IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

GARY ZIEROTH, as representative of the estate of SHARON ZIEROTH,

Plaintiff,

v.

ALEX AZAR, in his capacity as Secretary of Health and Human Services,

Defendant.

Case No. 20-cv-00172-MMC

ORDER GRANTING PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT; DENYING DEFENDANT'S CROSS-MOTION FOR SUMMARY JUDGMENT

Re: Doc. Nos. 23, 30

Before the Court are the following two motions: (1) the Motion for Summary Judgment, filed May 22, 2020, by plaintiff Gary Zieroth ("Zieroth"), and (2) the Cross-Motion for Summary Judgment, filed August 3, 2020, by defendant Alex Azar, Secretary of Health and Human Services ("Secretary"). Pursuant to Civil Local Rule 16-5, the motions have been submitted on the papers without oral argument. Having read and considered the parties' respective written submissions, the Court rules as follows.

BACKGROUND

Zieroth's wife, Sharon Zieroth, was a type 1 diabetic[1] with hypoglycemic unawareness[2]. (See Certified Administrative Record ("CAR") at 8.) To manage her condition, she used a continuous glucose monitor ("CGM"), specifically, a Medtronic

[1] Type 1 diabetes is a disease in which the pancreas produces limited insulin, a hormone required "to allow sugar (glucose) to enter cells to produce energy." See https://www.mayoclinic.org/diseases-conditions/type-1-diabetes.

[2] Hypoglycemic unawareness occurs when a diabetic does not have, or is unable to recognize, early symptoms of hypoglycemia, i.e., low blood sugar. See https://www.mayoclinic.org/diseases-conditions/diabetic-hypoglycemia.

MiniMed 530G system ("MiniMed 530G"), which device consists of several components, one of which is a sensor. (See id. at 7-8.)

Medicare is a federal health insurance program for elderly and disabled individuals and is administered by the Secretary through the Centers for Medicare and Medicaid Services ("CMS"). Between July 2017 and May 2018, Sharon Zieroth submitted claims, under Part B of the Medicare program, for reimbursement of the costs of three sensors.

Thereafter, at the fourth level of administrative review, the Medicare Appeals Council ("Appeals Council") denied all three claims, on the ground that a CGM system of the type exemplified by the MiniMed 530G does not qualify as durable medical equipment as defined in the applicable regulation, namely, 42 C.F.R. § 414.202, as interpreted by CMS-1682-R, a ruling issued by CMS. (See id. at 4, 11-13.)

On January 8, 2020, Sharon Zieroth filed the instant action seeking, pursuant to 42 U.S.C. §§ 405(g) and 1395ff, review of the denial of her claims by the Appeals Council. Subsequently, on February 7, 2020, Sharon Zieroth passed away from complications of diabetes. (See Mot. to Substitute, filed April 3, 2020.) Zieroth, as the representative of her estate, now brings the instant action on her behalf.

DISCUSSION

A district court's review of a final decision of the Secretary is governed by the Administrative Procedure Act, under which "[t]he reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." See 5 U.S.C. § 706.[3] "Generally, judicial review of agency action is limited to review of the record on which the administrative decision was based." See Thompson v. U.S. Dep't of Labor, 885 F.2d 551, 555 (9th Cir. 1989). A reviewing court can, however, "go outside the administrative record . . . for the limited purpose of background information." See id.

[3] A decision by the Appeals Council constitutes the final decision of the Secretary. See 42 C.F.R. § 405.1130.

Here, at the outset, Zieroth asserts CMS-1682-R was issued without notice and comment in violation of 42 U.S.C. § 1395hh and, consequently, that the Appeals Council's denial, which, as noted, was based on CMS-1682-R, was unlawful. The Secretary contends such procedural argument was waived as it was not raised before the Appeals Council.[4]

In Avol v. Sec'y of Health & Human Servs., 883 F.2d 659 (9th Cir. 1989), the Ninth Circuit held that, where an "issue [is] not raised before the . . . Appeals Council," the reviewing court "need not . . . address [such] issue." See id. at 661 (declining to address issue not raised before Appeals Council). Zieroth, while not disagreeing with such authority, contends compliance therewith was not required in this instance. In particular, Zieroth, noting CMS-1682-R was "binding" on the Appeals Council, see 42 C.F.R. § 401.108(c), asserts it would have been futile to raise his procedural challenge at that earlier stage of the proceedings. The cases on which Zieroth relies for such proposition are, however, distinguishable, as, in contrast to the instant case, none concerns the question of the preservation of an issue for appeal.[5]

With regard to that question, in "any adjudicative system, whether judicial or

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[4] The Court finds unpersuasive Zieroth's argument that the Secretary, by failing to assert waiver as an affirmative defense in his Answer, waived any such defense. Although, as Zieroth points out, Rule 8 of the Federal Rules of Civil Procedure requires a party, when "responding to a pleading," to "affirmatively state any . . . affirmative defense," including "waiver," see Fed. R. Civ. P. 8(c)(1), an affirmative defense may be pleaded for the first time in a motion for summary judgment "absent prejudice to the plaintiff," see Ledo Fin. Corp. v. Summers, 122 F.3d 825, 827 (9th Cir. 1997). Here, Zieroth has identified "no tangible way in which [he] was prejudiced by the delay." See id. (holding passage of time without more not sufficient to demonstrate prejudice).

