No. 20-1114

IN THE

Supreme Court of the United States

AMERICAN HOSPITAL ASSOCIATION, et al.,

Petitioners,

v.

XAVIER BECERRA, in his official capacity as the Secretary of Health and Human Services, et al.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

BRIEF FOR THE PETITIONERS

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QUESTIONS PRESENTED

Under federal law, the reimbursement rate paid by Medicare for specified covered outpatient drugs is set based on one of two alternative payment methodologies. If the Department of Health and Human Services (HHS) has collected certain required "hospital acquisition cost survey data," HHS sets the reimbursement rate equal to the "average acquisition cost for the drug," and "may vary" that rate "by hospital group." 42 U.S.C. 1395*l*(t)(14)(A)(iii)(I). If HHS has not collected the required "hospital acquisition cost data," it must set a reimbursement rate equal to the "average price for the drug," which is "calculated and adjusted by [HHS] as necessary for purposes of this paragraph"—*i.e.*, paragraph (14) of subsection (t) of Section 1395*l*. 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II).

The questions presented are:

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

2. Whether *Chevron* deference permits HHS to set reimbursement rates based on acquisition cost and vary such rates by hospital group if HHS has not collected required hospital acquisition cost survey data.

PARTIES TO THE PROCEEDING

Petitioners 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. Petitioners were appellees in the court of appeals.

Respondents are Xavier Becerra, in his official capacity as Secretary of Health and Human Services, and the Department of Health and Human Services. Appellants in the court of appeals were Alex M. Azar II, in his official capacity as then-Secretary of Health and Human Services, and the Department of Health and Human Services.

CORPORATE DISCLOSURE STATEMENT

The corporate disclosure statement included in the petition for a writ of certiorari remains accurate.

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OPINIONS BELOW

The opinion of the court of appeals (Pet.App.1a-43a) is published at 967 F.3d 818. The order denying rehearing en banc (Pet.App.118a) is unpublished. The district court's opinions granting petitioners relief (Pet.App.44a-112a) are published at 348 F. Supp. 3d 62 and 385 F. Supp. 3d 1. The district court's order requiring entry of judgment (Pet.App.113a-117a) is available at 2019 WL 3037306.

JURISDICTION

The judgment of the court of appeals was entered on July 31, 2020. A timely petition for rehearing en banc was denied on October 16, 2020. The petition for a writ of certiorari was granted on July 2, 2021. The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

Relevant portions of 42 U.S.C. 1395*l* are reproduced in the appendix to this brief at 1a-29a. Section 1395*l* is reproduced in full in the joint appendix (JA) at JA212-354.

INTRODUCTION

In the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, Congress included comprehensive coverage of outpatient prescription drugs under the Medicare program. As part of that massive expansion of Medicare, Congress provided for the first time that hospitals would be separately reimbursed for certain outpatient drugs. Congress also set forth a methodology for deciding the amount of that reimbursement—a methodology that would govern billions of dollars of annual payments.

Although Congress has historically delegated considerable discretion to the Department of Health and Human Services (HHS or the agency) to develop reimbursement methodologies for other services covered by Medicare, in 42 U.S.C. 1395*l*(t)(14) Congress took a distinctly different approach to the reimbursements that hospitals would be paid for providing outpatient drugs. That provision sets forth in meticulous detail the methodology for outpatient drug reimbursement rates. The agency is given authority to set rates based on drug acquisition cost (and to vary rates among hospital groups) only if the agency first conducts cost surveys that meet the statute's rigorous requirements. If the agency has not conducted the analysis that the statute requires, it must set rates based on the drug's average price and may not differentiate among hospital groups.

Notwithstanding those unambiguous statutory directives, HHS decided starting in 2018 that it would single out one particular group of hospitals—Section 340B hospitals, whose mission is to provide care to impoverished and underserved communities—and set acquisition-cost-based reimbursement rates for most hospitals in that group *without* meeting the statutory requirements for such rates. That change cut reimbursement to those hospitals by 28.5% and imposed upon them a devastating $1.6 billion annual revenue loss, imperiling their vital mission.

The agency purported to justify that draconian cut by citing statutory language giving it the authority to "adjust[]" price-based rates (*i.e.*, the rates the agency must set when it has *not* done the statutorily required cost analysis). 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II). What the agency did was make assumptions about drug acquisition cost for Section 340B hospitals, compare that

figure to the price-based rate, and then provide that the price-based rate should be reduced by the percentage necessary to produce a number equivalent to the agency's estimate of a cost-based rate. As a result, Section 340B hospitals—and only Section 340B hospitals—are now reimbursed based on cost-based rates that were set without meeting any of the requirements that Congress mandated for establishing such rates.

The agency's action in this case was nothing less than an audacious administrative repeal of the express limitations Congress imposed on its authority. Congress took particular care to constrain the agency's power to set rates for outpatient drugs, and the agency simply decided that it would prefer not to respect those limitations. This is not merely a situation in which the agency has departed from the best meaning of the text of the statute it is charged with implementing. Here the agency has violated unambiguous statutory commands. That action cannot be defended under *Chevron, U.S.A., Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), or on any other ground. It is an affront to the separation of powers, and it should be reversed.

STATEMENT

1. a. Medicare is a federally administered health-insurance program for people who are age 65 or older or who have certain disabilities. About 60 million Americans are enrolled in Medicare, which spends approximately $800 billion per year.[1] Medicare Part A

[1] See CMS, *Medicare Beneficiaries at a Glance* (2020), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Beneficiary-Snapshot/Bene_Snapshot; CMS, *NHE Fact Sheet* (2020), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet.

primarily covers inpatient hospital services, hospice and skilled nursing-facility care, and home health care, while Part B primarily covers outpatient hospital care and doctors' services. Pet.App.2a.

Part B pays hospitals for covered outpatient services through the Outpatient Prospective Payment System, which fixes reimbursement amounts before a particular year begins (rather than after the services are provided). Pet.App.2a. For care other than provision of specified drugs, hospitals are reimbursed according to a formula that takes into account regional cost variation, technological changes, and other relevant information.

The operation of that reimbursement formula is detailed in 42 U.S.C. 1395*l*(t)(2) (paragraph (2)) and 42 U.S.C. 1395*l*(t)(9) (paragraph (9)). Under paragraph (2), HHS establishes groups of comparable outpatient services, determines "relative payment weights" for those services based on hospital costs, applies a "wage adjustment factor" that accounts for labor differences "across geographic regions," and applies other specified "adjustments." 42 U.S.C. 1395*l*(t)(2). And under paragraph (9), the agency annually "review[s] * * * and revise[s] the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) 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." 42 U.S.C. 1395*l*(t)(9)(A). If the agency makes adjustments under paragraph (9), then those adjustments must be budget neutral—that is, they "may not cause the estimated amount of expenditures" absent the adjustments "to increase or decrease." 42 U.S.C. 1395*l*(t)(9)(B).

In response to concerns about prescription drug coverage and reimbursement, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the Act), which mandates a separate payment methodology for certain separately payable outpatient drugs (*i.e.*, drugs that are reimbursed on a drug-by-drug basis rather than as part of a package with other services). See U.S. GAO, GAO-06-372, *Medicare Hospital Pharmaceuticals: Survey Shows Price Variation and Highlights Data Collection Lessons and Outpatient Rate-Setting Challenges for CMS* 2, 6 (Apr. 2006), https://www.gao.gov/assets/250/249967.pdf; Pub. L. No. 108-173, § 621, 117 Stat. at 2307-2308. Today, the Act's methodology determines how much Medicare pays hospitals for all separately payable outpatient drugs.[2]

That methodology, codified in paragraph (t)(14) of 42 U.S.C. 1395*l* (paragraph 14), specifies the "amount of payment" for a drug "that is furnished as part of a covered [outpatient-department] service." 42 U.S.C. 1395*l*(t)(14)(A). Section 1325*l*(t)(14)(A)(iii) provides that, for every year after 2005, the reimbursement rate for such a drug shall be "equal" to one of two measures:

> (I) to the average acquisition cost for the drug for that year (which, at the option of the Secretary [of HHS], may vary by hospital group (as defined by

[2] The methodology applies to "specified covered outpatient drugs," a subset of separately payable drugs used to treat serious conditions. GAO-06-372, *supra*, at 1-2. But HHS has a "longstanding policy" to use the Act's payment methodology for all separately payable drugs. 77 Fed. Reg. 68,210, 68,383 (Nov. 15, 2012). For ease of discussion, this brief refers generally to "drugs" when describing the relevant provisions.

> 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, [to] 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).[3]

The choice between the measures in subclause (I) and subclause (II) thus depends on whether the agency has collected "the hospital acquisition cost survey data under subparagraph (D)." 42 U.S.C. 1395*l*(t)(14)(A)(iii)(I). If the agency has done so, then subclause (I) applies, and the agency must take the data into account and set reimbursement rates based on each drug's "average acquisition cost," with the option to "vary" rates "by hospital group." *Ibid.* If the agency does not have the statutorily prescribed data, then subclause (II) applies, and reimbursement rates are determined based on each drug's average sales price (ASP)—specifically, ASP+6%. 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II); see 42 U.S.C. 1395w-3a;

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[3] For 2004 and 2005, Congress mandated rates based on "average wholesale price" and specified the range or maximum amount of those rates—except with respect to certain "orphan drugs," as to which "payment" was to "equal such amount as" the agency "may specify." 42 U.S.C. 1395*l*(t)(14)(A)(i)-(ii), (C).

Pet.App.4a (average sales price is based on data provided by drug manufacturers). Both subclauses are "subject to subparagraph (E)," 42 U.S.C. 1395*l*(t)(14)(A)(iii), which authorizes the agency to make "[a]djustment[s] in payment rates" so as to "take into account" a 2005 report issued by the Medicare Payment Advisory Commission (MedPAC) on "overhead and related expenses," 42 U.S.C. 1395*l*(t)(14)(E).[4]

Congress prescribed detailed requirements governing collection of hospital acquisition-cost data. Congress instructed the Comptroller General to conduct acquisition-cost surveys in 2004 and 2005. See 42 U.S.C. 1395*l*(t)(14)(D)(i)(I). Congress also directed the Comptroller General to furnish data to HHS for use in subsequently setting payment rates, and to "determine and report to Congress" any "variation in hospital acquisition costs for drugs among hospitals." 42 U.S.C. 1395*l*(t)(14)(D)(i)(I), (iv). For years after 2005, Congress shifted the responsibility to HHS, which must "conduct periodic subsequent surveys," taking into account Comptroller General recommendations as to their "frequency and methodology." 42 U.S.C. 1395*l*(t)(14)(D)(i), (ii); see 42 U.S.C. 1395*l*(t)(14)(D)(v). Congress provided that a survey carried out by HHS is adequate only if it includes "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." 42 U.S.C. 1395*l*(t)(14)(D)(iii).

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[4] Under subparagraph (14)(H), "[a]dditional expenditures" resulting from reimbursement under paragraph (14) are to be taken into account after 2005 "in establishing the conversion, weighting, and other adjustment factors * * * under paragraph (9)." 42 U.S.C. 1395*l*(t)(14)(H).

b. In paragraph (t)(12) of Section 1395*l*, Congress precluded judicial review of certain determinations made under certain paragraphs of subsection (t)—but did not mention paragraph (14). Paragraph (12) states, *inter alia*, that "[t]here shall be no * * * judicial review" of "(A) the development of the classification system under paragraph (2), including the establishment of groups and relative payment weights for covered [outpatient-department] services, of wage adjustment factors, other adjustments, and methods described in paragraph (2)(F)," or "(C) periodic adjustments made under paragraph (6)." 42 U.S.C. 1395*l*(t)(12)(A), (C).[5]

2. HHS did not collect hospital acquisition-cost survey data that meets Congress's criteria. Pet.App.3a; see n.11, *infra*. Accordingly, for the first twelve years following the Act's effective date, HHS did not set drug reimbursement rates based on acquisition cost and did not vary reimbursement rates by hospital group. Instead, the agency set reimbursement rates for separately payable drugs based on the average price of each drug and applied those rates uniformly across all hospital groups. See JA46-47; 80 Fed. Reg. 70,298, 70,439 (Nov. 13, 2015); 77 Fed. Reg. 68,210, 68,383-68,386 (Nov. 15, 2012).

HHS broke from that practice in its 2018 rule, applying a reimbursement rate based on an estimated acquisition cost to only one group of hospitals while continuing to apply the default average-price reimbursement rate to all others. See JA46-47, 118-119.

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[5] The lower courts decided that the reference to "paragraph (6)" was a scrivener's error and that Congress meant to refer to paragraph (9). Pet.App.9a-10a, 67a n.13.

Specifically, HHS singled out participants in the 340B program.

