No. 20-1114

IN THE

Supreme Court of the United States

THE 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 Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

REPLY BRIEF FOR PETITIONERS

DONALD B. VERRILLI, JR.
Counsel of Record
MUNGER, TOLLES & OLSON LLP
601 Massachusetts Ave. NW
Suite 500E
Washington, DC 20001
(202) 220-1100
Donald.Verrilli@mto.com

Counsel for Petitioners

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INTRODUCTION

The statutory provision at issue in this case is unambiguous: The Department of Health and Human Services (HHS) may set reimbursement rates 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). HHS purported to set cost-based rates for Section 340B hospitals but it did not collect (and therefore did not rely on) the survey data that Congress made a precondition for setting cost-based rates. As a matter of law, therefore, HHS acted without "statutory … authority," and its order should be "set aside." 5 U.S.C. 706(2).

The government's effort to shield HHS's action from review by this Court epitomizes all that is wrong with *Chevron* deference. The government does not defend HHS's decision as the best reading of the statutory text. In fact, the government makes no real effort to come to grips with the textual requirement that cost-based rates be set based on specified cost survey data. Instead, the government spends page after page touting the reasonableness of HHS's decision. According to the government, it was reasonable for HHS to use alternative data in lieu of the required survey data because the alternative data was reliable. Opp.18. And it was reasonable for HHS to "align 340B hospitals' payment rates with their acquisition costs," Opp.14, because Congress had authorized HHS to base rates on costs—never mind that the statute authorizes cost-based rates *only* if HHS conducts the required cost surveys, and otherwise requires that rates be based on price. Thus, the government says, what HHS did was appropriate "in the circumstances presented," Opp.17, a phrase the government repeats like a mantra as

though "circumstances" could justify disregard of a statutory command. See Opp.14-24.

Whatever vitality *Chevron* retains, it cannot justify this result. In defending the court of appeals' decision, the government does not undertake the rigorous analysis that this Court requires to justify the conclusion that Congress has delegated lawmaking authority to an agency. See *Kisor* v. *Wilkie*, 139 S. Ct. 2400, 2415 (2019) (Deference is warranted "only when th[e] legal toolkit is empty and the interpretive question still has no single right answer."). Instead, like the court of appeals, the government seizes on the supposedly ambiguous scope of Subclause (II)'s authority to "adjust" *price-based* rates to leapfrog over the limits Congress imposed on HHS's authority to set *cost-based* rates—effectively rewriting the statute and freeing HHS to use whatever procedure it wants for cost-based rates merely by describing its action as an "adjustment" of a price-based rate. See *Util. Air Regulatory Grp.* v. *EPA*, 573 U.S. 302, 325 (2014) (an "agency has no power to 'tailor' legislation to bureaucratic policy goals by rewriting unambiguous statutory terms.").

This Court's review is urgently needed. As is typical, the recent change of Administration will produce agency actions that seek to redirect federal policy. Some will doubtless rest on creative reinterpretations of agency authority. *Chevron* will be invoked to defend those actions when they are challenged. Many of those challenges will arise in the D.C. Circuit, and the majority opinion in this case reflects the views of distinguished members of that Court. A denial of certiorari will be interpreted as a green light for agencies to stretch the limits of their authority through creative exploitation of even the most ancillary statutory ambiguities, and for reviewing courts to subject those

agency actions to minimal scrutiny. It is therefore imperative that this Court grant review to clarify what is expected when courts review agency action.

The real-world consequences of the decision below are as important as its jurisprudential consequences. If the court of appeals' decision remains undisturbed, Section 340B Hospitals will continue to lose about $1.6 billion *annually*, damaging their ability to serve the vulnerable communities that depend on them. A great deal is therefore at stake.

In view of the jurisprudential *and* practical importance of the question presented, review by this Court is manifestly appropriate.

ARGUMENT

A. The Medicare Act Does Not Preclude this Court's Review.

In an effort to muddy the waters, the government raises a threshold non-reviewability argument. Opp.14-17. The D.C. Circuit rejected that meritless argument and it poses no obstacle to this Court's consideration of the question presented in the petition.

1. In light of the "'strong presumption' favoring judicial review of administrative action," the government "bears a 'heavy burden'" to "show that Congress 'prohibit[ed] all judicial review' of the agency's compliance with a legislative mandate." *Mach Mining, LLC* v. *EEOC*, 575 U.S. 480, 486 (2015) (citations omitted). See also *Guerrero-Lasprilla* v. *Barr*, 140 S. Ct. 1062, 1069 (2020).

