Nos. 19-5048 & 19-5198

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

THE AMERICAN HOSPITAL ASSOCIATION, et al.,

Plaintiffs-Appellees,

v.

ALEX M. AZAR II, in his official capacity as the Secretary of Health and Human Services, et al.,

Defendants-Appellants.

On Appeal from the United States District Court for the District of Columbia, No. 1:18-cv-02084

APPELLEES' PETITION FOR REHEARING EN BANC

William B. Schultz
Margaret M. Dotzel
Ezra B. Marcus
ZUCKERMAN SPAEDER LLP
1800 M Street NW, Suite 1000
Washington, DC 20036
Tel: (202) 778-1800
Fax: (202) 822-8106

Donald B. Verrilli, Jr.
Jeremy S. Kreisberg
MUNGER, TOLLES & OLSON LLP
1155 F Street NW, 7th Floor
Washington, DC 20004
Tel: (202) 220-1100
Fax: (202) 220-2300
Donald.Verrilli@mto.com

Attorneys for Plaintiffs-Appellees

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

FEDERAL CASES

FEDERAL STATUTES

FEDERAL RULES

TABLE OF AUTHORITIES
(Continued)

GLOSSARY

340B	Section 340B of the Public Health Service Act (42 U.S.C. § 256b)
AHA	American Hospital Association
ASP	Average Sales Price
HHS	U.S. Department of Health and Human Services

INTRODUCTION AND RULE 35(b)(1) STATEMENT

Each year, the Department of Health and Human Services (HHS) issues a rule with billions of dollars of implications for hospitals and the patients they serve: it determines the amount that Medicare will reimburse for vital prescription drugs. Since Congress enacted the relevant statutory scheme, HHS has carried out its mission by setting forth a uniform reimbursement formula based on the sales price of each drug—a formula that governed every hospital in the nation. That practice was in strict accord with the statutory scheme, which prohibits HHS from "vary[ing] by hospital group" the amount Medicare reimburses, or setting reimbursement rates based on average cost rather than average sales price, *unless* HHS considers a robust set of "hospital acquisition cost survey data"—data that HHS has never collected. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I), (II).

In 2017, HHS departed from its longstanding practice. The Department purported to find, hiding in plain sight, a statutory lever to do *without* the necessary data precisely what Congress said it could do only *with* the necessary data. The statute, HHS observed, permits the Secretary to "adjust" the rate for drug payments even if hospital acquisition cost survey data are not available. 82 Fed. Reg. 52,356, 52,500 (Nov. 13, 2017). That authority, in HHS's newfound view, is not limited to "minor changes" in how HHS calculates the payment rate, but instead provides HHS with "broad discretion" to set payment rates as it chooses. *Id.* According to HHS,

that discretion includes even the vast power to pay some hospitals more than others—to pick winners and losers in the allocation of billions of dollars. *Id.*

In the few years since HHS arrived at this view, the only losers under HHS's novel use of its "adjustment" authority have been certain 340B Hospitals—public and nonprofit hospitals that care for the nation's most underserved communities. These hospitals receive discounts on their drug costs pursuant to the 340B Program—a statutory initiative that enables financially vulnerable hospitals to retain savings from discounted drugs to ensure they have sufficient funding to provide essential services to low-income patients. In the rule at issue, HHS "recognize[d] the intent of the 340B program," but came to a judgment different than Congress: HHS declared it "inappropriate for Medicare to subsidize other activities" by 340B Hospitals. *Id.* at 52,495. HHS accordingly slashed drug reimbursements to nearly all 340B Hospitals, cutting them by about 30% and imposing devastating losses on those hospitals.

In this challenge to HHS's novel view of its authority, the district court held that HHS had acted *ultra vires*. But a panel of this Court reversed over Judge Pillard's dissent.

En banc rehearing is warranted for two reasons:

First, the panel decision conflicts with Circuit precedent. *See* Fed. R. App. P. 35(b)(1)(A). In *Amgen, Inc. v. Smith*, 357 F.3d 103 (D.C. Cir. 2004), this Court held

as to an analogous provision of the Medicare Act that HHS cannot invoke its "adjustment" authority to "work 'basic and fundamental changes in the scheme' Congress created." *Id.* at 117 (citation omitted) To the contrary, "similar limits inhere in the term 'adjustments' to those the Supreme Court found in the word 'modify,'" *id.*—a term the Court limited to "moderate[]" or "minor" changes, *MCI Telecomms. Corp. v. Am. Tel. & Tel. Corp.*, 512 U.S. 218, 225 (1994). The panel here held to the contrary: it *rejected* the argument that the term "adjust" refers "only to minor changes," suggesting that there may be no "limits to what HHS could permissibly consider an 'adjustment.'" Majority 29. That is a clear departure from settled precedent.

Second, the panel erred on a question of exceptional importance. *See* Fed. R. App. P. 35(b)(1)(B). For decades, 340B Hospitals relied on savings from high-priced prescription drugs to serve the low-income communities that depend on them. HHS's rate cut, if upheld, would deprive these financially vulnerable hospitals of about $1.6 billion per year—threatening their ability to care for patients who need it most. It is critical that this Court enforce the limits that Congress placed on HHS's authority—limits that prevent HHS from singling out 340B Hospitals for abrupt, disfavored treatment.

BACKGROUND

A. Legal and Factual Background.

HHS sets the amount that Medicare reimburses for separately payable drugs according to a statutory scheme enacted within the Medicare Modernization Act of 2003. The statute provides that the reimbursement rate is equal—

> (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 [outpatient department] services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D); or
>
> (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.

42 U.S.C. § 1395*l*(t)(14)(A)(iii). These provisions (hereinafter Subclause (I) and Subclause (II)) are "subject to subparagraph (E)," *id.*, which authorizes HHS to make "[a]djustment[s] in payment rates for overhead costs," *id.* § 1395*l*(t)(14)(E).

Central to this statutory scheme is the availability of "hospital acquisition cost survey data." *Id.* § 1395*l*(t)(14)(A)(iii). If HHS has collected such data, it proceeds under Subclause (I), which directs HHS to set payments rates according to "average acquisition cost" and permits HHS to "vary" rates by "hospital group." *Id.* If HHS has not collected this data, it must proceed under Subclause (II), which directs HHS to set payment rates equal to a statutory default based on each drug's average sales

price (ASP)—specifically, ASP+6%. *See id.*; *id.* § 1395w-3a. That payment rate is "calculated," and may be "adjusted," by HHS. *Id.* § 1395(t)(14)(A)(iii)(II).

Congress prescribed strict, detailed requirements that define when sufficient "hospital acquisition cost survey data" have been collected. Among them, HHS must use a "large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug." *Id.* § 1395(t)(14)(D)(iii).

HHS has never collected acquisition-cost data that meets Congress's criteria. Accordingly, from 2006 to 2016, HHS consistently set the payment rate for separately payable drugs using a uniform rate of ASP plus a small fixed percentage. While HHS varied the rate from ASP+4% to ASP+6%, generally to account for overhead costs, *see* 77 Fed. Reg. 68,210, 68,383-86 (Nov. 15, 2012), it always applied the same rate to all hospitals.

That changed in 2017, when HHS for the first time set a payment rate for one hospital group different from the one it set for all others. HHS specifically singled out participants in the 340B Program. Under the 340B Program, prescription-drug manufacturers must offer participating hospitals that serve low-income communities a discount on certain drug costs. *See* 42 U.S.C. § 256b(a)(1). Congress created that Program "to stretch scarce Federal resources as far as possible" by pushing 340B Hospitals' drug costs below the amount that insurers reimburse. H.R. Rep. No. 102-

384, pt. 2, at 12 (1992). In 2017, HHS determined that Congress's decision to ensure 340B Hospitals benefit from prescription-drug savings was no longer good policy; HHS "recognize[d] the intent of the 340B Program," but decided that "it is inappropriate for Medicare to subsidize other activities through Medicare payments." 82 Fed. Reg. at 52,495. Accordingly, HHS slashed drug payments to most 340B Hospitals by nearly 30%, to ASP *minus* 22.5%, while retaining a payment rate of ASP+6% for all others.[1]

As support for its novel, non-uniform cut, HHS invoked its authority to "adjust[]" drug payments under Subclause (II), insisting that it grants "broad discretion to adjust payments for drugs"—discretion that is not "limited to what some might consider minor changes." *Id.* at 52,500. HHS candidly acknowledged that its rate cut for 340B Hospitals was intended to approximate acquisition costs, and that it had *not* collected the acquisition-cost data that Congress specified. But in the Department's view, that was of no moment; as long as HHS provided "a reasoned explanation" for its cut, it claimed it could act "in the absence of acquisition cost [data]." *Id.* at 52,501. HHS thus found a substitute data source it believed suitable and relied on that source, rather than the data Congress mandated for

[1] HHS exempted a small number of 340B Hospitals. *See* 82 Fed. Reg. at 52,493-511.

determining acquisition costs, in fashioning a rate cut for 340B Hospitals. *Id.* at 52,496.

B. Procedural Background.

Plaintiffs, hospital associations and member hospitals that participate in the 340B Program, sued to enjoin the rate cut.

The district court sided with Plaintiffs. JA61-96. The court rejected as "plainly wrong" HHS's view that "the statute's text does not impose any limits on the [Department's] authority to adjust rates." JA84. Indeed, the court explained, the "D.C. Circuit held as much under nearly identical circumstances in *Amgen*[, *Inc. v. Smith*]." *Id.* That case placed strict limits on HHS's authority to make "adjustments" under a "different, but related, Medicare provision." *Id.* The court held that "*Amgen*'s logic applies equally here" not only because the same words in the same statute generally bear the same meaning, but also because "the Medicare subsection at issue in *Amgen* followed [the] very same structure" as the statute here. JA85. The court thus applied *Amgen*, and straightforwardly determined that it barred HHS's rate cut for 340B Hospitals. *See* JA88-89.

A panel of this Court reversed 2-1. The panel majority did not conclude that HHS's interpretation was the best reading of the statute. Instead, invoking *Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842 (1984)—which HHS raised for the first time in a post-argument letter (Majority 18)—the majority

concluded that HHS's "adjustment" of 340B Hospitals' payment rates was a "permissible" reading of the statute. Majority 28. The majority acknowledged that the statute requires HHS to "take 'into account the hospital acquisition cost survey data'" that Congress specified if its "payment amounts are keyed to 'average acquisition cost.'" *Id.* at 23 (citation omitted). And the majority credited as "not without force" Plaintiffs' argument that, under HHS's interpretation, that requirement would be "meaningless." *Id.* at 23-24. But in the majority's view, Plaintiffs' argument nevertheless fails because the statute does not unambiguously prohibit HHS from using other "reliable cost measures." *Id.* at 24.

As to *Amgen*, the majority stated that it does "not read *Amgen* to prescribe that 'adjust' in the [relevant] statute refers only to minor changes." *Id.* at 29. And "[e]ven if there are limits to what HHS could permissibly consider an 'adjustment,'" which the majority did not concede, the "line" had not been "crossed" because "the agency acted on a conservative estimate" of 340B Hospitals' acquisition costs. *Id.*

Judge Pillard dissented. In her view, the rate cut could not be upheld under *Chevron* because the statute is unambiguous: "Only subclause (I), not subclause (II), authorizes HHS to set different reimbursement rates for distinct hospital groups," and it provides that authority only if HHS "tak[es] into account the different acquisition costs identified in the robust, hospital-specific data that Congress required." Dissent 4. The majority opinion, she explained, contravenes *Amgen*

because it allows HHS to use its "adjustment" authority to work "basic and fundamental changes" to the statutory scheme. *Id.* at 7 (citation omitted). Indeed, HHS's interpretation "essentially reads subclause (I) out of the statute" and "drains" of "meaning" each of the criteria that Congress established for the collection of adequate acquisition-cost data. *Id.* at 8-9. Though the majority echoed HHS's policy-based justifications for relying on other data sources, Judge Pillard explained that policy arguments "cannot somehow authorize the agency to do what the statute does not." *Id.* at 10.