Congress established the 340B program in 1992, see Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967-4971, and expanded it in 2010, see Pub. L. No. 111-148, § 7101, 124 Stat. 119, 821. That program requires that drug manufacturers, as a condition of having their drugs covered by Medicaid, offer participating hospitals and clinics (hereinafter 340B hospitals) a substantial discount on thousands of outpatient drugs. See 42 U.S.C. 256b(a). That discount is essential to 340B hospitals, which are nonprofit entities that serve underinsured populations. By pushing drug costs for those providers below the amount that insurers reimburse, the 340B program allows participating hospitals to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384, pt. 2, at 12 (1992); see HHS, *Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B*, at 15 (July 2005) (HRSA Manual), https://www.hrsa.gov/sites/default/files/opa/programrequirements/forms/hemophiliatreatmentcenter340bmanual.pdf.

Put another way, Congress designed the 340B program so that insurers like Medicare would subsidize critical services offered by safety-net hospitals. See HHS, *Part B Payments for 340B-Purchased Drugs* i (Nov. 2015) (OIG Report), https://oig.hhs.gov/oei/reports/oei-12-14-00030.pdf; see also HRSA Manual 14. And HHS's use of average-price reimbursement has been consistent with, and undertaken with full knowledge of, that design. See, *e.g.*, HHS, *Payment for Drugs Under the Hospital OPPS* 1 (Oct. 22, 2010) ("[I]n the aggregate, Medicare payments were 31 percent

higher than acquisition costs among responding 340B hospitals."), https://oig.hhs.gov/oei/reports/oei-03-09-00420.pdf.

In its 2018 rule, HHS disagreed with Congress's 340B policy, finding "subsidiz[ation]" of 340B hospitals "through Medicare payments for separately payable drugs" to be "inappropriate." JA58. Instead, the agency asserted, Medicare payments should be "aligned with the resources expended by hospitals to acquire" covered drugs. JA57. HHS "recogniz[ed] the intent of the 340B Program"—that is, "to allow covered entities, including eligible hospitals, to stretch scarce resources in ways that enable hospitals to continue providing access to care for Medicare beneficiaries and other patients." JA57-58. But the agency nonetheless chose to eliminate the gap between Medicare reimbursement and 340B hospitals' drug costs. See JA49-125.

Accordingly, while all other hospital groups retained an average-price-based reimbursement rate of ASP+6% for their separately payable drugs, the agency decided to reimburse 340B hospitals based on an estimated acquisition cost. See, *e.g.*, JA62, 77 (rate agency chose for 340B hospitals best "reflect[s] the hospital acquisition costs for 340-B acquired drugs"); JA51-54, 60-63, 78-82, 98-99. To achieve that end, the agency slashed rates to those hospitals by nearly 30%—to ASP minus 22.5%, thus cutting their annual funding by $1.6 billion. See JA60-63, 127-128; see also JA49-125 (excepting certain 340B hospitals from the change).

In the final 2018 rule, the agency acknowledged that it did "not have hospital acquisition cost data" meeting Congress's requirements, and therefore could not proceed under subclause (I)—the methodology

that bases reimbursement rates on acquisition cost and permits HHS to vary rates by hospital group. See JA61. But the agency believed that it could take those steps under subclause (II) because that provision grants the agency authority to "calculate[] and adjust[]" an average-price reimbursement rate "for purposes of" paragraph (14). 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II). According to the agency, that "adjustment" authority confers "broad discretion to adjust payments for drugs" as the agency sees fit—discretion that is not "limited" to "minor changes." JA76-78. The agency based its acquisition-cost reimbursement figure on a MedPAC report that, despite "data limitations," made various assumptions and estimated the average minimum discount received by 340B hospitals. JA52, 120; see JA53-63.

3. Petitioners filed suit in D.C. federal court challenging the agency's authority to cut reimbursement rates for 340B hospitals.[6]

The district court ruled for petitioners. The court explained that 42 U.S.C. 1395*l*(t)(12) does not preclude judicial review because the agency's action was patently outside the scope of its statutory authority. Pet.App.68a-70a, 77a-79a. The court reasoned that "the statutory scheme is clear": if, as here, HHS does not have "the required acquisition cost data," it "must calculate reimbursement rates by reference to the drugs' *average sales prices*" under subclause (II).

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[6] Petitioners' initial suit was dismissed because the agency had not yet denied a specific claim for reimbursement. Pet.App.8a. After that denial occurred, petitioners renewed their challenge to the 2018 rule. Pet.App.8a. And once the agency issued the 2019 rule, which continued the same policy, see JA178, petitioners amended the complaint to challenge that rule as well, Pet.App.93a-94a.

Pet.App.76a. Although subclause (II) authorizes the agency to make "adjustments," the agency "cannot fundamentally rework the statutory scheme—by applying a different methodology than the provision requires—to achieve under [subclause] (II) what [it] could not do under [subclause] (I) for lack of adequate data." Pet.App.76a; see Pet.App.77a. The court remanded to the agency to consider remedies. Pet.App.112a.

4. A divided panel of the D.C. Circuit reversed. Pet.App.1a-43a; see Pet.App.118a (denying rehearing).

a. All three judges agreed that judicial review is not precluded. Pet.App.8a-17a; Pet.App.31a (dissent). Noting the strong presumption in favor of review of administrative action, the court of appeals ruled that agency determinations under paragraph (14) are not encompassed by paragraph (12)'s preclusion of review. The court explained that the portions of paragraph (12) on which the government relied cover only determinations under paragraphs *other than* paragraph (14) and that "none of the actions described" in those other paragraphs "plausibly, let alone clearly, comprises [outpatient drug] reimbursement adjustments." Pet.App.11a; see Pet.App.9a-17a.

b. i. On the merits, the panel majority acknowledged the "force" of petitioners' argument that if the agency could set reimbursement rates based on acquisition cost and vary rates by hospital group without the "robust study data" that Congress required, then "subclause (I)'s requirement to take into account th[at] data * * * would be meaningless." Pet.App.23a-24a. The majority nevertheless deemed the subclause (II) adjustment authority ambiguous and deferred to HHS's rate cut under *Chevron*, concluding that there

may be no "limits to what HHS could permissibly consider an 'adjustment.'" Pet.App.29a; see Pet.App.24a.

ii. Judge Pillard dissented from that merits ruling. She concluded that the statute is unambiguous: "Only subclause (I), not subclause (II), authorizes HHS to set different reimbursement rates for distinct hospital groups" based on acquisition cost, and provides that authorization only if HHS "tak[es] into account the different acquisition costs identified in the robust, hospital-specific data that Congress required the agency to collect." Pet.App.35a. The agency's contrary interpretation, she explained, "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." Pet.App.39a. It also renders meaningless "nearly a full column in the U.S. Code" that "specifies in detail" how HHS must conduct acquisition-cost surveys. Pet.App.39a; see Pet.App.36a-37a. That allows "billion-dollar decisions differentiating among particular hospital groups" to "rest on significantly less exact information" than Congress required. Pet.App.37a.

Judge Pillard deemed the majority's contrary reasoning erroneous. Although the majority made much of Congress's purported desire to equate reimbursement rates with acquisition costs, Judge Pillard explained that a "statute's overarching goal is not its only goal, to be achieved however the agency sees fit." Pet.App.34a. She disagreed with the majority's assertion that a restrained interpretation of HHS's subclause (II) "adjust[ment]" authority would render it superfluous in light of subparagraph (14)(E), which permits a limited adjustment for overhead costs based on a particular 2005 report. Pet.App.36a-38a. And she

decried the majority's "repeated[]" attempts to "justif[y] its reading by reference to the policy benefits of the agency's rate reductions and the reasonableness of the agency's alternative data," explaining that those points "cannot somehow authorize the agency to do what the statute does not." Pet.App.40a-41a.

SUMMARY OF ARGUMENT

The statutory provision at issue in this case is unambiguous: HHS may set reimbursement for specified prescription drugs based on acquisition cost, and may vary such rates by hospital group, *only* if it first collects "hospital acquisition cost survey data" as defined by Congress and then sets rates based on that data. 42 U.S.C. 1395*l*(t)(14)(A)(iii)(I). For the years 2018 and 2019, the agency purported to set rates based on acquisition cost for Section 340B hospitals but did not collect (and therefore did not rely on) the survey data that Congress made a precondition for setting cost-based rates. The agency therefore acted without "statutory * * * authority," and its orders should be "set aside." 5 U.S.C. 706(2).

I. Rates set under the authority of Section 1395*l*(t)(14) are subject to judicial review. This Court applies a strong presumption in favor of judicial review of agency action, and the government has not come close to overcoming that presumption.

Congress did not expressly preclude review of rates set under paragraph (14), and the government has not contended otherwise. Instead, it has pointed to provisions precluding judicial review of certain rate-setting decisions taken under *other* paragraphs of Section 1395*l*(t). See 42 U.S.C. 1395*l*(t)(12)(A), (C). But the paragraph (14) "adjust[ment]" authority that HHS invoked here, 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II), sets forth what the agency itself has described as a methodology

separate from the one set forth in the paragraphs the government cites. As a textual matter, then, the bar on judicial review does not apply. Notably, the same 2003 statute that included paragraph (14) enacted other targeted amendments to Section 1395*l* that expressly precluded judicial review of certain other agency decisions—but conspicuously did not do so with respect to rate-setting for outpatient drugs under paragraph (14).

II. On the merits, the government cannot muster any persuasive response to the straightforward textual argument that the agency may not set rates based on acquisition cost unless it firsts conducts the cost study that paragraph (14) requires. The government purports to find the power to disregard Congress's cost-study requirement in the ancillary authority granted in subclause (II) to "adjust[]" price-based rates. But that reading cannot be reconciled with the text, structure, or purposes of paragraph (14). Congress gave the agency only the modest power to "adjust[]" price-based rates—that is, to take average price as a starting point and make slight changes—and did not confer a sweeping power to adopt whatever rate-setting policy the agency prefers. And it is implausible to think that Congress would have given the agency free rein to ignore the exacting cost-study requirements for cost-based rates mandated in the provision's immediately preceding subclause, especially given the evident importance Congress attached to tightly constraining the agency's authority to base rates on acquisition cost rather than average price.

III. *Chevron* deference cannot justify the agency's action, because the text of Section 1395*l*(t) unambiguously prohibits setting cost-based rates in the absence of the statutorily prescribed cost study. A reviewing

court cannot even consider whether to afford *Chevron* deference unless the statutory provision is "genuinely ambiguous" with respect to the question at issue, "even after a court has resorted to all the standard tools of interpretation." *Kisor* v. *Wilkie*, 139 S. Ct. 2400, 2414 (2019). There is no genuine ambiguity here. Whatever modest discretion subclause (II) may afford to adjust price-based rates to ensure that they reflect actual prices, the provision cannot reasonably be construed as a sweeping delegation to the agency to disregard the meticulous requirements Congress set forth for rates based on acquisition costs. Allowing the agency to invoke *Chevron* to supplant Congress's express judgments about how outpatient drug reimbursement should be set would raise profound separation-of-powers problems. It should not be countenanced.

ARGUMENT

I. Section 1395*l*(t)(12) Does Not Preclude Petitioners' Suit

A. The Government Cannot Overcome The Strong Presumption Favoring Judicial Review

This Court "applies a 'strong presumption' favoring judicial review of administrative action." *Mach Mining, LLC* v. *EEOC*, 575 U.S. 480, 486 (2015) (quoting *Bowen* v. *Mich. Acad. of Fam. Physicians*, 476 U.S. 667, 670 (1986) (refusing to preclude review of Medicare Part B regulations)). Where, as here, Congress limits an agency's authority, Congress does not normally give the agency the sole power to police those limits, thereby issuing a "blank check[] drawn to the credit of some administrative officer." *Bowen*, 476 U.S. at 671 (citation omitted); see *United States* v.

Nourse, 34 U.S. 8, 28-29 (1835) (Marshall, C.J.). Accordingly, "the agency bears a heavy burden in attempting to show that Congress prohibit[ed] all judicial review of the agency's compliance" with a "legislative mandate," *Mach Mining*, 575 U.S. at 486 (citation omitted; alteration in original)—one that can be met only by "clear and convincing evidence," *Reno* v. *Cath. Soc. Servs., Inc.*, 509 U.S. 43, 64 (1993); see, *e.g.*, *PDR Network, LLC* v. *Carlton & Harris Chiropractic, Inc.*, 139 S. Ct. 2051, 2060, 2064 (2019) (Kavanaugh, J., concurring in the judgment).

The government cannot satisfy that heavy burden. Congress could easily have precluded judicial review across the board in Section 1395*l*. But it did not do so. Instead, in subsection (t), and more generally throughout Section 1395*l*, Congress distinguished between determinations that should be left to the agency and those subject to judicial review. See 42 U.S.C. 1395*l*(t)(12), (t)(21)(E); see also, *e.g.*, 42 U.S.C. 1395*l*(i)(2)(D)(vi), (m)(4), (u)(4)(E), (x)(4). The jurisdiction-stripping provisions in Section 1395*l* single out particular subsections, paragraphs, or subparagraphs of Section 1395*l*—and often only particular *aspects* of the agency action authorized under those provisions. See, *e.g.*, 42 U.S.C. 1395*l*(t)(12)(E). The provision under which the agency acted here—paragraph (14)—is not mentioned anywhere in those jurisdiction-stripping provisions. See 42 U.S.C. 1395*l*(t)(12), (14). And, in contrast to some other paragraphs of subsection (t), paragraph (14) does not state that determinations made under its authority should be carried out *pursuant to* one of the paragraphs that *is* covered by a jurisdiction-stripping provision. See, *e.g.*, 42 U.S.C. 1395*l*(t)(13)(B), (t)(18)(B).