2. The government cannot meet that burden. It points to provisions precluding judicial review of certain actions taken under paragraphs (2) and (9) of 42 U.S.C. 1395*l*(t). See 42 U.S.C. 1395*l*(t)(12)(A), (C). But the "adjustment" authority that HHS invoked here is

located in a different provision—paragraph (14). As a textual matter, therefore, the bar on judicial review does not apply.

The government nonetheless insists that "adjustments" made under paragraph (14) are actually made under paragraph (9). Opp.16. As the court of appeals concluded, however, "paragraph (14) provides its own authorization for HHS to adjust" rates; that separate authority is in no way tied to or dependent on paragraph (9). Pet.App.14a. Nor is the government correct that HHS invoked paragraph (9) to justify the rate cuts at issue. Opp.16. The rule's preamble stated that it would "describe [that] and various other statutory authorities in the relevant sections," but the section imposing the rate cut on 340B Hospitals relied exclusively on paragraph (14); it did not mention paragraph (9). Pet.App.14a-15a (citations omitted).

3. If the government's non-reviewability argument were correct, HHS could flout the procedures Congress required in paragraph (14) for setting cost-based rates—and impose billions of dollars of increased expenses on Section 340B hospitals—with impunity. The government should have to do more than point to non-reviewability provisions applicable to *other* sections of the law to block judicial scrutiny of its disregard of a statutory command. See *Mach Mining*, 575 U.S. at 489 (explaining that the Court "has so long applied a strong presumption favoring judicial review" because "legal lapses and violations occur, and especially so when they have no consequence").[1]

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[1] If the Court remains concerned about the non-reviewability provision, the proper course is to hold for *American Hospital Association* v. *Becerra*, No. 20-1113. If the petitioners there prevail, the non-reviewability provision here would not only collapse with the

B. The Court Should Grant Certiorari to Enforce Critical Limits on *Chevron* Deference.

The tenor of the government's response on the merits leaves little doubt that the decision of the court of appeals cannot be defended as the best reading of the text of 42 U.S.C. 1395*l*(t)(14)(A)(iii) *or* as an appropriate exercise of *Chevron* deference. To the contrary, the lengths to which the government must go to justify the court of appeals' *Chevron* analysis reinforces the need for this Court's review.

1. *Chevron* applies only where a statute is "genuinely ambiguous." *Kisor* v. *Wilkie*, 139 S. Ct. 2400, 2414 (2019) (discussing analogous analysis for *Auer* deference). There is no genuine ambiguity here. HHS must set reimbursement rates based on price under Subclause (II) of 42 U.S.C. 1395*l*(t)(14)(A)(iii) unless it complies with the detailed cost-survey requirements of Subclause (I). The modest authority Congress gave the agency to "adjust[]" Subclause (II) price-based rates "as necessary for purposes of this Paragraph" cannot be stretched to justify HHS's decision to reduce the price-based rates to a level that, in HHS's judgment, approximates what a cost-based rate would be under Subclause (I). That is not an adjustment of a Subclause (II) rate. It is an effort to write Subclause (I) out of the statute. And it cannot be justified as "necessary for purposes of this Paragraph" because Subclause (I)'s cost survey requirement by definition reflects Congress' judgment about how the purposes of the Paragraph should be accomplished. This is, in short, as clear an example as this Court will ever see

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merits—it would strengthen petitioners' merits argument by removing any justification for *Chevron* deference.

of an agency misusing a "vague," "ancillary provision[]" to "alter the fundamental details of a regulatory scheme," *Whitman* v. *American Trucking Ass'ns*, 531 U.S. 457, 468 (2001). And it invites further abuse because "adjustment" provisions similar to the one at issue here appear throughout the U.S. Code. See Pet.27.

2. The government's principal defense of the court of appeals' decision focuses not on HHS's interpretation of the statutory text, but on the supposed reasonableness of HHS's policy choice. The government repeatedly invokes the appeals court's observation that, although HHS did not use the data source Congress required, HHS nevertheless "relied on data of undisputed reliability." E.g., Opp.18 (quoting Pet.App.28a). The relevant question, however, is whether the statute authorizes HHS to set cost-based rates using alternative data, not whether the rates HHS ultimately sets are reasonable. Because the answer to that question is no, the government's argument boils down to a plea that HHS should be given leeway to treat the cost-survey requirement of Subclause (I) as optional and be judged solely on the reasonableness of its ultimate decision.

