCUs” at pp. 13, 17, 18, 20, and 25, for a better understanding of the concept of precision in statistical analysis.

at a 95% confidence interval to be “intolerably high.”); Massachusetts Mut. Life Ins. Co. v. Residential Funding Co., LLC, 989 F.Supp.2d 165, 174 (D.Mass.2013) (“As other courts have concluded, the  $\pm$  10 percentage point margin of error does not render Dr. Cowan's methodology unreliable. The margin of error speaks to the persuasive power of the sample, not its admissibility”). See U.S. ex rel. Martin v. Life Care Centers of Am., Inc., 1:08-CV-251, 2014 WL 4816006, at \*16 (E.D. Tenn. Sept. 29, 2014)

AdvanceMed’s precision level of 32.4% is the highest reflected in the published case law nationwide (the previous highest was 26.17%). Although no other case has invalidated a statistical analysis of overpayment due to its precision level, no other case involved such a high precision level. It appears likely that the statistical analysis in this case is imprecise to such a high degree because AdvanceMed failed to fully follow the procedures set forth in the MPIM.

AdvanceMed’s poor precision level is indicative of the unreliability of its methodology and the results of its analysis. The 32.4 % precision level affects the weight it should be afforded in this Court. The statistical analysis is clearly too unreliable for it to constitute substantial evidence to support the Appeals Council’s decision.

Moreover, the Appeals Council erred in failing to find there are flaws inherent in AdvanceMed’s review procedures because it twice failed to discover its non-sampling errors. The Appeals Council reasoned the ALJ erred as a matter of law in

invalidating the “sample” (the Council appears to have meant the statistical analysis) based on its precision level and non-sampling errors. The Appeals Council found the ALJ’s ruling as to non-sampling errors was “not consistent with the preponderance of the evidence of record because the two known non-sampling errors had been corrected and no further non-sampling errors had been shown” (Doc. 32-1, p. 25/549). However, non-sampling errors occurred in both statistical analyses, and AdvanceMed failed to find them both times. Not only were there were two non-sampling errors in AdvanceMed’s first calculation, but there was one error (a line-item entry error) in AdvanceMed’s second calculation that the Appeals Council overlooked. Although the errors were eventually corrected, they were not found during AdvanceMed’s review process. Instead, the first two errors were found outside of AdvanceMed’s review process and were corrected late, while the third error was found by CLHHC’s expert.

Therefore, the Appeals Council erred as a matter of fact in overlooking the non-sampling error in AdvanceMed’s second calculation. That error was a line-item claim for over \$70,000. It was entered in error and inadvertently inflated the overpayment calculation in AdvanceMed’s second statistical analysis. The government’s expert statistician, Dr. Camp, conceded the existence of that error at the hearing.

AdvnceMed’s procedures demonstrably failed to find its non-sampling errors, and its report statements to the contrary were incorrect.

Accordingly, substantial evidence does not support the Appeals Council's finding that the ALJ erred in finding the non-sampling errors provided a legal basis for invalidating the sample and extrapolation.

**D. The Appeals Council erred in part in denying CLHHC's specific claims for beneficiary services.**

CLHHC contends Appeals Council's decision does not correctly apply the relevant legal standards and is unsupported by substantial evidence because it found that Medicare coverage did not exist for most of the remaining denied home health claims. CLHHC also argues the erred in finding that CLHHC is not entitled to payment for the denied home health services for 15 beneficiaries (GB, VC, WF, RG, MH, WH, OJ, FL, WM, WMc, AP, LP, ES, DS, and HT).<sup>24</sup>

This Court only reviews for substantial evidence and whether the law was followed. The Appeals Council applied the laws and regulations in effect in 2016, when it reviewed this case (Doc. 32-1, pp. 21-22/549). Some of those laws changed substantially since 2008 through 2010, when these claims arose. Agency actions must be assessed according to the statutes and regulations in effect at the time of the

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<sup>24</sup> The Medicare Program Benefit Manual ("MPBM"), Chapter 7, § 30 summarizes which beneficiaries qualify for Medicare home health benefits:

