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United States Court of Appeals
Tenth Circuit

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PUBLISH

UNITED STATES COURT OF APPEALS

FOR THE TENTH CIRCUIT

LINDA P. SMITH,

Plaintiff - Appellant,

v.

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

Defendant - Appellee.

No. 22-4012

Appeal from the United States District Court for the District of Utah (D.C. No. 1:21-CV-00047-HCN)

James C. Pistorino, Parrish Law Office, Pittsburgh, Pennsylvania, (Phillip Wm. Lear, Lear & Lear PLLC, Salt Lake City, Utah, with him on the briefs), for Plaintiff-Appellant.

Joshua M. Koppel, Appellate Staff Attorney, Civil Division, United States Department of Justice, Washington, DC (Brian M. Boynton, Principal Deputy Assistant Attorney General, Andrea T. Martinez, Interim United States Attorney, and Abby C. Wright, Appellate Staff Attorney, Civil Division, United States Department of Justice, Washington, DC, and Of Counsel: Daniel J. Barry, Acting General Counsel, Gerard Keating and Linda Keyser, Attorneys, Department of Health and Human Services, with him on the brief), for Defendant-Appellee.

Before **TYMKOVICH**, Chief Judge, **EID**, and **CARSON**, Circuit Judges.

TYMKOVICH, Chief Judge.

Like many diabetics, Linda Smith uses a prescribed continuous glucose monitor (CGM) to track and regulate her glucose levels. When Smith purchased her CGM and its necessary supplies between 2016 and 2018, she sought reimbursement for her expenses through her medical insurance program, Medicare Part B. Medicare administrators denied her claims. Relying on a 2017 ruling issued by the Centers for Medicare and Medicaid Services (CMS), Medicare administrators concluded that Smith's CGM is not "primarily and customarily used to serve a medical purpose" and therefore is not covered by Medicare Part B. Smith appealed the denial of her reimbursement claims through the multistage Medicare claims review process. At each stage, the respective adjudicator confirmed the denial of her claims.

Smith then sued the Secretary of the Department of Health and Human Services in federal court, seeking monetary, injunctive, and declaratory relief. Contending that her CGM and supplies satisfied the requirements for Medicare coverage, Smith requested that the district court (1) order the Secretary to pay her claims; (2) declare that CGMs are covered by Medicare; and (3) set aside the 2017 ruling as unlawful because it did not go through the proper rulemaking process.

Instead of asking the court to uphold the denial of Smith's claims, the Secretary admitted that Smith's claims should have been covered and that the agency erred by denying her claims. The Secretary requested a remand so the agency could reimburse Smith's claims. Rather than accept the Secretary's

admission of error, Smith argued that the Secretary only admitted error to avoid judicial review of the legality of the 2017 ruling.

During Smith's litigation, CMS changed its Medicare coverage policy for CGMs. Prompted by several adverse district court rulings, CMS promulgated a formal rule in December 2021 classifying CGMs as durable medical equipment covered by Medicare Part B. But the rule applied only to claims for equipment received after February 28, 2022, so pending claims for equipment received prior to that date were not covered by the new rule.

Considering the new rule and the Secretary's confession of error, the district court in January 2022 remanded the case to the Secretary with instructions to pay Smith's claims. The district court did not rule on Smith's pending motions regarding her equitable relief claims; instead, the court denied them as moot. Smith moved to alter or amend the judgment, contending that her equitable claims were still live, but the district court denied the motion.

Smith appealed, arguing that her equitable claims are justiciable because the 2017 ruling has not been formally rescinded and Medicare administrators can still rely on the ruling to deny claims for equipment received prior to February 28, 2022. But in May 2022—shortly before oral argument in this case—the Secretary issued a new ruling. The 2022 ruling expressly rescinded the 2017 ruling and ordered Medicare administrators to approve CGM claims for equipment received prior to February 28, 2022. The Secretary asserted the 2022 ruling further rendered Smith's claims moot.

We agree with the Secretary that Smith's claims are moot. Taken together, the December 2021 final rule and the 2022 CMS ruling ensure that pending and future claims for CGMs, including the equipment owned by Smith, will be covered by Medicare. Because the recent regulatory developments moot Smith's equitable claims, we do not have jurisdiction to consider Smith's appeal. We further conclude that although CMS voluntarily changed its CGM coverage policy during this litigation, the voluntary cessation doctrine to avoid mootness does not apply.

I. Background

Diabetes is a disease that affects how the body handles glucose, a sugar that is the main source of energy for many cells and tissues. Glucose enters the bloodstream through food or after being produced in the liver. Insulin, which is produced by the pancreas, helps the body process glucose by moving glucose from the bloodstream to cells and tissues. When the body does not produce enough insulin, glucose can build up in the bloodstream, causing severe health problems, such as heart disease, stroke, kidney failure, or even death.