In any event, Judge Pillard did not find HHS's policy arguments persuasive. 340B Hospitals, she explained, "[o]ften operat[e] at substantial losses" and thus "rely on the revenue that Medicare Part B provides in the form of standard drug-reimbursement payments that exceed those hospitals' acquisition costs." *Id.* at 11. They use their "additional resources to provide critical healthcare services to communities with underserved populations that could not otherwise afford these services." *Id.* (citation omitted). HHS's rate cut "redistribute[s] funds" from these "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." *Id.* at 12. As Judge Pillard saw it, Congress is free to pursue that policy, but "the statute as it is written" does not. *Id.*

This Petition follows.

ARGUMENT

I. The Panel Decision Conflicts with this Court's Precedent.

The Court should grant rehearing because the panel decision conflicts with *Amgen, Inc. v. Smith*, 357 F.3d 103.

In *Amgen*, this Court addressed (as here) a statute authorizing HHS to make "adjustments" to Medicare payments for certain outpatient services. Specifically at issue was HHS's authority to make "adjustments as determined to be necessary to ensure equitable payments." 42 U.S.C. § 1395*l*(t)(2)(E). HHS had used that authority to reduce payments for one of Amgen's drugs, and Amgen challenged the action as *ultra vires*.

This Court ultimately rejected Amgen's challenge, but in doing so established strict limits on HHS's "adjustment" authority. This Court explained that "similar limits inhere in the term 'adjustments' to those the Supreme Court found in the word 'modify.'" *Amgen*, 357 F.3d at 117. Those limits, under Supreme Court precedent, restrict agencies to "moderate[]" or "minor" changes. *MCI*, 512 U.S. at 225.[2] *Amgen* applied those limits to HHS's equitable "adjustment" authority: It held that HHS stays within the limits of that authority only if its action "does not work 'basic and fundamental changes in the scheme' Congress created," but is "rather of the sort

[2] The Supreme Court's decision echoed the limits established by this Court. *See Am. Tel. & Tel. Co. v. FCC*, 978 F.2d 727, 736 (D.C. Cir. 1992).

contemplated by the plain text" of the statute. *Amgen*, 357 F.3d at 117 (citing *MCI*, 512 U.S. at 225).

The panel here confronted materially identical circumstances. Here too, the statutory scheme concerns HHS's authority to set Medicare payment rates. Here too, the statutory process for setting such rates is subject to HHS's authority to "adjust[]" them. And here too, the challenge concerns whether HHS has exceeded its "adjustment" authority.

The panel majority did not dispute any of this—yet it wholly departed from the limits *Amgen* established. *Amgen* was explicit that "adjustments" are limited in the same way that "modifications" are; they must be moderate or minor changes. But the majority inexplicably did "not read *Amgen* to prescribe that 'adjust' in the [relevant] statute refers only to minor changes." Majority 29. It instead determined based on purported distinctions in dictionary definitions that the "term 'adjust' is ambiguous as to size," and thus deferred to HHS's expansive interpretation as a supposedly "straightforward application of *Chevron*." *Id.* at 28. The majority was candid about the consequences of its interpretation: there may be no "limits to what HHS could permissibly consider an 'adjustment.'" *Id.* at 29. That unbounded interpretation of HHS's authority is plainly irreconcilable with *Amgen*—not to mention the limits on *Chevron* deference set forth by the Supreme Court in comparable circumstances in *MCI*.

The conflict between the panel decision and *Amgen* does not end there. The majority held that even if *Amgen*'s limits apply, they had "not been crossed here" because the ~30% cut HHS imposed was based on a "conservative estimate" of 340B Hospitals' acquisition costs. *Id.* at 29. In other words, the panel determined that *Amgen*'s limits had not been crossed because HHS had not acted arbitrarily. But that is not the inquiry that *Amgen* demands. Under *Amgen*, courts determine whether an "adjustment" is sufficiently minor by asking whether it works "'basic and fundamental changes in the scheme' Congress created." 357 F.3d at 117 (citation omitted). The focus is on the *statute* Congress enacted, not the *policy* the agency achieved.

The majority's failure to ask the right question may well explain its curious conclusion. The statutory scheme here could hardly be clearer: It permits HHS to "vary by hospital group" payment rates for covered drugs based on "average acquisition cost" only if it has collected "hospital acquisition cost survey data" that meet congressionally defined specifications. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I). HHS's newfound view fundamentally changes that scheme: It permits HHS to vary by hospital group payment rates for covered drugs based on average acquisition cost *without* the data that Congress required. Whatever the benefits of HHS's alternative policy, its "adjustment" authority is not a license to override Congress's specific instructions, which require HHS to base differential payment rates on the particular

data that Congress defined. The panel majority simply wrote that requirement out of the statute.

It is imperative that this Court resolve the split between *Amgen* and the panel to restore uniformity in a critical area of this Court's jurisprudence. HHS, along with every other federal agency, looks to this Court to provide clear guidance on agency authority. That is especially true as to the issue here, because the term "adjust" and its variants pepper the U.S. Code. But an agency reviewing *Amgen* alongside the panel decision would find no clear guidance. The former recognizes limits on agency "adjustment" authority and restricts such authority to minor changes, while the latter questions whether there are *any* limits on agency "adjustment" authority and *rejects* the view that "adjustments" must be minor. Agency counsel would be lost in advising policymakers how to proceed.

Rehearing is likewise critical because, as to the interpretive split between *Amgen* and the panel, the panel's approach is mistaken. Numerous dictionaries explicitly limit "adjustments" to "slight" or "minor" changes. *See* AHA Br. 48 n.25. That understanding comports not only with the term's ordinary usage, but also its etymology; the word "adjust" derives from the Latin word *adiuxtare*—meaning "to put close to."[3] *Cf. MCI*, 512 U.S. at 225 (interpreting "modify" based on its Latin

[3] *Adjust*, American Heritage Dictionary, https://ahdictionary.com/word/search.html?q=adjust.

root). HHS (and the majority) cited some definitions that omit quantitative limitations. *See* Opening Br. 33 n.5; Majority 28. But that is even less support than the government invoked (unsuccessfully) in *MCI*, where the government found a dictionary that defined "modify" as "to make a basic or important change." 512 U.S. at 225-26. Here, HHS has not offered a single definition of "adjust" that supports its expansive interpretation. And even if HHS could find one, *MCI* squarely rejected the argument that competing dictionary definitions are sufficient to create ambiguity under *Chevron* where there is no genuine split between "accepted alternative meanings" of a term. *See id.* at 225-27.

Finally, the panel's departure from *Amgen* risks a dramatic expansion in regulatory power. The settled understanding before the panel decision was that, under *MCI* and this Court's cases that followed, an agency may not invoke "vague terms or ancillary provisions" to make major changes in a regulatory scheme—indeed, to find "elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001). Yet the panel decision is a license for agencies to do precisely that—to rely on the "adjustment" authority that runs throughout the U.S. Code to achieve any policy end an agency desires. That unrestrained approach to administrative law is contrary to precedent and to Congress's design.

II. The Panel Erred on a Question of Exceptional Importance.

Even if the panel decision could be reconciled with *Amgen*, rehearing en banc remains necessary because this case is exceptionally important—both to 340B Hospitals, and to the Medicare program more broadly.

The 340B Program includes thousands of participating hospitals, all of which are public hospitals or private nonprofit hospitals that provide safety-net services to medically underserved communities. Those services are vital, ranging from trauma care, to pediatric surgery, to obstetrics, to psychiatric care—and are provided at a far higher rate by 340B Hospitals than hospitals writ large. D.D.C. Dkt. 2-6 (AHA Comment) at 10. The provision of these services carries with it a large financial cost: 340B Hospitals provide tens of billions of dollars annually in uncompensated care. *Id.*[4] As a result, 340B Hospitals are financially vulnerable, with a significant percentage running a negative operating margin. *Id.* at 11.

For 25 years, these hospitals relied on savings from the otherwise exorbitant prices of prescription drugs made possible by the 340B Program. Those savings "support[ed] the financial stability" of hospitals that might otherwise have fallen

[4] *See* Am. Hosp. Ass'n, *340B Hospital Community Benefit Analysis* (2020), https://www.aha.org/system/files/media/file/2020/09/340b-community-benefits-analysis-report.pdf (finding that tax-exempt 340B Hospitals provided $64.3 billion of community benefits in 2017).

under the weight of their precarious financial position.[5] They allowed many 340B Hospitals to "maintain services" that are essential to their communities, and allowed still others to "serve more patients" and "provide services that they might not have otherwise provided."[6] All of this directly furthered Congress's goal of ensuring that the underserved would have a financially stable safety net.

The rate cut at issue here strikes at the heart of the 340B Program, subverting the statutory scheme and devastating its intended beneficiaries. "Under the design of the 340B Program and Part B payment rules, the difference between what Medicare pays and what it costs to acquire" drugs allows 340B Hospitals "to stretch scarce Federal dollars in service to their communities." HHS Office of Inspector General, *Part B Payments for 340B-Purchased Drugs* at i (Nov. 2015). But that is no longer possible after HHS's rate cut, which eliminates the payment gap on which the Program is premised. *Contra Can-Am Plumbing, Inc. v. NLRB*, 321 F.3d 145, 154 (D.C. Cir. 2003) (agencies must "minimize[] the impact of its actions on the policies" of other statutes).

The consequences of subverting the 340B Program will be dire. HHS's rate cut takes away $1.6 billion per year from participating entities, many of which are

[5] U.S. Gov't Accountability Office, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* at 17 (Sept. 2011), https://www.gao.gov/assets/330/323702.pdf.

[6] *Id.*

already on the financial brink. 82 Fed. Reg. at 52,623. That cut will threaten the ability of 340B Hospitals to maintain their services to vulnerable communities—a risk that is especially acute as a pandemic continues to sweep the nation with a disproportionate effect on low-income and minority populations. Before HHS is able to inflict such a devastating blow to safety-net hospitals and their patients, the full Court should review HHS's authority.

This case is exceptionally important for another reason as well: it will determine the scope of HHS's power in distributing billions of dollars in taxpayer funds each year. The Medicare program spends tens of billions of dollars annually reimbursing hospitals and other providers for prescription drugs. Previously HHS had always determined its drug reimbursements according to a uniform formula, applicable to every participating hospital in the nation. But if the rate cut here is sustained, HHS will have a brand new authority—the power to pay some providers more than others, unconstrained by the data that Congress mandated.

Determining whether "billion-dollar decisions differentiating among particular hospital groups [may] rest on significantly less exact information" than Congress thought required is an exceptionally important issue. Dissent 6. The four judges to review it thus far have split down the middle. The full Court should provide a final resolution.

CONCLUSION

The Court should rehear this case en banc and affirm the district court.

Respectfully submitted,

September 14, 2020

Donald B. Verrilli, Jr.
Jeremy S. Kreisberg
MUNGER, TOLLES & OLSON LLP
1155 F Street NW, 7th Floor
Washington, DC 20004
Tel: (202) 220-1100
Fax: (202) 220-2300
Donald.Verrilli@mto.com

William B. Schultz
Margaret M. Dotzel
Ezra B. Marcus
ZUCKERMAN SPAEDER LLP
1800 M Street NW, Suite 1000
Washington, DC 20036
Tel: (202) 778-1800
Fax: (202) 822-8106

Attorneys for Plaintiffs-Appellees

CERTIFICATE OF COMPLIANCE

I certify that the foregoing Petition for Rehearing En Banc complies with the type-volume limitation of Federal Rule of Appellate Procedure 35(b)(2)(A) because it contains 3896 words, excluding the parts of the Petition exempted by Federal Rule of Appellate Procedure 32(f).