That is the beginning and end of the inquiry. Especially where Congress has made such particularized judgments about reviewability, one can hardly say that Congress unambiguously foreclosed judicial review of the agency's actions under paragraph (14) simply by remaining silent on the matter. See, *e.g.*, *Lindahl* v. *OPM,* 470 U.S. 768, 779-780 (1985) ("[W]hen Congress intends to bar judicial review altogether, it typically employs language far more unambiguous and comprehensive.").

Congress had ample reason to provide for judicial review of agency determinations under paragraph (14). Unlike many Medicare rate-setting provisions, paragraph (14) tightly cabins rate-setting discretion for outpatient drugs. Subparagraph (14)(D) sets forth detailed, multi-step requirements for agency collection of rigorous survey data on hospitals' drug acquisition costs. See 42 U.S.C. 1395*l*(t)(14)(D). And subclauses (I) and (II) of subparagraph (14)(A) specify what reimbursement rates "shall be equal" to and permit the agency to set rates based on acquisition cost only if the agency takes "into account" the required data. 42 U.S.C. 1395*l*(t)(14)(A)(iii)(I)-(II). The methodology prescribed in paragraph (14) is thus the polar opposite of the open-ended, discretionary agency decision-making that Congress will sometimes insulate from judicial review. Rather, it is exactly the kind of specific "legislative mandate," *Mach Mining*, 575 U.S. at 486, that calls out for judicial enforcement.

Providing for judicial review of the agency's paragraph (14) determinations makes sense. Those determinations, which control the allocation of billions of dollars in hospital reimbursement for thousands of prescription drugs, Pet.App.6a, 75a, have an extraordinary impact on hospitals. The evident purpose of

Congress's decision to sharply limit agency discretion was to protect the interests of hospitals—particularly when the agency opts to set rates based on cost, and chooses to single out particular hospital groups for differential treatment, rather than following the default historical practice of setting uniform rates based on price. Judicial review is the only avenue for enforcing those limitations on agency discretion. See, *e.g.*, *Bd. of Governors of Fed. Rsrv. Sys.* v. *MCorp Fin., Inc.*, 502 U.S. 32, 42-44 (1991).

B. The Government's Preclusion Arguments Lack Merit

Unable to point to any statutory text precluding review of paragraph (14) determinations, the government has tried to devise a preclusion argument by relying on two other provisions: subparagraphs (t)(12)(A) and (t)(12)(C), which do not mention paragraph (14). See 42 U.S.C. 1395*l*(t)(12)(A), (C). Neither of those subparagraphs is applicable in this case.

1. a. Subparagraph (12)(A) precludes review of agency determinations made under paragraph (2), which requires the agency to develop a classification system for certain outpatient services. See 42 U.S.C. 1395*l*(t)(2). Paragraph (2) specifies that the agency "may establish groups of covered [outpatient department] services"; shall "establish relative payment weights" based on "hospital costs"; shall "determine a wage adjustment factor"; and shall "establish" certain specified "adjustments" and "other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals." *Ibid.*; see Pet.App.10a (discussing paragraph (2) and explaining that the agency "groups certain medical services together that are 'comparable clinically,'" then "establishes 'relative payment weights' for

the grouped services * * * based on hospital costs" and "sets default payment amounts for the services" in each group "corresponding to the weights") (citations omitted). Subparagraph 12(A) precludes review of "the development of the classification system under paragraph (2), including the establishment of groups and relative payment weights for covered [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).[7]

Subparagraph (t)(12)(C) precludes review of "periodic adjustments made under paragraph [(t)](6)." 42 U.S.C. 1395*l*(t)(12)(C). The courts below stated that the reference to paragraph (6) is a scrivener's error, concluding that the provision is really intended to refer to periodic adjustments under paragraph (9). Pet.App.9a-10a, 67a n.13. That leap to paragraph (9) is itself a far cry from clear and convincing textual evidence that Congress precluded review of determinations made under paragraph (9)—let alone determinations made under paragraph (14). In any event, paragraph (9) simply refers back to paragraph (2), stating that "[t]he Secretary shall review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) 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." 42 U.S.C. 1395*l*(t)(9)(A).

None of that has anything to do with the paragraph (14) determinations at issue here. Paragraph (14) specifies rates for outpatient drugs, dictating that the agency reimburse hospitals in an amount "equal to"

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[7] Subparagraph (t)(2)(F) addresses "controlling" service volume. 42 U.S.C. 1395*l*(t)(2)(F).

drug acquisition cost (if statutorily required survey data is available) or average drug price. 42 U.S.C. 1395*l*(t)(14)(A)(iii). Paragraph (14) requires that the agency calculate the reimbursement for those drugs on a yearly basis. See *ibid.* (referring to acquisition cost or average price for the "year"). And paragraph (14) does not call for consideration of the factors that go into determining payments under paragraph (2) or updating those payments under paragraph (9)—for instance, hospital costs, geographically disparate wage costs, the relative costs of other services, or "changes in technology." 42 U.S.C. 1395*l*(t)(2)(C)-(D), (t)(9)(A). Thus, although most outpatient services are compensated through the paragraph (2) and (9) methodology, outpatient drugs are "separately payable" under the entirely different, targeted methodology set forth in paragraph (14). JA43-47; see, *e.g.*, 77 Fed. Reg. at 68,262 (paragraph (14) payments "are developed through a separate methodology, outside the relative payment weight based process").

Paragraphs (2) and (9) do authorize the agency to make certain "adjustments" when the agency sets payment weights and the like for outpatient services other than separately payable drugs. But paragraph (14) contains its own separate authority for "adjust[ments]" to drug reimbursement rates—and its own separate limitations on what "adjust[ments]" the agency can make in implementing paragraph (14). 42 U.S.C. 1395*l*(t)(14); see Pet.App.14a. If the required survey data is available, and the agency must therefore reimburse based on drug acquisition cost, then the agency "may vary" the reimbursement rate "by hospital group." 42 U.S.C. 1395*l*(t)(14)(A)(iii)(I). If the data is not available and the agency must reimburse based on average price, then the agency may "calculate[] and adjust[]" that price for a particular drug "as necessary

for purposes of *this* paragraph"—*i.e.*, paragraph (14) itself. 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II) (emphasis added). In either event, under subparagraph (14)(E) the agency may "adjust" the payments to account for recommendations contained in a particular report on "overhead and related expenses, such as pharmacy services and handling costs." 42 U.S.C. 1395*l*(t)(14)(E).

As the court of appeals recognized, it would be "odd" indeed for Congress to provide the agency in paragraph (14) "with those specific authorities to 'adjust'" drug reimbursement rates if the agency "nonetheless has the general authority to adjust those rates as it sees fit under paragraph (2) or (9)." Pet.App.14a. For instance, if paragraph (14) reimbursement rates were subject to adjustment under subparagraph (2)(E), which allows "adjustments for certain classes of hospitals," then there would have been no reason for Congress to include in subclause (I) of paragraph (14) authorization for the agency to vary the drug reimbursement rate "by hospital group" under limited circumstances. 42 U.S.C. 1395*l*(t)(2)(E), (14)(A)(iii)(I).

Subparagraph (14)(H) underscores that the payment-amount calculation required under paragraph (14) is something *different* from the annual adjustments that occur under paragraph (9) (which in turn revise determinations previously made under paragraph (2)). Subparagraph (14)(H) states that "[a]dditional expenditures resulting from this paragraph [(14)] shall not be taken into account in establishing the conversion, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years." 42 U.S.C. 1395*l*(t)(14)(H). Paragraph (9), in turn, provides for annual "adjustments" under subparagraph (9)(A),

states that those "adjustments for a year may not cause the estimated amount of expenditures * * * for the year to increase or decrease," and mandates that for 2004 and 2005 "the Secretary shall not take into account under this subparagraph or paragraph (2)(E) any expenditures" made as a result of paragraph (14). 42 U.S.C. 1395*l*(t)(9)(A)-(B).

Those provisions make clear that the self-contained paragraph (14) methodology results in an independently determined "expenditure" that must later be taken into account when paragraph (9) adjustments are made, to ensure that those adjustments do not cause overall expenditures to exceed a budgeted amount. Pet.App.15a-16a. Subparagraph (14)(H) dictates that the agency will arrive at some number representing "expenditure[s]" as a result of carrying out all the instructions set forth in paragraph (14)(A)(iii), including making any appropriate "adjust[ment]" under subclause (II), and only *afterwards* will proceed to "establish[] the conversion, weighting, and other adjustment factors" under paragraph (9). 42 U.S.C. 1395*l*(t)(14)(H); see 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II). If the paragraph (14) methodology, by which the amount of the "expenditures resulting from" paragraph (14) is determined, were actually *part of* the "establish[ment]" of the "adjustment factors" under paragraph (9), then paragraph (14)(H) could hardly state that the result of that methodology should be taken into account when those "adjustment factors" are "establish[ed]" in the first instance. 42 U.S.C. 1395*l*(t)(14)(H).

The court of appeals put the point in practical terms: "Congress conceived of the [paragraph (14)] rate-setting program as entirely distinct from the general paragraph (2) and (9) program," yet still "wanted

to achieve budget neutrality for Part B payments as a whole" in order to "control Medicare Part B spending." Pet.App.17a. Accordingly, the expenditures resulting from paragraph (14) are set "in a vacuum," and are themselves "unaffected by" the paragraph (9) "budget-neutrality requirement." Pet.App.15a; see, *e.g.*, JA47 ("budget neutral weight scalar" is not applied to paragraph (14) payments); 77 Fed. Reg. at 68,262. Once the agency determines paragraph (14) expenditures for separately payable drugs, "those set-in-stone numbers" get added to whatever expenditures result from any paragraph (9) adjustments—and if the total exceeds the existing "estimate[]" of expenditures for that year, then the paragraph (9) adjustments must be revised downward in order to render the budget neutral. Pet.App.15a-16a; see 42 U.S.C. 1395*l*(t)(9)(B), (14)(H).

A close reading of the statutory text thus leads to only one conclusion: paragraph (14) determinations, including adjustments made under the authority of that paragraph, are not determinations under paragraph (2) or paragraph (9). Congress's preclusion of judicial review of paragraph (2) and paragraph (9) adjustments is therefore irrelevant. If Congress had wanted to preclude review of paragraph (14) determinations, Congress would have said so.

b. That conclusion is cemented by examining other provisions in Section 1395*l* and the history of their enactment. Congress enacted what are now subparagraphs (12)(A) and (12)(C) in 1997. See Pub. L. No. 105-33, § 4523(a), 111 Stat. 251, 449. Congress later added many new paragraphs to subsection (t), and expressly precluded judicial review of agency determinations made pursuant to some of those paragraphs. But

Congress did not do the same with respect to paragraph (14), which was enacted in 2003. See Pub. L. No. 108-173, § 621(a), 117 Stat. at 2307.

In some instances, Congress precluded judicial review by amending paragraph (12) or by precluding review directly in one of the newly added paragraphs. For example, when Congress added paragraphs (5), (6), and (7) to subsection (t) in 1999, Congress simultaneously added a new clause to paragraph (12): clause (E), which precludes judicial review of some determinations made under paragraphs (5) and (6), but notably does not preclude judicial review of any determination made under paragraph (7). See 42 U.S.C. 1395*l*(t)(12)(E); Pub. L. No. 106-113, appendix F, §§ 201(a)-(b), (d), 202(a), 113 Stat. 1501, 1501A-336 to 1501A-344; see also Pet.App.12a.[8] In addition, when Congress added paragraph (21) to subsection (t) in 2015, Congress included a preclusion-of-review provision directly within the new paragraph, providing that "[t]here shall be no * * * judicial review" of certain paragraph (21) determinations. See 42 U.S.C. 1395*l*(t)(21)(E); Pub. L. No. 114-74, § 603, 129 Stat. 584, 598.[9] When Congress enacted paragraph (14), however, Congress did not take either of those steps.

In other instances, Congress precluded judicial review by invoking subparagraph (t)(2)(E) in a newly added paragraph—thus triggering subparagraph

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[8] Paragraph (5) addresses "outlier" charges; paragraph (6) addresses innovative drugs; and paragraph (7) addresses "transitional" adjustments. 42 U.S.C. 1395*l*(t)(5), (6), (7). Congress also included in paragraph (2) instructions for adjustments relating to paragraphs (5) and (6)—and a preclusion-of-review provision in paragraph (12) covers paragraph (2) determinations. See 42 U.S.C. 1395*l*(t)(2)(E); 42 U.S.C. 1395*l*(t)(12)(A).

[9] Paragraph (21) addresses payments for "off-campus outpatient department" services. 42 U.S.C. 1395*l*(t)(21).

