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APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT, FILED FEBRUARY 16, 2024

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 23-5020

ROW 1 INC., D/B/A REGENATIVE LABS,

Appellant,

v.

XAVIER BECERRA, SECRETARY OF HEALTH AND HUMAN SERVICES, SOLELY IN HIS OFFICIAL CAPACITY, *et al.*,

Appellees.

October 6, 2023, Argued
February 16, 2024, Decided

Appeal from the United States District Court
for the District of Columbia
(No. 1:22-cv-00718).

Before: PILLARD and CHILDS, *Circuit Judges*, and EDWARDS, *Senior Circuit Judge.*

Opinion for the Court filed by *Senior Circuit Judge* EDWARDS.

Appendix A

EDWARDS, *Senior Circuit Judge*: In establishing Medicare, a federally funded health insurance program for the elderly and disabled, *see* 42 U.S.C. §§ 1395 *et seq.* ("Medicare Act" or "Act"), Congress enacted a "reticulated statutory scheme" "detail[ing] the forum and limits of review" of all claims for Medicare benefits, *Bowen v. Mich. Acad. of Fam. Physicians*, 476 U.S. 667, 675, 106 S. Ct. 2133, 90 L. Ed. 2d 623 (1986). The Medicare program is administered by the Centers for Medicare and Medicaid Services ("CMS") on behalf of the Secretary of Health and Human Services ("Secretary"). Section 405(h) of the Social Security Act, incorporated into the Medicare Act by 42 U.S.C. § 1395ii, makes it clear that claims arising under the Medicare Act — such as claims seeking Medicare reimbursement for a particular treatment or product — must be pursued through administrative procedures adopted by the Secretary. 42 U.S.C. § 405(h). Such claims may not be raised in judicial actions purporting to rest on federal question jurisdiction under 28 U.S.C. § 1331 or federal defendant jurisdiction under 28 U.S.C. § 1346. *Id.* A claimant may seek judicial review only after receiving a "final decision" from the Secretary. *Id.* § 405(g); *see also id.* § 1395ff(b)(1)(A). This statutory scheme "assures the [Secretary] greater opportunity to apply, interpret, or revise policies, regulations, or statutes without possibly premature interference by different individual courts." *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 13, 120 S. Ct. 1084, 146 L. Ed. 2d 1 (2000).

Appellant Row 1 Inc., d/b/a Regenative Labs ("Regenative"), manufactures, markets, and distributes medical products containing human cells, tissues,

or cellular or tissue-based products ("HCT/Ps"). In February 2022, CMS issued two technical direction letters instructing Medicare contractors to deny reimbursement for claims for products manufactured by Regenative. Without first exhausting its administrative remedies, Regenative filed suit in the District Court challenging the CMS letters, claiming that the Secretary failed to engage in notice-and-comment rulemaking before implementing a policy to automatically deny all reimbursement claims for Regenative's products. Regenative's complaint asked the District Court to, *inter alia*, enter injunctive, declaratory, and mandamus relief that: vacates the Secretary's policy; declares that the Secretary's policy determination was arbitrary, capricious, an abuse of discretion, otherwise not in accordance with law, in excess of authority granted by law, and without observance of procedure required by law; and declares that Regenative's product is of a type that does not require FDA approval and should be reimbursed as such to maintain the status quo. Amended Verified Complaint ("Compl.") Prayer for Relief ¶ 1(a), Joint Appendix ("J.A.") 134-35; *see also* Compl. ¶ 25, J.A. 113. The District Court dismissed the case for lack of subject matter jurisdiction under 28 U.S.C. § 1331 because Regenative had failed to exhaust its administrative remedies. *Row 1 Inc. v. Becerra*, 2023 U.S. Dist. LEXIS 6242, 2023 WL 183687, at *1 (D.D.C. Jan. 12, 2023). The court also found that Regenative had not satisfied the jurisdictional requirements for mandamus relief. 2023 U.S. Dist. LEXIS 6242, [WL] at *4.

On appeal, Regenative contends that Section 405(h) does not bar federal question jurisdiction over its case,

because it seeks not to recover on claims for reimbursement but rather to vindicate interests in procedural regularity and reputational image. Regenative further claims that if it were required to pursue administrative remedies, there would be "no [judicial] review at all" of its claims. *See Ill. Council*, 529 U.S. at 19. Separately, Regenative also argues that its claims meet the threshold requirements for mandamus jurisdiction, and that compelling equitable grounds justify the issuance of a writ of mandamus ordering Defendants to comply with administrative rulemaking procedures.

We affirm the District Court's dismissal of this case, in part for lack of subject matter jurisdiction and in part on grounds of mootness. CMS has already rescinded the two technical direction letters, thus mooting Appellant's request for the court to vacate the contested policy. An order to vacate an already-rescinded policy on grounds of procedural deficiencies will not provide Appellant any meaningful relief, and this case is not the appropriate vehicle to address Appellant's interest in clarification of or changes to the agency's current policy regarding HCT/Ps. While Appellant's further allegation that Medicare contractors have continued to apply the contested terms of CMS's two rescinded letters is not moot, it is nonetheless barred because it arises under the Medicare Act and therefore must be channeled through the agency.

Appendix A

I. Background

A. Statutory and Regulatory Framework

Enacted in 1965, the Medicare Act established a federal program that provides health insurance for the elderly and disabled. *See* Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (codified as amended at 42 U.S.C. §§ 1395 *et seq.*). The Medicare program is administered by CMS on behalf of the Secretary. *St. Luke's Hosp. v. Sebelius*, 611 F.3d 900, 901 n.1, 391 U.S. App. D.C. 400 (D.C. Cir. 2010). CMS contracts with private entities known as Medicare administrative contractors, who help with processing claims and administering benefits. *See* 42 U.S.C. § 1395kk-1. The Medicare program covers only items and services "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." *Id.* § 1395y(a)(1)(A); *see also* 42 C.F.R. § 411.15(k)(1). Absent a binding national policy or direction from the Secretary, Medicare contractors make the initial coverage decision as to whether an item or service is reasonable and necessary. *See* 42 U.S.C. § 1395kk-1(a)(4)(A).

Generally, challenges to a Medicare contractor's reimbursement decision must first be raised and exhausted pursuant to the administrative processes established by the Secretary. Known as the channeling requirement, the Medicare Act creates a "special review system" specifically designed for Medicare claims, *Ill. Council*, 529 U.S. at 8, and "it demands the 'channeling' of virtually all legal attacks through the agency," *id.* at 13. To such

ends, Section 405(h) displaces general federal question jurisdiction over actions seeking "to recover on any claim arising under" the Medicare Act. 42 U.S.C. § 405(h); *see also id.* § 1395ii. A party may obtain judicial review only after a "final decision of the [Secretary] made after a hearing to which he was a party." *Id.* § 405(g); *see also Ill. Council*, 529 U.S. at 10 ("Section 405(h) purports to make exclusive the judicial review method set forth in § 405(g)."). Those who can bring Medicare claims before the agency include program beneficiaries and their providers. *See* 42 C.F.R. §§ 405.906(a), 405.912(a). Providers can either assert claims on their own behalf or as assignees of the beneficiaries. *See id.*

B. Factual and Procedural History

Plaintiff Regenative manufactures, markets, and distributes medical products containing HCT/Ps. The products include AmnioText (previously marketed as CoreText) and ProText, which consist of a connective tissue found in the umbilical cord. Compl. ¶ 1, J.A. 105. In its Complaint, Regenative asserts its products have been registered and listed with the United States Food and Drug Administration ("FDA") as meeting the criteria necessary for lighter-touch regulation under Section 361 of the Public Health Service Act, 42 U.S.C. § 264, as opposed to the more demanding requirements of Section 351 of the Public Health Service Act, 42 U.S.C. § 262. *Id.* ¶ 3, J.A. 105-06. To be subject solely to Section 361 oversight, the product must satisfy four criteria, including minimal manipulation. *See* 21 C.F.R. § 1271.10(a). Regenative believes its products are minimally manipulated and fit

these criteria, and the Complaint asserts that, "[t]o date, the FDA has not . . . indicated any disagreement." Compl. ¶ 3, J.A. 106. Regenative claims it sold its products as Section 361 HCT/Ps from February 14, 2020 to late 2021 and had been reimbursed by Medicare contractors as such. *Id.* ¶¶ 4-5, J.A. 106. According to Regenative, its Section 361 products, unlike products regulated under Section 351, are exempt from licensing and pre-market approval from the FDA. *Id.* ¶ 2, J.A. 105.

