**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF KANSAS**

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| **CARING HEARTS PERSONAL HOME SERVICES, INC.,** | ) | |
| **Plaintiff,** | ) | |
| **v.** | ) | |
| | ) | **Case No. 12-2700-CM** |
| **KATHLEEN SEBELIUS, Secretary of the United States Department of Health and Human Services,** | ) | |
| **Defendant.** | ) | |

**MEMORANDUM AND ORDER**

Plaintiff filed this action under 42 U.S.C. §§ 405(g) and 1395ff(b)(1) seeking judicial review of the final decision of Kathleen Sebelius, Secretary of the United States Department of Health and Human Services ("Secretary"), which denied Medicare coverage for home health services for twenty-two Medicare beneficiaries under Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 et seq., ("Medicare Act").

## I. Medicare Overview

"Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 et seq. (2006), establishes the federally funded health insurance program for the aged and disabled, commonly known as Medicare." *Via Christi Reg'l Med. Ctr., Inc. v. Leavitt*, 509 F.3d 1259, 1261 (10th Cir. 2007). The Secretary utilizes the Centers for Medicare and Medicaid Services ("CMS"), a division of the United States Department of Health and Human Services ("HHS") to administer the program. Under Medicare Part A, payment is made for covered services administered by hospitals and other institutional providers

such as home health agencies. 42 U.S.C. §§ 1395c–1385i-5. Medicare Part B pays for covered "medical and other services" and is a voluntary insurance program. 42 U.S.C. §§ 1395j–1395w-5.

For services to be covered, the beneficiary must (1) be homebound and in need or needed skilled nursing care, physical or speech therapy, or in some cases occupational therapy; (2) be receiving services under a plan of care created by a physician who periodically reviews the plan; (3) be under a physician's care; and (4) in cases certified after January 1, 2010, meet face-to-face with the physician or other medical professional prior to certification. *Id.* §§ 1395f(a)(2)(C), 1395n(a)(2)(A), 1395x(m); 42 C.F.R. §§ 409.42–409.43, 424.22. Additionally, only services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" are eligible for coverage. 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 411.15(k)(1).

A provider may challenge a coverage or reimbursement decision by utilizing the following levels of review:

- The Medicare Administrative Contractor ("MAC") issues an "initial determination" notice informing the provider whether services are covered and, if not, the amount owed. 42 U.S.C. § 1395ff(a)(1); 42 C.F.R. § 405.920.
- The provider may request a "redetermination" from the same MAC. 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. § 405.940.
- The provider may seek "reconsideration" from a Qualified Independent Contractor ("QIC"). 42 U.S.C. § 1395ff(b)(1)(A), (c); 42 C.F.R. § 405.960.
- The next step is to request a hearing before an Administrative Law Judge ("ALJ"). 42 U.S.C. § 13955(b)(1)(A), (E), (d)(1); 42 C.F.R. § 405.1002.

- The Medicare Appeals Council ("Council") reviews ALJ decisions. 42 U.S.C. § 1395ff(d)(2); 42 C.F.R. § 405.1100.
- The provider may then seek judicial review. 42 U.S.C. § 405(g) (incorporated into the Medicare statute by 42 U.S.C. § 1395ff(b)(1)(A)); 42 C.F.R. § 405.1136.

## II. Factual and Procedural Background

Plaintiff is a home health services provider. In June 2010, a Medicare Program Safeguard Contractor ("PSC")[1] notified plaintiff of its intent to reopen and review plaintiff's claims for services between January 1, 2008, and January 31, 2009. From a sample of thirty claims, the PSC determined that the services provided in twenty-four claims failed to meet Medicare coverage requirements. The PSC determined that plaintiff had been overpaid $63,153.39 for the twenty-four claims. An additional overpayment amount of $792,490.12 was calculated by extrapolation, resulting in a total overpayment amount of $855,643.51. Plaintiff then requested a redetermination of the twenty-four claims. In its redetermination, the MAC issued a fully favorable decision on one of the claims and issued partially favorable or entirely unfavorable decisions on the other twenty-three claims. The MAC determined a revised overpayment amount of $814,245.39 based on the redetermination.

Plaintiff then sought reconsideration of the twenty-three denied claims. The QIC affirmed the denials of the twenty-three claims and also affirmed the statistical sampling and extrapolation methodology utilized by the PSC in reviewing the claims. Plaintiff further appealed the decision, requesting an ALJ hearing. The hearing took place on April 21, 2011, before ALJ Wendy A. Weber. In her June 2, 2011 decision, the ALJ held that some of the home health services provided in eight claims should be covered. The ALJ denied coverage for all of the home health services provided in the remaining fifteen claims. The ALJ also affirmed the statistical sampling and extrapolation

[1] Under the Medicare Integrity Program, contractors may audit claims to ensure compliance with the Act. 42 U.S.C. § 1395ddd; 42 C.F.R. § 421.304. The PSC may reopen claims selected for review. 42 C.F.R. § 403.980.

methodologies. Further, the ALJ denied plaintiff's claim that it was not financially liable for the noncovered services.

At the final level of agency review, plaintiff requested review from the Council. The Council issued a decision on August 29, 2012, finding that all home health services should be covered for one claim, allowing partial coverage for four claims, and denying coverage for the remaining eighteen claims. The Council also affirmed the statistical sampling and extrapolation methodology, as well as the ALJ's rejection of plaintiff's argument that it was not financially liable for noncovered services. As a result, the Council's decision—as well as the portions of the ALJ's decision the Council upheld—represent the final decision of the Secretary.