(t)(12)(A)'s preclusion of judicial review of subparagraph (t)(2)(E) determinations. Pet.App.13a. For example, paragraph (13), which was added to subsection (t) by the very same 2003 statute that added paragraph (14), provides that adjustments relating to various "costs incurred by" rural hospitals shall be made "under paragraph [(t)](2)(E)." 42 U.S.C. 1395*l*(t)(13)(B); see Pub. L. No. 108-173, § 411(b), 117 Stat. at 2274. And paragraph (18), which was enacted in 2010 and provides for adjustments relating to cancer hospitals, similarly states that those adjustments shall be made "under paragraph [(t)](2)(E)." 42 U.S.C. 1395*l*(t)(18)(B); see Pub. L. No. 111-148, § 3138, 124 Stat. at 439. But Congress made no reference to subparagraph (t)(2)(E) when providing in paragraph (14) for the possibility of a limited adjustment to carry out the purposes of paragraph (14). See 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II).

Because paragraph (14) is housed in subsection (t), that subsection is most relevant to the analysis here—but there are also targeted preclusion provisions sprinkled throughout Section 1395*l*, several of which were added in the same 2003 enactment that added paragraph (14). See Pub. L. No. 108-173, §§ 413(a)-(b)(1), 621(a)(1), 626(b)(2), 117 Stat. at 2275-2277, 2307-2310, 2319. The 2003 enactment inserted a provision in subsection (i), which deals with ambulatory surgical centers, stating that "[t]here shall be no * * * judicial review" of "the classification system, the relative weights, payment amounts, and the geographic adjustment factor, if any, under this subparagraph." Pub. L. No. 108-173, § 626(b)(2), 117 Stat. at 2319; see 42 U.S.C. 1395*l*(i)(2)(D)(vi). The 2003 enactment also added a provision to subsection (m) stating that "[t]here shall be no * * * judicial review respecting"

various matters relating to incentive payments for underserved areas. Pub. L. No. 108-173, § 413(b)(1), 117 Stat. at 2277; see 42 U.S.C. 1395*l*(m)(4). And the 2003 enactment added to Section 1395*l* a new subsection (u) that precludes judicial review of several determinations relating to payments for physician-scarcity areas. Pub. L. No. 108-173, § 413(a), 117 Stat. at 2275-2276; see 42 U.S.C. 1395*l*(u)(4)(E).[10] Paragraph (14) contains no such preclusion provision.

Congress was thus highly attuned to the preclusion issue when it enacted paragraph (14). Congress's choice *not* to preclude judicial review of paragraph (14) determinations, while in the very same enactment precluding review of other determinations, is necessarily a "significan[t]" one. *Babb* v. *Wilkie*, 140 S. Ct. 1168, 1177 (2020); see, *e.g.*, *Salinas* v. *U.S. R.R. Ret. Bd.*, 141 S. Ct. 691, 698 (2021).

c. That conclusion is further confirmed by longstanding agency practice, including in the rulemaking at issue here. Since paragraph (14)'s enactment in 2003, the agency has *never* invoked paragraph (2) or paragraph (9) to set payment amounts for the drugs covered by paragraph (14). Pet.App.14a-15a. And when the agency made the radical change that is the subject of this suit, the agency identified only one provision as authority for doing so: subparagraph (14)(A)(iii)(II), which states that "average price for the drug" may be "calculated and adjusted by the Secretary as necessary for purposes of" paragraph (14). See JA73-81; see also JA169-178. In response to commenters' challenges to the "[s]tatutory [a]uthority" for the change, the agency emphasized that "we are *using*"

[10] Other paragraphs of Section 1395*l*, added on other dates, preclude judicial review in similarly express terms. See 42 U.S.C. 1395*l*(x)(4), (z)(4).

subparagraph (t)(14)(A)(iii)(II)—not paragraphs (2) or (9)—"to apply a downward adjustment * * * to better reflect acquisition costs of th[e] drugs." JA78 (emphasis added); see, *e.g.*, JA118-119.

The preamble of the 2018 rule, which covers a variety of Medicare payments, does advert generally to paragraph (9). But the preamble explains that the rule will "describe [that] and various *other* statutory authorities in the relevant sections of this final rule," JA40 (emphasis added), and the rule itself contains no mention of paragraph (2) or (9) as an authority for the outpatient-drug rate change, see JA49-125. That is notable given that the 2018 rule elsewhere relies on paragraph (2) as the authority for different rate changes. Pet.App.15a; see 82 Fed. Reg. 52,356, 52,364-52,365, 52,421 (Nov. 13, 2017).

2. In addition to its flawed textual argument, the government has advanced a policy argument: that Congress could not have wanted judicial review because there is no remedy for underpayments under paragraph (14). See Opp.14-17. The government argued precisely the opposite in opposing a preliminary-injunction motion in the district court. Dkt. No. 18, at 40 (D.D.C. No. 17-cv-2447, Dec. 1, 2017) (arguing that petitioners' "economic loss here would be recoverable if the Court were to enter a final judgment in their favor"). In all events, even if a policy argument of that kind could justify preclusion of review in the absence of a clear textual bar (and it cannot), the argument fails on its own terms.

That is so for multiple reasons. The statute's budget-neutrality requirement does not bar retroactive relief for underpayments in 2018 and 2019 because the statute requires budget neutrality only as to

"estimate[s]" for future years, not retroactive remedies. 42 U.S.C. 1395*l*(t)(9). Indeed, the agency has retroactively corrected underpayments voluntarily, without "suggest[ing] any conflict between that retroactive adjustment and budget neutrality." *H. Lee Moffitt Cancer Ctr.* v. *Azar*, 324 F. Supp. 3d 1, 15 (D.D.C. 2018). And even if budget neutrality were required, the agency could achieve it by factoring retroactive adjustments into rates for future years, leaving undisturbed the existing budget neutrality of payments made in 2018 and 2019. The agency proposed just that approach as a possible remedy on remand after the district court's ruling in this case, see 84 Fed. Reg. 39,398, 39,505 (Aug. 9, 2019), and the agency previously has taken such a step, see *Shands Jacksonville Med. Ctr., Inc.* v. *Azar*, 366 F. Supp. 3d 32, 39, 52-54 (D.D.C. 2018) (after challenge to rate reduction for inpatient services of 0.2 percent for 2014-2016, agency "adopt[ed] a one-time 0.6 percent rate increase" for 2017 "to address the effect of" that reduction) (citation omitted), *aff'd*, 959 F.3d 1113, 1120 (D.C. Cir. 2020). Other budget-neutral remedies also exist, including issuance of a declaratory judgment about the scope of the agency's paragraph (14) authority that would prospectively govern the agency's behavior. See *Bowen*, 487 U.S. at 893-905.

There is thus no "persuasive reason to believe," *Whitman* v. *Dep't of Transp.*, 547 U.S. 512, 514 (2006) (per curiam) (citation omitted), that Congress wanted to withhold judicial review of paragraph (14) determinations based on budget-neutrality concerns. As Congress would have been aware in enacting paragraph (14), courts have approved judicial review of similar determinations in the past—and the sky has not fallen. See *Universal Health Servs. of McAllen, Inc.* v. *Sullivan*, 770 F. Supp. 704, 711-712 (D.D.C. 1991)

(permitting review of certain system-wide agency determinations under Medicare Part A program), *aff'd*, 978 F.2d 745 (D.C. Cir. 1992) (per curiam) (unpub.); see also *Amgen, Inc.* v. *Smith*, 357 F.3d 103, 113 (D.C. Cir. 2004) (discussing importance of "reducing the risk of systematic misinterpretation" in Medicare B program).

C. Even Assuming That Section 1395*l*(t)(12) Encompasses Paragraph (14) Determinations, Preclusion Is Still Unwarranted

Even if the government could show that paragraph (12)'s preclusion provisions encompass paragraph (14) determinations, preclusion still would be unwarranted. The government's argument hinges on the premise that an "adjust[ment]" under paragraph (14) also constitutes an "adjustment" within the meaning of subparagraph (12)(A) or (12)(C), both of which use that term. See 42 U.S.C. 1395*l*(t)(12)(A), (C). But petitioners contend, on the merits, that what the agency has done here cannot be considered an adjustment in any sense of that word. See pp. 35-46, *infra*. If that contention is correct, then subparagraphs (12)(A) and (12)(C) have no application.

This Court can certainly *reject* the government's preclusion argument without first resolving that merits question. But the Court cannot *accept* it without addressing whether the agency's action here constitutes an "adjustment" within the meaning of Section 1395*l*(t). See, *e.g.*, *Bolivarian Republic of Venezuela* v. *Helmerich & Payne Int'l Drilling Co.*, 137 S. Ct. 1312, 1319 (2017) (court must sometimes "decide some, or all, of the merits issues" in resolving threshold jurisdictional question); *E.I. du Pont de Nemours & Co.* v. *Train*, 430 U.S. 112, 124-125 (1977). And if the Court

decides that the action does not constitute an "adjustment" at all, then both the jurisdictional question and the merits question must be resolved in petitioners' favor.

II. Section 1395*l*(t)(14) Unambiguously Bars The Agency's Change In Reimbursement Rates

Turning to the merits, the text of Section 1395*l*(t)(14) unambiguously bars the agency's decision to base the outpatient-drug reimbursement rate for 340B hospitals on acquisition cost. Accordingly, the analysis need go no further. See, *e.g.*, *Epic Sys. Corp.* v. *Lewis*, 138 S. Ct. 1612, 1630 (2018).

1. a. i. In Section 1395*l*(t)(14)(A)(iii), Congress laid out alternative reimbursement-rate methodologies for outpatient drugs and made the agency's choice between them dependent on the availability of certain statutorily defined data.

Under subclause (I) of subparagraph (14)(A), if the agency has obtained "hospital acquisition cost survey data under subparagraph [(14)](D)," then the reimbursement for a particular drug must be equal "to the average acquisition cost for the drug for that year," as "determined by the [agency] taking into account the hospital acquisition cost survey data." 42 U.S.C. 1395*l*(t)(14)(A)(iii)(I). Subclause I also provides that, if the data-availability requirement is met, the average acquisition cost for a drug may, at the "option" of the agency, "vary by hospital group." *Ibid.*

Subclause (II) of the same subparagraph sets the "default rate," JA47: it dictates how the agency must reimburse for a drug "if" those "hospital acquisition cost data are not available." 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II). In that circumstance, the

agency must set a reimbursement amount equal to "the average price for the drug in the year," as defined under cross-referenced statutory provisions and as "calculated and adjusted by the [agency] as necessary for purposes of this paragraph"—*i.e.*, paragraph (14) itself. *Ibid.* Those cross-referenced provisions state that the average price for a drug for purposes of subclause (II) is the average sales price charged to hospitals and other providers, as reported by drug manufacturers. See, *e.g.*, 42 U.S.C. 1395w-3a(c).

ii. That statutory text establishes two unambiguous limitations on the agency's authority.

First, if the agency does not have data that meets the requirements of subparagraph (14)(D) in hand, the agency lacks the authority to base reimbursement rates on a drug's average acquisition cost. Congress expressly conditioned use of acquisition cost on the agency "taking into account the hospital acquisition cost survey data under subparagraph (D)," and required a different measure—average price—"if" that data is "not available." 42 U.S.C. 1395*l*(t)(14)(A)(iii)(I)-(II). Congress could not have been clearer on that point.

Indeed, Congress emphasized the importance of the acquisition-cost survey data by setting forth the requirements for collecting that data in painstaking detail in subparagraph (14)(D). That provision required the Comptroller General to conduct acquisition-cost surveys in 2004 and 2005, report to Congress on "the justification for the size of the sample used in order to assure * * * validity," and inform Congress whether there is "variation in hospital acquisition costs for drugs among hospitals." 42 U.S.C. 1395*l*(t)(14)(D)(i), (iii)-(v). The Comptroller then was required to recommend to the agency "the frequency

and methodology of subsequent surveys." 42 U.S.C. 1395*l*(t)(14)(D)(i)(II). Taking the Comptroller General's recommendations into account, HHS was thereafter to "conduct periodic subsequent surveys to determine the hospital acquisition cost for each specified covered outpatient drug for use in setting the payment rates under subparagraph [(14)](A)." 42 U.S.C. 1395*l*(t)(14)(D)(ii); see 42 U.S.C. 1395*l*(t)(14)(D)(i), (iii)-(iv). Those HHS surveys must "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." 42 U.S.C. 1395*l*(t)(14)(D)(iii).

Second, the agency lacks the authority to set different rates for different hospital groups unless it possesses the statutorily required data and is therefore setting the rate based on acquisition cost pursuant to subclause (I). If the data is not available and the agency must set a rate equal to average price, the rate must be set by drug for *every* hospital—that is, the agency's rate must be equal to "the average price *for the drug* in the year." 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II) (emphasis added); see 42 U.S.C. 1395*l*(t)(14)(A) (dictating "amount of payment under this subsection for a specified covered outpatient drug"). Subclause (I) similarly requires that an acquisition-cost rate be set "for the drug for that year"—but it contains an express authorization for the agency to "vary" the payment "for the drug" by "hospital group." 42 U.S.C. 1395*l*(t)(14)(A)(iii)(I); see 42 U.S.C. 1395*l*(t)(14)(D)(iv). Subclause (II) contains no such authorization, and Congress's choice to withhold it there—having conferred it in the preceding subclause—must be given force. See, *e.g.*, *Salinas*, 141 S. Ct. at 698.

