CIVIL ACTION NO. 5:16-CV-00080-RWS
United States District Court, E.D. Texas, Texarkana Division.

Cypress Home Care, Inc. v. Azar

326 F. Supp. 3d 307 (E.D. Tex. 2018)
Decided Jun 11, 2018

ROBERT W. SCHROEDER III, UNITED STATES DISTRICT JUDGE

309 *309 Adam L. Bird, Pro Hac Vice, Calhoun Bhella & Sechrest LLP, Washington, DC, Geoffrey Patton Culbertson, Patton Tidwell & Culbertson, LLP, Texarkana, TX, Leonard Vincent Schneider, IV, Liles Parker PLLC, Kingwood, TX, for Plaintiff.

Robert Austin Wells, US Attorney's Office Tyler, TX, Daniel Ray Wolfe, Jr., U.S. Department of Health and Human Services Office of the General Counsel, Texas, TX, for Defendant.

ORDER

ROBERT W. SCHROEDER III, UNITED STATES DISTRICT JUDGE
310 *310 On February 10, 2017, Plaintiff Cypress Home Care, Inc. ("Cypress") filed a Motion for Summary Judgment. Docket No. 23. Defendant Sylvia Mathews Burwell (now Alex Azar) filed a Cross-Motion for Summary Judgment and a Response to Cypress's Motion for Summary Judgment. Docket No. 26. Cypress filed a Response to Defendant's Cross-Motion. Docket No. 29. Defendant filed a Reply to Cypress's Response. Docket No. 33. Cypress filed a Sur-Reply. Docket No. 35. The Court held a hearing on the motions. Docket No. 43. After the hearing, the Court issued an Order for Supplemental Briefing. Docket No. 49. Cypress filed a Supplemental Brief (Docket No. 53), and Defendant filed a Response (Docket No. 54). Cypress filed a Reply. Docket No. 55. Based on the briefing and argument and for the reasons below, Plaintiff's Motion for Summary Judgment (Docket No. 23) is **GRANTED-IN-PART** and **DENIED-IN-PART** and Defendant's Cross-Motion for Summary Judgment (Docket No. 26) is **GRANTED-IN-PART** and **DENIED-IN-PART** .

BACKGROUND

Cypress filed a complaint for judicial review, asking the Court to overturn the final agency decision of the Medicare Appeals Council ("Council"). Docket No. 1 at 1. Cypress is a Medicare-certified home health agency with its principal place of business located in Mount Pleasant, Texas. *Id.* at 2. Cypress provides home health services to residents of Texas, many of whom are Medicare beneficiaries. *Id.*

Medicare is a Federal health insurance program for the elderly and disabled that was established in 1965. The Medicare statute is codified at 42 U.S.C. § 1395 *et seq.* The Medicare program is administered by the Centers for Medicare and Medicaid Services (CMS), which, in turn, contracts with private entities to perform certain functions on its behalf. These functions include claims processing and audits of claims for reimbursement submitted by Medicare providers to ensure that those claims meet the requirements set forth in the Medicare statute and the implementing regulations.

Medicare claims are processed by contractors known as Medicare Administrative Contractors (MACs). Audits are undertaken by several different CMS contractors, including Zone Program Integrity Contractors (ZPICs). ZPICs may, among other functions, audit claims on a post-payment basis to ensure that the claims

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complied with Medicare coverage and documentation requirements at the time they were submitted for reimbursement.

Due to the extraordinarily high volume of claims processed by CMS and its contractors every year, CMS issued an administrative ruling in 1986 that empowered it and its contractors to use statistical sampling in the context of post-payment claim audits for the purposes of overpayment estimation. *See* CMS Rul. 86-1, *Use of Statistical Sampling to Project Overpayments to Medicare Providers and Suppliers* (Feb. 20, 1986). CMS then promulgated sub-regulatory guidelines in the form of manual instructions that contain requirements for sampling and overpayment estimation. Medicare Program Integrity Manual *311 (MPIM) Ch. 8 § 8.4.1.3 (Pub. No. 100-08, Rev. 377) (2011).

In the event that a Medicare contractor denies a claim (or claims) submitted by a provider, that provider may avail itself of an administrative appeals process to contest the claim denials and, in cases involving statistical sampling, challenge the validity of the sampling methodology. *See* CMS Rul. 86-1. The Medicare appeals process consists of five stages: redetermination, reconsideration, a hearing before an Administrative Law Judge (ALJ), a request for review by the Council, and judicial review in federal district court. Requests for redetermination are processed by Medicare Administrative Contractors (MACs). *See* 42 C.F.R. § 405.940. Requests for reconsideration are handled by separate contractors known as Qualified Independent Contractors (QICs). *See id.* at § 405.960. Hearing requests are adjudicated by ALJs in the Office of Medicare Hearings and Appeals. *See id.* at § 405.1000. Requests for Council review are processed by the Council, which is a component of the U.S. Department of Health and Human Services. *See id.* at § 405.1100.

In August 2010, Health Integrity, a ZPIC acting on behalf of CMS, delivered a letter to Cypress requesting medical records in support of 45 claims for home health services billed to the Medicare program in 2008 and 2009. A.R. 001293–001296. In December 2011, Health Integrity sent a letter to Cypress summarizing the results of the post-payment audit. A.R. 001297–001301. Health Integrity stated that it believed that 95 percent of the claims under review had been paid incorrectly and also alleged that the claims it reviewed constituted a statistically valid random sample of Cypress's Medicare claims. A.R. 001297–001301; 001811. Based upon the results of the review, the ZPIC extrapolated an alleged Medicare overpayment to Cypress in the amount of $11,531,832.00. A.R. 001297.

In a letter dated December 28, 2011, Palmetto GBA, the MAC for home health and hospice providers in Texas, formally notified Cypress of the alleged overpayment. A.R. 001302–001306; *see also* 42 C.F.R. 405.921(b). Cypress filed a request for redetermination and, subsequently, a request for reconsideration with the responsible CMS contractors. Both decisions were partially favorable in that they resulted in reversals of some, but not all, of the claim denials. A.R. 001307–001513; 001553–001594.

Cypress filed a request for a hearing before an ALJ on March 21, 2013. A.R. 001241–001289. The ALJ conducted an evidentiary hearing on April 1, 2015. Health Integrity elected to participate in the hearing consistent with the procedure set forth in 42 C.F.R. § 405.1010. A.R. 001853. In a decision dated November 30, 2015, the ALJ reversed one claim denial, affirmed the remaining claim denials, and invalidated the sampling methodology; the ALJ accordingly directed the Medicare contractor to recalculate the alleged overpayment without extrapolation. A.R. 000475–000554.

In a memorandum dated January 29, 2016, CMS, acting through its contractor, referred the portion of the ALJ's decision invalidating the extrapolation to the Council for review on the Council's own motion. A.R. 000459–000474; *see* 42 C.F.R. § 405.1110. The same day, Cypress filed an appeal with the Council seeking review of all unfavorable aspects of the ALJ's decision. A.R. 000135–000414. *See* 42 C.F.R. § 405.1102. In a consolidated action dated April 28, 2016, the

Council reversed the ALJ's decision as to the extrapolation, issued coverage decisions in favor of Cypress as to eight of the claims, and affirmed the denial of the remaining claims. *312 A.R. 000004–000114. The Council's action constitutes the agency's final decision.

LEGAL STANDARD

The Court, upon review of the final agency decision in a Medicare reimbursement appeal, must determine: "(1) whether the Commissioner applied the proper legal standards; and (2) whether the Commissioner's decision is supported by substantial evidence on the record as a whole." *Estate of Morris v. Shalala* , 207 F.3d 744, 745 (5th Cir. 2000). Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Richardson v. Perales* , 402 U.S. 389, 401, 91 S.Ct. 1420, 28 L.Ed.2d 842 (1971). While deferential, the substantial evidence test is not intended to constitute a "rubber stamp" for the agency decision; the Court should scrutinize the administrative record as a whole and consider whatever fairly detracts from the substantiality of the evidence supporting the decision. *Cook v. Heckler* , 750 F.2d 391, 393 (5th Cir. 1985) (quotation omitted).

