No. 20-1114

In the Supreme Court of the United States

AMERICAN HOSPITAL ASSOCIATION, ET AL., PETITIONERS

v.

XAVIER BECERRA,
SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

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QUESTIONS PRESENTED

Under the Outpatient Prospective Payment System, the Department of Health and Human Services (HHS) sets annual Medicare payment rates in advance through notice-and-comment rulemaking. For specified covered outpatient drugs (specified drugs), the statute directs HHS to set a payment rate equal to a drug's "average acquisition cost" (which may vary by hospital group) as determined by the Secretary, taking into account certain hospital survey data. 42 U.S.C. 1395*l*(t)(14)(A)(iii)(I). If "hospital acquisition cost data are not available," however, the statute establishes a default rate of 106% of a drug's average sales price and provides that the rate may be "adjusted by the Secretary as necessary for purposes of this paragraph." 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II).

Following a series of reports by the Government Accountability Office, the Medicare Payment Advisory Commission, and HHS's Inspector General finding that Medicare's payments to providers known as "340B hospitals" were significantly higher than the costs those providers incurred for specified drugs, HHS exercised its authority under Section 1395*l*(t)(14)(A)(iii)(II) to adjust those providers' payment rates downward for the 2018 and 2019 years to bring those payments into line with their acquisition costs. Petitioners brought this action challenging those reductions. The questions presented are as follows:

1. Whether petitioners' suit challenging HHS's adjustments is precluded by 42 U.S.C. 1395*l*(t)(12).

2. Whether, assuming arguendo that judicial review is not precluded, HHS permissibly exercised its statutory authority in adjusting the Medicare payment rates of 340B hospitals for specified drugs to bring their payments into line with their acquisition costs.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-43a) is reported at 967 F.3d 818. The opinion of the district court addressing the merits (Pet. App. 44a-86a) is reported at 348 F. Supp. 3d 62. The opinion of the district court addressing the appropriate remedy (Pet. App. 87a-112a) is reported at 385 F. Supp. 3d 1. The opinion of the district court directing entry of final judgment (Pet. App. 113a-117a) is not published in the Federal Supplement but is available at 2019 WL 3037306.

JURISDICTION

The judgment of the court of appeals was entered on July 31, 2020. A petition for rehearing was denied on October 16, 2020 (Pet. App. 118a). On March 19, 2020, this Court extended the time within which to file any petition for a writ of certiorari due on or after that date

to 150 days from the date of the lower-court judgment, order denying discretionary review, or order denying a timely petition for rehearing. The effect of that order was to extend the deadline for filing a petition for a writ of certiorari in this case to March 15, 2021. The petition for a writ of certiorari was filed on February 10, 2021. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. The Medicare program, established in 1965 by Title XVIII of the Social Security Act (Medicare Act), 42 U.S.C. 1395 *et seq.*, provides health-insurance coverage to individuals who are at least 65 years old and are entitled to monthly Social Security benefits, and to disabled individuals who meet certain requirements. 42 U.S.C. 426(a) and (b). Part A provides insurance coverage for inpatient hospital care, home health care, and hospice services. 42 U.S.C. 1395c *et seq.* Part B is a voluntary program that provides supplemental coverage for other types of care, including outpatient hospital care. 42 U.S.C. 1395j *et seq.*

This case involves Medicare Part B payment rates under the Outpatient Prospective Payment System (OPPS), which the Department of Health and Human Services (HHS) establishes through annual notice-and-comment rulemaking. The rates are generally based on the average costs of providing particular services in past years, with adjustments for regional cost variations and other specified factors. See, *e.g.*, 42 U.S.C. 1395*l*(t)(2)(C) and (D). The statute directs HHS to revise components of the OPPS each year to take into account (*inter alia*) new cost data, 42 U.S.C. 1395*l*(t)(9)(A), and it authorizes HHS to make other adjustments as necessary to ensure

equitable payments, 42 U.S.C. 1395*l*(t)(2)(E). The statute generally requires that OPPS adjustments be budget neutral, which means that an increase in rates for particular services must be offset by a reduction in rates for other services. See 42 U.S.C. 1395*l*(t)(2)(E), (9)(B), and (14)(H).

The OPPS rates at issue here involve specified covered outpatient drugs (specified drugs).[1] These rates are set pursuant to paragraph (14) of 42 U.S.C. 1395*l*(t). Subclause (I) of Section 1395*l*(t)(14)(A)(iii) provides that, for years after 2005, the Medicare payment amount for each specified drug shall be equal

> to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered [outpatient] services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D).

42 U.S.C. 1395*l*(t)(14)(A)(iii)(I) (subclause (I)). Thus, in subclause (I), Congress established a default Medicare payment amount for specified drugs that is based on a drug's average acquisition cost, as informed by hospital survey data.

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[1] Specified covered outpatient drugs are a form of separately payable drugs, which means they are not bundled with other services and are instead reimbursed on a drug-by-drug basis. See 42 U.S.C. 1395*l*(t)(14)(B). The drugs in this category are primarily used to treat or diagnose serious conditions, such as cancer, in an outpatient hospital setting. See U.S. Gov't Accountability Off., GAO-06-372, *Medicare Hospital Pharmaceuticals: Survey Shows Price Variation and Highlights Data Collection Lessons and Outpatient Rate-Setting Challenges for CMS* 1 (Apr. 2006), https://go.usa.gov/xHwje.

