United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued November 17, 2025 Decided July 21, 2026

No. 25-5177

NOVARTIS PHARMACEUTICALS CORPORATION,
APPELLANT

v.

ROBERT F. KENNEDY, JR., IN HIS OFFICIAL CAPACITY AS SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL.,
APPELLEES

Consolidated with 25-5179, 25-5220, 25-5221, 25-5236

Appeals from the United States District Court
for the District of Columbia
(No. 1:25-cv-00117)
(No. 1:24-cv-03337)
(No. 1:21-cv-02608)
(No. 1:24-cv-03220)
(No. 1:24-cv-03188)

Catherine E. Stetson argued the cause for Novartis appellants. With her on the briefs were *John C. O'Quinn*, *Megan McGlynn*, *Susan M. Cook*, *Sean Marotta*, *Paul J.*

Zidlicky, *Keenan Roarty*, and *Jackson B. Skeen*. *Matthew S. Owen* entered an appearance.

Jeffrey L. Handwerker argued the cause for appellant Johnson & Johnson Health Care Systems Inc. With him on the briefs were *Paula Ramer* and *Samuel I. Ferenc*.

William A. Sarraille was on the brief for amici curiae CF United ACT Now and ADAP Advocacy in support of appellants.

Jeffrey L. Handwerker, *Paula Ramer*, and *Samuel I. Ferenc* were on the brief for amicus curiae Johnson & Johnson Health Care Systems Inc. in support of reversal.

Phillip J. Perry, *Andrew D. Prins*, and *Abid R. Qureshi* were on the brief for amici curiae Pharmaceutical Research and Manufacturers of America and Biotechnology Innovation Organization in support of appellants.

Matthew Modafferi was on the brief for amicus curiae Community Oncology Alliance, Inc. in support of appellants.

Maxwell A. Baldi, Attorney, U.S. Department of Justice, argued the cause for federal appellees. With him on the brief were *Eric J. Hamilton*, Deputy Assistant Attorney General, and *Michael S. Raab* and *Lindsey Powell*, Attorneys. *Jane M. Lyons*, Assistant U.S. Attorney, entered an appearance.

William B. Schultz argued the cause for intervenor appellees 340B Health, Genesis Healthcare System, and University of Massachusetts Memorial Medical Center. With him on the brief was *Margaret Dotzel*.

Chad Golder was on the brief for amici curiae American Hospital Association, et al. in support of appellees.

Jeffrey I. Davis and *Scott D. Gallisdorfer* were on the brief for amici curiae 37 State and Regional Hospital Associations, et al. in support of appellees.

Before: HENDERSON, PILLARD, and GARCIA, *Circuit Judges*.

Opinion for the Court filed by *Circuit Judge* GARCIA.

GARCIA, *Circuit Judge*: Since 1992, Section 340B of the Public Health Service Act has required participating drug manufacturers to sell certain drugs at reduced prices to eligible healthcare providers. For more than three decades, manufacturers complied with the statute primarily by allowing providers to purchase those drugs at upfront discounted prices. In 2024, four manufacturers proposed to the Secretary of Health and Human Services (HHS) that they would instead use post-purchase rebates to implement the required price reductions. The Secretary responded that the manufacturers could not proceed without his approval and requested more information.

The manufacturers sued. They principally argue that the statute permits them to unilaterally impose their proposed rebate models on Section 340B purchasers unless and until the Secretary disapproves them. Like the district court, we disagree. Based on the statutory text and structure, we conclude that Section 340B requires the Secretary to provide for a rebate mechanism before manufacturers may implement one. And because it is undisputed that the Secretary has never authorized a mechanism encompassing the manufacturers' rebate models, the Secretary properly required the manufacturers to await his approval while he further studied their proposals.

I

A

Under Section 340B of the Public Health Service Act, participating drug manufacturers "must offer discounted drugs to covered entities, dominantly, local facilities that provide medical care for the poor." *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 115 (2011); *see also* Veterans Health Care Act, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967–71 (1992) (codified as amended at 42 U.S.C. § 256b). To encourage manufacturer participation, Congress has conditioned Medicaid and Medicare Part B payment for a manufacturer's drugs on the manufacturer's enrollment in the 340B Program. *See* 42 U.S.C. § 1396r-8(a)(1).

