

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

CAROL A. LEWIS, et al.,

Plaintiffs,

v.

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

Defendant.

Civil Action No. 18-2929 (RBW)

MEMORANDUM OPINION

The plaintiffs, Carol Lewis and Douglas Sargent, bring this civil action against Xavier Becerra, in his official capacity as the Secretary (the “Secretary”) of the United States Department of Health and 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. ¶¶ 164–66.¹ Currently pending before the Court is the Defendant’s Motion for Partial Entry of Judgment in Plaintiffs’ Favor, and to Dismiss Remaining Causes of Action and Claims for Relief on Mootness Grounds (“Def.’s Mot.” or the “Secretary’s motion”), ECF No. 120. Upon careful

¹ On May 30, 2019, the Secretary 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, which alleged 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.

consideration of the parties' submissions,² the Court concludes for the following reasons that it must grant the Secretary's motion.

I. BACKGROUND

The Court previously set forth the factual background of this case in three prior Memorandum Opinions, which were issued on January 29, 2021, see Memorandum Opinion at 2–11 (Jan. 29, 2021), ECF No. 77; January 13, 2022, see Lewis v. Becerra, No. 18-cv-2929 (RBW), 2022 WL 123909, at *1–3 (D.D.C. Jan. 13, 2022); and April 28, 2022, see Lewis v. Becerra, No. 18-cv-2929 (RBW), 2022 WL 1262122, at *2–4 (D.D.C. Apr. 28, 2022). Thus, the Court will not reiterate it in full again here. The Court will, however, set forth the factual background and procedural history that are pertinent to the resolution of the pending motion.

A. Statutory and Regulatory Background Relating to Continuous Glucose Monitors

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). The Secretary has issued a regulation clarifying the definition of “[d]urable medical equipment[.]” which states:

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 [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.

² In addition to the filings already identified, the Court considered the following submissions in rendering its decision: (1) the Plaintiffs' Opposition to the Secretary's Motion (“Pls.’ Opp’n”), ECF No. 124; and (2) the defendant's Reply in Support of Defendant's Motion for Partial Entry of Judgment in Plaintiffs' Favor, and to Dismiss Remaining Causes of Action and Claims for Relief on Mootness Grounds (“Def.’s Reply”), ECF No. 125.

42 C.F.R. § 414.202. The Medicare statute, 42 U.S.C. §§ 1395–1395lll, expressly designates “blood-testing strips and blood glucose monitors for individuals with diabetes” as “durable medical equipment” and, therefore, covered under Medicare Part B. 42 U.S.C. § 1395x(n). However, the Centers for Medicare and Medicaid Services (“CMS”) has not always applied the “durable medical equipment” designation to continuous glucose monitors (“CGMs”). CGMs are devices that consist of “disposable sensor[s]” which “[are] placed below the skin in the space between tissues (interstitial space) that is filled with fluids going to and from cells” and “last for a week[,] [] measur[ing] 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.” Compl. ¶ 33.

1. CMS 1682-R

On January 12, 2017, CMS issued CMS 1682-R,³ a ruling which concluded that “in all [] cases in which a CGM does not replace a blood glucose monitor for making diabetes treatment decisions, a CGM is not considered [durable medical equipment].” Centers for Medicare & Medicaid Services Ruling 1682-R (“CMS 1682-R”) (Jan. 12, 2017) at 15. This ruling applied to all claims for CGMs submitted on or after January 12, 2017, and “[t]hus, after January 12, 2017, all levels of Medicare . . . were required to deny CGM cla[i]ms . . . whenever the presented CGM did not replace [a blood glucose monitor].” Id. at 7. Although CMS’s former ongoing classification of CGMs as not constituting “durable medical equipment” formed the basis for all claims denials alleged in this case, CMS’s application of CMS 1682-R specifically formed the

³ CMS 1682-R is a “CMS Ruling.” See Centers for Medicare & Medicaid Services Ruling 1682-R (“CMS 1682-R”) (Jan. 12, 2017) at 1. CMS Rulings are “precedent final opinion[s] or order[s] or statement[s] of policy or interpretation that ha[ve] not been published in the Federal Register as a part of a regulation or of a notice implementing regulations, but which ha[ve] been adopted by CMS as having precedent[.]” 42 C.F.R. § 401.108(a). These rulings are “binding on all CMS components[and] on all [United States Department of Health and Human Services] components that adjudicate matters under the jurisdiction of CMS[.]” § 401.108(c).

basis for the Secretary’s denial of plaintiff Sargent’s second claim referenced in this case. See infra Section I.B.

2. Proposed and Final Rules

CMS has since rescinded and replaced CMS 1682-R. On November 4, 2020, CMS issued a proposed rule to, among other things, “classify [all] . . . [CGMs] as [durable medical equipment] under Medicare Part B[.]” 85 Fed. Reg. 70,358, 70,358 (Nov. 4, 2020); see id. at 70,398–70,404. After proceeding through the notice-and-comment rulemaking process, see 86 Fed. Reg. 73,860, 73,862–73,863 (Dec. 28, 2021), CMS issued its final rule on December 28, 2021, formally replacing CMS 1682-R and “classify[ing] . . . [CGMs] as [durable medical equipment] under Medicare Part B[.]” id. at 73,860; see id. at 73,896–73,902. This final rule went into effect on February 28, 2022. See id. at 73,860.

3. TDL-220257

In order to apply the December 28, 2021 final rule to claims for reimbursement which predated the February 28, 2022 effective date, on February 25, 2022, CMS issued a “technical direction letter, TDL-220257,⁴ to its Durable Medical Equipment Medicare Administrative Contractors[.]” Def.’s Mot. at 6, instructing contractors to apply the new rule to reimbursement claims submitted prior to February 28, 2022, see id., Exhibit (“Ex.”) D (Technical Direction Letter) at 2–3, ECF No. 120-7.

4. CMS Ruling 1738-R

On May 13, 2022, CMS issued CMS Ruling 1738-R, which “rescind[s] . . . [CMS]1682-R . . . and instead applies the terms of the December 28, 2021 final rule . . . to

⁴ The “technical direction letter” was a letter sent from CMS to all Medicare Administrative Contractors, which “provide[d] instructions . . . regarding Medicare benefit policy classification and payment for . . . [CGMs]” in light of the December 28, 2021 final rule. See Def.’s Mot., Exhibit (“Ex.”) D (Technical Direction Letter) at 1, ECF No. 120-7.

Medicare Part B and Part C claims for payment of . . . []CGMs[.]” Centers for Medicare & Medicaid Services Ruling 1738-R (“CMS 1738-R”) (May 13, 2022) at 1. The ruling further provides that

[i]f a CGM monitor or receiver and/or its necessary supplies and accessories has been furnished to a Medicare beneficiary before the February 28, 2022 effective date of the December 2021 final rule and payment for the CGM is claimed under Part B . . . then the substantive CGM classification, coverage, and payment policies established by the December 2021 final rule and adopted in this Ruling shall be applied to claims for a CGM monitor or receiver and/or its necessary supplies and accessories where . . . a valid CGM claim or valid CGM appeal was pending as of February 28, 2022[.]

Id. at 9.

