No. _____

IN THE

Supreme Court of the United States

AMERICAN HOSPITAL ASSOCIATION, et al.,

Petitioners,

v.

NORRIS COCHRAN, in his official capacity as the Acting 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

PETITION FOR A WRIT OF CERTIORARI

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QUESTION 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 adequate "hospital acquisition cost survey data," it 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 adequate "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" the statute. 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II).

The question presented is whether *Chevron* deference permits HHS to set reimbursement rates based on acquisition cost and vary such rates by hospital group if it has not collected adequate 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 Norris Cochran, in his official capacity as Acting 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.

RULE 29.6 DISCLOSURE STATEMENT

Petitioners the American Hospital Association, the Association of American Medical Colleges, and America's Essential Hospitals are not-for-profit associations. Petitioners Northern Light Health, Henry Ford Health System, and Fletcher Hospital, Inc., d/b/a AdventHealth Hendersonville (a member of AdventHealth) are not-for-profit health care systems. There is no parent or publicly held company owning 10% of their stock.

RELATED PROCEEDINGS

The proceedings directly related to this case are:

- *American Hospital Association, et al.* v. *Azar, et al.*, Nos. 19-5048 & 19-5198, U.S. Court of Appeals for the D.C. Circuit. Judgment entered July 31, 2020. Rehearing denied October 16, 2020.
- *American Hospital Association, et al.* v. *Azar, et al.*, No. 1:18-cv-02084. U.S. District Court for the District of Columbia. Judgment entered July 10, 2019.

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Petitioners 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 respectfully petition for a writ of certiorari to review the judgment of the U.S. Court of Appeals for the D.C. Circuit.

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a) is published at 967 F.3d 818. The order denying rehearing en banc (Pet. App. 118a) is unpublished. The district court's memorandum opinion granting Petitioners' motion for a permanent injunction (Pet. App. 44a) is published at 348 F. Supp. 3d 62. The district court's memorandum opinion granting in part Petitioners' motion for a permanent injunction and remanding the rules at issue to the Department of Health and Human Services (Pet. App. 87a) is published at 385 F. Supp. 3d 1. The district court's memorandum opinion granting Respondents' motion for entry of final judgment (Pet. App. 113a) is available at 2019 WL 3037306.

JURISDICTION

The judgment of the court of appeals was entered on July 31, 2020. Pet. App. 1a. A timely petition for rehearing was denied on October 16, 2020. Pet. App. 118a. By order dated March 19, 2020, this Court extended the deadline to file any petition for a writ of certiorari to 150 days from (as relevant here) an order denying a timely rehearing petition. This Court's jurisdiction is invoked under 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

The relevant statutory provisions are reproduced in the appendix to the petition. Pet. App. 119a.

STATEMENT OF THE CASE

1. Medicare is a federally administered health insurance program for people age 65 or older, people with certain disabilities, and people with End-Stage Renal Disease. About 60 million Americans are enrolled in Medicare,[1] which spends about $800 billion per year.[2] For those who enroll in Medicare's fee-for-service coverage option, the program pays for a wide range of care. Part A of the program primarily covers inpatient hospital services, hospice care, nursing facility care, and home health care, while Part B primarily covers outpatient hospital care and doctors' services. Critical to the Medicare program, and a rapidly growing source of its spending,[3] is Medicare Part B's coverage of separately payable prescription drugs.[4] The payment rules for such drugs are at issue here.

Medicare Part B pays hospitals for covered outpatient services through the Outpatient Prospective Payment System (OPPS). Most care is reimbursed according to a formula that takes into account regional cost

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[1] See *Medicare Beneficiaries at a Glance*, Centers for Medicare & Medicaid Services, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Beneficiary-Snapshot/Bene_Snapshot.

[2] See *NHE Fact Sheet*, Centers for Medicare & Medicaid Services, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet.

[3] See *Medicare Part B Drugs: Trends in Spending and Utilization, 2006-2017*, HHS Asst. Sec. for Planning and Evaluation 13 (Nov. 20, 2020), https://aspe.hhs.gov/system/files/pdf/264416/Part-B-Drugs-Trends-Issue-Brief.pdf (ASPE Brief).

