[DO NOT PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 20-11454
Non-Argument Calendar

D.C. Docket No. 5:20-cv-00565-LCB

EDWIN R. BANKS,

Plaintiff-Appellant,

versus

SECRETARY OF HEALTH AND HUMAN SERVICES,

Defendant-Appellee.

Appeal from the United States District Court
for the Middle District of Florida

(July 26, 2021)

Before WILSON, MARTIN, and ROSENBAUM, Circuit Judges.

PER CURIAM:

Edwin R. Banks, a Medicare recipient, appeals the district court's grant of summary judgment to the Secretary of Health and Human Services ("the Secretary") in his action for judicial review of the agency's denial of coverage. The Secretary argues for the first time on appeal that Banks lacks Article III standing. Banks disagrees and asks this Court to take judicial notice of additional evidence to support that he has standing. After careful consideration, we remand this case to the district court for additional jurisdictional factfinding and a ruling on the issue of Article III standing in the first instance. We further instruct that the determination of standing proceed on an expedited basis.

I

Banks is a 76-year-old Medicare beneficiary living in Alabama. In 2009, he was diagnosed with glioblastoma multiforme, a lethal form of brain cancer that famously affected Senators Edward Kennedy and John McCain, as well as Beau Biden. Following this diagnosis, Banks underwent surgery, chemotherapy, and radiation. Despite this treatment, however, his cancer progressed. Banks was then prescribed Optune, a type of medical device that provides tumor treating field therapy ("TTFT"). The device sends "alternating electric fields—or tumor treating fields—into the brain" in order to "slow[] or stop[] cancer growth." The device requires frequent servicing and is rented on a monthly basis.

Banks receives coverage from Medicare Part B, which provides supplemental medical insurance to cover health care costs. Recipients pay a monthly premium in exchange for certain types of coverage, including for durable medical equipment like Optune. See 42 U.S.C. § 1395k. Part B does not cover services that "are not 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). The Secretary has interpreted "reasonable and necessary" to mean that an item or service must be "[s]afe and effective" and "[n]ot experimental" in order to qualify for reimbursement. See Medicare Program Integrity Manual § 13.5.4 (2019).

Banks submitted claims for Medicare coverage of TTFT treatment in every month of 2018. On June 3, 2019, Administrative Law Judge ("ALJ") Bruce Kelton denied Banks's claims for the months of January, March, and April 2018, because he determined that TTFT was not medically reasonable and necessary. As a result, Novocure, the supplier of Optune, was liable for the cost of TTFT for those months.[1] Three days later, a different ALJ, Jeffrey Gulin, approved Banks's claims for the months of February and May through December 2018. Unlike ALJ

[1] The claims processer determined that Novocure was financially liable for the cost of the denied claims because Novocure "could have been expected to know these services were non-covered" under Medicare. The claims processor found that Banks "could not have been expected to know these services were non-covered" and therefore was not liable for the cost.

Kelton, ALJ Gulin found that TTFT treatment was medically reasonable and necessary and a covered Medicare benefit.

As relevant to this appeal, Banks sought judicial review of ALJ Kelton's unfavorable determination. See 42 C.F.R. § 405.1132. Banks argued collateral estoppel prevented the Secretary from relitigating the issue of TTFT coverage in the claims decided by ALJ Kelton, because ALJ Gulin's decisions conclusively determined an issue litigated between the same parties and became final before ALJ Kelton's decisions. The district court granted the Secretary's motion for summary judgment, concluding that the "Medicare scheme is incompatible with the doctrine of collateral estoppel."

On appeal, Banks argues the district court erred in finding collateral estoppel inapplicable. In response, the Secretary argues for the first time that Banks lacks Article III standing and that Banks "submitted no evidence" showing he was injured by the claims denial. In reply, Banks filed a motion asking this Court to take judicial notice of additional evidence supporting standing. We now address the parties' arguments on standing.

II

We review de novo questions concerning our subject matter jurisdiction. Club Madonna, Inc. v. City of Miami Beach, 924 F.3d 1370, 1378 (11th Cir. 2019).

III

Among the jurisdictional doctrines, "standing is perhaps the most important." Bischoff v. Osceola County, 222 F.3d 874, 878 (11th Cir. 2000) (quotation marks omitted). Standing is a jurisdictional prerequisite to suit in federal court and is not subject to waiver. See Alabama v. EPA, 871 F.2d 1548, 1554 (11th Cir. 1989); United States v. Hays, 515 U.S. 737, 742, 115 S. Ct. 2431, 2435 (1995). To establish standing, a litigant must show that she has "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." Spokeo, Inc. v. Robins, 578 U.S. __, 136 S. Ct. 1540, 1547 (2016).

