

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

CAROL A. LEWIS, et al.,

Plaintiffs,

v.

XAVIER BECERRA,¹ in his official
capacity as Secretary of the Department of
Health and Human Services,

Defendant.

Civil Action No. 18-2929 (RBW)

MEMORANDUM OPINION

The plaintiffs, Carol Lewis and Douglas Sargent, on behalf of themselves and all others similarly situated, bring this civil action against the defendant, Xavier Becerra, in his official capacity as the Secretary (the “Secretary”) of the United States Department of Health & Human Services (the “Department”), pursuant to Title XVIII of the Social Security Act, 42 U.S.C. § 1395ff(b), see Class Action Complaint (“Compl.”) ¶ 8, ECF No. 1; the Administrative Procedure Act (“APA”), 5 U.S.C. § 706, as modified by 42 U.S.C. § 405(g), see id. ¶¶ 146–63; and the Declaratory Judgment Act, 28 U.S.C. §§ 2201, see id. ¶¶ 164–66.² Currently pending before the Court is the plaintiffs’ motion for a preliminary injunction to enjoin “the Secretary from continuing to reject [] claims based on CMS 1682-R and/or the claim that a [continuous

¹ Xavier Becerra is the current Secretary of the United States Department of Health and Human Services, and he is therefore substituted for Alex M. Azar II as the proper party defendant pursuant to Federal Rule of Civil Procedure 25(d).

² On May 30, 2019, the defendant filed a partial motion to dismiss for lack of jurisdiction, see Partial Motion to Dismiss for Lack of Jurisdiction and Failure to State a Claim at 1, ECF No. 22, which the Court granted in part and denied in part on January 29, 2021, see Order at 1 (Jan. 29, 2021), ECF No. 78. The Court granted the motion to dismiss to the extent that it sought to dismiss Counts I and II of the Complaint, alleging violations of 42 U.S.C. § 405(g), and 5 U.S.C. § 706(1). Id. The Court denied the motion in all other respects. Id.

glucose monitor (“CGM”)] is not ‘primarily and customarily used to serve a medical purpose.’” See Plaintiffs’ Motion for Preliminary Injunction (“Pls.’ Mot.” or the “plaintiffs’ preliminary injunction motion”) at 2, ECF No. 97. Upon careful consideration of the parties’ submissions,³ the Court concludes for the following reasons that it must deny the plaintiffs’ motion.

I. BACKGROUND

The Court previously discussed much of the relevant background of this case in detail, see Memorandum Opinion at 2–11 (Jan. 29, 2021), ECF No. 77, and therefore will not reiterate that information again here. The Court will, however, briefly discuss the background of this case as it relates to the issues the Court must consider in deciding the plaintiffs’ preliminary injunction motion.

A. Statutory and Regulatory Background Relating to CGMs

Medicare “Part B is an optional supplemental insurance program that pays for medical items and services . . . , including . . . durable medical equipment.” Ne. Hosp. Corp. v. Sebelius, 657 F.3d 1, 2 (D.C. Cir. 2011) (citing 42 U.S.C. §§ 1395j–1395w-4). However, 42 U.S.C. § 1395y excludes from coverage items and services “not reasonable and necessary for the diagnosis or treatment of illness or injury[.]” 42 U.S.C. § 1395y(a)(1)(A). The Secretary has issued regulations clarifying the definition of “[d]urable medical equipment.” See 42 C.F.R. § 414.202.

Durable medical equipment means equipment, furnished by a supplier or a home health agency that meets the following conditions:

(1) Can withstand repeated use.

³ In addition to the filings already identified, the Court considered the following submissions in rendering its decision: (1) the defendant’s Memorandum in Opposition to Plaintiffs’ Motion for Preliminary Injunction (“Def.’s Opp’n”), ECF No. 99; (2) the plaintiffs Carol Lewis’ and Douglas Sargent’s Reply in Support of Motion for Preliminary Injunction (“Pls.’ Reply”), ECF No. 100; and (3) the defendant’s Surreply in Opposition to Plaintiffs’ Motion for Preliminary Injunction (“Def.’s Surreply”), ECF No. 102.

- (2) Effective with respect to items classified as [durable medical equipment] 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.

Id. The Medicare statute expressly designates “blood-testing strips and blood glucose monitors for individuals with diabetes” as “durable medical equipment” and, therefore, covered. 42

U.S.C. § 1395x(n).

CGMs consist of a “disposable sensor” which “is placed below the skin in the space between tissues (interstitial space) that is filled with fluids going to and from cells.” Compl. ¶ 33. These fluids contain glucose that “is correlated with the glucose in blood itself.” Id. “Current CGM sensors last for a week and measure glucose levels every five to seven minutes (i.e., more than 200 times a day) without requiring patient interaction, including when the patient is sleeping.” Id. The information from the CGM sensors is then “transmitted, via a transmitter, to a CGM receiver/monitor or even a smart phone/tablet. A CGM transmitter typically lasts for several months.” Id. ¶ 34. CGMs monitor users’ blood glucose levels more frequently than traditional blood glucose monitors, see id. ¶ 36; can “trigger an alert[,]” id. ¶ 34; “may be connected to an insulin pump such that the amount of insulin delivered can be automatically controlled based on the sensed glucose levels[,]” id.; and “can plot glucose trends and perform further analyses[,]” id. “Typically, the CGM is calibrated by finger prick/test strip testing twice a day[,]” though “some newer CGMs do not require calibration. Id. ¶ 35.

