UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

PATRICIA FINIGAN, Plaintiff, v. SYLVIA M. BURWELL, Secretary of Health and Human Services, Defendant.	)	CIVIL ACTION NO. 15-12246-WGY

YOUNG, D.J. May 19, 2016

MEMORANDUM & ORDER

I. INTRODUCTION

Patricia Finigan, a diabetic, brings this action under 42 U.S.C. § 405(g) to challenge her Medicare Part C plan's denial of coverage for disposable sensors, which are used as part of a Continuous Glucose Monitoring System ("CGMS").

A. Factual Background

The underlying facts in this case are not in dispute, as Finigan's claims on appeal relate solely to legal issues. See Pl.'s Mem. Supp. Mot. Reverse Remand Decision Secretary Leave File Granted Jan. 21, 2016 ("Pl.'s Mem.") 8-13, ECF No. 24. The Court thus sketches only a brief history of the facts, as found by the hearing officer.

Finigan has type 1 diabetes. Admin. R. 0058. She "has been insulin dependent for the past thirty-five years" and has also suffered from a variety of other medical ailments during that time span. Id. To treat her diabetes, Finigan's physician "established a blood glucose testing regimen requiring the use of a [CGMS.]" Id. at 0062. The hearing officer summarized the effects of the CGMS on her health:

> [Finigan has] had severe medical issues before [she began using the CGMS, including an] episode of a seizure during sleep, episodes of passing out in public and an episode of awaking during the night and injuring her hand in a fan due to low blood sugar and confusion. Before use of the [CGMS, Finigan] suffered harm from low blood sugars and has required multiple emergency room visits and hospitalizations. Since ceasing use of [the CGMS, Finigan] has had episodes of testing at home before a short walk and then experiencing significant decreases in blood glucose levels requiring assistance only minutes later. The use of the [CGMS] allowed [Finigan] to control her blood sugars and to avoid anxiety, symptoms[,] and injury. . . . [Finigan's] physician determined [Finigan] required [the CGMS] with sensors due to [her] fluctuating blood sugar and that the supplies [for the CGMS] were critical[.]

Id. at 0059 (internal citation omitted). Although the language of her initial request for coverage does not appear to be in the record, the parties agree that she requested coverage for supplies for her CGMS from her insurer (under a Medicare Advantage Plan, explained infra Part II-A). Compare Pl.'s Mem. 2, with Mem. Law Supp. Def.'s Mot. Affirm Decision Medicare

Appeals Council ("Def.'s Mem.") 10, ECF No. 28. Finigan's insurer denied her request. See Admin. R. 0145.

B. Procedural History

After this initial denial, Finigan embarked on a journey into the Medicare appeals process, making six stops on her way to this Court. Finigan appealed her insurer's initial determination internally on December 31, 2013, and, on January 2, 2014, her insurer affirmed its initial denial of coverage for her CGMS. Admin. R. 0141. Next, she began the external appeals process, which, for her, started with Maximus Federal Services, a contractor hired by Medicare to conduct preliminary appeals. Id. at 127. Maximus affirmed her insurer's denial, relying solely on Local Coverage Determination L11530, which, it claimed, "incorporates [Policy] Article A33614," the latter of which states that CGMS's are not covered. Id. at 0139.

Onwards she went, to a hearing officer,[1] who, in contrast to the three previous decision-makers, granted Finigan coverage on July 17, 2014. Id. at 0047. Her insurer then successfully petitioned for review before the Medicare Appeals Council (the "Council"). Id. at 0008. On January 20, 2015, the Council issued a decision reversing the hearing officer's determination

[1] For an explanation of the Court's use of this term, see Vega v. Colvin, No. CV 14-13900-WGY, 2016 WL 865221, at *1 n.1 (D. Mass. Mar. 2, 2016).

and declining coverage for Finigan's CGMS. Id. at 0012. Four-and-a-half months later, Finigan filed a complaint in this Court, challenging the Council's decision.[2] See Compl., ECF No. 1.

II. LEGAL FRAMEWORK

Finigan's claim for coverage implicates an intricate statutory and regulatory scheme. It also involves the interpretation of two particular documents. The Court will first sketch out the basic framework, then will describe the two documents at issue here.