To avoid a medical emergency, diabetics must constantly monitor their glucose levels. The traditional means of doing so is with a blood glucose test, which involves pricking a finger and placing a drop of blood on a test strip to determine current glucose levels. Depending on the results of the test, diabetics may need to take insulin or ingest glucose to adjust their blood sugar levels. While blood glucose tests are accurate, they can be painful and inconvenient for

many diabetics, some of whom must wake up several times throughout the night to perform a test.

To address these issues, researchers developed CGMs, which are capable of automatically measuring blood glucose levels at short intervals—some monitors can take readings as frequently as every five minutes. To use a CGM, diabetics insert a disposable sensor underneath their skin. The sensor detects glucose levels and sends the data via a transmitter to a display monitor. Some CGM devices include insulin pumps, which dispense insulin automatically if there is a high glucose reading. Diabetics typically need to replace a sensor once a week, a transmitter once every few months, and a monitor after several years. CGMs are often preferred because they monitor glucose levels automatically and more frequently than blood glucose tests. More frequent readings decrease the risk that a sudden onset of symptoms will lead to a medical emergency. They also lead to better overall glucose-level control, which can prevent long-term health problems.

Smith's Medicare Claims

Linda Smith has suffered from diabetes for over 55 years. Her condition is particularly dangerous because she has hypoglycemic unawareness, which means she is unable to physically sense when her blood glucose levels are too low. Smith is also prone to rapid and unpredictable changes in her glucose levels. Because Smith often has few physical warnings of an impending diabetic emergency, Smith must be vigilant in monitoring her glucose levels—failing to

do so could be catastrophic for her. On at least one occasion, Smith lost consciousness and had to be hospitalized.

To better manage Smith's diabetes, a doctor prescribed her a Medtronic MiniMed 630G CGM with disposable sensors. Smith, who has Medicare Part B health insurance, filed Medicare reimbursement claims for the monitor and sensors. Specifically, Smith sought reimbursement for a MiniMed monitor prescribed to her in December 2016, and disposable glucose sensors she received in November 2017 and May 2018.

Medicare administrators denied Smith's claims. The administrators determined that Smith's specific monitor and supplies were not "durable medical equipment" covered by Medicare. Smith appealed her claims all the way to the Medicare Appeals Council, but her claims were rejected.[1]

Medicare administrators denied Smith's claims based on CMS-1682-R, a ruling issued by CMS in January 2017. That ruling—which is binding on Medicare administrators and constitutes an "official statement[] of agency policy

[1] Medicare reimbursement claims must go through the following administrative process before a beneficiary may seek judicial review: (1) initial coverage determination made by a CMS administrative contractor; (2) redetermination decision made by same contractor; (3) reconsideration by a qualified independent contractor; (4) review by an administrative law judge (ALJ) (subject to a minimum amount-in-controversy requirement); and (5) de novo review by the Medicare Appeals Council (MAC), which constitutes a final decision by the Secretary.

and interpretation"—explains that a CGM will only be covered by Medicare if it meets the definition of "durable medical equipment." App., Vol. 2 at 314. The Medicare regulations define "durable medical equipment" as

> [E]quipment, 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.

42 C.F.R. § 414.202. In CMS-1682-R, CMS explained that some CGMs require a separate blood glucose test to confirm blood sugar levels before corrective measures can be taken. Because these CGMs cannot be used independently to make diabetes treatment decisions, CMS concluded that such devices—which CMS refers to as "non-therapeutic" or "adjunctive" devices—are not "primarily and customarily used to serve a medical purpose" and thus do not meet the definition of durable medical equipment. App., Vol. 1 at 85–87. CMS reasoned that only those CGMs "approved by the [Food and Drug Administration] for use *in place of* a blood glucose monitor for making diabetes treatment decisions" are durable medical equipment. *Id.* at 92 (emphasis added).

Medicare administrators and an administrative law judge determined that CMS-1682-R precluded coverage for Smith's claims because the Food and Drug Administration "has not approved the beneficiary's CGM system . . . as a replacement for a blood glucose monitor." App., Vol. 2 at 320. In a final agency decision, the Medicare Appeals Council adopted the reasoning of the administrative law judge, ruled that Smith's claims were not covered by Medicare, and deemed Smith financially responsible for the incurred expenses.