Manufacturers "opt into the 340B Program by signing a form Pharmaceutical Pricing Agreement" with the HHS Secretary. *Astra*, 563 U.S. at 113. The statutory provision at the heart of these appeals states:

> The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for [certain] covered outpatient drugs . . . does not exceed . . . [a] "ceiling price" [set by a statutory formula].

42 U.S.C. § 256b(a)(1).

That "ceiling price" can be significantly lower than the general commercial price a manufacturer charges for its drug. *See Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 456 (D.C. Cir. 2024). The statute does not specify whether the required reduction in drug price should be obtained by an upfront "discount" or an after-purchase manufacturer "rebate."

In theory, for a covered drug priced commercially at $200 per unit, manufacturers might charge purchasers a ceiling price of $100 by offering the drug at $100 through an upfront discount, or by requiring a payment of $200 combined with a subsequent $100 rebate. The primary House committee report concerning Section 340B acknowledges that optionality and states that the Committee "expects that the Secretary of HHS, in developing these agreements, will use the mechanism that is the most effective and most efficient from the standpoint of each type of 'covered entity.'" H.R. Rep. No. 102-384, pt. 2, at 16 (1992).

In 1997, the Health Resources and Services Administration (HRSA)—the agency within HHS tasked with administering the 340B Program—explained that "[i]nitially, [agency] guidance for the section 340B program described only a discount process." 62 Fed. Reg. 45,823, 45,824 (Aug. 29, 1997). "Covered entities generally preferred a discount system" because it required "less initial outlay of drug purchasing money." *Id.* But a particular type of covered entity—State AIDS Drug Assistance Programs (ADAPs)—was unable to "access section 340B pricing" because most ADAPs' "drug purchasing systems" were incompatible with the discount process. *Id.* HRSA thus proposed to recognize the validity of an ADAP-specific rebate model and, after notice and comment, finalized that proposal in 1998. *Id.*; *see also* 63 Fed. Reg. 35,239, 35,239–42 (June 29, 1998). Importantly, the 1998 guidance did not "further expan[d]" the rebate option "to other categories of entities." 63 Fed. Reg. at 35,241–42.

In 2010, Congress added a second sentence to Section 340B(a)(1), stating that each Pharmaceutical Pricing Agreement "shall require that the manufacturer offer each covered entity covered drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7102(b)(1), 124

Stat. 119, 827 (2010) (codified as amended at 42 U.S.C. § 256b(a)(1)).

B

Bristol Myers Squibb Company (BMS), Eli Lilly and Company and Lilly USA, LLC (Lilly), Johnson & Johnson Health Care Systems Inc. (J&J), and Novartis Pharmaceuticals Corporation (Novartis) are four pharmaceutical manufacturers participating in the 340B Program.

For years, these manufacturers have implemented the required reduction in their drug prices through a so-called product-replenishment model. *See Novartis*, 102 F.4th at 457–58. Under that model, covered entities—or the pharmacies covered entities contract with to dispense drugs they prescribe, referred to as "contract pharmacies"—"fill prescriptions from inventories that intermingle discounted and non-discounted drugs." *Id.* at 457. "[A]fter dispensing the drugs," covered entities or contract pharmacies "attempt to discern" whether "individual prescriptions were eligible for the discount," and they often "outsource this determination to third-party administrators." *Id.* Once the covered entity, contract pharmacy, or third-party administrator "categorizes a certain number of prescriptions as eligible," the covered entity or contract pharmacy "places an order" with the manufacturer at the discounted 340B price "to replenish its section 340B purchases." *Id.*

Starting in the summer of 2024, the manufacturers each proposed to HRSA that they switch from the product-replenishment model to some form of rebate model for some or all of their 340B drugs. The manufacturers' proposed models would work in the following fashion: Covered entities (or their contract pharmacies) would initially purchase drugs at full price. Then, after dispensing the drugs to 340B patients, they would submit claims to the manufacturers for a cash

refund equal to the difference between that price and the 340B ceiling price. The manufacturers would then review the claims and approve them for refunds or designate them for further review. The manufacturers assert that this reform is needed to address alleged "programmatic noncompliance that is rampant among covered entities"—they assert, for example, that the product-replenishment model can create opportunities for covered entities to obtain impermissible duplicate discounts undetected. J.A. 818 (Novartis); *see also* J.A. 503 (J&J); J.A. 687 (Lilly); J.A. 718–20 (BMS). All parties agree that the manufacturers' scheme constitutes a rebate model, not an upfront discount.