B. The Plaintiffs

The two plaintiffs in this case are individuals who are Medicare eligible, see Compl. ¶¶ 20–21, have Type I brittle diabetes, see id. ¶¶ 97, 109, and were denied coverage for CGMs based on CMS’s refusal to classify CGMs as “durable medical equipment” under CMS 1682-R, see id. ¶¶ 101–04, 113–25. Specifically, three coverage denials form the basis of the plaintiffs’ claims against the Secretary—Lewis’s coverage claim was denied on March 31, 2016, see id. ¶ 101, and Sargent’s two coverage claims were denied on September 9, 2016, see id. ¶ 113, and April 21, 2017, see id. ¶ 121. The Secretary represents—and the plaintiffs do not contest, see generally Pls.’ Opp’n—that, following issuance of technical direction letter TDL-220257 on February 25, 2022, “CMS directed its Medicare contractor[,] Noridian Healthcare Solutions, LLC ([‘]Noridian[’])[,] to pay the three Medicare reimbursement claims at issue in this case.” Def.’s Mot. at 4. The Secretary further represents—and the plaintiffs again do not contest, see generally Pls.’ Opp’n—that “[o]n March 28, 2022, Noridian paid [] Sargent’s August 2016 claim and April 2017 claim[,]” Def.’s Mot. at 4 (citing id., Ex. A (Declaration of Karen Grasso

(“Grasso Decl.”)) ¶ 6, ECF No. 120-1); and “[o]n June 3, 2022, Noridian sent [] Lewis payment for her October 2015 claim[.]” id. (citing id., Ex. A (Grasso Decl.) ¶ 8).

C. Applicable Procedural History

On July 14, 2022, the Secretary filed his motion that is the subject of this Memorandum Opinion. See Def.’s Mot. at 1. The plaintiffs then filed their opposition to the Secretary’s motion on August 8, 2022, see Pls.’ Opp’n at 1, and the Secretary filed his reply on August 25, 2022, see Def.’s Reply at 1.

II. STANDARD OF REVIEW

“Federal [district] courts are courts of limited jurisdiction[.]” Kokkonen v. Guardian Life Ins. Co. of Am., 511 U.S. 375, 377 (1994), and therefore, “[a] motion for dismissal under [Rule] 12(b)(1) ‘presents a threshold challenge to the [C]ourt’s jurisdiction[.]’” Morrow v. United States, 723 F. Supp. 2d 71, 75 (D.D.C. 2010) (Walton, J.) (quoting Haase v. Sessions, 835 F.2d 902, 906 (D.C. Cir. 1987)). Thus, the Court is obligated to dismiss a claim if it “lack[s] [] subject-matter jurisdiction[.]” Fed. R. Civ. P. 12(b)(1). And, because “it is presumed that a cause lies outside [] [the Court’s] limited jurisdiction,” Kokkonen, 511 U.S. at 377, the plaintiff bears the burden of establishing by a preponderance of the evidence that a district court has subject matter jurisdiction, see Lujan v. Defs. of Wildlife, 504 U.S. 555, 561 (1992).

In deciding a motion to dismiss based upon lack of subject matter jurisdiction, the Court “need not limit itself to the allegations of the complaint.” Grand Lodge of the Fraternal Ord. of Police v. Ashcroft, 185 F. Supp. 2d 9, 14 (D.D.C. 2001) (citation omitted). Rather, the “[C]ourt may consider such materials outside the pleadings as it deems appropriate to resolve the question [of] whether it has jurisdiction to hear the case.” Scolaro v. D.C. Bd. of Elections and Ethics, 104 F. Supp. 2d 18, 22 (D.D.C. 2000) (citation omitted); see also Jerome Stevens Pharms., Inc.

v. Food & Drug Admin., 402 F.3d 1249, 1253 (D.C. Cir. 2005) (holding that a “district court may consider materials outside [of] the pleadings” when deciding “to grant a motion to dismiss for lack of jurisdiction”). Additionally, the Court must “assume the truth of all material factual allegations in the complaint and ‘construe the complaint liberally, granting [the] plaintiff the benefit of all inferences that can be derived from the facts alleged[.]’” Am. Nat’l Ins. Co. v. Fed. Deposit Ins. Corp., 642 F.3d 1137, 1139 (D.C. Cir. 2011) (quoting Thomas v. Principi, 394 F.3d 970, 972 (D.C. Cir. 2005)). However, “the [p]laintiff’s factual allegations in the complaint . . . will bear closer scrutiny in resolving a [Rule] 12(b)(1) motion than in resolving a [Rule] 12(b)(6) motion for failure to state a claim.” Grand Lodge, 185 F. Supp. 2d at 13–14 (alterations in original) (citation and internal quotation marks omitted).

III. ANALYSIS

The Secretary asks the Court to “enter judgment in [the] plaintiffs’ favor on Count III of their Complaint . . . and to vacate the three Administrative Law Judge ([‘]ALJ[’]) and Medicare Appeals Council decisions from which [the] plaintiffs appealed[.]” Def.’s Mot. at 1–2, which he argues would obviate the need for the Court to reach the plaintiffs’ APA claims, see id. at 10–11. Furthermore, the Secretary argues that the “[p]roposed partial judgment in [the plaintiffs’] favor, and vacatur of the final agency decisions from which they appealed, provides them with all the judicial relief to which they are entitled[.]” and therefore, the plaintiffs’ remaining claims should be dismissed as moot. Id. at 11. In response, the plaintiffs do not respond to the Secretary’s proposal regarding Count III, but argue that their remaining claims are not moot because the Secretary has failed to satisfy his burden to show that (1) “his alleged ‘voluntary cessation’ has rendered this case moot[.]” Pls.’ Opp’n at 14, and (2) the claims in this case are not “capable of repetition while evading review[.]” id. at 20. The Court will first consider whether it should

enter judgment for the plaintiffs as to Count III in light of the Secretary's concessions, before determining whether the remaining claims in this case should be dismissed as moot.

A. The Secretary's Request for Entry of Partial Judgment for the Plaintiffs

The Secretary "concedes that the final agency decisions from which the plaintiffs appealed are not in accordance with the agency's current policy regarding CGMs[.]" Def.'s Mot. at 8–9, because "[CMS 1738-R] made the policy of the December 2021 final rule applicable to any pending or properly appealed claim for reimbursement of a CGM device or supplies, regardless of date of service, including [the] plaintiffs' three reimbursement claims at issue in this case[.]" id. at 9. The Secretary therefore states that "the Court should enter judgment in [the] plaintiffs' favor on Count III[.]" id., in which the plaintiffs

ask the Court to reverse the Secretary's [d]ecisions as arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with the law, and issue an order finding that a CGM and its related supplies [are] covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

Compl. ¶ 154. The Secretary further "acknowledges that vacatur of the (prior) final agency decisions may provide [the] plaintiffs with some[] nominal relief" and "proposes that the Court . . . vacate the final agency actions from which [the plaintiffs] appealed." Def.'s Mot. at 10 (noting that "[t]he Court may order vacatur even though [the] plaintiffs' Complaint did not explicitly demand it" and "[v]acatur of the ALJ and Medicare Appeals Council decisions is the relief to which [the] plaintiffs are entitled" (citing Fed. R. Civ. P. 54(c))). Finally, the Secretary argues that, based upon this proposal, "there is no need for the Court to reach the plaintiffs' other [APA] causes of action" because "[e]ntering judgment for [the] plaintiffs based on the government's concession with respect to Count III, and vacating the final agency decisions, provides [the] plaintiffs with complete relief on their [APA] claims." Id. at 11.

