No. 23-1326

In the Supreme Court of the United States

ROW 1 INC., DBA REGENATIVE LABS, PETITIONER

v.

XAVIER BECERRA, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE FEDERAL RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

Whether the court of appeals correctly determined that it lacks subject-matter jurisdiction over petitioner's claims for declaratory and injunctive relief because they arise under the Medicare statute but were not presented to the agency.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-24a) is reported at 92 F.4th 1138. The opinion of the district court (Pet. App. 25a-34a) is not published in the Federal Supplement but is available at 2023 WL 183687.

JURISDICTION

The judgment of the court of appeals was entered on February 16, 2024. On May 9, 2024, the Chief Justice extended the time within which to file a petition for a writ of certiorari to and including June 16, 2024. The petition for a writ of certiorari was filed on June 17, 2024 (Monday). The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. a. The Medicare program provides federally funded health insurance for the elderly and disabled. See 42 U.S.C. 1395 *et seq.* The Centers for Medicare and Medicaid Services (CMS), a component of the Department of Health and Human Services (HHS), administers the Medicare program.

Medicare pays only for services and products that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. 1395y(a)(1)(A); see 42 C.F.R. 411.15(k)(1). If the Secretary, or his designee, determines that a product or service was not necessary and reasonable in the context of a particular claim, the statute mandates that "no payment may be made." 42 U.S.C. 1395y(a). To justify payment for items and services under Medicare Part B, a physician, supplier, or beneficiary must submit a claim for reimbursement. 42 U.S.C. 1395y(e); 42 C.F.R. 424.5(a)(5) and (6).

CMS contracts with private entities, known as Medicare Administrative Contractors, to process Medicare claims and ensure that payments meet Medicare coverage criteria, including that products and services billed to Medicare satisfy the reasonable-and-necessary requirement. 42 U.S.C. 1395kk-1; see 42 U.S.C. 1395u(a); 42 C.F.R. 421.400. Program beneficiaries or their assignees who are dissatisfied with a Medicare contractor's reimbursement determination have several layers of administrative review available to them. 42 U.S.C. 1395ff; 42 C.F.R. 405.906(a)(2), 405.912. They can first request a redetermination review by the same contractor, 42 U.S.C. 1395ff(a)(3); 42 C.F.R. 405.940; and then can request "reconsideration" by a qualified independ-

ent contractor, see 42 U.S.C. 1395ff(b)(l)(A) and (c); 42 C.F.R. 405.960. For claims that satisfy the statutory amount-in-controversy requirement, a still-dissatisfied claimant may request a hearing, "as is provided in [42 U.S.C.] 405(b)," before an administrative law judge. 42 U.S.C. 1395ff(b)(l)(A), (E), and (d)(l); 42 C.F.R. 405.1002. The administrative law judge's decision may be reviewed by the Medicare Appeals Council of the Departmental Appeals Board. 42 U.S.C. 1395ff(d)(2); 42 C.F.R. 405.1100.

To guide contractors' application of the reasonable and necessary requirement during the administrative process, the Secretary may establish "reasonable and necessary" coverage standards by regulation. 42 U.S.C. 1395y(a)(1)(A), 1395ff(a)(1), 1395hh. In addition, the Secretary may issue binding National Coverage Determinations "with respect to whether or not a particular item or service is covered nationally." 42 U.S.C. 1395ff(f)(1)(B); see 42 U.S.C. 1395y(a); 42 C.F.R. 400.202, 405.1060(a)(4). The Secretary may also issue technical direction letters to contractors addressing coverage and payment issues. Cf. CMS, *General Information, Eligibility, and Entitlement Manual* (Rev. May 4, 2022), ch. 7, § 50, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/ge101c07.pdf ("Contractors shall * * * comply with all issued Technical Direction Letters."). In the absence of a binding national policy, such as a regulation or a National Coverage Determination, coverage decisions are made by Medicare contractors, which may issue a local coverage determination or use a claim-by-claim adjudicatory model. See 42 U.S.C. 1395ff(c)(3)(B)(ii)(II) and (f)(2)(B); 42 C.F.R. 400.202, 405.1062.