[5] See In re Two Appeals Arising Out of San Juan Dupont Plaza Hotel Fire Litig., 994 F.2d 956, 961 (1st Cir. 1993) (finding no waiver where party failed to file bill of costs after court ordered each party to bear own costs); N. Heel Corp. v. Compo Indus., Inc., 851 F.2d 456, 461 (1st Cir. 1988) (finding, where plaintiff brought claim for breach of contract, conditions precedent excused where defendant "deprived [plaintiff] of the opportunity to demonstrate the fulfillment of [those] conditions"); Kinslow v. Am. Postal Workers Union, Chicago Local, 222 F.3d 269, 276 (7th Cir. 2000) (finding plaintiff Union member not obliged to provide "notice of reasons" in support of request for Union records where Union "would still have refused to produce the documents"); Miller v. Drexel Burnham Lambert, Inc., 791 F.2d 850, 854 (11th Cir. 1986) (finding no waiver of right to arbitrate where claims were, by law, not arbitrable).

administrative," the doctrines of waiver and forfeiture, as the Ninth Circuit has observed, serve to "preserve the integrity of the appellate structure." See Honcharov v. Barr, 924 F.3d 1293, 1295-96 (9th Cir. 2019) (internal quotation and citation omitted) (characterizing waiver and forfeiture as "important tools" for "allowing appellate courts to act as courts of review, not first view"; upholding Board of Immigration Appeals' application of procedural default rule to argument raised for first time on appeal). Moreover, Zieroth has made no showing that the Appeals Council, even if bound by a finding made in CMS-1682-R, was precluded from considering whether such ruling was issued improperly, and, in any event, a requirement that an issue be raised at such stage of the proceedings allows for development of the record and discourages parties from "withholding secondary, back-up theories." See id. at 1296 (internal quotation and citation omitted).

Accordingly, the Court finds the procedural challenge asserted by Zieroth was waived. The Court next turns to the content of CMS-1682-R, in particular, the conclusion by CMS therein that a CGM like the MiniMed 530G does not qualify as durable medical equipment.

In 42 C.F.R. § 414.202, the Secretary has defined "durable medical equipment" as equipment that meets the following requirements: (1) "[c]an withstand repeated use"; (2) "has an expected life of at least 3 years"; (3) "[i]s primarily and customarily used to serve a medical purpose"; (4) "[g]enerally is not useful to an individual in the absence of an illness or injury"; and (5) "[i]s appropriate for use in the home." See id. The ruling here at issue, CMS-1682-R, was issued by the Secretary for the purpose of "articulat[ing] CMS policy concerning the classification of [CGM] systems as durable medical equipment" under the above-referenced regulation. See CMS-1682-R at 1.

Where a regulation is ambiguous, the promulgating agency's interpretation thereof is entitled to deference "unless it is plainly erroneous or inconsistent with the regulation." See Kisor v. Wilkie, 139 S. Ct. 2400, 2411 (2019) (internal quotation and citation omitted). As the Supreme Court has cautioned, however, such deference should not be

afforded unless the regulation is "genuinely ambiguous." See id. at 2415.

Here, Zieroth first contends CMS-1682-R is not ambiguous and, consequently, is not entitled to deference. The Court agrees.

In particular, the regulation, as noted, defines "durable medical equipment" as equipment that, in addition to other requirements, is "primarily and customarily used to serve a medical purpose." See 42 C.F.R. § 414.202. The adjective "medical" is commonly understood to mean relating to the practice of medicine, and "medicine," in turn, means "the science and art of preventing, curing, and alleviating sickness or affliction." See Black's Law Dictionary 1131 (10th ed. 2014); see also Yith v. Nielsen, 881 F.3d 1155, 1165 (9th Cir. 2018) (holding, for purposes of statutory interpretation, courts, "[w]hen determining the plain meaning of language, . . . may consult dictionary definitions") (internal quotation and citation omitted). In short, the regulation "is clear on its face." See Whitcomb v. Hargan, No. 17-CV-00014-DEJ, at 11 (E.D. Wis. Oct. 26, 2017).