[4] Separately payable prescription drugs are drugs that are reimbursed on a drug-by-drug basis, rather than packaged with other services and reimbursed as part of a bundled payment.

variation, changes in medical practice, changes in technology, and other relevant information. See 42 U.S.C. 1395*l*(t). In the years following the establishment of the OPPS, "concerns were expressed about the adequacy of payments for innovative pharmaceutical products."[5] In response, Congress set forth a separate payment methodology for such products in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). See Pub. L. No. 108-173, 117 Stat. 2066, 2307-08. Today, the MMA's payment methodology determines how much Medicare will pay hospitals for all separately payable prescription drugs.[6]

The payment methodology set forth in the MMA specifies a reimbursement rate equal—

> (I) to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered [outpatient department] services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D); or

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[5] U.S. Gov't Accountability Off., *GAO-06-372, Medicare Hospital Pharmaceuticals: Survey Shows Price Variation and Highlights Data Collection Lessons and Outpatient Rate-Setting Challenges for CMS* 6 (Apr. 2006), https://www.gao.gov/assets/250/249967.pdf.

[6] The methodology set forth in the MMA applies to "specified covered outpatient drugs," a subset of separately payable drugs generally consisting of newly introduced drugs, biologicals, and radiopharmaceuticals used to treat serious conditions, such as cancer. GAO, note 5, *supra*, at 2. But it is HHS's "longstanding policy" to use the MMA's payment methodology for all separately payable drugs. 77 Fed. Reg. 68,210, 68,383 (Nov. 15, 2012).

> (II) if hospital acquisition cost data are not available, the average price for the drug in the year established under section 1395u(o) of this title, section 1395w-3a of this title, or section 1395w-3b of this title, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of this paragraph.

42 U.S.C. 1395*l*(t)(14)(A)(iii).[7]

The MMA thus provides alternative reimbursement rates for covered prescription drugs—Subclause (I) and Subclause (II). Under Subclause (I), reimbursement rates are determined based on each drug's "average acquisition cost" and "may vary by hospital group." 42 U.S.C. 1395*l*(t)(14)(A)(iii)(I). Under Subclause (II), reimbursement rates are determined according to a statutorily defined default rate 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. That rate is "calculated" and may be "adjusted" by HHS. 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II).

The statute further specifies which of the alternative reimbursement rates HHS must apply. The determinative factor is whether HHS has collected sufficient "hospital acquisition cost survey data." 42 U.S.C. 1395*l*(t)(14)(A)(iii)(I). If it has, HHS must proceed under Subclause (I), which directs HHS to take account of that data in determining each drug's average acquisition cost and any variances by hospital group. *Ibid.* If it has not, HHS must proceed under Subclause (II), which (in the absence of sufficient acquisition cost

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[7] Those provisions are "subject to subparagraph (E)," 42 U.S.C. 1395*l*(t)(14)(A)(iii), which authorizes HHS to make "[a]djustment[s] in payment rates for overhead costs" based on a 2005 report issued by the Medicare Payment Advisory Commission. 42 U.S.C. 1395*l*(t)(14)(E).

data) directs HHS to base its reimbursement rates on sales price rather than acquisition cost. 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II).

Congress likewise prescribed strict, detailed requirements governing the collection of hospital acquisition cost data. The statute initially 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). It directed the Comptroller General to furnish its data to HHS for use in setting payment rates in 2006, and to "determine and report to Congress if there is (and the extent of any) variation in hospital acquisition costs for drugs among hospitals." 42 U.S.C. 1395*l*(t)(14)(D)(i)(I), (iv). For the ensuing years, Congress shifted the responsibility to HHS, which must "conduct periodic subsequent surveys," taking into account recommendations from the Comptroller General as to their "frequency and methodology." 42 U.S.C. 1395*l*(t)(14)(D)(i), (ii). Critically, a survey 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). HHS may proceed under Subclause (I) only if it conducts such a statistically significant survey.

2. HHS has never collected hospital acquisition cost survey data that meets Congress's criteria. Pet. App. 3a.[8] Accordingly, for the first twelve years following

[8] In HHS's OPPS rule 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's survey plainly failed to satisfy the standards set forth in the statute, and the agency did not set rates under Subclause (I) based on that data. See pp. 29-30, *infra*.

the effective date of the MMA's new payment methodology, HHS did not set reimbursement rates based on average acquisition cost, nor did it vary reimbursement rates by hospital group. Instead, HHS set reimbursement rates for separately payable drugs based on the average sales price of each drug, and it applied those rates uniformly across all hospital groups. See 82 Fed. Reg. 52,362, 52,490 (Nov. 13, 2017); 80 Fed. Reg. 70,298, 70,439 (Nov. 13, 2015); 77 Fed. Reg. 68,210, 68,383-68,386 (Nov. 15, 2012).[9]

HHS broke from that practice in its OPPS rule for 2018. In that rule, HHS for the first time set a prescription-drug reimbursement rate for one hospital group different from the rate it set for all others. Specifically, HHS singled out participants in the 340B Program.