This Petition complies with the type-face requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word and with 14-point Times New Roman font.

September 14, 2020

/s/ *Donald B. Verrilli, Jr.*
Donald B. Verrilli, Jr.

CERTIFICATE OF SERVICE

I hereby certify that on September 14, 2020, I caused the foregoing to be electronically filed with the Court using the CM/ECF system. All parties to the case have been served through the CM/ECF system.

September 14, 2020

/s/ *Donald B. Verrilli, Jr.*
Donald B. Verrilli, Jr.

ADDENDUM

Certificate as to Parties, Rulings, and Related Cases

Pursuant to Circuit Rule 35(c), and in accordance with Circuit Rule 28(a)(1), counsel for Appellees makes the following certifications:

A. Parties and Amici Curiae. Plaintiffs-Appellees are the American Hospital Association, the Association of American Medical Colleges, America's Essential Hospitals, Northern Light Health, Henry Ford Health System, and Fletcher Hospital, Inc., d/b/a AdventHealth Hendersonville. Defendants-Appellants are Alex M. Azar II, in his official capacity as Secretary of Health and Human Services, and the United States Department of Health and Human Services. The Federation of American Hospitals participated as amicus curiae in district court and in this Court.

B. Rulings Under Review. The district court rulings at issue in this case are the opinion and order entering final judgment on July 10, 2019 (Dkt. Nos. 58, 59); and all prior orders and decisions that merge into the final judgment, including the December 27, 2018 opinion and order (Dkt. Nos. 24, 25), and the May 6, 2019 opinion and order (Dkt. Nos. 49, 50). Those rulings were issued by the Honorable Rudolph Contreras in Case No. 1:18-cv-02084 (D.D.C.). The December 27, 2018 opinion is reported at 338 F. Supp. 3d 62. The May 6, 2019 opinion is reported at 385 F. Supp. 3d 1. The July 10, 2019 opinion is unreported but available at 2019 WL 3037306. In this Petition, Appellees seek rehearing en banc of the opinion and judgment dated July 31, 2020, issued by the panel (Srinivasan, C.J., and Millett, J.;

Pillard, J., dissenting), which reversed the judgment of the district court. The opinion of the panel is included in this Addendum and is reported at 967 F.3d 818.

C. Related Cases. This Court previously issued an opinion as to jurisdiction involving the same dispute between the same parties. *See American Hosp. Ass'n v. Azar*, 895 F.3d 822 (D.C. Cir. 2018). In this case, the government initially filed a notice of appeal as to the district court's December 27, 2018 order. This Court held that appeal in abeyance pending further district court proceedings. After the district court entered final judgment, this Court consolidated the earlier appeal (No. 19-5048) with the appeal from final judgment (No. 19-5198). We are not aware of any pending related cases within the meaning of Circuit Rule 28.

September 14, 2020

/s/ *Donald B. Verrilli, Jr.*
Donald B. Verrilli, Jr.

Disclosure Statement Pursuant to Circuit Rule 26.1

Appellees American Hospital Association (AHA), the Association of American Medical Colleges (AAMC), America's Essential Hospitals (AEH), Northern Light Health, Henry Ford Health System (Henry Ford), and Fletcher Hospital, Inc., d/b/a AdventHealth Hendersonville state as follows:

Appellee AHA is a not-for-profit association headquartered in Washington, D.C. It represents and serves nearly 5,000 hospitals, healthcare systems, and networks, plus 43,000 individual members. Its mission is to advance the health of individuals and communities by leading, representing, and serving the hospitals, health systems, and other related organizations that are accountable to the community and committed to health improvement.

Appellee AAMC is a not-for-profit association headquartered in Washington, D.C. Its membership consists of all 154 accredited U.S. and 17 accredited Canadian medical schools, nearly 400 major teaching hospitals and health systems, and more than 80 academic societies. AAMC is dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research.

Appellee AEH is a not-for-profit association headquartered in Washington, D.C. It represents 325 hospital members that are vital to their communities, providing primary care through trauma care, disaster response, health professional

training, research, public health programs, and other services. AEH is a champion for hospitals and health systems dedicated to high-quality care for all, including the most vulnerable.

Appellee Northern Light Health is a not-for-profit integrated health care system headquartered in Brewer, ME. The system provides a broad range of health care and related services in Northern, Eastern, and Southern Maine through its subsidiaries and affiliated entities, including to poor and vulnerable persons in those communities.

Appellee Henry Ford is a not-for-profit health care system headquartered in Detroit, MI. The system provides a broad range of health care and related services to the people of southeastern and southcentral Michigan, including poor and vulnerable persons in those communities.

Appellee AdventHealth Hendersonville is a not-for-profit health care system headquartered in Hendersonville, NC. It is a member of AdventHealth, a faith-based not-for-profit health care system that provides health care services to communities in nine states. AdventHealth Hendersonville in particular provides health care and related services at 30 locations across Henderson, Buncombe, and Haywood Counties in North Carolina, including poor and vulnerable persons in those communities.

No publicly held corporation has a 10 percent or greater ownership interest in any Appellee.

September 14, 2020

/s/ *Donald B. Verrilli, Jr.*
Donald B. Verrilli, Jr.

Panel Opinion

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued November 8, 2019 Decided July 31, 2020

No. 19-5048

AMERICAN HOSPITAL ASSOCIATION, ET AL.,
APPELLEES

v.

ALEX MICHAEL AZAR, II, IN HIS OFFICIAL CAPACITY AS THE SECRETARY OF HEALTH AND HUMAN SERVICES AND UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
APPELLANTS

Consolidated with 19-5198

Appeals from the United States District Court
for the District of Columbia
(No. 1:18-cv-02084)

Alisa B. Klein, Attorney, U.S. Department of Justice, argued the cause for appellants. With her on the briefs were *Mark B. Stern* and *Laura E. Myron*, Attorneys, *Robert P. Charrow*, General Counsel, U.S. Department of Health & Human Services, *Janice L. Hoffman*, Associate General Counsel, *Susan Maxson Lyons*, Deputy Associate General Counsel for Litigation, and *Robert W. Balderston*, Attorney.

Thomas R. Barker and *Andrew M. London* were on the brief for *amicus curiae* Federation of American Hospitals in support of defendants-appellants.

William B. Schultz argued the cause for plaintiffs-appellees. With him on the brief was *Margaret M. Dotzel*.

Before: SRINIVASAN, *Chief Judge*, and MILLETT and PILLARD, *Circuit Judges*.

Opinion for the Court filed by *Chief Judge* SRINIVASAN.

Opinion dissenting in part filed by *Circuit Judge* PILLARD.

SRINIVASAN, *Chief Judge*: When hospitals provide outpatient care to patients insured by Medicare Part B, the federal government reimburses the hospitals for the care. Until recently, the government reimbursed all hospitals at a uniform rate for providing covered drugs. In 2018, though, the Department of Health and Human Services reduced the reimbursement rate for covered drugs by 28.5% for certain hospitals known as "340B hospitals" by virtue of their participation in the federal 340B Drug Pricing Program for underserved populations. HHS cut the reimbursement rate for 340B hospitals because they can obtain drugs far more cheaply than other hospitals. As HHS saw it, Medicare should not reimburse hospitals more than they paid to acquire the drugs.

Several hospitals and hospital associations challenge HHS's decision, claiming that it rests on an impermissible construction of the governing statute. The district court agreed with the plaintiffs that HHS had exceeded its statutory authority by reducing drug reimbursement rates for 340B hospitals. We disagree. We hold that HHS's decision to lower

drug reimbursement rates for 340B hospitals rests on a reasonable interpretation of the Medicare statute.

I.

A.

The Medicare program provides health insurance to the elderly and disabled. Medicare Part A provides coverage for inpatient care, i.e., care provided while a patient is admitted to a hospital or skilled nursing facility. Medicare Part B covers various other services including outpatient (or same-day) hospital care. Part B thus pays for certain drugs, such as immunosuppressants or chemotherapy drugs, administered in a hospital setting on an outpatient basis. Part B beneficiaries generally pay 20% of their bill out of pocket as coinsurance.

The Department of Health and Human Services (HHS) annually establishes Part B reimbursement rates through notice-and-comment rulemaking. In setting the rates, HHS uses the "Outpatient Prospective Payment System," or OPPS. *See* 42 U.S.C. § 1395*l*(t). *See generally Am. Hosp. Ass'n v. Azar*, No. 19-5352, slip op. at 3–6 (D.C. Cir. July 17, 2020). The OPPS requires HHS to fix the amounts it will pay providers for certain services before the year begins (rather than after the care has been provided). Congress moved to that prospective system to enhance HHS's ability to control Part B costs. *See* Medicare Program; Prospective Payment System for Hospital Outpatient Services, 65 Fed. Reg. 18,434, 18,436–37 (Apr. 7, 2000); *Paladin Cmty. Mental Health Ctr. v. Sebelius*, 684 F.3d 527, 528–29 (5th Cir. 2012).

For most types of covered care, the Medicare statute instructs HHS to set annual OPPS reimbursement rates through a complex formula that gives the agency significant discretion.

See 42 U.S.C. § 1395*l*(t)(2). For certain kinds of services, however, the OPPS limits that discretion and sets out a specific methodology for calculating payment rates. That is the case for certain drugs covered by Part B, known as "specified covered outpatient drugs" or SCODs.

The statute requires HHS to calculate the reimbursement rate for SCODs in one of two ways. First, under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I), which we will refer to as subclause (I), HHS may use "the average acquisition cost for the drug . . . as determined by the Secretary taking into account . . . hospital acquisition cost survey data." Second, under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II), which we call subclause (II), "if hospital acquisition cost data are not available," HHS must use "the average price for the drug" as established by a separate, cross-referenced statute. In the event HHS uses average price under subclause (II), that price metric may be "adjusted by [HHS] as necessary for purposes of this paragraph." *Id.*

Since 2006, when those two statutory pricing alternatives took effect, HHS has not had the "hospital acquisition cost survey data" contemplated by subclause (I). As a result, HHS has had to use the average price metric. *See* Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 77 Fed. Reg. 68,210, 68,385–86 (Nov. 15, 2012). The parties here agree that, by virtue of a statutory cross-reference, a drug's default "average price" equals 106% of its "average sales price," or ASP. *See* 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) (citing 42 U.S.C. § 1395w-3a(c)). HHS calculates ASP every quarter using sales data confidentially provided by drug manufacturers.

HHS's average price "methodology . . . has always yielded a finalized payment rate [for SCODs] in the range of

ASP+4 percent to ASP+6 percent," or 104% to 106% of ASP. 77 Fed. Reg. at 68,386. As a result, all hospitals have been paid the same rate—104% to 106% of ASP—for SCODs. Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 52,356, 52,494–95 (Nov. 13, 2017). From 2013 to 2017, that rate was 106% of ASP, unadjusted from the statutory default average price.

B.

That changed in late 2017, when HHS announced SCOD payment rates for the upcoming 2018 OPPS year. Invoking its subclause (II) authority to "adjust" the average price metric, HHS for the first time established two separate rates: one rate for hospitals participating in a drug discount program known as the "340B program," and another rate for all other hospitals. The rate for non-340B hospitals remained at ASP+6%, or 106% of ASP. The rate for 340B hospitals was "adjusted" down to ASP minus 22.5%, or 77.5% of ASP.