The party invoking federal jurisdiction bears the burden of proving standing. Lujan v. Defs. of Wildlife, 504 U.S. 555, 561, 112 S. Ct. 2130, 2136 (1992). Each element of standing "must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, i.e., with the manner and degree of evidence required at the successive stages of the litigation." Id. Therefore, when standing is raised at the summary judgment stage, "the plaintiff can no longer rest on mere allegations." Id. at 561, 112 S. Ct. at 2137 (quotation marks omitted)). Instead, the plaintiff must "set forth by affidavit or other evidence specific facts," which for purposes of the summary judgment motion "will be taken to be true." Id. (quotation marks omitted).

We begin by setting forth the parties' arguments on standing. The Secretary argues Banks lacks standing because he failed to show two elements: injury in fact and redressability. The Secretary cites to the claims processor's finding that Novocure, and not Banks, was liable for the cost of the TTFT treatment for the January, March, and April 2018 claims. The Secretary says that because Banks was not financially liable for these claims, he cannot show injury or redressability.

Banks makes two arguments in support of his standing to bring this suit. First, he argues the violation of his statutory right to Medicare coverage alone is sufficient to establish standing. Second, he argues he has standing because the denial of claims exposes him to a risk of harm. Specifically, he says the agency will rely on the denial of the January, March, and April 2018 claims to hold him financially liable for other claims. We address each argument in turn.

We make quick work of Banks's first argument, which is foreclosed by circuit precedent. This Court has rejected the assertion that the allegation of a statutory violation alone is sufficient to confer standing. See Muransky v. Godiva Chocolatier, Inc., 979 F.3d 917, 924 (11th Cir. 2020) (en banc) ("[W]e know one thing to be true—alleging a mere statutory violation is not enough to show injury in fact."). Under Muransky, we instead must first ask if the statutory violation caused a direct harm to the plaintiff—if so, the plaintiff has stated an injury in fact. Id. at 926. In the absence of any direct harm, a plaintiff can still establish an injury

in fact "by showing that a statutory violation created a 'risk of real harm.'" Id. at 927 (quoting Spokeo, 136 S. Ct. at 1549). Banks's argument that the statutory violation itself is sufficient to confer standing fails because it overlooks these requirements. Novocure, and not Banks, is liable for the cost of the January, March, and April 2018 claims. Because he does not have to pay these claims, Banks has not shown how the statutory violation caused a direct harm.

Banks's second argument is different. He says he faces a substantial risk of harm because he will be expected to pay future claims based on these denials. See Muransky, 979 F.3d at 927. Banks says losing his appeal from the denial of benefits allows the agency to impute knowledge to him of possible non-coverage. He argues the agency will hold him liable for the cost of future TTFT treatment based on this imputed knowledge.[2] He characterizes this as losing a "Medicare mulligan." See 42 C.F.R. § 411.404(b)(3) ("After a beneficiary is notified that there is no Medicare payment for a service that is not covered by Medicare, he or she is presumed to know that there is no Medicare payment for any form of subsequent treatment for the non-covered condition."). Put another way, although Novocure was deemed liable for the cost of the January, March, and April 2018

[2] Banks says he is all but certain to submit additional claims for TTFT coverage in light of his present and consistent reliance on the device to treat his glioblastoma multiforme. See Appellant's Br. at 2 (Banks has used the TTFT device since 2013 and believes his "medical need for TTFT treatment has been the same."); R. Doc. 1 ¶ 17 ("[P]atients prescribed TTFT treatment will have to continue that treatment for the rest of their . . . lives.").

claims, Banks argues he will be liable for the cost of treatment going forward based on his knowledge of non-coverage. Thus he argues losing the Medicare mulligan confers standing because it exposes him to financial liability. In support of this argument, Banks moves for this Court to take judicial notice of an agency decision issued by ALJ Leslie Holt (the "Holt Decision"). Banks says the Holt Decision supports his Medicare mulligan argument because ALJ Holt found that a Medicare recipient "knew that his TTFT would not be covered by Medicare" based on a prior claim denial and was "therefore personally liable for the cost of the TTFT treatment." Banks argues unless the January, March, and April 2018 claims denials are "reversed now, [he has] no ability to challenge the denial of coverage in this case when his right to receive payment on subsequent claims is adjudicated." Cf. Jayne v. Sherman, 706 F.3d 994, 1000 (9th Cir. 2013) (concluding that litigants have standing to challenge an agency decision that essentially "pre-determines the future," and that "plaintiffs must, at some point, have standing to challenge" the decision and "[t]hat point is now, or it is never") (quotation marks omitted).