In February 2022, CMS issued two non-public technical direction letters to the Medicare contractors. The first instructed Medicare contractors to automatically "deny payments for claims of manipulated amniotic and/or placental tissue biologics for injections." J.A. 200. The letter noted the FDA's concern that these products were "illegally marketed" and had "not been shown to be safe or effective." *Id.* The second letter provided specific instructions to deny claims bearing certain codes, including the code that corresponded with the products manufactured by Regenative. *See* J.A. 205-06; *see also* Compl. ¶ 4, J.A. 106. Following CMS's issuance of these two February letters, Medicare contractors proceeded to automatically deny reimbursement claims for Regenative's products. Compl. ¶¶ 74-80, J.A. 121-22.

On March 15, 2022, Regenative filed a Complaint in the District Court against the Secretary in his official capacity, the Department of Health and Human Services, the Administrator of CMS in her official capacity, CMS, and several Medicare contractors (together, "Government"). The Complaint alleged that

the Government improperly held Regenative's Section 361 products to the more stringent Section 351 requirements, and that it did so without following proper procedures. *See* Verified Complaint ¶ 10, J.A. 15. Specifically, the Complaint challenged the Government's policy as (1) being arbitrary and capricious, (2) exceeding statutory authority, (3) contradicting Congressional intent, and (4) violating procedural requirements and Regenative's due process rights by failing to provide an opportunity for notice and comment. *Id.*

On March 25, 2022, ten days after Regenative filed its initial Complaint, CMS issued a third technical direction letter rescinding the two February letters. J.A. 211. In this third letter, CMS instructed the Medicare contractors to institute claim-by-claim review rather than automatic denial for amniotic and placental tissue product injections, to reopen any claims that had been automatically denied, and to delete all related coverage articles and educational materials issued in accord with the February letters. *Id.* On July 12, 2022, Regenative amended its Complaint, alleging that the Government's rescinded policy remained in full effect in practice despite the policy's formal recission. Compl. ¶ 11, J.A. 110. As the remedy, Regenative asked the court to vacate the policy, declare it unlawful, and "[d]eclare[] that Regenative is a Section 361 product that does not require FDA approval and should be reimbursed as such to maintain the status quo." Compl. Prayer for Relief ¶ 1(a), J.A. 134-35.

The District Court dismissed the Complaint for lack of subject matter jurisdiction. *Row 1 Inc.*, 2023 U.S. Dist.

LEXIS 6242, 2023 WL 183687, at *1. Reasoning that Regenative's claims arise under the Medicare Act and finding the no-review exception inapplicable, the court determined that Section 405(h) required Appellant's claims to be channeled through the Secretary's administrative processes. 2023 U.S. Dist. LEXIS 6242, [WL] at *2-3. Accordingly, the court held it lacked federal question jurisdiction under 28 U.S.C. § 1331 over Appellant's claims. *Id.* The court further found mandamus jurisdiction under 28 U.S.C. § 1361 inappropriate, on grounds that Regenative failed to establish that it met the threshold jurisdictional requirements for mandamus relief. 2023 U.S. Dist. LEXIS 6242, [WL] at *4. We affirm the District Court's order dismissing Appellant's case, in part for want of subject matter jurisdiction and in part on grounds of mootness.

II. Analysis

A. Standard of Review

We review a District Court's dismissal for lack of subject matter jurisdiction *de novo*, "assuming the truth of all well-pled material factual allegations in the complaint and granting the plaintiff the benefit of all reasonable inferences from the alleged facts." *RICU LLC v. U.S. Dep't of Health & Hum. Servs.*, 22 F.4th 1031, 1034, 455 U.S. App. D.C. 281 (D.C. Cir. 2022). With respect to mandamus jurisdiction, we review a District Court's legal determination about whether the plaintiff met the jurisdictional requirements *de novo*, whereas we review a District Court's assessment of the equities for abuse of

discretion. *In re Medicare Reimbursement Litig.*, 414 F.3d 7, 10, 367 U.S. App. D.C. 116 (D.C. Cir. 2005).

B. Mootness

Although the District Court did not reach the question of mootness, we are obliged to address the issue "because mootness goes to the jurisdiction of this court." *Mine Reclamation Corp. v. FERC*, 30 F.3d 1519, 1522, 308 U.S. App. D.C. 152 (D.C. Cir. 1994). "Without jurisdiction the court cannot proceed at all in any cause. Jurisdiction is power to declare the law, and when it ceases to exist, the only function remaining to the court is that of announcing the fact and dismissing the cause." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94, 118 S. Ct. 1003, 140 L. Ed. 2d 210 (1998) (quoting *Ex parte McCardle*, 74 U.S. 506, 7 Wall. 506, 514, 19 L. Ed. 264 (1869)). The Government raised the issue of mootness in the District Court and again on appeal, arguing that Appellant's claims are moot because CMS has already rescinded the challenged instructions. *See* Compl. ¶ 11, J.A. 110; Brief ("Br.") for Appellees 52-58; Def's Mem. Supp. Mot. Dismiss 26-29. We agree in part. The Government's recission of the contested February letters moots Appellant's request for the court to vacate the policy announced in the letters.

Article III of the Constitution grants federal courts power to "adjudicate only actual, ongoing cases or controversies." *Lewis v. Cont'l Bank Corp.*, 494 U.S. 472, 477, 110 S. Ct. 1249, 108 L. Ed. 2d 400 (1990). A case is moot "when the issues presented are no longer 'live' or the parties lack a legally cognizable interest in the outcome."

Already, LLC v. Nike, Inc., 568 U.S. 85, 91, 133 S. Ct. 721, 184 L. Ed. 2d 553 (2013) (quoting *Murphy v. Hunt*, 455 U.S. 478, 481, 102 S. Ct. 1181, 71 L. Ed. 2d 353 (1982) (per curiam)). However, it is well-settled that "[m]ere voluntary cessation of allegedly illegal conduct does not moot a case." *United States v. Concentrated Phosphate Exp. Ass'n*, 393 U.S. 199, 203, 89 S. Ct. 361, 21 L. Ed. 2d 344 (1968). "[I]f it did, the courts would be compelled to leave '[t]he defendant . . . free to return to his old ways.'" *Id.* (second alteration in original) (quoting *United States v. W. T. Grant Co.*, 345 U.S. 629, 632, 73 S. Ct. 894, 97 L. Ed. 1303 (1953)). Therefore, a defendant claiming mootness due to voluntary cessation "bears the formidable burden" of demonstrating (1) "that it is absolutely clear the allegedly wrongful behavior could not reasonably be expected to recur," *Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 190, 120 S. Ct. 693, 145 L. Ed. 2d 610 (2000); and (2) that "interim relief or events have completely and irrevocably eradicated the effects of the alleged violation," *County of Los Angeles v. Davis*, 440 U.S. 625, 631, 99 S. Ct. 1379, 59 L. Ed. 2d 642 (1979).

Regarding Appellant's request for the court to vacate the contested policy, the Government's recission of CMS's two letters gives Appellant what it seeks. In CMS's third technical direction letter, CMS explicitly informed the Medicare contractors that the third letter "rescind[ed]" the two February letters. J.A. 211. The third letter directed the Medicare contractors to "suspend automatic denials" of Appellant's category of products and to instead "institute claim-by-claim review." *Id.* The third letter further instructed the Medicare contractors to reopen and

evaluate claims that had been automatically denied under the previous policy, as well as delete all related materials issued in accord with the February letters. *Id.*

As this court has recognized, "the government's abandonment of a challenged [policy] is just the sort of development that can moot an issue." *Friends of Animals v. Bernhardt*, 961 F.3d 1197, 1203, 447 U.S. App. D.C. 209 (D.C. Cir. 2020). Appellant challenges CMS's two February letters as unlawful under both the Medicare Act and the Administrative Procedure Act, and it requests that the court declare the policy announced in the letters as such and set it aside. But the Government has already rescinded the automatic-denial policy that Appellant challenges. And the Government has not indicated any intention to reinstate the February letters. The recission of the contested policy has "completely and irrevocably eradicated the effects" from the alleged procedural and substantive violations committed by CMS in its issuance of the first two letters. *Davis*, 440 U.S. at 631. Claims that had been automatically denied must now, pursuant to the third letter, be subject to claim-by-claim review. Additionally, coverage articles and educational materials describing the products at stake as unsafe and ineffective, issued in accord with the first two letters, must be deleted. In short, CMS has made explicitly clear that Medicare contractors should no longer be following the automatic-denial policy.