To understand HHS's reasons for reducing SCOD reimbursement rates for 340B hospitals, it is helpful to review the background of the 340B program. The program takes its name from the section of the Public Health Service Act that authorizes it. *See* Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967–71 (1992). The program allows covered entities (including eligible hospitals) to purchase drugs from manufacturers at heavily discounted rates. *See* 42 U.S.C. § 256b(a)(4). The covered entities generally care for underserved populations, and the discounted rates enable the providers to "stretch scarce Federal resources as far as possible." H.R. Rep. No. 102-384 (II), at 12 (1992).

The program requires manufacturers, as a condition of having their drugs covered by Medicaid, to sell each covered drug to 340B entities at a "ceiling price" (set by statutory formula). 42 U.S.C. § 256b(a). The program covers at least 3,500 drugs, 82 Fed. Reg. at 52,494, and the government estimates that 340B sales make up approximately 2.8% of the total U.S. drug market. Health Resources and Services Administration, *Justification of Estimates for Appropriations Committees Fiscal Year 2018*, at 244, https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-2018.pdf.

Over the past several years, observers have raised concerns about the intersection of the 340B program with Medicare Part B. Government reports found that 340B hospitals typically pay between 20% and 50% below ASP for covered drugs. When hospitals provide 340B drugs that qualify as SCODs to patients, the hospitals then seek reimbursement from Medicare Part B. Until 2018, the reimbursement rate was 106% of ASP. There was thus a large gap between the amount a 340B hospital would spend to acquire a SCOD and the higher amount Medicare would reimburse that hospital. The gap ranged from 25% to 55% of the cost of the drug. *See, e.g.*, U.S. Government Accountability Off., GAO-15-442, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals (June 2015), https://www.gao.gov/assets/680/670676.pdf.

When it came time to set 2018 OPPS rates, HHS decided to address the 340B-Part B payment gap. HHS believed that the gap "allow[ed] [340B] providers to generate significant profits when they administer[ed] Part B drugs." 82 Fed. Reg. at 52,494. Seeking to shrink those revenues, HHS imposed a 28.5% cut, from 106% of ASP to 77.5% of ASP, to the rates at which it would reimburse 340B hospitals for SCODs. *See id.*

at 52,496. The new rate was based on a "conservative" estimate, presented by the Medicare Payment Advisory Committee, that 22.5% below ASP equaled the "average minimum discount that a 340B participating hospital receive[d]" when purchasing SCODs. *Id.* HHS estimated that its 28.5% cut to SCOD reimbursement rates for Part B hospitals would save Medicare $1.6 billion in 2018. *Id.* at 52,509. As called for by the OPPS statute, HHS did not pocket the savings, but instead redistributed them to all hospitals in a budget-neutral manner by raising other Part B reimbursement rates. *Id.* at 52,623; *see* 42 U.S.C. § 1395*l*(t)(14)(H).

By addressing the 340B-Part B payment gap, HHS hoped to mitigate "unnecessary utilization and potential overutilization of [Part B] drugs." Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 33,558, 33,633 (July 20, 2017). HHS cited a GAO study which found that 340B hospitals prescribed more drugs than other hospitals, a disparity unexplained by salient distinctions between the hospitals or their patient populations. *Id.* at 52,494. HHS also sought to reduce the disproportionate coinsurance payments borne by Medicare Part B beneficiaries (mostly elderly patients) for 340B SCODs: because the amount of a patient's coinsurance payment is a fixed percentage of the medical bill as measured by the OPPS payment level, and because the latter amount for SCODs exceeded 340B hospitals' actual costs to obtain the drugs, patients' out-of-pocket coinsurance payments for SCODs became inflated, sometimes even exceeding a hospital's costs to acquire the drugs. *See id.*

Ultimately, HHS found it "inappropriate for Medicare to subsidize other activities" by 340B hospitals—as laudable as those activities may be—"through Medicare payments for [Part

B] drugs." *Id.* at 52,495. In order to "better and more appropriately reflect the resources and acquisition costs that [340B] hospitals incur," HHS acted to close the Part B-340B gap. *Id.* (formatting modified). HHS relied on its authority to "adjust" the average price metric under subclause (II) of the statute:

> We believe our authority under section [1395*l*](t)(14)(A)(iii)(II) of the Act to "calculate and adjust" drug payments "as necessary for purposes of this paragraph" gives the Secretary broad discretion to adjust payments for drugs, which we believe includes an ability to adjust Medicare payment rates according to whether or not certain drugs are acquired at a significant discount.

Id. at 52,499.

C.

The plaintiffs here are three hospitals and three hospital associations, to whom we will refer collectively as the Hospitals. On November 13, 2017, the day HHS published the rule reducing 340B reimbursement rates for SCODs, the Hospitals brought a challenge to HHS's action. *See Am. Hosp. Ass'n v. Hargan*, 289 F. Supp. 3d 45, 50 (D.D.C. 2017). The district court dismissed the suit on the ground that the Hospitals had yet to present a concrete claim for payment to HHS, as required by statute. *See id.* at 47. We affirmed. *Am. Hosp. Ass'n v. Azar*, 895 F.3d 822, 828 (D.C. Cir. 2018).

The Hospitals quickly submitted payment claims as required. HHS rejected them, claiming that the Medicare statute precludes administrative review of adjustments to OPPS

payment rates, including SCOD reimbursement rates. The Hospitals then filed this action. Before the district court ruled, HHS promulgated OPPS rates for fiscal year 2019, which retained the 28.5% SCOD reimbursement cut for 340B hospitals that the Hospitals had initially challenged. 53 Fed. Reg. 83,818 (Nov. 21, 2018). After submitting additional payment claims, the Hospitals filed a supplemental complaint challenging the 2019 Rule as well. *See* Suppl. Compl. ¶¶ 73–75 (Dkt. 39).

This time, the district court reached the merits. After concluding that the Medicare statute did not preclude its review of the reductions in SCOD reimbursement, the court held that the rate cut exceeded HHS's statutory authority to "adjust" SCOD rates. *Am. Hosp. Ass'n v. Azar*, 348 F. Supp. 3d 62, 79 (D.D.C. 2018). The court remanded to the agency to come up with a remedy in the first instance. The court then entered final judgment, paving the way for this appeal.

II.

We must first address a threshold challenge to our jurisdiction. The government asserts that paragraph 1395*l*(t)(12) of the OPPS statute, 42 U.S.C. § 1395*l*(t)(12), precludes judicial review of HHS's adjustments to SCOD rates. The district court disagreed, and so do we. Unable to find "clear and convincing evidence that Congress intended" that result, as would be required to overcome the "strong presumption that Congress intends judicial review of administrative action," we conclude that the challenged rate adjustment is subject to judicial review. *Amgen, Inc. v. Smith*, 357 F.3d 103, 111 (D.C. Cir. 2004) (quoting *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 670 (1986)).

Paragraph 1395*l*(t)(12) states that "[t]here shall be no administrative or judicial review" of certain enumerated actions undertaken by HHS in administering the OPPS. The question is whether changes to SCOD reimbursement rates are among the listed, nonreviewable actions. The government says yes, contending that changes to SCOD reimbursement rates fall within two provisions of paragraph (12): subparagraphs (12)(A) and (12)(C).

The first provision, subparagraph (12)(A), bars review of the "development of the classification system under paragraph (2), including the establishment of groups and relative payment weights for covered OPD [outpatient department] services, of wage adjustment factors, other adjustments, and methods described in paragraph (2)(F)." 42 U.S.C. § 1395*l*(t)(12)(A); *see also Am. Hosp. Ass'n*, No. 19-5352, slip op. at 11. The second provision, subparagraph (12)(C), bars review of "periodic adjustments made under paragraph ([9])." *Id.* § 1395*l*(t)(12)(C). (While the provision in fact refers to "paragraph (6)," all agree that the reference contains a scrivener's error and that Congress in fact intended to refer to paragraph (9).) The reach of subparagraphs (12)(A) and (12)(C) turns on the scope of the provisions they cross-reference: paragraphs (2) and (9), respectively.

Begin with paragraph (2), which sets out the general methodology HHS must use to set standard OPPS payments. Under paragraph (2), HHS "develop[s] a classification system." *Id.* § 1395*l*(t)(2)(A). In doing so, HHS groups certain medical services together that are "comparable clinically and with respect to the use of resources." *Id.* § 1395*l*(t)(2)(B). The resulting groups are known as ambulatory payment classifications, or APCs. Next, HHS establishes "relative payment weights" for the grouped services in an APC based on hospital costs. *Id.* § 1395*l*(t)(2)(C). HHS then sets default

payment amounts for the services in each APC corresponding to the weights.

Paragraph (9), meanwhile, requires HHS to annually review and adjust the standard OPPS payment rates initially set under paragraph (2). Specifically, HHS must reassess its grouping and weighting decisions, as well as the other separate payment adjustments it makes under paragraph (2) (such as labor-cost adjustments), to "take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors." *Id.* § 1395*l*(t)(9)(A).

HHS determines most annual OPPS payment levels through the exercise of paragraph (2) and (9) authority. Recall, however, that the Medicare statute does not allow HHS to use that discretion-laden authority to establish payment rates for *all* Part B services. Reimbursement rates for specified covered outpatient drugs—the rates at issue here—instead must be keyed to one of two statutory formulas set out in paragraph 1395*l*(t)(14): average acquisition cost (if hospital cost data are available) under subclause (I), or average price under subclause (II). SCOD payments "shall be equal" to one of those two options. *Id.* § 1395*l*(t)(14)(A)(iii).

Returning to our original question of whether HHS's adjustment to SCOD reimbursement rates fall within the bars on judicial review set out in subparagraphs (12)(A) or (12)(C), the answer is no as a textual matter. Neither (12)(A) nor (12)(C) addresses—and thus neither purports to preclude—any action taken by HHS under paragraph (14) of the statute. And none of the actions described in subparagraphs (12)(A) or (12)(C) plausibly, let alone clearly, comprises SCOD reimbursement adjustments.

In particular, subparagraph (12)(A) precludes review of "the development of the [APC] classification system," "the establishment of groups and relative payment weights," "wage adjustment factors," and "other adjustments." *Id.* § 1395(t)(12)(A). As just discussed, SCOD rates are not set using the paragraph (2) grouping and weighting process, so a change to SCOD rates does not come under the first two of those descriptions. Such a change is also not a "wage adjustment[]." Nor is it covered by the term "other adjustments," which we have read to reach only the "adjustments . . . necessary to ensure equitable payments" under subparagraph (2)(E) (i.e., "equitable adjustments"), *see Amgen*, 357 F.3d at 113.

Subparagraph (12)(C), similarly, does not by its plain terms appear to cover SCOD payment reductions. It covers "periodic adjustments made under paragraph [9]." 42 U.S.C. § 1395*l*(t)(12)(C). By the terms of paragraph (9), that annual adjustment power extends only to actions initially taken under paragraph (2). And as just discussed, none of those actions textually corresponds to a decision to reduce SCOD rates.

Our analysis of the text draws support from Congress's history of amendments to the OPPS statute. When adding new provisions to subsection 1395*l*(t), Congress has tended to say expressly when it wishes to preclude judicial review of decisions made under an added provision. In 1999, Congress added paragraphs (5), (6), and (7) to subsection (t). In the same legislation, Congress also added clause (E) to paragraph (12), which provided that certain "determination[s]" made under paragraphs (5) and (6), but not any decisions under paragraph (7), would not be judicially reviewable. *See* Pub. L. No. 106-113, § 201(d), 113 Stat. 1501 (1999). In 2015, Congress included a preclusion-of-judicial-review provision directly within the newly added paragraph (21), rather than amending

paragraph (12). *See* Pub. L. No. 114-74, § 603, 129 Stat. 584, 598 (2015). By contrast, when Congress added paragraph (14) in 2003, it did so without any indication of an intention to preclude judicial review of SCOD rate-setting decisions.

