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

REPLY BRIEF FOR THE PETITIONERS

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INTRODUCTION

When Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, it gave precise instructions for how the Department of Health and Human Services (the agency) should set reimbursement rates for outpatient drugs. Congress authorized the agency to set rates based on acquisition cost, and to vary reimbursement by hospital group, only if the agency based those rates and variances on the results of a cost study that met the rigorous requirements set forth in the statute. 42 U.S.C. 1395*l*(t)(14). Otherwise, the agency must set rates based on the average price of the drug and cannot vary reimbursement by hospital group. *Ibid.*

The government does not dispute that the agency singled out Section 340B hospitals as a group and set their reimbursement based on acquisition cost rather than price, without conducting the cost study that the statute requires. The agency's action was therefore contrary to law.

The government's arguments in defense of the agency's rate-setting decision are meritless. Essentially, the government contends that the agency is free to do whatever it wants when it sets reimbursement rates for outpatient drugs. So long as the agency uses the average price of the drugs as its starting point, it may "adjust" the price-based rate to transform it into a cost-based rate for targeted hospital groups in disregard of the express statutory limits on the agency's authority. The government also asserts that Congress has precluded all review of the agency's rate-setting decisions for outpatient drugs, depriving the courts of any power to question the agency's decision to ignore

those express statutory limits on its authority and to substitute its own policy judgments.

The government's arguments cannot be reconciled with the statutory text, structure, or history. The agency action at issue in this case violates the law, and this Court's power to review it is clear. This Court should therefore set it aside.

ARGUMENT

I. Section 1395*l*(t)(12) Does Not Preclude Judicial Review

A. The government's preclusion argument lacks any textual basis. The provisions on which the government relies—subparagraphs (A) and (C) of paragraph (12)—bar review of the agency's development of a classification system for covered services under paragraph (2) and the agency's periodic adjustments under paragraph (9) to certain paragraph (2) determinations. But when the agency sets reimbursement rates for outpatient drugs under paragraph (14), it is doing neither of those things. Paragraph (12) therefore does not preclude review here.

Rather than coming to terms with the carefully targeted text, the government paraphrases paragraph (12) to suggest that Congress wrote a broader preclusion provision than it did, repeatedly asserting (Br.4, 22, 26) that paragraph (12) precludes review of "OPPS components"—a phrase found nowhere in paragraph (12). When it comes to the actual language of subparagraphs (12)(A) and (12)(C), however, the government offers only a handful of bare-bones assertions (Br.24) that steadfastly ignore petitioners' detailed textual analysis. The government also (and without explana-

tion) throws overboard the agency's longstanding position that paragraph (14) reimbursement involves a "methodology" that is "separate" from the methodology covered by paragraphs (2) and (9) and is thus "outside the * * * process" that those paragraphs establish. *E.g.*, 77 Fed. Reg. 68,210, 68,262 (Nov. 15, 2012); JA43-47.

1. The government's principal contention is that subparagraph (12)(A) precludes review because setting reimbursement rates for outpatient drugs under paragraph (14) is actually an exercise of the agency's paragraph (2) authority. That contention is baseless. As the government notes, paragraph (2) instructs the agency to "develop a classification system for" outpatient services and permits the agency to "establish groups of" such services. 42 U.S.C. 1395*l*(t)(2)(A)-(B), *cited in* Govt.Br.24. But when the agency sets reimbursement rates in the amounts Congress has specified in paragraph (14), it does not "develop" or otherwise affect any classification; each drug is in its own classification category both before and after the agency makes its paragraph (14) reimbursement decision. In addition, the agency never establishes "groups" of separately payable drugs for reimbursement purposes; that is why outpatient drugs are called "separately payable." See, *e.g.*, MedPAC, *Report to the Congress: Medicare and the Health Care Delivery System* 167 (June 2020), https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun20_reporttocongress_sec.pdf.

The government's argument also proves too much. As the government would have it, *any* determination under subsection (t) involving any outpatient service that the agency has placed in a classification category

is necessarily a paragraph (2) determination—and review of that determination is therefore precluded under subparagraph (12)(A). But if that were correct, then the other targeted preclusion provisions Congress included in subsection (t) would be superfluous—because virtually *every* determination under any part of subsection (t) involves a drug, device, or service that the agency has classified. See, *e.g.*, MedPAC, *supra*, at 167. For instance, Congress would have had no need to expressly preclude review of paragraph (3) determinations, as Congress did in subparagraph (12)(B), because those determinations are just calculations of various amounts as to outpatient services that are covered by paragraph (2) and have received a classification code. See 42 U.S.C. 1395*l*(t)(3), (12)(B).

