# Supreme Court of the United States Office of the Clerk Washington, DC 20543-0001

Scott S. Harris Clerk of the Court (202) 479-3011

June 15, 2022

Clerk

United States Court of Appeals for the District of Columbia Circuit 333 Constitution Avenue, NW Washington, DC 20001

Re: American Hospital Association, et al. v. Xavier Becerra, Secretary of Health and Human Services, et al. No. 20-1114 (Your No. 19-5048, 19-5198)

Dear Clerk:

The opinion of this Court was announced today in the above stated case. A copy of the opinion is available on the Court's website at www.supremecourt.gov.

The judgment or mandate of this Court will not issue for at least twenty-five days pursuant to Rule 45. Should a petition for rehearing be filed timely, the judgment or mandate will be further stayed pending this Court's action on the petition for rehearing.

Sincerely,

Scott S. Harris, Clerk

WIL S. Hans

by

Laurie Wood Deputy Clerk (202) 479-3031

#### OCTOBER TERM, 2021

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#### Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.*, 200 U. S. 321, 337.

# SUPREME COURT OF THE UNITED STATES

#### Syllabus

# AMERICAN HOSPITAL ASSOCIATION ET AL. v. BECERRA, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.

# CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 20-1114. Argued November 30, 2021—Decided June 15, 2022

The Medicare statute lays out a formula that the Department of Health and Human Services must employ annually to set reimbursement rates for certain outpatient prescription drugs provided by hospitals to Medicare patients. 42 U. S. C. §1395l(t)(14)(A)(iii). That formula affords HHS two options. Option 1 applies if HHS has conducted a survey of hospitals' acquisition costs for each covered outpatient drug. Under this option, the agency may set reimbursement rates based on the hospitals' "average acquisition cost" for each drug, and may "vary" the reimbursement rates "by hospital group." §1395l(t)(14)(A)(iii)(I). Absent a survey, option 2 applies, and HHS must set reimbursement rates based on "the average price" charged by manufacturers for the "calculated and adjusted by the §1395l(t)(14)(A)(iii)(II). Option 2 does not authorize HHS to vary reimbursement rates for different hospital groups. From the time these provisions took effect in 2006 until 2018, HHS did not conduct surveys of hospitals' acquisition costs, relied on option 2, set the reimbursement rates at about 106 percent, and did not vary those rates by hospital group. For 2018, HHS again did not conduct a survey. But this time it issued a final rule establishing separate reimbursement rates for hospitals that serve low-income or rural populations through the 340B program and all other hospitals. For 2019, HHS set reimbursement rates the same way.

The American Hospital Association and other interested parties challenged the 2018 and 2019 reimbursement rates in federal court. In response, HHS first contended that various statutory provisions precluded judicial review of those rates. The agency also argued that

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it could vary the reimbursement rates by hospital group under its option 2 authority to "adjust" the price-based reimbursement rates. The District Court rejected HHS's argument that the statute precluded judicial review, concluded that HHS had acted outside its statutory authority, and remanded the case to HHS to consider an appropriate remedy. The D. C. Circuit, however, reversed. The court ruled that the statute did not preclude judicial review, and upheld HHS's reduced reimbursement rates for 340B hospitals.