30. Conditions Patient Must Meet to Qualify for Coverage of Home Health Services.  
To qualify for the Medicare home health benefit, under §§1814(a)(2)(C) and 1835(a)(2)(A) of the Act, a Medicare beneficiary must meet the following requirements:
- Be confined to the home;
  - Under the care of a physician;
  - Receiving services under a plan of care established and periodically reviewed by a physician;
  - Be in need of skilled nursing care on an intermittent basis or physical therapy or speech-language pathology; or
  - Have a continuing need for occupational therapy.

relevant activity. See Cypress Home Care, Inc. v. Azar, 326 F.Supp.3d 307, 317–18 (E.D. Tex. 2018) (citing Texas v. United States Environmental Protection Agency, 829 F.3d 405, 430 (5th Cir. 2016) and Caring Hearts Personal Home Services, Inc. v. Burwell, 824 F.3d 968, 972 (10th Cir. 2016)).

1. **Denials based on homebound status.**

Home health services are provided by Medicare to individuals who are confined to home and need skilled nursing care. 42 C.F.R. § 1395f(a)(2)(C).

In 2008, “homebound” was defined in 42 C.F.R. § 1395f(a) as follows: “[A] patient will be considered homebound if they [sic] have a condition due to an illness or injury that restricts their ability to leave the place of residence except with the aid of supportive devices such as crutches, canes, wheelchairs, and walkers....” See Caring Hearts Home Service, Inc., at 971; see also Cypress Home Health, 326 F. Supp. 3d at 315-17. In 2016, the regulation additionally stated that for a patient to qualify as homebound he must “normal[ly] be unable to leave home even with a wheelchair and any attempt to leave home must also ‘require a considerable and taxing effort.’” Caring Hearts Home Service, Inc., 824 F.3d at 971. Thus, the 2016 standard is much narrower. Although the 2008 version of the statute, 42 USC § 1395f(a),<sup>25</sup> included the proviso that “leaving home requires a considerable and taxing

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<sup>25</sup> The last paragraph of 42 C.F.R. § 1395f(a) currently states, in pertinent part:

“ For purposes of paragraph (2)(C), an individual shall be considered to be “confined to his home” if the individual has a condition, due to an illness or injury, that restricts the ability of the individual to leave his or her home except with the assistance of another individual or the aid of a supportive device (such as crutches, a cane, a wheelchair, or a walker), or if the individual has a condition such that leaving his or

effort by the individual,” the interpretive regulation, 42 C.F.R. § 1395f(a), did not include that phrase in 2008. Thus, as discussed and concluded by (now) Justice Gorsuch in an opinion from the United States Court of Appeals for the Tenth Circuit, Caring Hearts Home Service, Inc., 824 F.3d at 972, there was arguably some confusion as to the correct interpretation of the statute. In 2008 through 2010, CLHHC could not have foreseen the legislative narrowing of the standard of “homebound.”

**VC.** The Appeals Council found VC was ineligible for Medicare home health services from September 13, 2009 to July 9, 2010 because she did not meet the criteria for “homebound” (Doc. 32-1, pp. 54-57/549). It was noted that she could dress independently; transfer and ambulate with the use of a cane or walker; bathe in the shower or tub independently with the use of grab bars; occasionally went on outings with other residents at her assisted living facility; ambulated to the dining room for her meals; and had no cognitive or neurological limitations (Doc. 32-1, p. 56/549). The Appeals Council specifically relied on the newer definition of “home bound” in

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her home is medically contraindicated. While an individual does not have to be bedridden to be considered “confined to his home”, the condition of the individual should be such that there exists a normal inability to leave home and that leaving home requires a considerable and taxing effort by the individual. Any absence of an individual from the home attributable to the need to receive health care treatment, including regular absences for the purpose of participating in therapeutic, psychosocial, or medical treatment in an adult day-care program that is licensed or certified by a State, or accredited, to furnish adult day-care services in the State shall not disqualify an individual from being considered to be “confined to his home”. Any other absence of an individual from the home shall not so disqualify an individual if the absence is of infrequent or of relatively short duration. For purposes of the preceding sentence, any absence for the purpose of attending a religious service shall be deemed to be an absence of infrequent or short duration.

concluding the evidence did not establish that VC was “normally unable to leave home, or that leaving home would require a considerable and taxing effort on her part” (Doc. 32-1, p. 56/549). The Appeals Council erred as a matter of law in applying the newer, more restrictive definition, rather than the broader requirement in effect in 2009, that she “have a condition due to an illness or injury that restricts their ability to leave the place of residence except with the aid of supportive devices.” Since VC met the definition of homebound in 2009, substantial evidence does not support the Appeals Council’s decision to disqualify VC from Medicare home health services coverage, and its decision should be reversed.