In subclause (II) of Section 1395*l*(t)(14)(A)(iii), however, Congress provided an alternative methodology for HHS to use in determining the Medicare payment amount for specified drugs in years after 2005 if the survey data described in subclause (I) are not available. 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II) (subclause (II)). Subclause (II) provides that, if "hospital acquisition cost data are not available," then the Medicare payment amount shall be equal to "the average price for the drug in the year established under * * * section 1395w-3a of this title * * * as calculated and adjusted by the Secretary as necessary for purposes of this paragraph." *Ibid.* The "average price * * * established under * * * section 1395w-3a" cross-referenced in subclause (II), 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II), is 106% of a drug's "average sales price," see 42 U.S.C. 1395w-3a (emphasis omitted); Pet. App. 4a; average sales price is typically a good proxy for a drug's acquisition costs. See, *e.g.*, Memorandum from Stuart Wright, Deputy Inspector General for Evaluation & Inspections, Office of Inspector General, HHS, to Donald M. Berwick, M.D., Administrator, Ctrs. For Medicare & Medicaid Servs., *Memorandum Report: Payment for Drugs Under the Hospital Outpatient Prospective Payment System* 1, 3, 9 (Oct. 22, 2010) (2010 Inspector General Report), https://go.usa.gov/xVg5Q (finding that Medicare payments were generally within one percent of the providers' reported acquisition costs); Pet. App. 22a.

2. a. This case involves the intersection of the Medicare program with a separate program established in 1992 by Section 340B of the Public Health Service Act, 42 U.S.C. 256b. See Veterans Health Care Act of 1992, Pub L. No. 102-585, sec. 602(a), § 340B, 106 Stat. 4967-4971. The 340B program requires drug manufacturers, as a condition of participation in Medicaid, to sell

drugs at discounted prices to providers known as "covered entities," including, for example, federally qualified health centers and, as relevant here, certain hospitals (340B hospitals). See generally 42 U.S.C. 256b. Moreover, in practice, 340B hospitals are able to negotiate even steeper discounts than the maximum statutory price, in part because HHS's Health Resources and Services Administration (HRSA) operates a program through which covered entities may contract with a prime vendor to purchase covered drugs at deeper discounts. See 82 Fed. Reg. 52,356, 52,494 (Nov. 13, 2017).

In a 2015 report, HHS's Inspector General determined that Medicare payments were "58 percent more than the statutorily based 340B ceiling prices [for 2013], which allowed covered entities to retain approximately $1.3 billion" in profit. Office of Inspector General, HHS, *Part B Payments for 340B-Purchased Drugs*, *Executive Summary* (Nov. 2015), https://go.usa.gov/xV2jK. Similarly, a 2015 Government Accountability Office (GAO) report found that "[t]he amount of the 340B discount ranges from an estimated 20 to 50 percent off what the entity would have otherwise paid" to purchase the drug. GAO, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals* 8 (June 2015), https://go.usa.gov/xHvpp. And a 2016 report of the Medicare Payment Advisory Commission (MedPAC) concluded that "the aggregate discount on Part B drugs received by covered entities equaled 33.6 percent of the average sales price * * * in 2013." MedPAC, *Report to the Congress: Medicare Payment Policy* 79 (Mar. 2016), https://go.usa.gov/xV2jj.

b. In light of those reports, as part of the OPPS rulemaking for the 2018 year, HHS exercised its adjustment authority under subclause (II) to adjust downward the Medicare payment rate for specified drugs acquired by 340B hospitals, from the default amount—the average sales price plus six percent—to average sales price minus 22.5%. See 82 Fed. Reg. at 52,362.[2] HHS reasoned that the lower rate would "better, and more appropriately, reflect the resources and acquisition costs that these hospitals incur," and "lower drug costs for Medicare beneficiaries for drugs acquired by hospitals under the 340B Program." *Ibid.*; see *id.* at 52,495 (noting that a beneficiary's 20% coinsurance is tied to the Medicare payment rate).

In adopting that rate (average sales price minus 22.5%), HHS explained that the 22.5% figure represented the "lower bound" of the "minimum" average discount for 340B hospitals. 82 Fed. Reg. at 52,496. HHS noted that it had not received any comments during the rulemaking that had argued that a different figure would better reflect the hospital acquisition costs for drugs acquired by 340B providers. See *id.* at 52,500. HHS explained that the absence of any such comments was "notable because hospitals have their own data regarding their own acquisition costs, as well as data regarding OPPS payment rates for drugs." *Ibid.* HHS observed that the absence of an objection by 340B hospitals to that figure supported HHS's conclusion that

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[2] HHS exempted from the rate adjustment rural sole-community hospitals, children's hospitals, and prospective-payment-system-exempt cancer hospitals; the adjustment also does not apply to covered entities that are paid under a separate payment scheme outside OPPS, such as critical-access hospitals. See 82 Fed. Reg. at 52,493-52,511.