#### Held:

- 1. The statute does not preclude judicial review of HHS's reimbursement rates. Judicial review of final agency action is traditionally available unless "a statute's language or structure" precludes it, Mach Mining, LLC v. EEOC, 575 U.S. 480, 486, and this Court has long recognized a "strong presumption" in its favor, Weyerhaeuser Co. v. United States Fish and Wildlife Serv., 586 U.S. \_\_\_, \_\_. Here, no provision in the Medicare statute precludes judicial review of the 2018 and 2019 reimbursement rates. HHS cites two nearby provisions that preclude review of the general payment methodology that HHS employs to set rates for other Medicare outpatient services. §§1395l(t)(12)(A), (C). But HHS sets rates for outpatient prescription drugs using a different payment methodology. HHS also argues that other statutory requirements would make allowing judicial review of the 2018 and 2019 reimbursement rates impractical. Regardless, such arguments cannot override the text of the statute and the traditional presumption in favor of judicial review of administrative action. Pp.
- 2. Absent a survey of hospitals' acquisition costs, HHS may not vary the reimbursement rates only for 340B hospitals; HHS's 2018 and 2019 reimbursement rates for 340B hospitals were therefore unlawful. The text and structure of the statute make this a straightforward case. Because HHS did not conduct a survey of hospitals' acquisition costs, HHS acted unlawfully by reducing the reimbursement rates for 340B hospitals. HHS maintains that even when it does not conduct a survey, the agency still may "adjus[t]" the average price "as necessary." §1395l(t)(14)(A)(iii)(II). But HHS's power to increase or decrease the price is distinct from its power to set different rates for different groups of hospitals. Moreover, HHS's interpretation would make little sense given the statute's overall structure. Under HHS's interpretation, the agency would never need to conduct a survey of acquisition costs if it could proceed under option 2 and then do everything under option 2 that it could do under option 1. That not only would render irrelevant the survey prerequisite for varying reimbursement rates by hospital group, but also would render largely irrelevant the provision of the statute that precisely details the requirements for surveys of hospitals'

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acquisition costs. See \$1395l(t)(14)(D). Finally, HHS's argument that Congress could not have intended for the agency to "overpay" 340B hospitals for prescription drugs ignores the fact that Congress, when enacting the statute, was well aware that 340B hospitals paid less for covered prescription drugs. It may be that the reimbursement payments were intended to offset the considerable costs of providing healthcare to the uninsured and underinsured in low-income and rural communities. Regardless, this Court is not the forum to resolve that policy debate. Pp. 9–14.

967 F. 3d 818, reversed and remanded.

KAVANAUGH, J., delivered the opinion for a unanimous Court.

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# Opinion of the Court

NOTICE: This opinion is subject to formal revision before publication in the preliminary print of the United States Reports. Readers are requested to notify the Reporter of Decisions, Supreme Court of the United States, Washington, D. C. 20543, of any typographical or other formal errors, in order that corrections may be made before the preliminary print goes to press.

# SUPREME COURT OF THE UNITED STATES

No. 20-1114

AMERICAN HOSPITAL ASSOCIATION, ET AL., PETITIONERS v. XAVIER BECERRA, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.

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

[June 15, 2022]

JUSTICE KAVANAUGH delivered the opinion of the Court.

Under the Medicare statute, the Department of Health and Human Services must reimburse hospitals for certain outpatient prescription drugs that the hospitals provide to Medicare patients. HHS's total reimbursements to hospitals for prescription drugs add up to tens of billions of dollars every year.

To set the reimbursement rates for the prescription drugs, HHS has two options under the statute. First, if HHS has conducted a survey of hospitals' acquisition costs for the drugs, HHS may set the reimbursement rates based on the hospitals' average acquisition costs—that is, the amount that hospitals pay to acquire the prescription drugs—and may vary the reimbursement rates for different groups of hospitals. Second and alternatively, if HHS has not conducted such a survey, HHS must instead set the reimbursement rates based on the average sales price charged by manufacturers for the drugs (with certain adjustments), and HHS may *not* vary the reimbursement

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rates for different groups of hospitals.

For 2018 and 2019, HHS did not conduct a survey of hospitals' acquisition costs for outpatient prescription drugs. But HHS nonetheless substantially reduced the reimbursement rates for one group of hospitals—Section 340B hospitals, which generally serve low-income or rural communities. For those 340B hospitals, this case has immense economic consequences, about \$1.6 billion annually.

The question is whether the statute affords HHS discretion to vary the reimbursement rates for that one group of hospitals when, as here, HHS has not conducted the required survey of hospitals' acquisition costs. The answer is no. We therefore reverse the judgment of the U. S. Court of Appeals for the D. C. Circuit.