## III. Legal Standard

Under 42 U.S.C. § 405(g) (incorporated into the Medicare statute by 42 U.S.C. § 1395ff(b)(1)(A)), this court applies a two-pronged review to the Secretary's decision. This review determines (1) whether the Secretary's decision is supported by substantial evidence in the record as a whole, and (2) whether the Secretary applied the correct legal standards. *Lax v. Astrue*, 489 F.3d 1080, 1084 (10th Cir. 2007) (citation omitted). '"Substantial evidence is more than a mere scintilla and is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion."' *Hunter v. Astrue*, 321 F. App'x 789, 792 (10th Cir. 2009) (quoting *Flaherty v. Astrue*, 515 F.3d 1067, 1070 (10th Cir. 2007)). Although the court must give deference to the Secretary's findings of fact, the same is not true for legal findings. *Exec. Dir. of Office of Vt. Health Access v. Sebelius*, 698 F. Supp. 2d 436, 439 (D. Vt. 2010) (citing 42 U.S.C. § 405(g)).

In its analysis, the court may not reweigh the evidence or substitute its judgment for that of the Secretary. *See White v. Massanari*, 271 F.3d 1256, 1257 (10th Cir. 2001) (citing *Casias v. Sec'y of Health & Human Servs.*, 933 F.2d 799, 800 (10th Cir. 1991)). On the other hand, the court must

examine the entire record—including any evidence that may detract from the Secretary's decision. *Jaramillo v. Massanari*, 21 F. App'x 792, 794 (10th Cir. 2001) (citing *Glenn v. Shalala*, 21 F.3d 983, 984 (10th Cir. 1994)). Further, the court gives broad deference to the Secretary's interpretation of its own regulations. *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994) (noting that broad deference is warranted when the regulation covers "a complex and highly technical regulatory program") (quotation omitted).

Review of the Secretary's decision is also governed by the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701 et seq. The APA allows a court to set aside an agency decision only if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "unsupported by substantial evidence in a case . . . reviewed on the record of an agency hearing provided by statute." 5 U.S.C. § 706(2)(A), (E).

## IV. Discussion

Plaintiff argues that the Secretary erred in three different ways: (1) the Secretary failed to apply the statutory requirements in determining whether beneficiaries were homebound; (2) the Secretary failed to apply statutory criteria in determining whether home health services were reasonable and necessary; and (3) the Secretary incorrectly determined that plaintiff is not entitled to payment under the Doctrine of Waiver of Liability and that plaintiff is not a provider without fault. Each of plaintiff's arguments is addressed in turn.[2]

### A. The Secretary's Decision Finding that Coverage Was Inappropriate for Nine Beneficiaries Who Were Not Confined to the Home is Supported by Substantial Evidence[3]

[2] In addition, plaintiff's complaint challenged the determinations as to patients M.M. and W.H. However, plaintiff's brief did not include argument related to these patients, so the court does not address them here.

[3] The court does not address Patient #11-L.D. in this section. Plaintiff argued that the Secretary denied coverage to this beneficiary based on his homebound status. However, the court finds the Secretary's denial was based on a finding that the services were not "reasonable and necessary" and thus discusses this patient under that section.

One requirement for reimbursement of home health services is that the beneficiary is "confined to his home." 42 U.S.C. § 1395f(a)(1)(C); 42 C.F.R. § 409.42. A beneficiary qualifies as "confined to the home" if he or she:

> 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 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) (language following paragraph (8)). In addition, absences that are "infrequent or of relatively short duration," including attending a religious service, will not prevent a beneficiary from being considered "confined to the home." *Id.*

In determining whether a beneficiary was homebound, plaintiff argues that the Secretary used a two-part test. First, plaintiff claims that the Secretary determined whether the beneficiary has a condition such that trips outside the home (1) require assistance of another individual or the aid of a supportive device, or (2) are medically contraindicated. Second, upon determining that either one of the first elements is met, plaintiff contends that the Secretary then analyzed whether outings (1) require a considerable and taxing effort, and (2) are infrequent, of a short duration, or are taken to receive medical treatment. If a beneficiary did not meet both elements of the second prong, plaintiff contends that the Secretary then concluded that the beneficiary is not confined to the home.

Plaintiff argues that the Secretary incorrectly applied the test. According to plaintiff, a beneficiary must be considered homebound if one of two criteria is met: (1) he or she has a condition that restricts the ability to leave home without the assistance of another individual or the aid of a supportive device, or (2) he or she has a condition that would make leaving home medically contraindicated. Plaintiff argues that if a beneficiary needs aid from another person or a supportive

device to leave the home, then there is a presumption that there is a normal inability to leave the home and that doing so requires a considerable and taxing effort. Further, plaintiff argues that the presumption should apply unless there is some evidence to show that (1) the patient leaves the home frequently, for long durations, or (2) that leaving does not require a considerable and taxing effort. Essentially, plaintiff argues that the first sentence of 42 U.S.C. § 1395f(a) should be read separately from the second sentence. In its initial brief, plaintiff appears to argue that the use of a supportive device alone should qualify one as homebound, whether or not leaving home requires a considerable and taxing effort. In its reply brief, plaintiff changes its argument slightly, arguing that it is not necessarily the "use" of an assistive device, but whether one "needs" an assistive device that is important.

This court disagrees with plaintiff. Faced with the same issue, the district court in *Labossiere v. Secretary of Health & Human Services* found that:

> [r]ead in conjunction, the second sentence clarifies the first to require something more than the need of assistance to be considered homebound. This construction provides ample flexibility so as not to require a claimant to be "bedridden" to be entitled to home health benefits. However, it does not expand homebound status to include anyone who makes regular use of a cane. We believe this reading of the statute is in accordance with the "whole law, and to its objects and policy."

