United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued September 25, 2025 Decided June 26, 2026

No. 24-5290

ARDELYX, INC., ET AL.,
APPELLANTS

v.

ROBERT F. KENNEDY, JR., SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 1:24-cv-02095)

Michael E. Bern argued the cause for appellants. With him on the briefs were *James E. McCollum, Jr.*, *Amit K. Sharma*, *Christine C. Smith*, *Alexander G. Siemers*, *Delia Tasky*, and *Nicholas L. Schlossman.*

Caroline D. Lopez, Attorney, U.S. Department of Justice, argued the cause for appellees. With her on the brief were *Yaakov M. Roth*, Acting Assistant Attorney General, *Michael S. Raab*, Attorney, and *David L. Hoskins*, Deputy Associate General Counsel for Litigation, U.S. Department of Health and Human Services. *Anna O. Mohan*, Attorney, U.S. Department of Justice, entered an appearance.

Before: CHILDS and PAN, *Circuit Judges*, and GINSBURG, *Senior Circuit Judge*.

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

GINSBURG, *Senior Circuit Judge*: In 2008 the Congress directed the Secretary of Health and Human Services to "implement a payment system" that would provide a "single payment" for the reimbursement of "renal dialysis services" under Medicare, a federal health insurance program. *See* 42 U.S.C. § 1395rr(b)(14)(A)(i). In 2010 the Secretary, acting through the Centers for Medicare & Medicaid Services, defined "renal dialysis services" to include drugs with "only an oral form" — *i.e.*, oral-only drugs — furnished for the treatment of end-stage renal disease. 42 C.F.R. § 413.171(3) (2011). In 2024 the CMS identified XPHOZAH, an oral-only drug manufactured by Ardelyx, Inc., as a renal dialysis service covered by the new payment system starting on January 1, 2025. Before then, XPHOZAH, along with other orally administered drugs, had been reimbursed separately from the bundled payment under Medicare Part D.

Ardelyx, together with a healthcare research and advocacy organization and an organization representing the interests of kidney patients, challenged the CMS's definition of "renal dialysis services" as including oral-only drugs and the identification of XPHOZAH as a renal dialysis service.[*] The district court dismissed Ardelyx's complaint for lack of jurisdiction on the ground that the challenged actions were "identification[s] of renal dialysis services" within the meaning of 42 U.S.C.

[*] The Department of Health and Human Services, the Secretary of Health and Human Services, the CMS, and the Administrator of the CMS are all defendants and appellees in this lawsuit. For simplicity we refer to them collectively as the CMS.

§ 1395rr(b)(14)(G), which bars judicial review of such actions by the Secretary. *Ardelyx, Inc. v. Becerra* (*Ardelyx I*), 757 F. Supp. 3d 37, 46-47 (D.D.C. 2024). We agree and affirm the dismissal of Ardelyx's complaint.

I. Background

End-stage renal disease (ESRD) is a form of chronic kidney disease in which an individual's kidneys can no longer function on their own. Patients with ESRD who do not receive a kidney transplant will die unless they receive dialysis treatment several times per week. Medicare covers the cost of dialysis for patients suffering from ESRD. *See* 42 U.S.C. §§ 426-1, 1395rr(a).

A. Statutes and Regulations

In 1981 the Congress established a prospective payment system for the reimbursement of renal dialysis services in order to curb runaway costs. *See* Omnibus Budget Reconciliation Act of 1981, Pub. L. No. 97-35, § 2145, 95 Stat. 357, 799-800. Under this system, renal dialysis facilities and other providers of renal dialysis services would receive a prospective payment per treatment at a prescribed rate, regardless of their actual costs. *See* 48 Fed. Reg. 21254, 21260/3 (1983). This payment covered services including "routinely provided drugs, laboratory tests, and supplies." 75 Fed. Reg. 49030, 49032/1 (2010). A facility could retain any amount of the prospective payment that exceeded its actual costs. 48 Fed. Reg. at 21261/1. Certain items, such as erythropoiesis stimulating agents (ESAs), orally administered drugs, and most injectable drugs were reimbursed separately under Medicare Parts B or D.

The Congress believed this system would "encourage the more efficient delivery of dialysis services." 42 U.S.C. § 1395rr(b)(7). The system, however, also gave facilities an

incentive to use the separately reimbursed items to treat ESRD because doing so allowed them to increase their total reimbursement. By 2010 these separately reimbursed items accounted for "40 percent of total spending for outpatient maintenance dialysis." 75 Fed. Reg. at 49032/2.

In order to bring that spending under control, the Congress enacted the Medicare Improvements for Patients and Providers Act of 2008, Pub. L. No. 110-275, § 153, 122 Stat. 2494, 2553. The MIPPA instructed the Secretary to "implement a payment system under which a single payment is made under this subchapter to a provider of services or a renal dialysis facility for renal dialysis services (as defined in subparagraph (B)) in lieu of any other payment." 42 U.S.C. § 1395rr(b)(14)(A)(i). Subparagraph (B), § 1395rr(b)(14)(B), defines "renal dialysis services" as follows:

> For purposes of this paragraph, the term "renal dialysis services" includes--
>
> (i) items and services included in the composite rate for renal dialysis services as of December 31, 2010;
>
> (ii) erythropoiesis stimulating agents and any oral form of such agents that are furnished to individuals for the treatment of end stage renal disease;
>
> (iii) other drugs and biologicals that are furnished to individuals for the treatment of end stage renal disease and for which payment was (before the application of this paragraph) made separately under this subchapter, and any oral equivalent form of such drug or biological; and
>
> (iv) diagnostic laboratory tests and other items and services not described in clause (i) that are furnished to individuals for the treatment of end stage renal disease.[†]

Subparagraph (B) goes on to exclude vaccines from the definition of "renal dialysis services."