In their opposition, the plaintiffs do not address any of these proposals or arguments put forth by the Secretary. See generally Pls.’ Opp’n. And, where “a party files an opposition to a motion and therein addresses only some of the movant’s arguments, the [C]ourt may treat the unaddressed arguments as conceded.” Wannall v. Honeywell, Inc., 775 F.3d 425, 428 (D.C. Cir. 2014) (interpreting District of Columbia Local Civil Rule 7(b)); see LCvR 7(b) (providing that “[i]f [] a memorandum [in opposition to a dispositive motion] is not filed within the prescribed time, the Court may treat the motion as conceded”). Accordingly, the Court will treat the Secretary’s request and arguments regarding the entry of judgment for the plaintiffs as to Count III, and vacatur of the underlying administrative decisions in this case, as conceded. As a result, the Court will enter judgment in favor of the plaintiffs as to Count III of the Complaint, except to the extent that Count III requests that the Court “direct the Secretary to make appropriate payment for the claims that are the subject of this case[.]” Compl. ¶ 154.⁵ Cf. MCI Commc’ns Servs., Inc. v. Fed. Deposit Ins. Corp., 808 F. Supp. 2d 24, 27 (D.D.C. 2011) (entering judgment in favor of the defendant as to one count of the Complaint based solely upon a concession by the plaintiff).

Regarding the Secretary’s request for voluntary vacatur, the Court questions whether it may vacate an administrative decision based solely upon the Secretary’s request and the plaintiff’s implicit concession. Other members of this Court have disapproved of vacating agency rules based only upon an agency’s request, see Carpenters Indus. Council v. Salazar, 734 F. Supp. 2d 126, 136 (D.D.C. 2010) (concluding that a district court “lacks the authority to grant

⁵ The Court concludes that, because the Secretary has completed payments for all of the plaintiffs’ claims at issue in this case, see Def.’s Mot. at 4 (citing id., Ex. A (Grasso Decl.) ¶¶ 6, 8), the plaintiffs’ request in Count III that the Court “direct the Secretary to make appropriate payment for the claims that are the subject of this case[.]” Compl. ¶ 154, is rendered moot. See Conservation Force, Inc. v. Jewell, 733 F.3d 1200, 1204 (D.C. Cir. 2013) (“In general, a c[laim] becomes moot . . . when, among other things, the court can provide no effective remedy because a party has already ‘obtained all the relief [it has] sought.’” (quoting Monzillo v. Biller, 735 F.2d 1456, 1459 (D.C. Cir. 1984) (third alteration in original))).

[an agency’s] request for vacatur without a determination of the merits”), because doing so, absent a judicial determination of legal error, ““would allow the [agencies] [] to do what they cannot do under the APA[—]repeal a rule without public notice and comment, without judicial consideration of the merits[.]”” id. at 135 (quoting Nat’l Parks Conservation Ass’n v. Salazar, 660 F. Supp. 2d 3, 5 (D.D.C. 2009)). However, where, as here, the ruling that formed the basis for the administrative decisions has since been rescinded based upon the Secretary’s admission of legal error, see CMS 1738-R (May 13, 2022) at 1, the potential for an agency to bypass these requirements under the APA is not implicated, and the Court therefore concludes that vacatur of administrative decisions made pursuant to the since-rescinded ruling is not inappropriate, cf. Endangered Species Comm. of Bldg. Indus. Ass’n of S. Cal. v. Babbitt, 852 F. Supp. 32, 38 (D.D.C. 1994) (vacating an administrative decision based upon a legally erroneous agency rule). See Def.’s Mot. at 8–10 (explaining that CMS has rescinded and replaced CMS 1682-R and therefore, administrative decisions based upon the erroneous classification of CGMs in CMS 1682-R are invalid). The Court will therefore vacate the administrative decisions which denied the plaintiffs’ claims for coverage of their CGMs based upon CMS 1682-R.⁶ Additionally, the Court will enter judgment for the plaintiffs on Count III of the Complaint, to the extent that it seeks: (1) “revers[al and vacatur of] the Secretary’s [d]ecisions as arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with the law,” and (2) “issu[ance of] an

⁶ As the Secretary correctly notes, see Def.’s Mot. at 10–11, in light of the Court’s decision to vacate the underlying administrative decisions, which denied the plaintiffs’ claims on the basis articulated in Count III of the Complaint, the Court need not reach the plaintiffs’ other arguments under alternative provisions of the APA, which request the same relief, see Compl. ¶¶ 155–63. See Dist. Hosp. Partners, L.P. v. Sebelius, 932 F. Supp. 2d 194, 199 n.5 (D.D.C. 2013) (declining to reach alternative grounds under the APA asserted by the plaintiff in vacating an administrative decision). Therefore, and in light of the plaintiffs’ decision not to address the Secretary’s argument that the Court need not reach alternative grounds for entry of judgment and vacatur under the APA, see generally Pls.’ Opp’n, the Court enters judgment for the plaintiffs as to Count III only.

order finding that [] CGM[s, including those CGMs for which the plaintiffs sought coverage,] and its related supplies [are] covered durable medical equipment[.]” Compl. ¶ 154.

B. Whether the Remaining Claims Must Be Dismissed as Moot

Having entered judgment for the plaintiffs on Count III, the Court will next consider whether the plaintiffs’ remaining claims are now moot. The Secretary argues that, “in light of the Secretary’s payment of [the] plaintiffs’ reimbursement claims and the Secretary’s policy changes, [the] plaintiffs’ remaining claims for relief beyond vacatur of the ALJ and Medicare Appeals Council decisions are moot[.]” Def.’s Mot. at 12, because “[t]he additional relief requested by [the] plaintiffs—including a Court order directing the Secretary to provide coverage for their CGM claims, the invalidation of the now-rescinded policy CMS[]1682-R, and a declaration that [the] plaintiffs’ CGM devices are durable medical equipment—would have no practical effect,” id. at 12–13. The Secretary further argues that neither the “voluntary cessation” nor the “capable of repetition, yet evading review” exceptions to the mootness doctrine apply to the plaintiffs’ remaining claims for relief. See id. at 13.

In response to the Secretary’s motion, the plaintiffs start by articulating their requests for relief as the following:

- 1) An order setting aside CMS 1682-R;
- 2) A finding that CGMs are “durable medical equipment” [] under both the statute and the Secretary’s regulations;
- 3) A specific declaration that the Medtronic MiniMed and Dexcom CGMs are “durable medical equipment”; and
- 4) An order directing the Secretary to provide coverage of the claims-in-suit.

Pls.’ Opp’n at 13. The plaintiffs argue that, “[o]ther than the last item, these requests are not co-extensive with [the p]laintiffs’ . . . coverage [claims,]” and “[t]he Secretary’s proposed order grants none of the above requests for relief.” Id. Furthermore, the plaintiffs argue that, not only are their claims not moot, but “the Secretary has failed to sustain his burden of showing that his

alleged ‘voluntary cessation’ has rendered this case moot[.]” *id.* at 14, or that the claims in this case are not “capable of repetition while evading review[.]” *id.* at 20.⁷

“Article III of the Constitution restricts the federal courts to deciding only ‘actual, ongoing controversies,’” *Nat’l Black Police Ass’n v. District of Columbia*, 108 F.3d 346, 349 (D.C. Cir. 1997) (quoting *Honig v. Doe*, 484 U.S. 305, 317 (1988)), and “a federal court has no ‘power to render advisory opinions [or] . . . decide questions that cannot affect the rights of litigants in the case before them[.]’” *id.* (quoting *Preiser v. Newkirk*, 422 U.S. 395, 401 (1975)) (alterations in original) (internal quotation marks omitted) (first and second alterations in original). Moreover, “[e]ven where litigation poses a live controversy when filed, . . . [the C]ourt [must] refrain from deciding it if ‘events have so transpired that the decision will neither presently affect the parties’ rights nor have a more-than-speculative chance of affecting them in the future.’” *Clarke v. United States*, 915 F.2d 699, 701 (D.C. Cir. 1990) (quoting *Transwestern Pipeline Co. v. Fed. Energy Regul. Comm’n*, 897 F.2d 570, 575 (D.C. Cir. 1990)). For example, “[a] party may lack a legally cognizable interest in the outcome [of a case] ‘when, among other things, the court can provide no effective remedy because a party has already obtained all the relief it has sought[.]’” *Indian River Cnty. v. Rogoff*, 254 F. Supp. 3d 15, 18 (D.D.C. 2017) (quoting *Conservation Force, Inc. v. Jewell*, 733 F.3d 1200, 1204 (D.C. Cir. 2013)) (internal quotation marks omitted).