HRSA responded to each proposal with a similar letter. HRSA stated that "[t]o date, the Secretary has not provided for" a "rebate" model and that "implementing such a proposal at this time would be inconsistent with the statutory requirements for the 340B Program, which require the approval of a rebate model." J.A. 450 (J&J); *see also* J.A. 460 (Lilly); J.A. 466, 471 (BMS); J.A. 473 (Novartis). HRSA also asked several questions about the manufacturers' proposals—for example, "[w]hat specific claims level information would covered entities be required to submit?"; "[w]hat protections and safeguards would [the manufacturers] plan to implement to ensure [rebate claim] information would solely be used in support of the 340B Program?"; and "[w]hat are the specific reasons that will lead [the manufacturers] to reject claims?" HRSA additionally stated in its letters to BMS and Novartis that "[t]he Secretary has neither approved [n]or disapproved [the respective] rebate model[s]."

Notwithstanding HRSA's letter, J&J announced that it planned to implement its proposed rebate model. So HRSA responded with follow-up letters, reiterating that the Secretary expected J&J "to cease implementation of" its "unapproved rebate proposal." HRSA warned J&J that if it "proceed[ed]

with implementing its rebate proposal without Secretarial approval," the Secretary would "terminate" J&J's 340B Pharmaceutical Pricing Agreement, which would make Medicaid and Medicare Part B payment unavailable for J&J's drugs.

C

The four manufacturers each sued the Secretary in district court under the Administrative Procedure Act, seeking to vacate the letters they had received. So did Kalderos, Inc., a technology company with which Lilly contracted to develop a digital platform to implement Lilly's proposed model. A 340B advocacy organization and two hospitals that purchase 340B drugs intervened in the manufacturers' cases as defendants. In each case, the district court entered summary judgment in favor of the Secretary. This court consolidated the cases on appeal.

We now affirm.

II

"When a district court reviews agency action under the APA, we in turn review the district court's decision *de novo*." *Cigar Ass'n of Am. v. FDA*, 964 F.3d 56, 61 (D.C. Cir. 2020). The APA "instructs a reviewing court to set aside agency action found to be 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *Id.* (quoting 5 U.S.C. § 706(2)(A)).

The parties raise several distinct issues concerning the Secretary's position that the manufacturers may not implement their proposed rebate mechanisms without his approval. The intervenors argue that Section 340B does not permit any rebate mechanism and instead always requires a time-of-purchase discount. The manufacturers argue that rebate mechanisms are permitted, but that the Secretary lacks the authority to require preapproval of their proposals. They also argue that even if the

Secretary has such authority, he was required to exercise it through the manufacturers' Pharmaceutical Pricing Agreements, which he failed to do. And they argue that he failed to adequately explain his decision to exercise that authority here and failed to consider key benefits of the manufacturers' proposals before—in the manufacturers' view—denying them.

We reject both the intervenors' and the manufacturers' arguments and affirm the district court's judgments in favor of the Secretary.

A

To start, the intervenors—an advocacy organization and two hospitals—argue that Section 340B does not permit any form of rebate model at all. Given the plain language of the statute, we disagree.

The statute begins: "The Secretary shall enter into an agreement with each manufacturer . . . under which the amount required to be paid (taking into account any *rebate or discount*, as provided by the Secretary) to the manufacturer for [certain] covered outpatient drugs . . . does not exceed . . . the ceiling price." 42 U.S.C. § 256b(a)(1) (emphasis added). This provision explicitly envisions that although the "amount required to be paid" may not exceed the "ceiling price," that amount can "tak[e] into account" a "rebate." *Id.*

Because the statute does not define the word "rebate," we interpret the word "as taking [its] ordinary, contemporary, common meaning." *Perrin v. United States*, 444 U.S. 37, 42 (1979). That is, a "deduction or refund of money in consideration of prompt payment." *Rebate*, Black's Law Dictionary 1266 (6th ed. 1990); *see also Rebate*, Merriam-Webster's Collegiate Dictionary 974 (10th ed. 1993) (defining "rebate" as "a return of a part of a payment"). Translated into

the statute's terms, if a manufacturer charges $200 up front but issues a $100 rebate, the "amount required to be paid," "taking into account" the rebate, is $100, not $200. 42 U.S.C. § 256b(a)(1).