The Congress also limited review of the Secretary's actions with respect to the services covered by the new payment system. As relevant here, the Congress provided that

[†] For consistency with the district court's opinion, we refer to these categories as "subparts" of subparagraph (B).

"[t]here shall be no administrative or judicial review" of the Secretary's "identification of renal dialysis services included in the bundled payment." Subparagraph (G).

In 2009 the CMS published a notice of proposed rulemaking to implement the new prospective payment system. *See* 74 Fed. Reg. 49922. The CMS explained that it believed subpart (B) (iii) required it to include in the bundled payment "all drugs and biologicals formerly payable under either Medicare Part B or Part D used to treat ESRD, regardless of the route of administration," one effect of which was to include oral-only drugs. *Id.* at 49928/2-3. The CMS acknowledged that one could read "any oral equivalent form of such drug or biological" at the end of subpart (B)(iii) as "limit[ing] the scope of the drugs and biologicals included in the bundle to only oral versions of injectables (or other non-oral routes of administration)." *Id.* at 49928/3. Still, the CMS rejected that reading as "unduly constrained" because it would undermine the Congress's intent to include "all renal dialysis services furnished to ESRD patients in a comprehensive payment bundle." *Id.* The CMS alternatively invoked subpart (B)(iv), which covers "other items and services not covered in [subpart (B)] (i)," to support its inclusion of oral-only drugs in the bundled payment. *Id.*

In 2010 the CMS published the final rule implementing the bundled payment system. 75 Fed. Reg. 49030. In response to the "[m]any comments" it had received disagreeing with its reading of "renal dialysis services" to include oral-only drugs, *see id.* at 49038/2, the agency explained its view that the reference to oral equivalents in subpart (B)(iii) "pertains to the oral versions of injectable drugs." *Id.* at 49039/1. The CMS construed the reference earlier in subpart (B)(iii) to "other drugs [covered] under this [subchapter]" as including oral-only drugs in the definition of "renal dialysis services." *Id.* (cleaned up). In case the agency was wrong about the scope of subpart

(B)(iii), it again invoked subpart (B)(iv) in further support of its decision, characterizing that subpart as a "residual or catch all category for drugs which do not fall under the scope of those specified renal dialysis services identified" in subparts (ii) and (iii). *Id.* As a result, the final rule defines "renal dialysis services" reimbursed under the bundled payment to include:

> Other drugs and biologicals that are furnished to individuals for the treatment of ESRD and for which payment was (prior to January 1, 2011) made separately under Title XVIII of the Act (including drugs and biologicals with only an oral form).

42 C.F.R. § 413.171(3).

The CMS set an effective date of January 1, 2014 for the inclusion of oral-only drugs in the bundled payment to allow facilities, providers, pharmacies, and Medicare Part D plans to make necessary adjustments. 75 Fed. Reg. at 49044/1. Before the regulation went into effect, the Congress thrice delayed implementation of the bundled payment with respect to oral-only drugs, making the effective date January 1, 2025. *See* American Taxpayer Relief Act of 2012, Pub. L. No. 112-240, § 632(b), 126 Stat. 2313, 2354 (2013) (delaying implementation until January 1, 2016); Protecting Access to Medicare Act of 2014, Pub. L. No. 113-93, § 217(a), 128 Stat. 1040, 1061 (extending the delay until January 1, 2024); Achieving a Better Life Experience Act of 2014, Pub. L. No. 113-295, § 204, 128 Stat. 4010, 4065 (extending the delay until January 1, 2025). Along the way, the Congress also imposed other requirements related to the inclusion of oral-only drugs in the bundled payment. *See* § 632(b), 126 Stat. at 2354 (ordering the CMS to monitor the bone and mineral metabolism in ESRD patients "[w]ith respect to the implementation of oral-only ESRD-

related drugs in the ESRD prospective payment system"); § 632(d), 126 Stat. at 2354-55 (directing the Government Accountability Office to report on "the Secretary's preparations to implement payment for oral-only ESRD-related drugs in the bundled prospective payment system"); § 217(d)(3), 128 Stat. at 1062-63 (requiring the CMS to establish performance measures for facilities regarding the quality of patient care "that are specific to the conditions treated with oral-only drugs").

B. The Identification of XPHOZAH

XPHOZAH is an oral-only drug manufactured by Ardelyx to treat hyperphosphatemia, a condition characterized by an abnormally high level of phosphate in the blood. Advanced kidney failure is the leading cause of hyperphosphatemia, which occurs in 80% of ESRD patients on maintenance dialysis. Patients with ESRD may begin treating hyperphosphatemia with phosphate binders, which prevent phosphate from entering the bloodstream by attaching to phosphate in the gastrointestinal tract. Of those patients with ESRD on maintenance dialysis who have hyperphosphatemia, however, 70% experience an inadequate response to phosphate binders and cannot maintain their target phosphate level.

In a declaration filed in support of its motion for a preliminary injunction, Ardelyx describes XPHOZAH as a "novel treatment option" for those patients. XPHOZAH blocks phosphate from entering the bloodstream through a different mechanism of action than phosphate binders. According to its FDA-approved label, XPHOZAH is indicated for use only by "adults with chronic kidney disease . . . on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy." The label also tells prescribers to "[i]nstruct

patients not to take XPHOZAH right before a hemodialysis session."