Summary judgment is proper "if the movant shows that there is no genuine dispute as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Summary judgment is the preferred procedural mechanism for resolving appeals of final agency decisions. *Girling Health Care, Inc. v. Shalala* , 85 F.3d 211, 214 (5th Cir. 1996).

ANALYSIS

In its Motion for Summary Judgment, Cypress makes three main points. First, it argues that the Council's decision affirming the statistical validity of the ZPIC's sampling methodology did not correctly apply the relevant legal standards and is supported by nothing more than the speculative assertion of one expert (Dr. John Adams). Docket No. 23 at 18. Second, Cypress argues that the Council incorrectly applied the relevant coverage guidelines for home health services and erroneously determined that the claims at issue did not qualify for payment under the home health benefit. Docket No. 23 at 28. Specifically, Cypress contends that the Council applied the wrong version of the Medicare Benefit Policy Manual (MBPM) to this case, citing to the 2013 version in its decision, rather than the 2008 version, which Cypress argues was in effect when the beneficiaries were actually treated. *Id.* at 29–34. Third, Cypress argues that it is entitled to payment for any denied services under 42 U.S.C. § 1395pp because it did not know, nor could it have reasonably been expected to know, that the Council would apply the incorrect legal standards when assessing its claims for Medicare coverage. *Id.* at 36.

In its Cross-Motion for Summary Judgment, Defendant responds to Cypress's three main points. Docket No. 26. First, Defendant argues that the Council applied the proper legal standards when determining that Health Integrity selected a valid probability sample. *Id.* at 15. Defendant further contends that the Council's determination is supported by substantial evidence, including the expert report of Dr. Adams. *Id.* at 16. Second, Defendant argues that the Council's individual coverage denials are supported by substantial evidence and the proper legal standard. *Id.* at 21. Defendant further contends that Cypress waived any objection to the application of the statutory provisions regarding "homebound" coverage guidelines by failing to present the issue to the Council. *Id.* at 22. Third, Defendant argues that the Council's denial of waiver of liability under 42 U.S.C. § 1395pp is supported by substantial evidence. *313 The Court must review 23 individual coverage decisions:

Beneficiary Dates of Service Administrative Record Page Ranges M.C. 10/11/09 - 12/09/09 004516 - 004772 E.C. 06/17/08 - 08/15/08 004780 - 005025 D.C. 08/19/09 - 10/17/09 005029 - 005536 V.D. 06/29/09 - 09/26/09 005544 - 005800 S.D. 01/07/09 - 03/07/09 005807 - 006002 M.T.G. 12/24/09 - 02/21/10 006430 - 007010 E.G.

11/06/09 - 01/04/10 007015 - 007262 O.H.
07/26/09 - 09/23/09 007270 - 007528 R.J.
12/28/08 - 02/25/09 007830 - 008030 C.J.
11/17/08 - 01/15/09 008036 - 008169 C.J.
03/17/09 - 05/15/09 008174 - 008550 C.Y.J.
01/31/09 - 03/31/09 008555 - 008679 W.K.
09/05/09 - 11/03/09 008687 - 008942 J.M.
11/02/08 - 12/31/08 009281 - 009581 A.M.
08/07/08 - 10/05/08 009591 - 009856 M.M.
10/11/08 - 12/09/08 009861 - 010026 M.N.
04/11/09 - 06/09/09 010031 - 010245 V.P.
09/10/08 - 11/08/08 011107 - 011249 P.S.
07/06/08 - 09/03/08 011905 - 012289 Me.W.
09/23/08 - 11/21/08 012293 - 012509 Ma.W.
07/12/09 - 09/09/09 012513 - 012877 F.W.
10/21/08 - 12/19/08 013119 - 013470

P. App. 265 (Docket No. 23-1 at 265).[1] To guide the analysis, the Court will classify the denials into three different groups. Of the 23 denials, 14 were denied because they did not qualify as "homebound" ("homebound denials"); six qualified as "homebound" but were denied "skilled nursing" services ("skilled nursing denials"); and three qualified as "homebound" and were covered for "skilled nursing" services but were denied physical therapy coverage ("physical therapy denials"). *See* Council's Chart, A.R. 000112–000114. The Court will first analyze the homebound denials, then the physical therapy denials, and lastly the skilled nursing denials. Finally, if any denials are affirmed, the Court will inquire as to whether the Council's decision on the statistical extrapolation is supported by substantial evidence and whether the Council applied the proper legal standards. *Estate of Morris v. Shalala* , 207 F.3d at 745.

[1] Cypress's chart found in its Appendix lists 22 of the 23 denials. The 23rd denial under review relates to a beneficiary known as "M.We." *See* A.R. 000103–000104; *see also* A.R. 000114.

I. Individual Claim Denials

A. Homebound Denials

The Court's analysis begins with the statute itself. The relevant statutory language that explains when a patient is "homebound" provides:

> [A]n 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 her

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> *314 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.

42 U.S.C. § 1395f(a) (emphasis added).

In addition, CMS promulgated regulations. During the time period that the beneficiaries in this case received the disputed treatment (June 2008 to Feb. 2010), the regulation stated:

> Generally speaking, a patient will be considered to be homebound if they have a condition due to an illness or injury that restricts their ability to leave their place of residence ***except with the aid of*** : supportive devices such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or the assistance of another person; or if leaving home is medically contraindicated.

MBPM Ch. 7 § 30.1.1 (Pub. 100-02, Rev. 1) (2003) (emphasis added).

In 2013, CMS changed the MBPM. Docket No. 23-1 at 1–10. In explaining the changes, CMS stated that the new regulation "clarifies the definition of the patient as being 'confined to the home' to more accurately reflect the definition as

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articulated at Section 1835(a) of the Social Security Act." *Id.* at 5. The new regulation added a few requirements:

> 1. Criteria-One:
>
> The patient must either:
>
> - Because of illness or injury, need the aid of supportive devices such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or the assistance of another person in order to leave their place of residence
>
> OR
>
> - Have a condition such that leaving his or her home is medically contraindicated.
>
> If the patient meets one of the Criteria-One conditions, then the patient must ALSO meet two ***additional*** requirements defined in Criteria-Two below.
>
> 2. Criteria-Two:
>
> - There ***must*** exist a normal inability to leave home;
>
> AND
>
> - Leaving home ***must*** require a considerable and taxing effort.

Docket No. 23-1 at 10 (redlined italics omitted from original; emphasis added).