b. The Medicare statute provides a "reticulated statutory scheme, which carefully details the forum and limits of review" of all claims arising under Medicare. *Bowen* v. *Michigan Acad. of Family Physicians*, 476 U.S. 667, 675 (1986); see 42 U.S.C. 405(h); see also 42 U.S.C. 1395ii (incorporating Section 405(h) into the Medicare statute). In general, it provides that "[n]o action against * * * the [Secretary] shall be brought * * * to recover on any claim arising under [the Medicare statute]" except as provided under 42 U.S.C. 405(g). 42 U.S.C. 405(h). Section 405(g), in turn, states that judicial review may be obtained only after an individual receives a "final decision of the [Secretary] made after a hearing to which he was a party." 42 U.S.C. 405(g).

As this Court has explained, that limited authorization of judicial review "contains two separate elements: first, a 'jurisdictional' requirement that claims be presented to the agency, and second, a 'waivable . . . requirement that the administrative remedies prescribed by the Secretary be exhausted.'" *Smith* v. *Berryhill*, 587 U.S. 471, 478 (2019) (quoting *Mathews* v. *Eldridge*, 424 U.S. 319, 328 (1976)). A party, therefore, can obtain judicial review of a claim that it is entitled to payment by Medicare only by first presenting that claim to the agency in the context of the applicable administrative procedure governing specific payment requests. 42 U.S.C. 405(h), 1395ii; see, *e.g.*, *Weinberger* v. *Salfi*, 422 U.S. 749, 757, 762 (1975); *Heckler* v. *Ringer*, 466 U.S. 602, 614-615 (1984); *Shalala* v. *Illinois Council on Long Term Care*, *Inc.*, 529 U.S. 1, 13 (2000).

c. The Food and Drug Administration (FDA) is responsible for protecting the public health by ensuring the safety, efficacy, and security of, *inter alia*, drugs,

biological products, and medical devices. 21 U.S.C. 393(b).

In 1998, FDA adopted a tiered, risk-based approach for regulating a rapidly growing category of biological products—human cells, tissues, and cellular or tissue-based products (HCT/Ps or HCT/P products). That approach was designed to provide only the degree of government oversight necessary to protect the public health, and it largely relies on manufacturers to accurately self-designate their products. See FDA, Dkt. No. 97N-0068, *Proposed Approach to Regulation of Cellular and Tissue-Based Products* (Feb. 28, 1997), http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/UCM062601.pdf; see also FDA, *Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products*, 63 Fed. Reg. 26,744 (May 14, 1998).

Pursuant to its authority under Section 361 of the Public Health Service Act, 42 U.S.C. 264(a), FDA subsequently issued several regulations governing HCT/Ps. See, *e.g.*, FDA, *Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing*, 66 Fed. Reg. 5447 (Jan. 19, 2001) (Final Registration Rule). The regulations define HCT/Ps as "articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient." 21 C.F.R. 1271.3(d). FDA determined that, in limited circumstances, certain HCT/Ps can be effectively regulated for FDA purposes solely by controlling the infectious-disease risks that they present. Such products are regulated only under Section 361 of the Public Health Service Act and FDA's HCT/P regulations (21

C.F.R. Pt. 1271), even if they would otherwise meet the Public Health Service Act's definition of a "biological product." These products are sometimes referred to as "Section 361 HCT/Ps," after the communicable disease provision in Section 361 of the Public Health Service Act, 42 U.S.C. 264. All other human and tissue-based products are regulated as drugs, devices, and/or biological drugs because they may present a greater degree of risk. 21 C.F.R. 1271.20; Final Registration Rule, 66 Fed. Reg. at 5450. Those products are sometimes referred to as "Section 351 HCT/Ps" and are subject to adulteration, misbranding, and premarket approval requirements of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321, 351-353. See 21 C.F.R. 1271.20; Final Registration Rule, 66 Fed. Reg. at 5449, 5456.

In order to fulfill its public health mission, FDA issues guidance related to its interpretation of the criteria governing HCT/Ps. See, *e.g.*, FDA, *Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use* (July 2020), https://www.fda.gov/media/109176/download. FDA also issues public statements warning of the potentially serious health risks of HCT/Ps, including public safety notifications informing the public of serious adverse event reports, consumer alerts, and other patient and consumer resources.