The use of rebates is also consistent with the statute's reference to a "ceiling *price*." *Id.* (emphasis added). It is common to regard the "price" charged for an item as accounting for a rebate. *See Price*, Black's Law Dictionary 1188 (6th ed. 1990) (defining "price" as "[t]he cost at which something is obtained"); *Price*, Webster's II New Riverside University Dictionary 933 (1994) (same). Judicial opinions reflect the same understanding: Drug manufacturers have long "*offered* lower *prices* . . . through *rebates* or discounts." *Cash & Henderson Drugs, Inc. v. Johnson & Johnson*, 799 F.3d 202, 206 (2d Cir. 2015) (emphases added); *see also Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 681 (2003) (Thomas, J., concurring) (Medicaid Act "does not preclude States from negotiating prices, including manufacturer discounts and rebates for non-Medicaid drug purchases" (citation omitted)); *Pharm. Rsch. & Mfrs. of Am. v. David*, 510 F. Supp. 3d 891, 898 (E.D. Cal. 2021) ("The transaction price of a prescription drug . . . includes discounts and rebates.").

Moreover, the key committee report supporting Section 340B explained that the bill "does not specify whether 'covered entities' would receive these favorable prices through a point-of-purchase discount, through a manufacturer rebate, or through some other mechanism." H.R. Rep. No. 102-384, pt. 2, at 16. "[T]o the extent [legislative history] plays any role" in our analysis, here it only "undercuts" the intervenors' argument that manufacturers can charge the ceiling price exclusively through a point-of-purchase discount. *United States v. Miller*, 604 U.S. 518, 535 (2025).

The intervenors do not dispute that the ordinary meaning of a "rebate" encompasses the manufacturers' proposed pricing models. But they raise two arguments that the term as used in Section 340B(a)(1) should not have that meaning. Neither succeeds.

First, the intervenors argue that the second sentence of Section 340B(a)(1)—that each Pharmaceutical Pricing Agreement "shall require that the manufacturer *offer* each covered entity covered outpatient drugs *for purchase* at *or below the applicable ceiling price*," 42 U.S.C. § 256b(a)(1) (emphases added)—requires manufacturers to "offer" a discounted price upfront, not later issue a rebate. This "shall offer" provision requires manufacturers to offer covered drugs to covered entities at or below the ceiling price, thus preventing manufacturers from refusing to offer their drugs to covered entities at all. But the provision does not speak to *how* manufacturers may "offer" drugs at the ceiling price. And as explained, as a matter of common usage and industry practice, an offered "price" can incorporate a later-received rebate. Moreover, this argument relies on statutory language introduced in 2010 to suggest that Congress implicitly repealed a reference to "rebates" that has existed since 1992. Yet the proposition that Congress repeals statutory language by mere implication is strongly disfavored. *See Fogg v. Gonzales*, 492 F.3d 447, 453 (D.C. Cir. 2007).

Second, the intervenors argue that rebate models are inconsistent with Section 340B's auditing provision, under which "[a] covered entity shall permit the Secretary and the manufacturer . . . to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with" the 340B Program. 42 U.S.C. § 256b(a)(5)(C). They say that rebate models—which require covered entities or contract pharmacies to submit claim-level data to manufacturers before receiving 340B

benefits—render the audit provision unnecessary. But although rebate models might reduce the need to audit covered entities, they do not necessarily eliminate it. For example, as the manufacturers explain, and the intervenors do not dispute, manufacturers may seek different data when implementing rebate models than they would in an audit.