WH. The Appeals Council found WH was ineligible for Medicare home health services in 2008 because she was not homebound (Doc. 32-1, pp. 72-75). The Appeals Council found WH was able to independently dress himself, shower with a bench, and transfer and ambulate with the use of a cane (Doc. 32-1, pp. 72-73/549). Again, the Appeals Council specifically relied on the newer definition of “home bound” in concluding the evidence did not establish that WH was “normally unable to leave home, or that leaving home would require a considerable and taxing effort on her part” (Doc. 32-1, P. 56/549). The Appeals Council erred as a matter of law in applying the newer, more restrictive definition, rather than the broader requirement in effect in 2009 that WH “have a condition due to an illness or injury that restricts their ability to leave the place of residence except with the aid of supportive devices.” However, WH did not meet the definition of homebound in 2008. WH did not have a

condition or illness that restricted his ability to leave home. Although the doctor noted he was no longer able to drive after his hip replacement surgery and should not be out alone due to his heart disease, those two qualifications clearly do not meet the requirement of a condition or illness that restricts his ability to leave home (Doc. 32-1, p. 74/549). Substantial evidence supports the Appeals Council's denial of Medicare home health services for WH because he did not meet the definition of "homebound".

OJ. The Appeals Council found OJ was ineligible for Medicare home health services in 2008 because he was not homebound from October 9, 2008 through December 7, 2008 (Doc. 32-1, pp. 75-). Again, the Appeals Council specifically relied on the newer definition of "home bound" in concluding the evidence did not establish that OJ was "normally unable to leave home, or that leaving home would require a considerable and taxing effort on her part" (Doc. 32-1. P. 56/549). The Appeals Council erred as a matter of law in applying the newer, more restrictive definition, rather than the broader requirement in effect in 2008-2010, that OJ "have a condition due to an illness or injury that restricts their ability to leave the place of residence except with the aid of supportive devices." However, OJ did not meet the definition of homebound in effect in 2008 because he did not have a condition or illness that restricted his ability to leave home. OJ had a stroke earlier in the year, but by October 9, 2008, the effects of his stroke had substantially resolved—his standing balance was excellent, and his lower extremity strength and ranges of motion were within functional limits (Doc. 32-1, p. 79-549). Moreover, OJ was independent in his

activities of daily living and was able to leave home, albeit using a cane (Doc. 32-1, p. 79/549). Therefore, substantial evidence supports the Appeals Council's decision that OJ did not meet the definition of "homebound".

**LP.** The Appeals Council found LP was ineligible for home health services from November 21, 2007 to January 19, 2008 because she was not homebound (Doc. 32-1, pp. 91-94/549). Although the Appeals Council erred in applying the newer version of the regulation to LP, LP did not meet the requirements for homebound in the older version of the regulation. Although LP claimed frailty and an inability to drive, she did not have a condition or illness that made her unable to leave home without the aid of an assistive device, and there was no evidence that LP used an assistive device to ambulate. (Doc. 32-1, pp. 92-94). Therefore, substantial evidence supports the Appeals Council's decision that LP did not meet the definition of "homebound".

**2. Denials based on the need for skilled nursing care.**

Home health skilled nursing care "must be reasonable and necessary to the diagnosis and treatment of the patient's illness or injury within the context of the patient's unique condition. To be considered reasonable and necessary for the diagnosis or treatment of the patient's illness or injury, the services must be consistent with the nature and severity of the illness or injury, the patient's particular medical needs, and accepted standards of medical and nursing practice." MBPM Ch. 7 § 40.1.1 (Pub. 100-02, Rev. 1) (2003); see also 42 C.F.R. § 409.44(b); Cypress Home Care, Inc. v. Azar, 326 F.Supp.3d 307, 322 (E.D. Tex.2018); Caring

Hearts, 824 F.3d at 975–76. The definition of skilled nursing care is essentially the same now as it was in 2008. See Medicare Program, 59 F.R. 65482-01, 1994 WL 705126 (1994).

