

FILED IN THE
U.S. DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

Mar 31, 2022

SEAN F. MCAVOY, CLERK

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

JEREMY OLSEN,

Plaintiff,

v.

XAVIER BECERRA, in his official
capacity as the Secretary of the United
States Department of Health and
Human Services,

Defendant.

No. 2:21-cv-00326-SMJ

**ORDER DENYING MOTION FOR
PRELIMINARY INJUNCTION**

Before the Court, without oral argument, is Plaintiff's Motion for Preliminary Injunction, ECF No. 6. The Court has reviewed the record and pleadings in this matter, is fully informed, and denies the motion.

BACKGROUND

The Court has previously set forth the facts relevant to this dispute in several orders issued in a related case: *Olsen v. Azar*, No. 20-cv-00374-SMJ (E.D. Wash) ("*Olsen I*"), ECF Nos. 34, 39, 50. Briefly, though, Plaintiff Jeremy Olsen is a Type I diabetic who has suffered kidney failure and undergone a kidney transplant due to his condition. *Olsen I*, ECF No. 1 at 10. Plaintiff uses a Medtronic MiniMed Continuous Glucose Monitor ("CGM"), which he alleges a doctor prescribed to

1 help avoid failure of his transplanted kidney and prevent other complications from
2 his diabetes. *Id.* at 11. After his claim for Medicare coverage of the CGM supplies
3 was initially denied as not “durable medical equipment,” an Administrative Law
4 Judge eventually approved Plaintiff’s claim. *Id.* at 11–12. But the Medicare Appeals
5 Council/Departmental Review Board (“Appeals Council”) reversed the ALJ,
6 determining that a CGM is not “durable medical equipment” because it is not
7 “primarily and customarily used to serve a medical purpose.” *Id.* at 12.

8 On December 23, 2019, Plaintiff sought judicial review,¹ alleging six causes
9 of action. *See generally id.* Relevant here, Plaintiff claimed the Appeals Council
10 based its decision on CMS-1682-R, a “final opinion and order” regarding CGM
11 coverage, which the Department of Health and Human Services issued without a
12 public notice and comment period. *Id.* at 8. He also argued substantial evidence did
13 not support the Appeals Council’s decision to deny coverage and its decision was
14 arbitrary and capricious. *Id.* at 15. The Court granted Plaintiff’s motion for summary
15 judgment and ordered Defendant to provide coverage, finding that Plaintiff’s CGM
16 constitutes durable medical equipment. *Olsen I*, ECF No. 39. The Court also granted
17 Plaintiff’s motion for attorney fees, finding that Defendant’s position in defending
18 this matter was in bad faith. *Olsen I*, ECF No. 50.

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20 ¹ Plaintiff filed the lawsuit in the U.S. District Court for the District of Columbia,
but the case was transferred to this Court. *Olsen I*, ECF No. 16.

1 Thereafter, Defendant again denied two of Plaintiff’s claims for coverage of
2 CGM supplies submitted during the pendency of *Olsen I*. Both claims were for
3 reimbursement of a 90-day supply of CGM sensors that Plaintiff’s supplier,
4 MiniMed Distribution Corporation (“MiniMed”) furnished to Plaintiff on April 19,
5 2019 (the “April 2019 claim”) and March 10, 2021 (the “March 2021 claim”).
6 Defendant admits the claims were erroneously denied but attributes the denials to a
7 Medicare Administrative Contractor (“MAC”) employee’s failure “to make a
8 manual adjustment to the submission code assigned to Plaintiff’s claims in the
9 contractor’s claims processing system that was needed to facilitate payment.” ECF
10 No. 18 at 3.

11 Defendant requested ALJ hearings to challenge both denials. The April 2019
12 claim was rejected by the Appeals Council on October 22, 2021, ECF No. 32-1 at
13 3, and the March 2021 claim was denied by an ALJ on October 30, 2021, ECF No.
14 32-2 at 67.² In denying the claims, both the Appeals Council and ALJ relied on
15 CMS-1682-R to conclude that CGM does not constitute durable medical equipment,
16 in direct contravention of this Court’s previous order. ECF Nos. 32-1 at 8; 32-2 at
17 71; *see also Olsen I* at ECF No. 39 (“[T]he Court joins the district courts who have
18 found that the CGM constitutes durable medical equipment.”).