In its Motion for Summary Judgment, Cypress argues that the Council, when making its coverage determinations as to the beneficiaries, applied the wrong law. Docket No. 23 at 28. Specifically, Cypress contends that the Council applied the more stringent 2013 regulation, when it instead should have applied the 2008 regulation. *Id.* at 29–35. Cypress argues that the recent decision of *Caring Hearts Pers. Home Servs., Inc. v. Burwell* , 824 F.3d 968 (10th Cir. 2016) (J. Gorsuch) is especially instructive. *Id.*

The Court finds *Caring Hearts* to be persuasive, as *Caring Hearts* dealt with the same statute and regulations at issue in this case. In *Caring Hearts* , the federal government sought repayment for an alleged overpayment to a home health care provider, Caring Hearts. *See Caring Hearts* , 824 F.3d at 970. Specifically, the government argued the beneficiaries did not meet the definition of when a patient is "homebound." *Id.* As in this case, the beneficiaries in *Caring Hearts* received their care in 2008, but Caring Hearts argued that CMS applied a more stringent version of the MBPM that was not promulgated until after the beneficiaries had received treatment. *Id.* 315 Originally, the district court *315 ruled against Caring Hearts and affirmed the coverage denials. *See generally Caring Hearts Pers. Home Servs., Inc. v. Sebelius* , No. 12-2700-CM, 2014 WL 4259151 (D. Kan. Aug. 28, 2014), *vacated and remanded sub nom. Caring Hearts Pers. Home Servs., Inc. v. Burwell* , 824 F.3d 968 (10th Cir. 2016). But on appeal, the Tenth Circuit vacated the decision and waived Caring Hearts's overpayment, explaining that "[t]he trouble is, in reaching its conclusions CMS applied the wrong law.... [T]he agency didn't apply the regulations in force in 2008 when Caring Hearts provided the services in dispute. Instead, it applied considerably more onerous regulations the agency adopted only years later." *Caring Hearts* , 824 F.3d at 970.

In *Caring Hearts* , the court explained the key difference between the 2008 regulation and the 2013 version. *Caring Hearts* , 824 F.3d at 971–72. In short, the 2008 version encompasses a wider universe of people who might qualify as "homebound." Under the 2008 version, a patient would be considered homebound if she could not leave home "except with the aid of" a supporting device. MBPM Ch. 7 § 30.1.1 (Pub. 100-02, Rev. 1) (2003). Yet under the 2013 version, simply requiring the use of a supportive device is not enough, as the patient must also satisfy the two additional requirements under criteria two: "

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[t]here must exist a normal inability to leave home" and "[l]eaving home must require a considerable and taxing effort." Docket No. 23-1 at 10. Thus, the key difference is "rather than asking whether a patient could leave home *with* a supportive device, the regulations back then [in 2008] seemed to ask whether a patient could leave home *without* one." *Caring Hearts* , 824 F.3d at 971–72.

In *Caring Hearts* , the health care provider argued that it had relied on this wider universe found in the 2008 version of the MBPM for guidance as to who would be considered "homebound." *Caring Hearts* , 824 F.3d at 972. The court scrutinized the language of the statute itself and found that it "support[ed] the reasonableness of Caring Hearts's reading." *Id.* The court explained that the statute has two sentences with two different verbs: the first one uses "shall" and the second one uses "should." [2]*See supra* 42 U.S.C. § 1395f(a). The choice of the verbs supported the health care provider's understanding of the state of the law in 2008: "The first sentence says a person 'shall be' considered homebound if he or she cannot leave without supportive assistance. Meanwhile, the second sentence says that certain additional clues 'should be' present, suggesting that the second sentence provides useful but not necessarily dispositive tests for homebound status." 824 F.3d at 973. *Caring Hearts* further explained that other textual clues supported the health care provider's interpretation as well:

> Next consider the fact that the first sentence suggests individuals shall be homebound either because they need to use supportive devices to leave or because leaving is medically contraindicated (because of, say, the risk of infection). In this way the statute again seems to contemplate the possibility that some persons will be considered homebound even if they don't use supportive devices and can leave the home without considerable or taxing effort. And consider, too, the statute's use of the term "condition."
>
> 316 *316 The first sentence says the patient must suffer from a "condition" that restricts his or her ability to leave home "except with" (but for) the use of a supportive device. Assuming (as we usually do) that Congress means the same thing when using the same word in adjoining sentences, the second sentence's use of the term "condition" may be best read as meaning that the patient's condition normally renders him unable to leave home without considerable and taxing effort but for his supportive device.

Caring Hearts , 824 F.3d at 973 (internal citation omitted). Lastly, *Caring Hearts* explained that subsequent sentences in the statute supported the reasonableness of the health care provider's position. *See id.*

Here, as in *Caring Hearts* , the Council applied an improper standard. On numerous occasions, the Council applied the 2013 requirements to the beneficiaries in this case, all of whom received treatment in the 2008–2010 time period. For example, for beneficiary V.D., the Council determined she was not homebound, explaining:

[2] The difference of verbs between the first and second sentences is especially important because the new requirements imposed in the 2013 regulation may also be found in the second sentence of the statute, which itself existed in 2008. *See* "normal inability to leave home" and "considerable and taxing effort" in both 42 U.S.C. § 1395f(a) and Docket No. 23-1 at 10.

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> Overall, despite the appellant's responsibility for creating a contemporaneous record of the beneficiary's home health care, the appellant has not shown that the beneficiary was normally unable to leave home, or that she could leave home only with a considerable and taxing effort. Although the beneficiary used a walker for ambulating, she required only minimal assistance for most [activities of daily living] and her arthritis pain was largely controlled by medication. Therefore, the Council determines that the record in this case does not establish that the beneficiary was homebound, as required to qualify for Medicare coverage of home health services.

A.R. 00053. As *Caring Hearts* shows, this analysis is flawed. Cypress should not have been required to show that V.D. could leave home only with "a considerable and taxing effort." That requirement falls squarely within the domain of the 2013 regulation and was not required at the time V.D. received treatment. And while the statute *was* in effect at this time, as *Caring Hearts* explained, this "considerable and taxing effort" language was found only in the second sentence of the statute, where "should" was the controlling verb (and not "shall"). Thus, it was incorrect for the Council to require Cypress to meet this burden in order to show that V.D. was homebound.

The administrative record is rife with this error. *See e.g.* , A.R. 90 ("The documentation in the medical record establishes that beneficiary J.M. required assistance to leave home. However, the documentation does not establish that he was normally unable to leave home, and could not leave home without a considerable and taxing effort. Therefore, the Council determines that he was not homebound."). Defendant defends some of these decisions by repeating the same argument *Caring Hearts* deemed incorrect. *See e.g.* , Docket No. 54 at 14 ("Although the beneficiary was reported to have required some assistance for ambulating, the Council determined that the plaintiff has not shown that the beneficiary was normally unable to leave home, and could not leave home without a considerable and taxing effort."); *see also id* at pp. 15 & 16 (explaining that for W.K. and P.S., "leaving home did not require a considerable and taxing effort").

In total, out of 14 "homebound" denials, 11 clearly exhibited this same error, i.e., requiring Cypress to show that the patient was "normally unable to leave home" and/or "could not leave home without 317 a *317 considerable and taxing effort."[3] Those 11 denials cannot stand. *See Caring Hearts* , 824 F.3d at 977 ("[A]n agency decision that loses track of its own controlling regulations and applies the wrong rules in order to penalize private citizens can never stand.").

[3] *See* A.R. 0047 (M.C.), 0053 (V.D.), 0055 (S.D.), 0059 (M.T.G.), 0069 (R.J.), 0074 (C.Y.J.), 0075 (W.K.), 0080 (J.M.), 0099 (P.S.), 00100 (Me.Wa.), 00104 (M.We).

Thus, the Court must find an appropriate remedy. One possible solution, as shown by *Caring Hearts* , involves another section of the Medicare statute: 42 U.S.C. § 1395pp.

Waiver under 42 U.S.C. § 1395pp

42 U.S.C. § 1395pp allows for the Medicare overpayment to be waived in cases where the provider "did not know, and could not reasonably have been expected to know, that payment would not be made." 42 U.S.C. § 1395pp. *Caring Hearts* 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." *Caring Hearts* , 824 F.3d at 970.

In addition, CMS has promulgated regulations interpreting this statute. One such regulation explains various criteria to be used to determine

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whether a provider knew or should have known that services would not be covered:

> (e) Knowledge based on experience, actual notice, or constructive notice. It is clear that the provider, practitioner, or supplier could have been expected to have known that the services were excluded from coverage on the basis of the following:
>
> (1) Its receipt of CMS notices, including manual issuances, bulletins, or other written guides or directives from intermediaries, carriers...
>
> (2) Federal Register publications containing notice of national coverage decisions or of other specifications regarding noncoverage of an item or service.
>
> (3) Its knowledge of what are considered acceptable standards of practice by the local medical community.