Procedural Background

Having exhausted her administrative remedies, Smith sued the Secretary of the Department of Health and Human Services in federal court.[2] In addition to seeking monetary reimbursement for her claims, Smith also sought injunctive and declaratory relief. Specifically, she requested that the district court (1) set aside CMS-1682-R because it did not go through notice and comment rulemaking as required by statute; (2) declare that CGMs are durable medical equipment, regardless of whether they replace blood glucose tests; and (3) declare that the Secretary's denials of CGM claims were unsupported by substantial evidence, arbitrary and capricious, abuses of discretion, and not in accordance with the law.

Rather than contest Smith's claims, the Secretary admitted that Medicare administrators erred by denying coverage. The Secretary explained that because Smith's CGM also serves as an insulin pump, it meets the definition of durable

[2] CMS is part of the Department of Health and Human Services.

medical equipment under the Medicare statute and regulations. Based on this admission of error, the Secretary requested that the district court enter judgment in favor of Smith and remand to the agency for payment of Smith's claims.[3]

Despite the Secretary's confession of error, the district court allowed the case to proceed. Shortly after the Secretary filed his answer, Smith moved for summary judgment. Smith argued that the district court should vacate CMS-1682-R because the ruling did not go through the notice and comment process as required by 42 U.S.C. § 1395hh. In a separate summary judgment motion, Smith argued that the Secretary should be collaterally estopped from litigating the issue of whether Smith's CGM is durable medical equipment because an administrative law judge had previously ruled that Smith's monitor was covered.

In response, the Secretary contended that the district court does not have the power to vacate CMS-1682-R because the Medicare statute does not authorize a court to set aside agency actions such as CMS rulings, citing 42 U.S.C. §§ 405(g), 1395ii. The Secretary also alerted the district court to the fact that in November 2020, CMS published a notice of proposed rulemaking stating that the agency planned to change its policy regarding coverage of CGMs. Unlike CMS-

[3] The Secretary initially said that only Smith's claim for the monitor itself should be paid on remand. While the Secretary acknowledged that administrators erred in denying Smith's other two claims for the sensors, the Secretary explained that it had yet to be determined "whether the sensors should be covered as reasonable and necessary for the operation of the insulin pump." App., Vol. 1 at 38. The Secretary later amended his position based on intervening regulation changes and requested that the district court "remand to the Secretary for payment of [all] three claims." *Id.* at 271.

1682-R, the new rule would classify CGMs as durable medical equipment regardless of whether they can be relied on to make diabetes treatment decisions without the use of a separate blood glucose test. *See* 85 Fed. Reg. 70,358 (Nov. 4, 2020). The Secretary explained to the district court that the "proposed rule would supersede [CMS-1682-R], if finalized, and in doing so would moot Mrs. Smith's claim for vacatur." App., Vol. 1 at 263.

Following a public comment period, CMS issued a final rule in December 2021 classifying CGMs, transmitters, and sensors as durable medical equipment covered by Medicare Part B. *See* 86 Fed. Reg. 73,860 (Dec. 28, 2021) ("Final Rule"). Based on this regulatory change, the Secretary renewed his request for the court to enter judgment in favor of Smith and to remand the case. In January 2022, the district court entered a judgment remanding the matter to the Secretary with instructions to pay Smith's three claims. In a docket text order, the court denied Smith's pending summary judgment motions regarding CMS-1682-R and collateral estoppel as moot.

Finding the court's order and judgment inadequate, Smith moved to alter or amend the judgment, arguing that her motions were not moot because she sought equitable relief and collateral estoppel, both of which the court had not addressed, and the Secretary's concession did not resolve. Smith contended that the Final Rule issued by CMS did not moot her claims because the rule only applies to claims for CGMs and supplies received *after* February 28, 2022. Smith informed the court that she had other reimbursement claims pending before the agency for

CGM sensors she received on July 14, 2021. Since Medicare administrators had denied those July 2021 claims even after the Secretary confessed error as to Smith's 2016, 2017, and 2018 claims, Smith asserted there was a reasonable probability that the Secretary would continue to deny pending CGM claims based on CMS-1682-R. Therefore, Smith argued her equitable relief claims still presented a live controversy.

The district court denied Smith's motion to alter or amend the judgment. It explained that Smith's pending motions were moot because the court granted judgment in Smith's favor. The court further explained that "while [Smith] appears to desire additional relief . . . the court granted [Smith] all of the relief authorized by statute." App., Vol. 1 at 11 (citing 42 U.S.C. §§ 405(g), 1395ii).