As to the MiniMed 530G, the CGM here at issue, such device is, as noted, used by individuals with type 1 diabetes, a disease in which the pancreas produces limited insulin, a hormone required "to allow sugar (glucose) to enter cells to produce energy." See https://www.mayoclinic.org/diseases-conditions/type-1-diabetes. CGM systems estimate a diabetic's glucose level on a continuous basis; additionally, the MiniMed 530G can automatically suspend delivery of insulin when the sensor glucose value falls below a predefined threshold value and the user does not respond to an alarm, a function of particular importance when a patient, like Sharon Zieroth, suffers from hypoglycemic unawareness. (See CAR at 7-8.) The Court thus finds the MiniMed 530G is "primarily and customarily used to serve a medical purpose," see 42 C.F.R. § 414.202, and, as the record before the Appeals Council makes clear, Sharon Zieroth used the MiniMed 530G for such purpose (see CAR at 50-51).

Moreover, as Zieroth next argues, even if 42 C.F.R. § 414.202 could be characterized as "genuinely ambiguous," the Secretary's interpretation thereof, as

provided in CMS-1682-R, is not, as set forth below, reasonable.

In finding the MiniMed 530G does not qualify as durable medical equipment, the Appeals Council relied on CMS's distinction between CGM systems that are approved by the Food and Drug Administration ("FDA") "for use in place of a blood glucose monitor" and CGM systems that, like the MiniMed 530G, are approved by the FDA "for use as adjunctive devices to complement, not replace, information obtained from blood glucose monitors." See CMS-1682-R at 6-7, 13. According to CMS, as set forth in CMS-1682-R, the latter do not qualify as durable medical equipment because they do not "serve the medical purpose of making diabetes treatment decisions," see id. at 7, in that, once hypoglycemia has been detected by such device and the patient alerted thereby, the patient "may be required to confirm those levels with a fingerstick before taking appropriate action" (see CAR at 8). In other words, according to CMS, systems used as "adjunctive devices to complement, not replace, information obtained from blood glucose monitors" are not covered under Part B of the Medicare program.

There is nothing in the phrase "primarily and customarily used to serve a medical purpose," see 42 C.F.R. § 414.202, however, that requires covered devices to serve a "primary medical purpose," as opposed to an "adjunctive medical purpose." Consistent with this finding, at least three other district courts have found the MiniMed 530G constitutes durable medical equipment. See Whitcomb at 12 (noting, if Secretary "did not intend to provide coverage for secondary medical equipment, then the regulatory definition . . . must be revised to reflect that ideal"); Bloom v. Azar, 2018 WL 583111, at *10 (D. Vt. Jan. 29, 2018) (holding requirement that device be "primarily and customarily used to serve a medical purpose" has "nothing to do with whether the equipment is the 'primary' equipment used to serve that purpose"); Lewis v. Azar, 308 F. Supp. 3d 574, 579 (D. Mass. 2018) (rejecting Secretary's argument that "a device loses its medical nature if it is used in conjunction with another medical device"). Indeed, the medical purpose for which the MiniMed 530G is used is clearly, and rather dramatically, evidenced in the instant case. (See CAR at 50-51 (noting Sharon Zieroth, prior to using

the MiniMed 530G, experienced "frequent and severe episodes of hypoglycemia, which . . . resulted in multiple presentations to the emergency room (ER)"; further noting "she has had no ER visits since starting its use").)

Accordingly, the Court finds the Secretary's interpretation of 42 C.F.R. § 414.202, even if such regulation were deemed genuinely ambiguous, is not reasonable and thus not entitled to deference. See Kisor, 139 S. Ct. at 2415-16 (holding, to be entitled to deference, interpretation must be "within the bounds of reasonable interpretation").

Lastly, as the Court has found the MiniMed 530G is "primarily and customarily used to serve a medical purpose," and there is no apparent dispute that the other four requirements in 42 C.F.R. § 414.202 are satisfied, the Court finds the MiniMed 530G constitutes durable medical equipment as defined in 42 C.F.R. § 414.202, and, as a district court may enter a judgment "reversing the decision of the [Secretary], with or without remanding the case for a rehearing," see 42 U.S.C. § 405(g), further finds Zieroth is entitled, under Part B of the Medicare program, to reimbursement for the costs of the three MiniMed 530G sensors.

CONCLUSION

For the reasons stated above, Zieroth's Motion for Summary Judgment is hereby GRANTED, the Secretary's Cross-Motion for Summary Judgment is hereby DENIED, and the action is hereby REMANDED, under sentence four of 42 U.S.C. § 405(g), with instructions to authorize coverage for the three MiniMed 530G sensors at issue.

IT IS SO ORDERED.

Dated: September 22, 2020

MAXINE M. CHESNEY
United States District Judge

United States District Court
Northern District of California