As relevant here, FDA issued several public statements from 2019 to 2021 that addressed risks associated with consumers' use of certain HCT/Ps, including certain products marketed as regenerative medicine therapies. See FDA, *Public Safety Notification on Exosome Products* (Dec. 6. 2019), https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/public-safety-notification-exosome-products; FDA, *Consumer Alert on*

Regenerative Medicine Products Including Stem Cells and Exosomes (Rev. Apr. 9, 2024), https://www.fda.gov/vaccines-blood-biologics/consumers-biologics/consumer-alert-regenerative-medicine-products-including-stem-cells-and-exosomes; FDA, *Important Patient and Consumer Information About Regenerative Medicine Therapies* (Rev. April 8, 2024), https://www.fda.gov/vaccines-blood-biologics/consumers-biologics/important-patient-and-consumer-information-about-regenerative-medicine-therapies.

2. Concerned about the potential public health ramifications of HCT/Ps, CMS issued a technical direction letter on February 2, 2022, instructing Medicare contractors to deny claims for Medicare payment for certain processed amniotic and/or placental tissue intended to treat diseases and conditions. See Pet. App. 48a-52a. The letter stated that "[m]anipulated amniotic and/or placental tissue biologics for injections * * * have not been proven to be safe and effective" and referenced FDA's safety notices. *Id.* at 49a. The letter was made effective as to services rendered on or after December 6, 2019. *Id.* at 50a. On February 24, 2022, CMS issued a follow-up technical direction letter listing billing codes associated with particular HCT/P products that Medicare contractors could use to identify relevant products as part of an automated denial process. See *id.* at 41a-47a.

On March 25, 2022, however, CMS issued a third technical direction letter rescinding the two February letters and providing guidance on how Medicare contractors should handle any claims that had already been processed under the two prior letters. See Pet. App. 35a-40a. Specifically, the letter instructed Medicare contractors to remove system edits that automatically

denied payment for amniotic and placental tissue product injections and to institute a claim-by-claim review process by medically knowledgeable individuals who would review each beneficiary's medical records to determine whether a claim was for reasonable and necessary services under 42 U.S.C. 1395y(a)(1)(A), as well as any other applicable coverage and payment requirements. See Pet. App. 36a. The letter also directed Medicare contractors to re-open any claims processed in accordance with the previous two letters and evaluate them under that same manual claim-by-claim review process. *Ibid.* Finally, the letter instructed Medicare contractors to remove all coverage articles and educational materials that had been issued in response to the February letters. *Ibid.* The letter required that Medicare contractors comply within ten business days. *Id.* at 39a.

3. a. Petitioner manufactures, markets, and distributes medical products containing HCT/Ps. Pet. App. 2a-3a. Petitioner filed suit in district court, alleging that HHS, CMS, and Medicare contractors have improperly denied reimbursement for its products pursuant to CMS's technical direction letters to Medicare contractors regarding reimbursement for products containing HCT/Ps. See *id.* at 3a.

Petitioner alleged that it has sold its products since 2020 and that Medicare generally covered those products until around the time of the February 2022 letters. C.A. App. 106-107, 122-123. Although petitioner acknowledged that the third technical direction letter instructed Medicare contractors to cease "automatically den[ying] payment for amniotic and placental tissue product injections and to institute claim-by-claim review to determine whether a claim meets the reasonable

and necessary criteria," *id.* at 109 (citation omitted), petitioner alleged that that instruction amounted to a "faux-ceasing" of the prior policy and that Medicare contractors continued to deny claims thereafter, *id.* at 129; see *id.* at 110-111, 126-129.

