UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

STIMLABS, LLC, *et al.*,	)	
Plaintiffs,	)	
v.	)	**Civil No. 22-cv-01988 (APM)**
XAVIER BECERRA, *et al.*, *Secretary of Health and Human Services*,	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

I.

The court previously dismissed this action after determining that it lacked subject matter jurisdiction under three statutes: (1) 28 U.S.C. § 1331 (federal question jurisdiction); (2) 42 U.S.C. § 405(g) (the Social Security Act, as incorporated by the Medicare Act, 42 U.S.C. § 1395ii); and (3) 28 U.S.C. § 1361 (Mandamus Act). *See StimLabs, LLC v. Becerra*, No. 22-cv-01988-APM, 2022 WL 13840218 (D.D.C. Oct. 21, 2022). Plaintiffs now ask the court to reconsider its ruling with respect to 42 U.S.C. § 405(g).

The court makes two corrections to its earlier opinion. First, the court now finds that Plaintiff Anesthesia and Pain Consultants ("APC") has satisfied the presentment requirement. Second, the court applied the incorrect standard for irreparable harm, and improperly focused the irreparable harm analysis on Plaintiff StimLabs, LLC ("StimLabs") instead of just APC—the only party that has met the presentment requirement. Nevertheless, these corrections do not warrant reconsideration: the court still lacks jurisdiction under § 405(g) because APC has not

administratively exhausted its claim and has not shown irreparable harm by enforcement of the exhaustion requirement. For the reasons that follow, Plaintiffs' motion is denied.

II.

StimLabs, APC, and Plaintiff Wound Institute of America ("Wound Institute") seek amendment pursuant to Federal Rule of Civil Procedure 59(e) or, in the alternative, reconsideration under Rule 60(b)(6). *See* Pls.' Mot. to Amend the Court's Judg. or, in the Alt., for Recons. of the Court's Order, ECF No. 27 [hereinafter Pls.' Mot.].

Rule 59(e). Altering or amending a judgment under Rule 59(e) "is an extraordinary remedy which should be used sparingly." *Mohammadi v. Islamic Republic of Iran*, 782 F.3d 9, 17 (D.C. Cir. 2015). "A district court need not grant a Rule 59(e) motion unless there is an 'intervening change of controlling law, the availability of new evidence, or the need to correct a clear error or prevent manifest injustice.'" *Id.* (quoting *Patton Boggs LLP v. Chevron Corp.*, 683 F.3d 397, 403 (D.C. Cir. 2012). "Rule 59(e) permits a court to alter or amend a judgment, but it 'may not be used to relitigate old matters, or to raise arguments or present evidence that could have been raised prior to the entry of judgment.'" *Exxon Shipping Co. v. Baker*, 554 U.S. 471, 486 n.5 (2008) (quoting 11 CHARLES ALAN WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE AND PROCEDURE § 2810.1, 127–128 (2d ed.1995).

Plaintiffs do not argue that there was a change in controlling law or that new evidence has become available. They urge the court to reverse course because of "clear error" and to prevent "manifest injustice." Rule 59(e)'s "clear error" standard is a "very exacting standard." *Bond v. U.S. Dep't of Just.*, 286 F.R.D. 16, 22 (D.D.C. 2012), *aff'd*, No. 12-cv-5296, 2013 WL 1187396 (D.C. Cir. Mar. 14, 2013). A court "should have 'a clear conviction of error' before finding a final judgment was predicated on clear error." *Id.* Manifest injustice "must entail at least (1) a clear

and certain prejudice to the moving party that (2) is fundamentally unfair in light of governing law." *Mohammadi v. Islamic Republic of Iran*, 947 F. Supp. 2d 48, 78 (D.D.C. 2013), *aff'd*, 782 F.3d 9 (D.C. Cir. 2015).

Rule 60(b). In the alternative, based on the same arguments, Plaintiffs seek relief under Rule 60(b), which allows a court to grant a party relief from a final judgment for six enumerated reasons. FED. R. CIV. P. 60(b). Plaintiffs seek relief under Rule 60(b)(6), a residual provision that "grants federal courts broad authority to relieve a party from a final judgment . . . provided that the motion . . . is not premised on one of the grounds for relief enumerated in clauses (b)(1) through (b)(5)." *Liljeberg v. Health Servs. Acquisition Corp.*, 486 U.S. 847, 863 (1988). Because the language of Rule 60(b)(6) is "essentially boundless," *Twelve John Does v. D.C.*, 841 F.2d 1133, 1140 (D.C. Cir. 1988), the Supreme Court has clarified that relief is only appropriate in "extraordinary situations," *Ackermann v. United States*, 340 U.S. 193, 202 (1950), and the D.C. Circuit has cautioned that it "should be only sparingly used," *Good Luck Nursing Home, Inc. v. Harris*, 636 F.2d 572, 577 (D.C. Cir. 1980).