19 _____
20 ² Following the ALJ’s unfavorable decision on the March 2021 claim, the Appeals
Council subsequently denied Plaintiff’s request for expedited access to judicial
review pursuant to 42 C.F.R. § 405.990. ECF No. 1 at 18.

1 Article III case or controversy, and a court has no constitutional jurisdiction to
2 resolve the issues it presents.” *Goldin v. Bartholow*, 166 F.3d 710, 717 (5th
3 Cir.1999); *see also Oregon v. FERC*, 636 F.3d 1203, 1206 (9th Cir. 2011) (“A case
4 is moot when it has lost its character as a present, live controversy of the kind that
5 must exist if we are to avoid advisory opinions on abstract propositions of law.”)
6 (internal quotation marks omitted).

7 A claim “becomes moot when the issues presented are no longer live or the
8 parties lack a legally cognizable interest in the outcome.” *Murphy v. Hunt*, 455 U.S.
9 478, 481 (1982) (cleaned up). In general, an issue is no longer live when a party’s
10 injury is not redressable by a favorable decision. *Id.*; *see also Lee v. Schmidt-*
11 *Wenzel*, 766 F.2d 1387, 1389 (9th Cir. 1985) (“[A] live question is no longer present
12 because even a favorable decision by the district court would not have entitled the
13 appellees to relief.”).

14 Under the “voluntary cessation” exception to mootness, it is well established
15 that the “voluntary cessation of a challenged practice does not deprive a federal
16 court of its power to determine the legality of the practice.” *Friends of the Earth,*
17 *Inc. v. Laidlaw Environmental Services (TOC), Inc.*, 528 U.S. 167, 189 (2000).
18 Rather, a party’s voluntary abandonment of a challenged practice will moot a case
19 only when “it can be said with assurance that there is no reasonable expectation that
20 the alleged violation will recur and interim relief or events have completely and

1 irrevocably eradicated the effects of the alleged violation.” *Ranchers Cattlemen*
2 *Action Legal Fund United Stockgrowers of Am. v. Vilsack*, 6 F.4th 983, 991 (9th
3 Cir. 2021). In analyzing voluntary cessation, “[t]he government receives greater
4 deference than private parties.” *Id.* However, the government “must still
5 demonstrate that the change in its behavior is entrenched or permanent.” *Id.*
6 (quoting *Fikre v. Fed. Bureau of Investigation*, 904 F.3d 1033, 1037 (9th Cir.
7 2018)). In other words, the court must be assured that “the challenged conduct
8 cannot reasonably be expected to start up again.” *Fikre*, 904 F.3d at 1037.

9 **B. Preliminary Injunction**

10 “A preliminary injunction is an extraordinary remedy never awarded as of
11 right.” *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). To prevail on
12 a request for a preliminary injunction, a plaintiff “must establish [1] that he is likely
13 to succeed on the merits, [2] that he is likely to suffer irreparable harm in the
14 absence of preliminary relief, [3] that the balance of equities tips in his favor, and
15 [4] that an injunction is in the public interest.” *Id.* at 20. In assessing whether a
16 plaintiff is entitled to a preliminary injunction, “courts of equity should pay
17 particular regard for the public consequences in employing the extraordinary
18 remedy of injunction.” *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312 (1982).

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DISCUSSION

1
2 Plaintiff argues that he is entitled to a preliminary injunction “barring the
3 Secretary from continuing to reject continuous glucose monitor (CGM) claims
4 based on CMS 1682-R and/or the claim that a CGM is not ‘primarily and
5 customarily used to serve a medical purpose.’” ECF No. 6 at 1. The Court interprets
6 this request as a request for a nationwide preliminary injunction. Defendant opposes
7 the motion on jurisdictional grounds and on the merits.

A. Plaintiff’s claim for injunctive relief is not moot.

8
9 As a threshold matter, the Court finds that Plaintiff’s claim for injunctive
10 relief is not moot. While it undisputed that each claim for reimbursement has in fact
11 been paid, the Government has not met its “heavy burden of persua[ding]” the Court
12 under the voluntary cessation doctrine. *United States v. Concentrated Phosphate*
13 *Exp. Ass’n*, 393 U.S. 199, 203 (1968). “[A] voluntary change in official stance or
14 behavior moots an action only when it is ‘absolutely clear’ to the court, considering
15 the ‘procedural safeguards’ insulating the new state of affairs from arbitrary reversal
16 and the government’s rationale for its changed practice(s), that the activity
17 complained of will not reoccur.” *Fikre v. Fed. Bureau of Investigation*, 904 F.3d
18 1033, 1039 (9th Cir. 2018). While the Government receives more deference under
19 this assessment, the Court still must find that the Government “could not reasonably

1 be expected” to resume its unlawful conduct. *Friends of the Earth, Inc.*, 528 U.S.
2 167, 189 (2000).