"hospitals will not be underpaid for their acquisition costs of such drugs." *Ibid.*

HHS estimated that, for the 2018 year, the adjusted payment rate for specified drugs acquired under the 340B program would reduce Medicare payments for such drugs by $1.6 billion. See 82 Fed. Reg. at 52,509. Because the adjustment was subject to the OPPS budget-neutrality requirement, however, see 42 U.S.C. 1395*l*(t)(14)(H), HHS directed that the $1.6 billion in savings be redistributed—resulting in a 3.2% increase in the Medicare payment rates for non-drug items and services for 2018, see 82 Fed. Reg. at 52,623. HHS carried forward the same methodology for the 2019 year. See 83 Fed. Reg. 58,818, 58,975-58,977 (Nov. 21, 2018).[3]

3. Petitioners, which include several 340B hospitals, attempted to challenge the rate adjustment for the 2018 year before it went into effect. Pet. App. 7a-8a. The district court dismissed that suit for lack of jurisdiction, finding that petitioners had not presented a concrete claim for reimbursement to the agency, as required by the Medicare statute. See *id.* at 8a; *American Hosp. Ass'n* v. *Hargan*, 289 F. Supp. 3d 45, 50-55 (D.D.C. 2017); see also 42 U.S.C. 405(g) and (h), 1395ii. The court of appeals affirmed the dismissal on that ground. See Pet. App. 8a; *American Hosp. Ass'n* v. *Azar*, 895 F.3d 822 (D.C. Cir. 2018). In light of that disposition, the court of appeals in that prior appeal found it unnecessary to address the government's alternative argument that judicial review of petitioners' suit was independently foreclosed by a provision of OPPS statute, 42 U.S.C. 1395*l*(t)(12), which provides that "[t]here shall be no administrative or judicial review under section 1395ff of

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[3] HHS also carried forward the same methodology for the 2020 and 2021 years, but those years are not at issue in this litigation.

this title, 1395*oo* of this title, or otherwise" of various determinations under Section 1395*l*. *Ibid.*; see *American Hosp. Ass'n*, 895 F.3d at 828.

4. The hospital petitioners subsequently presented concrete reimbursement claims for the 2018 and 2019 years, and petitioners brought this action challenging the adjusted payment rates for those years. See Pet. App. 8a. The district court concluded that Section 1395*l*(t)(12) did not preclude petitioners' challenge to HHS's rate adjustment on the theory that it was ultra vires. See *id.* at 65a-70a.

The district court concluded that HHS had exceeded its authority under subclause (II) in making the adjustment. Pet. App. 70a-79a. The court reasoned that, to align Medicare payment rates with hospital acquisition costs, HHS must collect hospital survey data pursuant to subclause (I), and that the agency cannot "achieve under subsection (II) what" it "could not do under subsection (I) for lack of adequate data." *Id.* at 76a. The court recognized, however, that the retroactive payments sought by petitioners would likely be "highly disruptive." *Id.* at 84a. It additionally observed that, as a result of the OPPS budget-neutrality requirement, the "retroactive OPPS payments" that petitioners sought "would presumably require similar offsets elsewhere," resulting in "a quagmire that may be impossible to navigate considering the volume of Medicare Part B payments made in 2018." *Id.* at 84a-85a.

After further briefing on the appropriate remedy, the district court remanded without vacatur, with instructions to HHS to devise a remedy. Pet. App. 88a.

5. The court of appeals reversed in a divided decision. Pet. App. 1a-43a.

a. The court of appeals first held that judicial review was not precluded by 42 U.S.C. 1395*l*(t)(12), concluding that HHS's adjustment of specified-drug payment rates is not among the determinations listed in that provision of which "no administrative or judicial review" is available, *ibid.*; see Pet. App. 8a-17a. The court rejected the government's contention that such an adjustment is encompassed both by subparagraph (t)(12)(A), which bars review of "the development of the classification system under paragraph (2), including the establishment of groups and relative payment weights for covered OPD services, of wage adjustment factors, other adjustments, and methods described in paragraph (2)(F)" of Section 1395*l*(t), 42 U.S.C. 1395*l*(t)(12)(A); and by subparagraph (t)(12)(C), which bars review of "periodic adjustments made under paragraph ([9])" of Section 1395*l*(t). 42 U.S.C. 1395*l*(t)(12)(C).[4] The court reasoned that HHS's establishment and adjustment of specified-drug payment rates are not determinations made under paragraph (2) or (9) of Section 1395*l*(t) but are instead actions taken under paragraph (14). Pet. App. 9a-17a.

On the merits, the court of appeals determined that "HHS reasonably interpreted subclause (II)'s adjustment authority to enable reducing" Medicare "payments to 340B hospitals, so as to avoid reimbursing those hospitals at much higher levels than their actual costs to acquire the drugs." Pet. App. 18a. The court accordingly upheld that "reasonable" interpretation. *Id.* at 19a (citing *Chevron U.S.A. Inc.* v. *Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984)).

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[4] Although Section 1395*l*(t)(12)(C) refers to "paragraph (6)," 42 U.S.C. 1395*l*(t)(2)(C), "all agree that the reference contains a scrivener's error and that Congress in fact intended to refer to paragraph (9)," Pet. App. 9a.