I A

In 2003, Congress passed and President George W. Bush signed landmark legislation expanding Medicare to cover prescription drugs. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 117 Stat. 2066, 42 U. S. C. §1395. Under that 2003 law, HHS must annually set reimbursement rates for certain outpatient prescription drugs provided by hospitals. §1395l(t)(14).

The Medicare statute meticulously lays out the formula that HHS must employ to set those reimbursement rates. As relevant here, the agency's reimbursement rate for each covered outpatient prescription drug "shall be equal" to one of two measures:

"(I) 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 the hospital acquisition cost survey data under subparagraph (D); or

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"(II) if hospital acquisition cost data are not available, the average price for the drug in the year established under section 1395u(o) of this title, section 1395w-3a of this title, or section 1395w-3b of this title, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of this paragraph."  $\S1395l(t)(14)(A)(iii)$  (emphasis added).

To simplify a bit: Congress afforded HHS two options to set the reimbursement rates for hospitals. Option 1 applies if the agency has conducted a survey of hospitals' acquisition costs—that is, the amount that hospitals pay to acquire the prescription drugs. If the agency has conducted a survey and collected that data, HHS may set reimbursement rates based on the hospitals' "average acquisition cost" for each drug. See \$1395l(t)(14)(A)(iii)(I); see also \$1395l(t)(14)(D) (requirements for conducting surveys of hospitals' drug acquisition costs). Importantly for present purposes, if HHS has conducted a survey of hospitals' acquisition costs, option 1 authorizes HHS to vary those reimbursement rates for different groups of hospitals.

Option 2 applies if HHS has not conducted a survey of hospitals' acquisition costs. In that circumstance, the agency must set reimbursement rates based on "the average price" charged by manufacturers for the drug, as "calculated and adjusted by the Secretary as necessary for purposes of" this statutory provision. \$1395l(t)(14)(A)(iii)(II). The statute in turn sets "the average price" as 106 percent of the drug's average sales price. See ibid. (citing \$1395w-3a). Critically, option 2 does *not* authorize HHS to vary reimbursement rates for different groups of hospitals.

For more than a decade after those provisions took effect in 2006, HHS did not conduct a survey of hospitals' acquisition costs. Indeed, HHS has only once attempted to conduct such a survey—in 2020, after this litigation commenced. At oral argument in this Court, the Government

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explained that HHS had not previously attempted to conduct such surveys because the surveys are "very burdensome on the study takers," are "very burdensome on the hospitals," and do not "produce results that are all that accurate." Tr. of Oral Arg. 41–42.

As a result, until 2018, HHS consistently relied on option 2 and set reimbursement rates for each drug based on the average-sales-price data provided by manufacturers. Every year, HHS set the reimbursement rates at about 106 percent of each covered drug's average sales price, and HHS used the same reimbursement rates for all hospitals. In other words, until 2018, HHS never varied the reimbursement rates by hospital group. See Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 52490, 52494–52495 (2017).

During its rulemaking for 2018, HHS proposed a change to reduce the reimbursement rates only for 340B hospitals. Importantly, HHS did not conduct a survey of hospital acquisition costs. As a policy matter, HHS said that its existing reimbursement rates resulted in what the agency viewed as overpayments to hospitals that serve low-income or rural populations through the federal 340B program. Federal law requires drug manufacturers to sell prescription drugs to those 340B hospitals at prices below those paid by other hospitals. See 42 U.S.C. §256b(a)(1) (setting a "ceiling price" that manufacturers can charge to 340B hospitals). Consistent with the Medicare statute, however, HHS historically had reimbursed 340B hospitals for covered outpatient prescription drugs at the same reimbursement rates that were set for all other hospitals. For 2018, HHS said that the uniform reimbursement rates combined with the discounted prices paid by 340B hospitals for prescription drugs meant that 340B hospitals were able to "generate significant profits" when they provided the prescription drugs to Medicare patients. 82 Fed. Reg. 52494.