**GB.** The Appeals Council found GB was ineligible for Medicare home health services from February 5, 2008 to February 5, 2010 because she did not require “skilled nursing care” (Doc. 32-1, pp. 50-54/549). The Appeals Council found that skilled nursing was not needed for venipuncture, to give repetitive instructions, or to monitor GB’s stable blood pressure and other long-standing, chronic, stable diseases (Doc. 32-1, pp. 52-54/549). Substantial evidence supports the Appeals Council’s denial of skilled nursing care coverage for GB.

**WF.** The Appeals Council found WF was ineligible for Medicare home health services from June 10 to August 9, 2009 because he did not require skilled nursing care at that time (Doc. 32-1, pp. 57-61/549). The Appeals Council found WF was living in an assisted living facility where the nurse there helped him with his medications and B-12 injections, and there was no evidence that WF was at a high risk for hospitalization (Doc. 32-1, pp. 59-61/549). Therefore, substantial evidence supports the Appeals Council’s decision to deny skilled nursing care coverage for WF.

**RG.** The Appeals Council found RG was ineligible for skilled nursing services<sup>26</sup> from August 28, 2008 to October 16, 2008 because she did not require skilled nursing services to monitor her chronic diabetes, to monitor her chronic hypertension, or for

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<sup>26</sup> The Appeals Council granted coverage for RG’s physical therapy (Doc. 32-1, p. 66/549).

the use of familiar medications (Doc. 32-1, pp. 65-66). CLHHC argues the erred in focusing on an after-the-fact analysis of whether skilled nursing care was medically necessary, instead of determining whether skilled nursing care was medically necessary at the time of the treating physician's orders. CLHHC contends that, just because RG's diabetes and hypertension were subsequently proven to be controlled was not a reason to find she did not require skilled nursing care before they were found to be controlled. However, the Appeals Council found skilled nursing case was not required to monitor, observe, and assess RG's diabetes and hypertension because those conditions were not new. Moreover, there is no evidence that RG's diabetes and hypertension were not stable before she began receiving skilled nursing care. Therefore, substantial evidence supports the Appeals Council's denial of skilled nursing services for RG.

**MH.** The Appeals Council found MH was ineligible for Medicare home health services because she did not require skilled nursing services from June 6, 2008 to May 26, 2010 (Doc. 32-1, pp. 67-72). The Appeals Council found the repetitive instructions given concerning MH's medications and blood pressure monitoring were unnecessary, and they were unable to teach MH to be compliant with her medications (Doc. 32-1, pp. 67-72/549). See 42 C.F.R. 409.42(c)(1)(ii).<sup>27</sup> Substantial evidence supports the Appeals Council's decision to deny skilled nursing care coverage for MH.

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<sup>27</sup> 42 C.F.R. § 409.42(c)(1)(ii) states:

In the home health setting, skilled education services are no longer needed if it becomes apparent, after a reasonable period of time, that the patient, family, or caregiver could not or would not be trained. Further teaching and training would cease

**FL.** The Appeals Council found FL was ineligible for Medicare home health services from December 15, 2007 to July 6, 2010 because she did not require or receive skilled nursing services (Doc. 32-1, pp. 83-85/549). The Appeals Council found FL's medical condition was stable during that time and instructions given as to her medications were repetitive (Doc. 32-1, pp. 84-85/549). Therefore, substantial evidence supports the Appeals Council's decision to deny skilled nursing care benefits for FL.

**WM.** The Appeals Council found WM was ineligible for Medicare home health services from March 27, 2008 through May 15, 2010 because he did not require skilled nursing services after it became apparent he could not or would not be trained to follow his dietary restrictions, take his medications, and stop smoking a pack of cigarettes per day (Doc. 32-1, pp. 85-87). See 42 C.F.R. 409.42(c)(1)(ii). Substantial evidence supports the Appeals Council's decision to deny skilled nursing care benefits for WM.