The implausibility of the intervenors' construction of the parenthetical phrase "any rebate or discount" confirms our conclusion. They posit that those words refer only to the Secretary's authority to set a drug's ceiling price when the statutory formula for doing so cannot practicably be used. That can occur, for example, when a drug is new to market, and the statutory formula—which relies on data from "the preceding calendar quarter," 42 U.S.C. § 256b(a)(1), (a)(2)(A)(i)—cannot yet be applied. In those circumstances, the intervenors say, the Secretary may provide for a "rebate or discount" to set the ceiling price. But nothing in the statutory text supports that theory. The statute broadly states that the "amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer" shall not exceed the ceiling price. *Id.* § 256b(a)(1). We see no basis to read that language as referring to a narrow gap-filling authority triggered only when the ordinary ceiling-price formula cannot practicably be used.

To reject the intervenors' argument, it is enough to hold that rebate models *can be* consistent with Section 340B's auditing scheme. We do not decide whether some rebate models—including the appellants'—might operate in a manner that runs afoul of the statute in some way.

B

Having concluded that Section 340B permits rebate models, we now address the primary dispute between the manufacturers and the Secretary: Whether the statute requires

the Secretary to affirmatively approve rebate models before the manufacturers may implement them. We hold that it does.

Recall the key statutory provision: "The Secretary shall enter into an agreement with" the manufacturers "under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer[s] for [certain] covered outpatient drugs . . . does not exceed" the "ceiling price." 42 U.S.C. § 256b(a)(1). The phrase "the amount required to be paid (taking into account any rebate or discount, *as provided by the Secretary*)" envisions that the Secretary will "provide" for permissible mechanisms of implementing the "ceiling price." *Id.* (emphasis added). That is, the Secretary will "supply" or "make . . . available" the relevant mechanisms. *Provide*, Black's Law Dictionary 1224 (6th ed. 1990); *Provide*, Merriam-Webster's Collegiate Dictionary 940 (10th ed. 1993). This amounts to a preapproval requirement: Manufacturers may not unilaterally impose a rebate or discount mechanism unless the Secretary has "provided" for it.

Indeed, Congress often uses the phrase "as provided by the Secretary" to give cabinet Secretaries control over the details of statutory programs. *See, e.g.*, 7 U.S.C. § 1309(a) (annual crop acreage limits "shall be determined as provided by the Secretary"); 26 U.S.C. § 5000B(c)(2) (certain taxes to be collected "at such time and in such manner as provided by the Secretary"). This reading also comports with the key committee report we have already referenced: Congress "d[id] not specify whether 'covered entities' would receive [Section 340B's] favorable prices through a point-of-purchase discount, through a manufacturer rebate, or through some other mechanism" because it "expect[ed] that *the Secretary of HHS*, in developing these agreements, w[ould] use the mechanism that is the most effective and most efficient from the standpoint

of each type of 'covered entity.'" H.R. Rep. No. 102-384, pt. 2, at 16 (1992) (emphasis added).

The contrary reading—that manufacturers can unilaterally impose on covered entities any pricing mechanism of their own design even if the Secretary has not "provided" for such a mechanism—conflicts with Section 340B's text. The statute says that the amount required to be paid may take into account a rebate "as provided by the Secretary." 42 U.S.C. § 256b(a)(1). It does not say, for example, that the amount required to be paid may take into account any rebate or discount "unless otherwise provided by the Secretary." Such a provision would have been easy to write, but Congress chose not to do so. *See, e.g.*, 21 U.S.C. § 356c(a), (h)(1)(B) (manufacturers need not "notify the Secretary . . . of a permanent discontinuance in the manufacture of . . . biological products . . . unless otherwise provided by the Secretary"); 26 U.S.C. § 1473(1)(A) (the term "withholdable payment" has specific definitions "[e]xcept as otherwise provided by the Secretary").

The manufacturers' reading would also counterintuitively let manufacturers, rather than the Secretary, take the lead in administering the 340B Program, rendering the Secretary's role largely reactive. HRSA's correspondence with the manufacturers illustrates the stakes. In response to the manufacturers' proposals, HRSA asked numerous questions about the proposals' likely impact on 340B providers and patients and how they would operate in practice—including how covered entities would demonstrate rebate eligibility, how disputes would be resolved, and how privacy concerns would be addressed. *See* J.A. 450–52 (J&J); 460–62 (Lilly); 466–68 (BMS); 473–75 (Novartis). Yet on the manufacturers' telling, any one of them could experiment on all 340B hospitals and patients with whatever rebate model best suits its own interests, no matter how many complex issues arise, unless and until the

Secretary intervenes. As the Supreme Court has explained, "Congress placed *the Secretary* (acting through her designate, HRSA) in control of § 340B's drug-price prescriptions," and Section 340B should be read to "maintain[]" that Secretarial control. *Astra*, 563 U.S. at 114 (emphasis added). Put simply, the statute places the Secretary, not the manufacturers, in the driver's seat of this important program.

