No. _____

In The
Supreme Court of the United States

PALM VALLEY HEALTH CARE, INCORPORATED,

Petitioner,

v.

ALEX M. AZAR II, Secretary, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court of Appeal for the Fifth Circuit

PETITION FOR WRIT OF CERTIORARI

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June 12, 2020

QUESTIONS PRESENTED

1. Whether an administrative process that is fraught with delay and fundamental unfairness and that clearly violates the provider's constitutional Due Process rights rendered a valid and defensible decision.

2. Whether Respondent applied an incorrect and more onerous Medicare coverage criteria for homebound status based on subsequently issued rules due to its excessive delay in adjudicating the home health denials.

3. Whether Respondent committed error in adopting a non-scientific sampling methodology and extrapolation of the overpayment to the universe of 10,699 claims.

RULE 29.6 DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of the Rule of this Court, petitioner Palm Valley Health Care Incorporated states that it has no parent corporation, and no publicly held company owns 10% or more of its stock.

LIST OF RELATED PROCEEDINGS

Pursuant to Supreme Court Rule 14.1(b)(iii), petitioner states that there are no proceedings directly related to this case in this Court.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Constitution

Statutes

Regulations

Other Authorities

PETITION FOR WRIT OF CERTIORARI

Palm Valley Health Care Incorporated respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Fifth Circuit in this case.

OPINION BELOW

The opinion of the court of appeals in this case is reported at 947 F.3d 321 and is attached at Appendix A. The district court's opinion and judgment are attached at Appendix B.

JURISDICTION

The judgment of the court of appeals was entered on January 15, 2020. On March 19, 2020, the Chief Justice extended the time within which to file a petition for a writ of certiorari to and including June 15, 2020. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254 (1).

CONSTITUTIONAL PROVISIONS AND STATUTES INVOLVED

The relevant provisions of U.S. CONST. amend. V are reproduced in the appendix to this petition (Appendix E).

The relevant provisions of the Medicare provisions of the Social Security Act, 42 U.S.C. § 1395 *et seq*., are reproduced in the appendix to this petition (Appendix F).

STATEMENT OF CASE

A. Overview

This case, although disguised as a "garden variety" judicial review of an administrative appeal of a Medicare overpayment determination, presents important issues in the oversight and regulation of America's federal Medicare program. At issue are the payments earned by providers that have delivered healthcare services to our nation's Medicare beneficiaries and the administrative process extended to them to dispute and contest the federal agency's overpayment determination. What has been described as a labyrinth that is rivaled only by the tax code is fraught with delays and fundamental unfairness. However, these are not merely obstacles to be avoided or hurdles that must be by cleared by providers, they are constitutional violations that are occurring in the murkiness of the review process that are hidden or not otherwise obvious. Moreover, they have become tactical advantages Respondent enjoys and exploits, and yet the government nonetheless asserts that health care providers have absolutely no property interest in earned payments and they are entitled to no constitutional protections. The Circuits are split on this issue. As it comes to this Court, the case presents three exceptionally important questions concerning the adjudication of a provider's overpayment liability. The first question is whether an administrative process that is fraught with delay and fundamental unfairness and violates the provider's constitutional Due Process rights renders a valid and defensible decision. The second question is whether Respondent applied an incorrect and more onerous

Medicare coverage criteria for homebound status based on subsequently issued rules due to the excessive delay in adjudicating the home health denials. The third question is whether Respondent committed error in adopting a non-scientific sampling methodology and extrapolation of the overpayment to the universe of 10,699 claims.

B. The Medicare Program

The Medicare program is a federally-funded health insurance program for the elderly and disabled that is overseen by the Secretary of U.S. Department of Health and Human Services ("Secretary") through the Centers for Medicare and Medicaid Services ("CMS"). *See* 42 U.S.C. § 1395, *et seq*. The Social Security Act ("the Act") governs and sets forth general conditions under which items and services will be covered by the Medicare program. The Secretary, through CMS, is charged with interpreting the Medicare statute and promulgating regulations, guidelines, and other instructional policies that intend to refine conditions of Medicare coverage and payment. CMS further contracts with private companies to facilitate the administration of the Medicare program. *See* 42 U.S.C. § 1395h; 42 U.S.C. § 1395u; 42 C.F.R. §§ 421.1 - 421.404.

Four Medicare Administrative Contractor(s) ("MAC") primarily determine which Medicare claims may be reimbursed and the appropriate amount of the reimbursement, *see* 42 C.F.R. §§ 421.200, 421.400-421.404. In our area of the U.S., Palmetto GBA, L.L.C. ("Palmetto") is the MAC for home health services paid by Medicare. Palmetto makes coverage and payment determinations for services,

handles beneficiary inquiries, and adjudicates appeals. Certain other "functional" contractors perform audits, investigations, and adjudicate appeals of denied claims and unfavorable payment determinations. 42 C.F.R. §§ 421.300 - 421.316. In 2006, Palmetto was awarded CMS's contract for the jurisdiction that included home health providers operating in sixteen (16) states including Texas. Around the same time, Palmetto began to issue and utilize local coverage determination(s) ("LCD") to provide explanation of specific home health benefit criteria.