Subsequent Developments

After Smith filed her notice of appeal, CMS sent a Technical Direction Letter to all Medicare administrative contractors. The Letter explained that although the coverage and payment provisions of the Final Rule only apply to CGMs and supplies received after February 28, 2022, contractors should approve valid reimbursement claims for equipment received before that date. *See* Technical Direction Letter 220257, Docket 20-1, *Olsen v. Becerra*, No. 21-cv-326

(E.D. Wash. Feb. 25, 2022).[4] The Letter said that by applying the coverage provisions of the Final Rule retroactively to pending claims, CMS will "avoid expending administrative resources on further application of [CMS-1682-R] on CGMs and additional appeals challenging application of [CMS-1682-R]." *Id.* at 2. Even though the Letter is not binding on Medicare contractors, the Secretary contends on appeal that the Letter serves as further evidence that Smith's remaining claims are moot because "future valid claims for continuous-glucose-monitor supplies should be covered regardless of the date of service." Resp. Br. at 26 n.2. Smith insists that because the Letter is not binding and CMS-1682-R has not been formally rescinded, there is no guarantee that pending claims for CGMs will be approved.

On May 13, 2022—four days before the parties' oral argument in this case—CMS issued a binding ruling to formally implement its policy of applying the Final Rule retroactively to claims for CGM supplies received prior to February 28, 2022. *See* CMS-1738-R, available at https://www.cms.gov/regulations-and-guidanceguidancerulingscms-rulings/cms-1738-r. In CMS-1738-

[4] Because the Letter was issued after the district court's entry of final judgment, it was not before the district court and is not part of the record on appeal. Nevertheless, we may take judicial notice of this publicly filed letter for the first time on appeal. *See Winzler v. Toyota Motor Sales U.S.A., Inc.*, 681 F.3d 1208, 1213 (10th Cir. 2012).

R, CMS expressly rescinded CMS-1682-R and prohibited its further application to pending claims.[5]

II. Analysis

Smith contends the district court erred by denying her equitable claims as moot. The Secretary counters that even if Smith's equitable claims were still live when the district court declined to address them, they have since become moot due to the recent regulatory changes affecting coverage of CGMs. The Secretary also argues that the voluntary cessation doctrine—which obviates mootness—does not apply here because there is no indication that the Secretary changed his coverage policy in response to this litigation or that he will reverse course once this litigation concludes.

We dismiss the appeal as moot. The Final Rule concerning future claims for CGMs, coupled with the recent issuance of Technical Direction Letter 220257

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[5] Specifically, CMS-1738-R states:

> This Ruling provides notice of the CMS Administrator's determination to rescind a January 17, 2017 CMS Ruling (CMS-1682-R) . . . the substantive CGM classification, coverage, and payment policies established by the December 2021 final rule shall be applied to claims for a CGM monitor or receiver and/or its necessary supplies and accessories where either: (1) a valid CGM claim or valid CGM appeal was pending as of February 28, 2022; or (2) the right to submit a valid CGM claim or file a valid CGM appeal had not expired as of February 28, 2022.

CMS-1738-R at 1–2.

and CMS-1738-R, fully redress Smith's equitable claims. Vacating CMS-1682-R and declaring that CGMs are durable medical equipment covered by Medicare would have no effect because CMS has already rescinded CMS-1682-R and issued a formal rule classifying CGMs and their supplies as durable medical equipment. In short, Smith no longer suffers from an actual or imminent injury that can be redressed by this court.

We also conclude that the voluntary cessation doctrine does not apply. Although CMS changed its CGM coverage policy during this litigation, mooting Smith's claims, the Secretary has met his burden of establishing that the policy change will not be rescinded after this case concludes.

A. Mootness

Article III of the Constitution limits the jurisdiction of federal courts to actual "Cases" and "Controversies." U.S. Const. art. III, § 2; *Genesis Healthcare Corp. v. Symczyk*, 569 U.S. 66, 71 (2013). The case-or-controversy requirement "ensures that the Federal Judiciary confines itself to its constitutionally limited role of adjudicating actual and concrete disputes, the resolutions of which have direct consequences on the parties involved." *Genesis Healthcare*, 569 U.S. at 71. "This means that, throughout the litigation, the plaintiff 'must have suffered, or be threatened with, an actual injury traceable to the defendant and likely to be redressed by a favorable judicial decision.'" *Spencer v. Kemna*, 523 U.S. 1, 7 (1998) (quoting *Lewis v. Cont'l Bank Corp.*, 494 U.S. 472, 477 (1990)). The

case-or-controversy requirement applies "through all stages of federal judicial proceedings, trial and appellate." *Id.*