A. Statutory and Regulatory Scheme

The First Circuit has provided an overview of Medicare and Parts A, B, and C:

> Enacted in 1965, Medicare is a federally run health insurance program benefitting primarily those who are 65 years of age and older. Before the recent extension of Medicare to cover a portion of

[2] By the Court's count, it will be at least the sixth decision-maker to weigh in on this coverage issue. And, because of the relief ordered, see infra Part V, it unfortunately will not be the last. Is this too much process? Would those like Finigan be better off with fewer levels of review, but with more resources dedicated to each level? These are important questions obviously outside the scope of this decision and the Court's power, but that are raised every time the Court details a Social Security petitioner's bureaucratic appeals-on-appeals path to the Court. The Court has previously lamented the myriad delays faced by claimants. See, e.g., Vega, 2016 WL 865221, at n.1 *10 (D. Mass. Mar. 2, 2016) (citing Kelli Kennedy, Some Struggle to Live While Waiting More Than 2 Years for Social Security Disability Hearings, U.S. News, (Nov. 28, 2015, 11:00 AM), http://www.usnews.com/news/us/articles/2015/11/28/long-wait-times-plague-social-security-disability-process).

> prescription drug costs, Medicare covered only inpatient care through Part A and outpatient care through Part B. Parts A and B are fee-for-service insurance programs operated by the federal government. 42 U.S.C. § 1395c et seq. (Part A); 42 U.S.C. § 1395j et seq. (Part B). In 1997, Congress enacted Medicare Part C to allow Medicare beneficiaries to opt out of traditional fee-for-service coverage under Parts A and B. 42 U.S.C. § 1395w–21 et seq. (Part C). Under Part C, beneficiaries can, inter alia, enroll in "Medicare Advantage" plans, privately-run managed care plans that provide coverage for both inpatient and outpatient services. Id. § 1395w–22(a)(1).

First Med. Health Plan, Inc. v. Vega-Ramos, 479 F.3d 46, 48 (1st Cir. 2007) (internal footnote omitted). Finigan is enrolled in one such Medicare Advantage Plan, namely AARP Medicare Complete (the "Plan"). Admin. R. 0137. Although privately run, the Plan is heavily regulated. It must cover all services under Medicare Parts A and B (or those covered solely by Part B). See 42 C.F.R. § 422.101(a). At issue here is what Finigan claims is "durable medical equipment," Pl.'s Reply 4, which, if it is also "reasonable and necessary for the diagnosis or treatment of illness or injury," is covered under Part B, 42 U.S.C. § 1395y(a)(1)(A)-(B). The sole issue with regard to Finigan's appeal is whether her CGMS supplies qualify as "durable medical equipment."

"Durable medical equipment" is a listed term in the "Definitions" section of the Medicare statute, but there is no definition provided. See 42 U.S.C. § 1395x(n). Instead, the statute (mistakenly?) provides examples of "durable medical

equipment," most of which are irrelevant to the current case, except for "blood-testing strips and blood glucose monitors for individuals with diabetes." Id. The regulations do provide a definition for "durable medical equipment" in the form of a five-part test:

> Durable medical equipment means equipment, furnished by a supplier or a home health agency that meets the following conditions:
>
> (1) Can withstand repeated use.
> (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
> (3) Is primarily and customarily used to serve a medical purpose.
> (4) Generally is not useful to an individual in the absence of an illness or injury.
> (5) Is appropriate for use in the home.

42 C.F.R. § 414.202. In addition to the statutory examples and regulatory definition of "durable medical equipment," the regulations provide instructions to hearing officers and the Council with regard to certain other documents:

> (a) [Hearing officers and the Council] are not bound by [Local Coverage Determinations], [Local Medical Review Policies], or [Centers for Medicare & Medicaid Services] program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case.
>
> (b) If [a hearing officer or the Council] declines to follow a policy in a particular case, the [hearing officer or the Council's] decision must explain the reasons why the policy was not followed. [A hearing officer or the Council's] decision to disregard such policy applies only to the specific

> claim being considered and does not have precedential effect.
>
> (c) [A hearing officer or the Council] may not set aside or review the validity of an LMRP or LCD for purposes of a claim appeal. [A hearing officer] . . . may review or set aside an [Local Coverage Determination] (or any part of a [Local Medical Review Policy] that constitutes a [Local Coverage Determination]) in accordance with part 426 of this title.

42 C.F.R. § 405.1062 (emphasis supplied). Out of the documents to which "substantial deference" is owed, pursuant to the regulation above, only a Local Coverage Determination is present here.[3] The Court now turns to it, along with a Policy Article, unmentioned in the relevant regulation, but, at least in the Secretary's view, also deserving of "substantial deference," see Def.'s Mem. 18-20.