Both limitations have the same rationale. Without the "hospital-specific cost data" that Congress mandated, "billion-dollar decisions" made by an unelected administrative body "could rest on significantly less exact information" than Congress deemed appropriate and could draw unwarranted distinctions among hospitals that reflect agency policy preferences rather than substantiated cost differentials. Pet.App.37a (dissent).

iii. The rules challenged in this case violate both of those plain-text limitations. It is undisputed that the agency has not collected subparagraph (14)(D) survey data. Pet.App.19a, 34a.[11] The agency's 2018 rulemaking did rely on some cost information gathered by other entities, but that information—which was based in significant part on assumptions rather than on actual data—did not meet the rigorous requirements of subparagraph (14)(D). See JA51-64, 75-78. Yet, invoking subclause (II), the agency nevertheless chose a rate that it thought best "reflect[s] the hospital acquisition costs," based largely on the agency's policy judgment that using acquisition cost is preferable to using average price. JA77; see JA58, 79-82. Moreover, the agency applied that reimbursement rate to only a *sub-*

[11] In the rulemaking for 2021, the agency for the first time asserted that it had collected hospital acquisition-cost survey data. See 85 Fed. Reg. 85,866, 86,043-86,044 (Dec. 29, 2020). But the agency did not survey "a large sample of hospitals that is sufficient to generate a statistically significant estimate," 42 U.S.C. 1395*l*(t)(14)(D)(iii); the agency surveyed only 340B hospitals and received actual acquisition-cost data "for each individual" drug from only 7% of those surveyed, 85 Fed. Reg. at 86,044-86,045. The agency did not purport to set rates under subclause (I) based on that limited data. *Id.* at 86,052.

set of hospitals: 340B hospitals, which provide essential medical care to low-income, underserved communities.

b. In violating the statute's unambiguous instructions about how drug-reimbursement rates must be set, the agency relied exclusively on the statement in subclause (II) that in the absence of the statutorily required data the payment for a drug shall be equal to "average price for [a] drug" as "calculated and adjusted by the [agency] as necessary for purposes of this paragraph." 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II). According to the agency, the statute's conferral in subclause (II) of modest power to "adjust[]" price-based rates carries with it the sweeping authority to transform a rate that Congress said must be based on average price into a rate based on the agency's approximation of acquisition costs—without meeting the requirements of subclause (I) for cost-based rates. That is plainly wrong.

i. Most importantly, the agency's reading of the statute would nullify both subclause (I), which explains when and how cost-based rates may be set, and subparagraph (14)(D), which explains at length how the required acquisition-cost data must be collected.

Under the agency's interpretation of its "adjust[ment]" authority, collecting and taking into account cost-survey data before setting cost-based rates or imposing a variance among hospital groups would be entirely optional. That interpretation reads subclause (I) right out of the statute by permitting the agency to do under subclause (II), without the required data, the very things that subclause (I) authorizes only *with* the required data—that is, setting reimbursement rates based on acquisition cost and exercising

the power to make "billion-dollar decisions differentiating among particular hospital groups." Pet.App.37a, 39a (dissent).

The agency's interpretation makes subparagraph (14)(D) equally meaningless. If the agency can set reimbursement rates based on acquisition cost without the cost-survey data through the expedient of "adjust[ing]" a price-based rate, then the agency never has any need to collect that data, and Congress never had any need to require collection of the data in the first place—let alone on a "periodic" basis. 42 U.S.C. 1395*l*(t)(14)(D)(ii); see Pet.App.39a-40a (dissent). And Congress's careful specification of which cost data is adequate—that is, how thorough, rigorous, and "statistically significant" the data must be, 42 U.S.C. 1395*l*(t)(14)(D)(iii)—is rendered a dead letter.

This is therefore as clear a case as can be imagined of an agency "constru[ing] the statute in a way that completely nullifies textually applicable provisions meant to limit" the agency's "discretion." *Whitman* v. *Am. Trucking Ass'ns*, 531 U.S. 457, 485 (2001). "Whatever effect may be accorded" the agency's adjustment authority under subclause (II), that authority "cannot be thought to render" the statute's "carefully designed restrictions on [the agency's] discretion utterly nugatory." *Id*. at 484.

ii. The agency's reading of the statute also cannot be reconciled with Congress's choice of the verb "adjust[]." 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II).

First, "adjust" carries a "connotation of increment or limitation." *MCI Telecomms. Corp.* v. *AT&T*, 512 U.S. 218, 225 (1994) (discussing definition of "modify"); see, *e.g.*, *Amgen*, 357 F.3d at 117 ("[S]imilar limits inhere in the term 'adjustments' to those the Supreme Court found in the word 'modify.'"). Dictionary

definitions of "adjust" from the relevant time state that to adjust something is to make only a slight change. See, *e.g.*, *The New Oxford American Dictionary* 20 (2001) (to "alter or move (something) slightly in order to achieve the desired fit, appearance, or result"); *Cambridge International Dictionary of English* 17 (1995) ("to change (something or yourself) slightly, esp. in order to make it more correct, effective, or suitable").[12] The word's etymology indicates the same thing. See *Microsoft Encarta College English Dictionary* 17 (2001) ("adjust" derives from Latin word "adjuxtare," meaning to "put close to"). Common usage confirms that understanding. A man who adjusts his tie makes a slight change in tightness or length; he does not take off the tie and use it as a tourniquet. An office worker who adjusts the computer monitor on her desk moves it up, down, or to the side by a few inches; she does not unplug the monitor and place it on the floor. And adjusting a picture on the wall, a stray lock of hair, the seasoning in the soup, or the driver's side mirror is a similarly limited endeavor.

Second, the word "adjust" connotes tethering to the thing that is being adjusted. When an adjustment occurs, there is always a starting point—and any adjustment takes place from that initial position, based on a

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[12] See also, *e.g.*, *Microsoft Encarta College English Dictionary* 17 (2001) ("change slightly[:] to make slight changes in something to make it fit or function better"); *Bloomsbury English Dictionary* 21 (2d ed. 2004) ("change something slightly[:] to make slight changes in something to make it fit or function better"); *Collins English Dictionary* 20 (7th ed. 2005) ("to alter slightly, esp to achieve accuracy; regulate"); *Cassell's English Dictionary* 17 (2000) ("to make slight alteration to, esp. to achieve greater accuracy"); *Longman Dictionary of American English* 12 (3d ed. 2004) ("to change or move something slightly in order to improve it, make it more effective, etc.").

determination that a minor change will yield a more "correct * * * or suitable" outcome. *Cambridge International Dictionary*, *supra*. But one does not make an adjustment by discarding the starting point in favor of something entirely new. For instance, no one would say that a person has adjusted the driver's side mirror if, rather than shifting its angle a bit, she removes the mirror entirely and replaces it with a new one.

The agency's rate change here is not an "adjust[ment]," for both of those reasons. It rewrites the statutory scheme by permitting the agency to do without limitation something on which Congress placed clear and express limits. In so doing, it takes billions of dollars in reimbursements away from a particular class of hospitals and drops the reimbursement rate for those hospitals by 28.5 percent. Pet.App. 1a, 6a. That is not a slight modification to the average-price measure of reimbursement that Congress dictated; it is an act of legislation by an unelected administrative body.

In addition, the agency did not, by any stretch of the imagination, start with the "average price" commanded in subclause (II) and then adjust it downward. Rather, the agency—in its own words—started and ended with "acquisition cost," and then figured out how to express the resulting rate as a percentage of average price. See, *e.g.*, JA77-78 (rate best "reflect[s] the hospital acquisition costs for 340-B acquired drugs"); JA60-63. That kind of reverse engineering is not an adjustment, even if there is necessarily some numerical relationship between the old number (average price) and the new number (the agency's estimate of acquisition cost). It is, instead, a *substitution* of one measure of reimbursement for an entirely different measure.

If Congress had intended to give the agency free rein, Congress well knew how to do so. See, *e.g.*, 42 U.S.C. 1395*l*(t)(14)(C) (reimbursement for rare-disease drugs in 2004 and 2005 is "such amount as the Secretary may specify"). But Congress instead chose a narrow verb that has limitations built directly into its basic definition.

iii. More generally, it is implausible that Congress gave the agency authority to override numerous express statutory requirements, and to make more-than-billion-dollar changes, by burying an adjustment provision at the end of one subclause of Section 1395*l*(t)(14)(A)(iii). Congress does not "hide elephants in mouseholes," *Whitman*, 531 U.S. at 468 (citing *MCI*, 512 U.S. at 231)—that is, it does not secrete the power to take highly consequential action in "vague terms or ancillary provisions" or confer that power through "modest words," *ibid.*

But the agency's action here is extraordinarily consequential. It reworks the statutory scheme that Congress designed. It breaks sharply from years of agency rate-setting under that scheme, which has acknowledged that in the absence of the statutorily required data the agency could not rely on acquisition cost and has repeatedly referred to the "average price" rate under subclause (II) as the "default rate." *E.g.*, JA47; see also, *e.g.*, 77 Fed. Reg. at 68,386-68,387. It affects large numbers of 340B hospitals, including major academic medical centers, public and not-for-profit hospitals, and small community hospitals, as well as the communities those hospitals serve. See *Astra USA, Inc.* v. *Santa Clara Cnty.*, 563 U.S. 110, 113 (2011); OIG Report 2. And it cuts the drug-reimbursement amount received by 340B hospitals by $1.6 billion or more for each year the cuts are in effect, Pet.App.6a,

which represents a crushing blow to providers that were already operating on razor-thin or negative margins and to the vulnerable populations they serve, see, *e.g.*, Allen Dobson *et al.*, *The Role of 340B Hospitals in Serving Medicaid and Low-income Medicare Patients* 3-4 (July 10, 2020), https://www.340bhealth.org/files/340B_and_Medicaid_and_Low_Income_Medicare_Patients_Report_7.10.2020_FINAL_.pdf; Tom Nickels, *Report Misrepresents 340B Program to Deflect from Sky High Drug Prices*, AHA Stat: An American Hospital Association Blog (Nov. 22, 2019), https://www.aha.org/news/blog/2019-11-22-report-misrepresents-340b-program-deflect-sky-high-drug-prices.

In circumventing the requirements of subclause (I), the agency purposefully took action to damage Congress's 340B program—a fact that underscores just how consequential the agency's action was. Congress intended that, due to legally required drug-manufacturer discounts, insurers like Medicare would subsidize critical services offered by 340B hospitals. See H.R. Rep. No. 102-384, pt. 2, at 12 (1992) (340B program allows covered hospitals to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services"); see also OIG Report, at i; HRSA Manual 14-15. And the program has been successful; indeed, in 2010 Congress expanded the kinds of hospitals eligible for that subsidization. See Pub. L. No. 111-148, § 7101, 124 Stat. at 821-822; 42 U.S.C. 256b(a)(4)(M)-(O). But the agency's purported "adjustment" seriously harms the ability of 340B hospitals to continue to provide essential services to low-income, underserved communities. See *Astra USA*, 563 U.S. at 115; Dobson, *supra*, at 13-16. Strikingly, the agency acknowledged that the challenged rate reduction reflected agency disagreement with Congress's objectives. See JA58

("While we recognize the intent of the 340B Program, we believe it is inappropriate for Medicare to subsidize other activities through Medicare payments for separately payable drugs.").

The agency has purported to justify those weighty actions on the basis of an "adjust[ment]" authority that is a quintessential example of a "modest" grant of power housed in a "vague" and "ancillary" provision. *Whitman*, 531 U.S. at 468. As this Court has repeatedly found in other contexts, it is highly unlikely that Congress would use "such a subtle device" to authorize the agency to remake Medicare reimbursement. *MCI*, 512 U.S. at 231; see, *e.g.*, *Gonzales* v. *Oregon*, 546 U.S. 243, 267 (2006); *Whitman*, 531 U.S. at 468; *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159-61 (2000).

2. The panel majority below gave several reasons for rejecting the conclusion that the statutory language unambiguously forecloses the rate change. None survives scrutiny.

a. The majority began by noting that under subclause (II) the agency is permitted to "calculate[] and adjust[]" the average price as "necessary *for purposes of this paragraph*." 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II) (emphasis added). And the majority read paragraph (14) as expressing a clear preference for rates based on acquisition cost. Pet.App.20a-23a. Indeed, the majority went so far as to assert that subclause (I) is "[p]aragraph (14)'s primary (and default) instruction for determining" drug "payment amounts," pointing to the fact that Congress chose to list subclause (I) (acquisition cost) before subclause (II) (average price). Pet.App.21a.