As Article III requires an actual controversy, we lack subject-matter jurisdiction over a case that is moot. *Prison Legal News v. Fed. Bureau of Prisons*, 944 F.3d 868, 879 (10th Cir. 2019). We review mootness determinations de novo. *Id.* at 878. A case becomes moot "when the issues presented are no longer 'live' or the parties lack a legally cognizable interest in the outcome." *City of Erie v. Pap's A.M.*, 529 U.S. 277, 287 (2000) (quoting *Cty. of Los Angeles v. Davis*, 440 U.S. 625, 631 (1979)). In other words, "[i]f an intervening circumstance deprives the plaintiff of a 'personal stake in the outcome of the lawsuit,' at any point during litigation, the action can no longer proceed and must be dismissed as moot." *Genesis Healthcare*, 569 U.S. at 72 (quoting *Lewis*, 494 U.S. at 472). "The crucial question is whether granting a present determination of the issues offered . . . will have some effect in the real world." *Citizens for Responsible Gov't State Political Action Comm. v. Davidson*, 236 F.3d 1174, 1182 (10th Cir. 2000) (quotations and citation omitted). "No matter how vehemently the parties continue to dispute the lawfulness of the conduct that precipitated the lawsuit, the case is moot if the dispute is no longer embedded in any actual controversy about the plaintiffs' particular legal rights." *Already, LLC v. Nike, Inc.*, 568 U.S. 85, 91 (2013) (quotations and citation omitted).

We take a claim-by-claim approach to mootness and "must decide whether a case is moot as to 'each form of relief sought.'" *Prison Legal News*, 944 F.3d

at 880 (quoting *Collins v. Daniels*, 916 F.3d 1302, 1314 (10th Cir. 2019)). The defendant bears the burden of establishing that a "once-live case has become moot." *West Virginia v. Env't Prot. Agency*, 142 S. Ct. 2587, 2607 (2022). An injunctive relief claim becomes moot when the "plaintiff's continued susceptibility to injury" is no longer "reasonably certain" or is based on "speculation and conjecture." *Jordan v. Sosa*, 654 F.3d 1012, 1024 (10th Cir. 2011) (quotations and citation omitted). Similarly, a declaratory relief claim is moot if the relief would not affect "the behavior of the defendant toward the plaintiff." *Rio Grande Silvery Minnow v. Bureau of Reclamation*, 601 F.3d 1096, 1110 (10th Cir. 2010) (quotations and citation omitted); *Jordan*, 654 F.3d at 1025 ("[I]n the context of an action for declaratory relief, a plaintiff must be seeking more than a retrospective opinion that he was wrongly harmed by the defendant.").

In her complaint, Smith requested that the district court enter an order providing the following relief:

> (1) setting aside CMS-1682-R and its determination that CGMs that do not completely replace finger prick/test strips are not [durable medical equipment] within the meaning of 42 U.S.C. § 1395x(n) and 42 C.F.R. § 414.202;
>
> (2) finding that CGMs (whether they completely replace finger prick/test strips or not) are [durable medical equipment] within the meaning of 42 U.S.C. § 1395x(n) and 42 C.F.R. § 414.202;
>
> (3) finding the Secretary's denials of CGM coverage on the grounds that a CGM is not [durable medical equipment] is not supported by substantial evidence, are

> arbitrary and capricious, an abuse of discretion, and not in accordance with the law.

App., Vol. 1 at 35.[6]

The Secretary contends that intervening events during this litigation have rendered Smith's claims moot. We agree. The Final Rule, the Technical Direction Letter, and CMS-1738-R already classify CGM systems as durable medical equipment and mandate coverage for pending and future Medicare reimbursement claims. Thus, granting Smith any of the relief requested above would have no real-world effect.

We begin with Smith's first request for relief. Smith alleges that CMS-1682-R should be set aside because it was issued "without observance of the procedure required by law (e.g., notice and comment [rulemaking])." *Id.* at 32–34. Smith argues that because her Medicare reimbursement claims have been continuously denied based on CMS-1682-R, invalidating the ruling would eliminate any basis for the Secretary to deny her claims for CGM supplies in the future.

Smith's argument fails because CMS formally rescinded CMS-1682-R and replaced it with the Final Rule and CMS-1738-R, both of which mandate Medicare coverage for CGMs. The Final Rule, which became effective on

[6] Smith also requested that the district court order "the Secretary to provide coverage for the CGM claims at issue in this case." App., Vol. 1 at 35. Because the district court indisputably ruled in Smith's favor on that claim, we need not address whether the claim is moot.