The Secretary disagrees with Banks's version of the facts and argues Banks would receive additional notice before he is held financially liable. The Secretary asserts that a Medicare recipient is typically given an "Advance Beneficiary Notice" of non-coverage and a request for the beneficiary to agree to pay if coverage is denied. However, Banks says the Holt Decision "rebuts the erroneous

factual assertion" regarding the role of the Advance Beneficiary Notice and an agreement to pay that the Secretary makes on appeal. In this respect, the parties' arguments on standing require resolving factual disputes.

We think the parties' factual disputes are material to resolving the standing question. The Secretary urges this Court to adopt the holding in a Seventh Circuit ruling in a similar appeal, but the posture of that case is different. In Prosser v. Becerra, 2 F.4th 708, 2021 WL 2621119 (7th Cir. 2021), which was decided after Banks's appeal was fully briefed, the Seventh Circuit ruled that a Medicare recipient lacked standing to challenge the denial of TTFT coverage. Unlike the parties here, however, the parties in Prosser had an opportunity to develop a record on standing. The Seventh Circuit found that Prosser failed to show that the typical "layer[s] of protection for recipients of medical equipment and devices" would not apply in her case. Id. at *5–6. These protections include an "advance notice that Medicare is likely to deny coverage for the treatment" and a request for a "written agreement from the beneficiary[] acknowledging that the recipient will be personally liable if Medicare denies coverage for the treatment." Id. at *5–6 (citing 42 U.S.C. § 1395m(j)(4); Medicare Claims Processing Manual ch. 30, § 30.1).

Here, however, Banks says he "has not previously had the opportunity" to provide evidence rebutting the Secretary's assertions and now asks this Court to

take judicial notice of the Holt Decision. Because Banks disputes a central factual finding relied on in Prosser, we decline the Secretary's invitation to adopt the holding in Prosser at this stage. Cf. U.S. ex rel. Miss. Rd. Supply Co. v. H. R. Morgan, Inc., 528 F.2d 986, 987 (5th Cir. 1976) (per curiam) (noting that, where "prior cases . . . have turned on [a particular] factual fulcrum, it is vital to a proper determination of the jurisdictional issue for the record to be properly developed");[3] see also Appellant's Motion for Judicial Notice at 5–6 ("Secretary Becerra did not challenge Mr. Bank's Article III standing in the District Court, and therefore Mr. Banks never had the opportunity to present the Holt Decision."); Steele v. Nat'l Firearms Act Branch, 755 F.2d 1410, 1415 (11th Cir. 1985) (noting that the record's "inadequacy [was] due, in part, to the appellees' failure to raise the standing argument in the court below").

Therefore, we remand this case to the district court for additional jurisdictional factfinding and a ruling on the issue of Article III standing in the first instance. Remand is appropriate where, as here, the record before us is incomplete and the question of standing was not litigated before the district court. See Steele, 755 F.2d at 1415 (remanding the "to allow appellant to establish the factual

[3] In Bonner v. City of Prichard, 661 F.2d 1206 (11th Cir. 1981) (en banc), we adopted as binding precedent all decisions of the former Fifth Circuit handed down before October 1, 1981. Id. at 1209.

background necessary to permit the district court to resolve the standing question" in the first instance); Bischoff, 222 F.3d at 885 (reversing grant of summary judgment and remanding for further record development on standing); H. R. Morgan, 528 F.2d at 987 (holding "it is vital to a proper determination of the jurisdictional issue for the record to be properly developed" and remanding "for the appropriate factual development"). Of course, if the district court finds Banks to have standing, a ruling on the parties' cross-motions for summary judgment would be appropriate, and an appeal may again follow. At this juncture, however, we will not pass on the merits of Banks's collateral estoppel argument in light of the outstanding jurisdictional issue.

In sum, we vacate the grant of summary judgment to the Secretary and remand this case to the district court to make a determination on standing, with consideration of supplemental evidence submitted by the parties as appropriate.[4] We further direct that the determination of standing proceed on an expedited basis.[5]

VACATED AND REMANDED.

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[4] Banks's motion to take judicial notice of the Holt Decision is **DENIED** as moot.

[5] This Court granted Banks's motion to expedite the appeal filed pursuant to 28 U.S.C. § 1657(a) ("[E]ach court of the United States . . . shall expedite the consideration of . . . any . . . action if good cause therefor is shown.") and Federal Rule of Appellate Procedure 27. See also 11th Cir. R. 34-4(f) ("The court may, on its own motion or for good cause shown on motion of a party, advance an appeal for hearing and prescribe an abbreviated briefing schedule."). In light of Banks's health condition, we instruct an expedited consideration of Banks's case on remand.