"Since we can do nothing to affect [Appellant's] rights relative to those now-withdrawn [letters], [Appellant's] challenges to them are 'classically moot.'" *Friends of*

Animals, 961 F.3d at 1203 (quoting *Akiachak Native Cmty. v. U.S. Dep't of the Interior*, 827 F.3d 100, 106, 423 U.S. App. D.C. 458 (D.C. Cir. 2016)). An order requiring notice and comment on a rescinded policy would provide Appellant no meaningful relief. This case is not an appropriate vehicle to address Appellant's interest in prospective clarification of or changes to CMS's current, claim-by-claim approach to HCT/Ps.

Appellant contends that, despite CMS's clear instructions to scrap the automatic-denial system and institute claim-by-claim review, Medicare contractors still apply the rescinded policy. Appellant claims that "the Policy [from the February letters] continues and is in effect behind the scenes." Compl. ¶ 118, J.A. 128. Thus, according to Appellant, there remains a live controversy over whether Medicare contractors are improperly denying reimbursement claims for Appellant's products on the belief that CMS continues to endorse *sub silentio* the policy outlined in the two February 2022 letters. We agree that Appellant's challenge to the Medicare contractors' alleged mishandling of reimbursement claims is not moot. Indeed, Appellant may have a legitimate concern over these alleged practices. However, as we explain in the next section, any challenge to the contractors' contested practices is barred in this case because of the Medicare Act's channeling requirement.

C. Federal Question Jurisdiction

1. "Arising Under" the Medicare Act

Section 405(h), as incorporated by 42 U.S.C. § 1395ii, provides that "[n]o action against the United States, the [Secretary], or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under" the Medicare Act. 42 U.S.C. § 405(h). The Supreme Court has interpreted this provision to "demand[] the 'channeling' of virtually all legal attacks through the agency." *Ill. Council*, 529 U.S. at 13. The Court rejected proposals to limit these channeling provisions "based upon the 'potential future' versus the 'actual present' nature of the claim, the 'general legal' versus the 'fact-specific' nature of the challenge, the 'collateral' versus 'noncollateral' nature of the issues, or the 'declaratory' versus 'injunctive' nature of the relief sought." *Id.* at 13-14. The Court also rejected "a distinction that [would] limit[] the scope of § 405(h) to claims for monetary benefits." *Id.* at 14.

The Supreme Court's capacious understanding of the scope of Section 405(h) bars this action. Appellant's assertion that certain types of injuries — for example, procedural and reputational — are not subject to Medicare Act channeling fails because those injuries are "inextricably intertwined" with the underlying Medicare claims. *See, e.g., Heckler v. Ringer*, 466 U.S. 602, 614, 104 S. Ct. 2013, 80 L. Ed. 2d 622 (1984). At its core, Appellant's challenge is to the Government's Medicare reimbursement decisions, and Appellant seeks for the court to declare that

its products "should be reimbursed." Compl. Prayer for Relief ¶ 1(a), J.A. 134-35. Such claims for reimbursement "aris[e] under the Medicare Act," and accordingly "must be channeled through the agency." *Ill. Council*, 529 U.S. at 23.

That Appellant brings a challenge to the procedural irregularity of the policy, rather than challenging only the Government's substantive decision to deny the claims, is irrelevant to the Section 405(h) jurisdictional analysis on the facts presented here. In *Heckler v. Ringer*, several individuals who had been or anticipated being denied Medicare reimbursement for surgeries "assert[ed] objections [in federal court before administrative exhaustion] to the Secretary's 'procedure' for reaching her decision." *Ringer*, 466 U.S. at 614. Bringing procedural claims, the plaintiffs "challenge[d] [the Secretary's] decision to issue a generally applicable rule rather than to allow individual adjudication," as well as "her alleged failure to comply with the rulemaking requirements of the [Administrative Procedure Act]." *Id.* The Supreme Court held that Section 405(h) barred the plaintiffs' action and declined to distinguish between procedural and substantive claims. *Id.* at 613-14. The Court reasoned that "it ma[de] no sense to construe the claims . . . as anything more than, at bottom, a claim that [plaintiffs] should be paid" for their surgery. *Id.* at 614. Finding the plaintiffs' procedural claims "inextricably intertwined" with their claims for benefits, the Court instructed that "the inquiry in determining whether § 405(h) bars federal-question jurisdiction must be whether the claim 'arises under' the Act, not whether it lends itself to a 'substantive' rather than a 'procedural' label." *Id.* at 614-15.

As in *Ringer*, although Appellant here makes a facially procedural claim, at bottom, the relief that Appellant seeks is a substantive declaration that its products are reimbursable under the Medicare Act. Appellant protests that Medicare contractors continue to apply the rescinded policy in full force, Compl. ¶ 11, J.A. 110, claiming that the Government merely "faux-ceas[ed]" the policy, *id.* ¶ 120, J.A. 129. In Appellant's view, because CMS promulgated its February letters without notice and comment, CMS foreclosed input from Appellant that could have averted adoption of the policy and attendant harms, including the alleged continued application of the rescinded policy by Medicare contractors. As discussed above, Appellant's request to vacate the February policy on procedural grounds is moot, because the policy has already been rescinded. To the extent Appellant believes the harms from the procedural deficiency linger in the Medicare contractors' incorrect processing of reimbursements, such procedural challenges are "inextricably intertwined" with claims for Medicare benefits and therefore must be channeled through the agency. *See Ringer*, 466 U.S. at 614.

For similar reasons, Section 405(h)'s channeling requirement also bars Appellant's reputational-injury claim. Appellant contends that CMS's characterization of its products as potentially unsafe, ineffective, and illegally marketed damaged its reputation and caused it financial harm beyond the Medicare system. Appellant claims that non-Medicare doctors no longer use its products because of the contested, now-rescinded policy. But, as with Appellant's procedural argument, Appellant's reputational argument is "inextricably intertwined"

with the claim for Medicare benefits. *See Ringer*, 466 U.S. at 614. Appellant's perceived reputational harm derives directly from the Government's reimbursement policy. Under Appellant's theory of reputational injury, approval of Medicare reimbursement indicates the product's safety and effectiveness, whereas continued denial of reimbursement signifies a lack thereof. In short, Appellant's reputational-injury claim cannot be separated from the claim that Regenative's products should be reimbursed, and accordingly it is subject to the Medicare Act's requirements of presentation to and exhaustion before the agency. *See Ill. Council*, 529 U.S. at 13.

2. *Illinois Council's* No-Review Exception to Section 405(h)

Appellant argues that even if Section 405(h) might otherwise bar review, the exception to Section 405(h) enunciated in *Illinois Council* applies. In *Illinois Council*, the Supreme Court observed that Section 405(h) does not apply when its application "would not simply channel review through the agency, but would mean no review at all." *Ill. Council*, 529 U.S. at 19. The Court characterized Section 405(h) as "a channeling requirement, not a foreclosure provision." *Id.* However, the Court emphasized that "added inconvenience or cost in an isolated, particular case" is insufficient to trigger this exception. *Id.* at 22. The hardship must result in "*complete* preclusion of judicial review." *Id.* at 23.

In *Council for Urological Interests v. Sebelius*, this court explained that "the *Illinois Council* exception is

primarily concerned with whether a particular *claim* can be heard through Medicare Act channels." *Council for Urological Ints. v. Sebelius*, 668 F.3d 704, 712, 399 U.S. App. D.C. 159 (D.C. Cir. 2011). It noted that "the *Illinois Council* exception is not intended to allow section 1331 federal question jurisdiction in every case where section 405(h) would prevent a particular individual or entity from seeking judicial review." *Id.* at 711. If another party can bring the general claim through the administrative channels, and has sufficient incentive to do so, the *Illinois Council* exception does not apply. *See id.* at 712; *see also Fam. Rehab., Inc. v. Azar*, 886 F.3d 496, 505 (5th Cir. 2018) ("[W]e have required channeling so long as there potentially were other parties with an interest and a right to seek administrative review.") (footnote omitted) (quotation marks omitted). Some of our sister circuits have held that the plaintiff carries the "heavy burden of showing that the *Illinois Council* exception applies." *Sw. Pharmacy Sols., Inc. v. Centers for Medicare & Medicaid Servs.*, 718 F.3d 436, 439 (5th Cir. 2013); *see also Retina Grp. of New England, P.C. v. Dynasty Healthcare, LLC*, 72 F.4th 488, 497 (2d Cir. 2023). We need not decide the question of burden in the context of *Illinois Council*, because the record in this case makes it clear that there are potentially other parties with an interest and a right to seek administrative review.