2. The government's alternative argument that setting outpatient drug reimbursement rates under paragraph (14) should be considered a determination under paragraph (9) (and thus shielded from review by subparagraph (12)(C)) is similarly misconceived. The government (Br.24, 27) identifies no language in paragraph (9) that encompasses paragraph (14) determinations—which is not surprising given that those determinations entail no consideration of service "groups," "wage" adjustments, "changes in technology," or any other factor that paragraph (9) commands the agency to consider. 42 U.S.C. 1395*l*(t)(9). Instead, the government insists (Br.27) that without paragraph (9) the agency would lack authority to revisit paragraph (14) determinations annually. But Paragraph (14) mandates that for every year "subsequent" to 2005 the "amount of payment * * * shall be equal" to a specified cost or price for a drug "for that year." 42 U.S.C. 1395*l*(t)(14)(A)(iii)(I); see 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II)

("in the year"). Accordingly, paragraph (14) itself requires the agency to generate drug-reimbursement rates annually.[1]

The government all but ignores petitioners' discussion (Petr.Br.22-24) of subparagraphs (9)(B) and (14)(H), which expressly treat the paragraph (14) payment-amount calculation as something *separate* from the annual adjustments under paragraph (9)—and, for that matter, from the determinations previously made under paragraph (2) that paragraph (9) periodically revises. As petitioners explained, paragraph (14) "expenditures" must be "taken into account" when later "establishing" the "adjustment factors * * * under paragraph (9)," which as a matter of basic logic could not occur unless those expenditures are distinct from the paragraph (9) adjustments. 42 U.S.C. 1395*l*(t)(14)(H). The government's only response is to assert (Br.24) without explanation that those "cross-reference[d]" provisions help its cause. With respect, that assertion does not amount to an argument.

3. The government also fails to address petitioners' detailed analysis (Petr.Br.24-27) of the many provisions in Section 1395*l*, including provisions enacted at the same time as paragraph (14), that preclude judicial review in careful and targeted ways—something that Congress did *not* do as to paragraph (14) determinations. But it is fundamental that "where Congress includes particular language in one section of a statute but omits it in another section of the same Act," a court

[1] The government also asserts (Br.24) that the agency used paragraph (9) adjustment authority in the relevant rulemakings. But the agency's own statements in the Federal Register demonstrate that the agency relied *exclusively* on paragraph (14) here. Petr.Br.27-28.

"presume[s] that Congress act[ed] intentionally and purposely in the disparate inclusion or exclusion." *Babb* v. *Wilkie*, 140 S. Ct. 1168, 1177 (2020) (citation omitted). The government's reading presumes the opposite—and, in doing so, bulldozes all of the fine preclusion distinctions that Congress painstakingly created.

4. Instead of engaging with those dispositive textual points, the government posits the overarching theory (*e.g.*, Br.21) that Congress intended to permit judicial review of individual reimbursement determinations but not broader agency determinations. That is wishful thinking, and even a cursory perusal of the statute disproves it. For instance, subparagraph (12)(D) precludes review of "the establishment of a separate conversion factor under [sub]paragraph (8)(B)," which must mean that review of other paragraph (8) determinations is not precluded; subparagraph (8)(C) requires the agency to set a *national* copayment rate in a particular way, which means that review of that systemic rate-setting is open to judicial examination. See 42 U.S.C. 1395*l*(t)(8)(C), (12)(D). The only support the government can point to for its theory is legislative history from well before the 2003 enactment of paragraph (14) and an agency regulation about eligibility for *internal* agency review of reimbursement decisions. Govt.Br.21. Neither of those has anything to say about whether review of paragraph (14) determinations is precluded—and, even if they did, neither can override the statute's text.

It should go without saying that the government has not come close to overcoming the strong presumption in favor of judicial review. Indeed, given that the government can point to nothing in the statute that supports its position, that presumption is just icing on

a cake already frosted. The analysis begins and ends with the text: Congress did not preclude judicial review of paragraph (14) rate-setting determinations.