With respect to the Secretary’s designation and regulatory treatment of CGMs, the plaintiffs contend that

[i]n the period before January 2017, the Secretary frequently denied claims for CGM coverage on the grounds that CGMs were not “durable medical equipment” because they were not “primarily and customarily used to serve a medical purpose.”

This was so, the Secretary contends, because they were “precautionary” – a non-statutory/regulatory term.

Without prior notice and comment, on January 12, 2017, the Secretary issued CMS Ruling 1682-R. There, the Secretary maintained that any CGM which did not completely replace finger sticks was “precautionary” and not covered. The Secretary asserted that if the reading from a CGM sensor had to be confirmed with a fingerstick prior to making a treatment decision, the CGM was not “primarily and customarily used to serve a medical purpose.”

Conversely, CGMs which do replace finger sticks the Secretary labeled “therapeutic” and considered covered. By its own terms, CMS 1682-R was effective as of the very date it issued – i.e., January 12, 2017. Pursuant to 42 C.F.R. § 405.1063, [Administrative Law Judges (“ALJs”)] and the Medicare Appeals Council are bound by CMS Rulings and must apply them. Thus, any claim with a date of service after January 12, 2017, which does not match CMS 1682-R’s definition of “therapeutic” must be rejected.

Pls.’ Mot. at 3 (internal citations omitted). Therefore, unlike blood glucose monitors, CGMs are not covered under Medicare because, as CMS has ruled, they are not “primarily and customarily used to serve a medical purpose” and thus do not constitute “durable medical equipment.”

Centers for Medicare & Medicaid Services Ruling 1682-R (Jan. 12, 2017).

B. Factual Background

The two named plaintiffs in this case, Carol Lewis and Douglas Sargent, are individuals who are eligible for Medicare, have Type I brittle diabetes,⁴ and have been denied coverage for CGMs. Compl. ¶¶ 97, 101–04, 109, 113–25. The plaintiffs state that they and others with diabetes “are in danger of suffering from severe hypoglycemic events.” Pls.’ Mot. at 2; see Compl. ¶ 39. Furthermore, the plaintiffs assert that

[t]hese events, in both the short and long term, cause irreparable injury in the form of injury to various systems of the body. If not treated, in the short term, these

⁴ According to the American Diabetes Association, the term “brittle diabetes” is “not recognized” by the Association, but is “sometimes used to describe when a person’s blood sugar (blood glucose) levels move in extremes from low to high and from high to low.” See For Students: Common Terms, Am. Diabetes Ass’n, <https://www.diabetes.org/resources/students/common-terms> (last visited Dec. 9, 2021).

events can lead to death. In the long term, cumulatively, these events can lead to blindness, nerve damage leading to loss of limbs, kidney damage, and reduced cognitive function.

Id. Regarding the utility of CGMs, the plaintiffs state that “[o]ne purpose of a CGM is to avoid these events by alerting users to out[-]of[-]range glucose values and, when combined with an insulin pump, controlling dispensed insulin.” Pls.’ Mot. at 2–3. Furthermore, the plaintiffs state that

[a]pproximately half of those on Medicare have annual incomes of less than \$30,000 and one quarter of Medicare enrollees have annual incomes of less than \$17,000. As shown in the initial denial of CGM claims for both Mrs. Lewis (AR309) and Mr. Sargent (AR1935 and AR2187) a 90-day supply of CGM sensors costs ~\$1,500 for a yearly of cost of ~\$6,000.

Id. at 4–5.

Both Lewis and Sargent were denied coverage for CGMs, see Compl. ¶¶ 101–04, 113–25, and the plaintiffs allege that “[b]ased on information produced by the Secretary, it is believed that ~13,000 claims are denied on the bad faith/illegal grounds each month[,]” Pls.’ Mot. at 2, based on what they argue is the illegal issuance of CMS 1682-R, id. at 8–9, and the conclusion by one district court that the Secretary acted in “bad faith” by issuing the regulation, id. at 7–8.⁵

C. Procedural Background

On September 22, 2021, the plaintiffs filed their motion for a preliminary injunction. See Pls.’ Mot. at 1.⁶ Thereafter, the defendant filed an opposition on September 29, 2021, see Def.’s

⁵ The plaintiffs also assert that they should be certified as members of a class consisting of “[a]ll persons who submitted claims for coverage of CGM equipment or supplies whose claims were denied (and not later reversed on appeal) since December 13, 2012.” Compl. ¶ 127. The plaintiffs’ motion for class certification is currently pending a ruling by the Court. See Carol Lewis and Douglas Sargent’s Re-Notice of Class Certification Motion (Feb. 26, 2021), ECF No. 81. Therefore, the plaintiffs’ motion for a preliminary injunction concerns only the currently named plaintiffs, Lewis and Sargent.