Petitioner alleged that the technical direction letters should have been issued through the notice-and-comment process, that they reflected a misunderstanding of distinctions between Section 351 and Section 361 HCT/P products, and that they intruded on FDA's statutory authority. See, *e.g.*, C.A. App. 108-109, 111, 122-126. Petitioner sought a preliminary injunction and an order that would, among other things, "[d]eclare[] that Regenative is a Section 361 product that does not require FDA approval and should be reimbursed as such" under Medicare "to maintain the status quo." *Id.* at 135.

b. As relevant here, the district court dismissed the suit for lack of subject-matter jurisdiction, explaining that petitioner's claim that the technical direction letters should have been issued through notice-and-comment rulemaking arose under the Medicare statute and therefore should have been presented to the agency, as required by 42 U.S.C. 405(h). See Pet. App. 27a-30a.[1]

Relying on this Court's decisions in *Illinois Council*, 529 U.S. at 13-14, and *Ringer*, 466 U.S. at 614-615, the district court rejected petitioner's contention that its claims are exempt from Section 405(h)'s channeling requirement because they are procedural rather than substantive. See Pet. App. 28a-30a. The court also rejected

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[1] The district court also denied petitioner's mandamus claim. Pet. App. 33a-34a. The court of appeals affirmed that denial, *id.* at 22a-24a, and petitioner does not seek review of that aspect of its decision.

petitioner's alternate argument that without review in this suit there would be "no review at all." *Id.* at 31a; see *id.* at 31a-32a. The court explained that affected beneficiaries and providers could seek review of denied Medicare claims, and found that petitioner had not shown that those "potential prox[ies] [are] 'highly unlikely' to pursue administrative review to challenge those requirements, thereby creating a 'practical roadblock' to judicial review." *Id.* at 31a (citation omitted).

4. The court of appeals affirmed. Pet. App. 1a-24a. It first held that, insofar as petitioner challenged CMS's issuance of the two February 2022 technical direction letters, that aspect of petitioner's suit had become moot after the third March 2022 technical direction letter "explicitly informed the Medicare contractors that the" first two letters had been "'rescind[ed].'" *Id.* at 11a (citation omitted; brackets in original).

The court of appeals next determined that although petitioner's suit was not moot to the extent that it claimed that "CMS continues to endorse *sub silentio* the policy outlined in the two February 2022 letters," that portion of petitioner's suit was "barred in this case because of the Medicare Act's channeling requirement." Pet. App. 13a. The court explained that this Court has interpreted Section 405(h) "to 'demand the "channeling" of virtually all legal attacks through the agency.'" *Id.* at 14a (quoting *Illinois Council*, 529 U.S. at 13) (brackets omitted). Accordingly, any claimed "injuries" that "are 'inextricably intertwined' with the underlying Medicare claims" must be presented and administratively exhausted before the agency. *Ibid.* (quoting *Heckler*, 466 U.S. at 614).

Applying that standard, the court of appeals determined that petitioner's remaining allegations were in-

extricably intertwined with the underlying Medicare claims and therefore arise under the Medicare statute for purposes of Section 405(h). See Pet. App. 14a-17a. The court explained that "[a]t its core, [petitioner's] challenge is to the Government's Medicare reimbursement decisions, and [petitioner] seeks for the court to declare that its products 'should be reimbursed.'" *Id.* at 14a-15a (citation omitted).

The court of appeals likewise rejected petitioner's assertion that it was entitled to an exception to the channeling requirement. Pet. App. 17a-21a. The court explained that the exception petitioner invoked is applicable only where application of Section 405(h) would "result in '*complete* preclusion of judicial review.'" *Id.* at 17a (quoting *Illinois Council*, 529 U.S. at 23). Here, however, the record "makes it clear that there are potentially other parties with an interest and a right to seek administrative review" who could raise the same types of claims. *Id.* at 18a; see *id.* at 18a-21a (summarizing examples).

ARGUMENT

Petitioner renews its contention (Pet. 7-10) that it is exempt from the channeling requirement of Section 405(h) because, as a manufacturer, it cannot directly present claims for payment to the Secretary. The court of appeals correctly rejected that argument, and its decision does not conflict with any decision of this Court or any other court of appeals. The petition for a writ of certiorari should be denied.