In August 2023 — with the inclusion of oral-only drugs in the bundle still more than a year away — Ardelyx submitted a letter to the CMS asking it to continue excluding oral-only drugs such as XPHOZAH from the definition of "renal dialysis services" beyond January 1, 2025. Two months later, XPHOZAH received FDA approval and first became available to patients. XPHOZAH was initially covered under Medicare Part D and reimbursed separately from the bundled payment.

On May 13, 2024 the CMS notified Ardelyx that it had "identified XPHOZAH™ [as] a renal dialysis service under 42 C.F.R. 413.171, because it is furnished to individuals to treat a condition associated with ESRD and is essential to the delivery of maintenance dialysis." The letter informed Ardelyx that XPHOZAH would be included in the bundled payment for renal dialysis services beginning January 1, 2025.

C. Procedural History

On July 17, 2024 Ardelyx and the other appellants filed suit challenging both (1) the CMS's rule defining "renal dialysis services" to include oral-only drugs furnished for the treatment of ESRD, 42 C.F.R. § 413.171(3), and (2) the CMS's identification of XPHOZAH as a "renal dialysis service" included in the bundled payment. Ardelyx alleged these actions were arbitrary and capricious, an abuse of discretion, not in accordance with law, violative of statutory right, and in excess of the CMS's statutory authority, in violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A), (C). The CMS moved to dismiss the complaint, arguing that sub-paragraph (14)(G) deprived the district court of authority to review the challenged actions. Ardelyx then moved for a

preliminary injunction or, alternatively, for expedited summary judgment.

The district court granted the CMS's motion to dismiss. *Ardelyx I*, 757 F. Supp. 3d at 41. The district court first explained that in order to determine whether the bar to judicial review in subparagraph (14)(G) precluded it from reviewing the challenged actions, it had to determine whether the disputed actions were of the sort subparagraph (14)(B) authorized the Secretary to take. *Id.* at 48. The district court concluded they were.

The court first determined that defining "renal dialysis services" to include oral-only drugs was an "identification" within the meaning of the bar to judicial review in subparagraph (G), *id.* at 47, and was consistent with the definition of "renal dialysis services" in subparagraph (B), *id.* at 52-56. Specifically, the district court held that subpart (B)(iii) "directly incorporates into 'renal dialysis services' oral-only drugs by covering 'drugs and biologicals,' other than ESAs, that were previously reimbursed separately from the bundle." *Id.* at 52. The court also read subparagraph (B), which lists four types of things included in the definition of "renal dialysis services," as providing a non-exhaustive definition of that term. *Id.*

The district court next determined the CMS had the authority to identify XPHOZAH as a "renal dialysis service." The district court reasoned that XPHOZAH was furnished "for the treatment of" ESRD because it treats a condition "*caused by* or at least closely associated with kidney disease." *Id.* at 58. Having thus held the CMS had acted within its statutory authority, the district court did not consider Ardelyx's other arguments. *Id.*

Ardelyx moved to alter or amend the judgment or, alternatively, for an injunction pending appeal. The district court denied that motion. *Ardelyx, Inc. v. Becerra* (*Ardelyx II*), No. 24-cv-2095, 2024 WL 5186613 (D.D.C. Dec. 20, 2024). Ardelyx filed a timely notice of appeal and sought an injunction pending appeal, which we denied. As a result, the challenged portion of the rule went into effect on January 1, 2025, and XPHOZAH was included in the bundled payment.

II. Analysis

We review the district court's dismissal of Ardelyx's complaint de novo. *See Amgen, Inc. v. Smith*, 357 F.3d 103, 108 (D.C. Cir. 2004). On questions of statutory interpretation, this court "must exercise [its] independent judgment in deciding whether an agency has acted within its statutory authority." *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 412 (2024).

A. The Judicial-Review Provision, Subparagraph (14)(G)

Ardelyx challenges the Secretary's inclusion of oral-only drugs generally, and XPHOZAH specifically, in the bundled payment for renal dialysis services. At the outset, we must determine the scope of our authority to review the challenged actions. Recall that subparagraph (14)(G) bars judicial review of "the identification of renal dialysis services included in the bundled payment." According to the CMS, we lack the authority to review the challenged actions because they are "identification[s] of renal dialysis services" within the meaning of (14)(G). Ardelyx argues that (14)(G) does not cover the challenged actions because the CMS lacked authority to take those actions.

"We begin with the strong presumption that Congress intends judicial review of administrative action." *Bowen v. Mich. Acad. of Fam. Physicians*, 476 U.S. 667, 670 (1986).

This presumption is "particularly strong" where, as here, a party claims an agency has acted "in excess of delegated authority." *Amgen*, 357 F.3d at 111. As we have explained, the Congress "rarely intends to foreclose review of action exceeding agency authority." *Id.* at 112. To overcome the presumption, the party invoking the purported bar to judicial review must provide "clear and convincing evidence that Congress intended to preclude the suit." *Id.* at 111 (cleaned up); *cf. McLaughlin Chiropractic Assocs., Inc. v. McKesson Corp.*, 606 U.S. 146, 159 (2025) ("When Congress wants to bar a district court in an enforcement proceeding from reviewing an agency's interpretation of a statute, Congress can and must say so"). Most relevant here, the presumption can be overcome by "specific language" evincing a "congressional intent to preclude judicial review." *Ascension Borgess Hosp. v. Becerra*, 61 F.4th 999, 1003 (D.C. Cir. 2023) (cleaned up).

At first blush, (14)(G) seems to be precisely that. It simply says there "shall be no administrative or judicial review" of "the identification of renal dialysis services included in the bundled payment." As the district court observed, "[t]his stripping of judicial review . . . could not be clearer." *Ardelyx I*, 757 F. Supp. 3d at 47.