No. 90-150, 1991 WL 531922, at*5 (D. Vt. July 24, 1991) (quoting *Phillbrook v. Glodgett*, 421 U.S. 707, 713 (1975)); *Apollo Med., Inc. v. Sebelius*, No. 4:09CV1380JCH/MLM, 2010 WL 2132648, at *10 (E.D. Mo. April 23, 2010) (finding that "homebound status is not established merely because a beneficiary 'makes regular use of a cane'") (quoting *Labossiere*, 1991 WL 531922, at *5).

The court also disagrees with plaintiff's argument regarding the "use" versus "need" of an assistive device. As defendant pointed out, the use of an assistive device (even when it is "needed" by the beneficiary) can sometimes allow a person to leave the home with minimal

effort. Thus, use or need of an assistive device does not necessarily mean that leaving the home requires a considerable and taxing effort. Further, as described below, the court finds that the Secretary properly analyzed whether each beneficiary was able to ambulate, transfer, complete daily activities, and drive or ride in a vehicle.

The Secretary's application of the homebound test is consistent with the *Labossiere* court's finding. The Secretary properly read both sentences together and, finding that one of the first elements was met, then looked to whether leaving the home required a considerable and taxing effort, even if the beneficiary required some sort of assistance to leave the home. Further, plaintiff's reliance on *Quality Home Health Services, Inc.*, a MAC decision, is misplaced. (*See* R. at 10–13.) *Quality Home* did not hold that the use of a supportive device alone was enough to be considered confined to the home. Instead, the decision expressly stated the requirement that a beneficiary maintain "a 'normal inability' to leave home without considerable and taxing effort." (*Id.* at 432.) Finding that the Secretary applied the correct legal standard, the court now reviews whether substantial evidence supports the Secretary's decision regarding whether each beneficiary was homebound.

**Patient #3-V.M.**

As to this patient, the Council found that the ALJ correctly determined that V.M. was not confined to the home. The Council acknowledged the evidence that V.M. uses an assistive device and is legally blind. Although plaintiff pointed to two nursing notes to establish that V.M. experienced tremors, dizziness, diminished respiratory status, and weakness, the Council noted that "these notes simply contain a checked box for these indications and provide no further support for these conditions or offer any indication of compounding factors." (*Id.* at 15.) The Council then determined that the documentation as a whole must support the assertion that V.M. was unable to leave the home

unassisted or that doing so would require a considerable and taxing effort. The Council found that the record evidence did not support that conclusion.

Plaintiff argues that V.M.'s use of a cane and walker mandates a finding that V.M. is homebound, and that the Secretary was required to analyze whether V.M.'s absences from the home were infrequent or of relatively short duration. But as discussed above, the Secretary is not required to reach this analysis if she determines that leaving the home does not require a considerable and taxing effort. The Council properly analyzed the evidence and determined that the record did not support a finding that leaving the home required a considerable and taxing effort. The Secretary's decision is supported by substantial evidence, and the court will not disturb the Secretary's findings. *See White*, 271 F.3d at 1257 (citation omitted).

**Patient #7-C.L.**

The Council affirmed the ALJ's finding that patient C.L. was not homebound, finding no evidence of a normal inability for C.L. to leave the home. The ALJ pointed to evidence that the beneficiary "was able to transfer with assistance from a device, she was able to walk alone with the use of a device, was able to independently go to and from the toilet, and was able to ride in a car." (R. at 114–15.) Further, the ALJ found that there was no diagnosis to support the beneficiary's reported dyspnea, and that even if C.L. had dyspnea on exertion, this would not necessarily mean that leaving the home requires a considerable and taxing effort. Plaintiff again argues that C.L's use of a walker automatically means she is homebound, but this is not the case. The Secretary's decision is supported by substantial evidence and is affirmed.

**Patient #8-R.S.**

The Council also affirmed the ALJ's decision that patient R.S. was not homebound, citing a lack of documentation in the record establishing that leaving home required a considerable and taxing

effort. The ALJ cited evidence that the beneficiary "was able to transfer with assistance from a device, walk alone with use of a device, independently go to and from toilet, and ride in a car." (*Id.* at 115.) The ALJ explained that the "[u]se of an assistive device and shortness of breath do not, standing alone, confirm that [R.S.] could not leave home, or that leaving home would require considerable or taxing effort." (*Id*.) Further, the Council noted that although the boxes on nursing notes were checked for endurance, impaired gait, and impaired balance, the checked boxes were not enough to establish homebound status. (*Id.* at 15–16.) The Council also found that a note indicating R.S. experienced shortness of breath and had fallen in his apartment complex—drafted some two years after the dates of service—was entitled to little weight because it was not written contemporaneously with the service dates. (*Id*. at 16.) Finally, the Council reasonably determined that the fact that R.S. fell after service did not support a finding that he was homebound. Again, substantial evidence supports the Secretary's decision, and it should be upheld.

**Patient #9-D.S.**

The Council affirmed the ALJ's decision that insufficient evidence existed to find D.S. was confined to the home. The ALJ found that the evidence did not show a normal inability for D.S. to leave her home. Specifically, the ALJ focused on an Outcome and Assessment Information Set ("OASIS") report that D.S. "was able to transfer with an assistive device, able to walk alone with a device, and able to ride in a car." (*Id.* at116.) The ALJ also pointed to a physical therapy evaluation, which stated that D.S. "could transfer independently with no assistive devices" and physical therapy notes stating that D.S. "was able to ambulate alone with a device for 200 feet." (*Id*.) Contrary to plaintiff's assertion, D.S.'s use of a walker does not automatically render her homebound, and no analysis of the frequency or duration of the beneficiary's trips outside the home is required. The Secretary's decision is supported by substantial evidence and is affirmed.