The court of appeals observed at the outset that "[m]uch [wa]s undisputed about HHS's application of subclause (II)'s adjustment authority to reduce [specified-drug] payment rates to 340B hospitals." Pet. App. 19a. It was common ground that "'hospital acquisition cost data' contemplated by subclause (I) was unavailable, such that HHS needed to determine payment rates in accordance with subclause (II)'s fallback" approach; that 340B hospitals obtain specified covered outpatient drugs "at substantially lower costs than other providers"; that the rate reduction at issue here is "a fair, or even conservative, measure of the reduction needed to bring payments to those hospitals into parity with their costs to obtain the drugs"; and that excessive Medicare payments for such drugs lead to inflated copayments for Medicare beneficiaries, "with beneficiaries' copayments sometimes exceeding 340B hospitals' full cost to purchase the drugs." *Id.* at 19a-20a (emphasis omitted). The court also noted that the roughly $1.6 billion in annual savings from reducing the payment rate for 340B hospitals was redistributed as additional Medicare payments for other OPPS services. See *id.* at 19a.

The court of appeals explained that the statute's text and structure "support[] HHS's understanding that the 'purposes' of paragraph 14 for which the agency can 'adjust' [the payment rate] under subclause (II) include aligning payments to hospitals with their drug acquisition costs," which is "precisely what HHS did" in the rulemaking at issue here. Pet. App. 23a (brackets and citation omitted). The court emphasized that petitioners had "point[ed] to no other 'purpose' that could permissibly support an adjustment." *Id.* at 24a.

The court of appeals rejected petitioners' suggestion that the adjustment authority in subclause (II) authorizes only "adjustments to account for overhead costs." Pet. App. 25a. The court reasoned that such a reading "would leave subclause (II)'s adjustment authority duplicative of authority already conferred by subparagraph (14)(E)," which separately "authorizes HHS to make adjustments to account for 'overhead and related expenses, such as pharmacy services and handling costs.'" *Ibid.* (quoting 42 U.S.C. 1395*l*(t)(14)(E)(i)). The court concluded that petitioners' "argument thus renders subclause (II)'s adjustment authority superfluous." *Id.* at 24a.

The court of appeals also rejected petitioners' contention that HHS could not bring Medicare payments into line with hospital acquisition costs unless the agency collected survey data pursuant to subclause (I). See Pet. App. 20a. The court reasoned that subclause (II) expressly authorizes HHS to adjust the average-sale-price rate as "necessary for the purposes of this paragraph"—*i.e.*, paragraph (14)—and it determined that paragraph (14)'s structure "supports HHS's understanding that the provision's core purposes include reimbursing hospitals for their costs to acquire [specified drugs]." *Id.* at 20a-21a (citation omitted). The court observed that paragraph (14)'s "primary (and default) instruction for determining [specified-drug] payment amounts, set out in subclause (I), is to equate them to 'average acquisition cost,'" which "alone indicates that Congress's primary goal is to reimburse providers for their acquisition costs." *Id.* at 21a (citation omitted). The court explained that, "[b]y prescribing the use of [average sale price] as a backup when the requisite acquisition-cost data is unavailable, Congress

signaled that average price functions as a stand-in for costs." *Ibid.*

The court of appeals further reasoned that "[t]he OPPS statute exhibits in other ways Congress's evident purpose of aligning [specified-drug] reimbursement with hospital costs." Pet. App. 22a. The court noted that paragraph (14) itself authorizes a separate adjustment to specified-drug payment rates to account for "overhead costs" and "related expenses" such as "pharmacy services and handling costs." *Ibid.* (citation omitted). And it noted that "many other OPPS provisions reflect the goal of aligning payments to hospitals with their costs." *Ibid.* (citing examples).

The court of appeals additionally noted that "HHS has long understood average price under subclause (II) to serve as a 'proxy for average acquisition cost'" and that, "[f]or non-340B hospitals, [average sale price] is an accurate approximation of acquisition costs." Pet. App. 21a-22a (citation omitted). It thus observed that "HHS's Inspector General has found that, for non-340B hospitals, [average sale price] comes within roughly 1% of acquisition costs." *Id.* at 22a (citing 2010 Inspector General Report 9). But the court further observed that, "for 340B hospitals, [average sale price] substantially exceeded [specified-drug] acquisition costs by the time of the 2018 Rule," which created "the need for an adjustment under subclause (II) to bring payments to 340B hospitals into line with their costs." *Ibid.*

The court of appeals rejected petitioners' related contention that HHS's interpretation of the subclause (II) adjustment authority would make the survey-data requirement in subclause (I) "meaningless." Pet. App. 23a. The court explained that, "[g]iven that the survey data

contemplated by subclause (I) aims to assure the reliability of cost-acquisition data," the court did "not read the statute to foreclose an adjustment to [average sale price] under subclause (II) that is based on reliable cost measures of the kind undisputedly at issue here." *Id.* at 24a. The court observed that, in any event, "when competing readings of a statute would each occasion their own notable superfluity, that manifests the kind of statutory ambiguity that *Chevron* permits the agency to weigh and resolve." *Id.* at 27a.

Finally, the court of appeals rejected petitioners' alternative contention that HHS cannot tailor a subclause (II) rate adjustment to a particular hospital group, even if that group has far lower (or far higher) costs than others. Pet. App. 30a-31a. The court noted that subclause (I) expressly grants HHS authority to vary rates by hospital group, and it found no reason to conclude that HHS's general adjustment authority forecloses such a targeted rate adjustment. *Id.* at 30a. The court concluded that, at a minimum, "the statute does not clearly preclude HHS from adjusting the [specified-drug] rate in a focused manner to address problems with reimbursement rates applicable only to certain types of hospitals," which is "enough to reject the Hospitals' argument under *Chevron*." *Id.* at 31a.

b. Judge Pillard dissented with respect to the merits. Pet. App. 31a-43a. She stated that she would interpret the adjustment authority in subclause (II) "as primarily cross-referencing incremental modifications like the overhead-cost adjustment described in subparagraph (E)." *Id.* at 36a. Judge Pillard additionally concluded that "HHS may only segment reimbursement rates by hospital group if it has collected" the specified survey data under subclause (I) "and set the rates keyed to hospital acquisition costs in view of that data." *Id.* at 33a.