According to the government, though, Congress had no need to expressly preclude judicial review of actions taken under paragraph (14) because those actions are *inherently* ones under paragraphs (2) and (9) (and thus necessarily fall within the judicial-review bars in subparagraphs (12)(A) and (12)(C)). The nub of the government's argument is that paragraph (14) does not in fact set up a "standalone payment regime" outside the general paragraph (2) system. Appellant's Reply Br. 15. Rather, the government contends, paragraph (14) merely "provides instructions to HHS about how to exercise its paragraph 2 and 9 authority when setting and revising payments" for SCODs. *Id.* On that view, even though HHS must follow paragraph (14)'s specific commands when setting the SCOD reimbursement rate, when HHS does so, it exercises authority located not in (14) but in paragraphs (2) and (9).

Ultimately, it is the government's burden to support that theory by "clear and convincing evidence," *Amgen*, 357 F.3d at 111, especially given the absence of statutory text unambiguously precluding judicial review. Applying that standard, we are insufficiently persuaded of the proposition that HHS's authority to annually set SCOD rates is located in paragraphs (2) and (9) rather than paragraph (14).

First, Congress on several occasions has specifically noted, directly in the statutory text, that certain OPPS-related decisions fall under paragraph (2). When Congress authorized HHS to make "outlier adjustments" and "pass-through payments," it fleshed out how those actions would work in paragraphs (5) and (6) respectively, but lodged the authority to

make the adjustments in the newly added subparagraph (2)(E). *See* 42 U.S.C. § 1395*l*(t)(2)(E). When Congress added paragraphs (13) and (18), which address adjustments for rural and cancer hospitals, respectively, it similarly provided that those adjustments would fall under subparagraph (2)(E). 42 U.S.C. § 1395*l*(t)(13)(B) ("the Secretary shall provide for an appropriate adjustment under paragraph (2)(E)"); *id.* § 1395*l*(t)(18)(B) ("the Secretary shall . . . provide for an appropriate adjustment under paragraph (2)(E)"). But when Congress added the SCOD reimbursement provisions of paragraph (14) in 2003, it included no such language referencing paragraph (2).

Second, both the statute's text and HHS's longstanding practice strongly suggest that paragraph (2) and (9)'s "adjustment" authorities do not encompass paragraph (14). If setting SCOD rates were an exercise of paragraph (2) authority, HHS would be authorized to use its subparagraph (2)(E) equitable-adjustment authority to change the rates. But it does not appear HHS may make such adjustments to SCOD rates.

As a matter of statutory text, paragraph (14) provides its own authorizations for HHS to adjust SCOD rates. Subclause (I) of paragraph (14), which sets out the average-acquisition-cost formula, says that the Secretary "may vary [the calculated reimbursement rate] by hospital group." 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I). Subclause (II), which requires SCOD reimbursement to reflect a drug's average price, allows the Secretary to "calculate[] and adjust[] [the average price metric] as necessary for purposes of this paragraph." *Id.* § 1395*l*(t)(14)(A)(iii)(II). And both the average-acquisition-cost and average-price formulas are "subject to subparagraph (E)," which authorizes the Secretary to "adjust" SCOD payments to account for "overhead and related expenses, such as pharmacy services and handling costs." *Id.*

§ 1395*l*(t)(14)(E). It would be odd for Congress in paragraph (14) to provide HHS with those specific authorities to "adjust" SCOD rates if HHS nonetheless has the general authority to adjust those rates as it sees fit under paragraph (2) or (9).

HHS's longstanding practice, and the 2018 and 2019 Rules at issue here, corroborate that understanding. HHS has never purported to use its paragraph (2) or (9) authorities either to set SCOD rates or to deviate from the default "average price" rate set out in subclause (II). And it did not do so here. Instead, in the 2018 Rule, HHS grounded its action in in the "calculate and adjust" provision of paragraph (14), subclause (II). 82 Fed. Reg. at 52,499–500. The government claims that HHS invoked its paragraph (9) authority in the 2018 Rule's preamble. But the preamble stated only that the Rule would "describe [that] and various other statutory authorities in the relevant sections of this final rule." *Id*. at 52,362. And in the section of the Rule explaining HHS's statutory authority to make the 340B-related reduction to SCOD rates, there is no reference to paragraph (9). *See id*. at 52,496, 52,499–502.

Of particular note, HHS made no claim that the rate cut at issue here was an exercise of its subparagraph (2)(E) equitable-adjustment authority, even though the change might be seen to serve equitable goals. HHS relied solely on its paragraph (14), subclause (II) adjustment authority, even as it invoked its subparagraph (2)(E) equitable-adjustment power in connection with at least two other rate changes in the 2018 OPPS Rule. *See id*. at 52,364–65 (explaining that HHS makes an additional payment for radioisotopes used in diagnostic imaging "based on the authority set forth at section [1395*l*](t)(2)(E)"); *id*. at 52,421 ("we are using our equitable adjustment authority" to change reimbursement for retinal procedure).

Third, paragraph (14) operates as a standalone payment regime for all practical purposes. The statute contemplates that HHS will set SCOD payment rates in a vacuum, without taking into account other OPPS rate-setting decisions. SCOD rates are not set through relative weighting with rates for other reimbursable care. And if HHS changes the payment weights for other APCs, SCOD prices need not change because SCOD rates are unaffected by the statute's budget-neutrality requirement. Recall that SCOD rates must equal either average acquisition cost or average price. Although subparagraph (14)(H) requires that "[a]dditional expenditures resulting from this paragraph" be "taken into account" for overall budget neutrality for the OPPS, that language recognizes that the expenditures "resulting" from the application of paragraph (14) will be calculated first, irrespective of other adjustments made to other OPPS payments. 42 U.S.C. § 1395*l*(t)(14)(H). Only then are those set-in-stone numbers put into the budget-neutrality calculator.

On this score, HHS again has consistently read the statute the way we do. *See, e.g.*, 77 Fed. Reg. at 68,262 ("Payments for [SCODs] are included in the budget neutrality adjustments . . . but the budget neutral weight scaler is not applied to their payments because they are developed through a separate methodology, outside the relative payment weight based process."). That understanding of the statute's structure sits uncomfortably, to say the least, with HHS's position in this case that paragraph (14) does no more than instruct HHS how to exercise its paragraph (2) and (9) authorities.

The government lastly relies on subparagraph (14)(H), reading that provision to indicate that setting of SCOD rates is an exercise of paragraph (9)'s annual-adjustment authority. Subparagraph (14)(H), enacted along with the rest of paragraph (14) in 2003, requires that SCOD payments be counted for

budget-neutrality purposes in years after 2005, but specifies that the payments "shall *not* be taken into account" for budget-neutrality purposes in 2004 and 2005. 42 U.S.C. § 1395*l*(t)(14)(H) (emphasis added); *see also id.* § 1395*l*(t)(9)(B). According to the government, the specification that SCOD payments would not be subject to budget neutrality in 2004 and 2005 suggests that budget neutrality otherwise applies, which would be the case if SCOD rate-setting were an exercise of paragraph (9) authority (given that all paragraph (9) adjustments must be budget neutral, *see id.* § 1395l(t)(9)(B)).

We disagree with the premise that SCOD rates can factor into OPPS budget neutrality only if the setting of SCOD rates is an exercise of paragraph (9) authority. It is at least possible, if not probable, that Congress conceived of the SCOD rate-setting program as entirely distinct from the general paragraph (2) and (9) program, yet still wanted the output of the SCOD program to matter for overall budget neutrality. Recall that Congress required HHS to move to the prospective OPPS system, constrained by a budget-neutrality requirement, in order to control Medicare Part B spending and promote more predictable annual growth. In view of those goals, Congress, when creating a standalone payment regime for SCODs, might still have wanted to achieve budget neutrality for Part B payments as a whole. Thus, Congress's choice to make that desire explicit for years after 2005 (and to carve out the two prior years) does not necessarily imply that HHS exercises paragraph (9) authority whenever it adjusts SCOD rates.

To sum up: subparagraphs (12)(A) and (12)(C) do not, by their terms, clearly cover HHS's decision to cut SCOD reimbursement to 340B hospitals. While the government argues that SCOD rate-setting is merely a species of general OPPS rate-setting under paragraphs (2) and (9), and that

Congress thus intended SCOD payment decisions to be similarly insulated from review, that account, at a minimum, is not *clearly* correct. As a result, the government has failed to "overcom[e] the strong presumption that Congress did not mean to prohibit" our review. *Bowen*, 476 U.S. at 672.

III.

Proceeding to the merits, the sole question before us is whether HHS had statutory authority to impose its 28.5% cut to SCOD reimbursement rates for 340B hospitals. HHS located its authority in subclause (II) of paragraph (14) of the OPPS statute. Under that provision, when HHS sets SCOD payment amounts tethered to average drug prices, HHS has express authority to "adjust[]" the amounts "as necessary for purposes of this paragraph." 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II). In our view, HHS reasonably interpreted subclause (II)'s adjustment authority to enable reducing SCOD payments to 340B hospitals, so as to avoid reimbursing those hospitals at much higher levels than their actual costs to acquire the drugs.

On that issue of statutory interpretation, HHS is entitled to *Chevron* deference, which it has invoked here (although it did not do so expressly until a post-argument letter submitted to the Court). *See Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842 (1984). When an agency "interpret[s] a statute it is charged with administering in a manner (and through a process) evincing an exercise of its lawmaking authority," that interpretation is entitled to *Chevron* treatment, and the agency cannot forfeit *Chevron*'s applicability. *SoundExchange, Inc. v. Copyright Royalty Board*, 904 F.3d 41, 54–55 (D.C. Cir. 2018). HHS established SCOD reimbursement rates for 340B hospitals through notice-and-comment rulemaking and explained why it "believe[d] that [its]

proposal [was] within [its] statutory authority to promulgate." 82 Fed. Reg. at 52,499. HHS's understanding of its statutory authority thus is entitled to *Chevron* deference. *See Am. Hosp. Ass'n*, No. 19-5352, slip op. at 14; *Tenet HealthSystems HealthCorp. v. Thompson*, 254 F.3d 238, 248 (D.C. Cir. 2001); *see also Barnhart v. Walton*, 535 U.S. 212, 222 (2002).

Under *Chevron*, we first ask whether "Congress has directly spoken to the precise question at issue." *Chevron*, 467 U.S. at 842. Here, the "precise question at issue" is whether HHS's adjustment authority in subclause (II) encompasses a reduction to SCOD reimbursement rates aimed at bringing reimbursements to 340B hospitals into line with their actual costs to acquire the drugs. If the statute does not directly foreclose HHS's understanding, we defer to the agency's reasonable interpretation. *See id.* at 844. We conclude that HHS's interpretation of subclause (II) is not directly foreclosed and is reasonable.

By way of brief review, paragraph (14), as its title confirms, addresses "[d]rug . . . payment rates"—specifically, the rates at which hospitals are reimbursed for SCODs furnished to beneficiaries in supplying covered care. 42 U.S.C. § 1395*l*(t)(14). Under subclause (I) of the paragraph, the "amount of payment," as a default matter, "shall be equal" to hospitals' "average acquisition cost for the drug." *Id.* § 1395*l*(t)(14)(A)(iii)(I). But if pertinent "hospital acquisition cost data are not available," then payment levels are determined under subclause (II). Under that provision, the amount of payment equals "the average price for the drug"—which, by statutory cross-reference, is the drug's average sales price (ASP) charged by manufacturers—but subject to "adjust[ment] . . . as necessary for purposes of this paragraph." *Id.* § 1395*l*(t)(14)(A)(iii)(II).