B. Lacking any substantial textual arguments, the government instead relies principally (*e.g.*, Br.21-23, 29-30) on the policy argument that Congress would not have wanted judicial review of paragraph (14) determinations because it is too difficult for a court to award relief if the agency ignores Congress's instructions. That argument is no match for the presumption of judicial review, particularly given that this case involves enforcement of a clear limit on the agency's discretion. The argument is also meritless.

Starting with the obvious, reviewing courts can set aside a paragraph (14) rate-setting order as contrary to law under the APA. Such declaratory relief would not disturb the budget neutrality of existing Medicare payments, but it would block the government from repeating its statutory violation in a subsequent year's rulemaking, as the government has now done every year since 2018.[2]

Moreover, courts *can* award monetary relief for the agency's statutory violation, as the government itself acknowledged below in successfully opposing issuance of a preliminary injunction. Petr.Br.28. Specifically, the agency can make 340B hospitals whole for past shortfalls without running afoul of the budget-neutrality provision in Section 1395*l*(t). That provision states only that the agency may not "increase or decrease * * * the *estimated* amount of expenditures" for a given year. 42 U.S.C. 1395*l*(t)(9)(B) (emphasis added). The estimates are thus one of the inputs into the

[2] See, *e.g.*, 86 Fed. Reg. 63,458, 63,640-63,641 (Nov. 16, 2021).

agency's notice-and-comment rulemaking each year—but after those rules are issued for a particular year, the estimates do not change. Accordingly, once expenditures are actual rather than estimated, as is true for any past year, the budget-neutrality requirement is inapplicable by its own terms. Notably, the agency has agreed with that interpretation in the past in exactly the situation presented here: correction of an erroneous underpayment under Section 1395*l*(t) by means of retrospective payments. *H. Lee Moffitt Cancer Ctr.* v. *Azar*, 324 F. Supp. 3d 1, 16 (D.D.C. 2018); see Fed.Am.Hosp.Br.26 (government's amicus agreeing). And it could hardly be otherwise, since requiring budget neutrality as to *actual* expenditures would force the agency to make additional payments or recoup costs each year to account for any ultimate inaccuracy in the relevant estimates (*e.g.*, differences between expected and actual amounts of drugs prescribed)—something that the agency does not do.[3]

All of that underscores petitioners' observation that "courts have approved judicial review of" determinations like the paragraph (14) determination "in the past—and the sky has not fallen." Petr.Br.29. The government's denial of that proposition (Br.30) is artfully phrased, and for good reason: it excludes or mischaracterizes several cases that petitioners cited. For instance, the government asserts that *H. Lee Moffitt* did not "order any additional payments," Br.30, but the district court there remanded to the agency with instructions to take "act[ion]" that would make the

[3] Budget neutrality also would not bar other kinds of monetary relief. As the agency proposed on remand from the district court, the agency could factor retroactive adjustments into future-year rates, which would themselves be budget neutral. See Petr.Br.29.

plaintiff monetarily whole, 324 F. Supp. 3d at 16, 18-19. And the government omits that *H. Lee Moffitt* relied on the agency's *existing* practice of "correct[ing] its own" erroneous underpayments under Section 1395*l*(t) "by means of a retroactive" payment—*without* any budget-neutrality problem. *Id.* at 15-16, 19 (citing 71 Fed. Reg. 67,960, 68,010 (Nov. 24, 2006)). The government also ignores petitioners' citation (Petr.Br.29-30) to *Universal Health* v. *Sullivan*, 770 F. Supp. 704, 711-712 (D.D.C. 1991), *aff'd*, 978 F.2d 745 (D.C. Cir. 1992) (per curiam) (unpub.), which approved judicial review of "system-wide determinations" under a prospective-payment "Medicare A program" that "operates under budget-neutrality constraints," *Amgen, Inc.* v. *Smith*, 357 F.3d 103, 113 (D.C. Cir. 2004). And a D.C. Circuit decision on which the government places heavy reliance refutes the government's view, stating that any "interference with the administration of the Medicare B program that would result from judicial review pertaining to the overall scope of the Secretary's statutory adjustment authority" would be "sufficiently offset by the likely gains from reducing the risk of systematic misinterpretation." *Ibid*.