ARGUMENT

Petitioners contend (Pet. 16-28) that HHS exceeded its authority under 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II) to "adjust[]" specified-drug prices for 340B hospitals—based on HHS's recognition, relying on data of undisputed reliability, that such hospitals obtain specified drugs at significantly lower prices—in order to align 340B hospitals' payment rates with their acquisition costs. The court of appeals correctly rejected that contention in these circumstances, and its decision does not conflict with any decision of this Court or of another court of appeals. That decision also does not preclude petitioners from advancing their policy arguments in future annual rulemakings; the court of appeals concluded that the rate adjustments were permitted, not compelled, by the statute. Further review is not warranted.

1. As an initial matter, this Court's review is not warranted because a provision of the OPPS statute, 42 U.S.C. 1395*l*(t)(12), precludes judicial review of petitioners' challenge to HHS's rate adjustment. This Court would have no occasion to reach the merits of petitioners' challenge unless it first determined that judicial review is available notwithstanding that provision.

Section 1395*l*(t)(12) states that "[t]here shall be no administrative or judicial review under section 1395ff of this title, 1395*oo* of this title, or otherwise of" certain actions by HHS under Section 1395*l*. 42 U.S.C. 1395*l*(t)(12). The court of appeals has previously recognized that this express preclusion of review is "unsurprising," because "review could result in the retroactive ordering of payment adjustments after hospitals have already received their payments for the year," and "judicially mandated changes in one payment rate would affect the aggregate impact of the Secretary's decisions

by requiring offsets elsewhere." *Amgen Inc.* v. *Smith*, 357 F.3d 103, 112 (D.C. Cir. 2004).

As the government explained in detail in the court of appeals, that preclusion-of-review provision bars judicial review of OPPS rate adjustments, including adjustments to specified-drug payment rates addressed by Section 1395*l*(t)(14) at issue here. Gov't C.A. Br. 22-24; Gov't C.A. Reply Br. 13-20. Among other actions, Section 1395*l*(t) precludes review of "the development of a classification system under" paragraph (2) of Section 1395*l*(t), including certain "adjustments," and "periodic adjustments made under" paragraph (9). 42 U.S.C. 1395*l*(t)(12)(A) and (C). The specified-drug adjustments at issue here are encompassed by that bar.

Although the court of appeals concluded that specified-drug adjustments in Section 1395*l*(t)(14) are exempt from that preclusion-of-review provision, Pet. App. 8a-17a, we respectfully submit that its conclusion was mistaken. The court stated that Section 1395*l*(t) does not address "action taken by HHS under paragraph (14)," which it portrayed as creating a freestanding framework for the establishment of payment rates for particular items wholly separate from the actions under paragraphs (2) and (9) of subsection (t) enumerated in the judicial-review bar. *Id.* at 11a; see *id.* at 9a-17a. That characterization is incorrect.

Paragraphs (2) and (9) confer on HHS authority to establish and subsequently to adjust the OPPS, and they prescribe various requirements for the system and later adjustments. Paragraph (2) establishes "[s]ystem requirements" for the entire OPPS, which include the development of a classification system for covered outpatient department services. 42 U.S.C. 1395*l*(t)(2) (emphasis omitted). Under paragraph (2), HHS classifies

covered services into groups, 42 U.S.C. 1395*l*(t)(2)(A); establishes relative payment weights for covered services, 42 U.S.C. 1395*l*(t)(2)(C); and, in a budget-neutral manner, makes various adjustments, including "adjustments as determined to be necessary to ensure equitable payments," 42 U.S.C. 1395*l*(t)(2)(E). Under paragraph (9), HHS periodically revises these groups, relative payment rates, and adjustments in a budget-neutral manner, to take into account (*inter alia*) new cost data. 42 U.S.C. 1395*l*(t)(9). HHS makes the revisions required by paragraph (9) through annual notice-and-comment rulemaking, as illustrated by the rules at issue here.

Paragraph (14) does not establish a standalone payment regime for specified drugs. Instead, it provides instructions to HHS about how to exercise its authority under paragraphs (2) and (9) when setting and revising payments with respect to specified drugs. The rulemakings at issue here were accordingly conducted to make the periodic adjustments to OPPS required by paragraph (9), and the preambles thus invoked Secretary's authority under "section 1833(t)(9)(A)," that is, paragraph (9)(A). See, *e.g.*, 82 Fed. Reg. at 52,361-52,362.

The policies that underlie the OPPS statute's preclusion of review apply with full force to the specified-drug adjustments here. As the court of appeals recognized, the Medicare payment amounts set for specified covered outpatient drugs must be "put into the budget-neutrality calculator" for purposes of determining the payment amounts for other OPPS services. Pet. App. 16a (citing 42 U.S.C. 1395*l*(t)(14)(H)). Thus, the $1.6 billion in savings from the rate reduction at issue here was "not kept by the agency," but instead was "redistributed to all providers as additional reimbursement payments for other

services." *Id.* at 20a. Undoing the adjustment now would result in the remedial "quagmire" the district court identified, *id.* at 84a.