C. Home Health Services

Home health services consist of medical care, such as nursing and therapy, that is provided to a patient in his or her home. Medicare covers home health services furnished to beneficiaries who meet three principal conditions. *See* 42 C.F.R. § 409.42 (1995).[1] First, the beneficiary must be "homebound." A beneficiary will be considered homebound where he or she has a condition, due to illness or injury, that restricts his or her ability to leave 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. *Id.* Second, the beneficiary must be under the care of a physician who certifies that his or her patient is eligible for the Medicare home health benefit and establishes a plan of care under which the patient will receive treatment. 42 U.S.C. § 1395f(a)(2)(C). Third, the beneficiary must be in need of a skilled service as certified by a physician, meaning, the home health services must

[1] HHS, through its contractor, audited 54 out of 10,699 claims for services delivered by Palm Valley between July 1, 2006 and January 31, 2009. The applicable regulation was promulgated in 1994, *see* 59 Fed. Reg. 65494, Dec. 20, 1994 and 60 Fed. Reg. 39122, Aug. 1, 1995; the next substantive revision to the regulation occurred in 2009, *see* 74 Fed. Reg. 58133, Nov. 10, 2009.

be medically reasonable and necessary for the treatment or diagnosis of the beneficiary's illness or injury. *See id*. at § 1395y(a)(1); 42 C.F.R. § 409.42(c)(1) (1995).

D. Statistical Sampling for Overpayment Estimation

The Health Care Financing Administration (HCFA)[2] issued an administrative ruling in 1986 that permitted it and its contractors to use statistical sampling in the context of post-payment claim audits for the purposes of overpayment estimation. *See* Health Care Financing Administration (HCFA) Ruling 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 manuals that contain the requirements for sampling and overpayment estimation. The steps to be applied or used in a sampling case can be found in the Medicare Program Integrity Manual ("MPIM"), pub. 100-08, ch. 3, § 10 (eff. 5-10-04, now at MPIM ch. 8, eff. 6-28-11).

The sampling guidance, in turn, defines statistical validity in relation to two principal concepts: (1) probability sampling and (2) the proper execution of the chosen sample design. *Id.* 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

[2] HFCA later changed names and became known as CMS.

projecting the overpayment. The "universe" consists of all Medicare claims submitted by a provider within a certain timeframe. *Id*. The "sampling unit" may be defined based on the particular sample design chosen by the contractor, such as a claim. 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*.

Once the sampling frame has been created, the contractor's staff select a particular sample design to be used. 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 of claims to be audited and used for extrapolation. *Id*.

E. Procedural History

On February 20, 2010, Respondent determined a $12,589,185.00 Medicare overpayment for services provided from July 1, 2006 to January 31, 2009. Health Integrity, LLC, a Medicare zone program integrity contractor (ZPIC) audited the provider's home health records and from a sample of 54 claims denied a total of 29 of them. The actual overpayment for the 29 claims amounted to $81,681.03. Utilizing extrapolation, however, the contractor projected the audit results for the

29 claims and determined a Medicare overpayment on the "universe" of 10,699 claims totaling $12,589,185.00. Shortly, thereafter, Palmetto GBA, a Medicare administrative contractor formally noticed the overpayment and demanded refund of the full amount of the overpayment within 30 days.

1. First Level of Administrative Process

On or about April 15, 2010, Palm Valley requested a redetermination of the overpayment determination pursuant to 42 C.F.R. § 405.940 *et seq.*, to dispute and contest the overpayment determination. ROA.15-16. Palm Valley contested the Medicare overpayment determination alleging, among other things, that the ZPIC failed to properly apply the rules and regulations in making its decision that the home health services should be denied. Additionally, Palm Valley challenged the ZPIC's sampling and extrapolation method used to project the amount of the overpayment.

A partially favorable redetermination decision was issued by Palmetto on June 17, 2010. ROA.405. Palmetto sustained all but one partial denial among the claims on appeal and confirmed the ZPIC's statistical sampling and extrapolation of the overpayment. Palmetto did not include the recalculated amount of the overpayment and Palm Valley timely filed its appeal within 180 days of the decision without knowing the amount.

2. Second Level of Administrative Process

On or about August 16, 2010, Palm Valley requested reconsideration of the overpayment determination by the Qualified Independent Contractor (QIC)

pursuant to 42 C.F.R. § 405.960 *et seq*. ROA.405. Palm Valley contended, among other things, that Palmetto did not properly apply the requirements for payment of home health services claims under 42 C.F.R. § 405.960 *et seq*. An unfavorable reconsideration decision was issued on October ROA.405. Palm Valley's challenge to the claim denials and the extrapolation method was overturned. The QIC did not include the recalculated amount of the overpayment and Palm Valley timely filed its request for ALJ hearing within 60 days of the decision without knowing the amount.

3. Third Level of Administrative Process

On or about December 11, 2010, Palm Valley requested an ALJ hearing and *de novo* review of the overpayment determination pursuant to 42 C.F.R. § 405.1000 *et seq*. ROA.406-407. Following a hearing, a partially favorable ALJ decision was issued on June 8, 2012. ROA.402-487. The ALJ reviewed all 54 claims and issued a decision denying 27 claims in the sample. *Id.* The ALJ also affirmed the ZPIC's statistical sampling and extrapolation method. The ALJ did not provide the recalculated amount of the overpayment and Palm Valley timely filed its request for Council review 60 days of the decision without knowing the amount.

Additionally, the ALJ decision, subject to 42 C.F.R. § 405.1016, was issued some one-and-a-half years after the initial request was filed by Palm Valley, far longer than the prescribed 90-calendar-day decision-making timeframe.

4. Fourth Level of Administrative Process

In early August 2012, Palm Valley requested Council review on the indeterminate overpayment determination pursuant to 42 C.F.R. § 405.1100, *et seq*. ROA.405. Subsequently on December 10, 2014, about two years later, Palm Valley was informed of the recalculated overpayment amount stemming from the ALJ decision. The Council's decision was issued on June 5, 2015. It slightly modified the decision of the ALJ, and served as the final administrative decision. ROA.626. Palm Valley timely sought judicial review in Federal District Court without knowing the amount of the overpayment following the Council's decision. Additionally, the Council's decision was issued some three years after the initial request by Palm Valley, far longer than the prescribed 90-calendar-day decision-making timeframe. *See* 42 C.F.R. § 405.1100.