⁶ On February 26, 2021, the plaintiffs filed their motion for class certification. See Carol Lewis and Douglas Sargent’s Re-Notice of Class Certification Motion (Feb. 26, 2021), ECF No. 81, which has since been fully briefed.

Opp’n at 16; the plaintiffs filed a reply on October 6, 2021, see Pls.’ Reply at 10; and the defendant was permitted to file a surreply on October 20, 2021, see Def.’s Surreply at 5. A hearing was held on the motion for preliminary injunction on November 22, 2021. See Min. Entry (Nov. 22, 2021).

II. STANDARD OF REVIEW

A party moving for a preliminary injunction must show “(1) a substantial likelihood of success on the merits, (2) that [he or she] would suffer irreparable injury if the injunction were not granted, (3) that an injunction would not substantially injure other interested parties, and (4) that the public interest would be furthered by the injunction.” Chaplaincy of Full Gospel Churches v. England, 454 F.3d 290, 297 (D.C. Cir. 2006). In “seeking a preliminary injunction, the movant has the burden to show that all four factors, taken together, weigh in favor of the injunction.” Abdullah v. Obama, 753 F.3d 193, 197 (D.C. Cir. 2014) (internal quotation marks omitted).⁷

III. ANALYSIS

The plaintiffs argue that they are entitled to “a preliminary injunction barring the Secretary from continuing to reject CGM claims based on CMS 1682-R and/or the claim that a CGM is not ‘primarily and customarily used to serve a medical purpose.’” Pls.’ Mot. at 2.

⁷ “The four factors have typically been evaluated on a ‘sliding scale[.]’” in this jurisdiction. Davis v. Pension Ben. Guar. Corp., 571 F.3d 1288, 1291 (D.C. Cir. 2009). But the Supreme Court’s decision in Winter v. Natural Resources Defense Council, Inc., 555 U.S. 7 (2008), casts doubt on the propriety of that approach. See Save Jobs USA v. U.S. Dep’t of Homeland Sec., 105 F. Supp. 3d 108, 112 (D.D.C. 2015) (noting that “[i]t is not clear whether th[e sliding scale] approach survives after Winter, which suggested that a likelihood of success on the merits must always be shown”). Indeed, “the [District of Columbia] Circuit has suggested that a positive showing on all four preliminary injunction factors may be required.” Holmes v. Fed. Election Comm’n, 71 F. Supp. 3d 178, 183 n.4 (D.D.C. 2014). And at least some Circuit judges have “read Winter at least to suggest[—]if not to hold[—]‘that a likelihood of success is an independent, freestanding requirement for a preliminary injunction[.]’” Sherley v. Sebelius, 644 F.3d 388, 393 (D.C. Cir. 2011) (citing Davis, 571 F.3d at 1296 (Kavanaugh, J., concurring)). However, “[i]t matters not in this case whether the [C]ourt applies the sliding scale: either way, [the p]laintiffs have not met their burden.” Pantoja v. Martinez, Civil Action No. 21-2197 (APM), 2021 WL 4891532, at *3 (D.D.C. Oct. 19, 2021).

According to the plaintiffs, “[t]he Secretary’s underlying position on which the claim denials in this case are based is in bad faith,” *id.*, based in part on the Secretary’s illegal issuance of CMS 1682-R “[w]ithout prior notice and comment . . . [in] violation of 42 U.S.C. § 1395hh,” *id.* at 8. The plaintiffs further contend that “[a] preliminary injunction will prevent tens of thousands of persons from continuing to suffer from the Secretary’s bad faith misconduct.” *Id.* at 2.

In addition to contesting the merits of the plaintiffs’ request for a preliminary injunction, Def.’s Opp’n at 12–16, the defendant also lodges two jurisdictional and procedural arguments. First, the defendant argues that because the plaintiffs’ requested relief constitutes “prospective relief,” *id.* at 1, pursuant to the channeling requirement under 42 U.S.C. § 405(h), “judicial review may be had only after [each] claim has been presented to the Secretary[,]” and, that having not occurred, this Court does not have jurisdiction, *id.* at 8 (quoting Am. Chiropractic Ass’n v. Leavitt, 431 F.3d 812, 816 (D.C. Cir. 2005)). Second, the defendant argues that the proposed injunction would constitute a “[n]ationwide injunction,” which is “irreconcilable with [] constitutional and equitable limitations, because [it] extend[s] relief to those who [are] not ‘plaintiffs in the lawsuit,’” *id.* at 11 (alterations omitted) (quoting Lewis v. Casey, 518 U.S. 343, 358 (1996)). The Court will first address the defendant’s jurisdictional and procedural arguments.