B. The Local Coverage Determination and Local Policy Article at Issue

The Local Coverage Determination relevant here is titled "Local Coverage Determination (LCD) for Glucose Monitors (L11530)." Admin. R. 0018. Its "Coverage Guidance" section provides that "home blood glucose monitors and related

[3] The parties have pointed to no relevant Local Medical Review Policies, instead agreeing that these have been phased out, compare Pl.'s Mem. 6, with D.'s Mem. 5 n.7, and although the Secretary attempts to rely on guidance from the Center for Medicare and Medicaid Services to obtain an affirmance of the Council's decision, see Def.'s Mem. 15-16, such argument is improperly made for the first time on appeal to this Court, see infra Part IV-B.

accessories and supplies" are covered for claimants who "ha[ve] diabetes" and whose physicians have prescribed the supplies and trained them in their use. Id. at 0019. Although the section excludes certain related accessories (e.g., a "laser skin piercing device") as "not reasonable and necessary[,]" it does not mention CGMS's. Id. The Local Coverage Determination includes an "Attachments" section, but it is empty. See id. at 0034 ("There are no attachments for this [Local Coverage Determination.]"). On that same page, under "Related Local Coverage Documents," "A33614 -- Glucose Monitors -- Policy Article -- Effective January 2014" is listed. Id.

The document to which the Local Coverage Determination refers has a confusing, seemingly two-part name: "Local Coverage Article for Glucose Monitors - Policy Article - Effective January 2014 (A33614)." Id. at 0035. Referring to this document as a "Local Coverage Article," right on the heels of describing a "Local Coverage Determination," invites trouble, so the Court follows the parties in calling it the "Policy Article." See, e.g., Pl.'s Mem. 8; Def.'s Mem. 6, 7.

The Policy Article, in its first subsection of the main body of text, entitled "Non-Medical Necessity Coverage and Payment Rules," recounts the statutory requirements for coverage, then references the Local Coverage Determination's statement for "[h]ome blood glucose monitors." Id. at 0035.

The Coverage Article notes that "[i]n addition" to the Local Coverage Determination's reasonable-and-necessary requirements, "there are specific statutory payment policy requirements, discussed below, that also must be met." Id. The Article then lists seven devices, and explains why each is "non-covered." See id. at 0036. Relevant here, the Article asserts that CGMS is "considered precautionary and therefore non-covered under the [durable medical equipment] benefit." Id.

III. PRIOR DECISIONS

With the relevant legal framework established, this section moves from the general to the specifics of Finigan's case, recounting first the hearing officer's, then the Council's, coverage determinations.

A. Hearing Officer

The hearing officer ordered the Plan to cover Finigan's CGMS supplies. See Admin. R. 0042. He observed that the Policy Article labeled Finigan's CGMS "precautionary" and thus ineligible for reimbursement as "durable medical equipment," and stated that he must "give substantial deference" to this determination. Id. at 0045-46. The hearing officer nonetheless found that based on the facts in Finigan's particular case,[4] her CGMS was "medically reasonable and necessary to maintain stable

[4] These facts are outlined supra Part I-A.

blood sugar levels and to prevent future complications and a worsening condition." Id. at 0045-46. For Finigan, the hearing officer found, the CGM "is not precautionary . . . but rather is reasonable and necessary for treatment and monitoring of her diabetes." Id. at 0046.[5]

B. Medicare Appeals Council

The Council reviewed the hearing officer's decision after the Plan appealed. Admin. R. 0008. It reversed the hearing officer's decision. Id. at 0012. The Council stated that Policy Article A33614 did not bind it under 42 C.F.R. § 405.1062(a), but that under subsection (b) the Coverage Article was entitled to "substantial deference." Id. at 0010. Its analysis regarding whether Finigan's particular situation was sufficient to overcome this "substantial deference" was conclusory: in asserting that the hearing officer's justification for "depart[ing] from [the Policy Article]" was "insufficient[,]" id. at 0011, the Council did not explain what

[5] The hearing officer also found persuasive that a different policy offered by the Medicare Advantage Plan provider used by Finigan does cover CGM's when a patient had "demonstrated adherence to a physician-ordered treatment plan" yet still had "experienced hypoglycemia unawareness and/or frequent episodes of hypoglycemia." Admin. R. 0046. The Council took issue with this analysis, see id. at 0011, but failed to appreciate that the hearing officer was using the private policy merely as circumstantial evidence that CGMS could be helpful to a patient with diabetes, not as logically requiring that the Plan make the same coverage determination with respect to its Medicare Plus plans.

more would have rendered the record sufficient, or if, for example, a different type of evidence ought have been proffered by Finigan. The only evidence to which the Council pointed, as an apparent contradiction to the particularized facts found by the hearing officer, was the safety label on Finigan's CGMS, which stated "the CGM is not a replacement for standard self-monitoring of blood glucose[.]" Id. at 0010. Instead of replacing the blood-testing method, CGM supplements it by "alert[ing] the patient" when her levels are low, so that a test should be performed. Id. These facts supported the Local Article's notation that the CGMS was precautionary only, the Council reasoned, as the CGMS "readings are not used directly in adjusting the patient's treatment regimen." Id.