**WMc.** The Appeals Council found WMc was ineligible for home health services in 2008-2010 because she did not require or receive skilled nursing services to help her manage pain, provide information about her medications, and monitor her blood pressure (Doc. 32-1, pp. 87-88/549). WMc's medical condition was stable, she

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to be reasonable and necessary in this case, and would cease to be considered a skilled service. Notwithstanding that the teaching or training was unsuccessful, the services for teaching and training would be considered to be reasonable and necessary prior to the point that it became apparent that the teaching or training was unsuccessful, as long as such services were appropriate to the patient's illness, functional loss, or injury.

completed chemotherapy for colon cancer, and her blood pressure was usually normal (Doc. 32-1, pp. 87-88/549). Therefore, substantial evidence supports the Appeals Council's decision to deny skilled nursing care benefits for WMc.

**WP.** The Appeals Council found AP was ineligible for home health services from December 19, 2008 to January 13, 2009 because she did not require skilled nursing services six weeks after her surgery because her wound was fully healed and she was no longer homebound (Doc. 32-1, pp. 88-91/549).<sup>28</sup> AP no longer had a condition that restricted her ability to leave home, her surgical wound was fully healed, and the instruction she was receiving from the nurses at that point was highly repetitive (Doc. 32-1, p. 91/549). Therefore, substantial evidence supports the Appeals Council's decision to deny skilled nursing care benefits for AP.

**ES.** The Appeals Council found ES was ineligible for home health services from December 24, 2007 to April 9, 2009 because she did not require skilled nursing services for senile dementia (Doc. 32-1, pp. 96-98/549). The Appeals Council concluded that ES did not have a condition or illness that required skilled nursing services at that time. Substantial evidence supports the Appeals Council's denial of skilled nursing care coverage for ES.

**DS.** The Appeals Council found DS was ineligible for home health services from March 19, 2008 to January 7, 2010 because he did not require skilled nursing

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<sup>28</sup> The Appeals Council reversed the ALJ's decision in part to grant benefits from November 15, 2008 to December 18, 2008, due to her post-surgery need for skilled nursing care (Doc. 32-1, p. 88/549).

services (Doc. 32-1, pp. 99-101/549).<sup>29</sup> His medical conditions, including his hypertension, were stable, and the education about his diseases and medications was repetitive (Doc. 32-1, p. 100/549). Substantial evidence supports the Appeals Council's denial of skilled nursing care coverage for DS.

**HT.** The Appeals Council found HT was ineligible for home health services from March 18, 2008 to November 10, 2008 because he no longer required skilled nursing services (Doc. 32-1, pp. 101-/549).<sup>30</sup> The Appeals Council determined that skilled nursing services were not required to replace a lost glucometer, to perform venipuncture for blood samples at the request of the physician,<sup>31</sup> to obtain a urine sample, or to receive instructions his caregivers had already received many times (Doc. 32-1, pp. 108-09/549). Substantial evidence supports the Appeals Council's partial denial of skilled nursing care coverage for HT.

### 3. Conclusion as to individual beneficiary claims

The decisions of the Appeals Council to deny CLHHC's claims for payment for specific services should be affirmed as to GB, WF, RG, MH, WH, OJ, FL, WM, WMc, AP, LP, ES, DS, and HT, and reversed as to VC.

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<sup>29</sup> The Appeals Council approved coverage for DS's physical therapy (Doc. 32-1, p. 99/549).

<sup>30</sup> The Appeals Council reversed the ALJ's decision in part to grant benefits from November 19, 2007 to March 17, 2008.

<sup>31</sup> A need for skilled nursing care must be more than just venipuncture for the purpose of obtaining a blood sample. See 42 C.F.R. § 1395f(a)(2)(C).

The Appeals Council applied the incorrect legal standard to VC's homebound status, and VC met the old definition of homebound in 2009. Therefore, substantial evidence does not support the Appeals Council's decision to disqualify VC from Medicare home health services coverage, and its decision should be reversed.