A. The Defendant’s Jurisdictional and Procedural Arguments

1. Jurisdiction

The defendant argues that the plaintiffs’ requested relief constitutes prospective relief because it requests that the Secretary be precluded from denying future claims for CGMs, and is therefore subject to the channeling requirement of 42 U.S.C. § 405(h). *See* Def.’s Opp’n at 7–11. Thus, the defendant argues, “judicial review may be had only after the claim has been

presented to the Secretary.” Id. at 8 (alteration omitted) (quoting Am. Chiropractic Ass’n, 431 F.3d at 816). The defendant relies principally on Porzecanski v. Azar, where the Circuit ruled that ““after channeling a single claim for “medical and other health services”” under Medicare Part B, ‘a Medicare beneficiary’ cannot ‘obtain prospective equitable relief mandating that [the Department] recognize his treatment as a covered Medicare benefit in all future claim determinations.”” Id. at 9 (quoting Porzecanski v. Azar, 943 F.3d 472, 475 (D.C. Cir. 2019)). The defendant argues that the “plaintiffs seek a preliminary injunction that would ‘functionally determine future claims,’” and thus are requesting prospective relief. See id. at 10 (quoting Porzecanski, 943 F.3d at 484).

In response, the plaintiffs contend that their request is not for prospective relief, as “the ‘agency action’ being challenged is both the illegal issuance of CMS 1682-R^[8] and the denial of [the p]laintiffs’ claims” and “[t]hus, the result of this litigation w[ould], in addition to providing coverage for the denied claims, be the invalidation and vacatur of CMS 1682-R.” Pls.’ Reply at 3. The plaintiffs rely heavily on Bowen v. Michigan Academy of Family Physicians in emphasizing that “[c]hallenges to the validity of the Secretary’s instructions and regulations are cognizable in courts of law.” Id. (quoting Bowen, 476 U.S. 667, 680 (1986)). Further, the plaintiffs argue that this judicial review of the defendant’s “illegal” actions extends to the power to “enjoin agencies from enforcing regulations that have been found [to be] invalid.” Id. at 4 (alteration added) (quoting Blue Cross and Blue Shield Ass’n v. Shalala, Nos. 90-1528 (RCL), 90-1356 (RCL), 1996 WL 636131, at *3 (D.D.C. Aug. 27, 1996)). The plaintiffs’ basis for jurisdiction therefore rests heavily on the characterization of the defendant’s determination regarding CGMs as “illegal and [in] bad faith,” id. at 3, which they contend permits the court to

⁸ The plaintiffs contend that CMS 1682-R is illegal because it was issued without prior notice and comment in violation of 42 U.S.C. § 1395hh. See Pls.’ Mot. at 8.

exercise jurisdiction to enjoin illegal and bad faith conduct by the agency. See id. at 3–4.

Section 405(h) states that “[t]he findings and decision of the Commissioner of Social Security after a hearing shall be binding . . . [and n]o findings of fact or decision of the Commissioner of Social Security shall be reviewed by any person, tribunal, or governmental agency, except as herein provided.” 42 U.S.C. § 405(h). Section 405(g) provides for judicial review within 60 days of a decision rendered by the Secretary.⁹ See id. ¶ 405(g). Thus, these provisions require that claims must be channeled first through the Secretary before judicial review is sought. See Am. Chiropractic Ass’n, 431 F.3d at 816 (“Judicial review may be had only after the claim has been presented to the Secretary and administrative remedies have been exhausted. This bar against [federal question] actions applies to all claims that have their standing and substantive basis in the Medicare Act.” (internal citations and quotation marks omitted)).

“Litigants generally may seek review of agency action in district court under any applicable jurisdictional grant.” Jarkesy v. Secs. & Exchange Comm’n, 803 F.3d 9, 15 (D.C. Cir. 2015). However, “[i]f a special statutory review scheme exists,” id., “it is ordinarily supposed that Congress intended that procedure to be the exclusive means of obtaining judicial review in those cases to which it applies[.]” City of Rochester v. Bond, 603 F.2d 927, 931 (D.C. Cir. 1979). In assessing whether “Congress intended that a litigant proceed exclusively through a statutory scheme of administrative and judicial review[.]” Jarkesy, 803 F.3d at 15, a court must assess whether (1) “such intent is ‘fairly discernable in the statutory scheme,’” id. (quoting Thunder Basin Coal Co. v. Reich, 510 U.S. 200, 207 (1994)), and (2) “the litigant’s claims are

⁹ Although the statute technically refers to the “Commissioner of Social Security,” these same provisions apply to the Medicare Act, “with any reference to the ‘Commissioner of Social Security’ considered as one to the Secretary of [the Department].” 42 U.S.C. § 405(g).

‘of the type Congress intended to be reviewed within the statutory structure[.]’” *id.* (alteration omitted) (quoting Thunder Basin Coal Co., 510 U.S. at 212).

Here, the plaintiffs’ claims clearly fall within the purview of the following provisions referenced by the defendant because they are claims arising substantively under the Medicare Act.

Three statutes create the scheme for obtaining judicial review of Medicare claims. First, 42 U.S.C. § 405(h) divests the district courts of federal-question jurisdiction “on any claim arising under” Title II of the Social Security Act, and it bars any “decision of the Commissioner of Social Security” from being judicially reviewed, “except as herein provided” in other Title II provisions. Second, 42 U.S.C. § 405(g) provides for judicial review of Social Security Act claims, thus creating the exception “herein provided.” In pertinent part, it permits any person to file a civil action, “after any final decision of the Commissioner of Social Security made after a hearing to which he was a party,” to “obtain a review of such decision” in federal district court. Third, 42 U.S.C. § 1395ii states that certain provisions in § 405 and elsewhere in Title II “shall also apply with respect to” Title XVIII of the Social Security Act—*i.e.*, the Medicare Act—“to the same extent as they are applicable with respect to” Title II, with any reference to the “Commissioner of Social Security” considered as one to the Secretary of [the Department].