As the district court also realized, however, the judicial inquiry does not end there. A "jurisdiction-stripping provision does not apply if the agency's action fails to qualify as the kind of action for which review is barred." *Am. Hosp. Ass'n v. Azar*, 964 F.3d 1230, 1238 (D.C. Cir. 2020) (cleaned up). Consequently, in order "to determine whether the judicial-review bar applies in this case, we must decide whether the challenged agency action[s]" are the sort of actions shielded from review by (14)(G). *Id.*

We have previously applied this approach to another bar to judicial review involving prospective payments under Medicare. In 42 U.S.C. § 1395*l*(t)(12)(A), the Congress provided that "[t]here shall be no administrative or judicial review" of "the establishment of . . . other adjustments, and methods described in paragraph 2(F)." In *Amgen* we considered whether we had authority to review a challenge to a rule adjusting certain rates under Medicare Part B. 357 F.3d at 106-08. The CMS said it made the adjustments under § 1395*l*(t)(2)(E), which authorized it to establish "other adjustments as determined to be necessary to ensure equitable payments." *Id.* at 107. The CMS argued that subparagraph (12)(A) barred judicial review of the adjustments. Before dismissing the complaint, we had first to determine whether the equitable adjustments authorized by subparagraph (2)(E) qualified as "other adjustments" for purposes of the bar to judicial review in (12)(A) and, if so, whether (2)(E) authorized the Secretary to make the challenged adjustments. *Id.* at 111. These determinations were necessary, we explained, because the bar to judicial review "prevent[ed] review only of those 'other adjustments' that the Medicare Act authorizes the [CMS] to make." *Id.* at 112.

Similarly, in *American Hospital Association* we considered whether we had authority to review a challenge to a rate reduction implemented by the Department of Health and Human Services for a particular outpatient service. 964 F.3d at 1237. The agency had implemented the reduction pursuant to § 1395*l*(t)(2)(F), which authorized it to "develop a method for controlling unnecessary increases in the volume of covered [outpatient] services." *Id.* at 1235. HHS again invoked the bar to judicial review in (12)(A), which precludes review of "the establishment of . . . methods described in paragraph (2)(F)." *Id.* at 1237. The agency asked us to "dispose of the case on that basis at the threshold without examining HHS's authority to

implement the rate reduction." *Id.* at 1237-38. We declined, noting that the premise of the plaintiffs' claim was that the challenged reduction was "*not* a 'method described in paragraph (2)(F)' within the meaning of the statute." *Id.* at 1238 (cleaned up). Pursuant to the reasoning in *Amgen*, we held (12)(A) barred us from reviewing the reduction only if it "qualified as a 'method for controlling unnecessary increases in volume' under subparagraph (2)(F)." *Id.* at 1238-39 (cleaned up). We then proceeded to consider that question. *See id.* at 1239-45.

The same reasoning applies here. Ardelyx claims the CMS exceeded its statutory authority by including oral-only drugs, including XPHOZAH, in the payment bundle. In order to determine whether we have authority to review Ardelyx's claims, we must decide whether the agency's actions qualify as an "identification of renal dialysis services" within the meaning of the bar to judicial review in subparagraph (14)(G). This, in turn, requires us to consider the meaning of "renal dialysis services" in subparagraph (14)(B).

The CMS insists we need not look past subparagraph (14)(G) in order to dismiss Ardelyx's challenge. According to the CMS, the only question is whether the CMS purported to identify or to "recognize" a drug as a renal dialysis service, which it indisputably did in the May 13, 2024 letter to Ardelyx. Needless to say, the CMS's authority to include a particular drug in the bundled payment does not turn upon its say-so. Indeed, we have previously described this as a "preposterous position" because a "bald assertion of power by an agency cannot legitimize it." *COMSAT Corp. v. FCC*, 114 F.3d 223, 227 (1997) (cleaned up); *see Amgen*, 357 F.3d at 113-14 (relying upon *COMSAT* to determine the scope of the bar to judicial review); *Am. Hosp.*, 964 F.3d at 1238 (same). "Otherwise, agencies could characterize reviewable or unauthorized action as falling within the scope of no-review

provisions whose application to such action Congress did not intend." *Amgen*, 357 F.3d at 113.

We are also unpersuaded by the CMS's attempt to distinguish the reasoning of *Amgen* and *American Hospital Association*. The CMS claims the bar to judicial review in those cases expressly cross-referenced another provision, and reasons that we needed to consider the cross-referenced provisions only to determine the scope of the bar. Because (14)(G) does not cross-reference any other provision, the agency says, we need not look elsewhere.

As an initial matter, the CMS's description of the bar to judicial review we encountered in *Amgen* and in *American Hospital Association* is not entirely accurate. Although that provision included a specific cross-reference for "methods," it did not include one for "other adjustments" — the term at issue in *Amgen*. Even without an applicable cross-reference, we observed the use of "other adjustments" in the bar to judicial review "matches the language . . . in § 1395*l*(t)(2)(E), implying that Congress intended to reference adjustments made pursuant to that subsection." 357 F.3d at 113.

In this case, the CMS's argument fails for a simpler reason: The Congress expressly tied the bar to judicial review in (14)(G) to the definition of "renal dialysis services" in (14)(B) by defining that term "[f]or purposes of this paragraph" — *i.e.*, paragraph (14). As the district court observed, this "obviate[s] a need for an additional express link in" (14)(G) because that provision also refers to "renal dialysis services." *Ardelyx I*, 757 F.3d at 50. The term "renal dialysis services" has the same meaning in both provisions, so we must look to the definition in (14)(B) to determine the scope of (14)(G).