Finally, contrary to the government's suggestion, there are sound reasons why Congress would have wanted courts to review paragraph (14) determinations. *E.g.*, Petr.Br.34, 39-41. The most obvious such reason is the worry that the agency would do exactly what it did here: disregard Congress's instruction to apply the acquisition-cost measure and vary reimbursement by hospital group *only* if the statutorily specified cost study is available to support those actions. See 42 U.S.C. 1395*l*(t)(14)(A)(iii), (D). Although the government notes that Congress precluded review of some determinations under different paragraphs

that likewise "affect billions of dollars," those paragraphs confer greater discretion on the agency than does paragraph (14). Govt.Br.29 (citing paragraph (3)); see 42 U.S.C. 1395*l*(t)(3) (agency power to "estimate").

C. Even if this Court were to conclude that the statute precludes review of an "adjust[ment]" under paragraph (14), preclusion would nevertheless be inapplicable here because the agency's action does not qualify as an "adjust[ment]." No language in paragraph (12) could even conceivably have any bearing in this case except for that provision's cross-reference to paragraphs (other than paragraph (14)) that talk about "adjustments." Petr.Br.30. Petitioners' argument thus rests not on the diffuse assertion that the agency has exceeded its statutory authority (contra Govt.Br.30-31), but instead on concrete statutory text: if the agency's action is not an "adjust[ment]" under paragraph (14) (as petitioners argue on the merits), then it cannot be an "adjustment" for purposes of the preclusion provision either.

II. The Agency's Action Violates The Statute

Section 1395*l*(t)(14) could not be clearer: if the agency wishes to set drug-reimbursement rates equal to acquisition cost, or to vary rates by hospital group, or both, then the agency must "tak[e] into account the hospital acquisition cost survey data" that subparagraph (14)(D) requires the agency to collect. 42 U.S.C. 1395*l*(t)(14)(A)(iii), (D). If the agency has not collected and assessed that data using the rigorous standards that Congress prescribed, then the agency must set rates "for" a particular "drug"—that is, rates that apply the same way to *all* hospitals being reimbursed for that drug—that are equal to the "the average price for

the drug in the year," and can "calculate[] and adjust[]" that "average price" if "necessary for purposes of" paragraph (14). *Ibid.* Here, the agency did not collect the required cost-survey data, but nevertheless set drug-reimbursement rates for only one particular group of hospitals at the amount that the agency decided was equivalent to acquisition cost for these hospitals, rather than at an amount that bears any relationship to the "average price for the drug." *Ibid.* The agency thereby flouted Congress's unambiguous commands.

A. The government's defense of the agency's disregard of the statutory limits on its authority rests on two pillars: the contentions that the paramount purpose of paragraph (14) is to set rates based on acquisition cost and that Congress intended average price to serve as a proxy for acquisition cost in all circumstances. Those contentions are incompatible with the statute's text, structure, and history.

First, the government asserts (*e.g.*, Br.32, 34) that the paramount purpose of paragraph (14) is to reimburse hospitals based on acquisition cost. But the government never explains how a legislature that placed careful limits on use of acquisition cost, and prescribed average-price reimbursement as what the agency itself describes as the "default" reimbursement methodology when the statutorily required data is not available, Petr.Br.39, could have thought that paragraph (14)'s overriding purpose was to use acquisition cost as the basis for reimbursement in every possible circumstance. It would be perverse for Congress to limit the agency's use of acquisition cost in subclause (I) and then relieve the agency of those limits in the very next sentence of the statute. And it would be extraordinary for Congress to do so by burying the modest term "ad-

just[]" at the end of clause (t)(14)(A)(iii)'s second subclause. See *MCI Telecomms. Corp.* v. *AT&T*, 512 U.S. 218, 229 (1994).

As if to conjure its preferred state of affairs into being through sheer repetition, the government observes that subclause (I) (on acquisition cost) comes before subclause (II) (on average price) and then intones (Br.32-35, 37) that the former is Congress's "primary" instruction and the latter only a "backup." But the order of the subclauses, which are alternatives separated by "or," cannot possibly make any analytical difference. And the government does not explain how Congress could have intended that cost-based rates be the norm when—as the government's brief elsewhere acknowledges (*e.g.*, Br.32)—the cost study is a burdensome requirement that is difficult to carry out. The opposite inference is far more likely: had Congress intended cost-based rates to be the norm, then surely it would have streamlined rather than burdened the process for setting such rates. The government also points (Br.34-35) to scattered instructions to the agency in paragraphs (2) and (9) of subsection (t) to make certain reimbursement-related decisions on a cost basis for outpatient services *other than* the drugs covered by paragraph (14). But, as discussed above (pp. 2-5, *supra*), those paragraphs describe a methodology that is entirely distinct from the one laid out in the later-enacted paragraph (14), and cannot be read to control paragraph (14)'s different language.