5. Judicial Review

On July 31, 2015, Palm Valley timely sought review in United States District Court for the Southern District of Texas, and the trial court affirmed the decision of the Medicare Appeals Council. On appeal, the Fifth Circuit held that Respondent did not violate the provider's Due Process rights by failing to meet statutory deadlines established for administrative appeals; substantial evidence supported the agency's determination that the beneficiaries were not homebound and not eligible for Medicare coverage; and it found no error in the agency's sampling and extrapolation of the overpayment amount.

REASONS FOR GRANTING CERTIORARI

The questions presented in this case are of critical importance to healthcare providers participating the Medicare program. Because Respondent contends that providers have no property interest in earned payments for services to beneficiaries, the administrative process made available to them in adjudicating overpayment liability is not only fundamentally unfair to them, it fails to ensure that a hearing, *i.e.,* the congressionally-sanctioned step that decreases the risk of erroneous deprivation by the Medicare Act, is made available to them. Despite its recent decision in the *Family Rehabilitation* case, holding that a trial court has jurisdiction under the collateral-claim exception to the administrative exhaustion requirement over a provider's procedural due process and *ultra vires* claims because of the government's failure to make available a hearing (required by statute within 90 days) for up to five years while imposing 100% recoupment of Medicare payments,[3] the Fifth Circuit held in *Palm Valley Health Care, Inc. v. Azar*, 947 F.3d 321 (5th Cir. 2020) that Respondent's failure to adjudicate the overpayment liability in accordance with the statutory timeframe did not violate Due Process, the agency's determination that the beneficiaries were not homebound and not eligible for Medicare coverage was supported by substantial evidence, and it found no error in the agency's sampling and extrapolation.

[3] *See Family Rehabilitation, Inc. v. Azar*, 886 F.3d 496 (5th Cir. 2018).

A. Courts of Appeal have Taken Divergent Approaches on Providers' Rights in Medicare Administrative Appeals and this Court Should Grant Review to Decide Whether Due Process Violations Render the Administrative Process Fundamentally Unfair and Warrant Setting Aside Respondent's Decision to Provider Clarity in the Law

Palm Valley asserted a Due Process violation because of the extreme delay in the adjudication of the administrative appeal, and because the provider was not informed the amount of the overpayment throughout the appeal, it was forced to adjudicate each stage of the administrative process.[4] Just looking at the timeframes in Palm Valley's administrative case, it took about a year-and-a-half for Palm Valley to receive adjudication by the ALJ. ROA.405-406. It took another three years for the Council to issue the final agency decision for purposes of judicial review. ROA.625. The overpayment was first recalculated to advise Palm Valley how much of the overpayment stood to be challenged four years into the appeals. ROA.18. But even if these facts alone did not dissuade the District Court from advancing HHS's arguments, the current legal precedent requires a different consideration.

The District Court agreed with "HHS's interpretation of section 1395ff(d)(3)," that the delay experienced by Palm Valley was inconsequential because it had the option to bypass each appeal stage, or escalate, stating:

> Congress did not intend to create a due process claim for the Secretary's failure to abide by statutorily imposed deadlines, but instead provided a remedy in 42 U.S.C. § 1395ff(d)(3) in which the healthcare provider can bypass

[4] Receiving evidence on and full explanation of the method and manner of the statistical sampling and extrapolation method undertaken by the ZPIC "shortly before the ALJ hearing" did not cure the Due Process violation. ROA.613.

> each step in the administrative process and escalate the claim to the next level—ultimately allowing the provider to reach judicial review within a relatively prompt time.

ROA.614. Hence, Palm Valley takes issue with the District Court's decision that

> [Palm Valley] cannot establish a due process claim when it cannot show an absolute right to a hearing [within] a certain period of time and failed to take advantage of the alternative remedy available under the statute.

ROA.615.

Importantly, the timeframes guiding exhaustion of the administrative appeals process are set by statute. 42 U.S.C. § 1395ff(d)(1)(A). Nothing suggests that Congress intended escalation to serve as an adequate or exclusive remedy where, as here, a systemic failure causes virtually all appeals to be decided well after the statutory deadlines. *Am. Hosp. Ass'n v. Burwell*, 812 F.3d 183, 191 (D.C. Cir. 2016). As was recently held in *Family Rehab., Inc. v. Azar*, 886 F.3d 496, 503 (5th Cir. 2018), the ability to escalate an appeal to the Medicare Appeals Council does not cure the government's due process violation. *See also Adams EMS, Inc. v. Azar*, No. 4:18-cv-01443, 2018 WL 5264244 (S.D. Tex. Oct. 23, 2018).

In *Family Rehabilitation*, the Fifth Circuit noted "the timeline for escalation - combined with the massive backlogs at CMS - means that escalation would be...insufficient to avoid irreparable injury." *Family Rehab.*, 886 F.3d at 504 n.16. When a party requests review before an ALJ, the judge must "conduct and conclude a hearing." 42 U.S.C. § 1395ff(d)(1)(A). "The language requiring an ALJ to hear an appeal and render a decision within 90 days is clearly mandatory . . .

[w]hereas the statutory language allowing a party to escalate its appeal to the Appeals Council if an ALJ has not rendered a decision in 90 days is discretionary. . . . " *See Family Rehabilitation, Inc. v. Azar*, Civil Action No. 3:17-CV-3008-K, 2018 WL 3155911, at *5 (ND. Tex. June 28, 2018). Later, even if a party escalates their claim the Council may, but is not required, to conduct a hearing. *See* 42 C.F.R. § 405.1108. Instead, the Council may issue a decision based on the record without supplementation, remand the case to the ALJ, or dismiss the request. *Id*. Accordingly, "[e]scalation does not adequately protect the procedural safeguards the statute provides the appealing party." *Adams,* 2018 WL 5264244 at *10. Furthermore, the standard of review employed by the Council upon a provider's request for escalation to the Council is unclear, as the regulation sets forth a *de novo* standard of review only "[w]hen the Council reviews an ALJ's or attorney adjudicator's decision. . . . " 42 C.F.R. § 405.1100(c).