III.

Section 405(g) creates two prerequisites for judicial review: (1) "a plaintiff's claim must have been presented to the Secretary," and (2) "a plaintiff must fully exhaust the administrative remedies prescribed by the Secretary." *RICU LLC v. U.S. Dep't of Health & Hum. Servs.*, 22 F.4th 1031, 1036 (D.C. Cir. 2022) (quoting *Mathews v. Eldridge*, 424 U.S. 319, 328 (1976)) (cleaned up). The presentment requirement is a "nonwaivable element" of jurisdiction. *Eldridge*, 424 U.S. at 328. Exhaustion on the other hand is waivable, and "[w]aiver is warranted if the claim is (1) collateral to a substantive claim of entitlement (collaterality); (2) colorable in its showing that denial of relief will cause irreparable harm (irreparability); and (3) one whose resolution would

not serve the purposes of exhaustion (futility)." *Sensory Neurostimulation, Inc., v. Azar*, 977 F.3d 969, 981 (9th Cir. 2020) (internal quotation marks omitted).

Plaintiffs argue that they have met the jurisdictional requirements of 42 U.S.C. § 405(g). Their motion centers on Count I of their complaint, alleging that CMS has adopted a blanket, unwritten policy to deny coverage to human cell, tissue, and cellular and tissue-based products, or HCT/Ps, which did not proceed by notice and comment in violation of 42 U.S.C. § 1395hh. Compl. for Inj. and Decl. Rel., Mandamus, and Relief Under the All Writs Act, ECF No. 1 [hereinafter Compl.], ¶¶ 70–90. According to Plaintiffs, the court overlooked that claim in its jurisdictional analysis. Pls.' Mot. at 9.[1] Plaintiffs maintain that APC satisfied the presentment requirement by challenging a contractor's specific adverse reimbursement decision and that their § 1395hh claim qualifies for waiver of the exhaustion requirement because it is "entirely collateral to any claim for Medicare coverage and reimbursement." *Id.* at 6 (internal quotation marks omitted).

IV.

The court begins with presentment. The court previously held that Plaintiffs had not met the presentment requirement because they had not shown that APC—the sole plaintiff that presented any claim to CMS—had "challenged CMS's purported unwritten policy on the grounds advanced here 'in the context of a specific administrative claim for payment.'" *StimLabs*, 2022 WL 13840218, at *7 (quoting *Am. Hosp. Ass'n v. Azar*, 895 F.3d 822, 826 (D.C. Cir. 2018)). Plaintiffs now assert that the "presentment requirement does not require that every *issue* be raised before the agency. Rather it requires that a *claim* be presented to the agency." Pls.' Mot. at 13 (emphasis in original). In Plaintiffs' view, the fact that they did not make "the argument relating

[1] Because Plaintiffs have combined their motion and memorandum in support in a single filing, the court will use the CM/ECF pagination for ease of reference.

to rulemaking during the administrative process is not the relevant question" in the presentment inquiry. *Id*. at 15. The court agrees that it misapplied the presentment requirement.

Presentment requires that the agency have an "opportunity to rule on a concrete claim for reimbursement." *Heckler v. Ringer*, 466 U.S. 602, 622 (1984); *see RICU*, 22 F.4th at 1036 ("Section[] 405(g) . . . effectively preclude[s] the exercise of district court jurisdiction in the absence of presentment of a concrete dispute, regardless of the nature of the claim at issue."). That requirement is rooted in the statutory text of § 405(g), which authorizes review of only a "final decision of the Secretary made after a hearing." Absent presentment of a claim, the Supreme Court has said, "there can be no 'decision' of any type. And some decision by the Secretary is clearly required by the statute." *Eldridge*, 424 U.S. at 328. The Court in *Eldridge* also, at least, suggested, if not held, that satisfying the presentment requirement does *not* demand the full airing of all arguments before the agency. *See id.* at 329 (stating with respect to the presentment requirement, "[t]he fact that [plaintiff] failed to raise with the Secretary his constitutional claim to a pretermination hearing is not controlling"). Whether the plaintiff's failure to assert a particular argument before the agency defeats a court's exercise of jurisdiction would seem to be more appropriately considered under the second, waivable jurisdictional component: exhaustion of administrative remedies. *See id.* at 330 (stating with respect to the waivable exhaustion element, "[t]he question is whether the denial of [plaintiff's] claim to continued benefits was a sufficiently 'final' decision with respect to his constitutional claim to satisfy the statutory exhaustion requirement").