Second, the government asserts that average price is always supposed to function as a proxy for acquisition cost. Again, the government has not a shred of textual support for that assertion, and there is not a single indication in the legislative history of any such

congressional purpose. Moreover, the statutory history casts serious doubt on the claim. When Congress enacted paragraph (14) in 2003, it was well aware of the existence of the 340B program, which Congress had created eleven years earlier. See Petr.Br.9. Yet when Congress specified how the agency should calculate average price (by reference to other statutory provisions), Congress did not include in the required calculation the drug discounts that 340B hospitals receive—even though, as the government admits (*e.g.*, Br.32), Congress did require average price to reflect a *different* set of discounts that hospitals receive when they purchase drugs. Congress therefore must also have been aware that reimbursing 340B hospitals based on paragraph (14)'s average-price instructions would not, in fact, be anything close to a proxy for acquisition cost. And Congress must have been aware of the very same thing when it expanded the 340B program in 2010. See Petr.Br.40. As to reimbursement decisions affecting only 340B hospitals, where Congress *knew* that average price and acquisition cost necessarily diverge, it is rich indeed for the government to attempt to justify replacing average price with acquisition cost based on the notion that those measures are sometimes similar in *other* situations.

Without those two premises to undergird it, the government's argument collapses. There is no hidden purpose embedded in paragraph (14) that could justify giving the agency unfettered power to reimburse 340B hospitals—and 340B hospitals alone—based on acquisition cost without meeting the statute's express requirements. The only purpose that can be derived from paragraph (14) must be found in its plain terms, and those terms demonstrate that Congress prioritized above all else accuracy of whichever of the two

alternative reimbursement methodologies is applicable. See Petr.Br.42-43. Turning average price for a drug into acquisition cost for 340B hospitals is not a way of creating a more accurate measure of average price; it is just an end run around clear statutory limits on the agency's authority to set cost-based rates.

B. The government's arguments are fatally flawed in additional ways.

1. The government's interpretation renders much of paragraph (14) superfluous.

First, that interpretation writes the cost-study limitations in subclause (I) and the requirement for a periodic cost study in subparagraph (14)(D) out of the statute. Subclause (I) says that when the agency sets reimbursement based on acquisition cost it must "tak[e] into account the hospital acquisition cost survey data under subparagraph (D)." 42 U.S.C. 1395*l*(t)(14)(A)(iii)(I). But the government says that the agency can set reimbursement based on acquisition cost without taking that data into account or even possessing that data. Subparagraph (14)(D) says that the agency "shall conduct periodic * * * surveys to determine the hospital acquisition cost for each [drug] for use in setting the payment rates," and requires those surveys to use a "large sample" and to "generate a statistically significant estimate of the average hospital acquisition cost" for each drug. 42 U.S.C. 1395*l*(t)(14)(D). But the government says that the agency need never do a survey using those parameters and may "determine the hospital acquisition cost for each [drug] for use in setting the payment rates," *ibid.*, with any data on which the agency cares to rely. Those assertions are nothing less than an impermissible negation of "textually applicable provisions meant to

limit" an agency's "discretion." *Whitman* v. *Am. Trucking Ass'ns*, 531 U.S. 457, 485 (2001).

The government seeks to paper over that problem by arguing (Br.41-42) that the agency retains the option to do a cost study that satisfies subparagraph (14)(D) if it ever desires to, and in that circumstance could set rates based on acquisition cost directly under subclause (I) rather than indirectly under subclause (II). But the fact that the government's interpretation renders a mandatory study—"shall conduct"—entirely voluntary demonstrates that the government is rewriting the statute, not interpreting it. Congress did not include subclause (I) and subparagraph (14)(D) in the statute as a purely optional exercise; those provisions set forth *commands* about how drug reimbursement is to be carried out.[4]

Second, the government's interpretation writes out of paragraph (14) the language that dictates when reimbursement may vary by hospital group. Subclause (I) authorizes such variances if the agency is relying on the required cost study—language that is conspicuously not present in subclause (II). If the agency could vary reimbursement by hospital group at its whim by "adjust[ing]" subclause (II) price-based rates, then Congress would have had no reason to include that carefully worded authorization in subclause (I).