⁷ The plaintiffs also refer to the Secretary’s purported “bad faith” conduct throughout their opposition. *See generally* Pls.’ Opp’n at 1–9, 14–20. However, these “bad faith” allegations appear to stem from one district court’s ruling that the Secretary acted in bad faith by “micharakteriz[ing] [] the justification of the denial of coverage [for CGMs]” and that, based upon this and other determinations made by that court, the Secretary’s conduct “meets the high threshold for an award of bad-faith fees.” *Olsen v. Becerra*, No. 20-cv-374 (SMJ), 2021 WL 3683360, at *2 (E.D. Wash. Apr. 4, 2020) (internal quotation marks omitted); *see* Pls.’ Opp’n at 1 (citing *Olsen*, 2021 WL 3683360, at *2). However, whether or not the Court accepts the plaintiffs’ contention that the Secretary’s denials of coverage for CGMs were made in bad faith, any such determination would be irrelevant to the question of whether the plaintiffs’ claims in this case are moot. Rather, the applicable standards regarding mootness will be addressed *infra* Section III.B.1–2.

There are two exceptions to the mootness doctrine. First, under the “capable of repetition, yet evading review” exception, a case is not rendered moot where “(1) the challenged action was in its duration too short to be fully litigated prior to its cessation or expiration, and (2) there was a reasonable expectation that the same complaining party would be subjected to the same action again.” Ill. Elections Bd. v. Socialist Workers Party, 440 U.S. 173, 187 (1979) (quoting Weinstein v. Bradford, 423 U.S. 147, 149 (1975) (per curiam)). Second, under the “voluntary cessation” exception, “voluntary cessation of allegedly illegal conduct does not deprive [a court] of power to hear and determine the case,” and voluntary cessation will only moot a case if “there is no reasonable expectation . . . that the alleged violation will recur,” and “interim relief or events have completely and irrevocably eradicated the effects of the alleged violation.” Cnty. of L.A. v. Davis, 440 U.S. 625, 631 (1979) (internal quotation marks omitted). “The party seeking jurisdictional dismissal must establish mootness, while the opposing party has the burden to prove that a mootness exception applies.” Reid v. Hurwitz, 920 F.3d 828, 832 (D.C. Cir. 2019).

Accordingly, the Court will first analyze whether the Secretary has met his burden to establish mootness, before considering whether the plaintiffs have demonstrated that either of the two exceptions to the mootness doctrine applies.

1. Mootness

The Court must first determine whether the Secretary has satisfied his “initial heavy burden of establishing mootness[,]” Honeywell Int’l, Inc. v. Nuclear Regul. Comm’n, 628 F.3d 568, 576 (D.C. Cir. 2010) (internal quotation marks omitted). The Secretary contends that the relief requested by the plaintiffs through their remaining claims “would have no practical effect” and thus those claims are moot. Def.’s Mot. at 13. Specifically, it is noted that (1) “[t]he Secretary has already provided coverage for [the] plaintiffs’ CGM claims;” (2) “the Secretary

has already recognized that [the] plaintiffs’ CGM devices are durable medical equipment[;]” and (3) CMS 1682-R “has been rescinded by [] CMS[]1738-R and replaced by the December 2021 final rule.” Id. Based upon these events, the Secretary argues that “[f]urther adjudication would not be proper because it would not result in ‘action’ or ‘cessation of action[,]’” id. (quoting Hewitt v. Helms, 482 U.S. 755, 761 (1987)), “[n]or would the grant of declaratory relief achieve a useful objective[,]” id.

“A case is moot ‘when the issues presented are no longer live or the parties lack a legally cognizable interest in the outcome.’” Akiachak Native Cmty. v. U.S. Dep’t of Interior, 827 F.3d 100, 105 (D.C. Cir. 2016) (quoting U.S. Parole Comm’n v. Geraghty, 445 U.S. 388, 396 (1980)) (internal quotation marks omitted). In other words, for a case to be justiciable, the Court’s disposition of the claims must “affect the rights of litigants in the case before [it,]” Preiser, 422 U.S. at 401, and “[the C]ourt [must] refrain from deciding it if ‘events have so transpired that the decision will neither presently affect the parties’ rights nor have a more than speculative chance of affecting them in the future[,]’” Clarke, 915 F.2d at 701 (quoting Transwestern Pipeline Co., 897 F.2d at 575). Moreover, where the claims are founded on the invalidity of a policy or regulation and “that regulation no longer exists, [the Court] can do nothing to affect [the plaintiffs’] rights relative to it, thus making th[e] case classically moot for lack of a live controversy.” Akiachak Native Cmty., 827 F.3d at 106; see Larsen v. U.S. Navy, 525 F.3d 1, 4 (D.C. Cir. 2008) (“[B]ecause the [agency has] already eliminated the [challenged p]olicy and [the] plaintiffs never allege that the [agency] will reinstitute it, any injunction or order declaring it illegal would accomplish nothing—amounting to exactly the type of advisory opinion Article III prohibits.”). This rule applies with equal force to claims for declaratory relief. See Diffenderfer v. Cent. Baptist Church of Mia. Inc., 404 U.S. 412, 414–15

(1972) (dismissing as moot a request for a declaratory judgment regarding the unconstitutionality of a statute because the “relief [was], of course, inappropriate [given] that the statute ha[d] been repealed”).

Here, as a preliminary matter, the Court notes that it has already granted the plaintiffs’ second and third requests for relief—namely, a finding that CGMs are “durable medical equipment” and a specific declaration that the Medtronic MiniMed and Dexcom CGMs are “durable medical equipment[.]” see Pls.’ Opp’n at 13—through its entry of judgment for the plaintiffs as to Count III of the Complaint, see supra Section III.A. Specifically, the Court has concluded that it will enter judgment for the plaintiffs as to Count III of the Complaint to the extent that it seeks the issuance of an order finding that CGMs, including those CGMs for which the plaintiffs sought coverage, and their related supplies are covered durable medical equipment. See supra Section III.A. Therefore, the plaintiffs second and third requests for relief, see Pls.’ Opp’n at 13, have already been granted.