IV. ANALYSIS

Finigan challenges the Council's decision, ostensibly advancing four arguments. She claims that the Council erroneously deferred to a Policy Article, Pl.'s Mem. 8-9; that the medical evidence in the record constitutes "substantial evidence" that "[s]upports a finding that [Finigan's CGMS] is reasonable and [n]ecessary," id. at 10-11; that the hearing officer adequately explained his rejection of the Policy Article, id. at 11-12; and that the Council made legal error and used evidence outside the record in its decision, id. at 12-13.

Her four arguments, however, in fact converge on one main

point of contention: the Secretary, through the Council, treated the Policy Article as though it were a Local Coverage Determination, and that was legal error. See Pl.'s Reply Mem. Opp'n Def.'s Mot. Affirm Decision Medicare Appeals Council ("Pl.'s Reply") 1, ECF No. 29. This error prejudiced her, she asserts, because it was the basis for the Secretary's decision that her CGMS was not covered (reimbursable) "durable medical equipment." Id. In response, the Secretary claims that the Council's determination was supported by substantial evidence, Def.'s Mem. 16-20, but also, separately, that the CGMS is not "durable medical equipment" because the component performing the medically necessary function is non-durable, so affirmance of the coverage denial is warranted on that ground, as well, id. at 15-16. As to the Secretary's second argument, Finigan claims, in reply, that the Court cannot rely on it because it was not advanced by the agency in the proceedings below, Pl.'s Reply 1-2.

The Court first deals with the issue of the Policy Article, then explains why it is remanding for a determination of whether the CGMS qualifies as "durable medical equipment" under the regulations.

A. Unwarranted Deference

The Council, in denying Finigan coverage, relied on its assertion that Policy Article A33614 "represents the

contractor's determination that [CGMS] is not medically reasonable and necessary as required by the Medicare statute." Admin. R. 0009. The Council treated the Policy Article like it was a Local Coverage Determination, which would be entitled to "substantial deference," 42 C.F.R. § 405.1062(a), and the Secretary continues to do so before this Court, see Def.'s Mem. 19 (arguing that the Council's reliance on the Policy Article "was appropriate"). This is legal error.

The Policy Article is not a Local Coverage Determination because it does not make reasonable-and-necessary determinations, and the Secretary effectively admits as much. See Def.'s Mem. 5 n.7 (stating that Local Coverage Determinations contain reasonable-and-necessary determinations, while "contractor-issued 'Policy Articles'" contain information "not related to [the reasonable and necessary determination]," such as "benefit category and coding guidelines[.]"). While vacating the Secretary's decision because of the difference between a "Policy Article" and a "Local Coverage Determination" might sound like the height of legalistic formalism, this difference is a meaningful one. As Finigan points out, see Pl.'s Mem. 9, Magistrate Judge Duffin, of the Eastern District of Wisconsin, has explained why the two documents are apples and oranges:

> Looking to [Policy] Articles for coverage determinations would undermine [a Medicare statutory amendment,] whereby Congress created the right for certain beneficiaries to challenge coverage language contained in [Local Coverage Determinations]. Given their limited purpose, a [Policy] Article is not subject to challenge. Reading a [Policy] Article as if its language determined whether a service or item is covered would render such determination exempt from review. Moreover, [Policy] Articles may be created without the notice and comment period required for a [Local Coverage Determinations]. Accepting the Secretary's position that a [Policy] Article can determine coverage would seemingly open the door to a system whereby beneficiaries would not have the opportunity to provide input on coverage determinations before the policy went into effect or to challenge those policies once they were adopted.

