FILED

JUN 23 2025

MOLLY C. DWYER, CLERK
U.S. COURT OF APPEALS

NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

GEORGE BEITZEL, et al., Plaintiffs-Appellants, v. ROBERT F. KENNEDY JR., Secretary of Health and Human Services, Defendant-Appellee.	No. 24-3528 D.C. No. 2:23-cv-01932-WBS-DB MEMORANDUM[*]

Appeal from the United States District Court
for the Eastern District of California
William B. Shubb, District Judge, Presiding

Argued & Submitted June 10, 2025
San Francisco, California

Before: S.R. THOMAS and M. SMITH, Circuit Judges, and RAYES,[**] District Judge.

[*] This disposition is not appropriate for publication and is not precedent except as provided by Ninth Circuit Rule 36-3.

[**] The Honorable Douglas L. Rayes, United States District Judge for the District of Arizona, sitting by designation.

George Beitzel, Sharon Goldstein, and Katherine Kraig (collectively, "Plaintiffs") are three Medicare beneficiaries who previously received Stelara injections under Medicare Part B. Effective October 2021, Plaintiff's regional Medicare Administrative Contractors ("MACs") determined that Stelara is "usually self-administered" and therefore excluded from such coverage. Plaintiffs bring this putative class action claiming that the Due Process Clause and the Medicare Act require procedural safeguards when Medicare changes the coverage terms without individual notice. We have jurisdiction pursuant to 28 U.S.C. § 1291. Because the parties are familiar with the factual and procedural history of the case, we need not recount it here. We reverse and remand.[1]

I

We have subject matter jurisdiction over Plaintiffs' claims. To determine if we have subject matter jurisdiction to hear a claim related to Medicare, we apply a multi-step analysis. *Sensory Neurostimulation, Inc. v. Azar*, 977 F.3d 969, 976 (9th Cir. 2020). First, we must decide whether the claim "arises under" Medicare such that § 405(h)'s administrative channeling requirement applies. *Id.* If the claim does arise under Medicare, we proceed to step two, and consider whether the plaintiff satisfied the channeling requirements by properly presenting the claim and

[1] Plaintiffs' request to supplement the record, Dkt. 41, is GRANTED.

either exhausting the appropriate administrative channel or satisfying the requirements for judicial waiver of the exhaustion requirement. *Id*. If the plaintiff has satisfied steps one and two, they can proceed to court. *Id.*

It is undisputed that the Medicare Act provides the standing and substantive basis for Plaintiffs' claims. Plaintiffs also met the presentation requirement by presenting their claims to the Secretary before proceeding to court. Given only one of Beitzel's claims was fully administratively exhausted, our jurisdiction over the remaining claims rests on the applicability of judicial waiver of the exhaustion requirement.

We apply a three-part test to determine whether to judicially waive exhaustion: the claim must be "(1) collateral to a substantive claim of entitlement (collaterality), (2) colorable in its showing that refusal to the relief sought will cause an injury which retroactive payments cannot remedy (irreparability), and (3) one whose resolution would not serve the purposes of exhaustion (futility)." *Briggs v. Sullivan*, 886 F.2d 1132, 1139 (9th Cir. 1989) (quoting *Bass v. Social Security Admin.*, 872 F.2d 832, 833 (9th Cir. 1989)). Plaintiffs have satisfied all three elements for waiver.

First, Plaintiffs' claims are collateral to their claims for benefits. "A plaintiff's claim is collateral if it is not essentially a claim for benefits." *Johnson v.*

Shalala, 2 F.3d 918, 921 (9th Cir. 1993). "When benefits are [denied] . . . because of a requirement collateral to the Secretary's eligibility criteria, the claimant's dispute with the Secretary is not, strictly speaking, a 'claim for benefits[.]'" *Briggs*, 886 F.2d at 1139. Here, Plaintiffs are not asking this Court to award or reinstate benefits, and no one contests that Plaintiffs are eligible to receive Stelara. Plaintiffs' claims challenge systemwide policies governing notice and waiver of liability. The decision to change the classification of Stelara from a Part B to a Part D drug and not provide notice to Plaintiffs is collateral to their benefits determination. Plaintiffs' "challenge to the polic[ies governing notice and waiver of liability] rise[] and fall[] on [their] own, separate from the merits of their claim for benefits." *Johnson*, 2 F.3d at 921–22 (quoting *Johnson v. Sullivan*, 922 F.2d 346, 353 (7th Cir. 1990)). Therefore, the claims are collateral because they are not "bound up with the merits" of their claim for benefits. *Id.* at 922 (quoting *Johnson*, 922 F.2d at 353).