We see no basis on this record to apply the *Illinois Council* exception. Reviewed under our precedents, this record suggests there are adequate proxies for Appellant that have the incentive to seek administrative review. In *Council for Urological Interests*, this court found

the exception applied to a council of urologist-owned joint ventures that challenged a regulation prohibiting physicians from referring patients to hospitals that compensated physicians for use of certain equipment or from receiving reimbursement for procedures performed at such hospitals. *Council for Urological Ints.*, 668 F.3d at 705-06. Though the council's claims could be brought through the administrative process by its client hospitals, the court noted "several unique characteristics of the hospitals' relationship to the Council and to the challenged regulations" that rendered the hospitals unlikely to do so. *Id.* at 713. Specifically, the hospitals resented the council's control over the purchase of medical equipment, and the new regulations afforded the hospitals an opportunity to reassert control. *Id.* Furthermore, the new regulations financially benefited the hospitals by allowing them to purchase expensive laser equipment from the council at fire-sale prices. *Id.* The court also credited the fact that, "[i]n the three years since the Secretary announced the regulations, not one of the 5,795 hospitals in the United States has brought an administrative challenge to those regulations." *Id.*

Unlike in *Council for Urological Interests*, Appellant has not alleged any facts indicating a lack of alignment in incentives between itself and the providers using its products. Presumably, providers that purchase Appellant's products would also wish to be reimbursed by Medicare, and Appellant has not demonstrated otherwise. Rather, Appellant argues that many healthcare providers will simply no longer purchase and use its products because of the confusion with the reimbursement policy. While there

might be some force to the claim that the volume of future purchases may decrease, we cannot conclude that *no* providers would be incentivized to seek reimbursement.

For instance, Appellant acknowledges that there are providers who had successfully submitted reimbursement claims after February 2020. These providers would have later been subject to having their claims reopened and automatically denied pursuant to CMS's two February letters. In other words, there appears to be no dispute over the fact that there are providers who purchased Appellant's products, had their claims denied, and consequently would have incentive to challenge any misapplication of the current policy requiring that their cases be reopened for claim-by-claim review.

In addition, Appellant's Complaint recounts that one provider had contacted a Medicare contractor after the third letter and inquired about reimbursement, indicating that at least one provider has sufficient incentive to submit a concrete claim. Compl. ¶ 108, J.A. 127; *see RICU LLC*, 22 F.4th at 1038-39 (holding that supplier's client hospitals were "adequate proxies" for bringing supplier's claims, because the client hospitals had inquired about being reimbursed for supplier's services and thus had demonstrated sufficient incentive to submit a concrete claim for payment).

Indeed, contrary to Appellant's assertions that no proxy is sufficiently incentivized to bring suit, some providers have already challenged the contested letters from CMS on substantive and procedural grounds. In

April 2023, about a year after Appellant's initial Complaint was filed and two weeks before Appellant's opening brief in this court was due, some providers filed a suit "request[ing] review of final decisions of [the Secretary] that denied Medicare coverage and reimbursement" for similar products manufactured by another company. Compl. ¶ 1, *Greiner Orthopedics, LLC v. Becerra*, No. 1:23-cv-01047 (D.D.C. Apr. 14, 2023). As amended, the providers' complaint asserted claims comparable to those raised by Appellant, including that the Secretary's denial of Medicare coverage was "arbitrary, capricious, and not in accordance with the law," as well as "in violation of the notice and comment requirements" under the Medicare Act and the Administrative Procedure Act. Amended Compl. ¶¶ 161, 164, 180, *Greiner Orthopedics, LLC v. Becerra*, No. 1:23-cv-01047 (D.D.C. Jun. 16, 2023). Like Appellant, the providers seek declaratory and injunctive relief. *Id.* ¶ 5.

In sum, this record does not establish that Appellant's providers so lack incentive to seek reimbursement for its products such that invoking Section 405(h) would "turn[] what appears to be simply a channeling requirement into *complete* preclusion of judicial review." *Ill. Council*, 529 U.S. at 22-23. Because the *Illinois Council* exception does not apply, we therefore conclude that Section 405(h) bars the exercise of federal question jurisdiction over Appellant's claims.

D. Mandamus Jurisdiction

Appellant also invokes the District Court's jurisdiction pursuant to the Mandamus Act. Under the Mandamus Act, "[t]he district courts shall have original jurisdiction of any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff." 28 U.S.C. § 1361. Appellant contends mandamus is necessary to enforce CMS's "clear statutory duty to promulgate regulations following the required notice-and-comment procedure." Br. of Appellant 29. Contrary to Appellant's view, we agree with the District Court that Appellant has failed to show eligibility for mandamus relief.

Although Section 405(h) does not preclude mandamus jurisdiction under 28 U.S.C. § 1361, *Monmouth Med. Ctr. v. Thompson*, 257 F.3d 807, 813, 347 U.S. App. D.C. 214 (D.C. Cir. 2001), "[t]he remedy of mandamus is a drastic one, to be invoked only in extraordinary situations," *Kerr v. U.S. Dist. Ct. for N. Dist. of Cal.*, 426 U.S. 394, 402, 96 S. Ct. 2119, 48 L. Ed. 2d 725 (1976). To establish mandamus jurisdiction under 28 U.S.C. § 1361, a plaintiff "must demonstrate (1) a clear and indisputable right to relief, (2) that the government agency or official is violating a clear duty to act, and (3) that no adequate alternative remedy exists." *Am. Hosp. Ass'n v. Burwell*, 812 F.3d 183, 189, 421 U.S. App. D.C. 123 (D.C. Cir. 2016). These requirements are jurisdictional, and failure to meet these threshold criteria requires dismissal of the case. *Id.* "Even when the legal requirements for mandamus jurisdiction have been satisfied, however, a court may grant relief only when it

finds compelling equitable grounds." *Id.* (quoting *In re Medicare Reimbursement Litig.*, 414 F.3d at 10).

The District Court held that Appellant failed to meet its burden of showing that the jurisdictional requirements for mandamus relief are satisfied. *Row 1 Inc.*, 2023 U.S. Dist. LEXIS 6242, 2023 WL 183687, at *4. We agree. First, as discussed above, Appellant's request that the court order the Government to undertake notice-and-comment rulemaking on its automatic-denial policy is moot. The contested policy has been rescinded.

To the extent Appellant wishes to compel CMS to further clarify or change its current approach to HCT/Ps via notice-and-comment rulemaking, it has demonstrated neither a clear and indisputable right to such relief nor a governmental violation of a clear duty to act. Appellant has not identified any legal basis that would confer upon it a right to require CMS to promulgate across-the-board regulations concerning the reimbursement eligibility of HCT/P products. To the contrary, CMS's current policy of individual review falls squarely within the agency's longstanding ability to adjudicate claims on a case-by-case basis, and the policy fully comports with CMS's statutory duty under the Medicare Act to cover only items and services that are "reasonable and necessary." 42 U.S.C. § 1395y(a)(1)(A); *see also* 42 C.F.R. § 411.15(k)(1).

Because Appellant has failed to demonstrate "a clear and indisputable right" to the relief it requests and that the Government "is violating a clear duty to act," *see Am. Hosp. Ass'n*, 812 F.3d at 189, we need not consider the third

threshold requirement of mandamus jurisdiction that no adequate alternative remedy exists. Regardless of the third requirement, Appellant has failed to demonstrate that it has met the threshold requirements for mandamus jurisdiction.

III. Conclusion

For the reasons set forth above, we affirm the District Court's dismissal of this action.

So ordered.