1. The court of appeals correctly recognized that the channeling requirements of Section 405(h) apply to petitioner's suit even though petitioner itself cannot submit claims for payment directly to the Secretary. See Pet. App. 14a-21a.

a. Under the Medicare statute, a litigant cannot obtain judicial review of claims "arising under" Medicare unless those claims have first been presented to the agency and administratively exhausted. 42 U.S.C. 405(h); see 42 U.S.C. 405(g), 1395ii. That channeling requirement applies to "any claims in which 'both the standing and the substantive basis for the presentation' of the claims is the" Medicare statute, as well as any claims that are "'inextricably intertwined' with [a] claim for benefits." *Heckler* v. *Ringer*, 466 U.S. 602, 611, 614-615 (1984) (citations omitted).

Here, petitioner's alleged "injuries are 'inextricably intertwined' with the underlying Medicare claims" submitted by providers in connection with petitioner's products. Pet. App. 14a (quoting *Heckler*, 466 U.S. at 614). As the court of appeals explained, "[a]t its core, [petitioner's] challenge is to the Government's Medicare reimbursement decisions, and [petitioner] seeks for the court to declare that its products 'should be reimbursed.'" *Id.* at 14a-15a (citation omitted); see, *e.g.*, C.A. App. 111 (allegation in amended complaint that petitioner was "harm[ed]" because "many providers will not be able to purchase its products without reimbursement" from Medicare); C.A. App. 130-131 (allegation that CMS violated the Medicare statute's notice-and-comment requirement because CMS "change[d] [the] substantive legal standard governing the scope of benefits"). Petitioner's claims therefore "aris[e] under" the Medicare statute for purposes of Section 405(h)'s channeling requirement. 42 U.S.C. 405(h).

b. Petitioner contends (Pet. 7-11) that it is nevertheless entitled to immediate judicial review of its claims under the limited exception to Section 405(h)'s channeling requirement that this Court recognized in *Shalala*

v. *Illinois Council on Long Term Care, Inc.*, 529 U.S. 1 (2000). As the court of appeals correctly recognized (Pet. App. 17a-21a), that contention lacks merit.

In *Illinois Council*, this Court discussed a narrow exception to the channeling requirement where "application" of Section 405(h) "would not simply channel review through the agency, but would mean *no* review at all." *Illinois Council*, 529 U.S. at 19 (emphasis added). The Court emphasized that a plaintiff could not avoid the channeling requirement merely because channeling would result in "added inconvenience or cost in an isolated, particular case." *Id.* at 22. "Rather, the question is whether, as applied generally to those covered by a particular statutory provision, hardship likely found in many cases turns what appears to be simply a channeling requirement into *complete* preclusion of judicial review." *Id.* at 22-23.

Petitioner cannot establish complete preclusion of that sort here. Petitioner contends (Pet. 8) that it is unable to file a Medicare claim itself because it "is not a provider or beneficiary under the Medicare program." But as the court of appeals explained, the record reflects that there are "adequate proxies" available, including beneficiaries and providers who would like to receive reimbursement for using petitioner's products and therefore have "the incentive to seek administrative review" of the issues petitioner seeks to raise. Pet. App. 18a; see *id.* at 18a-20a. Indeed, the court noted that by the time of its decision, "some providers ha[d] already" filed suit seeking review of final decisions denying Medicare coverage and reimbursement for "similar products manufactured by another company * * * assert[ing] claims comparable to those raised by [petitioner]." *Id.* at 20a-21a (citation omitted). And several

additional suits have been filed since the court of appeals' decision.[2] The existence of those challenges confirms that enforcing Section 405(h)'s channeling requirement here will not result in the "*complete* preclusion of judicial review." *Illinois Council*, 529 U.S. at 23.

c. Petitioner does not contend that the court of appeals' application of Section 405(h) here conflicts with the decision of any other court of appeals. On the contrary, the decision below accords with longstanding precedent in the D.C. Circuit and every other court of appeals to have addressed this issue.