The 340B Program serves as a lifeline to hospitals that care for low-income, underserved communities. Established by Congress in 1992, the 340B 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 prescription drugs. See Pub. L. No. 102-585, 106 Stat. 4943, 4967-4971; 42 U.S.C. 256b(a). That discount is essential to 340B Hospitals, which are public and private

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[9] From 2006 to 2012, HHS purported to rely on Subclause (I) in setting reimbursement rates for separately payable drugs, even without relying on adequate hospital acquisition cost survey data. See 77 Fed. Reg. at 68,383-68,386. But HHS still applied a uniform reimbursement rate based on average sales price in those years. See *id.* at 68,386 (explaining that reimbursement rates from 2006 to 2012 varied from ASP+4% to ASP+6%). From 2013 to 2017, HHS expressly relied on Subclause (II), setting a uniform reimbursement rate of ASP+6%. See 82 Fed. Reg. at 52,490.

nonprofit entities that serve underinsured populations. By pushing drug costs for these 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). Put another way, Congress designed the 340B Program so that insurers like Medicare would subsidize critical services offered by safety-net hospitals. See HHS Off. of Inspector Gen., *Part B Payments for 340B-Purchased Drugs* i (Nov. 2015) (OIG Report).[10]

In its 2018 OPPS rule, HHS adopted a different policy view. As HHS saw it, "it is inappropriate for Medicare to subsidize" 340B Hospitals "through Medicare payments for separately payable drugs." 82 Fed. Reg. at 52,495. Instead, HHS asserted, Medicare payments should be "more aligned with the resources expended by hospitals to acquire" covered prescription drugs. *Ibid.* To be sure, 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." *Ibid.* But HHS nonetheless chose to eliminate the gap between Medicare reimbursement rates and 340B Hospitals' drug costs, thereby prioritizing this objective over the congressional judgment reflected in

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[10] https://oig.hhs.gov/oei/reports/oei-12-14-00030.pdf; see also HHS Health Resources & Services Administration, *Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Service Act* 14 (July 2005), https://www.hrsa.gov/sites/default/files/opa/programrequirements/forms/hemophiliatreatmentcenter340bmanual.pdf.

the 340B Program. See *id.* at 52,493-52,510. Accordingly, while all other hospital groups retained a reimbursement rate of ASP+6% for their separately payable drugs, HHS slashed rates to 340B Hospitals by nearly 30%—to ASP *minus* 22.5%. See *id.* at 52,496.[11] The result was a $1.6 billion cut in annual funding to 340B Hospitals. See *id.* at 52,623.

In its final rule, HHS addressed its purported statutory authority to enact this novel, non-uniform rate cut. HHS acknowledged that it still does "not have hospital acquisition cost data" meeting Congress's requirements, and therefore could not proceed under Subclause (I) of the MMA—the payment methodology that bases reimbursement rates on average acquisition cost and permits HHS to vary rates by hospital group. See *id.* at 52,496; p. 4, *supra.* HHS was instead required to proceed under Subclause (II)—the payment methodology that bases rates on average sales price and provides no authority to vary rates by hospital group. See p. 4, *supra*.

But in HHS's view, its statutory obligation to follow the rate-setting methodology in Subclause (II) did not preclude the agency from varying reimbursement rates by hospital group, nor did it preclude basing reimbursement rates on average acquisition cost. 82 Fed. Reg. at 52,499-52,500. HHS believed it could take those steps under Subclause (II) because that provision grants HHS the authority to "adjust[]" the reimbursement rates set under it. 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II). According to HHS, that "adjustment" authority gives the agency "broad discretion to adjust payments for drugs" as it sees fit—discretion that is not "limited to what some might consider minor

[11] HHS exempted a small number of 340B Hospitals from the rate cut. See 82 Fed. Reg. at 52,493-52,511.

changes." 82 Fed. Reg. at 52,500. That discretion is so broad, HHS asserted, that it permits the agency to set reimbursement rates based on average acquisition cost, and to vary such rates by hospital group, *without* using the statistically sound acquisition cost survey data that Congress required as a predicate for using those criteria to set rates. See *id.* at 52,501.

And that is precisely what HHS did in cutting reimbursement rates to 340B Hospitals. HHS acknowledged that it enacted its rate cut not in an effort to approximate average sales price, but instead to "better represent[] the *acquisition cost* for drugs and biologicals that have been acquired with a 340B discount." 82 Fed. Reg. at 52,505 (emphasis added). It likewise made clear that 340B Hospitals alone would receive disfavored treatment, while all other hospital groups would continue to receive a reimbursement rate of ASP+6%. See *id.* at 52,501. And HHS explicitly relied not on the robust set of acquisition cost survey data that Congress specified in Subclause (I), but on a substitute data source that HHS found sufficient—a report of the Medicare Payment Advisory Commission estimating the average minimum discount received by 340B Hospitals. See *id.* at 52,496.