The government resists that characterization, protesting that Congress would not want HHS to pay Section 340B Hospitals "at rates that far exceed their costs." Opp.22. But that assertion lacks any foundation in the statutory text, which expresses no preference for cost-based rates. If anything, Subclause (I)'s cost survey requirement makes it *harder* for HHS to set cost-based rates than price-based rates. The government likewise fails to account for the fact that in every year prior to 2018, HHS determined that the statutory purposes would be best advanced by reimbursing Section 340B hospitals at rates based on the

price rather than cost. See also Pet.7, 32 (discussing enactment history of the 340B Program).

Even if the government's view of congressional intent were correct, reversing HHS's misuse of *Chevron* would not bind HHS to use price-based rates in perpetuity. It would merely require HHS to set cost-based rates using the data source that Congress specified. And there is every reason to think that Congress cared about that requirement—because without the "hospital-specific cost data" that Congress required, "billion-dollar decisions differentiating among particular hospital groups could rest on significantly less exact information" than would be appropriate. Pet.App.37a.

It is also necessary to point out that the government's claim that the HHS relied on "reliable" and "conservative" data, Opp.21, is misleading. Precisely because HHS did not conduct the survey that Congress required, petitioners cannot assess the propriety of the rates HHS selected. Had HHS conducted that survey before setting these rates, it would have received public comments on the survey's design and results. With respect to 340B Hospitals, the survey could have revealed important information, such as evidence that certain drug manufacturers are withholding discounts[2]—which could have justified higher reimbursement rates.

3. Though the government does not offer a text-based defense of its own interpretation, it does offer one text-based criticism of petitioners' interpretation. Specifically, the government contends that petitioners' interpretation renders superfluous HHS's Subclause

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[2] See, *e.g.*, Letter from AHA et al. to Hon. Xavier Becerra, Sec'y of HHS (Apr. 20, 2021), *available at* https://www.aha.org/lettercomment/2021-04-20-letter-sec-becerra-urging-him-stop-six-drug-companies-are-denying-340b.

(II) "adjustment" authority. Opp.20-21. According to the government, because petitioners' reading would limit Subclause (II) to adjustments for overhead costs, while another provision of the statute already gives HHS that authority.

That argument is misconceived. To the extent HHS's "adjustment" authority is limited to overhead costs (as HHS itself had long thought, see Pet.App.37a), no superfluity results. The overhead-specific provision to which the government points—42 U.S.C. 1395*l*(t)(14)(E)—authorizes adjustments for overhead "with reference to a one-time, 2005 MedPAC report." Pet.App.36a. The Subclause (II) "adjustment" authority is not limited in that manner, and is thus not duplicative. And even if there were some overlap, the Subclause (II) "adjustment" authority would most naturally be read as a cross-reference to HHS's overhead-adjustment authority—not a superfluous provision.

Most fundamentally, there is no equivalence between a "little overlap" in the "complex statutory scheme" governing Medicare, Pet.App.37a (citation omitted), and the gutted statute that would be left in the wake of HHS's interpretation—an interpretation that would render meaningless "nearly a full column in the U.S. Code" providing specifications for congressionally specified surveys. Pet.App.39a. Still worse, it would transform the statutory scheme by making cost surveys purely optional. That goes far beyond a superfluity problem; HHS's interpretation "completely nullifies textually applicable provisions meant to limit its discretion." *Whitman*, 531 U.S. at 485. Superfluity is one thing, administrative aggrandizement quite another.

4. At bottom, the government's view of how little is required to trigger *Chevron* deference (which the court of appeals majority evidently shares) is perhaps the

most compelling reason for this Court to grant certiorari.

a. According to the government, a reviewing court need not undertake a searching analysis to determine the best meaning of a statute before deciding that it is genuinely ambiguous and therefore delegates lawmaking authority to an agency. It is enough, the government contends, for a court to identify any "reasonable construction" of the text that supports the agency's approach. Opp.22-23. That contention is remarkable, especially in light of this Court's recent decisions stressing that *Chevron* deference applies—if at all—"only when th[e] legal toolkit is empty and the interpretive question still has no single right answer." *Kisor*, 139 S. Ct. at 2415; see also *Epic Systems Corp.* v. *Lewis*, 138 S. Ct. 1612, 1630 (2018); *SAS Inst., Inc.* v. *Iancu*, 138 S. Ct. 1348, 1358 (2018). No wonder so many lower courts have been "rushing to find statutes ambiguous, rather than performing a full interpretive analysis." *Arangure* v. *Whitaker*, 911 F.3d 333, 336 (6th Cir. 2018) (Thapar, J.). That is precisely what the government urges.