Here, APC has challenged through the Medicare administrative appeals process specific adverse decisions with respect to its use of StimLab's product, Ascent. *See StimLabs*, 2022 WL 13840128, at *7. This qualifies as "presentment of a concrete dispute," *RICU*, 22 F.4th at 1036,

allowing the agency the "opportunity to rule on a concrete claim for reimbursement." *Heckler*, 466 U.S. at 622. Accordingly, APC has satisfied the presentment requirement. The court's prior finding that Plaintiffs StimLabs and Wound Institute did not satisfy the presentment requirement—which Plaintiffs do not contest—remains unchanged.

V.

The court now turns to § 405(g)'s exhaustion requirement, which can be waived "if the claim is (1) collateral to a substantive claim of entitlement (collaterality); (2) colorable in its showing that denial of relief will cause irreparable harm (irreparability); and (3) one whose resolution would not serve the purposes of exhaustion (futility)." *Sensory Neurostimulation*, 977 F.3d at 981 (quoting *Johnson v. Shalala*, 2 F.3d 918, 921 (9th Cir. 1993)).

A.

Governing Standard. Plaintiffs argue that their "challenge based on the failure of the Secretary to engage in the requisite rulemaking process is entirely 'collateral' to any claim for Medicare coverage and reimbursement." Pls.' Mot. at 6. Defendants respond that Plaintiffs' claim is not collateral and, even if it was, "the D.C. Circuit has held that 'categorizing [a] claim as 'collateral' has been rendered obsolete by *Illinois Council*[2].'" Def.s' Opp'n to Pls.' Mot., ECF No. 30 [hereinafter Defs.' Opp'n], at 5 (quoting *Action All. of Senior Citizens v. Leavitt*, 483 F.3d 852 (D.C. Cir. 2007)). Plaintiffs contend that "*Illinois Council* did not eliminate the 'collateral' exception to the 'exhaustion' requirement in a claim in which jurisdiction is asserted under 42 U.S.C. § 405(g)." Pls.' Mot. at 7. The court agrees with Plaintiffs that *Illinois Council* does

[2] *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1 (2000).

not render "obsolete" the exhaustion inquiry, but disagrees that their claim merits relieving them of the obligation to exhaust.

After *Illinois Council*, a party can no longer categorize its claim as "collateral" in order to meet the "no review at all" exception, which would permit jurisdiction under 28 U.S.C. § 1331. *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 13–14 (2000) (rejecting "distinctions based upon . . . the 'collateral' versus 'noncollateral" nature of the issues"). However, *Illinois Council* did not render obsolete the collateral analysis under § 405(g). *See e.g.*, *Nat'l Ass'n for Home Care & Hospice, Inc. v. Burwell*, 77 F. Supp. 3d 103, 110 (D.D.C. 2015) (conducting § 405(g) collateral analysis after *Illinois Council*); *Hall v. Sebelius*, 689 F. Supp. 2d 10, 18 (D.D.C. 2009) (same). In other words, *Illinois Council* did not change the fact that for purposes of § 405(g), after a claim is presented, a court can excuse exhaustion where the "challenge is entirely collateral to [a plaintiff's] substantive claim of entitlement." *Eldridge*, 424 U.S. at 330.

Analysis. The court finds, however, that excusing Plaintiffs' failure to exhaust is not warranted because their rulemaking claim is not collateral to their claim for benefits. It is true that the alleged violation of § 13955(h) is a "procedural" challenge. *See* Pls.' Mot at 8 ("The allegation that the Secretary failed to comply with Section 1395hh(a)(2) when he allowed Medicare contractors to set new policies governing Medicare coverage and reimbursement for HCT/Ps without following a notice and comment rulemaking process is entirely procedural."). But that label is not controlling, and Plaintiffs' myopic focus on the "procedural" nature of their claim ignores the entirety of their complaint, the status of APC's claim, and the specific relief Plaintiffs seek.