Regarding the plaintiffs’ remaining requests for relief—namely, an order setting aside CMS 1682-R and an order directing the Secretary to provide coverage for the plaintiffs’ claims—the Secretary has met his initial burden of establishing that these claims are moot. First, the Secretary has rescinded CMS 1682-R, see CMS 1738-R (May 13, 2022) at 1 (explicitly rescinding CMS 1682-R), which renders “[a]n order setting aside CMS 1682-R[.]” as requested by the plaintiffs, see Pls.’ Opp’n at 13, of no practical effect because “[the Court] can do nothing to affect [the plaintiffs’] rights relative to” the rescinded rule, Akiachak Native Cmty., 827 F.3d at 106 (dismissing as moot a claim challenging a regulation which was subsequently rescinded).

Second, the Secretary has “provide[d] coverage of the claims-in-suit” as requested by the plaintiffs, Pls.’ Opp’n at 13; see Def.’s Mot. at 4 (stating that “[o]n March 28, 2022, Noridian

paid [] Sargent’s August 2016 claim and April 2017 claim” and “[o]n June 3, 2022, Noridian sent [] Lewis payment for her October 2015 claim” (citing id., Ex. A (Grasso Decl. ¶¶ 6, 8)), and thus, with respect to the plaintiffs’ individual coverage claims, “the [C]ourt can provide no effective remedy because [the plaintiffs] ha[ve] already obtained all the relief [] [they] ha[ve] sought[.]” Conservation Force, Inc., 733 F.3d at 1204 (internal quotation marks omitted).⁸

Accordingly, the Court concludes that the Secretary has met his initial burden to establish that the plaintiffs’ remaining claims are moot. Having reached this conclusion, the Court must next determine whether the plaintiffs have demonstrated that either of the exceptions to the mootness doctrine apply in this case.

2. Exceptions to the Mootness Doctrine

a. Capable of Repetition, Yet Evading Review Exception

Having concluded that the Secretary has met his initial burden of establishing that the plaintiffs’ remaining claims are moot, see supra Section III.B.1, the Court must next determine whether the first of two exceptions to the mootness doctrine—the “capable of repetition, yet

⁸ In response to the Secretary’s arguments regarding mootness, the plaintiffs argue that (1) “[t]he requested relief . . . would have the effect of []stopping the Secretary from contending [that CGMs are not durable medical equipment] in future claims by [] Lewis and [] Sargent[.]” Pls.’ Opp’n at 13, and (2) because “there is no order that the Secretary provide coverage of the claims-in-suit[.]” id., “the Secretary could seek recoupment of payments made, which he can enforce by automatically deducting it from Social Security payments[.]” id. at 14. However, “[a]lthough the voluntary repeal of a regulation does not moot a case if there is reason to believe the agency will reinstitute it, ‘the mere power to reenact a challenged [rule] is not a sufficient basis on which a court can conclude that a reasonable expectation of recurrence exists’ absent ‘evidence indicating that the challenged [rule] likely will be reenacted.’” Akiachak, 827 F.3d at 106 (quoting Nat’l Black Police Ass’n, 108 F.3d at 349) (alterations in original). Here, the plaintiffs have not put forth evidence that the Secretary is likely to either reinstate a rule prohibiting classification of CGMs as durable medical equipment or recoup payments made to the plaintiffs. Rather, the plaintiffs have put forth a speculative and conclusory allegation of future bad faith by the Secretary, see Pls.’ Opp’n at 14, and otherwise rely on the Secretary’s authority to re-classify CGMs or recoup payments, but without more this is insufficient to create a “reasonable expectation” that these actions will occur, see Nat’l Black Police Ass’n, 108 F.3d at 349 (finding the legislature’s “power to reenact a challenged law” is an insufficient basis to find a reasonable expectation of recurrence, without “evidence indicating that the challenged law likely will be reenacted” (emphasis added)). Thus, these arguments by the plaintiffs do not detract from the Secretary’s initial establishment of mootness in this case. The Court will discuss later the plaintiffs’ arguments regarding potential recurrence in greater detail in the context of its determinations regarding the “capable of repetition, yet evading review” and “voluntary cessation” exceptions to the mootness doctrine. See infra Section III.B.2.

evading review” exception—applies in this case. In evaluating the application of this exception, the Court is mindful of the fact that the plaintiffs, as “the opposing party[,] ha[ve] the burden to prove that a mootness exception applies.” Reid, 920 F.3d at 832.

“[E]ven though the specific action that the plaintiff challenges has ceased, a claim for declaratory relief will not be moot” if “the specific claim fits the exception for cases that are capable of repetition, yet evading review.” Del Monte Fresh Produce Co. v. United States, 570 F.3d 316, 321 (D.C. Cir. 2009). “The capable of repetition but evading review exception applies if ‘(1) the challenged action was in its duration too short to be fully litigated prior to its cessation or expiration,’” i.e., “the evading review” prong, and “‘(2) there was a reasonable expectation that the same complaining party would be subjected to the same action again[.]’” i.e., the “capable of repetition” prong. J.T. v. District of Columbia, 983 F.3d 516, 523 (D.C. Cir. 2020) (quoting Weinstein, 423 U.S. at 149).

Regarding the first prong of the analysis, “[t]o evade review, the challenged action must be incapable of surviving long enough to undergo Supreme Court review.” United Bhd. of Carpenters & Joiners of Am. v. Operative Plasterers’ & Cement Masons’ Int’l Ass’n of the U.S. & Can., 721 F.3d 678, 688 (D.C. Cir. 2013). Generally, “agency actions of less than two years’ duration cannot be fully litigated prior to cessation or expiration, so long as the short duration is typical of the challenged action.” Del Monte Fresh Produce Co., 570 F.3d at 322 (internal quotation marks omitted). However, “Circuit precedent [also] requires [the Court] to determine whether the activity challenged is inherently of a sort that evades review[.]” Campbell v. Clinton, 203 F.3d 19, 34 (D.C. Cir. 2000) (internal quotation marks omitted) (emphasis added). Thus, the challenged action must, in and of itself, be so time-bound that it evades review. See Grant v. Vilsack, 892 F. Supp. 2d 252, 258 (D.D.C. 2012) (“The ‘capable of repetition[, yet

evading review]’ exception applies to claims that are inherently short-lived.”); compare, e.g., id. at 257–58 (concluding that the challenged action did not evade review because “the alleged wrong”—namely, an agency’s deregulation decision—was not time-bound), with Jenkins v. Squillacote, 935 F.2d 303, 307 (D.C. Cir. 1991) (“[T]here can be no doubt that a one-year placement order under the [Individuals with Disabilities Education Act] is, by its nature, too short [in duration] to be fully litigated prior to its . . . expiration.” (internal quotation marks omitted) (emphasis added)). Moreover, this Circuit “also adds in an additional requirement that a given action must meet before it results in an application of this exception: that ‘the short duration is typical of the challenged action.’” People for the Ethical Treatment of Animals, Inc. v. U.S. Fish & Wildlife Serv., 59 F. Supp. 3d 91, 97 (D.D.C. 2014) (quoting Del Monte Fresh Produce Co., 570 F.3d at 322).