42 C.F.R. § 411.406(e).

In deciding whether waiver should apply to this case, the Council concluded that Cypress "should have known that Medicare would not cover these charges based on knowledge of Medicare coverage criteria, including the criteria for when a beneficiary would be considered homebound, and when skilled nursing services and/or physical therapy services would be considered reasonable and necessary. Accordingly, [Cypress] is liable for the costs associated with the non-covered services at issue." A.R. 00110.

Yet, as explained in detail *supra* , in *Caring Hearts* , the court explained that Caring Hearts'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 e.g.* 824 F.3d at 972 ("More than a few clues seem to support the reasonableness of Caring Hearts's reading.") As a result, *Caring Hearts* ultimately reversed the district court and found waiver under 42 U.S.C. § 1395pp. *See* 824 F.3d at 977. In fact, *Caring Hearts* found the waiver argument so persuasive that it posited an award of attorney's fees might be appropriate: "Indeed, we would not be surprised if —should Caring Hearts bring an *318 otherwise eligible application for costs and fees under the Equal Access to Justice Act, 28 U.S.C. § 2412(d) —CMS were to accept on remand that its positions in this case were not 'substantially justified.' " 824 F.3d at 977. *See also Caring Hearts Pers. Home Servs., Inc. v. Sebelius* , C.A. No. 2:12-cv-2700-CM, Docket No. 52 (D. Kan. May 24, 2017) (granting motion for attorney fees).

Here, the facts and issues are similar to those in *Caring Hearts.* The statutes (42 U.S.C. § 1395pp and 42 U.S.C. § 1395f(a)), regulations (those interpreting 42 U.S.C. § 1395pp and 42 U.S.C. § 1395f(a)), and the time period in question (2008) are all the same. In addition, neither party has cited Fifth Circuit precedent that is on point. However, the Fifth Circuit has at least in one instance cited positively to the general principle of *Caring Hearts. See Texas v. United States Envtl. Prot. Agency* , 829 F.3d 405, 430 (5th Cir. 2016) ("Agency actions must be assessed according to the statutes and regulations in effect at the time of the relevant activity.") (citing to *Caring Hearts*). Thus, given the intellectual rigor applied in *Caring Hearts* , the fact that the issues presented are similar, and the positive citation by the Fifth Circuit to *Caring Hearts* , this Court finds it appropriate to adopt the reasoning and decision of *Caring Hearts* and therefore holds that as to the following 11 beneficiaries, any overpayment sought by Defendant because the beneficiary was allegedly not "homebound" is **WAIVED** under 42 U.S.C. § 1395pp : M.C., V.D., S.D., M.T.G., R.J., C.Y.J., W.K., J.M., P.S., Me.Wa., and M.We.

Remaining Homebound Denials

Since 11 of the 14 homebound denials have now been waived, three denials still remain. Two of the denials relate to the same patient—C.J., Jr. A.R. 00113. In the Council's decision on C.J., Jr., the Council did not explicitly recite the incorrect law, as it did with the denials above. *See* A.R. 0071.

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Instead, the Council makes a new error—when reviewing the forms submitted on behalf of C.J., Jr., the Council complained that:

> In this case it is not possible to determine whether Beneficiary C.J., Jr. was homebound during the first home health episode at issue, because the nurse who filled out the OASIS form at the start of home health care on November 17, 2008 marked two different answers, rather than one answer, for each question about the beneficiary's ability to perform his ADLs...As a result, it is impossible to determine from a review of the November 17, 2008 OASIS survey whether the beneficiary was so impaired as to be homebound at the start of care.

A.R. 0071.

Yet the Council did not consider the proper time period. The Outcome Assessment and Information Set (OASIS) has been revised multiple times. *See* P. App. 102 (Docket No. 23-1 at 105). During the time period in question, health care providers were specifically asked to make two marks: one for "current" status and one for "prior" status, i.e., 14 days prior. P. App. 204 (Docket No. 23-1 at 207). Here, Cypress followed those rules and made two markings but was reprimanded by the Council. In the briefing, Defendant conceded a mistake was made and asked the Court to "modify the findings," or in the alternative, to remand to the Council to fix. Docket No. 33 at 14–15.

In addition, the Court also notes that the Council stated that C.J., Jr. could "ambulate with an assistive device." A.R. 00071. As explained above, any fact tending to show that C.J., Jr. needed an assistive device to ambulate is highly relevant to the analysis under the homebound statute at the time services were rendered. *319 Thus, the Court **REMANDS** both denials as to C.J., Jr. to the Council. On remand, the Council should: 1) interpret the OASIS forms in light of the instructions at the time; and 2) re-examine its homebound denial in light of the law at the time as explained in *Caring Hearts* , specifically considering the fact that C.J., Jr. may have required an assistive device to ambulate.

The last homebound denial concerns A.M. The Council claimed that because certain documents were missing, and the burden is on the appellant to produce the documents, the claim "must be denied." A.R. 0080–81. However, "[i]f the reviewing court deems the administrative record incomplete ... the court should remand the matter to the administrative agency for further consideration." *Fleming Companies, Inc. v. U.S. Dep't of Agric.* , 322 F.Supp.2d 744, 755 (E.D. Tex. 2004), *aff'd sub nom. Fleming Companies, Inc. v. Dep't of Agric.* , 164 F. App'x 528 (5th Cir. 2006) (citing *Camp v. Pitts* , 411 U.S. 138, 143, 93 S.Ct. 1241, 36 L.Ed.2d 106 (1973)). Here, the decisions issued by the MAC, QIC, and ALJ as to A.M. do not reflect that any pertinent documents were missing from the file. A.R. 00518–19, 001528–29, 001422–28. Thus, the Council is the only adjudicator in the entire administrative appeals process that found that a document was missing. The Court hereby **REMANDS** A.M. to the Council so that the agency may locate the documentation it needs or alternatively, allow Cypress the opportunity to submit the documentation.

Now that all 14 homebound denials are complete, the Court addresses the remaining denials. The Court will next consider the physical therapy and skilled nursing denials.

B. Physical Therapy Denials

There are three beneficiaries who received physical therapy services that were ultimately denied. *See* A.R. 000112–000114. The Court now turns to these three beneficiaries: D.C., V.P., and Ma.Wa. *See id.*

At the outset, similar to the homebound denials, the relevant regulation has changed since the services were first rendered. The regulation in effect in 2009 when services were rendered provided as follows:

(c) Physical therapy, speech-language pathology services, and occupational therapy. To be covered, physical therapy, speech-language pathology services, and occupational therapy must satisfy the criteria in paragraphs (c)(1) through (4) of this section. Occupational therapy services initially qualify for home health coverage only if they are part of a plan of care that also includes intermittent skilled nursing care, physical therapy, or speech-language pathology services as follows:

(1) Speech-language pathology services and physical or occupational therapy services must relate directly and specifically to a treatment regimen (established by the physician, after any needed consultation with the qualified therapist) that is designed to treat the beneficiary's illness or injury. Services related to activities for the general physical welfare of beneficiaries (for example, exercises to promote overall fitness) do not constitute physical therapy, occupational therapy, or speech-language pathology services for Medicare purposes.

(2) Physical and occupational therapy and speech-language pathology services must be reasonable and necessary. To be considered reasonable and necessary, the following conditions must be met:

*320 (i) The services must be considered under accepted standards of medical practice to be a specific, safe, and effective treatment for the beneficiary's condition.