**Patient #10-L.Sm.**

Similarly, the Council upheld the ALJ's determination that there was insufficient evidence to conclude that patient L.Sm. was homebound, as the evidence failed to show a normal inability for the beneficiary to leave home. The ALJ acknowledged evidence that the beneficiary experienced "shortness of breath walking less than 20 feet, 'lived' in a wheelchair, and weighed 352 pounds"; however, the ALJ noted that these findings were contradicted by the OASIS report. (*Id*. at 117.) The report contained evidence that L.Sm. "was able to transfer with an assistive device, walk alone with a device, and ride in a car." (*Id*.) Considering these facts, the ALJ found the evidence did not establish that leaving the home required a considerable and taxing effort. The ALJ gave more weight to the evidence contained in the OASIS report, and the court will not disturb this opinion. *See Cowan v. Astrue*, 552 F.3d 1182, 1185 (10th Cir. 2008) (quotation omitted) ("We may not displace the agency's choice between two fairly conflicting views, even though the court would justifiably have made a different choice had the matter been before it de novo."). The Secretary's finding is supported by substantial evidence and should be upheld.

**Patient # 13-J.G.**

The ALJ's determination that J.G. was not homebound was also upheld by the Council. The ALJ found that the evidence did not show a normal inability for J.G. to leave the home. Despite evidence that J.G. required the use of a cane and was at high risk for falls, the ALJ focused on the OASIS report's findings to support her decision. The OASIS report stated that J.G. "only required minimal assistance with transfers, was able to walk on her own with no assistance, and was able to independently drive a car." (R. at 120.) That J.G. was able to drive herself to a doctor's appointment—although the ALJ acknowledged this was not alone enough to prevent J.G. from being homebound—also factored into the ALJ's analysis. Based on these findings, the ALJ concluded that

the evidence "overwhelmingly suggests" that leaving the home did not require a considerable and taxing effort. (*Id.*) There is substantial evidence to support the Secretary's conclusion, and the court affirms.

**Patient #14-O.M.**

The ALJ found there was insufficient evidence to determine patient O.M. was homebound, and the Council affirmed. The ALJ acknowledged plaintiff's argument that O.M.'s impaired vision, dementia, shortness of breath when walking twenty feet, and use of an assistive device rendered him homebound. However, the ALJ found that the evidence did not support this conclusion, citing the fact that "[t]he Plan of Care did not list shortness of breath or vision impairment as functional limitations" and that O.M. "was up as tolerated with no assistive device." (*Id*. at 121.) Further, the ALJ cited evidence that O.M. could "ambulate independently, ride in a car, and did not have shortness of breath to the extent that [O.M.] was unable to leave home without considerable or taxing effort." (*Id*.) Plaintiff argues that the ALJ did not consider OASIS report evidence that O.M. requires an assistive device to walk alone and is short of breath when walking distances less than twenty feet, but the ALJ mentioned these facts in her decision. The court will not disturb the ALJ's reliance on evidence indicating that O.M. should not be considered to be homebound. *See Cowan*, 552 F.3d at 1185 (quotation omitted). The Secretary's decision is supported by substantial evidence and the court affirms it.

**Patient #15-O.R.**

The Council also upheld the ALJ's decision that patient O.R. was not homebound, as the evidence did not demonstrate a normal inability for O.R. to leave the home or that leaving the home would require considerable or taxing effort. Plaintiff argues that, after finding that O.R. was "mentally retarded, had hypertension," had hearing problems, was obese and a heavy smoker, and had other

problems, the ALJ should have found that O.R. fell under the catchall category of having a condition that is medically contraindicated. (R. at 121.)

However, this argument fails for the same reasons as plaintiff's argument that use of an assistive device alone automatically qualifies one as homebound. The ALJ must still consider whether the condition results in a normal inability to leave the home or renders the beneficiary unable to leave the home without considerable and taxing effort. The ALJ did just this, finding that the evidence that O.R. could "ambulate independently, ride in a car, and transfer with minimal assistance" supported this finding. (*Id.* at 122.) The ALJ acknowledged O.R.'s other conditions, but noted that no behavior problems were reported or observed, and that no psychiatric nursing services were ordered. The Secretary's decision was based on substantial evidence and the court will not disturb it.

**Patient #16-C.R.**

The ALJ's decision that C.R. was not homebound was upheld by the Council. The ALJ noted that, although the evidence indicated C.R. required use of a walker and had shortness of breath on minimal exertion, the OASIS report stated that C.R. had only "slight mobility limitations." (*Id.*) The ALJ cited additional evidence that C.R. "required only minimal assistance with transfers, was able to wheel herself in a wheelchair, and able to ride in a car." (*Id.*) Plaintiff is correct that the ALJ unnecessarily focused on the conflict between the reports that C.R. needed a wheelchair versus a walker. Regardless, the ALJ cited substantial evidence to support the decision that C.R. is not homebound. Plaintiff is incorrect that C.R.'s use of an assistive device—whether it be a walker or a wheelchair—mandates a finding that C.R. is homebound. Plaintiff again ignores the second sentence of the statute, which states that "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). The Secretary properly applied the test and the decision was supported by substantial evidence. The court affirms the decision.