To be sure, this approach may "merge consideration of the legality of the [agency]'s action with consideration of this

court's jurisdiction." *COMSAT*, 114 F.3d at 227 (cleaned up). Here, for example, the question whether the CMS exceeded its authority by including oral-only drugs and XPHOZAH in the bundled payment coincides with the question whether each of those actions qualifies as an "identification of renal dialysis services." This inquiry does not, however, render the judicial-review bar irrelevant. That bar "still forecloses inquiry into whether the challenged agency decision is arbitrary, capricious, or procedurally defective." *Am. Hosp.*, 964 F.3d at 1239 (cleaned up). If the CMS acted within its authority by including oral-only drugs and XPHOZAH in the bundled payment, then we lack authority to review whether those actions were "reasonable and reasonably explained," as required by the APA. *FCC v. Prometheus Radio Proj.*, 592 U.S. 414, 423 (2021). We review the merits of Ardelyx's challenge, therefore, only "to the extent necessary to determine whether the challenged agency actions fall within the scope of the preclusion of judicial review." *Amgen*, 357 F.3d at 113 (cleaned up).

B. Ardelyx's Challenge to the Regulation, 42 C.F.R. § 413.171(3)

In this section we consider whether the CMS's inclusion of oral-only drugs in the bundled payment constitutes an "identification of renal dialysis services." Subparagraph (14)(G).[‡] Recall that the CMS has defined "renal dialysis services" to include drugs furnished for the treatment of ESRD that have "only an oral form." 42 C.F.R. § 413.171(3). Ardelyx

[‡] The CMS erroneously implies that Ardelyx's complaint did not challenge the regulation defining "renal dialysis services" to include oral-only drugs. Ardelyx's complaint plainly challenges § 413.171(3). *See* Compl. ¶¶ 212-15 (arguing the CMS's promulgation of § 413.171(3) was "arbitrary, capricious, an abuse of discretion, not in accordance with law, in excess of statutory jurisdiction and authority, and short of statutory right").

offers two reasons the bar to judicial review does not preclude its challenge to this aspect of the rule. First, Ardelyx argues the CMS's promulgation of the rule was not an "identification" for purposes of subparagraph (14)(G). Second, Ardelyx claims the definition of "renal dialysis services" does not include oral-only drugs, so the CMS lacks authority to include such drugs in the bundled payment.

1. "Identification"

Ardelyx asserts that an "identification" within the bar to review in (14)(G) means the selection of a particular drug rather than a category of drugs. Because 42 C.F.R. § 413.171(3) speaks of a category, Ardelyx argues (14)(G) does not preclude us from reviewing its challenge to the regulation.

The statute does not define "identification," so we give that term its ordinary meaning. *Taniguchi v. Kan Pacific Saipan, Ltd.*, 566 U.S. 560, 566 (2012). The parties offer several definitions of "identify." The CMS refers us to the Oxford English Dictionary, which defines to "identify" as to "recognize as belonging to a particular category or kind." Ardelyx points to the Merriam-Webster Dictionary, where to "identify" means to "state the identity of . . . something," and to the Federal Circuit, which has defined to "identify" as to "recognize or establish an object as being a particular thing," *Apple Inc. v. Omni MedSci, Inc.*, No. 2023-1034, 2024 WL 3084509, at *5 (June 21, 2024); *see also Ardelyx I*, 757 F. Supp. 3d at 47 (defining to "identify" as to "recognize something and say or prove what that thing is" (cleaned up)).

Each of these definitions is broad enough to cover the CMS's determination that oral-only drugs furnished for the treatment of ESRD qualify as renal dialysis services. The CMS has recognized something (oral-only drugs furnished for the

treatment of ESRD) as being a particular thing or as belonging to a particular category, namely, renal dialysis services. The CMS's promulgation of the regulation thus fits comfortably within the meaning of "identification" in (14)(G). Nothing in the statute or in the definitions offered by Ardelyx supports its narrower reading, which would preclude the CMS from making categorical determinations about which drugs to include in the bundle.

A contrary conclusion would too easily allow a plaintiff to circumvent subparagraph (G) and challenge the inclusion of a particular drug in the bundle. As the CMS notes, Ardelyx does not challenge the regulation "in a vacuum"; it also challenges the inclusion of XPHOZAH in the bundle "consistent with this regulation." Ardelyx does not argue that the May 13, 2024 letter selecting XPHOZAH for the bundle was not an "identification." Under Ardelyx's reading of "identification," however, "almost any challenge to an [identification of a particular drug] could be recast as a challenge to [the] underlying [regulation]," *DCH Reg. Med. Ctr. v. Azar*, 925 F.3d 503, 506 (D.C. Cir. 2019), an artful dodge we cannot allow. *Accord Palisades Gen. Hosp. Inc. v. Leavitt*, 426 F.3d 400, 405 (D.C. Cir. 2005) ("[W]hen a procedure is challenged solely in order to reverse an individual . . . decision" covered by a bar to judicial review, "judicial review is not permitted").

For this reason, the CMS argues we lack jurisdiction to consider Ardelyx's challenge to the regulation because that challenge is "inextricably intertwined" with the challenge to the identification of XPHOZAH. Yet Ardelyx raises distinct arguments as to why each action does not qualify as an "identification of renal dialysis services." For example, as just discussed, Ardelyx argues the CMS's promulgation of § 413.171(3) was not an "identification" for purposes of the bar to judicial review; it does not raise that argument with respect

to XPHOZAH. Moreover, even if we viewed Ardelyx's challenge to the regulation as "inextricably intertwined" with its challenge to XPHOZAH, we would still have to consider whether the CMS had authority to include XPHOZAH in the bundle for the reasons discussed. We therefore consider both of Ardelyx's challenges below.