Heckler is instructive. There, the plaintiffs challenged the Secretary's refusal to reimburse a certain surgical procedure, which the Secretary had instructed be denied through both informal

instructions and a formal ruling. 466 U.S. at 607–08. The plaintiffs asserted that (1) the procedure was covered under the Medicare Act and denial of the procedure was arbitrary and capricious (the "substantive" claims); and (2) the Secretary had acted improperly by issuing a generally applicable rule, instead of allowing individual adjudications, and by violating the rulemaking requirements of the Administrative Procedure Act (the "procedural" claims). *Id.* at 610 n.7, 614. The Court declined to draw a distinction between the plaintiffs' "procedural" and "substantive" claims, viewing both claims as essentially one for payment of benefits. *See id.* at 614, 620. The court refused to treat one of the plaintiff's claims as "collateral," "regardless of any arguably procedural components." *Id.* at 620.

Similarly, in this case, the only plaintiff to have presented a claim—APC—asserts both substantive and procedural violations by the Secretary. The substantive claim is that CMS's alleged blanket, unwritten policy of noncoverage for HCT/Ps (including StimLabs' products) is arbitrary and capricious, and the procedural claim is that CMS adopted the blanket, unwritten policy without proper notice and comment. For APC, each of those claims is essentially one for benefits. APC already has received reimbursement for its past use of Ascent, but CMS has made demands for repayment that APC has appealed. APC asks this court to "declar[e] invalid and set[] aside the MAC Policies that have been implemented to deny Medicare claims for Ascent and Corplex P," "enjoin[] CMS from reopening claims for procedures using Ascent or Corplex P without first documenting compliance with 42 C.F.R. § 405.980," and "enjoin[] CMS from continuing to engage in a pattern and practice of violating 42 U.S.C. § 1395hh." Compl. at 29–30; *see also* Pls.' Mot. for Inj. and Del. Relief, ECF No. 6 [hereinafter Pls.' Inj. Mot.], Pls.' Mem. of P. & A. in Supp. of Pls.' Mot. for Inj. and Decl. Relief, ECF No. 6-1, at 1 (seeking "injunctive and declaratory relief [barring] the Secretary . . . from implementing [the] new nationwide policies

that are arbitrary and capricious and violate the plain language of . . . the Medicare Law"). The upshot of the requested relief is coverage for APC's claims. If the court were to grant the injunctive relief sought, CMS would be barred from reopening claims which, in turn, would allow APC to keep reimbursements for claims as to which CMS has demanded repayment. As for future payments, injunctive relief would restore the status quo, under which Medicare "routinely covered and paid Medicare Part B claims for products composed of amniotic tissue, including Ascent and Corplex P, as reasonable and necessary." Compl. ¶ 52. Plaintiffs' "procedural" objection to the Secretary's failure to engage in rulemaking is, at bottom, a request for Medicare reimbursement.

Nor is Plaintiffs' procedural claim one that is sufficiently divorced from the merits of coverage determinations. *See Family Rehabilitation, Inc., v. Azar*, 886 F.3d 496, 501 (5th Cir. 2018) ("For a claim to be collateral, it must not require the court to 'immerse itself' in the substance of the underlying Medicare claim or demand a 'factual determination' as to the application of the Medicare Act.") (citation omitted). Plaintiffs' procedural claims rest on their contention that CMS has silently adopted a blanket, unwritten policy to deny coverage for HCT/P products, which constitutes a shift from the prior practice of "routinely" covering claims for such products. Compl. ¶ 52. That "change in policy," Plaintiffs insist, required rulemaking under § 1395hh. *Id.* ¶¶ 71–73. But the court cannot hold that CMS improperly failed to engage in rulemaking without first making a factual finding that CMS has indeed silently changed its coverage policy with respect to HCT/Ps. Making such a factual determination would require the court to delve not only into the merits of APC's denied claims, but arguably the coverage claims of other HCT/P providers and products. How else could the court determine whether there is in fact a new blanket, unwritten policy to deny coverage for HCT/P products, as Plaintiffs assert? That inquiry would be especially thorny because Plaintiffs acknowledge that CMS's most recent directive instructs

contractors to "suspend automatic denials of claims for amniotic and placental tissue product injections and institute claim-by-claim review to determine whether a claim meets the reasonable and necessary criteria." *Id*. ¶ 62. Plaintiffs' contention therefore is that contractors are issuing across-the-board coverage denials for StimLabs' products notwithstanding CMS's written policy to the contrary. Because Plaintiffs' procedural claim would require the court to "immerse itself" in the substance of the underlying Medicare claims for HCT/P products, it is not collateral. It is therefore not appropriate to excuse Plaintiffs' failure to exhaust remedies even for their "procedural" claim.