The D.C. Circuit has previously explained that the exception described in *Illinois Council* "is not intended" to allow for jurisdiction "in every case where section 405(h) would prevent a particular * * * entity from seeking judicial review." *Council for Urological Interests* v. *Sebelius*, 668 F.3d 704, 711 (2011). It has therefore limited application of the exception to circumstances in which "the only entities able to invoke Medicare Act review are highly unlikely to do so," such that "their unwillingness to pursue a Medicare Act claim poses a serious 'practical roadblock' to judicial review." *Id.* at 712; see *American Chiropractic Ass'n* v. *Leavitt*,

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[2] See Compl. at ¶¶ 160-164, 180, *Atlantic Coast Pain Specialists, Inc.* v. *Becerra*, No. 24-cv-01925 (D.S.C. Apr. 12, 2024) (seeking declaratory relief under the Medicare statute's procedural requirements and the APA's arbitrary and capricious standard, among other things); Am. Compl. at ¶¶ 97-125, *Macomb Foot Ankle & Wound Care* v. *Becerra*, No. 24-cv-869 (D.D.C. July 2, 2024) (same); see also Compl. at ¶¶ 70-73, *Center for Innovations in Evaluative Medicine, LLC* v. *Becerra*, No. 24-cv-362 (M.D. La. May 7, 2024) (asking that a denial of reimbursement be set aside because CMS required the provider to provide medical literature supporting its use of an HCT/P product); Compl. at ¶ 61, *Infinity Health of Ark., LLC* v. *Becerra*, No. 24-cv-6094 (W.D. Ark.) (July 17, 2024) (same).

431 F.3d 812, 816 (D.C. Cir. 2005) (holding that the exception applies only "when roadblocks practically cut off any avenue to federal court").

Other courts of appeals have applied a similar standard. See, *e.g.*, *National Athletic Trainers' Ass'n* v. *HHS*, 455 F.3d 500, 504, 507-508 (5th Cir. 2006) (holding that Section 405(h) barred a premature suit where the plaintiff athletic trainers could not bring administrative claims directly because the physicians who used the plaintiffs' services could "pursue administrative review" and had "sufficient incentive to challenge the rule"); *Sensory Neurostimulation, Inc.* v. *Azar*, 977 F.3d 969, 983-984 (9th Cir. 2020) (explaining that although a medical device supplier could not itself administratively challenge the agency's decision whether to cover its product under Medicare, no exception to Section 405(h) applied because "an administrative channel for review exist[ed]" for other aggrieved parties, such as beneficiaries, to bring such a claim); *Retina Grp. of New England, P.C.* v. *Dynasty Healthcare, LLC*, 72 F.4th 488, 497-498 (2d Cir. 2023) (holding that Section 405(h) barred a healthcare billing and consulting firm's third-party claims against a Medicare contractor for allegedly underpaying a provider because the provider could have channeled any challenge to that underpayment).

Because the court of appeals' resolution of the channeling question is correct and does not conflict with the decision of any other court of appeals, further review of that question in this Court is not warranted.

2. Petitioner also briefly contends (Pet. 11-12) that the court of appeals erred in holding that its challenge

to the February 2022 technical letters was moot.[3] That assertion of legal error depends on a mischaracterization of the court's decision.

The court of appeals held that to the extent that petitioner was seeking recission of the two February technical direction letters, the March technical letter had already explicitly "rescinded" them, thereby "giv[ing] [petitioner] what it seeks" as to those two letters. Pet. App. 11a (brackets and citation omitted). As the court explained, that recission "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." *Id.* at 12a (quoting *County of L.A.* v. *Davis*, 440 U.S. 625, 631 (1979)). Petitioner offers no reason for this Court to revisit that straightforward application of established mootness doctrine.

Petitioner instead asserts that the court of appeals held that its suit was also moot as to the assertion that CMS "merely 'faux-ceas[ed]' the policy." Pet. 11 (quoting Pet. App. 16a) (brackets in original). That assertion is incorrect. The court *agreed* with petitioner that its suit was not moot to the extent that petitioner alleges "CMS continues to endorse *sub silentio* the policy outlined in the two February 2022 letters." Pet. App. 13a. The court instead dismissed that aspect of petitioner's suit as "barred in this case because of the Medicare Act's channeling requirement." *Ibid.* As explained above, that determination was correct and does not warrant this Court's review.

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[3] Petitioner's argument regarding mootness appears to be unrelated to the question presented that it asks this Court to consider. See Pet. i; Sup. Ct. R. 14.1(a).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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