(ii) The services must be of such a level of complexity and sophistication or the condition of the beneficiary must be such that the services required can safely and effectively be performed only by a qualified physical therapist or by a qualified physical therapy assistant under the supervision of a qualified physical therapist, by a qualified speech-language pathologist, or by a qualified occupational therapist or a qualified occupational therapy assistant under the supervision of a qualified occupational therapist (as defined in § 484.4 of this chapter). Services that do not require the performance or supervision of a physical therapist or an occupational therapist are not considered reasonable or necessary physical therapy or occupational therapy services, even if they are performed by or supervised by a physical therapist or occupational therapist. Services that do not require the skills of a speech-language pathologist are not considered to be reasonable and necessary speech-language pathology services even if they are performed by or supervised by a speech-language pathologist.

(iii) There must be an expectation that the beneficiary's condition will improve materially in a reasonable (and generally predictable) period of time based on the physician's assessment of the beneficiary's restoration potential and unique medical condition, or the services must be necessary to establish a safe and effective maintenance program required in connection with a specific disease, or the skills of a therapist must be necessary to perform a safe and effective maintenance program. If the services are for the establishment of a maintenance program,

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> they may include the design of the program, the instruction of the beneficiary, family, or home health aides, and the necessary infrequent reevaluations of the beneficiary and the program to the degree that the specialized knowledge and judgment of a physical therapist, speech-language pathologist, or occupational therapist is required.
>
> (iv) The amount, frequency, and duration of the services must be reasonable.

42 C.F.R. § 409.44 (2009). In contrast, the regulation in place when the Council filed its decision in 2016 was greatly expanded, including a number of new requirements under CFR § 409.44 (c)(2)(i). *See* 42 CFR § 409.44 (2016).

This Court must analyze two key issues: "(1) whether the Commissioner applied the proper legal standards; and (2) whether the Commissioner's decision is supported by substantial evidence on the record as a whole." *Estate of Morris v. Shalala* , 207 F.3d 744, 745 (5th Cir. 2000).

Here, the Council included an "Applicable Legal Authority" section at the beginning of its decision. *See* A.R. 0010. In the section about physical therapy services, the decision invokes not one but three provisions of 42 CFR § 409.44 that did not exist at the time services were rendered. *See* A.R. 0022 (citing to numerous provisions that have no basis in the 2009 version.) For example, in one instance, the Council cited to 42 C.F.R. § 409.44(c)(2)(i)(A). *Id.* Yet in 2009, unlike in 2016, there was no 42 C.F.R. § 409.44(c)(2)(i)(A). *See* 42 C.F.R. § 409.44 (2009). This error is repeated 321 multiple *321 times with respect to other provisions. *See* A.R. 0022.

Caring Hearts dealt with this same problem as to physical therapy denials. *See Caring Hearts* , 824 F.3d at 974–75. In that case, the Council cited provisions that did not exist during the relevant time period. *See id.* The court explained the key differences between the provision in effect back then and the ones cited by the Council:

> [B]ack in 2008, when Caring Hearts provided its services, § 409.44(c)(2)(i) entailed no subdivisions, let alone spun out 22 separate enumerated subparagraphs all the way to (H)(4) and beyond. Instead, back then § 409.44(c)(2)(i) consisted of just one paragraph that spoke not at all of documentation and said only this: "services must be considered under the accepted standards of medical practice to be a specific, safe, and effective treatment for the beneficiary's condition." Rather than requiring extensive paperwork, then, the regulation focused on whether the provider's physical therapy services were consistent with accepted contemporary standards of medical practice. And that's a condition no one disputes Caring Hearts can satisfy: nowhere does CMS's opinion suggest the doctors who prescribed the care in this case defied accepted medical standards.

Caring Hearts , 824 F.3d at 975.

Here, V.P. provides a good example. The Council states that V.P.'s physical therapy evaluation "does not provide specificity in defining the beneficiary's level of function, prior level of function, and decline." A.R. 0092. Again, as shown in *Caring Hearts* , the requirement of extensive paperwork was not set forth in the regulation until after V.P. was treated. Instead, the regulation "focused on whether the provider's physical therapy services were consistent with accepted contemporary standards of medical practice." *Caring Hearts* , 824 F.3d at 975. Similar to *Caring Hearts* , no one disputes that V.P.'s treatment was consistent with accepted contemporary standards of medical practice. Thus, since the wrong law was applied, the denial as to V.P. cannot stand. Cypress could not have known, nor reasonably have been expected to know, that its coverage for V.P. would be denied. Therefore, the coverage decision as to V.P. is **WAIVED** under 42 U.S.C. § 1395pp.

As to beneficiary D.C., the Council goes further with its improper analysis: the Council cites provisions that did not exist during the time of treatment in the coverage decision itself. This was part of the Council's conclusion as to D.C.:

> The Medicare regulations require that the patient's function be initially assessed and periodically reassessed by a qualified therapist, of the corresponding discipline for the type of therapy being provided, using a method that includes objective measurement as described in the regulations. 42 C.F.R. § 409.44(c)(2)(i)(A). The regulations require that the method used to assess a patient's function include objective measurements of function in accordance with accepted professional standards of clinical practice enabling comparison of successive measurements to determine the effectiveness of therapy goals. 42 C.F.R. § 409.44(c)(1)(iv). Skilled nurses do not carry out physical therapy assessments, in accordance with accepted professional physical therapy standards.... The Council finds that the documentation does not support Medicare coverage for this physical therapy.

A.R. 0051–0052. Of course, 42 C.F.R. § 409.44(c)(2)(i)(A) 42 C.F.R. § 409.44(c)(1)(iv) did not exist when D.C. received treatment. *See supra* 42 C.F.R. § 409.44 (2009). Again, just as in *322 *Caring Hearts* , the Council cited (and applied) provisions from a later version of 42 C.F.R. § 409.44.

On the other hand, the Council's statement that "[s]killed nurses do not carry out physical therapy assessments, in accordance with accepted professional physical therapy standards" actually applied the proper law. Thus, the Court is left to guess whether the improperly cited provisions affected the Council's analysis in any meaningful way or if the Council would have reached the same result even without applying the incorrect provisions. "[W]e may not, of course, affirm an agency by guess." *Caring Hearts* , 824 F.3d at 975. Therefore, the proper remedy as to D.C. is to **REMAND** to the Council. On remand, the Council should focus on the version of 42 C.F.R. § 409.44 that was in effect when D.C. received treatment.

Lastly, as to Ma.Wa., the Council's analysis lacks any discussion as to "whether the provider's physical therapy services were consistent with accepted contemporary standards of medical practice." *Caring Hearts* , 824 F.3d at 975. According to the record, Ma.Wa.'s physician ordered physical therapy twice per week for three weeks. A.R. 12637. In the Council's analysis of Ma.Wa., as with V.P., it again focuses on the sufficiency of the documentation generally. *See* A.R. 102 ("The physical therapy plan itself (dated May 28, 2009) is cursory and unclear."). Thus, the Council should at least include some analysis as to "whether the provider's physical therapy services were consistent with accepted contemporary standards of medical practice." *Caring Hearts* , 824 F.3d at 975. Since this analysis is missing, the proper remedy as to Ma.Wa. is to **REMAND** to the Council.

In conclusion, as to the three physical therapy denials: D.C. and Ma.Wa. are **REMANDED** to the Council and any overpayment resulting from the denial as to V.P. is **WAIVED** under 42 U.S.C. § 1395pp. We now move to the skilled nursing denials.

C. Skilled Nursing Denials

While some beneficiaries received a favorable coverage decision as to the "homebound" statute, six received unfavorable decisions as to skilled nursing. *See* beneficiaries E.C., E.G., O.H., M.M., M.N., and F.W at A.R. 000112–000114. Medicare covers home health services when they are, among other things, medically reasonable and necessary for the treatment of a beneficiary's illness or injury. 42 U.S.C. § 1395y(a)(1)(A). The MBPM elaborates that 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

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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) ; *Caring Hearts* , 824 F.3d at 975–76.