February 28, 2022, ensures coverage for CGM supplies received after that date. CMS-1738-R applies the same coverage provisions to CGM claims that were pending as of February 28, 2022, or where the right to submit a claim or appeal had not expired as of February 28, 2022. Collectively, these changes mean that the Secretary no longer has any basis upon which to deny Smith's pending or future claims.[7] Because Smith's claims for her CGM supplies are now covered by Medicare, invalidating CMS-1682-R would provide Smith no further relief. Her first claim is therefore moot. *See Church of Scientology of Cal. v. United States*, 506 U.S. 9, 12 (1992) ("[I]f an event occurs while a case is pending on appeal that makes it impossible for the court to grant 'any effectual relief whatever' to a prevailing party, the appeal must be dismissed." (citation omitted)).

For similar reasons, Smith's second claim for declaratory relief is also moot. Smith asked the district court to declare that all CGMs are durable medical equipment under the Medicare statute and regulations. To begin with, Smith only

[7] Because Smith's equitable relief claims did not become moot until CMS issued CMS-1738-R in May 2022, the district court should not have found those claims moot in January 2022. The district court apparently denied Smith's pending motions as moot in part because the Final Rule rescinded CMS-1682-R. But the Final Rule only applies to claims for equipment received *after* February 28, 2022. Claims for equipment received before that date—such as Smith's July 2021 claims that were pending before the agency—could still be denied under CMS-1682-R. Since Smith still faced a risk that her pending claims would be denied, Smith retained a legally cognizable interest in the outcome of the case and her equitable claims remained live. It was not until CMS issued CMS-1738-R—applying the Final Rule retroactively to claims for equipment supplied prior to February 28, 2022, and expressly rescinding CMS-1682-R—that Smith's claims became moot. After that ruling went into effect, Smith no longer faced a risk of imminent harm from her claims being denied.

has standing to challenge the denial of her specific CGM because a declaration that other glucose monitors are covered by Medicare would not redress any injury suffered by Smith. *See Warth v. Seldin*, 422 U.S. 490, 499 (1975) ("[T]he plaintiff generally must assert his own legal rights and interests, and cannot rest his claim to relief on the legal rights or interests of third parties."). Regardless, the Final Rule and CMS-1738-R address Smith's concerns and grant Smith the full relief she seeks. The Final Rule recognizes that CGMs—irrespective of whether they complement a blood glucose test—are "primarily and customarily used to serve a medical purpose" and therefore meet the definition of durable medical equipment. 86 Fed. Reg. at 73,899. Similarly, CMS-1738-R adopts the Final Rule's coverage provisions and expressly rescinds CMS-1682-R. *See* CMS-1738-R at 11 ("CMS-1682-R, is hereby rescinded and shall not be applied to any additional CGM claims under Part B or Part C, as applicable, or to any further administrative appeals of CGM claims."). These regulatory changes make clear that CMS now classifies CGMs as durable medical equipment. Smith's declaratory relief claim is moot.

Smith's final request for relief—declaring that the Secretary's repeated denials of CGM claims was wrongful—is also moot. Smith requested that the district court declare that "the Secretary's denials of CGM coverage on the grounds that a CGM is not [durable medical equipment] [are] not supported by substantial evidence, are arbitrary and capricious, an abuse of discretion, and not in accordance with the law." App., Vol. 1 at 35. Smith asserts that this

declaration would prevent the Secretary from denying future CGM claims based on an improper interpretation of the regulatory definition of "durable medical equipment." Like Smith's other requests for relief, this request is moot because Smith no longer suffers from an imminent injury that would be redressed by declaring that the Secretary's previous denials of coverage were improper. In short, Smith seeks "a retrospective opinion that [s]he was wrongly harmed by the defendant." *See Jordan*, 654 F.3d at 1025. Without a redressable injury, such a declaration would be nothing more than an advisory opinion. *See TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2203 (2021) ("Under Article III, federal courts do not adjudicate hypothetical or abstract disputes.").

Smith also requested a separate ruling on the issue of whether the Secretary is collaterally estopped from litigating CGM coverage because an administrative law judge previously determined that Smith's CGM and supplies are covered by Medicare. As Smith notes, CMS-1738-R and the Final Rule do not address the issue of whether prior administrative law judge or district court decisions preclude the Secretary from re-litigating the coverage of CGMs. But the "crucial question" for mootness is whether "granting a present determination of the issues offered . . . will have some effect in the real world." *Davidson*, 236 F.3d at 1182 (quotations and citation omitted). Because a ruling on collateral estoppel would not redress any actual or imminent injury suffered by Smith, we do not have jurisdiction to consider the issue.

In sum, Smith has won all the relief she sought when she commenced this litigation. The Secretary has agreed to pay Smith's denied claims,[8] rescinded CMS-1682-R, and recognized CGMs as durable medical equipment covered by Medicare. Based on Smith's alleged injuries, there is no further relief that can be afforded to Smith.