2. "Renal dialysis services"

Ardelyx's principal challenge to 42 C.F.R. § 413.171(3) is that the definition of "renal dialysis services" in (14)(B) excludes oral-only drugs. That subparagraph lists four categories that the Congress "include[d]" in the definition of "renal dialysis services." Ardelyx maintains those categories provide an exhaustive definition of "renal dialysis services," and none of them includes oral-only drugs that are not provided by dialysis facilities during dialysis. The CMS justifies its inclusion of oral-only drugs in the bundle in three ways. First, it argues oral-only drugs fit within the definition of "renal dialysis services" in the third enumerated category, subpart (B)(iii). Second, it interprets the fourth enumerated category, subpart (B)(iv), as a catchall provision covering "newly developed items and services that are not otherwise covered by the prior [subparts]." Third, it claims it has discretion to include in the bundle drugs that are not expressly covered by the four categories in subparagraph (14)(B) because that subparagraph is a non-exhaustive definition of renal dialysis services. Because we agree with the agency's first point, we do not reach its other arguments.

Subpart (iii) defines "renal dialysis services" to include:

> [(1a)] other drugs and biologicals that are furnished to individuals for the treatment of end stage renal disease and [(1b)] for which payment was (before the application of this

> paragraph) made separately under this subchapter, and [(2)] any oral equivalent form of such drug or biological.

Based upon the plain text of this subpart, we hold the CMS has the authority to include oral-only drugs in the bundled payment. The first clause in the subpart establishes two criteria for inclusion in the definition of a renal dialysis service. The first, which we have denominated [1a], includes in the definition "other drugs and biologicals" furnished for the treatment of ESRD, of which the CMS claims XPHOZAH is one (a matter we take up later); it does not exclude drugs based upon their form of administration. Oral-only drugs also satisfy the second criterion in the first clause [1b] if they were paid for "separately under this subchapter" and "before the application of this paragraph." *Id.* As the district court said, "'this subchapter' refers to Subchapter XVIII, which includes Medicare Parts A, B, C, *and* D," and thus "'separately under this subchapter' includes all drugs paid [for] separately under any reimbursement system." *Ardelyx II*, 2024 WL 5186613, at *10. Ardelyx does not challenge that conclusion on appeal. Ardelyx also acknowledged in its complaint that under the prior payment system, "orally administered ESRD drugs were generally covered separately under Medicare Part D." Compl. ¶ 65. Therefore**,** payment for certain oral-only drugs was "made separately under this subchapter" and "before the application of" the new bundled payment system. It follows, as the district court said, that subpart (iii) "directly incorporates" oral-only drugs in the definition of "renal dialysis services." *Ardelyx I*, 757 F. Supp. 3d at 52.

Resisting this conclusion, Ardelyx focuses on the second clause [2] of subpart (iii), which includes in the definition "any oral equivalent form of such drug or biological" covered by the first clause. Ardelyx argues that the express inclusion of oral

drugs in this clause implies the Congress intended to exclude oral drugs from the first clause.

The CMS rejected this interpretation of the statute as "unduly constrained." 74 Fed. Reg. at 49928/3. We agree. The Congress spoke clearly when it wanted to address drugs administered in a certain form and when it wanted to omit particular items from the definition of "renal dialysis services." It did so by referring to oral drugs in both subparts (B)(ii) and (B)(iii), and by expressly excluding vaccines from subparagraph (B). The Congress did not exclude oral-only drugs from the first clause of subpart (iii), and we may not read that limitation into the statute. *See Lomax v. Ortiz-Marquez*, 140 S. Ct. 1721, 1725 (2020) ("Court[s] may not narrow a provision's reach by inserting words Congress chose to omit"); *Centro de Trabajadores Unidos v. Bessent*, 167 F.4th 1218, 1231 (D.C. Cir. 2026) (declining to read "address" to mean "*current* address" in a statute authorizing the disclosure of taxpayer information because the statute did "not specify what address must be included").

For similar reasons, we are unpersuaded by Ardelyx's contention that "renal dialysis services" include only drugs "provided by dialysis facilities during dialysis." That limitation appears nowhere in the subpart (B)(iii) definition of "renal dialysis services," which instead refers broadly to drugs furnished "for the treatment of" ESRD without regard to where or when they are furnished. In the medical context, "treatment" means "medical application of remedies so as to effect a cure," WEBSTER'S II DICTIONARY (3rd ed. 2005), and "management and care to prevent, cure, ameliorate, or slow progression of a medical condition," MERRIAM-WEBSTER DICTIONARY ONLINE. That definition easily encompasses a drug furnished to treat ESRD even if it is administered outside of a dialysis treatment.

This reading also accords with the Congress's intent to bring more services into the bundled payment.

Ardelyx erroneously contends this reading renders the second clause of subpart (iii) superfluous because the first clause would cover all oral drugs and because there cannot be an "oral equivalent form" of an oral-only drug. In fact, however, the first clause covers only drugs furnished to treat ESRD — regardless the form of administration — that were separately reimbursed "before the application of" paragraph (14). The second clause thus brings in any oral equivalent form of a drug covered by the first clause that became or becomes available after the application of paragraph (14). If an injectable drug is covered by the first clause, then the second clause would cover a subsequently developed oral-equivalent form of that drug. In those instances, the second clause is not superfluous. That some drugs covered by the first clause will not have an oral equivalent does not, as Ardelyx suggests, compel a different reading of the statute. "Language in a statute is not rendered superfluous merely because in some contexts that language may not be pertinent." *United States v. Turkette*, 452 U.S. 576, 583 n.5 (1981).