Second, Plaintiffs have made a colorable showing of irreparable injury. A "colorable" showing of irreparable injury for purposes of waiver of the exhaustion requirement is one that is not "'wholly insubstantial, immaterial, or frivolous.'" *Cassim v. Bowen*, 824 F.2d 791, 795 (9th Cir. 1987) (quoting *Boettcher v. Secretary of Health and Human Servs.*, 759 F.2d 719, 722 (9th Cir. 1985).

"[E]conomic hardship suffered by [] plaintiffs while awaiting administrative review constitutes irreparable injury." *Johnson*, 2 F.3d at 922. Here, all Plaintiffs have suffered economic hardship while awaiting administrative review, so they have suffered an irreparable injury.

"Back payments can have some ameliorative effect," but "they cannot erase either the experience or the entire effect of several months without . . . [medical] necessities." *Briggs*, 886 F.2d at 1140. Although back payments may solve Plaintiffs' financial issues, they will not address the distress and anxiety Plaintiffs have faced from incurring massive amounts of debt. Plaintiffs made, at the very least, a colorable showing that denial of relief will cause irreparable injury.

Third, Plaintiffs have demonstrated the futility of administrative review by showing that exhaustion of administrative remedies "would not serve the policies underlying exhaustion." *Id.* (quoting *Cassim*, 824 F.2d at 795). Exhaustion is futile where an action brings a "straightforward statutory and constitutional challenge" to agency policy. *Id*. at 1140; *see also Johnson*, 2 F.3d at 922–23. Because Plaintiffs assert a straightforward due process challenge, exhaustion of administrative remedies is futile.

In sum, we have subject matter jurisdiction over this case.

II

Plaintiffs have standing for prospective injunctive relief. To have standing for prospective injunctive relief, plaintiffs must allege "either 'continuing, present adverse effects' due to . . . [d]efendant['s] past illegal conduct . . . or 'a sufficient likelihood that [they] will again be wronged in a similar way.'" *Villa v. Maricopa Cnty.*, 865 F.3d 1224, 1229 (9th Cir. 2017) (first quoting *O'Shea v. Littleton*, 414 U.S. 488, 495–96 (1974); then quoting *City of L.A. v. Lyons*, 461 U.S. 95, 111 (1983)). Plaintiffs here have alleged ongoing injuries that are sufficient to confer standing. *See Haro v. Sebelius*, 747 F.3d 1099, 1109 (9th Cir. 2014). All three named Plaintiffs face ongoing financial harm that is traceable to Medicare's notice policies.

In addition, a properly framed injunction would redress Plaintiffs' injuries as it would prohibit the Secretary from holding beneficiaries liable for drugs added to the Self-Administered Drug ("SAD") list unless and until they are provided with adequate notice. "Because . . . a properly framed injunction would have redressed [Plaintiffs'] injur[ies], [Plaintiffs] ha[ve] demonstrated the necessary criteria for Article III standing on behalf of the class." *Id.*

III

Plaintiffs have sufficiently pleaded a due process claim because they alleged

they were deprived of a protected interest without notice.[2] A "procedural due process claim hinges on proof of two elements: (1) a protectible liberty or property interest ...; and (2) a denial of adequate procedural protections." *Thornton v. City of St. Helens*, 425 F.3d 1158, 1164 (9th Cir. 2005) (quoting *Foss v. Nat'l Marine Fisheries Serv.*, 161 F.3d 584, 588 (9th Cir. 1998)).

"To have a property interest in a government benefit . . . 'a person . . . must . . . have a legitimate claim of entitlement to it.'" *Id. (*quoting *Doran v. Houle,* 721 F.2d 1182, 1186 (9th Cir. 1983). The Medicare statute explicitly states that "[e]very individual" who "has attained age 65" "shall be entitled to" Medicare benefits. 42 U.S.C. § 426(a). "Being 'entitled' to Medicare benefits [] means . . . meeting the basic statutory criteria." *Becerra v. Empire Health Found., for Valley Hosp. Med. Ctr.*, 597 U.S. 424, 435 (2022).

---

[2] The "Legislative Act" doctrine, also referred to as the "laws of general applicability" does not apply here. In *Atkins v. Parker*, 472 U.S. 115 (1985), the Supreme Court held that in certain circumstances where a benefit was eliminated, the legislative process provided all the process was that due. However, *Atkins* is distinguishable because it involved a legislative initiative that applied across-the-board and did not involve "the procedural fairness of individual eligibility determinations." *See Atkins*, 472 U.S. at 129. Here, the reclassification of Stelara changed the coverage requirements. Although this change resulted in a denial of benefits, most, if not all beneficiaries, could meet the new requirements if given an opportunity to do so. Whether or not a particular beneficiary satisfied the Part D coverage requirements, and thereby could retain existing benefits, required an "individual eligibility determination" therefore brining it outside the scope of *Atkins*. *See Atkins*, 472 U.S. at 129.