Much of Plaintiffs' motion for reconsideration hinges on the Supreme Court's decision in *Bowen v. City of New York*, 476 U.S. 467 (1986). In *Bowen*, the plaintiffs asserted the defendants "had adopted an unlawful, unpublished policy under which countless deserving claimants were denied benefits." *Id.* at 473. The Court held that the plaintiffs' claims were collateral "because the class members neither sought nor were awarded benefits in the District Court, but rather challenged the Secretary's failure to follow the applicable regulations." *Id.* at 468. This case is different. Plaintiffs here seek to enjoin CMS from denying claims for use of HCT/Ps precisely to restore the prior "routine" practice of approving such claims. They also seek to bar CMS from reopening prior positive coverage decisions, so that claimants like APC will not be required to repay previously reimbursed claims. Thus, this is not a case like *Bowen*, where the plaintiffs merely sought to compel the Secretary to adhere to its published procedures of evaluating and processing claims on an individualized basis. 476 U.S. at 477 (noting the court of appeals' description of the plaintiffs' challenge as "complaining fundamentally of a procedural irregularity and not of the Secretary's substantive standards of eligibility"). Plaintiffs here seek to compel the Secretary to reimburse claims for StimLabs products. *See* Compl. at 29 (asking the court to

"declare[] invalid and set[] aside the MAC Policies that have been implemented to deny Medicare claims for Ascent and Corplex P"). Plaintiffs' rulemaking claim therefore is not "wholly" collateral to their claims for reimbursement. *See id.*

B.

Having found that Plaintiffs' rulemaking claim is not collateral, the court briefly addresses the element of irreparable harm. The court agrees with Plaintiffs that it applied the wrong standard. The court relied on the more stringent injunction standard that "[r]ecoverable monetary loss may constitute irreparable harm only where the loss threatens the very existence of the movant's business." *StimLabs*, 2022 WL 13840218, at *8 (quoting *Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985)). The proper standard requires a plaintiff to make "a colorable showing that his injury could not be remedied by the retroactive payment of benefits after exhaustion of his administrative remedies." *Heckler*, 466 U.S. at 618. The court also erred in focusing its irreparable harm analysis on StimLabs, when it should have evaluated the harm as to APC, the only plaintiff to have met the presentment requirement. *See StimLabs*, 2022 WL 13840218, at *8.

Still, the court cannot find that APC would be irreparably harmed if the exhaustion requirement is enforced. Thus far, APC has received overpayment demands in the amount of approximately $200,000. Pls.' Inj. Mot, Ex. 3, ECF. No 6-4 [hereinafter Dooley Decl.], ¶ 14. It contends that, if those payments are fully recouped, it "could result in the shuttering" of operations. *Id.* But nowhere does APC say that CMS has or is likely to enforce the repayment demands while the administrative process runs its course. If enforcement is unlikely during that period, then it is difficult to see how the mere prospect of future repayment of uncovered claims would constitute irreparable harm. *See Randolph-Sheppard Vendors of Am. v. Weinberger*, 795 F.2d 90, 108 (D.C. Cir. 1986) ("The usual time and effort required to pursue an administrative remedy does not

constitute irreparable injury."). Nor has APC asserted that other adverse consequences would flow from administrative review. It has not, for example, alleged that it has lost patients or revenue due to the alleged policy change. Nor has it said that its patients will be harmed if APC moves away from using Ascent. To the contrary, it seems that APC would be able to continue treatment with other products. *See* Dooley Decl. ¶ 13 (stating that "[APC] would have changed [its] prescribing practices" with notice of noncoverage); *cf. Arriva Med. LLC v. United States Dep't of Health & Hum. Servs.*, 239 F. Supp. 3d 266, 280 (D.D.C. 2017) (finding that the plaintiff met the "low bar" for a colorable showing of irreparable harm because the plaintiff (1) lost customers due to the challenged policy; (2) had to resort to "a practice that could push it out of business"; and (3) faced a "business risk [that] may ultimately fall on the shoulders of Medicare beneficiaries").

Accordingly, the court finds that exhaustion of remedies would not irreparably harm APC.[3]

VI.

For the foregoing reasons, Plaintiff's Motion to Amend the Court's Judgment Pursuant to Rule 59(e) or, in the Alternative, for Reconsideration of the Court's Order Pursuant to Rule 60(b), ECF No. 27, is denied.

Dated: January 12, 2023

Amit P. Mehta
United States District Court Judge

[3] Having found that Plaintiffs' rulemaking claim is not collateral and APC has not shown irreparable harm, the court need not consider the futility element.