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In response to HHS's proposed change, the 340B hospitals countered that, under the Medicare statute, HHS could not single out 340B hospitals without conducting a survey of hospitals' acquisition costs. With respect to HHS's policy arguments, the 340B hospitals explained that the reimbursement payments for prescription drugs helped those hospitals offset the considerable costs of providing healthcare to the uninsured and underinsured in lowincome and rural communities. The 340B hospitals pointed out, moreover, that Congress had long been aware of the situation. Indeed, the hospitals claimed that Members of Congress not only were aware, but actually intended for the 340B program's drug reimbursements to subsidize other services provided by 340B hospitals. The hospitals noted that Congress had never singled out 340B hospitals for lower Medicare reimbursements for outpatient prescription drugs. Nor, until 2018, had HHS ever done so. Furthermore, the 340B hospitals asserted that reducing their reimbursement rates for prescription drugs would force those hospitals to eliminate or dramatically curtail other crucial programs that provide a wide range of medical services in low-income and rural communities—such as treatments for cancer, mental health issues, opioid addiction, and diabetes.

In the final rule for 2018, HHS decided to establish two separate reimbursement rates: one rate for non-340B hospitals and another rate for 340B hospitals. The reimbursement rate for non-340B hospitals remained at the historical rate of approximately 106 percent of the average sales price for each drug. But HHS established a substantially reduced rate for 340B hospitals—a rate equal to 77.5 percent of the average sales price for each drug. In setting that rate, HHS relied on an estimate from the Medicare Payment Advisory Commission that 340B hospitals obtained prescription drugs at an average discount of at least 22.5 percent below the average sales price charged by manufacturers.

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Id., at 52496, 52499. HHS estimated that the reduction in the reimbursement rates for 340B hospitals would save Medicare (and deprive 340B hospitals of) about \$1.6 billion annually, which by law would be re-allocated for other Medicare services. Id., at 52509–52510. For 2019, HHS set reimbursement rates for 340B hospitals in the same way.

When setting the 2018 and 2019 reimbursement rates, HHS acknowledged that it had not conducted a survey of hospitals' acquisition costs—the statutory prerequisite for varying the reimbursement rates by hospital group. *Id.*, at 52496. Nonetheless, HHS pointed to its statutory authority under option 2 to "adjust" the average price "'as necessary for purposes of'" this statutory provision. *Id.*, at 52499. HHS claimed that its authority to "adjust" the average price for each drug also implicitly encompassed the authority to vary the reimbursement rates by hospital group. *Ibid.* 

В

The American Hospital Association, along with two other hospital industry groups and several hospitals, sued in U. S. District Court to challenge HHS's 2018 and 2019 reimbursement rates for 340B hospitals. Among other things, the Hospitals asserted that HHS did not conduct a survey of hospitals' acquisition costs and therefore could not impose different reimbursement rates on different groups of hospitals.

In response, HHS first contended that various statutory provisions precluded judicial review of the 2018 and 2019 reimbursement rates. As relevant here, HHS further argued that it could vary the reimbursement rates by hospital group under its authority to "adjust" the price-based reimbursement rates, even though HHS had not conducted a survey of hospitals' acquisition costs.

The District Court ruled for the Hospitals. The court rejected HHS's argument that the statute precluded judicial review. On the merits, the court concluded that HHS had

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acted outside its statutory authority, and the court remanded to HHS for the agency to consider an appropriate remedy. See *American Hospital Assn.* v. *Azar*, 385 F. Supp. 3d 1 (DC 2019) (remedy); *American Hospital Assn.* v. *Azar*, 348 F. Supp. 3d 62 (DC 2018) (merits).

A divided panel of the U. S. Court of Appeals for the D. C. Circuit reversed. On the question of judicial review, the court unanimously ruled that the statute did not preclude judicial review. See *American Hospital Assn.* v. *Azar*, 967 F. 3d 818, 824 (2020). On the merits, however, the court upheld HHS's reduced reimbursement rates for 340B hospitals. *Id.*, at 828.

In dissent, Judge Pillard contended that HHS's reduced reimbursement rates for 340B hospitals contravened the text and structure of the statute. *Id.*, at 835. In her view, "HHS may institute its large reductions, tailored for a distinct hospital group," only if the agency has conducted the required survey of hospitals' acquisition costs. *Ibid.* 

This Court granted certiorari. 594 U.S. \_\_\_ (2021).