3 **1. The Defendant has not demonstrated that its change in position is**
4 **entrenched or permanent.**

5 It is far from “absolutely clear” that Defendant will not continue to
6 unlawfully reject Plaintiff’s claims for reimbursement. More than one year ago, this
7 Court granted Plaintiff summary judgment, explicitly holding that “CGM
8 constitutes durable medical equipment.” *Olsen I*, ECF No. 39 at 9. Based upon that
9 ruling, the Court remanded the case with “instructions to authorize coverage.” *Id.*
10 at 10. In addition to these instructions, the Court also awarded Plaintiff’s counsel
11 attorney fees—finding the Defendant’s assertions that CGM does not constitute
12 durable medical equipment—was “so obviously wrong as to be frivolous.” *Olsen I*,
13 ECF No. 50 at 5. Yet, Defendant has since denied at least three of Plaintiff’s claims
14 on the same or similar grounds this Court previously held unlawful, one of which
15 was denied as recently as January of 2022. Although each of these claims has since
16 been paid without judicial intervention—which is to some extent a voluntary change
17 in position—the Court is not assured the pattern of reimbursement denials will not
18 continue.

19 While Defendant acknowledges these claims were erroneously denied, even
20 describing these denials as “admittedly unacceptable,” it attributes each denial to
errors in the claims processing, or coding, system. It does not however, offer any

1 explanation for the unfavorable ALJ or redetermination decisions once the initial
2 denials were challenged. Even granting the Government the deference owed to it,
3 the Court is not confident the complained-of activity will not reoccur.

4 **2. The new final rule does not moot Plaintiff's request for injunctive**
5 **relief.**

6 In December 2021, the Secretary issued a "final rule" that "makes changes
7 related to: The Durable Medical Equipment." 86 Fed. Reg. 73860 (Dec. 28, 2021)
8 (to be codified at 42 C.F.R. pt. 414). According to Defendant, this rule "supersedes
9 CMS 1682-R, with respect to CGM systems and classifies such systems, including
10 so-called 'non-therapeutic' or 'adjunctive' CGMs, as DME." ECF No. 18 at 4–5.
11 This final rule, which applies to claims dated February 28, 2022 and forward,
12 indicates that "[c]laims submitted for CGM sensors and transmitters used with
13 insulin pumps are being denied inappropriately based on CMS–1682–R even
14 though this Ruling only addressed the classification of CGM receivers as DME and
15 did not address coverage of CGM sensors and transmitters used with insulin
16 pumps." 86 Fed. Reg. at 73898.

17 This rule, Defendant argues, requires the Secretary to cover claims for CGM
18 sensors and transmitters used with insulin pumps, if submitted after February 28,
19 2022. ECF No. 18 at 7. Defendant's argument is essentially that the Secretary
20 cannot possibly continue to reject claims for CMS coverage because this new rule
prevents it from doing so. *See* ECF No. 18 at 8 ("This new rule effectively ensures

1 that future CGM claims submitted by Plaintiff and other similarly-situated
2 Medicare claimants will not be denied on the grounds that a CGM is not DME.”).

3 But so did this Court’s prior order, which the Secretary routinely defied,
4 issuing unfavorable decisions on Plaintiff’s reimbursement claims. Moreover, there
5 is some dispute over whether this new rule makes Plaintiff’s claims as bullet-proof
6 as Defendant suggests, but the Court need not assess the effect of this rule, if any,
7 on Plaintiff’s future reimbursement claims. Even if this rule directly covers the
8 types of claims submitted by Plaintiff, the Court has significant concerns that
9 Defendant will disregard the rule. For the better part of one year, Defendant failed
10 to comply with this Court’s directions to cover Plaintiff’s claims, despite a finding
11 that its position was taken in bad faith. The Court thus has little confidence that
12 Defendant will not similarly defy its own dictates. Accordingly, the Government
13 has failed to meet its heavy burden of persuading the Court that its voluntary change
14 in stance moots this action.⁴

15 **B. Plaintiff is not entitled to a preliminary injunction**

16 Having found that Plaintiff’s claim is not moot, the Court proceeds to analyze
17 the merits of the requested preliminary injunction. Because the Court finds that
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19 _____
20 ⁴ The Court’s assessment of mootness is limited to Plaintiff’s specific claim for
injunctive relief, the Court expresses no judgment on whether the other claims
asserted in Plaintiff’s Complaint are moot.