Other courts within the Fifth Circuit have followed the trial court's decision in *Family Rehabilitation* on the issue of escalation as a cure for a Due Process violation. *See Angels of Care Home Health, Inc. v. Azar*, 3:18-CV-3268-S-BK, 2019 WL 1101286, at *2 (N.D. Tex. Feb. 13, 2019); *Han Ma Eum, Inc. d/b/a Coastal Home Health v. Azar*, No. 4:18-cv-2946 (S.D. Tex. Sept. 20, 2018); *Adams*, 2018 WL 5264244 at *10; *Med-Cert Home Care, Inc. v. Azar*, No. 3:18-CV-2372-G, 2019 WL 426465, at *2 (N.D. Tex. Feb. 04, 2019). The successful argument presented by HHS on "escalation," or the bypassing of each step in the administrative process to the next level of appeal, has been unsuccessful in almost every case where HHS

cannot provide an appeal as required by timeframes mandated at 42 U.S.C. § 1395ff(d)(1)(A). Palm Valley's case should be no different.

Indeed, at the core of the government's argument is its contention that a provider does not have a property interest in earned Medicare payments on services provided to beneficiaries. Judge Kinkeade addressed the government's contention that a provider does not have a property interest in being reimbursed for the services provided to beneficiaries. He observed:

> Under Azar's view . . . a provider is supposed to dutifully administer services with the mere hope that the Medicare system would show mercy when deciding what amount to reimburse. A provider would be expected to plug along knowing that, if Medicare chose not to reimburse, it would not have any property interest upon which to claim. That position is so ludicrous as to be specious. . . . [T]he Medicare statute constitutes an 'independent source' that 'support[s] claims of entitlement' filed by Medicare providers. . . . Because the Medicare statute outlines a program for reimbursement, a provider who render services to Medicare patients has more than a unilateral expectation.

Family Rehab. v. Azar, No. 3:17-CV-3008-K, 2020 WL 230615, at *5 (N.D. Tex. Jan. 15, 2020). Defendant's obfuscation is obvious here, as it was in *Family Rehab.*, where the Court asserted that the authorities cited by the government on the issue, addressed "a property interest wholly separate from that being claimed" by the provider. *Id.*, at *6. Other District Courts throughout the Fifth Circuit have found that healthcare providers do, in fact, have a valid property interest in their earned Medicare payments. In *Med-Cert Home Health Care, LLC v. Azar*, the Honorable Judge Fish analyzed the issue and found that "precedent makes clear that [the plaintiff] has a valid property interest in receiving Medicare payments for services

rendered." 365 F. Supp. 3d 742, 751 (N.D. Tex. 2019); *see Family Rehab.*, 2020 WL 230615 at *4 (concluding a Medicare certified home health agency whose payments were being withheld had property interest in the Medicare payments for services rendered); *Adams EMS, Inc.*, 2018 WL 5264244 at *10 (finding a Medicare-certified ambulance supplier had a "property interest in received and retaining the Medicare payments it has earned"). *Cf. Noatex Corp. v. King Constr. of Houston, LLC*, 732 F.3d 479, 485 (5th Cir. 2013) (Mississippi's Stop Notice statute, which allowed subcontractors and materialmen to bind funds owed to a contractor, deprived the contractor of a significant property interest, the right to receive payment, and therefore the statute was subject to the strictures of Due Process).

Ultimately, Respondent contends that a hearing before an ALJ is not essential nor required under the Congressional scheme. In fact, the government has argued that even if a hearing is made available, the ALJ cannot require Medicare contractors that render decisions to participate. Astonished by such a contention, Judge Kinkeade noted the "government wins" essentially because it "was never going to provide due process even if there was a hearing." *Family Rehab.*, 2020 WL 230615 at *9. He concluded "[if] anything, this speaks further to the unfairness of the process available to the provider" and found that the ALJ hearing "is the congressionally-sanctioned step that decreases the risk of erroneous deprivation. *Id. But see Accident, Injury and Rehab. v. Azar*, 943 F.3d 195 (4th Cir. 2019) (Because the administrative process anticipates and accommodates potential delays in obtaining ALJ review, the due process validity of the process does not

depend on the timeliness of an ALJ hearing. Escalation ensures a timely post-deprivation review.) The Fifth Circuit and the Fourth Circuit have split on the issue.

The Fifth Circuit wrongly rejected Palm Valley's Due Process claim reasoning that in demanding an ALJ hearing, the provider has elected to endure any delay. *Palm Valley*, 947 F.3d at 326. The appellate court pointed out that Palm Valley "took advantage of every opportunity it had to undo the overpayment finding" and having done so, it cannot now make an "after-the-fact complaint about delay" - or have it "both ways." *Id.* Of course, this unfairly places blame on providers for insisting upon their Due Process rights, and it allows the government to impose upon them the heavy cost of years of delay, and the repayment of an unknown or non-final debt, for asserting their rights.[5] It also assumes that while a provider suffers delay as the price it must pay for a hearing, it nonetheless receives the process that it was due. But this overlooks very real problems that lurk in the administrative process that Judge Kinkeade noted when the government all but admitted it "was never going to provide due process even if there was a hearing." *Family Rehabilitation*, 2020 WL 230615 at *9. And that Judge Kinkeade concluded that the ALJ hearing "is the congressionally-sanctioned step that decreases the risk of erroneous deprivation." *Id.* Here, the agency conveniently "loses track of its own