That reasoning is exactly backwards. As the agency has long acknowledged, the "default" instruction for determining payment amounts is use of average price, since that is what Congress required in the event that the statutorily prescribed cost-survey data is not available. Pet.App.33a-34a (dissent); see, *e.g.*, JA47 (referring to average price as "default rate" and "statutory default").[13] And given that Congress forbade reimbursement based on acquisition cost unless the agency collected and used that cost-survey data, it cannot be said that Congress had some overarching purpose to encourage reimbursement based on acquisition cost when—as here—that data is not available. Congress "wrote the statute it wrote—meaning, a statute going so far and no further." *Cyan, Inc.* v. *Beaver Cnty. Emps. Ret. Fund*, 138 S. Ct. 1061, 1073 (2018) (citation omitted); see, *e.g.*, *Freeman* v. *Quicken Loans, Inc.*, 566 U.S. 624, 637 (2012) ("[e]very statute purposes, not only to achieve certain ends, but also to achieve them by particular means") (citation omitted). A statute that makes it harder to set cost-based rates than to set price-based rates does not express a policy favoring the former across the board.

In fact, given the emphasis Congress placed on the required data, the primary purpose of paragraph (14) is best understood as ensuring accuracy in carrying out Congress's specific reimbursement-rate instructions. Congress had the purpose of requiring that cost-based rates be based on certain cost-survey data—and so in carrying out subclause (I) the agency must come

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[13] Thus, in every year prior to 2018, the agency determined that paragraph (14)'s purposes would be best advanced by reimbursing 340B hospitals based on price rather than on cost. See, *e.g.*, 80 Fed. Reg. at 70,439; 77 Fed. Reg. at 68,383-68,386.

up with the most accurate, statistically significant acquisition-cost information that it can, consistent with Congress's directions in subparagraph (14)(D).[14] But if the required cost-survey data is not available and the agency therefore must use "average price," the agency should "calculate[] and adjust[]," 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II), so as to make that average-price amount as accurate as possible given the information at the agency's disposal and the instructions in the statutory provisions that subclause (II) cross-references. Nothing about the agency's choice to use acquisition cost in lieu of average price is consistent with that purpose.

b. In addition, the majority below asserted that petitioners' reading of subclause (II) creates superfluity on the theory that it allows only for an adjustment that is already separately permitted by subparagraph (14)(E). Pet.App.25a-28a. Subparagraph (14)(E) calls for issuance of a MedPAC report by no later than July 2005 on possible "adjustment of payment * * * to take into account overhead and related expenses, such as pharmacy services and handling costs," and permits the agency to "adjust" payments in order "to take into

[14] The majority suggested that the acquisition-cost information on which the agency relied was accurate. Pet.App.24a. Even if true, that would be irrelevant. Congress is free to require specific data gathered in a certain way, and the agency cannot override that legislative choice. See 42 U.S.C. 1395*l*(t)(14)(D). And once the agency is "unmoored" from the statute's data requirement, there is no telling what data it may rely on in future. Pet.App.42a (dissent). In any event, the majority was wrong to express such confidence in the ersatz data, given that the agency itself explained the data's flaws. See JA51-63 ("data limitations"). If the agency had conducted the required survey before setting the challenged rates, the agency would have received public comments on the survey's design and results—and the survey could have revealed important information justifying higher reimbursement.

account the recommendations contained in the report." 42 U.S.C. 1395*l*(t)(14)(E).

The majority's conclusion is baffling. First, it is not difficult to conceive of minor modifications to average price, other than adjustments for overhead and related expenses, that could ensure more accurate actual-price numbers under subclause (II). The statutes that subclause (II) cross-references themselves involve complicated calculations and leave room for agency choice. *E.g.*, 42 U.S.C. 1395w-3a(c)(3) (agency may include various "price concessions"), *cited in* 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II). And the agency also could "adjust" average-price numbers to focus more closely on price paid by hospitals, since those numbers include other kinds of medical providers as well. Pet.App.27a.

Second, even if the agency's "adjustment" authority were limited to overhead and related expenses (consistent with the agency's own long-standing practice, Pet.App.37a (dissent)),[15] no superfluity results. Subparagraph (14)(E) authorizes adjustments for such expenses "with reference to a one-time, 2005 MedPAC report." Pet.App.36a (dissent); see 42 U.S.C. 1395*l*(t)(14)(E); see also 42 U.S.C. 1395*l*(t)(14)(A)(iii) (subclauses (I) and (II) are "subject to subparagraph (E)"). The subclause (II) "adjust[ment]" authority is not so limited, but rather can operate at any time and without reference to that specific report—and it is

[15] See also, *e.g.*, 80 Fed. Reg. at 70,439; 77 Fed. Reg. at 68,383-68,386. The majority thought that taking account of overhead in setting payments based on average price is a way of moving those payments closer to an acquisition-cost measure. Pet.App.25a-26a. That is incorrect; for instance, costs incurred in "storage" of certain dangerous or fragile drugs, Pub. L. No. 106-554, appendix F, § 429(a), 114 Stat. 2763A-522 to 2763A-524 (2000), are additive to price and acquisition cost alike.

thus not duplicative of the authority that subparagraph (14)(E) confers.

Third, even if subclause (II) and subparagraph (14)(E) did overlap with each other in some more significant way, that would not justify the agency's sweeping statutory rewrite. Overlap may simply indicate that Congress intended to remove any doubt about the propriety of taking overhead and related expenses into account. See, *e.g.*, *Ali* v. *Fed. Bureau of Prisons,* 552 U.S. 214, 226 (2008). More fundamentally, there is no equivalence between a "little overlap" in the "complex statutory scheme" governing Medicare, Pet.App.37a (dissent) (citation omitted), and the gutted statute that would result from the agency's interpretation—an interpretation that would wipe away an express precondition that Congress placed on use of any acquisition-cost-based rate, and render meaningless "nearly a full column in the U.S. Code" governing how the agency is to gather cost data. Pet.App.39a (dissent); see pp. 35-36, *supra*. Overlap is one thing. "[C]omplete[] nullifi[cation]" of provisions Congress enacted to constrain the agency's authority is quite another. *Whitman*, 531 U.S. at 485.

c. Finally, the majority below allowed policy considerations to shade the statutory analysis. Pet.App.40a-41a (dissent). The majority found it inconceivable that Congress would prohibit the agency from basing reimbursement rates on acquisition costs if the agency failed to collect the statutorily required survey data. Pet.App.24a. But that is precisely what the text of the statute prohibits, see pp. 31-41, *supra*, and "policy considerations cannot create an ambiguity when the words on the page are clear." *SAS Inst., Inc.* v. *Iancu*, 138 S. Ct. 1348, 1358 (2018). Whatever the agency's "bureaucratic policy goals," the agency "has

no power to 'tailor' legislation" to those goals "by rewriting unambiguous statutory terms." *Util. Air Regul. Grp.* v. *EPA*, 573 U.S. 302, 325 (2014).

Enforcing Congress's commands does not foreclose the agency from setting a reimbursement rate based on acquisition cost, or from varying that rate by hospital group. The agency must simply do so in the manner Congress prescribed. What the agency cannot do is cast off legislative constraints and decide policy for itself on a matter of immense economic and medical significance.

III. *Chevron* Deference Cannot Justify The Agency's Action

Unsurprisingly, neither the government nor the court of appeals has defended the agency's interpretation of paragraph (14) as the best reading of the statute. They instead have fallen back on *Chevron* deference, asserting that the authority given to the agency in subclause (II) to adjust price-based rates can reasonably be read to justify the agency's decision to set cost-based rates without meeting the requirements of subclause (I).

If subclause (II)'s adjustment language could reasonably be read to confer such a power, then this Court would be required to confront whether *Chevron* continues to be good law. In other words, the Court would have to decide whether to continue to indulge the fiction that Congress implicitly delegated to the agency the power to adopt that interpretation merely based on ambiguity in the word "adjust[]"—even though the agency's reading plainly is not the best interpretation of the statutory text. The Court need not confront that question in this case, however, given that the adjustment authority in paragraph (14)'s second subclause cannot reasonably be interpreted to allow the agency

to disregard the statutory requirements clearly spelled out in the first subclause of that provision. Because the statute is unambiguous, *Chevron* has no role to play. That said, the arguments advanced by the government, and adopted by the panel majority below, vividly illustrate the mischief to which the *Chevron* doctrine is prone.

1. *Chevron* deference cannot save the agency's rate-setting decision because paragraph (14) is not genuinely ambiguous with respect to whether the agency may set reimbursement rates for outpatient drugs based on acquisition cost without conducting the statutorily prescribed cost study. A court may not even consider whether to afford *Chevron* deference unless a statutory provision is "*genuinely* ambiguous" as to the question at issue, "even after a court has resorted to all the standard tools of interpretation." *Kisor* v. *Wilkie*, 139 S. Ct. 2400, 2414 (2019) (emphasis added); see, *e.g.*, *Epic*, 138 S. Ct. at 1630; *SAS Inst.*, 138 S. Ct. at 1358.[16] Put another way, deference is appropriate "only when th[e] legal toolkit is empty and the interpretive question still has no single right answer," and a "court cannot wave the ambiguity flag just because it found the [statute] impenetrable on first read." *Kisor*, 139 S. Ct. at 2415. Because statutory ambiguity is deemed a delegation of authority from Congress, the possibility of *Chevron* deference should not even be considered unless the agency is able to clear that substantial hurdle. At a minimum, a reviewing court must have confidence that the authority has in fact been delegated and that the

[16] *Kisor* addressed judicial deference to an agency's interpretation of a regulation, but that decision's reasoning applies just as strongly where an agency seeks deference for interpretation of its organic statute. See *Kisor*, 139 S. Ct. at 2415.

agency's action is within the scope of the delegation. See, *e.g.*, *City of Arlington* v. *FCC*, 569 U.S. 290, 312 (2013) (Roberts, C.J., dissenting).

The panel majority barely opened the tool kit. Instead, it leapt to the conclusion that the any ambiguity in the statutory language gave the agency full license to make whatever rate changes it wished without regard to the requirements subclause (I) sets forth for cost-based rates. The majority acknowledged the "force" of petitioners' argument that, under the agency's interpretation, the entirety of subclause (I) would be rendered "meaningless." Pet.App.23a-24a. Yet the majority still held that petitioners' argument could not "carry the day under *Chevron*," on the ground that the statute does not expressly forbid HHS from using the adjustment authority of subclause (II) to eviscerate the requirements of subclause (I) or subparagraph (14)(D) and that "HHS's belief" that it could do so was not "unreasonable." Pet.App.24a. That is a far cry from the analysis this Court requires. Whatever the outer bounds of the agency's adjustment authority in subclause (II), Congress did not delegate to the agency the power to erase from the statute the requirements of subclause (I) or subparagraph (14)(D).

In short, all interpretive issues are not equal. It is not necessary to be able to say with absolute certainty what *does* fall within the scope of the agency's subclause (II) adjustment authority in order to rule that the agency's actions here *do not* constitute a permissible subclause (II) adjustment. See, *e.g.*, *Negusie* v. *Holder*, 555 U.S. 511, 550 (2009) (Thomas, J., dissenting). The agency's use of its adjustment authority was, at bottom, an act of legislation, not interpretation. It cannot be justified on the basis of *Chevron*.

2. In that dispositive respect, the present case is on all fours with this Court's decision in *MCI*. The Court in *MCI* rejected the FCC's argument that a statute that required common carriers to file tariffs with the FCC but also authorized the FCC to "modify" any requirement of the statute permitted the FCC to make tariff filing optional for all long-distance carriers but one. 512 U.S. at 220, 225. The Court ruled that the term "modify" did not delegate to the FCC the power to transform the regulatory scheme that Congress had enacted. That was so, the Court held, despite the fact that the FCC had identified a definition of "modify" that included "to make a basic or important change in." *Id.* at 225-226 (citation omitted). The Court explained that it was "highly unlikely that Congress would leave the determination of whether an industry will be entirely, or even substantially, rate-regulated to agency discretion—and even more unlikely that it would achieve that through" mere "permission to 'modify' rate-filing requirements." *Id.* at 231. *Chevron* thus could not rescue the FCC, as the FCC's interpretation went "beyond the meaning that the statute can bear." *Id.* at 229; see, *e.g.*, *Whitman*, 531 U.S. at 468-471; *Brown & Williamson*, 529 U.S. at 159-161.

It is equally unlikely that Congress would have left to the agency's discretion the determination of the shape of the multi-billion-dollar Medicare drug-reimbursement system, or that Congress would have achieved that goal through permission to "calculate[] and adjust[]" an average-price measure of payment. 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II). Thus, as in *MCI*, the agency's interpretation in this case, which arrogates to the agency vast power to redirect multi-billion-dollar reimbursement flows by jettisoning the reimbursement system that Congress put in place for outpatient

drugs, has gone "beyond the meaning that the statute can bear." 512 U.S. at 229.

