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. §1395*l*(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." §1395*l*(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 drug as "calculated and adjusted by the Secretary." §1395*l*(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

Syllabus

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. See §§1395*l*(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. 7–9.

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." §1395*l*(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'

Syllabus

acquisition costs. See §1395*l*(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.

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

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. §1395*l*(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

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.