B. Voluntary Cessation

We now turn to the question of whether the voluntary cessation doctrine applies.

Although a live controversy must exist at all stages of litigation, "a defendant cannot automatically moot a case simply by ending its unlawful conduct once sued." *Already*, 568 U.S. at 91. "Otherwise, a defendant could engage in unlawful conduct, stop when sued to have the case declared moot, then pick up where he left off, repeating this cycle until he achieves all his unlawful ends." *Id.* To address this concern, the Supreme Court has held that "a defendant claiming that its voluntary compliance moots a case bears the formidable burden of showing that it is absolutely clear the allegedly wrongful behavior could not reasonably be expected to recur." *Id.* (citation omitted).

[8] According to the Secretary, Smith's previously denied CGM claims have all been paid, including her claim for disposable sensors received in July 2021 after the filing of this case. *See* Resp. Br. at 24 ("CMS reprocessed and paid plaintiff's claim for disposable sensors received on July 14, 2021); Aple. Supp. Br. at 13 ("[T]he claims under review have been paid.").

Although the defendant faces a heavy burden in undermining the plaintiff's invocation of the voluntary cessation doctrine, we do not require a defendant to show that it would be impossible for him to resume his allegedly wrongful conduct. "For the voluntary cessation exception to apply, 'we must be convinced that the allegedly wrongful behavior could not *reasonably* be expected to recur . . . not that there is no possibility.'" *Prison Legal News*, 944 F.3d at 881 n.20 (quoting *Brown v. Buhman*, 822 F.3d 1151, 1175 (10th Cir. 2016)). For that reason, "[a] case ceases to be a live controversy if the possibility of recurrence of the challenged conduct is only a speculative contingency." *Rio Grande Silvery Minnow*, 601 F.3d at 1117 (quotations omitted and alterations incorporated).

When a plaintiff seeks to set aside the policy of a government agency, the rescission or modification of that policy can moot the challenge.[9] *Id.* Further, the "mere possibility that an agency might rescind amendments to its actions or regulations does not enliven a moot controversy." *Id.* (quotations and citation omitted); *see also id.* at 1116 ("[E]ven when a legislative body has the power to reenact an ordinance or statute, ordinarily an amendment or repeal of it moots a case challenging the ordinance or statute.").

[9] We have opined in past mootness cases that we may afford a government official's voluntary conduct "more solicitude" than that of private actors. *Rio Grande Silvery Minnow*, 601 F.3d at 1116 n.15 (quoting *Ragsdale v. Turnock*, 841 F.2d 1358, 1365 (7th Cir. 1988)); *Prison Legal News*, 944 F.3d at 881. But as the Supreme Court reminds us, government actors still bear the "heavy" burden of making "absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur." *West Virginia*, 142 S. Ct. at 2607 (quotations and citation omitted).

Smith claims (1) the Secretary changed his policy regarding coverage of CGMs solely for the purpose of evading judicial review; and (2) it can be reasonably expected that the Secretary will resume denying CGM claims once this litigation concludes. We disagree for two reasons. First, the timing of the Secretary's policy change toward CGMs suggests that the Secretary did not voluntarily change his conduct to moot Smith's litigation. Second, there is a minimal risk that the Secretary will suddenly revert to his rescinded policy of denying CGM claims given the wholesale change in policy that has developed over the past several years. To undo his policy recognizing CGMs as durable medical equipment, the Secretary would need to take the unlikely steps of disavowing his previous support for the coverage of CGMs, replacing the Final Rule—which can only be done after a notice and comment period, rescinding the Technical Direction Letter, and withdrawing CMS-1738-R.

We begin by examining the timing of the Secretary's voluntary cessation of the challenged conduct. Based on the sequence of events that led to CMS changing its CGM coverage policy, we cannot conclude that the Secretary voluntarily ceased denying CGM claims as a temporary measure to moot Smith's claims. *See Brown*, 822 F.3d at 1171 ("[W]e have indicated that mootness is more likely if . . . the case in question was the catalyst for the agency's adoption of the new policy." (quoting *Rosebrock v. Mathis*, 745 F.3d 963, 972 (9th Cir. 2014))). Although CMS did not issue the Final Rule providing Medicare coverage for CGMs until after this case commenced, CMS initiated the

rulemaking process well before this litigation. In November 2020—several months before the Medicare Appeals Council had even denied Smith's claims—CMS published a proposed rule to classify CGMs as durable medical equipment under Medicare Part B. *See* 85 Fed. Reg. at 70,358. CMS explained that the proposed change in policy was due in part to several district courts rejecting the reasoning of CMS-1682-R that CGMs "are not primarily and customarily used to serve a medical purpose." *Id.* at 70,401. While the outcome of other cases seems to have prompted the proposed rule change, the timing of the proposed rule in relation to Smith's case forecloses the possibility that the Secretary stopped denying CGM claims solely to avoid judicial review in Smith's case.