2. In any event, assuming arguendo that petitioners' challenge to HHS's rate adjustment is reviewable, the court of appeals correctly determined that the adjustment was a permissible exercise of HHS's statutory authority in the circumstances presented here, where the reliability of the data on which HHS based its adjustment was not contested during the rulemakings. That decision does not warrant further review.

a. Section 1395*l*(t)(14)(A)(iii) directs HHS to set annual payment rates for specified drugs in one of two ways. Subclause (I) establishes a default methodology that applies if "hospital acquisition cost survey data" obtained pursuant to Section 1395*l*(t)(14)(D) are available: in that event, the payment amount for a drug shall be equal "to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics)), as determined by the Secretary taking into account" such survey data. 42 U.S.C. 1395*l*(t)(14)(A)(iii)(I). Subclause (II) provides an alternative methodology where such "hospital acquisition cost data are not available": the payment amount is "the average price for the drug in the year established under" certain cross-referenced provisions of the statute, "as calculated and adjusted by the Secretary as necessary for purposes of this paragraph." 42 U.S.C. 1395*l*(t)(14)(A)(iii). Under the relevant cross-referenced provision here, 42 U.S.C. 1395w-3a, the average price is 106% of a drug's "average sales price," see *ibid.* (emphasis omitted); see also Pet. App. 4a; average sales

price is ordinarily a good proxy for a drug's acquisition costs. See p. 4, *supra*; Pet. App. 22a. The court of appeals correctly determined that subclause (II) permitted HHS to make the rate adjustments at issue "in the specific circumstances of this case." Pet. App. 28a; see *id.* at 17a-31a.

i. The court of appeals observed that, in the rulemakings here, "HHS relied on data of undisputed reliability" in finding that 340B hospitals obtained specified drugs at significant discounts relative to other providers. Pet. App. 28a. Petitioners have not contested that "340B hospitals obtain [specified drugs] at substantially lower cost than other providers, such that reimbursing those hospitals at the same rate as other providers would give sizable revenues to the hospitals." *Id.* at 20a. By obtaining such drugs at costs well below the Medicare payments they received, 340B hospitals were able "to generate significant profits." *Id.* at 6a (quoting 82 Fed. Reg. at 52,494).

The court of appeals correctly found that, faced with that disparity between 340B hospitals' acquisition costs and the Medicare payment amounts that they and other providers received, HHS was authorized by subclause (II) in these circumstances to "adjust[]" such hospitals' payment amounts to align their payments more closely with their costs. Pet. App. 20a-23a. Subclause (II) authorizes HHS to make "adjust[ments]" to payment rates under that provision as the Secretary deems "necessary for purposes of this paragraph," *i.e.*, Section 1395*l*(t)(14). 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II). As the court recognized, one "evident purpose" in enacting paragraph (14) was to "align[] [specified-drug] reimbursement with hospital costs." Pet. App. 22a. The default methodology for determining

specified-drug payment amounts in subclause (I) is expressly premised on acquisition costs based on survey data when such data are "[]available." *Id.* at 21a. The court observed that, "[b]y prescribing the use of [average sale price] as a backup when the requisite acquisition-cost data is unavailable, Congress signaled that average price functions as a stand-in for costs." *Ibid.* In addition, "many other OPPS provisions reflect the goal of aligning payments to hospitals with their costs." *Id.* at 22a (citing 42 U.S.C. 1395*l*(t)(2)(C) and (D), (5)(B), (9)(A), (13)(A), (14)(E), and (18)(B)). And "HHS has long understood average price under subclause (II) to serve as a 'proxy for average acquisition cost.'" *Id.* at 21a. In light of that statutory purpose, the court properly concluded that HHS was not "obligated to continue reimbursing 340B hospitals for [specified drugs] in amounts substantially exceeding their costs to obtain the drugs, with the resulting effects that concerned the agency on out-of-pocket copayments owed by Medicare beneficiaries," which could "substantially exceed the normal copay share" and sometimes even "exceed[ed] 340B hospitals' *full* cost to purchase the drugs." *Id.* at 20a.

Moreover, as the court of appeals recognized, not only were the rate adjustments premised on data of undisputed reliability, but HHS also "acted on that data in a cautious way." Pet. App. 28a. In determining the amount of the downward adjustment for 340B hospitals' specified-drug payments, HHS "adopt[ed] a 'conservative, lowerbound estimate' of the 340B discount's size." *Ibid.* (citation omitted). Indeed, it was undisputed below that the rate adjustment "is a fair, or even conservative, measure of the reduction needed to bring payments to those hospitals into parity with their costs to obtain the drugs." *Id.* at 20a.

ii. The court of appeals properly found petitioners' principal counterargument unpersuasive in the circumstances presented here. Pet. App. 23a-28a.