b. In a similar vein, the government is quick to dismiss longstanding limitations on *Chevron* deference imposed by this Court. Contrary to the government's argument, the decision below conflicts directly with this Court's decision in *MCI Telecommunications Corp.* v. *American Telephone & Telegraph Co.*, 512 U.S. 218 (1994). The word "adjust" in Subclause (II) is naturally understood to confer only the authority to make modest changes, Pet.25-26, just as the word "modify" in the statute at issue in *MCI* carried a "connotation of increment or limitation." 512 U.S. at 225. The government nonetheless contends that the Subclause (II) adjustment authority can be used to make

major changes in the statutory scheme because Congress authorized adjustments "necessary for purposes" of the statute. Opp.24. But that is plainly wrong. By definition an "adjustment" is an incremental change. Pet.25-26. Just as in *MCI*, therefore, the agency cannot invoke that authority to displace Congress's express decisions about how the core elements of a regulatory program will operate.

In sum, the decision of the court of appeals validates the worst excesses of *Chevron* deference, and invites federal agencies to engage in creative reimagining of their statutory mandates. If left undisturbed, the decision will have outsized influence on judicial review of agency action in the D.C. Circuit and in other courts. See page 1 *supra*. Review by this Court is therefore necessary to ensure that courts discharge their responsibilities under the Administrative Procedure Act with appropriate independence.

C. The Question Presented Is Critically Important to Safety-Net Providers, Underserved Communities, and the Proper Administration of the Medicare Program.

This case presents an issue of exceptional practical as well as jurisprudential importance. HHS took billions of dollars from Section 340B hospitals and reallocated that revenue to other Medicare providers. If the D.C. Circuit's affirmance of that order stands, HHS will be free to ignore the statutory requirements for setting cost-based rates when the agency makes similar multi-billion dollar decisions in the future. The government does not deny that the HHS decision under review had, and will continue to have, enormous practical consequences. To the contrary, the im-

portance of HHS's policy change is the principal justification the government has advanced for allowing HHS to skirt the statute's requirements for setting cost-based rates.

1. The decision of the court of appeals has redefined the scope of HHS's authority to allocate tens of billions of dollars annually in prescription-drug spending. See Pet.28. This case alone concerns a transfer of about $1.6 billion *annually* away from financially vulnerable 340B Hospitals. That massive revenue transfer is devastating to 340B Hospitals, which depend on above-cost Medicare reimbursements to maintain fiscal stability and serve the low-income communities that depend on them. Pet.30-32.

2. The government does not dispute that. Instead, it invites "petitioners [to] raise their policy concerns" in future rulemakings. Opp.25. But there is no reason to think that HHS is contemplating a change in direction. This case will therefore determine whether HHS can continue to transfer billions of dollars each year away from 340B Hospitals, and whether HHS can make other cost-based cuts in the future without abiding by the rate-setting procedures that Congress mandated.

3. Ignoring these prospective consequences, the government argues that this Court's review would be pointless because petitioners cannot obtain retroactive relief for past reimbursement years. Opp.27. That is incorrect. The district court did not *deny* reimbursement; it remanded to HHS to devise an appropriate remedy. See Pet.App.101a-112a. If HHS fails to do so, further litigation will likely follow. For now, what is critical is that HHS is not considering remedies because it "prevailed on appeal to the D.C. Circuit." 85 Fed. Reg. 85,866, 86,050 (Dec. 29, 2020); see Pet.29-30.

This Court's reversal would thus restart the remedial process.

But if retroactive relief is unavailable, that only heightens the need for this Court's intervention. Every passing year would inflict billions of dollars of additional revenue cuts on Section 340B Hospitals without any avenue for recoupment. HHS's willingness to inflict those harms in cavalier disregard of the procedures Congress has prescribed for making such decisions should not be countenanced.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

DONALD B. VERRILLI, JR.
Counsel of Record
MUNGER, TOLLES & OLSON LLP
601 Massachusetts Ave. NW
Suite 500E
Washington, DC 20001
(202) 220-1100
Donald.Verrilli@mto.com

Counsel for Petitioners

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