APPENDIX B — MEMORANDUM OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA, FILED JANUARY 12, 2023

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Case No. 22-cv-0718 (APM)

ROW 1 INC., D/B/A REGENATIVE LABS,

Plaintiff,

v.

XAVIER BECERRA, *et al.*, SECRETARY OF HEALTH AND HUMAN SERVICES,

Defendants.

MEMORANDUM OPINION

I.

This action raises many of the same background facts as *StimLabs, LLC. v. Becerra*, 22-cv-1988 (APM), a case recently resolved by this court. The court does not repeat those facts here but simply incorporates them by reference and recites only the additional allegations specific to this case.

Plaintiff Row 1 Inc. d/b/a/ Regenative Labs ("Regenative") is a company that manufactures, markets, and distributes medical products containing human cells, tissues, or cellular or tissue-based products ("HCT/Ps").

Appendix B

As relevant here, Regenative distributes two products, Coretext and Protext, which consist of minimally manipulated Wharton's Jelly tissue—a connective tissue found in the umbilical cord. Regenative brings this action to challenge policies that allegedly bar reimbursement for use of Coretext and Protext under the Medicare program. Just as the plaintiffs did in *StimLabs*, Plaintiff here alleges that the Secretary of Health and Human Services (the "Secretary") unlawfully bypassed the notice-and-comment rulemaking requirement for policies that change a substantive legal standard governing Medicare coverage and payment, and that the Secretary's decision to stop covering Coretext and Protext is arbitrary and capricious under the Administrative Procedure Act.

Plaintiff brings claims against the Secretary in his official capacity, the Department of Health and Human Services, the Administrator of the Center for Medicare and Medicaid Services ("CMS") in her official capacity, CMS, and several Medicare Administrative Contractors[1] ("MACs") (together, "Defendants"). Before the court is Defendants' motion to dismiss. *See* Defs.' Mot. to Dismiss, ECF No. 23 [hereinafter Defs.' Mot.]. The court concludes that, because Plaintiff failed to exhaust administrative remedies before filing suit, the court lacks subject matter jurisdiction over this action. Accordingly, Defendants' motion to dismiss is granted.

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1. Plaintiff brings claims against the following MACs: Noridian Healthcare Solutions, LLC., Wisconsin Physicians Service Insurance Corporation, Novitas Solutions, Inc., National Government Services Inc., CGS Administrators, LLC., Palmetto GBA, LLC., and First Coast Service Options Inc.

Appendix B

II.

Federal Question Jurisdiction. As in *StimLabs*, the "primary jurisdictional dispute centers on whether the court lacks general federal question jurisdiction to hear this action." *StimLabs, LLC, v. Becerra*, No. 22-cv-01988-APM, 2022 U.S. Dist. LEXIS 192682, 2022 WL 13840218, at *4 (D.D.C. Oct. 21, 2022); Memorandum Opinion and Order, *StimLabs, LLC., v. Becerra*, No. 22-cv-01988-APM (D.D.C.), ECF No. 32. Section 405(h), a Social Security Act provision incorporated into the Medicare Act, "channels most, if not all, Medicare claims through [the agency] review system." *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 8, 120 S. Ct. 1084, 146 L. Ed. 2d 1 (2000). Generally speaking, only after exhausting agency review procedures can claimants "seek judicial review [in federal court] pursuant to the Medicare Act." *Council for Urological Interests v. Sebelius*, 668 F.3d 704, 706, 399 U.S. App. D.C. 159 (D.C. Cir. 2011). In *Illinois Council*, the Court recognized an exception to the channeling requirement in cases "where application of § 405(h) would not simply channel review through the agency, but would mean *no review at all*." *Ill. Council*, 529 U.S. at 19 (emphasis added). In other words, for claims arising under the Medicare Act, if the channeling requirement leads to a "*complete* preclusion of judicial review," a party need not present and exhaust its claims before coming to federal court. *Id.* at 23. The *Illinois Council* exception is a narrow one—it is "not intended to allow section 1331 federal question jurisdiction in every case where section 405(h) would prevent a particular individual or entity from seeking judicial review." *Council for Urological*, 668 F.3d at 711.

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Courts conduct a "three-step analysis" when determining "whether a court has subject matter jurisdiction to hear a claim related to Medicare." *Sensory Neurostimulation, Inc. v. Azar*, 977 F.3d 969, 976 (9th Cir. 2020). First, the court must determine whether the claim "arises under" the Medicare Act. *Id.* If it does, the court next "must decide whether the plaintiff has satisfied the channeling requirements by properly presenting the claim and exhausting the appropriate administrative channel." *Id.* Finally, if plaintiff has not satisfied the channeling requirement, the court must inquire whether the "no review at all" exception applies. *Id.* "If it [does], the plaintiff may proceed in court under 28 U.S.C. § 1331 or some other jurisdictional predicate. If not, the plaintiff's claim cannot proceed and must be dismissed for lack of subject matter jurisdiction." *Id.*

Plaintiff here concedes that it has not satisfied the second step of the analysis—the channeling requirement. It nevertheless contends that the court has subject matter jurisdiction because it prevails at the first and third steps of the analysis. The court disagrees.

A.

Plaintiff first contends that its claim does not "arise under" § 405(h), rendering the channeling requirement inapplicable. According to Plaintiff, its "claims for relief here are purely procedural and are not within the scope of Section 405(h)." Pl.'s Opp'n to Defs.' Mot., ECF No. 25 [hereinafter Pl.'s Opp'n], at 13. Plaintiff continues, its "cause of action is not to recover unpaid Medicare claims;

rather it challenges CMS's failure to follow required rulemaking procedures and CMS's actions in excess of its statutory authority in improperly adopting policies." *Id.*

The Supreme Court in *Illinois Council* expressly rejected the distinctions Plaintiff makes here to avoid the channeling requirement. The Court observed that § 405(h)'s channeling requirement "assures the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes without possibly premature interference by different individual courts applying 'ripeness' and 'exhaustion' exceptions case by case. But this assurance comes at a price, namely, occasional individual, delay-related hardship." *Ill. Council*, 529 U.S. at 13. It further stated that the channeling requirement does not vary based on how a claim is characterized: "distinction[s] that limit[] the scope of § 405(h)" "based upon the 'potential future' versus 'actual present' nature of the claim, the 'general legal' versus the 'fact-specific' nature of the challenge, the 'collateral' versus the 'noncollateral' nature of the issues, or the 'declaratory' versus 'injunctive' nature of the relief sought" cannot be sustained. *Id.* at 13-14. Nor would the Court "accept a distinction that limits the scope of § 405(h) to claims for monetary benefits." *Id.* at 14.

> Claims for money, claims for other benefits, claims of program eligibility, and claims that contest a sanction or remedy may all similarly rest upon individual fact-related circumstances, may all similarly dispute agency policy determinations, or may all similarly

> involve the application, interpretation, or constitutionality of interrelated regulations or statutory provisions. There is no reason to distinguish among them in terms of the language or in terms of the purposes of § 405(h).

Id.; *see also Heckler v. Ringer*, 466 U.S. 602, 614-15, 104 S. Ct. 2013, 80 L. Ed. 2d 622 (1984) ("Thus, to be true to the language of the statute, the inquiry in determining whether § 405(h) bars federal-question jurisdiction must be whether the claim 'arises under' the Act, not whether it lends itself to a 'substantive' rather than a 'procedural' label."). Accordingly, just as the court held in *StimLabs*, the fact that Plaintiff "is unable to assert a claim directly, is challenging a policy and not an individual claim, and is seeking only procedural relief does not excuse it from the channeling requirement." 2022 U.S. Dist. LEXIS 192682, 2022 WL 13840218, at *5.

Plaintiff's citation to *American Clinical Laboratory Association v. Azar*, 931 F.3d 1195, 1206, 442 U.S. App. D.C. 357 (D.C. Cir. 2019), is perplexing. *See* Pl.'s Opp'n at 13. That case concerned a jurisdiction-stripping provision under a different statute altogether—the Protecting Access to Medicare Act—that eliminated administrative and judicial review of "establishment of payment amounts" for reimbursement rates of laboratory tests, 42 U.S.C. § 1395m-1(h)(1). *American Clinical* has nothing to do with understanding the scope of § 405(h).

B.