[5] While a provider's appeal is pending at the ALJ level of appeal (third level of appeal), the provider must either make arrangements for the repayment of the noticed overpayment, or have the overpayment recouped from their Medicare income. *See* 42 U.S.C. § 1395ddd(f)(2) (recoupment barred through the Reconsideration Decision, which is the second level of appeal). In the Palm Valley case, however, the agency never received a recalculation of the overpayment, and therefore, the overpayment was not recouped while the case was pending at the ALJ level.

controlling regulations and applies the wrong rules," the incorrect homebound standard. Thus, the District Court erred in determining, without more, that Palm Valley's option to escalate its appeal to the Council or Federal District Court provided adequate procedural Due Process, "as it 'does not adequately protect the procedural safeguards the statute provides the appealing party.'" *Med-Cert*, 2019 WL 426465 at *8 (citing *Adams*, 2018 WL 5264244, at *10). As such, the Due Process violation Palm Valley raises resulted not only in extreme delay, but allowed for Respondent applying considerably more onerous regulations the agency adopted years later to deny the provider's claims for home health services that were entirely consistent with the law as it was at the time they were rendered.

B. Courts of Appeal have Taken Divergent Approaches on Providers' Rights in Medicare administrative appeals and this Court should Grant Review to Decide Whether Respondent Applied Incorrect and More Onerous Medicare coverage Criteria for Homebound Status Based on Subsequently Issued Rules Due to the Excessive Delay in Adjudicating the Home Health Denials to Provider Clarity in the Law

Respondent imposed a more demanding standard despite the provider's services being entirely consistent with the law at the time they were rendered. Again, but for the government's excessive delays, it would have been impossible to apply the more demanding homebound standard that has evolved over the years. The District Court upheld all claim denials in this case. ROA.598-609.

1. The District Court Reviewed the Claims on Appeal Using the Wrong Parameters for Homebound Status

As with the home health provider in *Caring Hearts Pers. Home Servs. v. Burwell*, 824 F.3d 968, 977 (10th Cir. 2016), the District Court adopted HHS's

incorrectly applied Medicare coverage criteria for homebound status in Palm Valley's case. In the instances where homebound status was discussed, the Court adopted the Council's framework to uphold the denial of claims if there was any indication the beneficiary left the home – at all. As will be detailed below, absences from the home do not negate a beneficiary's homebound status. More importantly, that was not the legal standard for homebound status in 2006 to 2009 when Palm Valley provided the services at issue. *See Texas v. United States EP*A, 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.").

The applicable homebound status guidelines in effect at the time the services were rendered provided that:

> 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.

Medicare Benefit Policy Manual ("MBPM"), ch. 7, § 30.1.1 (pub. 100-02, Rev. 1) (2003). Importantly, the Medicare Act provided that an individual shall be considered [homebound] if the individual has a condition, due to illness or injury, that restricts the ability to leave the home. *See* 42 U.S.C. § 1395f(a)(8).
The District Court's focus as to the homebound denials was whether there were any indicia from the Council that the beneficiary left home, and not whether the beneficiary held a condition, due to illness or injury, that restricted his or her

ability to leave the home. According to the language of the statute and the version of the MBPM, ch. 7, § 30.1.1 (pub. 100-02, Rev. 1) (2003) in effect at the time the services were rendered, however, the primary inquiry should have instead been whether the beneficiaries had a condition which restricted their ability to leave their homes without supportive devices or the assistance of another person, or if a condition rendered leaving the home medically contraindicated. *See Caring Hearts*, 824 F.3d at 973-74 (noting the statute's alternating use of "shall" and "should"). The statute further suggested, but did not mandate, that leaving the home required a considerable and taxing effort. 42 U.S.C. § 1395f(a)(8). When assessed in light of the appropriate standards for homebound status, Palm Valley presented sufficient documentation to support that the beneficiaries were confined to their homes under the applicable Medicare guidelines. As will be further detailed below, there was not substantial evidence to support the Council's decisions on homebound status.

2. The District Court Ignored Homebound Rules that Permit Mobility and Absences from the Home

The Medicare rules expressly provide that beneficiaries can meet the homebound requirement yet be absent from the home for "an infrequent or short duration," *see* MBPM, ch. 7, § 30.1.1 (Rev. 1, Oct. 1, 2003), and the definition explicitly allows beneficiaries to take walks around the block, go for drives, and to go to church or visit friends without negating the homebound determination of the physician and the nurse. *Id.* The beneficiary's rare outing to visit family, attend religious services, a funeral, a graduation, or to receive medical treatment cannot be used to deny eligibility for the home health benefit. *Id.* The determination that a

beneficiary is not homebound is a factual conclusion that must be reviewed by the District Court and "scrutinize[d]" through review of the administrative record. *See Cook v. Heckler*, 750 F.2d 391, 393 (5th Cir. 1985). The entirety of the District Court's decision not only cites to notes from improper beneficiary interviews conducted by the ZPIC, but also focuses on the same conclusions made by the Council that should never negate homebound status under Medicare rules.

For beneficiary F.M.2, no factor cited by the Council and echoed in the District Court decision, including the beneficiary's assistance from family and [other] paid caregivers, legally defeats the Medicare requirements for homebound status. ROA.457-458; *see* MBPM, ch. 7, § 30.1.1 (Rev. 1, Oct. 1, 2003). Beneficiary J.B.'s denial was upheld because the Council noted s/he "visited Mexico" during the two months that s/he received home health care. ROA.444-445. The District Court did not consider Palm Valley's evidence that supported homebound status and explained that the beneficiary "visited Mexico," by going to the U.S./Mexico border, which was nearby, to obtain medications during a different service period. ROA.444. M.S.2's denial by the Council seemed to satisfy the Court because "[M.S.2.] had no cane, walker or wheelchair," which is not an exclusive requirement for homebound status. ROA.473-475; ROA.633. Beneficiary F.M.1 was diagnosed by his/her physician with Alzheimer's and dementia and certified as homebound. ROA.456-457. Yet because the ZPIC interviewer noted F.M.1 to be "83 and feels great!," meaning that F.M.1 presented well that day some two years later

and F.M.1's wife denied the diagnosis, the Court felt the denial of F.M.1's claim by the Council was "clearly supported substantial evidence on the record." ROA.633.