C

The manufacturers' primary response is that any restriction on their ability to adopt the rebate model must be explicit in the 340B Pharmaceutical Pricing Agreements between the Secretary and the manufacturers. Because the Secretary has not placed any limits on the use of rebate models in those Agreements, they say, the Secretary has no authority to prohibit their proposals. We find this response unpersuasive.

To start, *where* the Secretary must "provide" for the rebate model—whether through guidance, individual adjudications, or Pharmaceutical Pricing Agreements—is mostly beside the point here. As just explained, manufacturers may not unilaterally impose rebate models without Secretarial approval. And again, it is undisputed that the Secretary has not provided for a rebate mechanism that encompasses the manufacturers' proposed models *anywhere*.

Regardless, we disagree with the manufacturers that the Secretary may "provide" for the relevant pricing mechanisms only in the Pharmaceutical Pricing Agreements.

The manufacturers emphasize that the parenthetical "(taking into account any rebate or discount, as provided by the Secretary)" appears after the clause, "[t]he Secretary *shall enter into an agreement* with each manufacturer of covered outpatient drugs *under which* the amount required to be paid."

42 U.S.C. § 256b(a)(1) (emphases added). But that parenthetical speaks to the immediately preceding phrase, "the amount required to be paid," and is not obviously tethered to the more distant noun "agreement." *Id.* Moreover, if "any rebate or discount" must be provided by the terms of an Agreement, then the phrase that immediately follows "rebate or discount"—"as provided by the Secretary"—would seemingly have no effect: The Secretary is the one preparing the Agreement in the first place. As the Supreme Court has explained, the Agreements "are not transactional, bargained-for contracts." *Astra*, 563 U.S. at 113. They are "form agreements, composed by HHS," and "contain no negotiable terms." *Id.* at 118.

The manufacturers also emphasize that Subsection (a) of Section 340B has the heading "Requirements for *agreement* with Secretary." 42 U.S.C. § 256b(a) (emphasis added). True, "the heading of a section" is a "tool[] available" in discerning statutory meaning. *Dubin v. United States*, 599 U.S. 110, 121 (2023). But "where, as here, the statutory text is complicated and prolific, headings" can "do no more than indicate the provisions in a most general manner." *Lawson v. FMR LLC*, 571 U.S. 429, 446 (2014) (cleaned up). And here, Subsection (a) contains numerous requirements that no one argues must be penciled into the manufacturers' Pharmaceutical Pricing Agreements to have any effect. *See, e.g.*, 42 U.S.C. § 256b(a)(5)(A) ("Prohibiting duplicate discounts or rebates"); *id.* § 256b(a)(5)(C) ("Auditing").

If Congress intended to make Pharmaceutical Pricing Agreements the exclusive vehicle for instituting and modifying price-reduction mechanisms, it could have stipulated that "the amount required to be paid" would "take into account any rebate or discount, as provided by *the Agreement*." Or it could have used language found elsewhere in Subsection (a)(1)—for example, specifying that "[e]ach such agreement shall require

that" the Secretary specify the appropriate price-reduction mechanism. 42 U.S.C. § 256b(a)(1). Congress did not do so.

D

Applying that understanding of the statute, HRSA was correct to say that the manufacturers may not unilaterally implement their proposed rebate models at this time.