**E. CLHCC is entitled to a limited waiver of recoupment.**

Finally, CLHCC contends the Appeals Council erred in finding that CLHHC is not entitled to payment for the denied services under 42 U.S.C. § 1395pp.

CLHHC is entitled to waiver of recoupment as to the payment for VC's services. Medicare overpayment may be waived, pursuant to 42 U.S.C. § 1395pp, where the provider "did not know, and could not reasonably have been expected to know, that payment would not be made." Cypress Home Care, Inc., 326 F. Supp. 3d at 316–17. In Caring Hearts, the Tenth Circuit explained the purpose of 42 U.S.C. § 1395pp: "In seeming recognition of the complexity of the Medicare maze, Congress there indicated that providers who didn't know and couldn't have reasonably been expected to know that their services weren't permissible when rendered generally don't have to repay the amounts they received from CMS. A sort of good faith affirmative defense, if you will." Cypress Home Care, Inc., 326 F. Supp. 3d 316–17 (citing Caring Hearts, 824 F.3d at 970).

In VC's case, CLHHC's understanding of the applicable law at the time services were rendered was entirely reasonable and had a basis in the statute and the regulations in effect at the time. See Caring Hearts, 824 F.3d at 972. CLHHC

could not have known, nor reasonably have been expected to know, that its coverage for VC would be denied. Therefore, the coverage decision as to VC is waived under 42 U.S.C. § 1395pp.

For the reasons given to uphold the denial of the other claims, CLHHC is not entitled to a waiver of recoupment as to the overpayments for the other beneficiaries. CLHHC has not shown it did not know or could not reasonably have been expected to know that coverage would be denied for GB, WF, RG, MH, WH, OJ, FL, WM, WMc, AP, LP, ES, DS, and HT.

### **III. Conclusion**

For the foregoing reasons, IT IS RECOMMENDED that CLHHC's Motion for Summary Judgment (Doc. 51) be GRANTED, the Secretary's Motion for Summary Judgment be DENIED (Doc. 68), and the decision of the Appeals Council be REVERSED as to the award of overpayment due to the invalidity of the statistical analysis and extrapolation.

IT IS FURTHER RECOMMENDED that CLHHC's Motion for Summary Judgment (Doc. 51) be DENIED, the Secretary's Motion for Summary Judgment be GRANTED (Doc. 68), and the decision of the Appeals Council be AFFIRMED as to the individual beneficiary claims GB, WF, RG, MH, WH, OJ, FL, WM, WMc, AP, LP, ES, DS, and HT, and reversed as to VC.

IT IS FURTHER RECOMMENDED that CLHHC's Motion for Summary Judgment (Doc. 51) be GRANTED, the Secretary's Motion for Summary Judgment be

DENIED (Doc. 68), and the decision of the Appeals Council be AFFIRMED as to the denial of waiver of recoupment for payments for GB, WF, RG, MH, WH, OJ, FL, WM, WMc, AP, LP, ES, DS, and HT, and reversed as to VC. CLHHC should be granted a waiver of recoupment as to the payment for services for VC.

Under the provisions of 28 U.S.C. § 636(b)(1)(c) and Fed. R. Civ. P. 72(b), parties aggrieved by this Report and Recommendation have fourteen (14) calendar days from service of this Report and Recommendation to file specific, written objections with the Clerk of Court. A party may respond to another party's objections within fourteen (14) days after being served with a copy thereof. No other briefs (such as supplemental objections, reply briefs, etc.) may be filed. Providing a courtesy copy of the objection to the undersigned is neither required nor encouraged. Timely objections will be considered by the District Judge before a final ruling.

Failure to file written objections to the proposed findings, conclusions, and recommendations contained in this Report and Recommendation within fourteen (14) days from the date of its service, or within the time frame authorized by Fed. R. Civ. P. 6(b), shall bar an aggrieved party from attacking either the factual findings or the legal conclusions accepted by the District Judge, except upon grounds of plain error.

THUS DONE AND SIGNED in chambers in Alexandria, Louisiana, this  
28th day of December 2018.

  
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Joseph H.L. Perez-Montes  
United States Magistrate Judge