Am. Hosp. Ass’n v. Azar, 895 F.3d 822, 825 (D.C. Cir. 2018).

Because of the presentment requirement outlined above, the question for the Court to resolve is whether the injunctive relief requested by the plaintiffs constitutes “prospective relief,” and therefore requires that they exhaust their administrative remedies for each individual future claim before seeking judicial review. Because the plaintiffs seek to invalidate CMS 1682-R—and thus prevent it from being applied to deny future claims—and because district courts have the indisputable power to enjoin illegal agency action, *see, e.g., Serv. Emps. Int’l Union, AFL-CIO v. Gen. Servs. Admin.*, 830 F. Supp. 5, 8–9, 11 (D.D.C. 1993) (enjoining the enforcement of a regulation after finding it invalid); Blue Cross & Blue Shield Ass’n, 1996 WL 636131, at *3 (“[C]ourts frequently enjoin agencies from enforcing regulations that have been found invalid.”),

the Court concludes that the presentment requirement of § 405(h) does not apply here.

The relief requested by the plaintiffs is distinct from a request that the Court order the Department to grant each future claim made by the plaintiffs. Instead, the requested relief is the invalidation and prevention of enforcement of the rule that has been the basis for denying their claims in the past. See Pls.’ Mot. at 10–11 (“[T]he sought[-]after injunction will not require that claims are approved[—]it will merely preclude the Secretary from denying claims on ‘bad faith’/illegal grounds.”). Thus, granting the requested relief would not have the effect of requiring a particular result on future claims for CGMs; rather, granting the relief would require only that claims for CGMs not be denied based on the rule adopted by CMS 1682-R. Although this outcome might affect future claims, granting the plaintiffs’ injunction would not qualify as prospective relief because the Court would be addressing the enforcement of a purportedly invalid regulation, which the Court has the authority to enjoin, see Blue Cross and Blue Shield Ass’n, 1996 WL 636131, at *3 (“[C]ourts frequently enjoin agencies from enforcing regulations that have been found [to be] invalid.”). Accordingly, the Court has jurisdiction to consider the validity of CMS 1682-R and thus rule on the plaintiffs’ request for a preliminary injunction.

2. Limitations on Injunctive Relief

The defendant next argues that the plaintiffs’ “proposed injunction [] ‘preclude[s] the Secretary from denying claims on [certain] grounds,’” therefore rendering the injunction applicable to the class proposed by the plaintiffs, and not just to the plaintiffs themselves. Def.’s Opp’n at 11 (alteration omitted) (quoting Pls.’ Mot. at 11). The defendant then opines that, without a class having already been certified, granting the relief requested would constitute a “nationwide injunction[,]” that is “irreconcilable with [] constitutional and equitable limitations, because [such injunctions] extend relief to those who [are] not ‘plaintiff[s] in the lawsuit, and

hence [are] not the proper object of the court’s remediation.” Id. (some alterations in original) (quoting Lewis, 518 U.S. at 358).

In response, the plaintiffs again frame the requested relief as the invalidation of CMS 1682-R, which would necessarily result in preventing the denial of claims based on the regulation. See Pls.’ Reply at 4. Viewed from this perspective, the plaintiffs contend that they are not requesting relief on behalf of the class they seek to have certified, even though others would benefit from such a ruling in their favor. Id. (“[W]hen a regulation is determined to be invalid, the result is the invalidation of the regulation for everyone[—]not just the parties before the Court.” (citing Blue Cross & Blue Shield Ass’n, 1996 WL 636131, at *2–3)).

Regarding the Court’s authority to issue an injunction that impacts other individuals who are not before the Court, “[w]hen a reviewing court determines that agency regulations are unlawful, the ordinary result is that the rules are vacated—not that their application to the individual petitioners [or anyone else] is proscribed.” Harman v. Thornburgh, 878 F.2d 484, 495 n.21 (D.C. Cir. 1989). Injunctions having broad impact that stem from a facial challenge to a regulation are distinguishable from the “nationwide injunctions” referenced by the defendant. See Nat’l Mining Ass’n v. U.S. Army Corps of Eng’rs, 145 F.3d 1399, 1409 (D.C. Cir. 1998). Indeed, where a case does not “involve a facial challenge to the validity of a regulation[,] . . . a sweeping injunction would [likely] not be a proper remedy[.]” Id. But where a party does bring a facial challenge to a regulation, the enjoining of which would necessarily affect a large number of people, the general rule that injunctive relief should generally be limited to those who have suffered an injury and who are parties to the case does not apply, as broader relief in cases like this one is a valid and unavoidable by-product of an injunction based on a challenge to an agency regulation or rule. See Blue Cross and Blue Shield Ass’n, 1996 WL 636131, at *2–3.