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[4] The government incorrectly suggests (Br.42) that the agency has recently carried out a study that did meet those requirements. As explained (Pet.5.n.8, 29-30), that "study" was not even close to statistically significant or complete. The government also incorrectly indicates (Br.42) that the agency used subclause (I) authority once it had that study in hand. That is wrong. The agency used subclause (II) to set rates at that time—thus acknowledging that the study did not satisfy subparagraph (14)(D). See 85 Fed. Reg. 85,866, 86,052-86,054 (Dec. 29, 2020).

Equally to the point, subclause (II)'s language *forecloses* varying an average-price reimbursement rate by hospital group. It requires reimbursement in an "amount" that is "equal" to the "average price for the drug in the year," 42 U.S.C. 1395*l*(t)(14)(A) & (A)(iii)—that is, it requires reimbursement to be set *drug by drug*, not hospital by hospital. The existence of the agency's "adjust[ment]" authority does not change that requirement, because the only thing that the agency is permitted to adjust is the "average price for the drug in the year"; such an adjustment could consist of moving the average-price number slightly up or down, but it cannot consist of coming up with two *different* average-price numbers for a single drug for two different groups of hospitals, as the agency purported to do here.

There is an obvious reason why Congress allowed hospital-group variance when the agency is using the required study and setting acquisition-cost reimbursement under subclause (I), but not when the agency is acting without a study and setting average-price reimbursement under subclause (II). The study is, in part, intended to figure out whether there is meaningful, statistically significant variation among hospitals. Subparagraph (14)(D) states that the initial acquisition-cost surveys in 2004 and 2005, on which the agency here was to build, were to "determine and report to Congress" the "extent" of "variation in hospital acquisition costs for drugs among hospitals." 42 U.S.C. 1395*l*(t)(14)(D)(i)(I), (iv). Thus, the statute contemplates that HHS may "vary" cost-based rates "by hospital group" only when acting under subclause (I) and with "hospital acquisition cost survey data under subparagraph (D)" in hand because it is only by operation of subparagraph (D) that the agency could have data regarding "variation in hospital acquisition costs

for drugs among hospitals" sufficiently rigorous to justify such a move. 42 U.S.C. 1395*l*(t)(14)(A)(iii)(I), (D)(iv). The government ignores that aspect of the statutory design.

Those problems with the government's interpretation are insurmountable. In contrast, petitioners' straightforward text-based interpretation poses no difficulties. The court of appeals majority based its ruling against petitioners almost entirely on the notion that petitioners' position suffers from a cross-cutting superfluity problem: eliminating the significance of subparagraph (14)(E). Pet.App.25a-28a. Petitioners' opening brief (at 43-45) demonstrated that no such problem exists. The government apparently agrees. It has essentially dropped the point, relegating to a single sentence (Br.39) the principal driver of the court of appeals' statutory analysis. With that superfluity objection laid to rest, the government is left with no text-based objection to petitioners' reading of paragraph (14).

2. The government also has no meaningful response to petitioners' explanation of the textual limitations inherent in Congress's choice of the word "adjust[]," which connotes a modest change that is tethered to the starting point of the thing being adjusted. See Petr.Br.36-41. The limiting nature of Congress's word choice is particularly apparent given that the term appears in the phrase "calculate[] and adjust[]": read together, those verbs indicate that under the relevant clause the agency is permitted to take minor technical action that gets a number closer to the true "average price," not action that is unbounded and policy-driven. 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II).

The government suggests (Br.46) that an almost 30% change in reimbursement of 340B hospitals can reasonably be considered an "adjust[ment]." But that jarring change is hardly a "slight" alteration, Petr.Br.37 (citing dictionary definitions)—particularly when it is understood in real-world terms, as a more than $1.5-billion penalty inflicted on 340B hospitals every year. And even if such a large change could plausibly be described as an adjustment in the abstract, it still would not represent an "adjust[ment]" *of average price* because it is not tethered to that objectively knowable price in any way. The government does not respond to that lack of tethering, except perhaps by obliquely suggesting (Br.38) that acquisition cost and average price are both numbers and therefore necessarily have some mathematical relationship to each other. On that view, however, the agency would have infinite adjustment power—and even the government's argument does not reach so far.[5]