The Court must analyze two key issues: "(1) whether the Commissioner applied the proper legal standards; and (2) whether the Commissioner's decision is supported by substantial evidence on the record as a whole." *Estate of Morris v. Shalala* , 207 F.3d 744, 745 (5th Cir. 2000).

Here, as to all six skilled nursing denials, CMS's decision is supported by substantial evidence. There is ample evidence in the administrative record related to these beneficiaries on which CMS was able to base its decisions. *See e.g.* , A.R. 4838 – *323 4872 for E.C.; A.R. 7083–7127 for E.G. In addition, the proper legal standards were applied. Unlike with the "homebound" denials, Cypress does not argue that CMS applied the wrong law from an improper time period. While Cypress makes other technical coverage arguments pertaining to each beneficiary, under *Shalala* , this Court only reviews for substantial evidence and whether the law was followed. Thus, since CMS applied the proper legal standards and each decision is supported by substantial evidence in the record, the Court **AFFIRMS** the coverage denials as to skilled nursing for the following beneficiaries: E.C., E.G., O.H., M.M., M.N., and F.W. *See* A.R. 112–114.

Even though the coverage decisions are affirmed, Cypress argues these denials should be waived under 42 U.S.C. § 1395pp. Docket No. 23 at 36. As described above, the waiver provision relates to whether Cypress knew or could have reasonably been expected to know that its skilled nursing services would not have been covered.

In *Caring Hearts* , similar to the homebound and physical therapy denials, the court found the skilled nursing denials were waived. *See Caring Hearts* , 824 F.3d at 975–77. *Caring Hearts* found that the skilled nursing denials were waived because the denials were based on "want of sufficient documentation," and the skilled nursing provision in effect at the time did not demand "extensive documentation for every skilled nursing visit." *Id.* at 976–77. However, in the present case, the skilled nursing denials are of a different nature, as none of the six decisions seems to turn on sufficiency of documentation.[4] Rather, the denials were based on what services were covered under the skilled nursing provisions. Thus, since the rationale underlying the waiver of skilled nursing denials in *Caring Hearts* is not present in this case, waiver as to the skilled nursing denials in this case is **DENIED** .

4 Moreover, Cypress does not argue *Caring Hearts* should apply to the skilled nursing denials in any meaningful way, as Cypress's briefing on the skilled nursing denials is devoid of any citation to *Caring Hearts.* See Docket No. 53 at 24–33.

D. Defendant's Responsive Arguments

Defendant makes two general "waiver" arguments that apply to many of the beneficiaries. First, Defendant argues in its Cross-Motion for Summary Judgment that since Cypress specifically argues against only four individual coverage decisions in its Motion for Summary Judgment (Docket No. 23), Cypress waived any other individual coverage challenges not mentioned in Cypress's Motion. Docket No. 26 at 21. Second, Defendant argues that Cypress waived any objection to the application of the statutory provisions regarding "homebound" coverage guidelines by failing to present the issue to the Council. *Id.* at 22.

As to Defendant's first argument that any denials not briefed in Cypress's Summary Judgment motion should be affirmed, the Court ordered

supplemental briefing for the issues related to all beneficiaries to be briefed. Docket No. 49. Thus, Defendant's argument is moot.

As to Defendant's second argument, the legal argument under *Caring Hearts* is not waived merely because it was not presented to the Council. Sometimes known as issue exhaustion, this argument was discussed extensively in *Sims v. Apfel* , 530 U.S. 103, 120 S.Ct. 2080, 147 L.Ed.2d 80 (U.S. 2000). In *Sims* , the court held that, as to Social Security disability proceedings, "a judicially created issue-exhaustion requirement is inappropriate. Claimants who exhaust administrative remedies need not also exhaust issues in a request for review by the Appeals Council in order to 324 *324 preserve judicial review of those issues." *Sims* , 530 U.S. 103 at 112, 120 S.Ct. 2080. The court's rationale was essentially that the Social Security disability proceedings were not sufficiently adversarial to trigger strict issue exhaustion. *See id.* (The "analogy to judicial proceedings is at its weakest in [the area of Social Security disability proceedings]. The adversarial development of issues by the parties—the 'coming to issue'—on which that analogy depends simply does not exist.... We therefore agree with the Eighth Circuit that 'the general rule of issue exhaustion makes little sense in this particular context.' ") (internal citations omitted). The question before this Court then is whether that holding should be extended to the Medicare appeal process at issue here.

In this case, as in *Sims* , the rules of the Medicare appeal process are not sufficiently adversarial to trigger a strict issue exhaustion requirement. First, in a case like this one where CMS or its contractor appeared in the administrative proceedings as a non-party participant, the agency has stated that it considers that process to be non-adversarial. 74 Fed. Reg. 65,296, 65,316-65,318 (Dec. 9, 2009) (explaining the difference between CMS appearance as a "party" and a "non-party participant"); A.R. 001853 (CMS contractor notice of appearance as a non-party participant). In addition, as with Social Security disability cases, parties are permitted, but not required, to file briefs before the Council. *Compare Sims* , 530 U.S. at 111, 120 S.Ct. 2080 *with* 42 C.F.R. § 405.1120. Also, form DAB-101, which a party may use to request Council review, contains only four lines for the party to explain why it disagrees with the ALJ's decision. *Compare Sims* , 530 U.S. at 111–112, 120 S.Ct. 2080 *with* A.R. 000553. Lastly, this case has a slightly uncommon procedural posture, as the Council decided to review the case on its own motion after CMS recommended it do so. *See generally* 42 C.F.R. § 405.1110 ; *see also* A.R. 00459–00474. Thus, CMS acted more like an advisor than a litigant in this case, as CMS advised the Council that it should examine this case for possible review. *See* CMS's Report at A.R. 00459–00474.

Thus, given the rules of the Medicare appeal process, the Court declines to impose a strict judicially created issue-exhaustion requirement in this case.

II. Extrapolation

The lone remaining issue concerns extrapolation. Cypress argues that the Court should reverse the Council's decision as to extrapolation because the decision does not apply the correct legal standards and is not supported by substantial evidence. Docket No. 23 at 18. In response, Defendant argues that the proper legal standards were applied, and the Council's decision is supported by substantial evidence. Docket No. 26 at 15.

The major steps in statistical sampling are: (1) selecting the provider or supplier; (2) selecting the period to be reviewed; (3) defining the universe, the sampling unit, and the sampling frame; (4) designing the sampling plan and selecting the sample; (5) reviewing each of the sampling units and determining if there was an overpayment or underpayment; and (6) estimating or projecting the overpayment. Medicare Program Integrity Manual (MPIM) Ch. 8 § 8.4.1.3 (Pub. No. 100-08, Rev. 377) (2011). The "universe" consists of all Medicare claims submitted by a provider within a certain timeframe. *Id.* at § 8.4.3.2.1(A). The "sampling unit" may be defined based on the particular sample design chosen by the contractor;

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examples of sampling units include individual services, entire claims, or all claims submitted on behalf of certain Medicare beneficiaries. *Id.* at § 8.4.3.2.2. *325 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. The group of sampling units that remain following the application of the limiting criteria to the universe is referred to as the sampling frame. *Id.* at § 8.4.3.2.3.

Once the sampling frame has been created, the contractor's statisticians select a particular sample design to be used. *Id.* at § 8.4.4.1. According to the MPIM, the most common sample designs include simple random sampling, stratified sampling, systematic sampling, and cluster sampling. *Id.* at § 8.4.4.1. 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. The sampling units that are paired with the random numbers are then selected as the sample to be audited and used for extrapolation. *Id.* at § 8.4.4.2. The contractor requests medical records from the provider related to each of the units in the statistical sample, and these medical records are then reviewed by the contractor's clinical staff. The contractor's medical review staff renders a determination as to whether each unit in the sample was correctly paid, overpaid, or underpaid. *Id.* at § 8.4.6.3. 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. *Id.* at § 8.4.5.

