United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 18-5192 **September Term, 2018**

FILED DECEMBER 3, 2018

ALCRESTA THERAPEUTICS, INC. AND JONATHAN RICHARD FLATH,
APPELLANTS

v.

ALEX MICHAEL AZAR, II, SECRETARY OF HEALTH AND HUMAN SERVICES,
APPELLEE

Appeal from the United States District Court
for the District of Columbia
(No. 1:18-cv-00243)

Before: SRINIVASAN, PILLARD and KATSAS,* *Circuit Judges*.

J U D G M E N T

The appeal was considered on the record from the United States District Court for the District of Columbia, the briefs filed by the parties, and oral argument held on November 7, 2018. We accorded the issues full consideration and determined they do not warrant a published opinion. *See* D.C. Cir. R. 36(d). It is hereby

ORDERED and **ADJUDGED** that the preliminary injunction be granted in part. The Secretary is ordered to assign Relizorb a temporary billing code that is not encumbered by Medicare coverage indicators that treat Relizorb as a component of the enteral feeding supply kit (coded as B4035) not separately priced or payable.

I.

Plaintiff-Appellant Alcresta Therapeutics, Inc., developed and now manufactures Relizorb, a medical device designed to be used for improved enteral feeding via stomach tube for certain people with cystic fibrosis and other illnesses whose pancreatic function is inadequate to enable them to digest and absorb essential fats. Relizorb consists of a cartridge containing an enzyme that predigests fats in enteral formula before they enter the stomach, thereby facilitating their absorption. Alcresta sought a unique Medicare billing code for Relizorb from the Department of Health and Human Services (HHS). HHS denied the request on the ground that Relizorb was adequately described by B4035, a preexisting billing code that sets an all-inclusive daily price for

certain generic enteral feeding supplies, such as tubing, clamps, and tape. *See* 66 Fed. Reg. 45,173-74. (The included items are not pre-packaged together, but the record refers to a daily set of such supplies as an "enteral feeding supply kit." J.A. 154, 66 Fed. Reg. 45,173). HHS prices and codes dozens of other products patients use for enteral feeding separately from the daily enteral feeding supply kit. *See id.* at 45,173-74. The record does not reflect where or why the determination was made to bundle Relizorb into the enteral feeding supply kit under the code B4035.

Alcresta and Jonathan Richard Flath, a cystic fibrosis patient who needs Relizorb to maintain his health, filed a complaint in district court challenging HHS's coding decision. They alleged, among other things, that HHS should have issued Relizorb a unique billing code because it is distinct from other products included within the preexisting code for enteral feeding supplies. They promptly moved for a preliminary injunction directing the Secretary of HHS to issue a unique billing code for Relizorb to allow it to be separately identified and priced. Flath and Alcresta argued that the lack of a unique billing code prevented reimbursement for Relizorb, which caused them both irreparable harm.

While plaintiffs' motion for a preliminary injunction was pending, HHS issued a separate billing code for Relizorb: Q9994. That code did not resolve plaintiffs' claim, however, because it was encumbered by two coverage indicators. As the government explains, coverage indicators consist of numbers or letters appended to a billing code to facilitate contractor processing of Medicare claims—they do not themselves amount to reimbursement determinations. The two indicators HHS attached to Relizorb's code were "I," which means "not payable" by Medicare, and "00," which means the product is not separately priced. J.A. 300.

The district court denied the preliminary injunction, holding that Flath lacked standing because Medicare payment rules, not billing codes, determine the prices for medical supplies. The court reasoned that a new billing code would not change the underlying reimbursement-rate decision and thus would not redress Flath's injuries. The court also held that Alcresta had not demonstrated irreparable harm because it failed to show that the financial losses it incurred from Medicare's failure to reimburse patients for Relizorb threatened the survival of its business.