Nothing about the use of the term "adjust[ment]" elsewhere in subsection (t) changes that analysis. The word "adjust[]" in paragraph (14) must, as the government argues (Br.46), be read in the context of paragraph (14) itself. And the example the government gives—paragraph (2)'s requirement of a "wage adjustment factor to adjust" for geographic "differences in labor and labor-related costs," 42 U.S.C. 1395*l*(t)(2)(D)—is inapposite. That language, which gives specific in-

[5] The only case on which the government relies (Br.46) in its discussion of the meaning of "adjust[]" supports petitioners. See *Amgen*, 357 F.3d at 117 (discussing paragraph (2) adjustments and stating that a "substantial departure from the default amounts would, at some point, * * * cease to be an 'adjustment[]'" and "exceed" the agency's "statutory authority").

structions for how to make adjustments, bears no resemblance to paragraph (14)'s language and, in any event, provides no authority for an adjustment unconnected to a statutorily specified starting point.

3. The error of the government's statutory interpretation is emphasized by its novelty. Before the first challenged rulemaking in this case in 2018, more than a decade after paragraph (14) was enacted, the agency never suggested that paragraph (14) gave it such broad power. Until that date, the agency had never singled out 340B hospitals, or any other hospital group, for disadvantageous treatment under subclause (II). Instead, the agency had always applied a uniform drug-reimbursement rate based on average sales price. See, *e.g.*, 77 Fed. Reg. at 68,386; 82 Fed. Reg. 52,356, 52,490 (Nov. 13, 2017). Absent the statutorily required cost study, which the agency has not carried out, that uniform rate is what the statute unambiguously mandates.

C. Finally, the government contends that as a matter of policy "it is inappropriate for Medicare," Br.43-45, to pay a uniform "average price for the drug" to 340B hospitals, along with all other hospitals, as Congress required under subclause (II). That same desire to disfavor 340B hospitals animated the agency's rulemaking here. See Petr.Br.40-41. But whether (or how) 340B hospitals should be treated differently from hospitals that are not covered by 340B is a choice for Congress, not for an executive agency. As demonstrated above, Congress decided that when the agency must employ subclause (II), as it concededly must absent the required cost study, *no* group of hospitals can be singled out and average price *for each drug* is to be calculated without regard to any 340B drug discounts.

The government also suggests (*e.g.*, Br.10) that absent the challenged agency action 340B hospitals would unfairly "profit" from the differential between average price and acquisition cost. That is a misguided view—and one that Congress plainly did not share. Hospitals covered by 340B do not "profit" at all; they are non-profit organizations that plow money received through reimbursements back into critical life-enhancing and life-saving treatments for extremely vulnerable communities. See, *e.g.*, https://www.aha.org/system/files/media/file/2021/09/340b-community-benefits-analysis-0921.pdf; https://www.340bhealth.org/files/Meeting_Varied_Community_Needs_with_340B_Savings.pdf. The agency itself recently recognized the tremendous value that 340B hospitals deliver, stating that 340B hospitals are "safety net providers" that "utilize the 340B Program to address health equity by expanding the provision of under-reimbursed and often scarce services." HHS, *Comprehensive Plan for Addressing High Drug Prices* 22 (Sept. 9, 2021), https://aspe.hhs.gov/sites/default/files/2021-09/Drug_Pricing_Plan_9-9-2021.pdf. It is entirely reasonable for Congress to have decided to structure subclause (II) of paragraph (14) to allow 340B hospitals to obtain reimbursement over and above their acquisition cost, precisely to support those perennially cash-strapped institutions in delivering all of those extraordinary community health benefits.

That congressional choice does not harm other Medicare Part B players (although Congress could make the choice regardless). The government suggests (*e.g.*, Br.12) that the agency's statutory violation benefits Medicare beneficiaries who must make copayments. That is wrong. Most Medicare beneficiaries

have supplemental coverage that reduces or eliminates their copayments. See Petr.D.C.Cir.Br.13. And where such supplemental coverage is absent, the agency's approach *increases* beneficiaries' out-of-pocket costs for outpatient services other than drugs (and even increases out-of-pocket costs for drugs for some beneficiaries). See *ibid.* Given the requirement of budget neutrality, a decrease in reimbursements to 340B hospitals will be offset by an increase in reimbursements for other services, which will in turn increase copayments for those services. Amici, for their part, protest that other hospitals, including rural hospitals, are just as deserving as 340B hospitals. But Congress has already extended special benefits to rural hospitals in Section 1395*l*, including authorization for targeted additional payments. See 42 U.S.C. 1395*l*(t)(13); see also, *e.g.*, 42 U.S.C. 1395*l*(t)(7)(D)(I)(i).[6]

D. In the end, the government's argument in this case is a failed effort to stuff the biggest of elephants into the smallest of mouseholes. Some provisions of Section 1395*l*(t) give the agency power to set whatever payment amount it chooses, including a provision in paragraph (14) that abuts the subclause at issue here. See 42 U.S.C. 1395*l*(t)(14)(C). Subclause (II) does not, and this Court should not permit the agency to arrogate that power to itself.