In a last gasp, Ardelyx notes that if the Congress had intended subpart (B)(iii) to include oral-only drugs, then it could have done so "using far fewer and simpler words." Perhaps so, but providing for the inclusion of "other drugs and biologicals" is one clear and reasonably succinct way of including certain drugs regardless of their form of administration. "[T]he mere possibility of clearer phrasing cannot defeat the most natural reading of a statute." *Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 416 (2012).

We believe subpart (B)(iii) on its face defeats Ardelyx's challenge to the regulation. Seeking help elsewhere, Ardelyx

cites one failed bill introduced in the House of Representatives that would have expressly added oral-only drugs to subpart (B)(iii), as though they were not already included in that subpart. *See* America's Affordable Health Choices Act of 2009, H.R. 3200, 111th Cong. § 1232(b)(1). Because the bill did not pass, Ardelyx believes this shows the Congress did not intend for subpart (B)(iii) to cover oral-only drugs. "Failed legislative proposals," however, "are a particularly dangerous ground on which to rest an interpretation of a prior statute" because "several equally tenable inferences may be drawn from such inaction, including the inference that the existing legislation already incorporated the offered change." *United States v. Craft*, 535 U.S. 274, 287 (2002) (cleaned up); *see also Knapp Med. Ctr. v. Hargan*, 875 F.3d 1125, 1130 (D.C. Cir. 2017) ("We can infer nothing from the Congress's consideration and rejection of a differently worded provision in a separate piece of legislation").

Subsequent congressional enactments, on the other hand, have the force of law and reflect the Congress's understanding of the pre-existing state of the law. Consequently, these actions may inform our analysis because "the meaning of one statute may be affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000). Indeed, "it is well established that a court can, and should, interpret the text of one statute in the light of text of surrounding statutes, even those subsequently enacted." *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 786 n.17 (2000).

The relevant post-enactment history demonstrates that the Congress was aware of the CMS's position regarding oral-only drugs and subpart (B)(iii) and repeatedly acted in a manner consistent with that position rather than undermining or

correcting it. *See Brown & Williamson*, 529 U.S. at 155-56. As we have seen in its notice of proposed rulemaking and in the final rule, issued in 2009 and 2010 respectively, the CMS interpreted subpart (B)(iii) as including all drugs furnished for the treatment of ESRD "regardless of the route of administration." 74 Fed. Reg. at 49928/3; *see* 75 Fed. Reg. at 49039/1. Consequently, the final regulation defined "renal dialysis services" to include "drugs and biologicals with only an oral form." 42 C.F.R. § 413.171(3).

Against this backdrop, the Congress passed legislation that reflected its awareness of the CMS's position. "When Congress revisits a statute giving rise to a longstanding administrative interpretation without pertinent change, the congressional failure to revise or repeal the agency's interpretation is persuasive evidence that the interpretation is the one intended by Congress." *CFTC v. Schor*, 478 U.S. 833, 846 (1986) (cleaned up).

On three occasions in 2013 and 2014 the Congress expressly acknowledged the CMS's inclusion of oral-only drugs in the bundle without disapproving or amending subparagraph (B). *See* § 632(b)(1), 126 Stat. at 2354 (2013) (delaying the implementation of the bundled payment system to oral-only drugs until January 1, 2016); § 217(a)(1), 128 Stat. at 1061 (2014) (extending the delay until January 1, 2024); and § 204, 128 Stat. at 4065 (2014) (extending the delay until January 1, 2025); *see also* § 632(a), 126 Stat. at 2354 (amending paragraph (14) by adding subparagraph (I), which refers to "oral-only ESRD-related drugs, as such term is used in the final rule promulgated by the Secretary" (citing 75 Fed. Reg. 49030)). At the same time, the Congress ordered additional agency action to collect data on and assess the effect of oral-only drugs and their treatment of ESRD. *See* § 632(b)(2), 126 Stat. at 2354 (ordering the CMS to monitor the bone and mineral metabo-

lism in ESRD patients "[w]ith respect to the implementation of oral-only ESRD-related drugs in the ESRD prospective payment system"); § 632(d), 126 Stat. at 2354-55 (ordering the GAO to report on the Secretary's preparations for adding oral-only drugs to the bundled payment); § 217(c)(1), 128 Stat. at 1062 (ordering the CMS to "establish a process for . . . determining when a product is no longer an oral-only drug" as "part of the promulgation of [the] annual rule for the Medicare [ESRD] prospective payment system under [paragraph (14)] for calendar year 2016"); and § 217(d)(3), 128 Stat. at 1062-63 (directing the CMS to establish performance measures for facilities regarding the quality of patient care "specific to the conditions treated with oral-only drugs").

These congressional enactments not only left the CMS's definition of "renal dialysis services" unchanged; as the CMS notes, they would make no sense if the Congress had excluded oral-only drugs from the definition of "renal dialysis services." The only logical conclusion is that the Congress agreed with, and acted upon the basis of, the CMS's interpretation of the statute.