3. Upholding the agency's action on the basis of *Chevron* would "raise[] serious separation-of-powers questions." *Michigan* v. *EPA*, 576 U.S. 743, 760-63 (2015) (Thomas, J., concurring). When a court rushes to declare a statute ambiguous while leaving interpretive tools on the shelf, and while assuming that the slightest lack of clarity in the statute's language necessarily leaves the agency free to "dictate the outcome" through an "erroneous interpretation[]," *Baldwin* v. *United States*, 140 S. Ct. 690, 692 (2020) (Thomas, J., dissenting from denial of certiorari), then that court has abdicated its duty to say what the law is. No deference doctrine should endorse that untenable approach.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted,

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APPENDIX

APPENDIX

42 U.S.C. 1395*l* provides in pertinent part:

* * *

(i) Outpatient surgery

* * *

[(1)](D)(i) Taking into account the recommendations in the report under section 626(d) of Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the Secretary shall implement a revised payment system for payment of surgical services furnished in ambulatory surgical centers.

* * *

(vi) There shall be no administrative or judicial review under section 1395ff, 1395*oo* of this title, or otherwise, of the classification system, the relative weights, payment amounts, and the geographic adjustment factor, if any, under this subparagraph.

* * *

(m) Incentive payments for physicians' services furnished in underserved areas

(1) In the case of physicians' services furnished in a year to an individual, who is covered under the insurance program established by this part and who incurs expenses for such services, in an area that is designated (under section 254e(a)(1)(A) of this title) as a health professional shortage area as identified by the Secretary prior to the beginning of such year, in addition to the amount otherwise paid under this part, there also shall be paid to the physician (or to

an employer or facility in the cases described in clause (A) of section 1395u(b)(6) of this title) (on a monthly or quarterly basis) from the Federal Supplementary Medical Insurance Trust Fund an amount equal to 10 percent of the payment amount for the service under this part.

* * *

(4) There shall be no administrative or judicial review under section 1395ff of this title, section 1395*oo* of this title, or otherwise, respecting—

(A) the identification of a county or area;

(B) the assignment of a specialty of any physician under this paragraph;

(C) the assignment of a physician to a county under this subsection; or

(D) the assignment of a postal ZIP Code to a county or other area under this subsection.

* * *

(t) Prospective payment system for hospital outpatient department services

(1) Amount of payment

(A) In general

With respect to covered OPD services (as defined in subparagraph (B)) furnished during a year beginning with 1999, the amount of payment under this part shall be determined under a prospective payment system established by the Secretary in accordance with this subsection.

* * *

(2) System requirements

Under the payment system—

(A) the Secretary shall develop a classification system for covered OPD services;

(B) the Secretary may establish groups of covered OPD services, within the classification system described in subparagraph (A), so that services classified within each group are comparable clinically and with respect to the use of resources and so that an implantable item is classified to the group that includes the service to which the item relates;

(C) the Secretary shall, using data on claims from 1996 and using data from the most recent available cost reports, establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B)) based on median (or, at the election of the Secretary, mean) hospital costs and shall determine projections of the frequency of utilization of each such service (or group of services) in 1999;

(D) subject to paragraph (19), the Secretary shall determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner;

(E) the Secretary shall establish, in a budget neutral manner, outlier adjustments under paragraph (5) and transitional pass-through payments under paragraph (6) and other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals;

(F) the Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services;

(G) the Secretary shall create additional groups of covered OPD services that classify separately those procedures that utilize contrast agents from those that do not; and

(H) with respect to devices of brachytherapy consisting of a seed or seeds (or radioactive source), the Secretary shall create additional groups of covered OPD services that classify such devices separately from the other services (or group of services) paid for under this subsection in a manner reflecting the number, isotope, and radioactive intensity of such devices furnished, including separate groups for palladium-103 and iodine-125 devices and for stranded and non-stranded devices furnished on or after July 1, 2007.

For purposes of subparagraph (B), items and services within a group shall not be treated as "comparable with respect to the use of resources" if the highest median cost (or mean cost, if elected by the Secretary under subparagraph (C)) for an item or service within the group is more than 2 times greater than the lowest median cost (or mean cost, if so elected) for an item or service within the group; except that the Secretary may make exceptions in unusual cases, such as low volume items and services, but may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 360bb of Title 21.

* * *

(6) Transitional pass-through for additional costs of innovative medical devices, drugs, and biologicals

(A) In general

The Secretary shall provide for an additional payment under this paragraph for any of the following that are provided as part of a covered OPD service (or group of services):

(i) Current orphan drugs

A drug or biological that is used for a rare disease or condition with respect to which the drug or biological has been designated as an orphan drug under section 360bb of Title 21 if payment for the drug or biological as an outpatient hospital service under this part was being made on the first date that the system under this subsection is implemented.

(ii) Current cancer therapy drugs and biologicals and brachytherapy

A drug or biological that is used in cancer therapy, including (but not limited to) a chemotherapeutic agent, an antiemetic, a hematopoietic growth factor, a colony stimulating factor, a biological response modifier, a bisphosphonate, and a device of brachytherapy or temperature monitored cryoablation, if payment for such drug, biological, or device as an outpatient hospital service under this part was being made on such first date.

(iii) Current radiopharmaceutical drugs and biological products

A radiopharmaceutical drug or biological product used in diagnostic, monitoring, and therapeutic nuclear medicine procedures if payment for

the drug or biological as an outpatient hospital service under this part was being made on such first date.

(iv) New medical devices, drugs, and biologicals

A medical device, drug, or biological not described in clause (i), (ii), or (iii) if—

(I) payment for the device, drug, or biological as an outpatient hospital service under this part was not being made as of December 31, 1996; and

(II) the cost of the drug or biological or the average cost of the category of devices is not insignificant in relation to the OPD fee schedule amount (as calculated under paragraph (3)(D)) payable for the service (or group of services) involved.

(B) Use of categories in determining eligibility of a device for pass-through payments

The following provisions apply for purposes of determining whether a medical device qualifies for additional payments under clause (ii) or (iv) of subparagraph (A):

(i) Establishment of initial categories

(I) In general

The Secretary shall initially establish under this clause categories of medical devices based on type of device by April 1, 2001. Such categories shall be established in a manner such that each medical device that meets the requirements of clause (ii) or (iv) of subparagraph (A) as of January 1, 2001, is included in such a category

and no such device is included in more than one category. For purposes of the preceding sentence, whether a medical device meets such requirements as of such date shall be determined on the basis of the program memoranda issued before such date.

(II) Authorization of implementation other than through regulations

The categories may be established under this clause by program memorandum or otherwise, after consultation with groups representing hospitals, manufacturers of medical devices, and other affected parties.

(ii) Establishing criteria for additional categories

(I) In general

The Secretary shall establish criteria that will be used for creation of additional categories (other than those established under clause (i)) through rulemaking (which may include use of an interim final rule with comment period).

(II) Standard

Such categories shall be established under this clause in a manner such that no medical device is described by more than one category. Such criteria shall include a test of whether the average cost of devices that would be included in a category and are in use at the time the category is established is not insignificant, as described in subparagraph (A)(iv)(II).

(III) Deadline

Criteria shall first be established under this clause by July 1, 2001. The Secretary may establish in compelling circumstances categories under this clause before the date such criteria are established.

(IV) Adding categories

The Secretary shall promptly establish a new category of medical devices under this clause for any medical device that meets the requirements of subparagraph (A)(iv) and for which none of the categories in effect (or that were previously in effect) is appropriate.

(iii) Period for which category is in effect

A category of medical devices established under clause (i) or (ii) shall be in effect for a period of at least 2 years, but not more than 3 years, that begins—

(I) in the case of a category established under clause (i), on the first date on which payment was made under this paragraph for any device described by such category (including payments made during the period before April 1, 2001); and

(II) in the case of any other category, on the first date on which payment is made under this paragraph for any medical device that is described by such category.

(iv) Requirements treated as met

A medical device shall be treated as meeting the requirements of subparagraph (A)(iv), regardless of whether the device meets the requirement of subclause (I) of such subparagraph, if—

(I) the device is described by a category established and in effect under clause (i); or

(II) the device is described by a category established and in effect under clause (ii) and an application under section 360e of Title 21 has been approved with respect to the device, or the device has been cleared for market under section 360(k) of Title 21, or the device is exempt from the requirements of section 360(k) of Title 21 pursuant to subsection (*l*) or (m) of section 360 of Title 21 or section 360j(g) of Title 21.

Nothing in this clause shall be construed as requiring an application or prior approval (other than that described in subclause (II)) in order for a covered device described by a category to qualify for payment under this paragraph.

(C) Limited period of payment

(i) Drugs and biologicals

Subject to subparagraph (G), the payment under this paragraph with respect to a drug or biological shall only apply during a period of at least 2 years, but not more than 3 years, that begins—

(I) on the first date this subsection is implemented in the case of a drug or biological described in clause (i), (ii), or (iii) of subparagraph (A) and in the case of a drug or biological described in subparagraph (A)(iv) and for which payment under this part is made as an outpatient hospital service before such first date; or

(II) in the case of a drug or biological described in subparagraph (A)(iv) not described in subclause (I), on the first date on which payment

is made under this part for the drug or biological as an outpatient hospital service.

(ii) Medical devices

Payment shall be made under this paragraph with respect to a medical device only if such device—

(I) is described by a category of medical devices established and in effect under subparagraph (B); and

(II) is provided as part of a service (or group of services) paid for under this subsection and provided during the period for which such category is in effect under such subparagraph.

(D) Amount of additional payment

Subject to subparagraph (E)(iii), the amount of the payment under this paragraph with respect to a device, drug, or biological provided as part of a covered OPD service is—

(i) subject to subparagraph (H), in the case of a drug or biological, the amount by which the amount determined under section 1395u(o) of this title (or if the drug or biological is covered under a competitive acquisition contract under section 1395w-3b of this title, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary for purposes of this paragraph) for the drug or biological exceeds the portion of the otherwise applicable medicare OPD fee schedule that the Secretary determines is associated with the drug or biological; or

(ii) in the case of a medical device, the amount by which the hospital's charges for the device, adjusted to cost, exceeds the portion of the otherwise applicable medicare OPD fee schedule that the Secretary determines is associated with the device.

(E) Limit on aggregate annual adjustment

(i) In general

The total of the additional payments made under this paragraph for covered OPD services furnished in a year (as estimated by the Secretary before the beginning of the year) may not exceed the applicable percentage (specified in clause (ii)) of the total program payments estimated to be made under this subsection for all covered OPD services furnished in that year. If this paragraph is first applied to less than a full year, the previous sentence shall apply only to the portion of such year. This clause shall not apply for 2018 or 2020.

(ii) Applicable percentage

For purposes of clause (i), the term "applicable percentage" means—

(I) for a year (or portion of a year) before 2004, 2.5 percent; and

(II) for 2004 and thereafter, a percentage specified by the Secretary up to (but not to exceed) 2.0 percent.

(iii) Uniform prospective reduction if aggregate limit projected to be exceeded

If the Secretary estimates before the beginning of a year that the amount of the additional payments under this paragraph for the year (or

portion thereof) as determined under clause (i) without regard to this clause will exceed the limit established under such clause, the Secretary shall reduce pro rata the amount of each of the additional payments under this paragraph for that year (or portion thereof) in order to ensure that the aggregate additional payments under this paragraph (as so estimated) do not exceed such limit.

(F) Limitation of application of functional equivalence standard

(i) In general

The Secretary may not publish regulations that apply a functional equivalence standard to a drug or biological under this paragraph.

(ii) Application

Clause (i) shall apply to the application of a functional equivalence standard to a drug or biological on or after December 8, 2003, unless—

(I) such application was being made to such drug or biological prior to December 8, 2003; and

(II) the Secretary applies such standard to such drug or biological only for the purpose of determining eligibility of such drug or biological for additional payments under this paragraph and not for the purpose of any other payments under this subchapter.

(iii) Rule of construction

Nothing in this subparagraph shall be construed to effect the Secretary's authority to deem a particular drug to be identical to another drug if the 2 products are pharmaceutically equivalent and bioequivalent, as determined by the Commissioner of Food and Drugs.

(G) Pass-through extension for certain drugs and biologicals

In the case of a drug or biological whose period of pass-through status under this paragraph ended on December 31, 2017, and for which payment under this subsection was packaged into a payment for a covered OPD service (or group of services) furnished beginning January 1, 2018, such pass-through status shall be extended for a 2-year period beginning on October 1, 2018.

(H) Temporary payment rule for certain drugs and biologicals

In the case of a drug or biological whose period of pass-through status under this paragraph ended on December 31, 2017, and for which payment under this subsection was packaged into a payment for a covered OPD service (or group of services) furnished beginning January 1, 2018, the payment amount for such drug or biological under this subsection that is furnished during the period beginning on October 1, 2018, and ending on March 31, 2019, shall be the greater of—

(i) the payment amount that would otherwise apply under subparagraph (D)(i) for such drug or biological during such period; or

(ii) the payment amount that applied under such subparagraph (D)(i) for such drug or biological on December 31, 2017.