Here, the underlying action challenged by the plaintiffs is neither “inherently short-lived[.]” Grant, 892 F. Supp. 2d at 258, nor typically short in duration. The plaintiffs argue that “given the Secretary’s contention that he can issue ‘rulings’ at any time that render multi-year cases moot, it is hard to see how a case is capable of surviving through Supreme Court review[.]” and “the matter [at issue in this case] will evade review because, even if the insured survives through the appeal process before the Department, the Secretary could choose to evade review at any time” by rescinding the ruling at issue. Pls.’ Opp’n at 20–21. But the mere fact that the Secretary has the power to instate and rescind rulings such as CMS 1682-R does not make the duration of such rulings’ applicability to Medicare claims inherently time-bound. See generally CMS 1682-R (Jan. 12, 2017) (specifying no time limit to the applicability of the Secretary’s ruling). Rather, such rulings remain in place for an indefinite period of time, unless they are replaced, as was the case here. See CMS 1738-R (May 13, 2022) at 6 (describing the rescission

process as applied to CMS 1682-R). Furthermore, the plaintiffs have submitted no evidence of typicality, *i.e.*, that the alleged “short duration is typical of the challenged action[.]” Del Monte Fresh Produce Co., 570 F.3d at 322. See generally Pls.’ Opp’n at 20–21. In fact, here, the challenged ruling was operable for over two years, from January 2017 to December 2021. See CMS 1682-R (Jan. 12, 2017) at 16 (designating an effective date of January 12, 2017); CMS 1738-R (May 12, 2022) at 6 (stating that “[t]he December 2021 final rule replaced the 2017 CMS Ruling, CMS 1682-R”). Thus, the plaintiffs have not shown that the alleged wrong in this case—the allegedly invalid ruling and its application to the plaintiffs’ claims—lasted for less than two years, see Del Monte Fresh Produce Co., 570 F.3d at 322 (articulating the general rule that “agency actions of less than two years’ duration cannot be fully litigated prior to cessation or expiration” (internal quotation marks omitted)), much less that the alleged “short duration is typical of the challenged action[.]” *id.* (emphasis added). See People for the Ethical Treatment of Animals, Inc., 59 F. Supp. 3d at 97 (concluding that the plaintiff’s challenge to Secretary’s issuance of certain permits did not evade review, based upon the plaintiff’s failure to establish typicality, even where the plaintiff presented evidence that “21 of [a total of 95 permitting applications] had durations of less than three years”).

For the foregoing reasons, the Court concludes that the plaintiffs have not met their burden of establishing that “the challenged action was in its duration too short to be fully litigated prior to its cessation or expiration[.]” Weinstein, 423 U.S. at 149. And, because the “capable of repetition, yet evading review” test “requires that the challenged action be both capable of repetition and evading review[.]” People for the Ethical Treatment of Animals, Inc., 59 F. Supp. 3d at 97 (citing Weinstein, 423 U.S. at 149) (emphasis in original), and “a deficiency in one area renders the exception itself moot[.]” *id.*, the Court need not reach

the second prong of the analysis—namely, whether the challenged action is capable of repetition. See id. 97–98 (basing the court’s decision as to the “capable of repetition, yet evading review” exception on its dispositive determination regarding the “evading review” prong). Accordingly, the Court concludes that the “capable of repetition, yet evading review” exception does not apply in this case.

b. Voluntary Cessation

Having concluded that the “capable of repetition, yet evading review” exception does not apply in this case, see supra Section III.B.2.i, the Court must next considers whether the second exception to the mootness doctrine—the “voluntary cessation” exception—applies. Again, in evaluating the application of exceptions to the mootness doctrine, the Court is mindful of the fact that the plaintiffs, as “the opposing party[,] ha[ve] the burden to prove that a mootness exception applies.”⁹ Reid, 920 F.3d at 832.

The “voluntary cessation” exception to the mootness doctrine “prevent[s] a private defendant from manipulating the judicial process by voluntarily ceasing the complained of activity, and then seeking a dismissal of the case, thus securing freedom to ‘return to his old ways.’” Clarke, 915 F.2d at 705. Under this exception, “[a] defendant’s voluntary decision to cease the activities that gave rise to the suit extinguishes the live controversy[] ‘only if (i) there is no reasonable expectation that the alleged violation will recur, and (ii) interim relief or events have completely and irrevocably eradicated the effects of the alleged violation.’” Citizens for Resp. & Ethics in Wash. v. Wheeler, 352 F. Supp. 3d 1, 13 (D.D.C. 2019) (quoting Aref v.

⁹ The Court notes that, although it is the plaintiffs’ burden to establish that an exception applies, with respect to the recurrence prong of the “voluntary cessation” exception analysis, the party asserting mootness, i.e., the Secretary, “bears the ‘heavy’ burden of showing it is ‘absolutely clear that the allegedly wrongful behavior could not be reasonably expected to recur.’” Aref, 833 F.3d at 251 (quoting Friends of the Earth, Inc. v. Laidlaw Envtl. Servs., Inc., 528 U.S. 167, 189 (2000)).

Lynch, 833 F.3d 242, 251 (D.C. Cir. 2016)). However, this Circuit has been skeptical of applying this exception to agency actions. See Alaska v. U.S. Dep’t of Agric., 17 F.4th 1224, 1227 (D.C. Cir. 2021) (stating that the Circuit has expressed “‘serious doubts’ about whether the ‘voluntary cessation’ rationale appl[ies] to cases . . . [involving agency action]: ‘it would seem inappropriate for the courts either to impute such manipulative conduct to a coordinate branch of government, or to apply against that branch a doctrine that appears to rest on the likelihood of a manipulative purpose’” (quoting Clarke, 915 F.2d at 705)).

Regarding the first prong of the “voluntary cessation” exception, namely, whether “there is no reasonable expectation [] that the alleged violation will recur,” Aref, 833 F.3d at 251, where “the defendant is a government actor—and not a private litigant—there is less concern about the recurrence of objectionable behavior[.]” Citizens for Resp. & Ethics in Wash. v. Secs. & Exch. Comm’n, 858 F. Supp. 2d 51, 61 (D.D.C. 2012). The mere power to put in place a particular rule or regulation is “not a sufficient basis on which a court can conclude that a reasonable expectation of recurrence exists.” Nat’l Black Police Ass’n, 108 F.3d at 349. “Rather, there must be evidence indicating that the challenged [rule] likely will be re[instated].” Id. (emphasis added). “No entity of the federal government can ever guarantee that a statute, a regulation, or an executive order, after being repealed or withdrawn, will not be reenacted or reissued[.]” but “[c]ourts have noted that structural obstacles to reimposing a challenged law—such as a full repeal and the need to undertake new lawmaking—generally moot a case.” Alaska, 17 F.4th at 1229 n.5. Similarly, where an agency would have to “proceed through notice-and-comment rulemaking” to reinstate a rescinded rule, courts in this jurisdiction have declined to “impute voluntary cessation where nothing suggests it.” Id.; see, e.g., Citizens for Resp. & Ethics in Wash., 352 F. Supp. 3d at 14 (concluding that the “voluntary cessation”

exception did not apply to the Environmental Protection Agency’s revision of a challenged policy where “to resume its challenged conduct, [] it would have to decide to promulgate a new policy”); Cierco v. Lew, 190 F. Supp. 3d 16, 23–24 (D.D.C. 2016), aff’d sub. nom., Cierco v. Mnuchin, 857 F.3d 407 (D.C. Cir. 2017) (concluding that an agency’s “withdrawal [of the challenged] notices themselves convincingly establish that the ‘alleged violation’ . . . is not likely to recur”); cf. Nat’l Black Police Ass’n, 108 F.3d at 349–50 (“There is no evidence in the record to suggest that the D.C. Council might repeal the new legislation and reenact strict contribution limits. The Council has not ‘announced . . . such an intention,’ and indeed its enactment of the new legislation evinces an intent to the contrary.” (quoting City of Mesquite v. Aladdin’s Castle, Inc., 455 U.S. 283, 289 n.11 (1982) (alteration in original))).¹⁰