The court now turns to Plaintiff's contention at the third step that they are not required to satisfy the channeling requirement because the "no review at all" exception applies. *See* Pl.'s Opp'n at 15 ("Regenative is a manufacturer and not subject to these channeling requirements."). Plaintiff does not fall within the exception.

For the "no review at all" exception to apply, it is not enough for a plaintiff to claim it cannot itself file a claim. A plaintiff "must show that there is not an 'adequate proxy' that could raise claims on its behalf." *StimLabs*, 2022 U.S. Dist. LEXIS 192682, 2022 WL 13840218, at *5. Plaintiff argues that "there is no adequate proxy for Regenative" because "MACs now require providers to submit impossible-to-obtain documentation" when submitting claims for Coretext or Protext, and that "it is impossible for providers to [submit reimbursement claims], as the required documentation does not exist and is not required under Section 1361," "which does not require FDA Approval or a Clearance Letter." Pl.'s Opp'n at 16 (internal quotation marks omitted).

Plaintiff's argument misses the point. Even if Medicare approval of its products now requires "impossible-to-obtain documentation," the proper inquiry is not whether the Secretary has established insuperable requirements to secure reimbursement. Rather, it is whether a potential proxy is "highly unlikely" to pursue administrative review to challenge those requirements, thereby creating a "'practical roadblock' to judicial review." *Council for Urological*, 668 F.3d at 712. Plaintiff does not meet this high bar.

Plaintiff has not, for example, pleaded or produced facts showing that there are no existing providers of its products that have pending claims before CMS. *See Ricu LLC v. United States HHS*, 22 F.4th 1031, 1038-39, 455 U.S. App. D.C. 281 (D.C. Cir. 2022) (holding that the "client hospitals" of a telehealth medicine company were an adequate proxy to seek reimbursement for incurred physicians' costs). In *StimLabs*, for instance, there were providers whose incentives aligned with the plaintiff-manufacturer that could assert the very challenge that Plaintiff brings here to the alleged unwritten denial policy. 2022 U.S. Dist. LEXIS 192682, 2022 WL 13840218, at *5. Plaintiff has not shown that similarly situated providers with respect to its products do not exist. Nor has Plaintiff established that it has attempted but cannot secure a provider to designate them as a "appointed representative" under 42 C.F.R. § 405.910 (2019) to pursue administrative review of a claim. That regulation provides: "An appointed representative may act on behalf of an individual or entity in exercising his or her right to an initial determination or appeal. Appointed representatives do not have party status and may take action only on behalf of the individual or entity that they represent." Because Plaintiff has not shown that adequate proxies do not exist, the "no review at all" exception does not apply.[2]

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2. Plaintiff's opposition brief cites *Baxter Healthcare v. Weeks*, 643 F. Supp. 2d 111 (D.D.C. 2009), and *Akebia Therapeutics, Inc. v. Becerra*, 548 F. Supp. 3d 274 (D. Mass. 2021). *See* Pl.'s Opp'n at 17. The court explained in *StimLabs* why those cases are inapposite and adopts that reasoning here. *See StimLabs*, 2022 U.S. Dist. LEXIS 192682, 2022 WL 13840218, at *5-6.

Appendix B

III.

Mandamus Jurisdiction. Plaintiff also invokes the court's jurisdiction pursuant to the Mandamus Act, 28 U.S.C. § 1361. Pl.'s Opp'n at 18. Such relief is available in the Medicare Act context only "to review otherwise unreviewable procedural issues" that are "unrelated to the merits." *Randall D. Wolcott, M.D., P.A. v. Sebelius*, 635 F.3d 757, 765-66 (5th Cir. 2011). For the reasons set forth in *StimLabs*, Plaintiff's procedural claims rest on Plaintiff's merits contention that CMS in fact has changed its coverage policy. *StimLabs*, 2022 U.S. Dist. LEXIS 192682, 2022 WL 13840218, at *8. "For that reason alone, the exercise of mandamus jurisdiction is not appropriate." *Id.*

Additionally, mandamus relief is available only if: "(1) the plaintiff has a clear right to relief; (2) the defendant has a clear duty to act; and (3) there is no other adequate remedy available to the plaintiff." *Council of & for the Blind of Del. Cnty. Valley, Inc. v. Regan*, 709 F.2d 1521, 1533, 228 U.S. App. D.C. 295 (D.C. Cir. 1983). Even if all jurisdictional requirements are met, "a court may grant relief only when it finds compelling equitable grounds." *Am. Hosp. Ass'n v. Burwell*, 812 F.3d 183, 189, 421 U.S. App. D.C. 123 (D.C. Cir. 2016) (citation omitted). Here, Plaintiff has not shown that the administrative appeals process is not an adequate remedy, which by itself bars mandamus jurisdiction. *See Monmouth Med. Ctr. v. Thompson*, 257 F.3d 807, 810, 347 U.S. App. D.C. 214 (D.C. Cir. 2001) ("[W]e must first examine all other possible avenues of relief to ensure that the hospitals have fully

exhausted those which were available."); *id.* at 813 (stating that mandamus is available only when the claimant has exhausted administrative remedies). Moreover, as explained in *StimLabs*, mandamus relief is unavailable because there is no clear, "ministerial" duty to act. 2022 U.S. Dist. LEXIS 192682, 2022 WL 13840218, at *9. In short, Plaintiff has not plausibly established that this is the type of "extraordinary" case in which the "drastic" remedy of mandamus would be proper. *California Clinical Lab'y Ass'n v. Sec'y of Health & Hum. Servs.*, 104 F. Supp. 3d 66, 83 (D.D.C. 2015).

III.

For the foregoing reasons, Defendants' Motion to Dismiss, ECF No. 23, is granted. Plaintiff's Motion for Oral Hearing on Defendants' Motion to Dismiss, ECF No. 34, is denied as moot. A final, appealable order accompanies this Memorandum Opinion.

Dated: January 12, 2023

/s/ Amit P. Mehta
Amit P. Mehta
United States District Court Judge

APPENDIX C — MEMORANDUM OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES, CENTER FOR MEDICARE, FILED AUGUST 25, 2022

CMS
CENTERS FOR MEDICARE
& MEDICAID SERVICES
CENTER FOR MEDICARE

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

TDL-220299

MEMORANDUM

DATE: March 25, 2022

FROM: Contracting Officer's Representatives (CORs)
Medicare Administrative Contractors,
Center for Medicare

Director, Coverage and Analysis Group
Centers for Clinical Standards and Quality

Director, Medicare Contractor Management Group
Center for Medicare

Appendix C

SUBJECT: Amniotic Fluid and Placental Tissues Claims Payment Instructions--Rescission

TO: All Medicare Administrative Contractors (MACs)

The purpose of this Technical Direction Letter (TDL) is to rescind TDLs 220221 and 220240, and to provide guidance to Medicare Administrative Contractors (MACs) as to how they should handle claims that may have been processed and denied in accordance with the instructions in each.

Specifically, in rescinding each subject TDL, MACs are directed to remove the edit outlined in TDL-220240. Instead of the edit, in the absence of a Local or National Coverage Determination (LCD or NCD), MACs shall 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 outlined under section 1862(a)(1)(A) of the Social Security Act, as well as any other applicable requirements for coverage payment in any statute, regulation or guidance document. In addition, any claims that MACs may have processed following the guidance in TDL-220221 or edit instructions in TDL-220240 shall be re-opened and evaluated subject to the same claim-by-claim review. MACs shall delete all related coverage articles and educational materials that were issued in response to TDL-220221 and TDL-220240.

Appendix C

Many patients seeking cures and remedies may be misled by information about products that are illegally marketed, have not been shown to be safe or effective, and, in some cases, present potential, significant safety concerns that put patients at risk.

(Reference: https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/publicsafety-notification-exosome-products; and https://www.fda.gov/vaccines-bloodbiologics/consumers-biologics/important-patient-and-consumer-information-about-regenerativemedicine-therapies). While the subject TDLs were issued because of concerns that some reported uses of amniotic and placental tissue injections may present a danger to beneficiaries or not meet the requirements for coverage under Section 1862(a)(1)(A) as well as any other applicable Medicare statute, regulations and/or guidance documents that address coverage of claims for reimbursement, we are now requiring contractors to make these determinations on a claim-by-claim basis.

Contractors may direct inquiries regarding the framework for the regulation of regenerative medicine products to https://www.fda. gov/vaccines-blood-biologics/cellular-gene-therapy-products/framework-regulation-regenerative-medicine-products.