Much is undisputed about HHS's application of subclause (II)'s adjustment authority to reduce SCOD payment rates to 340B hospitals. First, HHS properly found that the "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 reliance on average drug prices. Second, 340B hospitals obtain SCODs 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. Third, HHS's 28.5% SCOD rate reduction for 340B hospitals 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. *See* 82 Fed. Reg. at 52,500. Fourth, absent the reduction, at least some Medicare beneficiaries served by 340B hospitals (generally underserved populations) would pay out-of-pocket copayments for the drugs that substantially exceed the normal copay share of providers' cost to obtain the drugs—with beneficiaries' copayments sometimes exceeding 340B hospitals' *full* cost to purchase the drugs. And fifth, the roughly $1.6 billion in savings from reducing SCOD reimbursement payments to 340B hospitals is not kept by the agency but is redistributed to all providers as additional reimbursement payments for other services. *See generally* pp. 6–8, *supra*.

That is the backdrop against which we consider whether HHS permissibly understood its subclause (II) adjustment authority to encompass its reduction to reimbursement payments to 340B hospitals for SCODs. Was HHS obligated to continue reimbursing 340B hospitals for SCODs 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? We think the agency was not compelled to continue doing so.

The central question is whether HHS permissibly conceived of the "purposes of this paragraph," i.e., paragraph (14), in exercising its subclause (II) authority to "adjust[]" payment rates "as necessary for the purposes of this paragraph," 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II). According to the agency, a "manifest purpose of paragraph 14 is to compensate providers for the average acquisition cost" of SCODs. Appellant's Br. 30. In accordance with that understanding, HHS explained in the 2018 Rule that "a payment amount of ASP minus 22.5 percent for drugs acquired under the 340B Program is better aligned to hospitals' acquisition costs and thus this adjustment . . . is necessary for Medicare OPPS payment policy." 82 Fed. Reg. at 52,501.

Paragraph (14)'s structure supports HHS's understanding that the provision's core purposes include reimbursing hospitals for their costs to acquire SCODs. Paragraph (14)'s primary (and default) instruction for determining SCOD payment amounts, set out in subclause (I), is to equate them to "average acquisition cost." 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I). That alone indicates that Congress's primary goal is to reimburse providers for their acquisition costs. And if direct acquisition-cost data of a kind contemplated by subclause (I) is unavailable, HHS must then, as a fallback matter under subclause (II), equate payment amounts to "average price," subject to adjustment. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II). By prescribing the use of ASP as a backup when the requisite acquisition-cost data is unavailable, Congress signaled that average price functions as a stand-in for costs.

HHS has long understood average price under subclause (II) to serve as a "proxy for average acquisition cost." 77 Fed. Reg. at 68,386. HHS has used ASP since 2006, stating then and all along that its "intent" in using ASP was "to pay for drugs and biologicals based on their hospital acquisition costs."

Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates, 70 Fed. Reg. 68,516, 68,642 (Nov. 10, 2005). For non-340B hospitals, ASP is an accurate approximation of acquisition costs: HHS's Inspector General has found that, for non-340B hospitals, ASP comes within roughly 1% of acquisition costs. HHS Office of Inspector General, Memorandum Report: Payment for Drugs Under the Hospital Outpatient Prospective Payment System 1, 9 (Oct. 22, 2010). But for 340B hospitals, ASP substantially exceeded SCOD acquisition costs by the time of the 2018 Rule—hence the need for an adjustment under subclause (II) to bring payments to 340B hospitals into line with their costs.

The OPPS statute exhibits in other ways Congress's evident purpose of aligning SCOD reimbursement with hospital costs. Paragraph (14) itself expressly authorizes a separate adjustment to SCOD payment rates to account for "overhead costs" and "related expenses" ("such as pharmacy services and handling costs"). *Id.* § 1395*l*(t)(14)(E). And more broadly, many other OPPS provisions reflect the goal of aligning payments to hospitals with their costs. *See id.* § 1395*l*(t)(2)(C) (grouping and weighting under paragraph (2) must be "based on median . . . hospital costs"); *id.* § 1395*l*(t)(2)(D) ("wage adjustment factor" must account for "relative differences in labor and labor-related costs"); *id.* § 1395*l*(t)(5)(B) ("outlier adjustments" must "approximate the marginal cost of care"); *id.* § 1395*l*(t)(9)(A) ("periodic . . . adjustments" must be based on "new cost data"); *id.* § 1395*l*(t)(13)(A) (authorizing adjustments if "costs incurred by hospitals located in rural areas . . . exceed those costs incurred by hospitals located in urban areas"); *id.* § 1395*l*(t)(18)(B) (same for cancer hospitals).

All of that supports HHS's understanding that the "purposes" of paragraph 14 for which the agency can "adjust[]" SCOD payments under subclause (II) include aligning payments to hospitals with their drug acquisition costs. *Id.* § 1395*l*(t)(14)(A)(iii)(II). That is precisely what HHS did when it imposed its 28.5% reduction in payments to 340B hospitals for SCODs.

In arguing that HHS lacked authority under subclause (II) to undertake that measure, the Hospitals focus on subclause (I)'s requirement that, if payment amounts are keyed to "average acquisition cost" under that provision—as opposed to average price under subclause (II)—then the agency must take "into account the hospital acquisition cost survey data under subparagraph (D)." *Id.* § 1395*l*(t)(14)(A)(iii)(I). And subparagraph (D) imposes stringent data-quality requirements, mandating that the cost surveys "shall have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each [SCOD]." *Id.* § 1395*l*(t)(14)(D)(iii).

Because Congress required HHS to "tak[e] into account" robust study data when setting SCOD rates at average acquisition cost under subclause (I), the Hospitals argue, HHS cannot use its subclause (II) authority to adjust ASP in order to approximate acquisition cost. As the Hospitals see it, if HHS wants to set SCOD rates based on the cost to hospitals to acquire the drugs, the agency must get the data contemplated by subclause (I). If it were otherwise, the Hospitals contend, subclause (I)'s requirement to take into account the data collected under subparagraph (D) would be meaningless: HHS could simply forgo the study required by subclause (I) and instead use subclause (II) to approximate drug acquisition costs. Our dissenting colleague, too, stresses the same point. Dissenting Op. 5.

That argument, on which the district court relied, *see Azar*, 348 F. Supp. 3d at 82–83, is not without force. We, though, are ultimately unpersuaded. For the Hospitals' argument to carry the day under *Chevron*, we would need to conclude that Congress unambiguously barred HHS from seeking to align reimbursements with acquisition costs under subclause (II), or that HHS's belief that it could do was unreasonable. And HHS would be barred from doing so even if, as here, it is undisputed both that payment amounts otherwise would substantially exceed hospitals' costs and that the proposed adjustment accurately and reliably approximates procurement costs.

Given that the survey data contemplated by subclause (I) aims to assure the reliability of cost-acquisition data, we do not read the statute to foreclose an adjustment to ASP under subclause (II) that is based on reliable cost measures of the kind undisputedly at issue here. That is particularly so because, whereas the Hospitals question whether HHS's interpretation could enable sidestepping subclause (I)'s data-reliability requirements altogether, the Hospitals' own reading raises a similar interpretive dilemma. Subclause (II), as explained, expressly empowers HHS to "adjust" payments based on ASP "as necessary for purposes of" paragraph (14). And under the Hospitals' reading, those "purposes" cannot include the goal of approximating hospital acquisition costs. But the Hospitals point to no other "purpose" that could permissibly support an adjustment. The Hospitals' argument thus renders subclause (II)'s adjustment authority superfluous.

The Hospitals submit that "[t]he purpose of paragraph (14) is to establish the rate for separately payable drugs." Appellees' Br. 42–43. That may be true at a high level of generality—indeed, the title of paragraph (14) is "Drug APC payment rates"—but it is unhelpful to the Hospitals for our

purposes. After all, HHS's rate reduction for payments to 340B hospitals does "establish the rate for separately payable drugs."

The Hospitals also suggest that subclause (II)'s adjustment authority enables adjustments to account for overhead costs. Appellees' Br. 49. But that reading would leave subclause (II)'s adjustment authority duplicative of authority already conferred by subparagraph (14)(E). That subparagraph, as noted, authorizes HHS to make adjustments to account for "overhead and related expenses, such as pharmacy services and handling costs." 42 U.S.C. § 1395*l*(t)(14)(E)(i). If subclause (II)'s adjustment authority were merely meant to reinforce subparagraph (14)(E)'s authority to account for overhead costs, then why would subclause (II) not simply say so, in comparable language? Instead, subclause (II) frames its grant of authority in notably broader terms addressed to the overall purposes of paragraph (14), not just the specific, "overhead and related expenses" focus of subparagraph (14)(E).

The Hospitals' reading of subclause (II)'s adjustment authority as addressed to overhead costs, it bears noting, would necessarily mean that the purpose of granting that authority is to enable bringing ASP closer to drug acquisition costs—precisely what the Hospitals otherwise say the agency cannot aim to do when exercising its subclause (II) authority. But under the Hospitals' evident understanding, the agency can try to get ASP closer to actual costs only to the extent of taking into account overhead costs, without going further to bring ASP all the way into alignment with acquisition costs. That half-measure understanding of subclause (II)'s adjustment authority is incompatible with its broad terms, which speak generally to the "purposes" of paragraph (14), including, in particular, approximating drug acquisition costs.

Our dissenting colleague nonetheless endorses the Hospitals' suggestion that subclause (II)'s adjustment authority, while framed generally, should be read as focused on overhead costs. Dissenting Op. 5–8. Our colleague briefly suggests that there may be no redundancy between subclause (II) and subparagraph (14)(E) under that reading because, she posits, the two provisions both allow for adjustments to account for overhead costs, but at different times, with (14)(E) in the nature of a time-limited, naturally-expiring allowance and subparagraph (II) an ensuing, ongoing one. *Id.* at 5–6. Again, though, if the provisions were designed to cover the same terrain (even if at different times), one would expect them to use similar language in defining the territory, which they conspicuously do not. And at any rate, the statutory text confirms that the provisions are designed to work side-by-side contemporaneously, not at different times: Congress rendered subclause (II)'s provisions expressly "subject to paragraph (E)," such that the agency, when acting under subclause (II), could make adjustments to ASP *both* under that provision's own, broadly-framed adjustment authority *and* under subparagraph (14)(E)'s more specific authority addressed to overhead costs. 42 U.S.C. § 1395*l*(t)(14)(A).

Our dissenting colleague ultimately allows that the Hospitals' overhead-costs interpretation of subclause (II)'s adjustment authority means that the provision may reiterate—i.e., make "double sure"—subparagraph (14)(E)'s express authority to account for overhead costs. Dissenting Op. 6. But our colleague still believes that the Hospitals' reading of the statute is unambiguously compelled at *Chevron* step one. *Id.* at 1. In her evident view, any superfluity occasioned by that reading is less substantial than the superfluity occasioned by the agency's reading. *Id.* at 8–9. But even assuming there is a reliable metric for comparing degrees of superfluity across readings in that fashion, that kind of comparison is not the stuff

of a *Chevron* step one resolution. Rather, 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. *See National Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 666 (2007); *Peter Pan Bus Lines, Inc. v. Fed. Motor Carrier Safety Admin.*, 471 F.3d 1350, 1354 (D.C. Cir. 2006) ("[S]ection 13902 contains surplusage under either reading and, as a result, we cannot say that either proffered construction reflects the Congress's unambiguously expressed intent.").

The Hospitals separately suggested in oral argument that subclause (II)'s adjustment authority could pertain to improving the accuracy of the sales-price metric specifically for hospitals (as opposed to other providers). ASP reflects sales prices to all manner of medical providers, including pharmacies, clinics, independent physician practices, and the like. *See* 42 U.S.C. § 1395w-3a(c). As the Hospitals see it, HHS can adjust ASP to arrive at a metric that better reflects the prices paid by hospitals alone. But nothing in subclause (II)'s general adjustment authority suggests that it is so narrowly focused. And in any event, to the extent HHS might adjust ASP to more accurately reflect prices paid by hospitals, it is unclear whether there would then remain any appreciable difference between such a hospital-specific ASP and hospital acquisition costs. Yet the Hospitals' whole point is that HHS cannot rely on its subclause (II) adjustment authority to approximate acquisition costs.