If the Court were to accept the defendant's characterization of the type of relief requested by the plaintiffs as a "nationwide injunction[]," Def.'s Opp'n at 11, it would effectively preclude challenges to the validity of any agency rule or regulation simply because precluding enforcement of the rule or regulation would affect not only parties seeking the relief, but also others who are subject to its application. Here, the plaintiffs contend, inter alia, that the defendant issued CMS 1682-R in violation of the Medicare statute's notice and comment requirements. Pls.' Mot. at 8 (citing 42 U.S.C. §§ 1395hh(a)(2), 1395hh(b)–(c)). The defendant does not argue that the Court lacks jurisdiction to consider this claim, nor could he. Blue Cross & Blue Shield Ass'n, 1996 WL 636131, at *2–3 ("[T]he government has failed to explain how it could have the authority to enforce an invalid regulation against a similar entity simply because that entity was not part of the litigation."). Rather, he essentially concedes that the plaintiffs are not jurisdictionally barred from seeking a ruling that would declare CMS 1682-R illegal, but that the Court lacks jurisdiction to entertain a request for injunctive relief that would have to be based on a finding that the plaintiffs are likely to prevail on their claim that the regulation was illegally issued. In either case, a favorable ruling for the plaintiffs would impact not only the plaintiffs, the only distinction being that prevailing on the injunction request would be only temporary. The Court can perceive of no reason why the Court's authority to exercise jurisdiction should differ in the two circumstances. And, as the Circuit concluded in the Administrative Procedure Act context:

The . . . Act permits suit to be brought by any person "adversely affected or aggrieved by agency action." In some cases the "agency action" will consist of a rule of broad applicability; and if the plaintiff prevails, the result is that the rule is invalidated, not simply that the court forbids its application to a particular individual. Under these circumstances a single plaintiff, so long as he is injured by the rule, may obtain "programmatic" relief that affects the rights of parties not before the [C]ourt.

Nat'l Mining Ass'n, 145 F.3d at 1409 (citing Lujan v. Nat'l Wildlife Fed'n, 497 U.S. 871, 913 (1990)). This reasoning applies equally here. Therefore, the Court finds that it has jurisdiction to entertain the plaintiffs' request for a preliminary injunction.

B. The Merits of the Plaintiffs' Request for a Preliminary Injunction

1. Irreparable Harm

The Court will begin its analysis of the plaintiff's request for injunctive relief by considering whether the plaintiffs have sufficiently shown "harm [that is] certain and great . . . and so imminent that there is a clear and present need for equitable relief to prevent irreparable harm." League of Women Voters v. Newby, 838 F.3d 1, 7 (D.C. Cir. 2016) (citation, internal quotation marks, and alterations omitted). "[P]ossibility of irreparable harm" is not sufficient. Winter, 555 U.S. at 22. "[P]roving 'irreparable' injury is a considerable burden," Power Mobility Coal. v. Leavitt, 404 F. Supp. 2d 190, 204 (D.D.C. 2005) (Walton, J.) (quoting Wis. Gas Co. v. Fed. Energy Regul. Comm'n, 758 F.2d 669, 674 (D.C. Cir. 1985)), "requiring proof that the movant's injury is 'certain, great and actual—not theoretical—and imminent, creating a clear and present need for extraordinary equitable relief to prevent harm[.]'" id. (emphasis omitted) (quoting Varicon Int'l v. Off. of Pers. Mgmt., 934 F. Supp. 440, 447 (D.D.C. 1996)).

The plaintiffs argue that "the very purpose of a CGM is to avoid severe hypoglycemic events that cause irreparable damage to the body, including death[.]" and, without Medicare coverage, many "beneficiaries would simply not be able to afford a CGM and, therefore, would suffer the irreparable harms associated with not having a CGM (e.g., death, blindness, loss of limbs, cognitive decline)." Pls.' Mot. at 9. The plaintiffs assert generally that "the Secretary [merely] faults [the p]laintiffs for not seeking the 'extraordinary' remedy of a preliminary

injunction sooner.” Pls.’ Reply at 7. More specifically, the plaintiffs represent that they “did not seek the ‘extraordinary’ remedy of a preliminary injunction sooner” for two reasons:

First, exactly as stated, a preliminary injunction is an “extraordinary” remedy and, therefore, if at all tolerable, it would be better to get a ruling on the merits rather than seeking such a remedy and creating more paperwork and issues for a Court to deal with. Thus, [they] would have preferred not to seek such a remedy and instead get a ruling on the merits – if it could be done in a remotely reasonable time. Simultaneously, it was hoped that the Secretary would come to his senses and cease the unreasonable conduct.

Id.

Despite their explanations, a “plaintiff[s] extensive delay in seeking a preliminary injunction weighs heavily against a finding of irreparable harm.” Maldonado v. District of Columbia, Civil Action No. 10-1511 (RJL), 2019 WL 6877913, at *3 (D.D.C. Dec. 16, 2019). This is because “[a]n unexcused delay in seeking extraordinary injunctive relief may be grounds for denial because such delay implies a lack of urgency and irreparable harm.” Newdow v. Bush, 355 F. Supp. 2d 265, 292 (D.D.C. 2005). With respect to specific lengths of time, the Circuit has found a delay of 44 days in seeking an injunction “inexcusable,” see Fund for Animals v. Frizzell, 530 F.2d 982, 987 (D.C. Cir. 1976), and this Court has found that a delay of two months “militates against a finding of irreparable harm,” see Mylan Pharms., Inc. v. Shalala, 81 F. Supp. 2d 30, 44 (D.D.C. 2000).