After reviewing the record for each of these patients, the court finds that the Secretary's decision was supported by substantial evidence and that the Secretary properly determined the beneficiaries were not homebound. Accordingly, the court affirms this portion of the Secretary's decision.

**B. The Secretary's Decision that the Skilled Nursing and Physical Therapy Services Administered to Eleven Beneficiaries Were Not Reasonable and Necessary is Supported by Substantial Evidence**

As stated above, only services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" are eligible for coverage. 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 411.15(k)(1). The Act does not define "reasonable and necessary." Instead, "Congress has vested final authority in the Secretary to determine what items or services are 'reasonable and necessary.'" *Garcia v. Sebelius*, No. CV 10-8820 PA (RZx), 2011 WL 5434426, at *1 (C.D. Cal. Nov. 8, 2011) (citing 42 U.S.C. § 1395ff(a); *Heckler v. Ringer*, 466 U.S. 602, 617 (1984)).

Plaintiff's case involves claims for physical therapy service and skilled nursing services, including observation and assessment of a patient's changing condition and patient education services. Under the regulations in effect during the time period at issue, physical therapy services must be generally regarded under acceptable medical standards to be a "specific, safe, and effective treatment" for the patient's condition and must be of a certain level of complexity such that a qualified physical therapist or other qualified professional must perform the services. 42 C.F.R. § 409.44(c)(2)(i)–(ii) (1994–2010). In addition, the physical therapy services must comport with one of the following criteria: (1) "[t]here 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"; (2) "the services must be necessary to establish a safe and effective maintenance program required in connection with a specific disease"; or (3) "the skills of a therapist must be necessary to perform a safe and effective maintenance program." *Id.* § 409.44(c)(2)(iii)(1994–2010). Finally, "the amount, frequency, and duration of the services must be reasonable and necessary." *Id.*. § 409.44(c)(2)(iv).

Skilled nursing services are those services that must be performed by a registered nurse or a practical or vocational nurse and meet certain Medicare regulation requirements. *Id.* § 409.44(b)(1). "[S]killed nursing services must be reasonable and necessary for the treatment of the illness or injury." *Id.* § 409.44(b)(3). Reasonable and necessary skilled nursing services "must be consistent with the nature and severity of the beneficiary's illness or injury, his or her particular medical needs, and accepted standards of medical and nursing practice." *Id.* § 409.44(b)(3)(i). This determination must consider the context of the beneficiary's condition and must be "based solely upon the beneficiary's unique condition and individual needs, without regard to whether the illness or injury is acute, chronic, terminal, or expected to last a long time." *Id.* § 409.44(b)(3)(ii)–(iii).

Plaintiff argues that the Secretary's decision was based on hindsight and a presumption of stability, citing the case of *Anderson v. Sebelius*, No. 5:09-cv-16, 2010 WL 4273238 (D. Vt. Oct. 25, 2010). Plaintiff is correct that the services must "be viewed from the perspective of the condition of the patient when the services were ordered." Medicare Benefit Policy Manual ("MBPM") CMS Pub. 100-02, Ch. 7, § 40.1.1 (http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS012673.html). It is also true that "[s]killed care may, depending on the unique condition of the patient, continue to be necessary for patients whose condition is stable." *Id*. Observation and assessment of a beneficiary's changing condition is reasonable and necessary if

skilled personnel are needed to analyze the need for additional treatment until the beneficiary's condition is stabilized. 42 C.F.R. § 409.33(a)(2)(i). The beneficiary's home health record must contain documentation showing "there is a reasonable potential for a future complication or acute episode" and include indications such as "abnormal/fluctuating vital signs, weight changes, edema, symptoms of drug toxicity, abnormal/fluctuating lab values, and respiratory changes on auscultation." MBPM CMS Pub. 100-02 Ch. 7, § 40.1.2.1. But where these signs and symptoms are "part of a longstanding pattern of the patient's condition which has not previously required a change in the prescribed treatment," the services are not reasonable and necessary. *Id.*

Further, patient education services can qualify as skilled services if a skilled professional is necessary to teach the patient how to manage a treatment regimen. 42 C.F.R. § 409.33(a)(3). If the patient, family, or caregiver is unable to learn the treatment after a reasonable time, however, the services are no longer reasonable and necessary. *Id.* § 409.42(c)(1)(ii). Reteaching is appropriate in circumstances were the procedure changes or the patient's condition is different, or where the patient or caregiver is deficient in performing the treatment. *See* MBMP CMS Pub. 100-02, Ch. 7, § 40.1.2.3.

After reviewing the record and the Secretary's decision, the court finds that the Secretary employed a forward-looking perspective and considered the beneficiary's condition at the time services were ordered. The Secretary also considered the lack of complications or alteration in the patients' conditions during the treatment period. And the Secretary correctly found many of the services were not reasonable and necessary because of a lack of documentation of the patient's prior level of functioning. The Secretary's decision regarding plaintiff's argument—that the approval or denial of certain visits within a sixty-day episode is inconsistent with the home health payment structure—is also supported by substantial evidence. The court agrees that the contractor can

determine the appropriate payment amount for approved services. The court examines the Secretary's decision as to each patient's treatment below.

**Patient #1-C.P**

The Council affirmed the ALJ's decision that physical therapy services were not covered. The Council pointed to the absence of evidence in the record showing an expectation that C.P.'s condition would improve materially in a reasonable amount of time. 42 C.F.R. § 409.44(c)(2)(iii). The Court agrees with the Council and the ALJ's determination that the lack of evidence showing quantitative or objective measurements of C.P.'s prior level of functioning precludes a finding that the services were necessary to reach progress goals within a reasonable amount of time. The Council's decision that the services were not reasonable and necessary is supported by substantial evidence, and the court affirms it.