¹⁰ The plaintiffs rely heavily upon Trinity Lutheran Church of Columbia, Inc. v. Comer, 137 S. Ct. 2012 (2017), and City of Mesquite v. Aladdin’s Castle, 455 U.S. 283 (1983), in arguing to the contrary that “government actors are put to the same heavy burden, formidable burden, and stringent standard as private actors.” Pls.’ Opp’n at 12. For several reasons, the plaintiffs are incorrect. First, the plaintiffs reference a single footnote from Trinity Lutheran Church of Columbia, Inc., in which the Supreme Court opined that the Missouri governor’s voluntary rescission of the challenged policy did not moot the petitioners’ claims because “[t]he [respondent] ha[d] not carried the ‘heavy burden’ of making ‘absolutely clear’ that it could not revert to [the challenged] policy[.]” 137 S. Ct. at 458 n.1 (quoting Friends of the Earth, Inc. v. Laidlaw Environmental Services (TOC), Inc., 528 U.S. 167, 189 (2000)); see Pls.’ Opp’n at 12. However, as the basis for this conclusion, the Supreme Court cited to a letter from the respondent which explicitly stated that “there [was] no clearly effective barrier that would prevent the [respondent] from reinstating [its] policy in the future[.]” Trinity Lutheran Church of Columbia, Inc., 137 S. Ct. at 458 n.1 (third alteration in original), as well as a letter from the petitioner stating that “[t]he policy change d[id] nothing to remedy the source of the [respondent’s] original policy—the Missouri Supreme Court’s interpretation of [a Missouri state constitutional provision,]” id. Second, the plaintiffs reference the Supreme Court’s holding in City of Mesquite that the amendment of a challenged city ordinance did not moot the case. See Pls.’ Opp’n at 12. However, in that case, the Supreme Court noted the city’s past conduct of rescinding and then reenacting a challenged ordinance in apparent manipulation of the judicial process. City of Mesquite, 102 S. Ct. at 289 (“In this case the city’s repeal of the [challenged ordinance provision] would not preclude it from reenacting precisely the same provision if the District Court’s judgment were vacated. The city followed that course with respect to [another challenged provision;] . . . then, in obvious response to the state court’s judgment, the exemption was eliminated. There is no certainty that a similar course would not be pursued if its most recent amendment were effective to defeat federal jurisdiction.”). Furthermore, the Supreme Court noted that “[i]ndeed the city ha[d] announced . . . an intention” to reenact the rescinded provision that was the subject of that litigation. Id. at 289 n.11.

Unlike the two cases relied upon by the plaintiffs, here, the Secretary has not stated an intention to, or even the possibility that he will reinstate CMS 1682-R. See Trinity Lutheran Church of Columbia, Inc., 137 S. Ct. at 458 n.1; City of Mesquite, 102 S. Ct. at 289 n.11. Rather, the Secretary has explicitly conceded that the plaintiffs’ coverage denials based upon CMS 1682-R are “not in accordance with law[.]” Def.’s Mot. at 9; see infra n.11, and expressly states that “[t]here is no indication that the Secretary intends to rescind the rescission of CMS[]1682-R,” id. at 15. Furthermore, there have been no allegations that the Secretary has engaged in this type of conduct in the past, i.e.,

(continued . . .)

Here, the Secretary has “formally rescinded and replaced CMS[]1682-R” and represents that “[t]here is no indication that [he] intends to rescind the re[s]cission of CMS[]1682-R.”

Def.’s Mot. at 15. Moreover, the Secretary states that “reverting to his prior policy would involve an unlikely sequence of events including rescinding not just CMS[]1738-R but also the December 2021 final rule, and engaging in a new round of notice-and-comment rulemaking.”

Def.’s Reply at 14. Therefore, based on the Secretary’s representations, see Citizens for Resp. & Ethics in Wash., 352 F. Supp. 3d at 14 (finding the agency’s affirmation that it would not revert back to the challenged policy was “sufficient to carry [the d]efendant’s burden”), as well as the lack of “evidence indicating that [CMS 1682-R] likely will be re[instated,]”¹¹ Nat’l Black Police

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rescinding a ruling in response to litigation only to reinstate it after the litigation has been rendered moot, as was the case in City of Mesquite. See 102 S. Ct. at 289; see generally Pls.’ Opp’n. Accordingly, the Court concludes that the cases cited by the plaintiffs are inapposite given the specific facts of this case.

¹¹ The plaintiffs argue that the Secretary has failed to show that the challenged decision in this case cannot be reasonably expected to recur because (1) “the timing of the Secretary’s change screams mere tactics to avoid judicial review[.]” Pls.’ Opp’n at 15; (2) “the Secretary continues to defend his illegal conduct[.]” id.; and (3) “the challenged practice is deeply rooted and long[-] standing” because “the Secretary has been denying CGM claims improperly for more than a decade[.]” id. at 16. However, the Court concludes for several reasons that the inferences the plaintiffs ask the Court to draw are too attenuated for it to conclude that the Secretary is likely to revert to the challenged position in this case.

First, while a finding that the Secretary rescinded and replaced CMS 1682-R “in direct response to this litigation[] . . . [would] make[] it more difficult for the [Secretary] to demonstrate recurrence is unlikely[.]” DL v. District of Columbia, 187 F. Supp. 3d 1, 11 (D.D.C. 2016), the Court is without a sufficient basis to make this finding. “Whether the [Secretary’s] cessation was timed in anticipation of [or in response to this] lawsuit[.] or motivated by a genuine change of heart is relevant to the voluntary cessation analysis.” Id. And, in this case, the Secretary’s rescission of CMS 1682-R could be a direct response to ongoing litigation, as the plaintiff suggests, see Pls.’ Opp’n at 15, or it could “reflect[] the Secretary’s consistent efforts to expand coverage for CGM devices and supplies,” as the Secretary asserts, Def.’s Reply at 7, especially given the lengthy proposal and notice-and-comment rulemaking processes required to rescind and replace an administrative rule. However, without more convincing direct evidence of a manipulative intent, see, e.g., DL, 187 F. Supp. 2d at 11–12 (citing to evidence of email correspondence and statements by the defendant indicating that the policy changes at issue were in direct response to pending litigation), the Court cannot definitively conclude that this type of intent played a role in the Secretary’s actions. Moreover, as noted earlier, this Circuit has found it “inappropriate for [] courts either to impute [] manipulative conduct to a coordinate branch of government, or to apply against that branch a doctrine that appears to rest on the likelihood of a manipulative purpose.” Clarke, 915 F.2d at 705. In fact, the Secretary’s rescission of CMS 1682-R may have even been “merely a prudent response to” the rulings of other courts regarding the coverage status of CGMs, a response which the Circuit has condoned. Nat’l Wildlife Fed’n v. Hodel, 839 F.2d 694, 742 (D.C. Cir. 1988).

(continued . . .)

Ass’n, 108 F.3d at 349 (emphasis added); see id. (stating that the mere power to reinstate a policy is “not a sufficient basis on which a court can conclude that a reasonable expectation of recurrence exists”), the Court concludes that the Secretary has met his burden to show that “there is no reasonable expectation [] that the alleged violation will recur,” Aref, 833 F.3d at 251.