1 Plaintiff cannot show irreparable harm, a prerequisite to injunctive relief, the Court
2 does not analyze the remaining factors.⁵

3 **1. Irreparable harm**

4 “At a minimum, a plaintiff seeking preliminary injunctive relief must
5 demonstrate that it will be exposed to irreparable harm.” *Caribbean Marine Servs.*
6 *Co. v. Baldrige*, 844 F.2d 668, 674 (9th Cir. 1988). Such harm must be “*likely*, not
7 just possible.” *All. for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1131 (9th Cir.
8 2011). To establish this factor, “[a] plaintiff must do more than merely
9 allege imminent harm sufficient to establish standing; a plaintiff
10 must *demonstrate* immediate threatened injury as a prerequisite to preliminary
11 injunctive relief.” *Caribbean Marine Servs. Co.*, 844 F.2d at 674.

12 On this front, Plaintiff submits that “absent Medicare coverage, a very large
13 portion of the Medicare beneficiaries (including [Plaintiff]) would simply not be
14 able to afford a CGM and, therefore, would suffer the irreparable harms associated
15 with not having a CGM (e.g., death, blindness, loss of limbs, cognitive decline).”
16 But these harms, while undeniably serious, are not immediately threatened. On this
17 point, the Court notes that each of Plaintiff’s reimbursement claims have ultimately
18 been paid, which militates against a finding of immediate threatened injury. Plaintiff
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20 ⁵ For the same reason, the Court does not reach Defendant’s argument that 42 U.S.C.
§ 405(h) bars the injunctive relief Plaintiff seeks.

1 does not allege, nor does the record indicate, that at any point Plaintiff has gone
2 without CGM supplies or been forced to pay for them out of pocket. Nor has
3 Plaintiff shown that the delay in reimbursement has impeded or will impede his
4 ability to receive the CGM supplies in a timely manner. Of course, Plaintiff may
5 renew his motion if these circumstances change.

6 Similarly, Plaintiff has failed to establish irreparable harm to other non-party
7 claimants. Plaintiff's request for injunctive relief seeks a ruling that affects not only
8 his future CGM claims, but also those of all other persons submitting such claims.
9 These unidentified persons are not parties to this action and there is no evidence
10 before the Court suggesting they will suffer the same harm alleged by Plaintiff. "In
11 the absence of medical evidence specific to their need for CGMs," and the absence
12 of medical evidence suggesting that each person submitting a CGM claim will
13 suffer similar harm if not covered, the Court cannot determine that all persons
14 submitting such claims are threatened with immediate, irreparable harm. *Lewis v.*
15 *Becerra*, 2022 WL 123909, at *9 (D.D.C. Jan. 13, 2022). The Court therefore denies
16 Plaintiff's request for a preliminary injunction on this prong alone.

17 Briefly, though, the Court again notes that Defendant has denied at least three
18 of Plaintiff's claims for reimbursement in direct violation of this Court's previous
19 order directing Defendant to cover such claims. This level of disregard is shocking
20 to the Court, and Defendant shall be on notice that should it deny another of

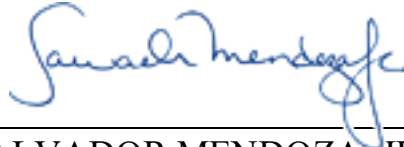
1 Plaintiff's claims on grounds previously held unlawful, the Court will take all
2 enforcement action within its sound discretion.

3 Accordingly, **IT IS HEREBY ORDERED:**

4 **1.** Plaintiff's Motion for Preliminary Injunction, **ECF No. 6**, is **DENIED.**

5 **IT IS SO ORDERED.** The Clerk's Office is directed to enter this Order and
6 provide copies to all counsel.

7 **DATED** this 31st day of March 2022.

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10 SALVADOR MENDOZA, JR.
United States District Judge