**Patient #2-L.St.**

The Council upheld the ALJ's decision denying coverage for skilled nursing and physical therapy services. The ALJ determined that patient education on medication compliance was not necessary for L.St., as there was no evidence that the medications were newly prescribed or for a new condition. The ALJ also found that observation and assessment of L.St.'s condition by a nurse was not reasonable and necessary because the documentation did not support a likelihood of change in L.St.'s condition. (R. at 109 (citing 42 C.F.R. § 409.33).) There was no documentation of abnormal vital signs or other changes. Further, the Council affirmed the ALJ's decision to deny patient education on wound care because there was no evidence that any such instruction was given. (*Id.* at 110.)

The Council came to the same conclusion as to physical therapy services, affirming the ALJ's decision that they were not reasonable and necessary. As the ALJ noted, there is an absence of documentation showing that L.St.'s condition would improve within a reasonable period of time. And

the physical therapy evaluation conflicted with other evidence that there was no change in L.St.'s prior level of function. The ALJ also pointed out that the physical therapy evaluation did not indicate the cause of L.St.'s symptoms or whether the symptoms were related to an exacerbation of L.St.'s condition. The ALJ correctly concluded, and the Council agreed, that "[w]ithout evidence of the causes of symptoms or prior level of function, an expectation that [L.St.]'s condition would significantly improve within a reasonable period of time is not established." (*Id.*) Finally, the ALJ concluded that there was no evidence that the services were "necessary to establish a safe and effective maintenance program." (*Id*.) The court finds that substantial evidence supports the Secretary's decision, and it is affirmed.

**Patient #4-E.I.**

In affirming the ALJ's decision denying coverage for physical therapy services, the Council agreed the record lacked evidence as to E.I.'s prior level of function. And there was no evidence to support an expectation that E.I.'s condition would improve materially in a reasonable amount of time or that the services were necessary. As the Council and the ALJ pointed out, "[t]his lack of documentation renders the goals set to purportedly improve function essentially meaningfulness[sic]; and calls into question the validity for the purpose of the [physical therapy] from the outset." (*Id.* at 22.) Finally, the Council noted that the record did not contain specific quantitative measurements. The court agrees that general descriptions included in the skilled nursing notes or OASIS report, such as "very weak," are insufficient and that the physical therapy notes do not comport with the documentation requirements of 42 C.F.R. § 409.44(c)(2)(i)(H)(4). The Secretary's decision was based on substantial evidence and the court upholds it.

**Patient #6-G.K.**

As to this patient, the Council affirmed the ALJ's decision, noting that for the remaining beneficiaries, the Council examined the documentation and evidence in the case and found that "the documentation is insufficient to support Medicare coverage criteria for the services at issue." (*Id.* at 29.) Further, "[t]he skilled nursing notes do not show the beneficiaries required or received" the services at issue. (*Id.*) Plaintiff argues that there was a new diagnosis of pneumonia here, but the ALJ noted that the OASIS report and the Plan of Care list gait disturbance as the principal diagnosis. Regardless, none of the nursing notes indicates that treatment was provided for pneumonia. The Secretary's decision is supported by substantial evidence and is affirmed.

**Patient #11-L.D**

The Council affirmed the ALJ's decision to deny both physical therapy services and skilled nursing services rendered to L.D. As to the physical therapy services, the Council noted that plaintiff pointed to a March 6, 2008 physical therapy evaluation stating that L.D.'s balance was 3/5 and that she could ambulate 100 feet with a cane. The Council found that, other than an April 15, 2008 visit note that stated L.D. could ambulate 150 feet, there was no other quantitative measurement in the notes. The court disagrees, as it found that several of the physical therapy visit notes contained statements regarding the distances L.D. was able to ambulate. Despite this, the court agrees with the Council that the notes do not provide sufficient information regarding the physical therapy provided, and the court cannot properly assess L.D.'s progress at each visit. The court agrees with the Council's decision to uphold the ALJ's finding that "there was no expectation that [L.D.]'s condition would improve materially in a reasonable (and generally predictable) period of time and that the physical therapy services were not of a reasonable amount, frequency, and duration, given the beneficiary's condition." (*Id.* (citing 42 C.F.R. § 409.44(c).)

Similarly, the Council affirmed the ALJ's decision denying coverage for the skilled services rendered to L.D. L.D.'s diagnoses were insulin dependent diabetes mellitus, degenerative joint disease, increased pain, and chronic obstructive pulmonary disease. But, as the Council pointed out, although there were some adjustments made to L.D.'s medication and some minor changes in her condition, the services provided were not at the level anticipated by the regulations. (*Id.* (quoting 42 C.F.R. § 409.33(a)(1)(ii).) Further, although plaintiff argues that the skilled nursing services were necessary to monitor L.D.'s diabetes and medication compliance, the ALJ correctly found that the condition was not new and the record did not support a finding that the services were reasonable and necessary. The Secretary's decision denying coverage for both physical therapy services and skilled nursing services is supported by substantial evidence and is affirmed.