П

HHS first argues that the Medicare statute precludes judicial review of the 2018 and 2019 reimbursement rates. See 42 U. S. C.  $\S1395l(t)(12)$ . The Court of Appeals rejected HHS's preclusion argument, as did the District Court. We likewise conclude that the statute does not preclude judicial review of HHS's reimbursement rates.

This Court has long recognized a "strong presumption" in favor of judicial review of final agency action. Weyerhaeuser Co. v. United States Fish and Wildlife Serv., 586 U. S. \_\_\_\_, \_\_\_ (2018) (slip op., at 11) (quoting Mach Mining, LLC v. EEOC, 575 U. S. 480, 489 (2015)). Judicial review of final agency action in an otherwise justiciable case is traditionally available unless "a statute's language or structure" precludes judicial review. Mach Mining, 575 U. S., at 486.

No provision in the Medicare statute precludes judicial

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review of the 2018 and 2019 reimbursement rates. Moreover, the detailed statutory formula for the reimbursement rates undermines HHS's suggestion that Congress implicitly granted the agency judicially unreviewable discretion to set the reimbursement rates. Cf. Weverhaeuser Co., 586 U. S., at \_\_\_\_\_ (slip op., at 13–14).

HHS cites two provisions— $\S1395l(t)(12)(A)$  and (C) that preclude judicial review of HHS's "development of the classification system under paragraph (2)" and "periodic adjustments made under paragraph [(9)]." But both of those provisions refer to the general payment methodology that HHS employs to set rates for other Medicare outpatient services. By contrast, when HHS sets rates for outpatient prescription drugs, it uses a different payment methodology namely, the methodology specified by paragraph (14) of  $\S1395l(t)$ . And nothing in the statute precludes judicial review of reimbursement rates set under paragraph (14).

HHS further argues that allowing judicial review of the 2018 and 2019 reimbursement rates would be impractical because the agency is required to operate the program on a budget-neutral basis. Due to that budget-neutrality requirement, HHS says that a judicial ruling invalidating the 2018 and 2019 reimbursement rates for certain hospitals would require offsets elsewhere in the program. The Hospitals respond that various potential remedies could make 340B hospitals whole for the past shortfalls without running afoul of the budget-neutrality provision. At this stage, we need not address potential remedies. Regardless, HHS's arguments against judicial review cannot override the text of the statute and the traditional presumption in favor of judicial review of administrative action.

In sum, HHS's preclusion argument lacks any textual basis. We agree with the District Court and the Court of Appeals that the Medicare statute does not preclude judicial review of the 2018 and 2019 reimbursement rates.

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#### Ш

We turn next to the merits. The question is this: If HHS has not conducted a survey of hospitals' acquisition costs, may HHS still vary the reimbursement rates for outpatient prescription drugs by hospital group? The answer is no.

The 2003 Medicare Act authorizes HHS to set reimbursement rates for covered outpatient prescription drugs provided by hospitals. The Act also specifies how HHS must reimbursement 42 those rates. U. S. C.  $\S1395l(t)(14)(A)$ . The statute therefore reflects a careful congressional focus not only on the goal of proper reimbursement rates, but also on the appropriate means to that end.

To reiterate, the statute affords HHS two options for setting reimbursement rates for outpatient drugs. Option 1 applies if HHS collects "hospital acquisition cost survey data" from hospitals. §1395l(t)(14)(A)(iii)(I). If the agency has conducted a survey and collected that data, then HHS may use the data to set reimbursement rates equal to "the average acquisition cost for the drug." *Ibid*. Importantly, in that circumstance, HHS may "vary" reimbursement rates "by hospital group." *Ibid*.