In other instances, the Court did not "scrutinize the administrative record" on judicial review and only perpetuated the Council's selective analysis. *See Cook*, 750 F.2d at 393. For example, for beneficiary M.A., the Court upheld the Council's denial by citing medical record deficiencies and "similar problems" for 2006 service dates; but M.A.'s appeal was based on home health visits in 2008, not 2006. ROA.629-630. There cannot be substantial evidence for the denial of a claim based on consideration of records for services from two years prior.

For beneficiary M.B., the Court noted the Council was correct to deny the claim in light of the physical therapist's observation that the beneficiary "was independent or required minimal assistance." ROA.630. But homebound status should be based on evaluation of the restricted ability to leave home without supportive devices or the assistance of another person, or if a condition renders leaving home medically contraindicated, not by the physical therapist's note. *See Caring Hearts*, 824 F.3d at 973-74. Certainly, one physical therapy note in the series of medical records compiled over the two months of a home health service period cannot discount all other information and benefits.

Likewise, for beneficiary M.P., the District Court's determination of [the lack of] homebound status was not based on "scrutiny of the administrative record" but on the Council's conclusions based on a physical therapist's note which stated that therapy would be discontinued and the beneficiary could ambulate 300 feet.

ROA.631. Beneficiary M.C.'s claim denials were upheld by the District Court because she was essentially "able to participate in multiple exercises calling for balance and strength." ROA.630. The District Court did not determine whether there was substantial evidence that the beneficiary had a condition due to illness or injury that restricted him/her from leaving the home by citing the one instance focused on by the Council to deny the claim. Moreover, the beneficiary's physician ordered physical therapy for help with balance and strength which naturally involved exercises to develop the areas. ROA.462-463.

An agency decision that loses track of its own controlling regulations and applies the wrong rules in order to penalize private citizens can never stand." *Caring Hearts*, 824 F.3d at 977. Despite documented facts and clear standards for the parameters of qualifying homebound status, the District Court cited select fragments evidencing beneficiaries occasionally left the home and concluded that all beneficiaries were not homebound. As such, Palm Valley calls for reversal of the District Court's decision and a determination that Palm Valley is not liable for non-covered services and the extrapolated overpayment under sections 1879 and 1870 of the [Medicare] Act.

3. The District Court's Heavy Reliance on Unverified Interviews Conducted a Year or More After Services was Reversible Error

Unverified interviews conducted by ZPIC staff, the same contractor who initiated Palm Valley's audit and calculated the overpayment, at least a year and in some instances several years after the services in question, should have been disregarded by the District Court in the determination of beneficiary eligibility.

ROA.598-604. Moreover, the interviews were of elderly persons with memory problems, dementia, and comorbidities of the aging process, and who required assistance with simply daily tasks, such as eating and dressing on a consistent basis. *Id.* The Court assumed that because Palm Valley was under investigation, the ZPIC had a "natural defense to the possibility of unrepresentative medical records" by acquiring "direct evidence" in the form of the interviews. ROA.599. The Court concluded that interview notes from visits by ZPIC "investigators" to beneficiaries who once were certified by physicians as homebound and in need of intermittent home care were more reliable or trustworthy than the contemporaneous medical records. *Id*.

Palm Valley was selected by the ZPIC for audit not because it provided sub-standard care to un- or under-qualified Medicare beneficiaries, but because it provided a high number of continuous episodes. ROA.419. Secondly, it is widely known that aggressive government contractors, such as the ZPICs, have issued numerous inappropriate claim denials. *See*, *e.g.*, *Am. Hosp. Ass'n*, Fact Sheet: Recovery Audit Contractors at 2 (Aug. 19, 2015) (Inappropriate RAC denials have contributed significantly to a backlog of appeals at the third level of appeal—the ALJ level.), available at http://www.aha.org/content/15/fs-rac.pdf. The proof is in the high reversal rate: "[r]eversal rate when providers are able to appeal these determinations through the Medicare appeals process is also "hardly negligible." *Am. Hosp. Ass'n v. Burwell*, 812 F.3d 183, 824 (D.C. Cir. 2016). The ZPIC's interviews of Medicare beneficiaries, conducted sometimes years after services were

rendered and medical conditions had changed, should have been given minimal, if any, weight by the District Court.

For example, the Court upheld denial of beneficiary R.L.'s claim because the ZPIC noted that during an interview conducted two years after services, R.L.'s daughter stated R.L. could drive. ROA.455-456. However, at the relevant time, R.L. was recertified, in part, for home health due to allergic rhinitis and uncontrolled Parkinson's symptoms; R.L. would shake uncontrollably as was noted in the medical records, a fact not mentioned by the Council in its decision.[6] Substantial evidence sufficient to negate R.L.'s homebound status at the time of the services is not the ZPIC noting the daughter's statement two years later.