**Patient #17-M.S.**

The Council upheld the ALJ's decision denying coverage for skilled nursing services of observation and assessment and patient education services. The Council again found that the documentation for M.S. was insufficient to support coverage and that the skilled nursing notes did not demonstrate that M.S. required or received the services at issue. The ALJ noted that the evidence did not indicate there was a likelihood of a future complication or acute episode that would warrant skilled intervention for M.S. Further, the conditions to be monitored (diabetes and hypertension) were not new diagnoses, and there were no changes in the nursing plan. MBPM CMS Pub. 100-02 Ch. 7, § 40.1.2.1. The Secretary had substantial evidence upon which it based its decision, and the court affirms.

**Patient #18-O.C.**

The Council affirmed the ALJ's decision denying coverage for skilled nursing services as to O.C. for similar reasons. Again, the Council noted the lack of documentation to support coverage and

the fact that the skilled nursing notes did not indicate the patient required or received the services in question. Further, the ALJ noted that the evidence did not indicate there was a likelihood of a future complication or acute episode that would warrant skilled intervention for O.C. MBPM CMS Pub. 100-02 Ch. 7, § 40.1.2.1. The nursing notes indicated the skilled nurse assessed blood pressure, monitored pain and panic attacks, and instructed on medications, but these were not new diagnoses, and the medications were not new. The ALJ pointed out that O.C. had a history of these conditions, and there was no evidence that there was a likelihood of a future complication or acute episode that would warrant skilled intervention for O.C. The Secretary's decision is supported by substantial evidence, and the court will not disturb it.

**Patient #19-C.S.**

Here, the ALJ allowed two skilled nursing visits, but denied coverage for the other visits. The Council upheld the ALJ's decision. The ALJ found that "[t]he primary purpose for the services was to observe, monitor vital signs, and provide assessment and instructions regarding conditions, particularly pain management." (R. at 125.) C.S. had an implanted morphine pump and "failed back syndrome," and the ALJ noted that under acceptable standards of medical and nursing practice, long-term pain management for C.S. should have occurred in a pain management clinic or more structured environment. (*Id.*); 42 C.F.R. § 409.44(b)(3)(i). The ALJ then found that C.S. did eventually attend a pain clinic, and that visits after that point were not covered. Further, the ALJ found that skilled nursing services were not required to recognize itching or to call for anti-itching medication, and that these interventions did not constitute a significant change in C.S.'s condition, treatment plan, or medications. The Council again found, and the court agrees, that the documentation was insufficient to support coverage of the skilled nursing services. The court affirms, as substantial evidence supports the Secretary's decision.

**Patient #21-J.B.**

The Council overturned the ALJ's decision regarding denying J.B.'s skilled nursing services, but the Council affirmed the ALJ's decision denying some of J.B.'s physical therapy services. The ALJ determined that physical therapy "for gait training was reasonable and necessary for the first two weeks, because it could be expected that the Beneficiary's ability to walk would improve during that time." (*Id.* at 127.) But without an exacerbation of J.B.'s condition, the ALJ found that continued physical therapy beyond the two-week period was repetitive and would not require the skills of a physical therapist. Thus, the ALJ denied coverage for the physical therapy beyond the first two weeks. Further, the Council found that the physical therapy notes lacked "objective evidence or clinically supportable statements of expectation that the beneficiary was continuing to progress toward the treatment goals or was responding to therapy in a reasonable and generally predictable period of time." (*Id.* at 21 (citing 42 C.F.R. § 409.44(c)(2)(i)(H)(4).) The court agrees that language such as "gaining strength" was not sufficiently descriptive to show that coverage was warranted and does not comport with documentation requirements. The Secretary's decision is supported by substantial evidence, and the court affirms it.

**Patient #22-D.B.**

The Council affirmed the ALJ's decision denying coverage of patient education services regarding exercises, diet, oxygen precautions, and signs and symptoms of infection provided to D.B. The Council stated that "the evidence does not establish that repeated assessment and instructions regarding the beneficiary's condition qualify as skilled nursing services pursuant to the applicable regulations and policy guidance." (*Id.* at 23.) The ALJ explained that "repeated assessment and instructions regarding the Beneficiary's chronic condition were not necessary." (*Id.* at 126); *see* 42

C.F.R. § 409.33(a)(3). The court agrees and finds that substantial evidence supports the Secretary's decision.

**Patient #23-T.V.**

For T.V., the Council affirmed the ALJ's denial of coverage for four skilled nursing and four physical therapy visits. The ALJ found that for the first three visits, patient education services given to T.V.'s daughters were covered, as the daughters required re-education on T.V.'s care and disease processes. (*Id*. at 128–29.) However, the ALJ denied coverage for subsequent visits. The ALJ likewise found that the first three physical therapy visits were covered, as the family required "a short window of training in order to instruct them on equipment, transfers, stretches, ROM, repositioning, and strengthening exercises." (*Id*. at 129.) The Council further found that the physical therapy notes lacked objective evidence of the expectation that the patient was continuing to progress toward treatment goals or would respond to therapy in a reasonable and generally predictable time period. (*Id.* at 21); 42 C.F.R. § 409.44(c)(2)(iii)(1994–2010). And the documentation failed to meet the requirements of 42 C.F.R. § 409.44(c)(2)(i)(H)(4). Because it is supported by substantial evidence, the Secretary's decision is affirmed.

The court reviewed the record as to each patient at issue, and finds that substantial evidence supports the Secretary's determinations as to each patient. For these reasons, the court affirms the Secretary's decisions as to whether the services at issue were reasonable and necessary.