Petitioners argued below that HHS may not exercise its subclause (II) authority to "adjust[]" specified-drug payment amounts established under that provision to reflect providers' acquisition costs because subclause (I) prescribes a particular method for setting specified-drug payment amounts based on acquisition costs that requires HHS first to obtain certain survey data. Pet. App. 23a-24a. Petitioners contended that construing subclause (II) to authorize such adjustments would render subclause (I) and its requirements superfluous. *Ibid.* The court of appeals noted, however, that petitioners' own position "raises a similar interpretive dilemma" by "render[ing] subclause (II)'s adjustment authority superfluous." *Id.* at 24a. The court explained that subclause (II) "expressly empowers HHS to 'adjust' payments * * * 'as necessary for purposes' of paragraph (14)," and although petitioners contended that "those 'purposes' cannot include the goal of approximating hospital acquisition costs," they "point[ed] to no other 'purpose' that could permissibly support an adjustment." *Ibid.* And the court observed that petitioners' proposed limitation on such adjustments to account only for overhead costs would render it "duplicative" of another nearby provision that specifically addresses overhead costs. *Id.* at 25a. In light of its conclusion that petitioners' own reading would render part of the statute superfluous, the court appropriately declined to deem HHS's adjustments foreclosed based on their contention that HHS's position gives insufficient import to subclause (I). See *Microsoft Corp.* v. *i4i Ltd. P'ship*, 564 U.S. 91, 106 (2011) ("[T]he canon against superfluity assists only

where a competing interpretation gives effect 'to every clause and word of a statute.'" (citation omitted).

In any event, as the court of appeals properly observed, whatever the force of petitioners' argument in other circumstances, it does not support "read[ing] the statute to foreclose an adjustment to [average sale price] under subclause (II) that is based on reliable cost measures of the kind undisputedly at issue here." Pet. App. 24a. Petitioners' concern (Pet. 20-22) that HHS's interpretation enables the agency to avoid collecting and analyzing survey data that meet specified criteria has little if any application where, as here, the agency "relied on data of undisputed reliability" to reach a factual conclusion about the existence and magnitude of 340B providers' discounts that petitioners have not contested. *Id.* at 28a. In addition, although a survey would be the ordinary mechanism in other contexts for determining whether Medicare payment amounts align with average acquisition costs for a particular hospital group, the particular discount that HHS identified for 340B hospitals is a function of the statutory and regulatory scheme itself, including the statutory ceiling on costs Medicaid providers may charge 340B hospitals and the HRSA prime-vendor program. See pp. 4-5, *supra*. Moreover, HHS further mitigated any concerns about the accuracy of those undisputed data by taking a "cautious" approach in setting the amount of the downward adjustment, using a "'conservative, lowerbound estimate'" of the discount. Pet. App. 28a (citation omitted).

Petitioners do not contest that, if HHS had obtained survey data and reached the same determination about the existence and size of 340B hospitals' specified-drug discount, HHS could implement under subclause (I) adjust-

ments specific to 340B hospitals identical to the adjustments it adopted here. See 42 U.S.C. 1395*l*(t)(14)(A)(iii)(I) (permitting rates under subclause (I) to "vary by hospital group (as defined by the Secretary based on the volume of covered * * * services or other relevant characteristics)"). They accordingly do not contend that the substantive outcome HHS's adjustments here implemented is incompatible with the statute. And although petitioners fault the agency for taking that step without obtaining survey data, they do not identify what value those data might add or what difference they would have made, given the absence of any challenge to the reliability of the data on which HHS did rely. Yet their interpretation would mean that, because the agency relied on different but undisputedly reliable data, it may not adjust 340B hospitals' rates to reflect their acquisition costs—and instead must continue to pay such hospitals at rates that far exceed their costs. The court of appeals correctly recognized that the statute does not compel that result.

b. In this Court, petitioners principally contend (Pet. 17-26) that the decision diverged from this Court's precedents addressing the application of judicial deference to agency interpretations under *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). That contention lacks merit.

Petitioners assert that "*Chevron* deference is 'not due unless a court, employing traditional tools of statutory construction,' is left with an unresolved ambiguity," and contend that the court of appeals' decision conflicts with that principle. Pet. 17 (quoting *Epic Systems Corp.* v. *Lewis*, 138 S. Ct. 1612, 1630 (2018), in turn quoting *Chevron*, 467 U.S. at 843 n.9; other internal quotation marks omitted). This Court has repeatedly recognized, however, that courts may appropriately defer under *Chevron* to an

agency's "reasonable construction of [a] statute, whether or not it is the only possible interpretation," and a court accordingly need not necessarily resolve whether the agency's interpretation is the only sound reading or whether other reasonable interpretations exist. *Holder* v. *Martinez Gutierrez*, 566 U.S. 583, 591 (2012) ("We think [the agency's] view * * * meets [*Chevron*'s reasonable-construction] standard, and so need not decide if the statute permits any other construction."); see *Entergy Corp.* v. *Riverkeeper, Inc.*, 556 U.S. 208, 218 & n.4 (2009) (rejecting the argument that "the supposedly prior inquiry of 'whether Congress has directly spoken to the precise question at issue'" is always necessary before a court may uphold an agency interpretation that it finds to be reasonable (citation omitted)).

In any event, the decision below does not conflict with the proposition that petitioner invokes. The court of appeals considered but was "unpersuaded" by petitioner's contention that "Congress unambiguously barred HHS from seeking to align reimbursements with acquisition costs under subclause (II)." Pet. App. 24a. The court emphasized in particular petitioners' "inability to present an interpretation of HHS's subclause (II) adjustment authority that would give it meaningful independent content," which undermined their contention that "the statute forecloses HHS from reducing [specified-drug] reimbursement[s]," at least where HHS makes a subclause (II) adjustment "based on reliable cost measures of the kind undisputedly at issue here." *Id.* at 24a, 28a. The court concluded that, "[a]t a minimum, the statute does not clearly preclude HHS from adjusting the [specified-drug] rate in a focused manner to address problems with reimbursement rates," including problems like those HHS identified

here that are "applicable only to certain types of hospitals." *Id.* at 31a. The court thus necessarily determined that the statute is at least ambiguous with respect to HHS's authority to make the adjustments at issue here.