Plaintiffs moved this court for an emergency injunction, which an earlier panel granted in part, directing the Secretary "to issue a temporary billing code for Relizorb that is not encumbered with the Medicare-coverage indicator." Order, July 13, 2018. In response to that order, HHS changed the coverage indicator on Q9994 from "I" to "D," which references section 30.7.2 of the Medicare Claims Processing Manual setting forth coverage terms for the all-inclusive daily supply kit for enteral feeding; HHS maintained the pricing indicator "00." *See* Letter from Centers for Medicare and Medicaid Services to All Medicare Administrative Contractors, on HCPCS code Q9994 (July 20, 2018). On November 5, 2018, HHS published its 2019 annual update to the Healthcare Common Procedure Coding System (HCPCS) codes. HHS therein converted the temporary Relizorb billing code, Q9994, to list it in the annual update as B4105, sequentially with other supplies and formula for enteral and parenteral feeding (also identified by B-four thousand codes), and retained its "D" and "00" coverage indicators. *See* November 6, 2018 Letter from Alex Azar to Mark Langer, pursuant to Fed. R. App. P. 28(j).

II.

The sole issue presented by this appeal is whether Alcresta and Flath have demonstrated irreparable injury so as to entitle them to a preliminary injunction. That is because HHS, on appeal, does not address the remaining preliminary injunction factors—likelihood of success on the merits, balance of the equities, and the public interest. *See Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). It has forfeited its arguments with respect to those factors, *see* Oral Arg. 1:09:17-11:03, and we consider this appeal on the assumption that Alcresta and Flath are likely to succeed on the merits of their underlying claims.

Alcresta and Flath contend that they have been irreparably harmed by the lack of a separate, unencumbered billing code for Relizorb. Before we address whether they are entitled to preliminary relief, however, we must resolve their standing to challenge HHS's coding determinations.

The heart of the dispute, both on standing and the merits, is whether a new billing code can afford Appellants the relief they seek. They seek a unique code, not for its own sake, but to enable Medicare and private insurance providers to reimburse Relizorb as a distinct medical supply, not encompassed within the enteral feeding supply kit at the all-inclusive per diem reimbursement rate on the Medicare fee schedule that HHS established before Relizorb existed. Appellants point out that the total reimbursement rate for the enteral feeding supply kit is substantially less than the market price of Relizorb alone, and that many patients who use the B4035 enteral feeding supply kit have no need for Relizorb.

According to HHS, coding decisions and the resultant billing codes do not determine reimbursement rates, but merely denominate the items, which are separately evaluated and assigned reimbursement rates under Medicare payment rules. *See* Appellee's Br. 22 (citing HCPCS Level II Coding Procedures 2-3, 6-7). HHS insists that Appellants cannot challenge the coding in court, but should instead challenge a particular reimbursement denial through the Medicare appeals process. *See* 42 U.S.C. § 1395ff(b)(1)(A). Alcresta and Flath respond that, as long as Relizorb is coded with coverage indicators that point Medicare contractors to the all-inclusive enteral feeding supply kit price, individualized payment for Relizorb will categorically be denied, and no Medicare appeal could remove that obstacle. Appellants have no quarrel with the reimbursement rate for the enteral feeding supply kit as such. Appellants' objection is that HHS irrationally and without explanation bundled Relizorb into that already-priced kit.

Coding and pricing may well be two separate processes, as HHS contends, but in the case of Relizorb it was a coding determination that dictated the Medicare reimbursement rate. HHS has been unable to point to any process or decision—apart from coding Relizorb as part of the B4035 enteral feeding supply kit—by which HHS determined the cartridge's reimbursement rate. Nothing in the record shows that HHS made any separate pricing determination other than through the challenged coding decisions: HHS initially declined to issue Relizorb its own billing code, and instead deemed the cartridge "adequately described" by the existing, already-priced enteral feeding supply kit. J.A. 189. Even when it successively issued codes unique to Relizorb (Q9994

and B4105), distinct from the supply-kit code (B4035), HHS appended coverage indicators that persisted in characterizing Relizorb as part of that kit.

We hold that Appellants have supported their standing by showing that they are harmed by lack of opportunity to obtain reimbursement that is caused at least in significant part by HHS's coding determination, and would be meaningfully redressed were that determination undone. A new billing code, unencumbered by the Medicare coverage indicators that bundle Relizorb into the pre-priced enteral feeding supply kit, would not guarantee any particular reimbursement rate. But it would open the way for the agency to establish a reimbursement rate for Relizorb. When a new, unencumbered billing code appears, Medicare contractors must first determine whether the product or service has "a pricing history and profile." Medicare Claims Processing Manual, ch. 23, § 60.3.1. If not, the contractors "make an individual consideration determination for pricing and payment." *Id.* § 30.2.1. To the extent that HCPCS billing codes are designed to treat like goods and services alike and serve as a framework for appropriate reimbursement decisions, HHS's decision to bundle Relizorb with tape, tubes, and other basic daily enteral feeding supplies for purposes of coding make it reasonably possible that a new billing code would prompt HHS to reimburse Relizorb separately.