Here, the Court finds that the plaintiffs have shown that their potential harm is “great” and “actual”, see League of Women Voters, 838 F.3d at 8, as the harm the plaintiffs reference entails significant and potentially irreparable health issues, including possible death caused by uncontrolled hypoglycemic events. See Pls.’ Mot. at 2 (“[The plaintiffs’ potential hypoglycemic] events, in both the short and long term, cause irreparable injury in the form of injury to various systems of the body. If not treated, in the short term, these events can lead to

death. In the long term, cumulatively, these events can lead to blindness, nerve damage leading to loss of limbs, kidney damage, and reduced cognitive function.”). Nonetheless, the fact that the plaintiffs waited three years into this litigation to move for a preliminary injunction “implies a lack of [the] urgency” that would accompany an imminent and irreparable harm. See Newdow, 355 F. Supp. 2d at 292.

In Maldonado, an analogous case, the plaintiffs sought a preliminary injunction “compelling the District [of Columbia] to provide individualized notice to persons denied Medicaid coverage for [] prescriptions,” Maldonado, 2019 WL 6877913, at *1, citing health consequences that resulted from plaintiffs being unable to obtain certain prescriptions due to Medicaid denials and lack of notice of these denials, id. at *1–2. Despite the health concerns at stake for the plaintiffs, the Court found that they had not made an adequate showing of irreparable harm due to their significant years-long delay in moving for a preliminary injunction. Id. at *3–4. Furthermore, the Court found the plaintiffs’ explanations for delay, which included strategic litigation choices such as engaging in settlement discussions, id., unpersuasive because ultimately the delay in moving for a preliminary injunction demonstrated a lack of urgency, id. at *4. Here, as in Maldonado, despite the health concerns at stake, a significant years-long delay in seeking preliminary injunctive relief “implies a lack of urgency.” Newdow, 355 F. Supp. 2d at 292. Furthermore, although the plaintiffs may have valid strategic reasons for not requesting a preliminary injunction earlier,¹⁰ see Pls.’ Reply at 7–8 (citing a desire to obtain a ruling on the merits, as well as the later development of case law to better support a motion for preliminary

¹⁰ The Court notes that, although the plaintiffs provided litigation-related reasons for their delay in seeking a preliminary injunction, they provided no case law or other authority regarding the import of these explanations. See generally Pls.’ Reply.

injunction, as reasons for the plaintiffs' delay),¹¹ with respect to preventing a true "irreparable harm" as contemplated by the preliminary injunction standard, the plaintiffs could have made this request at any time in the past three years but chose not to do so.

Additionally, while the plaintiffs argue that they need CGMs to monitor their diabetes, see Compl. ¶¶ 2, 36–38; Pls.' Mot. at 9–10 (highlighting Sargent's history of hypoglycemic events requiring medical attention prior to his use of a CGM, compared to the lack of events during his use of a CGM), they have not introduced any medical evidence that the named plaintiffs face the potential of suffering a life-endangering event if they cannot acquire CGMs, see generally Compl.; Pls.' Mot.; Pls.' Reply. In the absence of medical evidence specific to their need for CGMs, as opposed to traditional blood glucose monitors, the plaintiffs have failed to demonstrate with the degree of certainty required to satisfy the irreparable harm requirement, having failed to illustrate "harm [that is] certain and great . . . and so imminent that there is a clear and present need for equitable relief to prevent irreparable harm." League of Women Voters, 838 F.3d at 7. Although the plaintiffs' delay in seeking injunctive relief weighs most heavily against a finding of irreparable harm and is the primary reason for the Court's finding on this point, the lack of certainty of injury in the absence of the relief requested further compounds the implication of a lack of urgency presented by the plaintiffs' extensive delay in filing their motion. Cf. Air Transp. Assoc. of Am., Inc. v. Export-Import Bank of the U.S., 840 F. Supp. 2d 327, 340 (D.D.C. 2012) (stating that, while unreasonable delay was not the sole reason the Court denied the plaintiffs' motion for a preliminary injunction, "this inaction, coupled with the

¹¹ The plaintiffs also cite complications related to the COVID-19 pandemic as further reasons for their delay in seeking a preliminary injunction. See Pls.' Reply at 9. However, while the pandemic has certainly made the progression of litigation more challenging, if the potential injury faced by the plaintiffs is as severe and imminent as the plaintiffs claim, the pandemic should not have hindered their efforts to this extent. In any case, the pandemic does not excuse the significant delay in filing a motion for preliminary injunction that elapsed between the filing of this case in 2018 and the onset of the pandemic in 2020.

economic and speculative nature of [the p]laintiffs’ alleged impending harm, dictates against the granting of injunctive relief”).