### C. The Secretary's Decision that Plaintiff's Financial Liability is Not Waived or Limited for Noncovered Services is Supported by Substantial Evidence

Plaintiff points to several provisions of the Act to argue that plaintiff is not responsible for noncovered services and that the Secretary erred in finding the opposite. The Council first looked at Section 1879 of the Act, which is codified at 42 U.S.C. § 1395pp. Under this provision, a provider's liability may be waived if the provider "did not know, and could not reasonably have been expected to

know, that payment would not be made for such items or services . . . ." 42 U.S.C. § 1395pp(a). Similarly, overpayments may not be recovered from a provider under Section 1870 of the Act if the provider is "without fault" in incurring the overpayment. *Id.* § 1395gg(b)(1).

Upon review, the court finds that substantial evidence supports the Secretary's determination that plaintiff cannot avoid financial liability because plaintiff has not shown that it "did not know, and could not reasonably have been expected to know, that payment would not be made for such items or services . . . ." *Id.* § 1395pp(a). As the Council explained, plaintiff knew or had reason to know that the services at issue were not covered based on '"[i]t's receipt of CMS notices, including manual issuances, bulletins, or other written guides or directives from [Medicare contractors]"' and '"[i]ts knowledge of what are considered acceptable standards of practice by the local medical community."' (R. at 29 (quoting 42 C.F.R. § 411.406(e)(1), (3).) And, as defendant pointed out, plaintiff apparently had some knowledge that the services may be noncovered, because plaintiff issued advance beneficiary notices ("ABNs") to some beneficiaries stating that services may not be covered.

Therefore, plaintiff is liable unless it informed the beneficiary by providing an ABN that services would not be covered. 42 C.F.R. § 411.406(d)(1). After reviewing the ABNs, the court agrees with the Council's decision that the ABNs do not allow the beneficiary to make an informed decision regarding services because the ABNs fail to inform the beneficiary why services would not be covered. *See* Medicare Claims Processing Manual, CMS Pub. 100-04, Ch. 30, § 40.3.8 (discussing the need to provide enough information so the beneficiary can make an "informed consumer decision") (http://cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS018912.html?DLPage=1&DLSort=0&DLSortDir=ascending). And the court also agrees that the notices found in the files of three beneficiaries do not qualify as ABNs and thus do not limit

plaintiff's liability. The Council's decision finding that no waiver of liability is available to plaintiff under 42 U.S.C. § 1395pp(a) is supported by substantial evidence, and the court affirms.

Likewise, substantial evidence supports the Council's decision that plaintiff is not "without fault" in incurring the overpayment. The Council was correct that no rebuttable presumption holding plaintiff without fault applies, as the overpayment was not identified more than three calendar years after the initial determination was made. *See* 42 U.S.C. § 1395gg(b) (language after paragraph (4)); 42 C.F.R. § 405.350(c) (2010); Medicare Financial Management Manual ("MFMM"), CMS Pub. 100-06, Ch. 3, § 80 (http://cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019018.html?DLPage=1&DLSort=0&DLSortDir=ascending). [4]

The MFMM provides that a provider is without fault "if it exercised reasonable care in billing for, and accepting" Medicare payments. MFMM, CMS Pub. 100-06, Ch. 3, § 90. The MFMM further provides an example of a situation where a provider is not without fault as when "[t]he provider billed, or Medicare paid the provider for services that the provider should have known were noncovered." *Id.* at § 90.1(H). Again, plaintiff is charged with knowledge of Medicare policies and regulations, including those listed in the manual. *Id.*; 42 C.F.R. 411.406(e). As discussed above, plaintiff failed to support its claims with the proper documentation to show that the services provided should be covered. For these reasons, the Secretary's decision that plaintiff is not without fault is supported by substantial evidence and is affirmed.

**V. Plaintiff's Remaining Arguments**

Plaintiff raises additional arguments in its reply. First, plaintiff argues that the ALJ and the Council ignored significant evidence. But plaintiff fails to cite to the record to support its assertions. The ALJ's decision notes that "[a]ll exhibits contained in the Master File and each Beneficiary claim

[4] In 2010, the rebuttable presumption applied if the overpayment was identified more than three years after the initial determination. The current version of the law applies if the overpayment was identified more than five years after the initial determination.

folder . . . were admitted into evidence without objection" at the hearing before the ALJ. (R. at 73.) And the Council stated that it had "carefully considered the entire record . . . ." (*Id.* at 6.) Further, the opinions of both the ALJ and the Council were thorough and detailed. The court finds no indication that the ALJ and the Council ignored significant evidence.

Plaintiff also asks the court to apply the "treating physician rule" from social security disability cases to this case. Plaintiff appears to argue that a physician's certification alone is the determining factor as to whether coverage is appropriate. The court disagrees. Although physician certification is required for payment purposes, it is the role of the Secretary to determine whether services are covered. Plaintiff admits that the treating physician rule has not been applied in Medicare cases, and the court will not apply it here.

Finally, plaintiff's complaint objected to the Secretary's use of statistical sampling and extrapolation in this case. Plaintiff's claims on this issue were denied at each level of administrative review. But plaintiff's brief did not address this issue. Although it appears that plaintiff has waived the arguments here, the court finds that the Secretary's decision regarding the statistical sampling and extrapolation used in this case is legally sound and is supported by substantial evidence.

## VI. Conclusion

The Secretary's decision is supported by substantial evidence in the record. Based on the above analysis, the court affirms the decision of the Secretary.

**IT IS THEREFORE ORDERED** that the Secretary's decision is affirmed. Judgment shall be entered pursuant to the fourth sentence of 42 U.S.C. § 405(g).

Dated this 28th day of August, 2014, at Kansas City, Kansas.

s/ Carlos Murguia
**CARLOS MURGUIA**
**United States District Judge**