The change in Stelara's coverage, from Part B to Part D, deprived Plaintiffs of their property interest in Medicare benefits. To qualify for Part D coverage, Plaintiffs must separately enroll in a stand-alone, private prescription drug plan, or in a Medicare Advantage plan that includes prescription drug coverage. 42 U.S.C. § 1395w-101. Each of these Part D plans has its own "formulary" or list of covered drugs, as well as prior authorization requirements and a network of approved pharmacies. Therefore, although almost all drugs that are put on the SAD list can be covered by Part D, Part D is subject to particular requirements including formulary requirements, pharmacy network limitations, and possible prior authorization requirements.

The effect of Stelara's reclassification was to eliminate, at least temporarily, the benefits of current recipients while they attempted to apply for and acquire Part D coverage. Although the Secretary was free to alter its benefit program by changing the coverage requirements, the Due Process Clause does not permit the government to withhold benefits without giving current recipients the opportunity to meet the new requirements. Plaintiffs were deprived of their previously protected interests notwithstanding the possibility that they could continue to receive benefits if they applied for Part D coverage. The relevant inquiry is whether they were deprived of a protected interest when eligibility requirements

changed. They were. *See Greene v. Babbitt*, 64 F.3d 1266, 1273 (9th Cir. 1995) (finding that while Congress was "free to change eligibility criteria for federal benefits . . . once Congress has narrowed eligibility for fundamental health and welfare benefits by conditioning eligibility on [particular requirements], the due process clause requires a meaningful hearing to determine whether those previously eligible can meet the new and narrowed requirements").

Given Plaintiffs have been deprived of a protected interest, the next question is whether they were denied adequate procedural protections. *See Thornton*, 425 F.3d at 1164. "[O]ne of due process's central and undisputed guarantees is that, before the government permanently deprives a person of a property interest, that person will receive—at a minimum—notice." *Wright v. Beck*, 981 F.3d 719, 727 (9th Cir. 2020) (citing *Mullane v. Cent. Hanover Bank & Tr. Co.*, 339 U.S. 306, 313 (1950)).

Plaintiffs did not receive notice of the change in coverage status of Stelara from Part B to Part D until they received Medicare Summary Notices ("MSNs") showing denied claims well after they received their scheduled injections. Although the MACs provided notice of changes to the SAD list by updating the local coverage articles on their websites, the website changes were not "reasonably calculated to give notice to the average [Medicare beneficiary]" of whether a drug

they require can no longer be covered by Medicare Part B. *Nozzi v. Hous. Auth. of City of L.A.*, 806 F.3d 1178, 1194–95 (9th Cir. 2015). Simply posting the updated SAD lists was insufficient to provide adequate notice. Because of this, Plaintiffs were not meaningfully advised regarding the change in coverage and were, accordingly, deprived of the opportunity to have their injections covered under Part D.

IV

Plaintiffs plausibly alleged that the liability protections of the Medicare Act should apply. The liability protections of the Medicare Act are triggered when 1) payment is denied because the item or service is not "reasonable or necessary" (referencing 42 U.S.C. § 1395y(a)(1)); and 2) the beneficiary and the provider "did not know, and could not reasonably have been expected to know," that Medicare would not cover the service in question. *Id*. § 1395pp(a)(2). Plaintiffs have plausibly alleged both elements.

First, in determining that Stelara should be administered through Medicare Part D instead of Medicare Part B, the MACs made a medical determination that it was not "reasonable and necessary" for Stelara to be "furnished as an incident to a physician's professional service" because it is "usually self-administered by the patient." 42 U.S.C. §§ 1395k(a)(1), 1395x(s)(2)(A). This was a medical

determination—the fact that it was made on a categorical basis does not alter that conclusion.

The Medicare Benefit Policy Manual ("Manual") does not compel a different conclusion. The Manual states that a denial on the grounds that a drug is subject to the self-administered exclusion is not based on the item being "not reasonable and necessary," but a benefit category denial, "i.e., a denial based on the fact that there is *no benefit category under which the drug may be covered*." MBPM Ch. 15 § 50.2(I) (emphasis added). Here, however, this guidance is inapplicable because Stelara was provided under an enumerated benefit category for years when it was categorized as a drug "furnished as an incident to a physician's professional service." 42 U.S.C. § 1395x(s)(2)(A). Therefore, there is a benefit category under which the drug *may* be covered, but a medical determination has been made to no longer classify the drug as such. This situation is outside the scope of the guidance in the Manual because it involves a benefit category denial that was previously within a benefit category but based on a "reasonable and necessary" determination, is now excluded.

Second, Plaintiffs have plausibly alleged that the beneficiaries and providers "did not know, and could not reasonably have been expected to know," that

Medicare would not cover their Stelara injections. Therefore, Plaintiffs have plausible alleged that they may meet the second element for liability protection.

As such, Plaintiffs' allegations are plausible and do not warrant dismissal.

REVERSED AND REMANDED.