The recission of the subject TDLs is not intended by CMS, and shall not be construed, as a finding that any products are eligible for coverage or payment.

Appendix C

Provider Education

No national message will be distributed from CMS.

Contractors may use the information contained in this TDL to conduct normal operations in order to respond to inquiries from the provider community and to educate providers when appropriate, including the discretion to do local messaging as needed; however, the TDL number shall not be referenced.

Should you require further technical clarification, contact:

Larry Young, Larry.Young@cms.hhs.gov, and copy your COR.

Contractual questions should be directed to your CMS Contracting Officer (CO). Please copy your COR and CMS CO on all electronic and/or written correspondence in relation to this technical direction letter.

A/B MAC Contract Numbers

Jurisdiction 5 ~ 7SFCMC19C0043
Jurisdiction 6 ~ 7SFCMC20C0026
Jurisdiction 8 ~ 7SFCMC19C0002
Jurisdiction 15 ~ HHSM-500-2015-M0032Z
Jurisdiction E ~ 75FCMC21C0003
Jurisdiction F ~ 75FCMC18C0029
Jurisdiction H ~ 75FCMC19C0018
Jurisdiction J ~ HHSM-500-2017-M0001Z

Appendix C

Jurisdiction **K** - 75FCMC22C0003
Jurisdiction K ~ HHSM-500-2013-M0015Z
Jurisdiction L ~ 75FCMC21C0019
Jurisdiction M ~ HHSM-500-2015-M0028Z
Jurisdiction N ~ HHSM-500-2014-M0021Z

This Technical Direction Letter (TDL) is being issued to you as technical direction under your MAC contract and has been approved by your Contracting Officer's Representative (COR). This technical direction is not to be construed as a change or intent to change the scope of work under the contract and is to be acted upon only if sufficient funds are available. In this regard, your attention is directed to the clause of the General Provisions of your contract entitled Limitation of Funds, FAR 52.232-22 or Limitation of Cost, FAR 52.232-20 (as applicable). If the Contractor considers anything contained herein to be outside of the current scope of the contract, or contrary to any of its terms or conditions, the Contractor shall immediately notify the Contracting Officer in writing as to the specific discrepancies and any proposed corrective action.

Unless otherwise specified, contractors shall be in compliance with this TDL within 10 business days from its date of issuance.

Appendix C

/s/_____
Jeremy Adams, J5 A/B MAC COR
Connor Beck, J6 A/B MAC COR
James Wilkerson, J8 A/B MAC COR
Ann Clemens, J15 A/B MAC COR
Dorinda Fain, JE A/B MAC COR
Linda Tran, JF A/B MAC COR
Kathleen Fey, JH A/B MAC COR
Jennifer Johnson, JJ A/B MAC COR
Sylvia Sampson, JK A/B MAC COR
John DAlessandro, JL A/B MAC COR
Jennifer Johnson, JM A/B MAC COR
John DAlessandro, JL A/B MAC COR

/s/_____
Tamara Syrek Jenson
Larry Young

APPENDIX D — MEMORANDUM OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES, CENTER FOR MEDICARE, FILED AUGUST 25, 2022

CMS
CENTERS FOR MEDICARE
& MEDICAID SERVICES
CENTER FOR MEDICARE

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

TDL-220240

MEMORANDUM

DATE: February 16, 2022

FROM: Contracting Officer's Representatives (CORs)
Medicare Administrative Contractors,
Center for Medicare

Director, Coverage and Analysis Group
Centers for Clinical Standards and Quality

Director, Medicare Contractor Management Group
Center for Medicare

Appendix D

SUBJECT: Amniotic and Placental Tissue Derived Products – Claims Payment Instructions

TO: All Medicare Administrative Contractors (MACS)

TDL-220240 issued on February 16, 2022, is being reissued to remove HCPCS code 20525 from the Step 2 edit list. The original TDL compliance date remains the same. All other information remains the same.

This is a follow-up to TDL-220221 regarding claims for amniotic and placental tissue injection products. Specifically, Medicare Administrative Contractors (MACS) have requested additional guidance around how to operationally implement the instructions outlined in TDL-220221 in a consistent manner.

As noted in TDL-220221, manipulated amniotic and/or placental tissue biologics for injections to treat illness are experimental exosome biologic products that have not been proven to be safe and effective for any medical use, and all claims for dates of service on or after December 6, 2019, shall be denied under Section 1862(a)(1)(E) of the Social Security Act. Per the Food and Drug Administration these products may only be provided within approved investigational new drug (IND) trials. (See the public notices from the Food and Drug Administration (FDA) at:

https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologies/public-safety-notification-exosome-products

https://www.fda.gov/vaccines-blood-biologics/consumers-biologics/consumer-alert-regenerative-medicine-products-including-stem-cells-and-exosomes

https://www.fda.gov/vaccines-blood-biologics/consumers-biologics/important-patient-and-consumer-information-about-regenerative-medicine-therapies).

In developing operational edits and processes to implement this guidance, we have coordinated across all MACs to develop a set of implementation instructions for consistency. MACs shall follow the steps below for automated claim denials with the intention to deny claims for injected amniotic and placental tissue products. For assigned claims, MACs shall ensure that no beneficiary responsibility results from the claim denials, unless the claim line contains a GA modifier indicating an Advanced Beneficiary Notice of Non-Coverage has been executed.

Step 1: DENY any incoming claim lines that contain the following HCPCS Q Codes (does not include Q4244) codes:

Q4112, Q4113, Q4114, Q4139, Q4145, Q4149, Q4155, Q4162, Q4168, Q4171, Q4174, Q4177, Q4185, Q4189, Q4192, Q4202, Q4206, Q4212, Q4213, Q4215, Q4230, Q4231, Q4233, Q4240, Q4241, Q4242, Q4245, or Q4246.

Step 2: DENY any subsequent incoming claim lines for the following injection HCPCS Codes, if billed for the same beneficiary, by the same provider, for the same Date of Service (DOS) as the claim denied in Step 1:

20526, 20527, 20550, 20551, 20552, 20553, 20600, 20604, 20605, 20606, 20610, 20611, 20612, 27096, 62320, 62321, 62322, 62323, 64479, 64480, 64483, 64484, 64490, 64491, 64492, 64493, 64494, 64495, 0213T, 0214T, 0215T, 0216T, 0217T, 0218T, 0219T, 0220T, 0221T, 0222T, 0627T, 0628T, 0629T, or 0630T.

Step 3: DENY Q4244 as well as any injection service (as listed in Step 2) when both are billed for the same beneficiary, by the same provider, for the same DOS.

DENY the qualifying incoming claim line(s) received on or after the effective date of the edit with the following codes:

Claim Adjustment Reason Code 114: Procedure/product not approved by the Food and Drug Administration.

Remittance Advice Remark Code N623: Not covered when deemed unscientific/unproven/outmoded/experimental/excessive/inappropriate

Medicare Summary Notice (MSN) 21.22: Medicare does not pay for this service because it is considered investigational and/or experimental in these circumstances.

MSN 16.10: Medicare does not pay for this item or service.

MSN 16.35: You do not have to pay this amount. *

* *Do not include MSN 16.35 on claim lines with a GA modifier.*

Appendix D

Validated on Council for Affordable Quality Healthcare Committee on Operating Rules for Information Exchange, Feb. 2022 v3.7.0.

Group Code: Contractual Obligation (CO) or Patient Responsibility (PR)

MACs shall set up this denial to take primary precedence in their local systems. MACs shall implement the local editing no later than 20 business days after the issuance date of this TDL.

MACs shall re-open and adjust any paid claims for December 6, 2019, dates of service and later for these injection products. CMS will facilitate these recoveries by providing a list of paid claims identified following the edit criteria outlined above to the MACs within 10 business days of the issuance date of this TDL. MACs shall initiate the re-openings and adjustments on the claims within 45 business days from the date of issuance of this TDL. As a reminder, MACs shall coordinate with their respective UPICs on open investigations and law enforcement cases before initiating any claim re-opening and overpayment collection activities.

Provider Education

No national message will be distributed from CMS.

Contractors may use the information contained in this TDL to conduct normal operations in order to respond to inquiries from the provider community and to educate

providers when appropriate, including the discretion to do local messaging as needed; however, the TDL number shall not be referenced.