HRSA has taken the position that "[i]nitially, HRSA guidance for the section 340B program described *only* a discount process." 62 Fed. Reg. at 45,824 (emphasis added). Then, in 1998, the Secretary finalized guidance providing for a rebate mechanism in the "unique" context of ADAPs so that those entities may choose rebates "as an optional alternate means of accessing section 340B discount pricing." 63 Fed. Reg. at 35,239–42; *see also* 62 Fed. Reg. at 45,823–24 (proposal). In so providing, the Secretary "agree[d]" with commenters that "the rebate mechanism [would] be an option *only* for meeting the unique needs of the State ADAP programs." 63 Fed. Reg. at 35,241–42 (emphasis added). The Secretary thus made clear that the 1998 "notice *only* recognize[d] a rebate option for the State AIDS Drug Assistance Programs." *Id.* at 35,241–42 (emphasis added).[1]

Although one could quibble with how clearly the Secretary "provided" for the product-replenishment models that have prevailed to date, that issue is not squarely presented in these cases. It is undisputed here that the Secretary has not

[1] As the ADAP example illustrates, the Secretary is free to broadly approve a type of pricing mechanism for certain contexts without providing "in-depth implementation strategies"; the Secretary may leave the details to the regulated entities "so as to allow maximum flexibility." 63 Fed. Reg. at 35,240–41. But the Secretary must "provide[]" for a type of mechanism in some form before the manufacturers may implement it. 42 U.S.C. § 256b(a)(1).

"provided" for the manufacturers' preferred rebate models. Thus, when the manufacturers proposed to unilaterally implement their rebate models on a short timeframe in 2024, the Secretary appropriately explained that they could not do so immediately because "[t]o date, the Secretary has not provided for such a rebate model." J.A. 473 (Novartis); *accord* J.A. 450 (J&J); J.A. 460 (Lilly); J.A. 466 (BMS). At the same time, the Secretary made clear that the proposals were still under review. *See, e.g.*, J.A. 473 ("The Secretary has neither approved [n]or disapproved Novartis' rebate model."); J.A. 471 ("[T]o date, the Secretary has neither approved [n]or disapproved BMS's rebate model."). The Secretary said, in effect, "not yet," and requested more information from the manufacturers about their proposals. *See* J.A. 450–52 (J&J); J.A. 460–62 (Lilly); J.A. 466–68, 471 (BMS); J.A. 473–75 (Novartis). And the Secretary has since tried to implement a pilot program to further study the many important issues that the proposals raised.[2]

E

The manufacturers next argue that, even if the Secretary has authority to require preapproval of their rebate plans, his

[2] In July 2025, HRSA issued a program notice inviting manufacturers to participate in a voluntary rebate model pilot program. *See* Press Release, HRSA, HRSA Announces Application Process for the 340B Rebate Model Pilot Program and Request for Public Comment (July 31, 2025), https://perma.cc/8DXQ-2BA5. In February 2026, the agency withdrew that notice in response to litigation. *See Am. Hosp. Ass'n v. Kennedy*, 2026 WL 372131, at *1 (D. Me. Feb. 10, 2026). In June 2026, HRSA announced that it "intends to introduce a revised 340B Rebate Model Pilot Program" and "plans to publish a Federal Register Notice to notify 340B stakeholders of criteria and standards for implementation of the Pilot." 91 Fed. Reg. 35,989, 35,989 (June 15, 2026) (cleaned up).

invocation of that authority at this time was arbitrary and capricious. They argue, for example, that the Secretary has never before invoked this authority and did not sufficiently explain his decision to do so here.

This argument fails given our conclusion that Section 340B *requires* the Secretary to "provide" for rebates before manufacturers can permissibly implement them. The statute does not "delegate[] discretionary authority" to the agency in this respect. *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 395 (2024). As a result, "there is no reason to seek an agency's explanation as to why it may have changed its view on the meaning of the statute." *Centro de Trabajadores Unidos v. Bessent*, 167 F.4th 1218, 1237 (D.C. Cir. 2026).

F

In closing, we again observe that the Secretary's consideration of the manufacturers' proposals remains ongoing. Accordingly, we do not address whether the Secretary *should* "provide[]" for the manufacturers' proposed rebate models or with what limitations. 42 U.S.C. § 256b(a)(1). We hold only that the Secretary properly concluded that the manufacturers may not implement their proposed rebate models without Secretarial approval.

For the same reason, the manufacturers' claim that the Secretary failed to consider key aspects of the problem when supposedly rejecting their proposals is unripe for review. *See Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726, 733 (1998).

III

The district court's judgments are affirmed.

So ordered.