The MPIM sets forth the following rules for probability sampling:

Regardless of the method of sample selection used, the...ZPIC... ***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:

• It 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. Although only one sample will be selected, ***each distinct sample of the set has a known probability of selection.*** It is not necessary to actually carry out the enumeration or calculate the probabilities, especially if the number of possible distinct samples is large – possibly billions. It is merely meant that one could, in theory, write down the samples, the sampling units contained therein, ***and the probabilities*** if one had unlimited time; and

• ***Each sampling unit in each distinct possible sample must have a known probability of selection.*** For statistical sampling for overpayment estimation, one of the possible samples is selected by a random process according to which each sampling unit in the target population receives its appropriate chance of selection. The selection probabilities do not have to be equal but they should all be greater than zero. In fact, some designs bring gains in efficiency by not assigning equal probabilities to all of the sampling units.

For a procedure that satisfies these bulleted properties it is possible to develop a mathematical theory for various methods of estimation based on probability sampling and to study the features of the estimation method (i.e., bias, precision, cost) although the details of the theory may be complex. If a particular probability

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> sample design is properly executed, i.e., defining the universe, the *326 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. In other words, a probability sample and its results are always 'valid.'

MPIM Ch. 8 § 8.4.2 (emphasis added).

In this case, the ZPIC was Health Integrity. According to Health Integrity's statistical sampling plan, Health Integrity purported to have created a simple random sample in this case. A.R. 001811; 001858; 001864-001865. The MPIM describes simple random sampling as follows:

> Simple random sampling involves using a random selection method to draw a fixed number of sampling units from the frame without replacement, i.e., not allowing the same sampling unit to be selected more than once. The random selection method must ensure that, given the desired sample size, each distinguishable set of sampling units has the same probability of selection as any other set – thus the method is a case of 'equal probability sampling.'

MPIM Ch. 8 § 8.4.4.1.1. The sampling unit was the claim. A.R. 001864. Health Integrity used a software routine called SURVEYSELECT created by the SAS Institute, Inc. to generate the random numbers for the claim selection process. A.R. 002128-002142. The SURVEYSELECT procedure, when used for this and similar purposes, requires a positive integer, commonly referred to as a "seed value," in order to initialize the routine to generate the random numbers. *See* A.R. 002129. In this case, Health Integrity drew its sample of claims in two steps, both of which required a separate "call" to the SURVEYSELECT routine; each such "call" resulted in a stream of random numbers. During both stages of its sample selection process, Health Integrity used the same seed value, 072610, to initialize the random number generator. *Id.* First, Health Integrity selected 50 claims from the frame to serve as the overall sample. A.R. 002130. Second, it selected and removed five claims from the sample of 50 to set aside as a "reserve" sample. *Id.* The remaining 45 claims comprised the sample that was ultimately used by Health Integrity for extrapolation. Ultimately, Health Integrity stated that it believed that 95 percent of the claims under review had been paid incorrectly and extrapolated the overpayment to $11,531,832. A.R. 001297–001301; A.R. 001811.

After filing requests for redetermination and reconsideration, Cypress filed a request for a hearing before an ALJ on the extrapolation issue. A.R. 001241–001289. The ALJ to whom the case was assigned directed Cypress and Health Integrity to submit pre-hearing case materials outlining their respective positions as to the statistical extrapolation. *Id.* at 001836. Cypress submitted a report drafted by an independent statistician, Dr. Ross Mitchell Cox, along with a sworn affidavit from a second statistician, Dr. Bruce Levin. Dr. Cox concluded that the methodology employed by Health Integrity was statistically invalid because it did not meet the requirements for probability sampling or simple random sampling set forth in Medicare program guidance. *Id.* at 000760-000789. Dr. Levin attested that he agreed with Dr. Cox's conclusions and had independently verified the accuracy of Dr. Cox's mathematical calculations. *Id.* at 000792–000795. Health Integrity also submitted a report drafted by its chief statistician, Aimee Mason. *Id.* at 000883-000902. The ALJ retained his own independent statistician, Dr. John Adams, to review the parties' respective reports and to offer an opinion as to the validity of Health Integrity's *327 sampling methodology. Dr. Adams issued a final revised report on October 11, 2015. *Id.* at 000116–000125. The ALJ issued his decision on November 30, 2015, invalidating the sampling methodology and directing the Medicare contractor to recalculate the alleged overpayment

without extrapolation. *Id.* at 000475–000554. The Council thereafter reversed the ALJ and reinstated the extrapolation. *Id.* at 00038.

The Court must again analyze two key issues: "(1) whether the Commissioner applied the proper legal standards; and (2) whether the Commissioner's decision is supported by substantial evidence on the record as a whole." *Estate of Morris v. Shalala* , 207 F.3d 744, 745 (5th Cir. 2000).

Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Richardson v. Perales* , 402 U.S. 389, 401, 91 S.Ct. 1420, 28 L.Ed.2d 842 (1971). While deferential, the substantial evidence test is not intended to constitute a "rubber stamp" for the agency decision; the Court should scrutinize the administrative record as a whole and consider whatever fairly detracts from the substantiality of the evidence supporting the decision. *Cook v. Heckler* , 750 F.2d 391, 393 (5th Cir. 1985) (quotation omitted).

Here, there is a lack of substantial evidence supporting the Council's decision. The Council based its conclusion substantially on the report of the ALJ's independent expert, Dr. Adams. *See* 000035–000038. Yet Dr. Adams's report does not constitute substantial evidence for the Council's decision; in fact, after reviewing the same evidence as the Council did, the ALJ threw out the extrapolation because he found it invalid. *See* A.R. 000547 ("After careful review of the expert reports and hearing testimony, the ALJ finds that the statistical sampling methodology was invalid.... Specifically, the ALJ finds that the sample was not a probability sample because the claim selection in each step was not conducted independently, but rather the same seed was used."). In particular, there are two main points of concern: 1) Dr. Adams's comments (and the Council's admission) that the sample was not a simple random sample; and 2) Dr. Adams's comments that since it was not a simple random sample, the sample would need a different extrapolation technique.

First, Dr. Adams concluded that this sample was not a simple random sample, even though it was Health Integrity's intention to create one. *See* A.R. 00118 ("My conclusion is that this is not a simple random sample.") The use of the same seed number created a sample which mathematically was not a simple random sample, which the Council itself does not dispute. *Id.* at 00034 ("The appellant has proven mathematically that it is not a [simple] random sample, and the Council does not dispute that.").

While this alone would not invalidate the sample under the MPIM, Dr. Adams acknowledged there were still potential consequences. *See* A.R. 000119 ("It is important to underscore that it is not essential that the sample be a simple random sample. This does have consequences for how the extrapolation should be performed."). Rather, the key issue, as Dr. Adams explained, is "whether the sample is a probability sample. If it is not a probability sample it is not valid under the guidance of the [MPIM] regardless of how benign an error this may be." A.R. 000119. Thus, to fix the problem posed by the fact that the sample is not a simple random sample, he proposed ways to "salvage the extrapolation." *Id.* at 000122. Specifically, he believed that the extrapolation might need to be more in-depth: "If we can conclude that the sample is a probability sample then it may be possible to calculate a defensible 328 *328 extrapolation. However, the extrapolation would likely require the use of somewhat more elaborate statistical techniques than those used for a simple random sample." *Id.* at 000119–000120.