Whitcomb v. Burwell, No. 13-CV-990, 2015 WL 3397697, at *4 (E.D. Wis. May 26, 2015) (internal citation omitted). The Council's decision that "the record is insufficient to depart from the coverage standards articulated in [Policy] Article A33614[,]" Admin. R. 0011, thus incorporates a false premise: that this Policy Article, like a Local Coverage Determination, was entitled to "substantial deference" and thus that the hearing officer needed sufficient evidence before he could "depart" from it.[6]

[6] Even apart from the erroneous deference, the Secretary's construction of the term "precautionary" to include CGMS because Finigan's CGMS is "not intended to replace [Finigan's] traditional blood glucose monitoring[,]" but only to supplement it, Def.'s Mem. 15, is head-scratching, or at least under-explained. The Secretary's argument here seems to go: since Finigan uses CGMS to monitor her diabetes symptoms in conjunction with another piece of equipment, her CGMS cannot be "durable medical equipment." It is far from clear, though, why

Perhaps realizing this error, the Secretary advances a somewhat different argument: even if Policy Articles are generally different from Local Coverage Determinations, this Policy Article was entitled to substantial deference because it was incorporated into the Local Coverage Determination. Def.'s Mem. 19. This argument ignores the language of the Local Coverage Determination, which has a blank "Attachments" section that; were the Policy Article included in it, this case would present a closer issue. See Admin. R. 0034. The Secretary's argument, relying as it does on the listing of the Policy Article in the "Related Local Coverage Documents" section, id., conflates a document's being "related" to another one and its being "incorporated" into it. See Whitcomb, 2015 WL 3397697, at *3-*4 (holding that listing a policy article as a "related document" is not equivalent to incorporating it). The Court is persuaded that the Secretary's according the Policy Article "substantial deference" was legal error.

B. Finigan's CGMS

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the fact of her having other equipment is dispositive: the CGMS, as used by Finigan, helped her manage her diabetic symptoms, and, while it would not qualify were the category "Primary Device Used to Treat Symptoms," her blood-testing regime seems irrelevant to whether her CGMS is "durable medical equipment." Cf. Currier v. Leavitt, 490 F. Supp. 2d 1, 9 (D. Me. 2007) (ordering reimbursement for claimant even though the purported "durable medical equipment" did not "cure the underlying condition but only alleviate[d] its symptoms").

The Secretary argues that, even were deferring to the Policy Article error, a remand is unnecessary because, under the guidance of the Center for Medicare & Medicaid Services -- whose publications are due "substantial deference" -- the CGMS does not qualify as "durable medical equipment." Def.'s Mem. 15-16 (citing 42 C.F.R. § 405.1062(a)). The publication to which the Secretary points discusses "multi-component devices" -- a category into which Finigan's CGMS with its disposable sensors fits, the Secretary argues, id. at 16 -- and states that if "the component that performs the medically necessary function of the device is non-durable" then it is "considered non-durable[.]" Id. (quoting a statement made regarding the current rules, in a proposed rule statement in the Federal Register). Finigan claims that this argument was not advanced by the Council or the hearing officer, and thus cannot serve as the basis of an affirmance of the Secretary's decision. See Pl.'s Reply 4 n.3. She is right.

When reviewing an agency's determination, the Court is "not usually permitted to affirm . . . on grounds other than those advanced by the agency [below]," unless "it is clear what the agency's decision must be." Polanco-Quinones v. Astrue, 477 F. App'x 745, 746 (1st Cir. 2012); see also, e.g., Maine Med. Ctr. v. Burwell, 775 F.3d 470, 478 (1st Cir. 2015) ("[W]e are limited to the rationale advanced by the agency in the administrative

proceeding[.]") (internal citations and quotation marks omitted).

Although Finigan has convinced the Court that the Secretary's reasoning was erroneous, she has not convinced the Court that she is clearly entitled to coverage, and thus a remand is appropriate. See Vega v. Colvin, No. CV 14-13900-WGY, 2016 WL 865221, at *11 (D. Mass. Mar. 2, 2016) (citing Seavey, 276 F.3d at 11) ("The Court here takes issue with the basis for the hearing officer's decision; it does not follow from the Court's conclusion that the hearing officer's findings were not supported by substantial evidence that Vega is necessarily entitled to benefits. Accordingly, the appropriate course of action is to remand.").

V. CONCLUSION

For the foregoing reasons, the Court **DENIES** the Secretary's motion to affirm the decision of the Council, ECF No. 27, and **GRANTS IN PART** Finigan's motion to reverse or remand the Council's decision, ECF No. 23, remanding the matter to the Secretary for further proceedings consistent with this memorandum.

SO ORDERED.

/s/ William G. Young
WILLIAM G. YOUNG
DISTRICT JUDGE