Therefore, because there has been a significant delay in requesting a preliminary injunction that “implies a lack of urgency[,]” Newdow, 355 F. Supp. 2d at 292, and “weighs heavily against a finding of irreparable harm[,]” Maldonado, 2019 WL 6877913, at *3, the plaintiffs have not met their burden to show irreparable harm.

2. The Remaining Preliminary Injunction Factors

A party seeking a preliminary injunction also “bears the burden of demonstrating a ‘substantial likelihood of success on the merits,’” E.M. v. Shady Grove Reprod. Sci. Ctr. P.C., Civil Action No. 19-657 (RC), 2020 WL 7264048, at *3 (D.D.C. Dec. 10, 2020) (quoting Howard v. Evans, 193 F. Supp. 2d 221, 226 (D.D.C. 2002)), and that “the balance of harms and public interest” factors weigh in their favor—factors that merge when “the government is a party to the litigation,” Afghan Yar Int’l Constr. Co. v. U.S. Dep’t of State, Civil Action No. 21-1740 (CKK), 2021 WL 3472275, at *18 (D.D.C. Aug. 6, 2021) (internal quotation marks and citations omitted). Furthermore, of the four factors, “likelihood of success on the merits and irreparable harm are particularly crucial,” E.M., 2020 WL 7264048, at *2, and a court “may deny a motion for [a] preliminary injunction, without further inquiry, upon finding that a plaintiff is unable to show either irreparable injury or a likelihood of success on the merits,” Standing Rock Sioux Tribe v. U.S. Army Corps of Eng’rs, 205 F. Supp. 3d 4, 26 (D.D.C. 2016) (emphasis in original).

In seeking to establish a likelihood of success on the merits, the plaintiffs rely on five recent district court opinions, which have “already rejected the Secretary’s assertion that a CGM is not ‘primarily and customarily used to serve a medical purpose[,]’” and thus found CMS 1682-R invalid. Pls.’ Mot. at 7; see id. at 7–8 (collecting cases). The plaintiffs also claim that

CMS 1682-R is invalid because it was issued without notice and comment, see id. at 8–9, a claim that the defendant does not address, see generally Def.’s Opp’n; Def.’s Surreply. In seeking to establish the final two preliminary injunction factors, the plaintiffs argue regarding the balance of equities factor that they “and the public have an interest in the laws passed by Congress . . . [and] regulations adopted in accordance with the law being enforced[,]” and that the plaintiffs have an interest in “continuing to live and avoiding the permanent physical damage that results from each diabetic event.” Pls.’ Mot. at 10.

The plaintiffs appear to have made a colorable claim with respect to their likelihood of success on the merits, based on the referenced decisions from other district courts which have found CMS 1682-R, and thus denials based on CMS 1682-R, invalid. See id. at 7 (collecting cases). The lack of disagreement by the Secretary regarding the failure to comply with notice and comment requirements before issuing CMS 1682-R further supports the plaintiffs’ likelihood of success on the merits. However, because a court “may deny a motion for [a] preliminary injunction, without further inquiry, upon finding that a plaintiff is unable to show either irreparable injury or a likelihood of success on the merits[,]” Standing Rock Sioux Tribe, 205 F. Supp. 3d at 26 (emphasis in original), the Court need not consider the remaining factors, as is the case here, where the plaintiffs have failed to show irreparable harm.¹² See CityFed Fin. Corp. v. Off. of Thrift Supervision, 58 F.3d 738, 747 (D.C. Cir. 1995) (“Because [the plaintiff] has made no showing of irreparable injury here, that alone is sufficient for us to conclude that the district

¹² The plaintiffs argue that the preliminary injunction factors should be evaluated on a sliding scale, Pls.’ Mot. at 6, in that “if the movant makes an unusually strong showing on one of the factors, then it does not necessarily have to make as strong a showing on another factor,” Davis, 571 F.3d at 1291. However, as previously stated, the Supreme Court’s decision in Winter v. Natural Resources Defense Council, Inc., 555 U.S. 7 (2008), casts doubt on the propriety of that approach. See Save Jobs USA, 105 F. Supp. 3d at 112 (noting that “[i]t is not clear whether th[e sliding scale] approach survives after Winter, which suggested that a likelihood of success on the merits must always be shown”). Indeed, “the [District of Columbia] Circuit has suggested that a positive showing on all four preliminary injunction factors may be required.” Holmes, 71 F. Supp. 3d at 183 n.4.

court did not abuse its discretion by rejecting [the plaintiff's] request.”); Sea Containers Ltd. v. Stena AB, 890 F.2d 1205, 1210–11 (D.C. Cir. 1989) (upholding a district court decision denying a request for a preliminary injunction where the moving party may have been “likely to succeed” but did not show irreparable harm); Fisheries Survival Fund v. Jewell, 236 F. Supp. 3d 332, 337 (D.D.C. 2017) (“The court need not consider the remaining preliminary injunction factors in light of the lack of irreparable harm.”).

IV. CONCLUSION

For the foregoing reasons, the Court concludes that it must deny the plaintiffs’ motion for a preliminary injunction.

SO ORDERED this 13th day of January, 2022.¹³

REGGIE B. WALTON
United States District Judge

¹³ The Court will contemporaneously issue an Order consistent with this Memorandum Opinion.