It is unclear exactly how this process would play out for Relizorb, but "to have standing," plaintiffs "need not demonstrate that they would actually receive" the reimbursement rate they desire. *See W. Va. Ass'n of Cmty Health Ctrs., Inc. v. Heckler*, 734 F.2d 1570, 1574 (D.C. Cir. 1984). "Certainty of success" is "not required." *Id.* at 1575. When there exists an "absolute barrier" to relief, removal of that barrier can establish redressability. *Arlington Heights v. Metro. Hous. Dev. Corp.*, 429 U.S. 252, 261 (1977). Here, Relizorb's encumbered code acts as an absolute barrier to meaningful reimbursement. The government points to the availability of an ordinary Medicare appeal. That route could be available to Flath, but in this case we do not understand it to be to the exclusion of Appellants' APA claim seeking a unique, unencumbered billing code and alleging a violation of FACA.

III.

We further conclude that Appellants have met their burden to show that, in the absence of the preliminary relief they seek, their harm is irreparable. To support a preliminary injunction, a claimant's harm "must be both certain and great." *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006) (quoting *Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985) (per curiam)).

As a cystic fibrosis patient, Appellant Flath benefits from Relizorb as part of his treatment. But Flath cannot afford to buy Relizorb without insurance coverage. HHS does not dispute that lack of coverage for a medically necessary item constitutes irreparable harm. *See generally Nat'l Ass'n of Farmworkers Orgs. v. Marshall*, 628 F.2d 604 (D.C. Cir. 1980).

Appellant Alcresta has also demonstrated that it faces irreparable harm. HHS's coding of Relizorb prevents its use by patients who need it because they cannot get insurance reimbursement

for its cost. Alcresta estimates that it lost 15.3 million dollars from forgone sales in 2017 alone, and expects even greater losses in 2018. It is, of course, "well settled that economic loss does not, in and of itself, constitute irreparable harm." *Wis. Gas Co.*, 758 F.2d at 674. Here, however, it appears highly unlikely that Alcresta would be able to recover from the government its lost revenues. *See Armour & Co. v. Freeman*, 304 F.2d 404, 406 (D.C. Cir. 1962) (deeming a loss of profits that could "never be recaptured" to be irreparable). Additionally, Alcresta has submitted a declaration from its Chief Financial Officer attesting that the company will "likely be forced to cease operations" by the end of 2018 if there is no "meaningful change in insurance reimbursement" for Relizorb. J.A. 441; *see Wis. Gas Co.*, 758 F.2d at 674 (monetary loss can constitute irreparable harm when "the loss threatens the very existence of the movant's business").

Of course it is not enough for Appellants to demonstrate irreparable harm of any sort. The alleged harm must "directly result from the action which the movant seeks to enjoin." *Wis. Gas*, 758 F.2d at 674. For the reasons explained, Alcresta and Flath have demonstrated a sufficient causal nexus between their encumbered billing code and their injuries and that success on the merits would meaningfully redress those injuries.

* * *

Because Appellants have standing to challenge the agency's coding decision and have demonstrated that the decision is causing them irreparable harm, we grant the preliminary injunction with respect to Appellants' request for a separate, usable code for Relizorb unencumbered by Medicare coverage or pricing indicators that bundle it with B4035. We deny without prejudice the motion with respect to Appellants' Administrative Procedure Act claim for a reasoned decision and their Federal Advisory Committee Act claim, which have been proceeding in the district court simultaneous with this appeal.

Pursuant to D.C. Circuit Rule 36, this disposition will not be published. In light of Appellants' showing that they are suffering irreparable harm, the Clerk is directed to issue the mandate forthwith.

Per Curiam

FOR THE COURT:
Mark J. Langer, Clerk

BY:
/s/
Ken Meadows
Deputy Clerk

∗A separate dissenting statement by Circuit Judge Katsas is attached.