Especially in view of the Hospitals' inability to present an interpretation of HHS's subclause (II) adjustment authority that would give it meaningful independent content, we cannot conclude that the statute forecloses HHS from reducing SCOD reimbursement rates for 340B hospitals with the object of bringing payments into alignment with acquisition costs.

Rather, in the specific circumstances of this case, HHS permissibly read the statute to allow it to implement the 340B payment reduction. Although subclause (I) calls for the "average acquisition cost" payment metric to "tak[e] into account" subparagraph (D)'s survey data, here, HHS relied on data of undisputed reliability. Moreover, the agency acted on that data in a cautious way, adopting a "conservative, lower-bound estimate" of the 340B discount's size. 82 Fed. Reg. at 52,504 (quotation marks omitted). In those circumstances, HHS reasonably concluded that it need not continue subsidizing 340B providers with Part B (i.e. taxpayer) funds and Medicare beneficiaries' copayments. We of course do not consider the wisdom of that decision as a policy matter in the first instance, but only whether the agency had statutory authority to reach it. *See Chevron*, 467 U.S. at 845. We conclude that the agency's decision rests on a permissible understanding of its statutory authority.

Shifting tack, the Hospitals contend that even if HHS can seek to approximate acquisition costs in exercising its subclause (II) adjustment authority, HHS's 28.5% rate cut is simply too large and sweeping to qualify as an "adjustment." That argument falls short under a straightforward application of *Chevron*. The statutory term "adjust" is ambiguous as to size. The Hospitals offer various definitions of "adjust" that include qualifiers such as "slightly," *e.g.*, *Adjust*, Oxford Dictionaries, https://www.lexico.com/definition/adjust ("alter or move (something) slightly in order to achieve the desired fit, appearance, or result"), but HHS responds with many definitions that lack such qualifiers, *e.g.*, *Adjust*, Merriam-Webster, https://www.merriam-webster.com/dictionary/adjust ("to bring to a more satisfactory state").

The Hospitals point to our decision in *Amgen*, which considered an "adjustment" under HHS's subparagraph (2)(E)

authority to make equitable adjustments. In the course of upholding the challenged adjustment, we observed that "similar limits inhere in the term 'adjustments' to those the Supreme Court found in the word 'modify'" in *MCI Telecomms. Corp v. Am. Tel. & Tel. Co.*, 512 U.S. 218, 225 (1994). *Amgen*, 357 F.3d at 117. And the *MCI* Court stated that "modify" means "to change moderately or in minor fashion." *MCI*, 512 U.S. at 225. But we do not read *Amgen* to prescribe that "adjust" in the OPPS statute refers only to minor changes. To the contrary, *Amgen* explained that it "ha[d] no occasion to engage in line drawing to determine when 'adjustments' cease being 'adjustments.'" 357 F.3d at 117. Even if there are limits to what HHS could permissibly consider an "adjustment," that line has not been crossed here, where the agency acted on a conservative estimate drawn from data of undisputed reliability.

The Hospitals' last argument is that HHS's subclause (II) adjustment authority does not allow adjusting reimbursement rates for 340B hospitals alone. According to the Hospitals, the reimbursement rate set under subclause (II) must be uniform across all hospitals. The Hospitals rely on subclause (I)'s statement that payment rates set under that provision must equal "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))." 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I) (emphasis added). The Hospitals stress that subclause (II), by comparison, says nothing about authority to vary the average price metric by hospital group. That silence, to the Hospitals, means that when HHS sets SCOD reimbursement rates under subclause (II), it must apply the same rate to every recipient hospital.

Congress, however, was not silent about HHS's adjustment power in subclause (II). Whereas subclause (I) does not grant HHS any general authority to adjust reimbursement rates, subclause (II) affirmatively grants HHS general adjustment authority for deployment "as necessary for purposes of" paragraph (14). And as explained, HHS reasonably believes that a central purpose of paragraph (14) is to accurately reimburse hospitals for their acquisition costs. There is no reason to think that HHS's general adjustment authority when acting under subclause (II) excludes the more focused license to vary rates by hospital group when acting under subclause (I). In particular, the Hospitals provide no reason why, if HHS knows that a certain group of hospitals has far lower (or far higher) costs than others, Congress would want to preclude HHS from acting on that information in a suitably tailored fashion when exercising its adjustment authority under subclause (II). At a minimum, the statute does not clearly preclude HHS from adjusting the SCOD rate in a focused manner to address problems with reimbursement rates applicable only to certain types of hospitals. That is enough to reject the Hospitals' argument under *Chevron*.

* * * * *

For the foregoing reasons, we reverse the judgment of the district court.

So ordered.

PILLARD, *Circuit Judge*, dissenting in part: I agree with my colleagues that the Medicare Outpatient Prospective Payment System (OPPS) statute does not preclude judicial review of HHS's 28.5% reduction in reimbursement rates to 340B hospitals that administer Specified Covered Outpatient Drugs (SCODs). On the merits, however, I disagree that subclause (II) authorized HHS to implement for 340B hospitals alone the challenged rate reductions in its 2018 and 2019 OPPS rules.

The statute sets forth two alternative bases for HHS's calculation of the relevant reimbursement rates: It may set those rates under subclause (I) based on average acquisition cost (reflecting the average cost that hospitals actually incurred in purchasing the drug), or under subclause (II) based on average sales price (reflecting the average price, updated quarterly, at which manufacturers sold the drug to most purchasers, not limited to hospitals). *See* 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I)-(II). When the two subclauses at issue here are read together, the conclusion is unavoidable that HHS may institute its large reductions, tailored for a distinct hospital group, only under subclause (I), which requires the agency to take into account specific data undisputedly absent here.

The majority concludes that HHS may act on other data (not meeting Congress' specifications) to make those reductions pursuant to subclause (II). That reading impermissibly nullifies subclause (I) and the data requirements spelled out at length in subparagraph (D). *See id.* § 1395*l*(t)(14)(D). I would therefore hold that the agency's interpretation of subclause (II) is foreclosed at *Chevron* step one. Because HHS's actions cannot be squared with the text of the OPPS statute, I respectfully dissent from part III of the majority opinion.

* * *

Reproduced in full, subclauses (I) and (II) provide that, for every year after 2005, the reimbursement rate "shall be equal, subject to subparagraph (E)"—

> (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 the volume of covered [outpatient department] services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D); or
>
> (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.

42 U.S.C. § 1395*l*(t)(14)(A)(iii). Subparagraph (E) in turn authorizes the Secretary to make "adjustment[s] in payment rates for overhead costs," for instance to account for "pharmacy services and handling costs," based on the findings of a 2005 Medicare Payment Advisory Commission (MedPAC) report. *Id*. § 1395*l*(t)(14)(E).

The two subclauses together provide that, if HHS sets reimbursements rates based on hospitals' actual average acquisition costs, HHS must consider congressionally specified acquisition-cost data. *See id*. § 1395*l*(t)(14)(D). And—crucial for the challenged differential reimbursement rate for 340B hospitals—HHS may only segment reimbursement rates by hospital group if it has collected the specified data and set the rates keyed to hospital acquisition costs in view of that data.

The two subclauses operate as alternatives: Subclause (I) lays out what the agency may do when it has collected and taken into account the "hospital acquisition cost survey data under subparagraph (D)," whereas subclause (II) lays out what the agency may do "if the hospital acquisition cost data are not available." *Id.* § 1395*l*(t)(14)(A)(iii). If the agency has that data, it may set reimbursement rates based on the "average acquisition cost for the drug for that year," and "vary by hospital group" any reimbursement rates. *Id.* § 1395*l*(t)(14)(A)(iii)(I). But "if hospital acquisition cost data are not available," *id.* § 1395*l*(t)(14)(A)(iii)(II), the agency must set reimbursement amounts under subclause (II) by resort to what it has previously called the "statutory default" rate for a given drug in a given year, *see, e.g.*, 2013 OPPS Rule, 77 Fed. Reg. 68,210, 68,386 (Nov. 15, 2012). That statutory default rate is the drug's average sales price charged to hospitals, clinics, pharmacies, and other providers, drawn from data that drug manufacturers submit to HHS every quarter. *See id.* §§ 1395w-3a(c), 1396r-8(b)(3)(A)(iii). Subclause (II) provides for the average sales price to be "adjusted . . . as necessary for purposes of this paragraph" but, unlike subclause (I), grants no authority to vary the reimbursement rates by hospital group. *Id.* § 1395*l*(t)(14)(A)(iii)(II).

As everyone agrees, HHS has never collected the "hospital acquisition cost data" that the statute contemplates, so must proceed under its subclause (II) authority to set reimbursement rates for the 2018 and 2019 OPPS rules. *See, e.g.*, HHS Br. 9; 2018 Proposed OPPS Rule, 82 Fed. Reg. 33,558, 33,634 (proposed July 20, 2017). The question before us is whether the agency may set and vary by hospital group SCOD reimbursement rates in the manner that subclause (I) authorizes, without collecting and considering the data that subclause (I) specifies, by invoking its authority under subclause (II) to adjust the average-sales-price-based

reimbursement rate and, in effect, simply deem that to be a rate reflecting hospitals' average acquisition cost. The majority concludes that the agency's circumvention of subclause (I) in this manner is a permissible construction of the statute for several reasons, none of which I find persuasive.

First, the majority argues, based primarily on the text of subclause (I) and other provisions in the OPPS statute, that Congress' "primary goal is to reimburse providers for their acquisition costs." Maj. Op. at 21. But the statute's overarching goal is not its only goal, to be achieved however the agency sees fit. When it comes to Medicare Part B payments for SCODs, paragraph (14) specifically tells us when and how Congress intended HHS to pursue acquisition-cost-based reimbursement. Only subclause (I), not subclause (II), authorizes HHS to set different reimbursement rates for distinct hospital groups—rather than a uniform, drug-by-drug "average price for the drug in the year," 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II)—and to do so only by taking into account the different acquisition costs identified in the robust, hospital-specific data that Congress required the agency to collect.

The majority finds it inconceivable that Congress would require the same sales-price-based reimbursement rate for all types of hospitals when hospitals' acquisition costs vary widely. *See, e.g.*, Maj. Op. at 24. But in authorizing the average-sales-price methodology, which takes account of most discounts and rebates that purchasers receive, Congress was attuned to the many factors rendering non-uniform the amounts different hospitals actually pay for the same drugs. Given Congress' awareness that various hospitals—not only 340B hospitals—pay more or less than others, I see nothing inconceivable about Congress requiring disparities in reimbursement rates to certain types of hospitals to be

identified and acted upon based only on the most complete and accurate data.

If Congress wanted HHS, in the absence of subclause (I)'s hospital-specific data regarding average acquisition costs, just to do its best to approximate those costs and then vary them by hospital groups according to its unchecked policy judgment, it easily could have written the statute to say so. Instead, subclause (II) mandates that the base reimbursement rate "shall be equal" to the specified drug's statutory default rate premised on average sales price, subject to adjustments, and entirely omits the authority granted in subclause (I) to "vary by hospital group" the pricing data or resultant rate. 42 U.S.C. § 1395*l*(t)(14)(A)(iii). I cannot discern in the statute any congressional intention that the adjustment authority be used to set markedly different prices for different hospital groups. I would instead affirm the district court's conclusion that HHS "cannot fundamentally rework the statutory scheme—by applying a different methodology than the provision requires—to achieve under sub[clause] (II) what [it] could not do under sub[clause] (I) for lack of adequate data." *Am. Hosp. Ass'n v. Azar*, 348 F. Supp. 3d 62, 82 (D.D.C. 2018).