By contrast, if HHS does not conduct a survey of hospitals' acquisition costs and if acquisition cost data are therefore "not available," HHS must instead proceed under option 2 and obtain price data from drug manufacturers. §1395l(t)(14)(A)(iii)(II). And in that circumstance, HHS must set reimbursement rates based on "the average price for the drug" as "calculated and adjusted by the Secretary as necessary for purposes of" this statutory provision. *Ibid*. Critically, that second option does not authorize HHS to vary reimbursement rates by hospital group. Instead, HHS must set uniform reimbursement rates for all hospitals for each covered drug, and the rates must be equal to the average price for that drug for that year.

HHS's authority to proceed under option 1 and to vary

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reimbursement rates by hospital group thus depends on whether HHS has obtained acquisition cost survey data from hospitals. The statute expressly authorizes HHS to vary rates by hospital group if HHS has conducted such a survey. But the statute does not authorize such a variance in rates if HHS has not conducted a survey. Cf. *Babb* v. *Wilkie*, 589 U. S. \_\_\_, \_\_\_ (2020) (slip op., at 12); *Sandoz Inc.* v. *Amgen Inc.*, 582 U. S. \_\_\_, \_\_\_ (2017) (slip op., at 16); *Russello* v. *United States*, 464 U. S. 16, 23 (1983).

The statute thus protects all hospitals by imposing an important procedural prerequisite—namely, a survey of hospitals' acquisition costs for prescription drugs—before HHS may target particular groups of hospitals for lower reimbursement rates. The survey allows the agency to determine whether there is in fact meaningful, statistically significant variation among hospitals' acquisition costs. The data regarding variation in hospitals' acquisition costs in turn help HHS determine whether and how much it should vary the reimbursement rate among hospital groups. See  $\S1395l(t)(14)(D)(iii)$ —(iv). But absent that survey data, as Congress determined. HHS may not make "billion-dollar decisions differentiating among particular hospital groups." 967 F. 3d, at 837 (Pillard, J., dissenting).

In this case, all agree that HHS did not conduct a survey of hospitals' acquisition costs. See, *e.g.*, 82 Fed. Reg. 52501. HHS nonetheless varied the rates by hospital group, fixing a substantially lower reimbursement rate for 340B hospitals than for non-340B hospitals.

Under the text and structure of the statute, this case is therefore straightforward: Because HHS did not conduct a survey of hospitals' acquisition costs, HHS acted unlawfully by reducing the reimbursement rates for 340B hospitals.

HHS maintains that there is more to the case than that straightforward analysis would suggest. HHS emphasizes that even when it does not conduct a survey of acquisition costs and thus is required to employ option 2 (based on Cite as: 596 U.S. \_\_\_\_ (2022)

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price), the agency still may "adjus[t]" the average price "as necessary for purposes of" this statutory provision. \$1395l(t)(14)(A)(iii)(II).

It is true that the statutory text of option 2 affords HHS discretion to adjust the average price. The parties here vigorously debate how much HHS may adjust the price. To resolve this case, however, we need not determine the scope of HHS's authority to adjust the price up or down.

Regardless of the scope of HHS's authority to "adjust" the average price up or down under the statute, the statute does not grant HHS authority to vary the reimbursement rates by hospital group unless HHS has conducted the required survey of hospitals' acquisition costs. Under the statute, varying a rate by hospital group is not a lesser-included power of adjusting price. Otherwise stated, HHS's power to increase or decrease the price is distinct from its power to set different rates for different groups of hospitals.

The text of option 2 confirms the point. It requires reimbursement in an "amount" that is equal to "the average price for the drug in the year." *Ibid*. The text thus requires the reimbursement rate to be set drug by drug, not hospital by hospital or hospital group by hospital group. The only item that the agency is allowed to adjust is the "average price for the drug in the year." *Ibid*. Such an adjustment can consist of moving the average-price number up or down, but it cannot consist of giving a single drug two different average prices for two different groups of hospitals. (Tellingly, before 2018, the agency never used its adjustment authority to vary reimbursement rates by hospital group.)