KATSAS, *Circuit Judge*, dissenting: This appeal involves not one coding question, but two. The first is whether Relizorb should be bundled with other items covered by Healthcare Common Procedure Coding System (HCPCS) code B4035—a code issued under the Health Insurance Portability and Accountability Act, 42 U.S.C. § 1320d-2, for enteral-feeding supplies. Flath and Alcresta contend that Relizorb should have its own, separate HCPCS code, and HHS now agrees. On November 5, 2018, it issued HCPCS code B4105 for any "[i]n line cartridge containing digestive enzyme(s) for enteral feeding," thus unbundling Relizorb from the various items that are grouped together under code B4035. Citation of Supplemental Authorities for Appellee, *Alcresta Therapeutics, Inc. v. Azar*, No. 18-5192 (D.C. Cir. Nov. 6, 2018); CMS, 2019 Healthcare Common Procedures Coding System Annual Update, https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2019-Alpha-Numeric-HCPCS-File.html (last visited Nov. 28, 2018). This decision will become effective on January 1, 2019; it carries forward HHS's prior decision to issue a temporary HCPCS code for Relizorb effective July 1, 2018; and it will control HHS's still-pending reconsideration of the question whether to issue a separate HCPCS code for Relizorb for the rest of 2018. Accordingly, the dispute regarding the appropriate HCPCS billing code for Relizorb is now moot.

The second coding question arose only after HHS decided to establish a temporary HCPCS code for Relizorb. HHS appended to that code two separate *indicator* codes—a coverage indicator ("D") and a pricing indicator ("00"), which together informed Medicare Administrative Contractors that, for Medicare reimbursement purposes, Relizorb may not be reimbursed separately from the enteral-feeding supply kit. *See* Technical Direction Letter from CMS to All Medicare Administrative Contractors (July 20, 2018); CMS, Medicare Claims Processing Manual Ch. 20 § 30.7.2, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS018912.html (last visited Nov. 28, 2018); CMS, 2018 HCPCS Record Layout § 9, https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2018-HCPCS-Record-Layout-.html (last visited Nov. 28, 2018). HHS later appended the same indicators to the HCPCS code established for Relizorb for 2019. Flath and Alcresta now challenge HHS's decision to issue these two separate indicators.

I share my colleagues' uncertainty about when, how, or why HHS decided to bundle Relizorb with enteral-feeding supplies for Medicare reimbursement purposes, whether in the decision to attach the indicators to code B4105 (as the record seems to suggest) or in prior Medicare decisions that the indicators merely confirm (as HHS contends). Either way, the indicators do nothing more than provide guidance regarding coverage and reimbursement decisions *under Medicare*. Their lawfulness turns on questions of Medicare law, not HIPAA law. Accordingly, challenges to those decisions arise under the Medicare Act, and the only way to obtain judicial review of them is through 42 U.S.C. §§ 405(g), 405(h), and 1395ii, which together require a beneficiary first to present a specific claim for payment to HHS and then to administratively appeal any denial. *See*, *e.g.*, *Am. Hosp. Ass'n v. Azar*, 895 F.3d 822, 825–26 (D.C. Cir. 2018).

There is an exception when these requirements would frustrate rather than merely delay judicial review, but it does not apply here. Nothing prevents Flath from presenting to HHS a claim for payment for Relizorb. *See* 42 C.F.R. § 405.904(a)(2). Moreover, HHS repeatedly has represented to us that it will process such claims and ensuing appeals, thereby generating judicially reviewable orders at the end of the administrative process. On this record, we have no reason to

question those representations. To be sure, Alcresta, as a manufacturer of medical equipment, cannot itself present or exhaust payment claims within the Medicare channeling scheme. *See id.* § 405.906(a). But that does not justify an exception to the scheme, for Flath and other Relizorb users can present and exhaust claims, and their interests align with those of Alcresta. *See Council for Urological Interests v. Sebelius*, 668 F.3d 704, 712–13 (D.C. Cir. 2011).

In sum, the dispute regarding HCPCS billing codes is now moot, and the challenge regarding coverage and pricing indicators, which arises under the Medicare Act, fails for lack of presentment and exhaustion. I would dismiss the appeal on these grounds, without reaching the merits.