Similarly, beneficiary F.D. was upheld as not homebound because three years after services, the ZPIC noted F.D. saying s/he was "able to leave home without help to go to church, shopping, the grocery store, and visits to friends and relatives." ROA.451-452. Such infrequent activity would not negate Palm Valley's evidence that F.D. was homebound, even if accepted as true. Beneficiary P.M.'s denial was likewise upheld by the District Court's solely on the basis of the ZPIC's notes from the interview. ROA.459-450. P.M. was noted by Palm Valley's nurse to have a memory deficit one-and-a-half years prior to the ZPIC's interview, with an inability to recall events of the past 24 hours. *Id.* There was nothing in the medical record to indicate this beneficiary was not homebound and not entitled to receive home health services.

[6] Palm Valley submitted documentation that is included in the Administrative Record at 7-48, filed with the District Court at Docket No. 13.

Beneficiary R.M.'s medical records indicated s/he was forgetful and unable to leave home unassisted, yet again, the District Court analyzed the decision only from the standpoint of the ZPIC's unverified interview notes. ROA.460-461; ROA.631. The Court gave beneficiary E.P.'s interview greater weight because E.P. told the ZPIC s/he was not homebound and E.P.'s daughter "corroborated E.P.'s statements on homebound status." ROA.631. Three years earlier at the time of service, E.P.'s family indicated to Palm Valley's nurse that E.P. was very forgetful. ROA.461.

Throughout its decision, the Court referred to Council statements lifted from ZPIC interview notes as substantial evidence credible enough to warrant denial of homebound status. However, the references to unverified, untimely, and self-serving ZPIC interview note statements should not constitute substantial evidence. Further, for the beneficiaries referenced above, the District Court did not consider whether there was a condition which restricted the ability to leave home without supportive devices or the assistance of another person, or if a condition rendered leaving the home medically contraindicated. *See Caring Hearts*, 824 F.3d at 973-74. As such, the error Palm Valley raises calls for reversal of the District Court's decision.

Curiously, the Fifth Circuit concluded that Palm Valley's position that the agency applied "too demanding a standard" was raised for the first time on appeal. *Palm Valley*, 947 F.3d at 327. This overlooks that the provider argued the merits of homebound status and medical necessity in each of the home health claim denials, arguing that the claims were properly payable under the law in place when the

services were rendered. Palm Valley did this consistently throughout the four-stage administrative process. Obviously, if Palm Valley is arguing that its claims are payable upon a correct application of the homebound standard, it contends the agency is applying the wrong standard on the issue.[7] Clearly, Respondent incorrectly applied the Medicare coverage criteria for homebound status in Palm Valley's case, and, consequently, the government's decision on the merits in reviewing the denials is error.

C. Courts of Appeal have Taken Divergent Approaches on Providers' Rights in Medicare Administrative Appeals and this Court Should Grant Review to Determine if there is Error in Adopting a Non-Scientific Sampling Methodology and Extrapolation of the Overpayment to the Universe of 10,699 Claims to Provide Clarity in the Law

In *Maxmed Healthcare, Inc. v. Price*, 860 F.3d 335 (5th Cir. 2017), the Fifth Circuit discussed a viable argument to challenge the Secretary's extrapolation. Palm Valley made such an argument in this case, but it was misconstrued by the District Court as Palm Valley attacking the credentials of ZPIC's statistician, Dr. Pu, and attempting to render her calculations "meaningless." ROA.641. That was

[7] The Opinion notes that Petitioner did not press a defense that Respondent suggested, during oral argument before the Fifth Circuit, that might be available under which providers are not liable for overpayments if they "did not know, and could not reasonably be expected to know" that it was receiving overpayments. Respondent failed to inform the Court that should a provider obtain the "without fault" presumption under 42 U.S.C. § 1395gg, the agency will nevertheless find fault, or "evidence to the contrary" in terms of an overpayment, by virtue of the Medicare rules and regulations that all participating healthcare providers are predetermined to know. *See* 42 C.F.R. § 411.406. Respondent applied in this case a different Medicare homebound standard from the regulations in place at the time the services were provided. The standard Respondent applied is not applicable in this administrative appeal. So, Petitioner would never have been entitled to the defense when Respondent applies the wrong (later) version of the regulation/guideline, as it did in this case. Accordingly, Palm Valley disputed the claim denials on the merits, in accordance with the regulations and guidelines appropriate for the dates of service at issue, throughout the administrative process, and should prevail.

certainly not Palm Valley's aim nor the practical effect. Palm Valley asks the Circuit Court to consider its arguments as presented to the District Court, at ROA.514-521, which are also summarized below.

HHS created a policy and framework for extrapolating Medicare overpayments through CMS (formerly the Health Care Financing Administration) Ruling 86-1-9, 86-1-10. The steps to be applied or used in a sampling case can be found MPIM, § 3.10 (presently in § 8 of the MPIM). According to HHS, if all elements are properly executed per the MPIM, then the sampling and its results will be considered to be "valid." The District Court affirmed as much, generally reducing Palm Valley's arguments to "perceived shortcomings" and a mere difference in opinion.[8] ROA.462. Palm Valley's appeal means to challenge exactly the basis for the opinion that was given such overwhelming weight by the District Court and, indeed, most courts.

The Secretary imposes a blanket rule that validates its contractors' extrapolations no matter how flawed the calculation or scientifically invalid the method. ROA.641. HHS serves as its own expert and argues that its contractor's analysis has produced a valid statistical sample and extrapolation. In *Daubert v. Merrell Dow Pharm., Inc.*, the United States Supreme Court held that the subject of an expert's testimony must be founded upon "scientific knowledge" and that this requirement established a "standard of evidentiary reliability." 509 U.S.

[8] Palm Valley argued that the ZPIC manufactured an arbitrary error rate so as to generate the sample size, that it cherry-picked the sampling frame, and that the sampling unit was biased and not representative of the universe. ROA.520-521.