Second, the majority reasons that this data-sensitive reading of the two subclauses cannot be correct because it "renders subclause (II)'s adjustment authority superfluous." Maj. Op. at 24. But the Hospitals' reading of the subclause (II) adjustment authority as primarily cross-referencing incremental modifications like the overhead-cost adjustment described in subparagraph (E) does not make the former altogether redundant. As the Hospitals explain, subparagraph (E) authorized adjustments for overhead with reference to a one-time, 2005 MedPAC report, whereas subclause (II)'s authority to make "adjust[ments] . . . as necessary for purposes of this paragraph," 42 U.S.C.

§ 1395*l*(t)(14)(A)(iii)(II), encompasses "adjustments" for overhead in the same manner on an ongoing basis. *See* Hospitals Br. 5-6, 49.

In any event, reading section 1395*l*(t)(14) to contain overlapping references to a limited adjustment authority—making "double sure" the point is made—does not create the kind of superfluity that renders a statute ambiguous. *Mercy Hosp., Inc. v. Azar*, 891 F.3d 1062, 1068 (D.C. Cir. 2018) (quoting *Fla. Health Scis. Ctr., Inc. v. HHS*, 830 F.3d 515, 520 (D.C. Cir. 2016)). As we have recognized with respect to the Medicare statute, a "little overlap, either by accident or design, is to be expected in any complex statutory scheme with interdependent provisions" and does not alone create ambiguity. *Id*. The fact that average price data lumps together pharmaceutical sales to hospitals from sales to non-hospital providers seems to explain Congress' clear decision to omit from subclause (II) the authority in subclause (I) to vary reimbursement by hospital group. Without subclause (I)'s hospital-specific cost data, billion-dollar decisions differentiating among particular hospital groups could rest on significantly less exact information.

Moreover, to the extent that past agency practice bears on the question of statutory construction before us, it only confirms the Hospitals' reading that the agency's subclause (II) adjustment authority references overhead adjustments like those contemplated by subparagraph (E). As the agency described at length in 2012, during the preceding six years HHS had made no adjustments to its estimate of average sales prices other than occasional small tweaks to account for overhead costs (and, in any case, purported to rely only on its subclause (I) authority). *See* 2013 OPPS Rule, 77 Fed. Reg. at 68,383-86 (explaining the agency's methodology year by year over this period); *see also* 2016 OPPS Rule, 80

Fed. Reg. 70,298, 70,439 (Nov. 13, 2015) (providing a similar summary of the agency's past methodology); Hospitals Br. 49 ("[W]hen HHS previously made adjustments to the ASP-plus-6% rate, it explained at the time that it was doing so to account for estimates of overhead."). Indeed, the focus of the agency in those years was on collecting more accurate overhead-cost data to better tailor its adjustments. *See, e.g.*, 2013 OPPS Rule, 77 Fed. Reg. at 68,385. And, in the five years before the two challenged rules at issue, the agency simply adopted the statutory default rate of 106% of the average sales price under subclause (II) without making any adjustments at all. *See* 2018 OPPS Rule, 82 Fed. Reg. 52,362, 52,490 (Nov. 13, 2017).

In sum, at no point in any of the materials that the majority cites—and at no point of which I am aware—has HHS ever previously used its subclause (II) adjustment authority to make adjustments that are not modest changes to account for overhead. HHS itself has not claimed otherwise in its briefing before us. And HHS certainly has never used that adjustment authority to implement variations by hospital group. *See, e.g.*, HHS Br. 13 ("The final rule for 2018 established a *new sub-classification* for drugs purchased by 340B providers . . . ." (emphasis added)).

The Hospitals' limited reading of the adjustment authority that subclause (II) confers is supported by our previous caution that the term "adjustment" in this statute—like the term "modify" at issue in *MCI Telecommunications Corp. v. AT&T Co.*, 512 U.S. 218, 225 (1994), which the Court held "means to change moderately or in minor fashion"—cannot permit "basic and fundamental changes in the scheme." *Amgen, Inc. v. Smith*, 357 F.3d 103, 117 (D.C. Cir. 2004) (quoting *MCI*, 512 U.S. at 225). The majority distinguishes *Amgen* by quoting our observation there that we had "no occasion to engage in line drawing to determine when 'adjustments' cease

being 'adjustments.'" *Id*. But that observation made eminent sense in a dispute "involving only the payment amount for a single drug," and we went on to warn that a "more substantial departure from the default amounts would, at some point, violate the Secretary's obligation to make such payments and cease to be an 'adjustment.'" *Id*. (alteration omitted). Given the scale and segmentation of the rate cut at issue—reducing SCOD reimbursements by nearly a third, thereby eliminating $1.6 billion annually in reimbursements to many of the most financially vulnerable hospitals in the Medicare program—I disagree that, "[e]ven if there are limits to what HHS could permissibly consider an 'adjustment,' that line has not been crossed here." Maj. Op. at 29.

Not only is the majority wrong to reject the Hospitals' reading as creating unexplained surplusage, *see* Maj. Op. at 24-27, but the superfluity concerns cut decisively the other way. As discussed above, the majority essentially reads subclause (I) out of the statute by permitting the agency to do under subclause (II) without the requisite data what subclause (I) authorizes only with that data. The majority also renders superfluous the entirety of subparagraph (D). *See* 42 U.S.C. § 1395*l*(t)(14)(D). That subparagraph, occupying nearly a full column in the U.S. Code, specifies in detail how the "[a]cquisition cost survey for hospital outpatient drugs" is to be conducted, first by the Government Accountability Office (GAO) and later by HHS, after that agency has "tak[en] into account" the Comptroller General's "recommendations" as to the "frequency and methodology of subsequent surveys." *Id*. § 1395*l*(t)(14)(D)(i)-(ii). Subparagraph (D) further includes a provision dealing with "survey requirements," mandating that the GAO and HHS surveys "shall have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug." *Id*. § 1395*l*(t)(14)(D)(iii).

And a later clause details how acquisition-cost variations by hospital group are to be identified in GAO's initial surveys if they are to justify reimbursement-rate variations, noting that the Comptroller General "shall determine and report to Congress if there is (and the extent of any) variation in hospital acquisition costs for drugs among hospitals based on the volume of covered [outpatient department] services performed by such hospitals or other relevant characteristics of such hospitals (as defined by the Comptroller General)." *Id.* § 1395*l*(t)(14)(D)(iv).

The majority's reading drains each of these provisions of meaning. It allows the agency simply to purport to approximate hospital acquisition costs, and to claim authority to vary reimbursement rates by hospital group, based on adjusted average price data that HHS recasts as acquisition cost data, but that lacks the characteristics and process of collection that Congress specified in subclause (I). The Hospitals' reading does give distinct meaning to subclause (II)'s allowance for adjustment; it is the majority's reading that occasions significant superfluity without regard to Congress' structural decision to make subclauses (I) and (II) distinct alternatives.

Finally, the majority repeatedly justifies its reading by reference to the policy benefits of the agency's rate reductions and the reasonableness of the agency's alternative data and resulting estimates. *See, e.g.*, Maj. Op. at 18, 20, 22, 24, 27-28. The majority views it as relevant "backdrop," for example, that one result of the agency's proposed cuts will be to lower copayments for Medicare beneficiaries served by 340B hospitals, and to avoid the prospect of any beneficiary possibly paying more in a copayment than the hospital paid to buy the prescribed drugs. *Id.* at 20; *but see* HHS Off. of Inspector Gen., OEI-12-14-00030, Part B Payments for 340B-Purchased

Drugs 9 n.26 (Nov. 2015) (OIG Report) (noting that 340B hospitals "may waive all or part of the beneficiary's coinsurance"). And the majority notes HHS's worries that 340B hospitals might overprescribe drugs that bring reimbursement revenue. *See* Maj. Op. at 7; *but see* U.S. Gov't Accountability Off., GAO-15-442, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals 31 (June 2015) (noting HHS's view that "higher spending for Part B drugs at 340B hospitals" might "lead to better clinical outcomes" for patients served by those safety-net hospitals, who often are in "meaningful[ly]" poorer health than other patients). The majority also expresses confidence that the agency examined "data of undisputed reliability," Maj. Op. at 28, "acted on that data in a cautious way," *id*., and implemented a "fair, or even conservative, measure of the reduction needed to bring payments to those hospitals in parity with their costs to obtain the drugs," *id*. at 20. "In those circumstances," the majority declares, "HHS reasonably concluded that it need not continue subsidizing 340B providers with Part B (i.e. taxpayer) funds and Medicare beneficiaries' copayments." *Id*. at 28.

Those circumstances would perhaps be relevant were this a challenge to the agency's rules as arbitrary and capricious. But concerns about the program's effects, and confidence in the agency's care in using data other than those the statute requires, cannot somehow authorize the agency to do what the statute does not. As the Supreme Court has held, an "agency has no power to 'tailor' legislation to bureaucratic policy goals by rewriting unambiguous statutory terms." *Util. Air Regulatory Grp v. EPA*, 573 U.S. 302, 325 (2014). And, unmoored from the statute's express data-quality requirements, the asserted reliability of the quite different data HHS gathered here provides no assurance for its next rulemaking. Whether HHS's actions might have perceptible policy advantages does

not affect whether the statute authorizes what the agency has done.

It bears noting that, even were they relevant, the claimed policy benefits of the agency's new rate reductions are far from clear. The Section 340B drug discount program, enacted in 1992 as part of the Public Health Service Act, *see* 42 U.S.C. § 256b, permits 340B hospitals to "generate revenue" through "insurance reimbursement[] that may exceed the 340B price paid for the drugs." U.S. Gov't Accountability Off., GAO-11-836, Manufacturer Discounts in the 340B Program Offer Benefits, But Federal Oversight Needs Improvement 2 (2011) (GAO Report). As HHS itself has recognized, Congress anticipated that such above-cost reimbursement revenue would help to fund the public and nonprofit safety-net hospitals that qualify for 340B pricing: "Under the design of the 340B Program and Part B payment rules, the difference between what Medicare pays and what it costs to acquire the drugs is fully retained by the participating covered entities, allowing them to stretch scarce Federal dollars in service to their communities." OIG Report i (Executive Summary); *see also* HHS Off. of Inspector Gen. Memorandum Report: Payment for Drugs Under the Hospital Outpatient Prospective Payment System 8 (Oct. 22, 2010) (describing above-cost SCOD reimbursements to 340B hospitals as "an expected result given the purpose of the 340B Program").

The challenged rules took a major bite out of 340B hospitals' funding. Often operating at substantial losses, 340B hospitals rely on the revenue that Medicare Part B provides in the form of standard drug-reimbursement payments that exceed those hospitals' acquisition costs. 340B hospitals "have used the additional resources to provide critical healthcare services to communities with underserved populations that could not otherwise afford these services." Hospitals Br. 9 (citing GAO

Report at 17-18); *see also Cares Cmty. Health v. HHS*, 944 F.3d 950, 955 (D.C. Cir. 2019). Although stakeholders have debated "whether statutory changes should be made to enable Medicare and/or Medicaid to share in these savings," OIG Report 2, Congress has not made any such change. And, as written, subparagraph (E) does not empower the Secretary to "adjust" away from 340B hospitals substantial annual revenue they garner under the separate, unchallenged 340B statute to provide care to underserved communities.

The net effect of HHS's 2018 and 2019 OPPS 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. If that is a result that Congress intended to authorize, it remains free to say so. But because the statute as it is written does not permit the challenged rate reductions, I respectfully dissent.