Moreover, HHS's contrary interpretation of the statute—and its broad understanding of its adjustment authority—would make little sense given the statute's overall structure. To proceed under option 1 (based on cost) and vary the rate by hospital group, HHS must conduct a survey. In HHS's view, the agency can decline to conduct a survey and can proceed under option 2, and then can still do everything

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under option 2 that it could do under option 1—including varying the reimbursement rates by hospital group. So under HHS's interpretation, the agency would never need to conduct a survey of hospitals' acquisition costs. But why, then, would Congress have constructed this elaborate statute premised on HHS's surveys of hospitals' acquisition costs, including specifying when HHS could vary reimbursement rates by hospital group? HHS has no good answer to that question.

HHS's interpretation not only would render irrelevant the survey prerequisite for varying reimbursement rates by hospital group, but also would render largely irrelevant the provision of the statute that precisely details the requirements for surveys of hospitals' acquisition costs.  $\S1395l(t)(14)(D)$ . We must hesitate to adopt an interpretation that would eviscerate such significant aspects of the statutory text. See, e.g., Chicago v. Fulton, 592 U.S. (2021) (slip op., at 5); Maine Community Health Options v. United States, 590 U.S. \_\_\_\_, \_\_\_ (2020) (slip op., at 16); Whitman v. American Trucking Assns., Inc., 531 U.S. 457, 484-485 (2001).

In short, the statute allows HHS to set reimbursement rates based on average price and affords the agency discretion to "adjust" the price up or down. But unless HHS conducts a survey of hospitals' acquisition costs, HHS may not vary the reimbursement rates by hospital group.

As a final argument, HHS insists that Congress could not have intended for the agency to "overpay" 340B hospitals for prescription drugs. But when enacting this statute in 2003, Congress was well aware that 340B hospitals paid less for covered prescription drugs. After all, that had been the law for the duration of the 340B program, which began in 1992. In 2003, Congress nonetheless did not see fit to differentiate 340B hospitals from other hospitals when requiring that the reimbursement rates be uniform under option 2. And for more than a decade after this statute took Cite as: 596 U.S. \_\_\_\_ (2022)

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effect, HHS employed option 2 but did not differentiate 340B hospitals from other hospitals—an agency practice that was known in the wider hospital industry and in Congress.

If HHS believes that this Medicare reimbursement program overpays 340B hospitals, it may conduct a survey of hospitals' acquisition costs to determine whether and how much the data justify varying the reimbursement rates by hospital group—for example, reducing reimbursement rates paid to 340B hospitals as compared to other hospitals. Or if the statute's requirement of an acquisition cost survey is bad policy or is working in unintended ways, HHS can ask Congress to change the law.

Of course, if HHS went to Congress, the agency would presumably have to confront the other side of the policy story here: 340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support. As amici before this Court, many 340B hospitals contend that the Medicare reimbursement payments at issue here "help offset the considerable costs" that 340B providers "incur by providing health care to the uninsured, underinsured, and those who live far from hospitals and clinics." Brief for 37 State and Regional Hospital Associations as Amici Curiae 7. As the 340B hospitals see it, the "net effect" of HHS's 2018 and 2019 rules is "to redistribute funds from financially strapped, public and nonprofit safety-net hospitals serving vulnerable populations—including patients without any insurance at all—to facilities and individuals who are relatively better off." 967 F. 3d, at 840 (Pillard, J., dissenting). In other words, in the view of those hospitals, HHS's new rates eliminate the federal subsidy that has helped keep 340B hospitals afloat. All of which is to say that the 340B story may be more complicated than HHS portrays it. In all events, this Court is not the forum to resolve that policy debate.

In sum, after employing the traditional tools of statutory

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interpretation, we do not agree with HHS's interpretation of the statute. We conclude that, absent a survey of hospitals' acquisition costs, HHS may not vary the reimbursement rates for 340B hospitals. HHS's 2018 and 2019 reimbursement rates for 340B hospitals were therefore contrary to the statute and unlawful.

\* \* \*

We reverse the judgment of the U. S. Court of Appeals for the D. C. Circuit and remand the case for further proceedings consistent with this opinion.

It is so ordered.

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