While we agree with Smith that the timing of CMS-1738-R—issued four days before oral argument—invites greater scrutiny than the timing of the Final Rule, we conclude that the timing of CMS-1738-R does not support an application of the voluntary cessation doctrine. First of all, Smith's case is not the only case affected by the Final Rule or CMS-1738-R. As Smith repeatedly points out in her briefs, the Secretary has denied thousands of other CGM claims, forcing other beneficiaries to litigate their claims. We find it unlikely that the Secretary would issue CMS-1738-R merely to moot Smith's claims given the abundance of other CGM claims and related litigation. But even if the change in policy was prompted by Smith's litigation, "that does not necessarily make it suspect." *See Brown*, 822 F.3d at 1171. We have found that a "government official's decision to adopt a policy in the context of litigation may actually make

it *more* likely the policy will be followed, especially with respect to the plaintiffs in that particular case." *Id.* (emphasis added). CMS stated in CMS-1738-R that it decided to change its policy on pending CGM claims "to bring an orderly conclusion to pending (and potentially forthcoming) administrative claims and appeals relating to the requirements for classification, coverage, and payment of CGM claims." CMS-1738-R at 6. While issuing CMS-1738-R may have mooted Smith's current claims, rescinding the ruling after Smith's case concludes would reopen the floodgates for other beneficiaries to challenge the denial of their CGM claims. Such a shift in policy would impede CMS's stated goal of "avoid[ing] the expenditure of administrative resources on further application of [CMS-1682-R]." *Id.*

Second, we consider whether it can be reasonably expected that the Secretary will resume his allegedly wrongful conduct once this litigation ends. Smith contends that as soon as the Secretary is no longer under the watchful eye of the federal judiciary, the Secretary will revive CMS-1682-R and Medicare administrators will resume denying CGM claims.

We find this argument entirely speculative. While it is true that the Secretary long refused to recognize CGMs as durable medical equipment, the Secretary has spent the past two years formally revoking that policy. It cannot "reasonably be expected" that CMS would suddenly revert to denying CGM claims when it has gone through the lengthy rulemaking process and concluded in the Final Rule, Technical Direction Letter, and CMS-1738-R that CGMs are

durable medical equipment covered by Medicare. Unraveling those regulatory changes seems improbable, especially given that CMS has determined it to be more cost effective to pay pending CGM claims rather than continue litigating them. *See Brown*, 822 F.3d at 1167 ("Most cases that deny mootness following government officials' voluntary cessation rely on *clear showings* of reluctant submission by governmental actors and a desire to return to the old ways." (cleaned up)).

To be sure, the Letter and CMS-1738-R could be rescinded with relative ease. But we think it unlikely that the Secretary would rescind both and resume applying CMS-1682-R when that ruling directly conflicts with the coverage provisions of the Final Rule, which could only be replaced after another notice and comment period. *See id.* at 1171 (finding mootness because the risk that the county attorney's office "will revoke or ignore" its new policy is "minimal at best"). Although not set in stone, the Final Rule, Technical Direction Letter, and CMS-1738-R collectively "foreclose a reasonable chance of recurrence of the challenged conduct." *See Prison Legal News*, 944 F.3d at 884 (citation omitted).

Finally, Smith argues the voluntary cessation doctrine should apply because the Final Rule and CMS-1738-R have not "completely and irrevocably eradicated the effects" of the Secretary's wrongful conduct. *See Rio Grande Silvery Minnow*, 601 F.3d at 1115 (quoting *Davis*, 440 U.S. at 631). Even if the Final Rule and CMS-1738-R provide coverage for pending and future claims, Smith contends the rulings provide no relief to the thousands of Medicare

beneficiaries whose claims were denied in the past and the thousands more who never submitted claims or requested equipment due to the prohibitive coverage provisions of CMS-1682-R. But the injuries suffered by other beneficiaries have no bearing on whether Smith's claims are live. Intervening events—which include the district court's order for the Secretary to pay Smith's claims, the Final Rule, the Technical Direction Letter, and CMS-1738-R—have remedied the effects of the Secretary's allegedly wrongful conduct towards Smith, the only plaintiff in this case.

In sum, the Secretary took concrete steps to implement a new policy—through formal rulemaking and a binding CMS ruling—that cannot be easily reversed. The voluntary cessation doctrine does not apply.

III. Conclusion

For the foregoing reasons, we dismiss the appeal as moot.