579, 590 (1993). In order to qualify as "'scientific knowledge, ". . . [the testimony/opinion] must be derived by the scientific method," which is based on "generating hypotheses and testing them to see if they can be falsified." *Daubert*, 509 U.S. at 590, 593 (quoting Green, *Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litigation: The Legacy of Agent Orange and Benedictin Litigation*, 86 Nw. U.L. Rev. 63, 645 (1992)). *Daubert* requires trial judges to perform a gatekeeping role to "ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Id.* at 589.

The Fifth Circuit was quick to point out that *Daubert*, does not apply in agency proceedings. *Palm Valley*, 947 F.3d at 329-30. The Court observed that *Daubert* provided a "gate-keeping" function aimed at preventing a jury from being tainted by unreliable evidence, and that there are no risks of unreliable evidence when there is only a judge that "will only rely on evidence the judge deems reliable." *Id*. However, this still ignores that the government's sampling and method of extrapolation is not founded upon "scientific knowledge" and because of this it lacks a "standard of evidentiary reliability." It also overlooks that in the Medicare administrative process, the government contends that a hearing before an ALJ is not essential nor required under the Congressional scheme. Indeed, as the *Palm Valley* Court noted, Petitioner essentially must choose between a hearing that purportedly provides appropriate constitutional procedural safeguards or escalation to avoid the very high-cost of extreme delay, the price for any assurance of the

requisite constitutional protections. In reality, it is a lose-lose situation for providers.

In Palm Valley's case, there was no attribution of scientific principles in the ZPIC's calculations or any analysis of whether the theory or methodology employed by the ZPIC pursuant to the MPIM was peer reviewed or is generally accepted in the relevant scientific community. *See Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1197 (11th Cir. 2002). The ZPIC's extrapolation was upheld through the ZPIC's own statistician's testimony that the ZPIC followed the steps prescribed in the MPIM for the statistical sampling and extrapolation of overpayment. ROA.641. In allowing extrapolations so long as the steps outlined in the MPIM are followed, the District Court allowed for a non-scientific interpretation of sampling methodologies outside the range of accepted statistical concepts and principles to govern overpayment determinations. While the Legislature may have permitted statistical sampling to extrapolate Medicare overpayments, *see* 42 U.S.C. § 1395ddd(f), the Secretary created a set of statistical rules to quickly and cheaply assess large overpayments against healthcare providers. Not coincidentally, the Secretary also afforded his agency the added benefit of a "presumption of validity" to the statistical sampling and extrapolation performed by contractors.

Palm Valley asserts that statistical sampling and extrapolation must be based on competent scientific evidence, such that the methodology to be employed appropriately takes into account the variables in the claims and uses "a sample of sufficient size so as to permit a finding that there is a sufficient level of confidence

that the results obtained reflect results that would be obtained from trials of the whole." *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 1020 (1984). (citing Michael J. Saks & Peter David Blanck, *Justice Improved: The Unrecognized Benefits of Aggregation and Sampling in Mass Torts*, 44 Stan. L. Rev. 815 (1992)). The Legislature did not permit extrapolation based on unreliable, unscientific statistical principles that generate questionable overpayment liabilities. It follows that establishment of the MPIM's unscientific, unreliable "statistical" method as applied by contractors is outside the range of a permissible interpretation of 42 U.S.C. § 1395ddd(f). *Chevron*, 467 U.S. at 1020-1021.

In finding no error in the extrapolation, the Fifth Circuit stated that requiring a more precise methodology "ignores real world constraints imposed by conflicting demands on limited public funds." *Palm Valley*, 947 F.3d at 30. It acknowledged that the extrapolation methodology may be imperfect, but the Court asserted it is the product of a "complex balance of interests." *Id.* However, to be fair to providers, especially at such high stakes, statistical sampling and the methodology of extrapolation should not be based on unreliable, unscientific statistical principles that generate questionable overpayment liabilities. Clearly, this Court should grant review to decide whether respondent committed error in extrapolating the overpayment to the universe of 10,699 Claims.

D. Courts of Appeal have Taken Divergent Approaches on Providers' Rights in Medicare Administrative Appeals and the Questions Presented are Exceptionally Important and Warrant Review Due to Their Broader Medicare Implications and Their Impact on Providers Throughout the United States

Above their immediate implications, this case raises issues that warrant's the Court's attention for their broader implications and practical importance in Medicare appeals. Several years back, the Court issued its decision in *Illinois Council* where it held that § 405(h) demanded "channeling" of virtually all legal attacks through the agency, which assures the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes, but noted "this assurance comes at a price, namely, occasional individual, delay-related hardship." *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000). This analysis did not address what Judge Kinkeade identified as "the unfairness of the process available to the provider," however. The Fifth Circuit, and the Tenth Circuit in *Caring Hearts*, have taken divergent approaches to providers' rights in Medicare administrative appeals, and the Fifth Circuit and the Fourth Circuit courts disagree that the procedural delay violates the providers due process rights. Thus, this case is an ideal vehicle for considering the problems underlying the Medicare administrative process, which the Courts demand providers exhaust, but where Respondent seeks to withhold from them or otherwise insists that they forgo the ALJ hearing that has been found to be "the congressionally-sanctioned step that decreases the risk of erroneous deprivation." Moreover, the case is critically important to all providers in the Medicare program that are compelled to "channel"

such appeals – and at a heavy cost to them – when the appellate Court fails to heed warnings of fundamental unfairness. *See Family Rehab.*, 2020 WL 230615 at *9. Here, the Fifth Circuit excused Respondent violation of Petitioner's Due Process rights, and it permitted the government to apply the wrong homebound status standard, a result that could not occur but for the excessive delays, which led to the agency losing "track of its own controlling regulation and [applying] the wrong rules. . . . " The injury is further compounded by CMS's use of its own guidelines and rules for the extrapolation of an overpayment that does not follow industry standards. Clearly, this Court's review is unquestionably warranted.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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