(I) Special payment adjustment rules for last quarter of 2018

In the case of a drug or biological whose period of pass-through status under this paragraph ended on December 31, 2017, and for which payment under this subsection was packaged into a payment amount for a covered OPD service (or group of services) beginning January 1, 2018, the following rules shall apply with respect to payment amounts under this subsection for covered a OPD[13] service (or group of services) furnished during the period beginning on October 1, 2018, and ending on December 31, 2018:

(i) The Secretary shall remove the packaged costs of such drug or biological (as determined by the Secretary) from the payment amount under this subsection for the covered OPD service (or group of services) with which it is packaged.

(ii) The Secretary shall not make any adjustments to payment amounts under this subsection for a covered OPD service (or group of services) for which no costs were removed under clause (i).

[13] So in original. Probably should be "a covered OPD".

(J) Additional pass-through extension and special payment adjustment rule for certain diagnostic radiopharmaceuticals

In the case of a drug or biological furnished in the context of a clinical study on diagnostic imaging tests approved under a coverage with evidence development determination whose period of pass-through status under this paragraph concluded on December 31, 2018, and for which payment under this subsection was packaged into a payment for a covered OPD service (or group of services) furnished beginning January 1, 2019, the Secretary shall—

(i) extend such pass-through status for such drug or biological for the 9-month period beginning on January 1, 2020;

(ii) remove, during such period, the packaged costs of such drug or biological (as determined by the Secretary) from the payment amount under this subsection for the covered OPD service (or group of services) with which it is packaged; and

(iii) not make any adjustments to payment amounts under this subsection for a covered OPD service (or group of services) for which no costs were removed under clause (ii).

* * *

(9) Periodic review and adjustments components of prospective payment system

(A) Periodic review

The Secretary shall review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjust-

ments described in paragraph (2) 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. The Secretary shall consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the groups and weights. Such panel may use data collected or developed by entities and organizations (other than the Department of Health and Human Services) in conducting such review.

(B) Budget neutrality adjustment

If the Secretary makes adjustments under subparagraph (A), then the adjustments for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made. In determining adjustments under the preceding sentence for 2004 and 2005, the Secretary shall not take into account under this subparagraph or paragraph (2)(E) any expenditures that would not have been made but for the application of paragraph (14).

(C) Update factor

If the Secretary determines under methodologies described in paragraph (2)(F) that the volume of services paid for under this subsection increased beyond amounts established through those methodologies, the Secretary may appropriately adjust the update to the conversion factor otherwise applicable in a subsequent year.

* * *

(12) Limitation on review

There shall be no administrative or judicial review under section 1395ff of this title, 1395*oo* of this title, or otherwise of—

(A) the development of the classification system under paragraph (2), including the establishment of groups and relative payment weights for covered OPD services, of wage adjustment factors, other adjustments, and methods described in paragraph (2)(F);

(B) the calculation of base amounts under paragraph (3);

(C) periodic adjustments made under paragraph (6);

(D) the establishment of a separate conversion factor under paragraph (8)(B); and

(E) the determination of the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applicable percentage under paragraph (5) or the determination of insignificance of cost, the duration of the additional payments, the determination and deletion of initial and new categories (consistent with subparagraphs (B) and (C) of paragraph (6)), the portion of the medicare OPD fee schedule amount associated with particular devices, drugs, or biologicals, and the application of any pro rata reduction under paragraph (6).

(13) Authorization of adjustment for rural hospitals

(A) Study

The Secretary shall conduct a study to determine if, under the system under this subsection,

costs incurred by hospitals located in rural areas by ambulatory payment classification groups (APCs) exceed those costs incurred by hospitals located in urban areas.

(B) Authorization of adjustment

Insofar as the Secretary determines under subparagraph (A) that costs incurred by hospitals located in rural areas exceed those costs incurred by hospitals located in urban areas, the Secretary shall provide for an appropriate adjustment under paragraph (2)(E) to reflect those higher costs by January 1, 2006.

(14) Drug APC payment rates

(A) In general

The amount of payment under this subsection for a specified covered outpatient drug (defined in subparagraph (B)) that is furnished as part of a covered OPD service (or group of services)—

(i) in 2004, in the case of—

(I) a sole source drug shall in no case be less than 88 percent, or exceed 95 percent, of the reference average wholesale price for the drug;

(II) an innovator multiple source drug shall in no case exceed 68 percent of the reference average wholesale price for the drug; or

(III) a noninnovator multiple source drug shall in no case exceed 46 percent of the reference average wholesale price for the drug;

(ii) in 2005, in the case of—

(I) a sole source drug shall in no case be less than 83 percent, or exceed 95 percent, of the reference average wholesale price for the drug;

(II) an innovator multiple source drug shall in no case exceed 68 percent of the reference average wholesale price for the drug; or

(III) a noninnovator multiple source drug shall in no case exceed 46 percent of the reference average wholesale price for the drug; or

(iii) in a subsequent year, 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 volume of covered OPD services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D); or

(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.

(B) Specified covered outpatient drug defined

(i) In general

In this paragraph, the term "specified covered outpatient drug" means, subject to clause (ii), a covered outpatient drug (as defined in section 1396r-8(k)(2) of this title) for which a separate ambulatory payment classification group (APC) has been established and that is—

(I) a radiopharmaceutical; or

(II) a drug or biological for which payment was made under paragraph (6) (relating to pass-through payments) on or before December 31, 2002.

(ii) Exception

Such term does not include—

(I) a drug or biological for which payment is first made on or after January 1, 2003, under paragraph (6);

(II) a drug or biological for which a temporary HCPCS code has not been assigned; or

(III) during 2004 and 2005, an orphan drug (as designated by the Secretary).

(C) Payment for designated orphan drugs during 2004 and 2005

The amount of payment under this subsection for an orphan drug designated by the Secretary under subparagraph (B) (ii)(III) that is furnished as part of a covered OPD service (or group of services) during 2004 and 2005 shall equal such amount as the Secretary may specify.

(D) Acquisition cost survey for hospital outpatient drugs

(i) Annual GAO surveys in 2004 and 2005

(I) In general

The Comptroller General of the United States shall conduct a survey in each of 2004 and 2005 to determine the hospital acquisition cost for each specified covered outpatient drug. Not later than April 1, 2005, the Comptroller General

shall furnish data from such surveys to the Secretary for use in setting the payment rates under subparagraph (A) for 2006.

(II) Recommendations

Upon the completion of such surveys, the Comptroller General shall recommend to the Secretary the frequency and methodology of subsequent surveys to be conducted by the Secretary under clause (ii).

(ii) Subsequent secretarial surveys

The Secretary, taking into account such recommendations, shall conduct periodic subsequent surveys to determine the hospital acquisition cost for each specified covered outpatient drug for use in setting the payment rates under subparagraph (A).

(iii) Survey requirements

The surveys conducted under clauses (i) and (ii) 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. With respect to the surveys conducted under clause (i), the Comptroller General shall report to Congress on the justification for the size of the sample used in order to assure the validity of such estimates.

(iv) Differentiation in cost

In conducting surveys under clause (i), 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 OPD ser-

vices performed by such hospitals or other relevant characteristics of such hospitals (as defined by the Comptroller General).

(v) Comment on proposed rates

Not later than 30 days after the date the Secretary promulgated proposed rules setting forth the payment rates under subparagraph (A) for 2006, the Comptroller General shall evaluate such proposed rates and submit to Congress a report regarding the appropriateness of such rates based on the surveys the Comptroller General has conducted under clause (i).

(E) Adjustment in payment rates for overhead costs

(i) MedPAC report on drug APC design

The Medicare Payment Advisory Commission shall submit to the Secretary, not later than July 1, 2005, a report on adjustment of payment for ambulatory payment classifications for specified covered outpatient drugs to take into account overhead and related expenses, such as pharmacy services and handling costs. Such report shall include—

(I) a description and analysis of the data available with regard to such expenses;

(II) a recommendation as to whether such a payment adjustment should be made; and

(III) if such adjustment should be made, a recommendation regarding the methodology for making such an adjustment.

(ii) Adjustment authorized

The Secretary may adjust the weights for ambulatory payment classifications for specified covered outpatient drugs to take into account the recommendations contained in the report submitted under clause (i).

(F) Classes of drugs

For purposes of this paragraph:

(i) Sole source drugs

The term "sole source drug" means—

(I) a biological product (as defined under section 1395x(t)(1) of this title); or

(II) a single source drug (as defined in section 1396r-8(k)(7)(A)(iv) of this title).

(ii) Innovator multiple source drugs

The term "innovator multiple source drug" has the meaning given such term in section 1396r-8(k)(7)(A)(ii) of this title.

(iii) Noninnovator multiple source drugs

The term "noninnovator multiple source drug" has the meaning given such term in section 1396r-8(k)(7)(A)(iii) of this title.

(G) Reference average wholesale price

The term "reference average wholesale price" means, with respect to a specified covered outpatient drug, the average wholesale price for the drug as determined under section 1395u(*o*) of this title as of May 1, 2003.

(H) Inapplicability of expenditures in determining conversion, weighting, and other adjustment factors

Additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years.

* * *

(18) Authorization of adjustment for cancer hospitals

* * *

(B) Authorization of adjustment

Insofar as the Secretary determines under subparagraph (A) that costs incurred by hospitals described in section 1395ww(d)(1)(B)(v) of this title exceed those costs incurred by other hospitals furnishing services under this subsection, the Secretary shall, subject to subparagraph (C), provide for an appropriate adjustment under paragraph (2)(E) to reflect those higher costs effective for services furnished on or after January 1, 2011.

* * *

(21) Services furnished by an off-campus outpatient department of a provider

(A) Applicable items and services

For purposes of paragraph (1)(B)(v) and this paragraph, the term "applicable items and services" means items and services other than items and services furnished by a dedicated emergency department (as defined in section 489.24(b) of title 42 of the Code of Federal Regulations).

(B) Off-campus outpatient department of a provider

(i) In general

For purposes of paragraph (1)(B)(v) and this paragraph, subject to the subsequent provisions of this subparagraph, the term "off-campus outpatient department of a provider" means a department of a provider (as defined in section 413.65(a)(2) of title 42 of the Code of Federal Regulations, as in effect as of November 2, 2015) that is not located—

(I) on the campus (as defined in such section 413.65(a)(2)) of such provider; or

(II) within the distance (described in such definition of campus) from a remote location of a hospital facility (as defined in such section 413.65(a)(2)).

* * *

(E) Limitations

There shall be no administrative or judicial review under section 1395ff of this title, section 1395*oo* of this title, or otherwise of the following:

(i) The determination of the applicable items and services under subparagraph (A) and applicable payment systems under subparagraph (C).

(ii) The determination of whether a department of a provider meets the term described in subparagraph (B).

(iii) Any information that hospitals are required to report pursuant to subparagraph (D).

(iv) The determination of an audit under subparagraph (B)(vii).

* * *

(u) Incentive payments for physician scarcity areas

(1) In general

In the case of physicians' services furnished on or after January 1, 2005, and before July 1, 2008—

(A) by a primary care physician in a primary care scarcity county (identified under paragraph (4)); or

(B) by a physician who is not a primary care physician in a specialist care scarcity county (as so identified),

in addition to the amount of payment that would otherwise be made for such services under this part,

there also shall be paid an amount equal to 5 percent of the payment amount for the service under this part.

* * *

(E) Judicial review

There shall be no administrative or judicial review under section 1395ff, 1395*oo* of this title, or otherwise, respecting—

(i) the identification of a county or area;

(ii) the assignment of a specialty of any physician under this paragraph;

(iii) the assignment of a physician to a county under paragraph (2); or

(iv) the assignment of a postal ZIP Code to a county or other area under this subsection.

* * *

(x) Incentive payments for primary care services

(1) In general

In the case of primary care services furnished on or after January 1, 2011, and before January 1, 2016, by a primary care practitioner, in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid (on a monthly or quarterly basis) an amount equal to 10 percent of the payment amount for the service under this part.

* * *

(4) Limitation on review

There shall be no administrative or judicial review under section 1395ff of this title, 1395*oo* of this

title, or otherwise, respecting the identification of primary care practitioners under this subsection.

* * *

(z) Incentive payments for participation in eligible alternative payment models

(1) Payment incentive

(A) In general

In the case of covered professional services furnished by an eligible professional during a year that is in the period beginning with 2019 and ending with 2024 and for which the professional is a qualifying APM participant with respect to such year, in addition to the amount of payment that would otherwise be made for such covered professional services under this part for such year, there also shall be paid to such professional an amount equal to 5 percent of the estimated aggregate payment amounts for such covered professional services under this part for the preceding year.

* * *

(4) Limitation

There shall be no administrative or judicial review under section 1395ff of this title, 1395*oo*[17] of this title, or otherwise, of the following:

(A) The determination that an eligible professional is a qualifying APM participant under paragraph (2) and the determination that an entity is an eligible alternative payment entity under paragraph (3)(D).

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[17] So in original. Probably should be preceded by "section".

(B) The determination of the amount of the 5 percent payment incentive under paragraph (1)(A), including any estimation as part of such determination.

* * *