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[6] Moreover, although if the agency's action is declared unlawful then there may (as a result of paragraph (9) budget neutrality) be a small decrease going forward in the overall amount of reimbursement for outpatient services not covered by paragraph (14), that would simply mark a return to the long-time status quo, and 340B hospitals would be affected along with every other hospital.

III. *Chevron* Deference Does Not Justify The Agency's Action

The court of appeals' reliance on *Chevron* deference to justify its ruling vividly illustrates serious ills associated with the *Chevron* doctrine. See Petr.Br.46-50. There is no genuine ambiguity here—and so deferring to the agency amounts to abdication of the judicial function.

The government suggests (Br.48-49) that Congress gave the agency broad power through an "express delegation" because the statute says that "the Secretary" can perform a specified "calculat[ion] and adjust[ment]." 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II). But Congress's mere mention of an agency in a statute hardly constitutes a delegation to alter the statute's meaning. The express-delegation cases on which the government relies all involve statutes that authorize agencies to define particular statutory terms or to use unbounded discretion to implement a sweeping statutory scheme. See, *e.g.*, *Cuozzo Speed Techs., LLC* v. *Lee*, 136 S. Ct. 2131, 2136, 2144 (2016); *Sebelius* v. *Auburn Reg'l Med. Ctr.*, 568 U.S. 145, 156-157 (2013); *FCC* v. *Nat'l Citizens Comm. for Broad.*, 436 U.S. 775, 793-794 (1978); see also *Schweiker* v. *Gray Panthers*, 453 U.S. 34, 43-44 (1981) (cited in *Chevron*); *Batterton* v. *Francis*, 432 U.S. 416, 418, 424-426 (1977) (same). Such statutes are a far cry from the provision at issue here, which commands the agency to carry out precisely worded directives and affords no discretion to wipe out swaths of paragraph (14) by replacing "average price for the drug" for all hospitals with an approximation of drug-acquisition cost for only certain hospitals. 42 U.S.C. 1395*l*(t)(14)(A)(iii).

The government fares no better in defending (Br.49) the notion that Congress used the word "adjust[ment]" to give the agency discretion to remake the multi-billion dollar drug-reimbursement system. The government points out that the agency has, by statute, unreviewable power over certain reimbursement-related determinations involving other outpatient services. But Congress granted that power expressly and directly: it gave the agency discretion over those determinations in specific paragraphs of subsection (t), see, *e.g.*, 42 U.S.C. 1395*l*(t)(3)(B)(iii), (C)(i)(II), and it named those specific paragraphs in the provision that carefully precludes judicial review as to some agency determinations but not others, see, *e.g.*, 42 U.S.C. 1395*l*(t)(12)(B). Congress did neither of those things in enacting paragraph (14)—which is why the government cannot muster any textual argument that does not depend on stretching "adjust[ment]" far beyond the meaning it can bear. If Congress had wanted the agency to make multi-billion-dollar decisions about drug reimbursement in its discretion, Congress would not have hidden such authority in an ancillary provision buried among detailed commands designed to eliminate the agency's ability to carry out its own drug-reimbursement policy preferences.

At bottom, there is no denying that the agency's action here erases those commands from the statute Congress wrote—and thereby tears "the heart [out] of" paragraph (14), with immense economic consequences for hospitals that provide critical care for vulnerable populations. *MCI*, 512 U.S. at 229. Just as in *MCI*, the agency has attempted to arrogate power and remake a statutory scheme by seizing on an inherently modest term ("adjust[]") that cannot reasonably be read to confer such power. *Id.* at 229-231 (discussing

"modify"). No deference is due to the agency's self-aggrandizing interpretation.

CONCLUSION

The judgment below should be reversed.

Respectfully submitted,

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November 2021