3. "Before the application of this paragraph"

Here we address briefly one remaining dispute regarding the scope of subpart (B)(iii). The first clause in that subpart covers a drug only if payment for that drug was made separately "before the application of this paragraph." The district court concluded that "before the application of this paragraph" in that provision means before January 1, 2025 for oral-only drugs such as XPHOZAH because the Congress delayed the implementation of 42 C.F.R. § 413.171(3) until then. *Ardelyx I*, 757 F. Supp. 3d at 53. The CMS seemed to agree with the district court in its brief in this court, whereas Ardelyx's brief argues that approach would create a "nonsensical patchwork"

in which "before the application of this paragraph" takes on a different meaning based upon a drug's form of administration: before January 1, 2011 for non-oral drugs, and before January 1, 2025 for oral-only drugs. Ardelyx also asserts this reading of the statute would exclude from the bundle several injectable drugs approved after 2011 that the CMS has included and would preclude adding to the bundle any oral-only drugs launched after January 1, 2025. Ardelyx instead suggests "before the application of this paragraph" means before January 1, 2011 for all drugs.[§]

We need not decide the meaning of the disputed phrase. Despite the differing interpretations before us, we fail to see how its meaning affects the outcome of this appeal. Recall that the regulation applies to oral-only drugs "for which payment was (prior to January 1, 2011) made separately." § 413.171(3). If we accept Ardelyx's position that "before application of this paragraph" means before January 1, 2011, then the regulation uses the same date as the statute. If we adopt the district court's conclusion that "before the application of this paragraph" means before January 1, 2025 for oral-only drugs, then the regulation still works with the statute. As that court observed, "Any oral-only drug for which payment was made separately prior to January 2011, per § 413.171(3), is necessarily one for which payment was made separately . . . before January 1, 2025." *Ardelyx I*, 757 F. Supp. 3d at 54. Either way, the CMS acted within its delegated authority by promulgating the regulation.

[§] In a post-argument letter, the CMS offered an alternative interpretation: "at the time that the paragraph is actually applied to any newly developed drug, 'payment was . . . made separately under this subchapter' for that drug." We do not address the CMS's belated position below.

If Ardelyx had argued the CMS lacked authority to include XPHOZAH in the bundle because it was not available before January 2011, then we would need to resolve the meaning of "before the application of this paragraph" as applied to oral-only drugs, including XPHOZAH. Ardelyx did raise that argument in its motion asking the district court to alter the judgment, but it did not pursue the argument on appeal. Indeed, the only argument Ardelyx makes with respect to the identification of XPHOZAH is that the CMS exceeded its authority because XPHOZAH is not "furnished . . . for the treatment of" ESRD but rather "to treat hyperphosphatemia," to the merits of which we turn below. That argument does not depend on our resolution of Ardelyx's objections to the final rule or on the meaning of "before the application of this paragraph" in subpart (B)(iii).

We therefore have no need to address the precise meaning of "before the application of this paragraph." Insofar as the meaning of this phrase may matter for the identification of any other drugs as "renal dialysis services," those drugs are not before the court.

In sum, we conclude that subpart (B)(iii) defines "renal dialysis services" to include oral-only drugs furnished for the treatment of ESRD and for which payment was made separately "before the application of [that] paragraph." Because the regulation, 42 C.F.R. § 413.171(3), accords with the statutory definition, subparagraph (14)(G) precludes us from reviewing the regulation any further.

C. Ardelyx's Challenge to the Identification of XPHOZAH

Finally, as just mentioned, Ardelyx challenges the CMS's identification of XPHOZAH as a renal dialysis service covered by the bundled payment. Even if the CMS can include some oral-only drugs in the bundle, Ardelyx argues, the CMS cannot

include XPHOZAH because it is not furnished for the treatment of ESRD. Again, "XPHOZAH is furnished to treat hyperphosphatemia, not ESRD."

Ardelyx relies upon an unduly narrow reading of the phrase "for the treatment of [ESRD]" in subpart (B)(iii). Consider subpart (B)(ii), which defines "renal dialysis services" to include "erythropoiesis stimulating agents and any oral form of such agents that are furnished to individuals for the treatment of [ESRD]." ESAs treat anemia, a condition often caused by renal disease. Subpart (B)(ii) thus indicates the Congress intended the phrase "furnished . . . for the treatment of [ESRD]" to cover drugs that treat a condition commonly caused by ESRD. To read that phrase differently in a neighboring provision would run afoul of the "presumption that a given term is used to mean the same thing throughout a statute." *Brown v. Gardner*, 513 U.S. 115, 118 (1994).

Also, as we have seen, above at 21, "treatment" as used in the definition of "renal dialysis services" in (B)(iii) includes the management and care of a medical condition. That definition includes not only drugs that treat ESRD specifically but also drugs such as XPHOZAH that treat conditions closely associated with ESRD.

Hyperphosphatemia, which is most commonly caused by ESRD, occurs in 80% of ESRD patients on maintenance dialysis. Of those patients, 70% cannot maintain their target phosphate levels with phosphate binders. This is where XPHOZAH comes in.

As the CMS emphasizes, XPHOZAH's only approved use is to treat hyperphosphatemia "in adults with chronic kidney disease (CKD) on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy." Indeed,

Ardelyx itself said in a declaration supporting its motion for a preliminary injunction that XPHOZAH is "approved as an add-on therapy for patients with ESRD on maintenance dialysis." It is therefore unsurprising that even Ardelyx describes XPHOZAH, in that same declaration, as a "treatment option" for patients with ESRD on dialysis who experience an inadequate response to phosphate binders.

Finally, Ardelyx claims the CMS's identification of XPHOZAH "is at odds" with its exclusion of other drugs that treat conditions commonly associated with or caused by ESRD. This argument goes to the quality of the CMS's reasoning rather than the scope of its authority. Per subparagraph (14)(G), therefore, we lack jurisdiction to consider it.

III. Conclusion

For the foregoing reasons, the district court order dismissing Ardelyx's complaint is

Affirmed.