Regarding the second prong of the “voluntary cessation” exception, namely, whether “interim relief or events have completely and irrevocably eradicated the effects of the alleged violation[.]” Aref, 833 F.3d at 251 (quoting Am. Bar Ass’n v. Fed. Trade Comm’n, 636 F.3d 641, 648 (D.C. Cir. 2011)), “[t]he determination whether sufficient effects [of the alleged violation] remain . . . will turn on the availability of meaningful relief[.]” Cierco, 190 F. Supp. 3d at 24 (second alteration in original). In other words, “a case is not moot if a court can provide an effective remedy[.]” Larsen, 525 F.3d at 4, but “courts may not decide a controversy where

(. . . continued)

Second, while the plaintiffs are correct that a defendant’s “decision to contest liability also makes it more difficult to show there could be no reasonable expectation of recurrence[.]” DL, 187 F. Supp. 2d at 12 (citing Knox v. Serv. Emps. Int’l Union, Local 1000, 567 U.S. 298 (2012)), the Secretary cannot reasonably be said to have “continue[d] to defend the legality [of the Department’s prior decision,]” Knox, 567 U.S. at 307, of CMS 1682-R. The Secretary has explicitly conceded that the plaintiffs’ coverage denials are “not in accordance with law[.]” and, therefore, requested that judgment be entered for the plaintiffs on Count III of their Complaint. Def.’s Mot. at 9. Thus, the Secretary clearly does not maintain the legality of CMS 1682-R. And, to the extent that the Secretary continues to defend against allegations of bad faith, see Pls.’ Opp’n at 15 (referencing the Secretary’s oral argument in Smith v. Becerra, Civ. Action No. 21-47 (D. Utah)), these arguments are distinct from contesting the legality of CMS 1682-R.

Finally, while the plaintiffs are correct that a “long period of uninterrupted [alleged] violations weighs heavily against [a] defendant[.]” DL, 187 F. Supp. 2d at 12, CMS 1682-R was effective from 2017 to early 2022, when it was replaced by the December 2021 ruling, see supra Section I.A.1–2. However, “[n]ew notice-and-comment rulemaking[] . . . take[s] time.” Alaska, 17 F.4th at 1229. And, “[i]ntervening events, such as elections or changes in policy priorities, bearing on these processes are unpredictable.” Id. The Court therefore concludes that merely because CMS 1682-R was in place for approximately three to four years before the Secretary began the process of rescinding it, see Def.’s Reply at 7 (stating that “the Secretary’s consistent efforts to expand coverage for CGM devices and supplies[] beg[an] with his proposed rule in November 2020, 85 Fed. Reg. 70,358, 70,398, 70,403–70,404 (Nov. 4, 2020)”), does not weigh significantly in favor of finding that recurrence is likely. Moreover, in applying the voluntary cessation exception to agency action, this Circuit has concluded that manipulative intent is the most important consideration. See Alaska, 17 F.4th at 1229 (“The established law of this [C]ircuit is that ‘the voluntary cessation exception to mootness has no play’ when [an] agency did not act ‘in order to avoid litigation.’” (quoting Am. Bar Ass’n, 636 F.3d at 648 (internal quotation marks omitted))). Accordingly, having discerned no manipulative intent based upon either of the plaintiffs’ previous two arguments, the Court also concludes that the plaintiffs’ arguments concerning the length of time that the Secretary denied coverage for CGMs does not alone demonstrate voluntary cessation in this case. See id. at 1229–30.

post-filing events ‘make[] it impossible for the court to grant any effectual relief whatever[.]’” Cierco, 190 F. Supp. 3d at 24 (quoting Church of Scientology of Cal. v. United States, 506 U.S. 9, 12 (1992)) (internal quotation marks omitted) (alterations and emphasis in original). Thus, this exception to mootness does not apply where an “agency’s subsequent actions have given [the] plaintiffs the most they would be entitled to if they won this case.” Midcoast Fisherman’s Ass’n v. Blank, 948 F. Supp. 2d 4, 8 (D.D.C. 2013).

Here, as discussed with respect to the mootness of the plaintiffs’ remaining claims in this case, see supra Section III.B.1, the Secretary’s actions subsequent to the filing of this case have effectively provided the plaintiffs with the ultimate relief “they would be entitled to if they won this case[.]” Midcoast Fisherman’s Ass’n, 948 F. Supp. 2d at 8. The Secretary’s rescission of CMS 1682-R and re-classification of all CGMs as “durable medical equipment” under CMS 1738-R renders any subsequent “order setting aside CMS 1682-R[.]” see Pls.’ Opp’n at 13, that the Court would issue completely ineffectual.¹² See Cierco, 190 F. Supp. 3d at 24 (“[C]ourts may not decide a controversy where post-filing events ‘make[] it impossible for the court to grant any effectual relief whatever[.]’” (quoting Church of Scientology of Cal., 506 U.S. at 12) (emphasis in original)). In other words, the plaintiffs have already been “provide[d] coverage of the claims-in-suit[.]” Pls.’ Opp’n at 13, and therefore, they “ha[ve] already obtained all the relief that [they] sought[.]” Conservation Force, Inc., 733 F.3d at 1204 (internal quotation marks omitted), with respect to their individual coverage claims. For these reasons, the Court concludes that the Secretary’s rescission of CMS 1682-R, re-classification of all CGMs as

¹² The Court notes, however, that granting the Secretary’s request that judgment be entered for the plaintiffs on Count III of the Complaint and thereby ruling that CGMs constitute durable medical equipment, see supra Section III.A, imposes a significant roadblock to any potential reinstatement of CMS 1682-R. That impediment results from the fact that any reinstatement of the rescinded rule—or promulgation of a substantially similar ruling—would be in violation of this Court’s Order if it de-classified CGMs as durable medical equipment.

“durable medical equipment,” and reimbursement of the plaintiffs’ previously denied coverage claims “have completely and irrevocably eradicated the effects of the alleged violation[.]” Aref, 833 F.3d at 251, and the “voluntary cessation” exception to mootness does not apply in this case.¹³

Accordingly, having concluded that the Secretary has met his burden of establishing that the plaintiffs’ remaining claims are moot and that the plaintiffs failed to establish that either of the exceptions to mootness apply in this case, the Court concludes that it must dismiss the plaintiffs remaining claims as moot.

I. CONCLUSION

For the foregoing reasons, the Court concludes that it must grant the Secretary’s motion.

SO ORDERED this 8th day of June, 2023.¹⁴

REGGIE B. WALTON
United States District Judge

¹³ The plaintiffs argue that “the Secretary has not shown that the effects of his illegal conduct has been completely and irrevocably eradicated” because (1) “[he] refuses to revisit and grant all the claims for CGM coverage that were denied on the basis of the illegally issued and bad faith CMS 1682-R[.]” Pls.’ Opp’n at 19, and (2) many Medicare beneficiaries may not be aware that they may submit coverage claims because “CMS 1738-R is a secret policy[.]” id. at 19–20. However, the plaintiffs have previously failed to establish their entitlement to class certification, see Order at 1 (Apr. 28, 2022), ECF No. 115, and the Court may not order the Secretary to reimburse individuals who are not parties in this case. Moreover, regardless of the practical effects of the Secretary’s rescission of CMS 1682-R and instatement of CMS 1738-R, the Secretary’s actions have effectively satisfied the named plaintiffs’ requests for relief, see supra Section III.B.2, which is the relevant consideration in determining whether their claims are moot, see Conservation Force, Inc., 733 F.3d at 1204 (stating that a case is moot where a party “has already obtained all the relief that [he or she has] sought”).

¹⁴ The Court will contemporaneously issue an Order consistent with this Memorandum Opinion.