A/B MAC Contract Numbers

Jurisdiction 5 ~ 75FCMC19C0043
Jurisdiction 6 ~ 75FCMC20C0026
Jurisdiction 8 ~ 75FCMC19C0002
Jurisdiction 15 ~ HHSM-500-2015-M0032Z
Jurisdiction E ~ 75FCMC21C0003
Jurisdiction F ~ 75FCMC18C0029
Jurisdiction H ~ 75FCMC19C0018
Jurisdiction J ~ HHSM-500-2017-M0001Z
Jurisdiction K ~ 75FCMC22C00113
Jurisdiction K ~ HHSM-500-2013-M0015Z
Jurisdiction L ~ 75FCMC21C001 9
Jurisdiction M ~ HHSM-500-2015-M0028Z
Jurisdiction N ~ HHSM-500-2014-M0021Z

This Technical Direction Letter (TDL) is being issued to you as technical direction under your MAC contract and has been approved by your Contracting Officer's Representative (COR). This technical direction is not to be construed as a change or intent to change the scope of work under the contract and is to be acted upon only if sufficient funds are available. In this regard, your attention is directed to the clause of the General Provisions of your contract entitled Limitation of Funds, FAR 52.232-22 or Limitation of Cost, FAR 52.232-20 (as applicable). If the Contractor considers anything contained herein to be outside of the current

scope of the contract, or contrary to any of its terms or conditions, the Contractor shall immediately notify the Contracting Officer in writing as to the specific discrepancies and any proposed corrective action.

Unless otherwise specified, contractors shall be in compliance with this TDL within 10 business days from its date of issuance.

Should you require further technical clarification, you may contact your COR. Contractual questions should be directed to your CMS Contracting Officer. Please copy the COR and Contracting Officer on all electronic and/or written correspondence in relation to this technical direction letter.

/s/	/s/
Jeremy Adams, J5 A/B MAC COR	Tamara Syrek Jensen
Connor Beck, J6 A/B MAC COR	Larry Young
Jeremy Adams, J8 A/B MAC COR	
Jeremy Adams, J8 A/B MAC	
Ann Clemens, J15 A/B MAC COR	
Dorinda Fain, JE A/B MAC COR	
Linda Tran, JF A/B MAC COR	
Kathleen Fey, JH A/B MAC COR	
Jennifer Johnson, JJ A/B MAC COR	
Sylvia Sampson, JK A/B MAC COR	
John Dalessandro, JL A/B MAC COR	
Jennifer Johnson, JM A/B MAC COR	

APPENDIX E — MEMORANDUM OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES CENTER FOR MEDICARE, FILED AUGUST 25, 2022

CMS
CENTERS FOR MEDICARE
& MEDICAID SERVICES
CENTER FOR MEDICARE

DEPARTMENT OF HEALTH
& HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

TDL-220221

CENTER FOR MEDICARE

MEMORANDUM

DATE: February 2, 2022

FROM: Contracting Officer's Representatives (CORs)
Medicare Administrative Contractors,
Center for Medicare

Director, Coverage and Analysis Group
Centers for Clinical Standards and Quality

Director, Medicare Contractor Management Group
Center for Medicare

Appendix E

SUBJECT: Amniotic Fluid and Placental Tissues Claims Payment Instructions

TO: All Medicare Administrative Contractors (MACs)

The purpose of this Technical Direction Letter (TDL) is to instruct the Medicare Administrative Contractors (MACs) to deny payments for claims of manipulated amniotic and/or placental tissue biologics for injections. Manipulated amniotic and/or placental tissue biological injections are biologics that are produced from amniotic and/or placental tissues that have been particulated and placed into a form for injections into other parts of the body like muscles and joints.

Manipulated amniotic and/or placental tissue biologics for injections to treat illness are exosome biologic products that have not been proven to be safe and effective, and all claims for dates of service on or after December 6, 2019, shall be denied because these products are unsafe. (See the public safety notice from the Food and Drug Administration(FDA) at: https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/public-safety notification-exosome-products). The FDA is concerned that many patients seeking cures and remedies may be misled by information about products that are illegally marketed, have not been shown to be safe or effective, and, in some cases, may have significant safety issues that put patients at risk. (Reference: https://www.fda.gov/vaccines-blood-biologics/consumers biologics/consumer-alert-regenerative-medicine-products-including-stem-cells-and-exosomes and https://www.fda.gov/vaccines-

blood-biologics/consumers-biologics/important-patient-and consumer-information-about-regenerative-medicine-therapies).

MACs shall re-open and adjust any paid claims for December 6, 2019, dates of service and later for these injection products. As a reminder, MACs should coordinate with their respective UPICs on open investigations and law enforcement cases before initiating any claim re-opening and overpayment collection activities.

Provider Education

No national message will be distributed from CMS.

Contractors may use the information contained in this TDL to conduct normal operations in order to respond to inquiries from the provider community and to educate providers when appropriate, including the discretion to do local messaging as needed; however, the TDL number shall not be referenced.

DME MAC Contract Numbers

Jurisdiction A ~ HHSM-500-2016-M000IZ
Jurisdiction B ~ HHSM-500-2015-M0030Z
Jurisdiction C ~ 75FCMC20C0025
Jurisdiction D ~ HHSM-500-2015-M0031Z

A/B MAC Contract Numbers

Jurisdiction S ~ 75FCMCl9C0043
Jurisdiction 6 ~ 75FCMC20C0026

Appendix E

Jurisdiction 8 ~ 75FCMCl9C0002
Jurisdiction 15~ HHSM-500-2015-M0032Z
Jurisdiction E ~ 75FCMC21C0003
Jurisdiction F ~75FCMCl8C0029
Jurisdiction H ~ 75FCMC19C0018
Jurisdiction J ~ HHSM-500-2017-M000IZ
Jurisdiction K - 75FCMC22C0003
Jurisdiction K ~ HHSM-500-2013-M00ISZ
Jurisdiction L ~ 75FCMC21C00l9
Jurisdiction M ~ HHSM-S00-2015-M0028Z
Jurisdiction N ~ HHSM-S00-2014-M0021Z

This Technical Direction Letter (TDL) is being issued to you as technical direction under your MAC contract and has been approved by your Contracting Officer's Representative (COR). This technical direction is not to be construed as a change or intent to change the scope of work under the contract and is to be acted upon only if sufficient funds are available. In this regard, your attention is directed to the clause of the General Provisions of your contract entitled Limitation of Funds, FAR 52.232-22 or Limitation of Cost, FAR 52.232-20 (as applicable). If the

Contractor considers anything contained herein to be outside of the current scope of the contract, or contrary to any of its terms or conditions, the Contractor shall immediately notify the Contracting Officer in writing as to the specific discrepancies and any proposed corrective action.

Unless otherwise specified, contractors shall be in compliance with this TDL within 10 business days from its date of issuance.

Appendix E

Should you require further technical clarification, you may contact your COR. Contractual questions should be directed to your CMS Contracting Officer. Please copy the COR and Contracting Officer on all electronic and/or written correspondence in relation to this technical direction letter.

/s/
Pam Durbin, JA DME MAC COR
Lisa Laubach, JB DME MAC COR
Lisa Laubach, JC DME MAC COR
Pam Durbin, JD DME MAC COR
Jeremy Adams, J5 A/B MAC COR
Connor Beck, J6 A/B MAC COR
Jeremy Adams, J8 A/B MAC
Jeremy Adams, J8 A/B MAC COR
Ann Clemens, J15 A/B MAC COR
Dorinda Fain, JE A/B MAC COR
Linda Tran, JF A/B MAC COR
Kathleen Fey, JH A/B MAC COR
Jennifer Johnson, JJ A/B MAC COR
Sylvia Sampson, JK A/B MAC COR
John D Aiessandro, JL A/B MAC COR
Jennifer Johnson, JM A/B MAC COR
Jacqueline Brown, JN A/B MAC COR

/s/
Tamara Syrek Jensen
Larry Young

APPENDIX F — RELEVANT STATUTORY PROVISION

42 U.S.C. 405(h)

Finality of Commissioner's decision

The findings and decision of the Commissioner of Social Security after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Commissioner of Social Security shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346 of title 28 to recover on any claim arising under this subchapter.