Yet Defendant does not argue that any of these potential remedies suggested by Dr. Adams were, in fact, used to save the extrapolation. Instead, after the ALJ dismissed the extrapolation, the Council reversed the ALJ, deciding to uphold the extrapolation based in part on a conclusory statement from Dr. Adams: "Although no one would advocate the sampling process used by [Health Integrity], I believe I can make the argument that it produces a probability sample. Whether the hearing process allows us to go back

at this point and redo the extrapolation with a new characterization of the sample is a matter for the OMHA process to address." *Id.* at 000123.

This statement is not substantial evidence, as this type of speculative, conclusory statement does not constitute substantial evidence. *See Grogan v. Barnhart* , 399 F.3d 1257, 1261–62 (10th Cir. 2005) ("Evidence is not substantial if it is overwhelmed by other evidence in the record or constitutes mere conclusion."); *see also Amalgamated Clothing Workers of Am., El Paso Dist. Joint Bd., AFL-CIO v. N.L.R.B.* , 491 F.2d 595, 598 (5th Cir. 1974) ("This conclusory statement, unsupported by evidence in the record ... cannot be viewed as constituting substantial evidence."). Here, the statements by Dr. Adams described above suggest that the extrapolation method used was not appropriate because it was not a simple random sample; indeed, he wondered whether it was possible to go back and "redo the extrapolation." Thus, it was not appropriate for the Council to reinstate the extrapolation based on this conclusory statement.

The reason Dr. Adams made this statement relates to what he believed was the key sticking point—the meaning of the word "known" in MPIM Ch. 8 § 8.4.2:

> It comes down to the meaning of 'known' in the second PIM requirement above. A mathematical purist may read 'known' as calculable in a manner similar to the "counting" arguments in Dr. Cox's initial appendix. A more pragmatic modern interpretation would be that a properly designed simulation calculation could produce sampling probabilities that are known for all practical purposes. The PIM can be a problematic document for statistical experts. It contains some apparently quite formal statistical language while at the same time being occasionally vague. It certainly is not as prescriptive as many would like. It relies on references ... that were last revised in the 70s. These references did not anticipate the power of modern computers. My reading of the intent of the PIM is that this simulation could be an acceptable approach to calculating the sampling probabilities.

A.R. 000121.

However, as Dr. Adams himself acknowledged, each sampling unit did not have a "known" probability of selection as would be contemplated by what Dr. Adams called a "mathematical purist." A.R. 000121. Rather, Dr. Adams stated that, in theory, a computer simulation *could* figure out these probabilities. This is what leads him to the conclusion that he "believe[s] [he] can make the argument that it produces a probability sample." But, as explained below, the Court is not required to defer to the Council's interpretation of the meaning of the word "known." The Court's aim is to evaluate, under *Shalala* , whether substantial evidence exists in the record to support the Council's finding. And based on the comments from Dr. Adams in the *329 record, such as a section labeled "Other ways to 'salvage' the extrapolation," another section labeled "If we accept that the sample is a probability sample how should the extrapolation be performed?" and general comments wondering whether the Council

can go back and "redo the extrapolation," it seems clear that Dr. Adams had legitimate concerns about whether the MPIM was followed.

In sum, the core question is whether substantial evidence exists to support the Council's finding that the statistical sampling methodology was valid. Here, because the same seed number was used, each sample did not have a "known" probability of selection, which violates MPIM Ch. 8 § 8.4.2. Dr. Adams made multiple comments that suggested he was worried about this issue. *See e.g.* , A.R. 000122 ("I would be remiss if I did not mention some other logical possibilities for an extrapolation that works around the problem of the random number seeds."). Defendant does not argue that any of these remedies were actually used. Thus, the Court finds that there is a lack of substantial evidence in the record to support the Council's finding. Therefore, the Court **REVERSES** the Council's decision as to the extrapolation.

Lastly, a word about deference: the Defendant argues that the Council's interpretation of the MPIM (for example, the meaning of the word "known") deserves deference under *Skidmore v. Swift & Co.* , 323 U.S. 134, 65 S.Ct. 161, 89 L.Ed. 124 (1944). *See* Docket No. 26 at 16 and Docket No. 33 at 7. Under *Skidmore* , deference is extended on a sliding scale according to a multitude of factors, such as the thoroughness evident in the agency's consideration, the validity of the agency's reasoning, its consistency with earlier and later pronouncements, and all those factors which lend the administrative decision the power to persuade. *United States v. Mead Corp.* , 533 U.S. 218, 228, 121 S.Ct. 2164, 150 L.Ed.2d 292 (2001) ; *Skidmore* , 323 U.S. at 139–140, 65 S.Ct. 161.

Here, the factors do not weigh in favor of deference to the Council's interpretation of the MPIM. As to the thoroughness evident in the agency's consideration, as described above, this process was non-adversarial in nature. Council decisions do not carry precedential value, and they are not binding on other adjudicators within the Medicare claim appeal system. 74 Fed. Reg. 65,327 (Dec. 9, 2009). Moreover, the Council's lone citation to any case was to an unpublished decision of the Third Circuit that does not address the provisions involved here. *See* A.R. 00031 (citing *Balko & Assocs., Inc. v. Sebelius* , 555 Fed. Appx. 188 (3d Cir. 2014)). As to the validity of the Council's reasoning, its interpretation of the MPIM would essentially divest the first prong of MPIM Ch. 8 § 8.4.2 of any teeth whatsoever.[5] Lastly, as to consistency with earlier and later pronouncements, neither party cites any other Council decision that interprets § 8.4.2 in the same way the Council did here. "There is caselaw suggesting no deference is owed to an agency's interpretation where, like here, the interpretation appears for the first time in the agency's adjudication under consideration." *Employer Sols.Staffing Grp. II, L.L.C. v. Office of Chief Admin. Hearing Officer* , 833 F.3d 480, 487 n.4 (5th Cir. 2016). Thus, in sum, the *Skidmore* factors do not weigh in favor of deference, as the agency's interpretation is unpersuasive. *See Empl Sols.Staffing* , 833 F.3d at 490 (analyzing under the *Skidmore* factors and concluding that the agency provided "no persuasive interpretation"); 330 *330 *see also Tula Rubio v. Lynch* , 787 F.3d 288, 296 (5th Cir. 2015) (employing *Skidmore* analysis and finding the agency's interpretation unpersuasive "as it does not rest on thorough or valid reasoning").

5 A general principle of textual interpretation is to strive to give meaning to every word in the text. *E.g., Duncan v. Walker,* 533 U.S. 167, 174, 121 S.Ct. 2120, 150 L.Ed.2d 251 (2001).

CONCLUSION

Accordingly, the decision of the Medicare Appeals Council as to docket numbers M-16-394 and M-16-521 is:

• For the 14 Homebound Denials:

• As to the following 11 beneficiaries, any overpayment sought by Defendant because the beneficiary was allegedly not "homebound" is **WAIVED** under 42 U.S.C. § 1395pp : M.C., V.D., S.D., M.T.G., R.J., C.Y.J., W.K., J.M., P.S., Me.Wa., and M.We.

• As to the remaining three denials, the following are **REMANDED** to the Council with instructions consistent the "Analysis" section of this Order: C.J., Jr. (two separate denials) and A.M.

• For the three Physical Therapy Denials:

• Any overpayment sought by Defendant from the denial as to V.P. is **WAIVED** under 42 U.S.C. § 1395pp.

• D.C. and Ma.Wa. are **REMANDED** to the Council with instructions consistent with the "Analysis" section of this Order.

• For the six Skilled Nursing Denials:

• All are **AFFIRMED** : E.C., E.G., O.H., M.M., M.N., and F.W.

• Waiver under 42 U.S.C. § 1395pp is **DENIED** .

• For the extrapolation:

• The Council's decision is **REVERSED** .

SO ORDERED.

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