Petitioners also err in contending (Pet. 18-20, 24-26) that the decision below conflicts with decisions of this Court declining to defer to administrative interpretations of particular terms in other statutes. None of those decisions addressed the soundness of HHS's interpretation of subclause (II) at issue here, let alone in the particular circumstances presented in which the agency based its decision on data of undisputed reliability. For example, petitioners contend (Pet. 18, 24-25) that the Court's decision *MCI Telecommunications Corp.* v. *American Telephone & Telegraph Co.*, 512 U.S. 218 (1994), compels reading the term "adjust" in subclause (II), like the term "modify" at issue in *MCI*, to carry a "'connotation of increment or limitation,'" and that the rate adjustments at issue here are too large to qualify based on an unspecified metric. Pet. 25 (quoting *MCI*, 512 U.S. at 225); see Pet. 18, 24-25. But as the court of appeals explained, the relevant statutory text in this case already specifies the limitation on HHS's adjustment authority: HHS may do so "as necessary for purposes" of paragraph (14), which the court determined reasonably include aligning specified-drug payments with average acquisition cost. Pet. App. 19a-21a.

3. Petitioners acknowledge that the decision below does not conflict with any decision of another court of appeals. See Pet. 33 (recognizing "the absence of a circuit conflict"). Their assertions (Pet. 28-33) that the Court should nevertheless decline to defer review unless and until a lower-court conflict develops lack merit.

Prospectively, petitioners may raise their policy concerns (Pet. 28-32) with the agency as part of the annual notice-and-comment rulemaking through which OPPS rates are set. The court of appeals held that the challenged rate reduction was a permissible exercise of HHS's authority, not that it was required.

With respect to the 2018 and 2019 years that were the subject of this suit, petitioners' assertion of a need for immediate review (Pet. 30-32) is also unfounded, as illustrated by the district court's remedial decision that was overtaken by the court of appeals' decision. Despite erroneously concluding that judicial review is available and that HHS exceeded its statutory authority in adopting the adjustments, the district court recognized that the relief that petitioners sought—ordering retroactive payments without the adjustments—would be "highly disruptive." Pet. App. 84a. Because of the OPPS budget-neutrality requirements, such "retroactive OPPS payments * * * would presumably require similar offsets elsewhere," resulting in "a quagmire that may be impossible to navigate considering the volume of Medicare Part B payments made in 2018." *Id.* at 84a-85a.

After further briefing on the remedy, the district court reiterated that determining "how to 'unscramble the egg,' so to speak," is "no easy task, given Medicare's complexity." Pet. App. 101a. The court noted that, "if the Secretary were to retroactively raise the 2018 and 2019 340B rates, budget neutrality would require him to retroactively lower the 2018 and 2019 rates for other Medicare Part B products and services." *Id.* at 108a. "And because HHS has already processed claims under the previous rates, the Secretary would potentially be required to recoup certain payments made to providers;

an expensive and time-consuming prospect." *Ibid.* (citing C.A. App. 97-100 (¶¶ 5-9) (Richter Decl.) (providing HHS's estimate that recoupment would take a year, require between $25 million and $30 million in administrative costs, and adversely impact Medicare beneficiaries who would owe different amounts under their cost-sharing obligations)). The court also noted that the Federation of American Hospitals—which appeared as amicus on behalf of more than 1,000 non-340B hospitals—had urged that HHS "lacks authority to recoup any or all of the 3.2[%] budget neutrality adjustment" made in the 2018 OPPS Rule. Pet. App. 110a-111a & n.20.

In light of those concerns, the district court rejected petitioners' request that it order HHS to pay them the amounts they would have received in 2018 and 2019 if the payment rate for 2017 had been in effect for those years. Pet. App. 101a-112a. Instead, the court remanded the matter to the agency without vacatur, with instructions that the agency devise a remedy. See *ibid.* Petitioners did not cross-appeal that ruling and so cannot press arguments on appeal that would, if adopted, enlarge their rights under the district court's judgment. See *Jennings* v. *Stephens*, 574 U.S. 271, 276 (2015).[5]

Consequently, no present prospect exists that plenary review by this Court, even if petitioners prevailed

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[5] While the appeal was pending, HHS gathered the survey data from 340B hospitals that the district court had deemed necessary. See 85 Fed. Reg. 85,866, 86,044-86,045 (Dec. 29, 2020) (describing the survey). Petitioners now criticize (Pet. 29) HHS for surveying only 340B hospitals, and for giving 340B hospitals the option to have the agency treat the HRSA ceiling prices as reflecting their average acquisition costs rather than requiring them to submit detailed cost data. However, the district court's remand order did not preclude the agency from acting to mitigate the burden that the survey would impose on hospitals.

on the threshold issue of reviewability and on the merits, would result in immediate relief for affected 340B hospitals. Petitioners have not identified any sound reason for this Court's review at this juncture on a question that no other court of appeals has confronted.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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