3. Petitioners filed suit in the U.S. District Court for the District of Columbia challenging HHS's authority to cut reimbursement rates for 340B Hospitals.[12]

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[12] Petitioners initially filed suit in November 2017, but that suit was dismissed because HHS had not yet denied a specific claim for reimbursement under its new rule. See *Am. Hosp. Ass'n* v. *Azar*, 895 F.3d 822 (D.C. Cir. 2018). Petitioners thereafter submitted claims for reimbursement under the new rule. HHS reimbursed those claims at ASP-22.5%, rather than ASP+6%. Pet. App. 54a. Petitioners then filed suit again, seeking full reimbursements of their claims along with an injunction against the 2018 OPPS rule. See *ibid.* Moreover, once the 2019 OPPS rule

They argued that HHS had violated a clear statutory directive when it set rates based on average acquisition cost, and did so for one hospital group but not others, without collecting and considering the acquisition cost survey data that Congress required in Subclause (I) of the MMA as a prerequisite to taking such actions. The modest "adjustment" authority in Subclause (II), Petitioners contended, does not permit such an end-run around the unambiguous requirements Congress set forth in Subclause (I).

The district court agreed. In its view, "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). Pet. App. 76a. Although that provision authorizes HHS to make "adjustments" to those rates, "adjustments are all [it] can make." *Ibid.* HHS "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." *Ibid.* Yet here, the court explained, HHS "sought to mimic the result of [Subclause] (I)—by setting rates designed to approximate *acquisition costs*—under the authority of [Subclause] (II)." Pet. App. 77a. That effort was, according to the district court, a "patent violation of agency authority." Pet. App. 70a.

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became effective—and continued the same policy as the year prior, see 83 Fed. Reg. 58,818, 58,979 (Nov. 21, 2018)—Petitioners presented additional claims for reimbursement and supplemented their complaint to include the 2019 OPPS rule. See Pet. App. 93a-94a.

4. a. A divided panel of the D.C. Circuit reversed. The panel majority did not conclude that HHS's interpretation was the best reading of the statute. In fact, the majority acknowledged the "force" of Petitioners' argument that if HHS could set reimbursement rates based on average acquisition cost and vary rates by hospital group *without* the "robust study data" that Congress required, then "[S]ubclause (I)'s requirement to take into account th[at] data * * * would be meaningless." Pet. App. 23a-24a. The majority nevertheless upheld HHS's rate cut under *Chevron U.S.A., Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842 (1984).

As the majority saw it, "under *Chevron*, we would need to conclude that Congress unambiguously barred HHS from seeking to align reimbursements with acquisition costs under [S]ubclause (II), or that HHS's belief that it could do [so] was unreasonable." Pet. App. 24a. The majority did not find those criteria met here. It believed HHS had adopted a permissible interpretation of the statute because Subclause (II) authorizes the agency to "adjust[]" reimbursement rates "as necessary for purposes of [the] paragraph," 42 U.S.C. 1395*l*(t)(14)(A)(iii), and (according to the majority) the "primary goal" of the paragraph is to "reimburse providers for their acquisition costs," Pet. App. 21a. The majority likewise saw no clear statutory prohibition on HHS's use of data sources that failed to meet congressional specifications. See Pet. App. 24a. And the majority concluded that HHS acted reasonably because the data source it relied on was, in the majority's view, a "reliable cost measure[]." *Ibid.*

The majority also found no conflict between its decision and this Court's decision in *MCI Telecommunications Corp.* v. *American Telephone & Telegraph Co.*, 512 U.S. 218 (1994). In *MCI*, this Court rejected the

FCC's attempt to read the word "modify" as an authorization to make "basic and fundamental changes in the scheme" Congress created. See *id.* at 225. This Court held instead that a "modification" must be limited to "moderate[]" or "minor" changes. *Ibid.* The majority below, by contrast, did not read the word "adjust" to refer "only to minor changes," reasoning (based on purported variations in dictionary definitions) that the term is "ambiguous as to size." Pet. App. 29a. The majority thus suggested, in light of *Chevron*, that there may be *no* "limits to what HHS could permissibly consider an 'adjustment.'" *Ibid.*

b. Judge Pillard dissented. In her view, the statutory scheme is unambiguous: "Only [S]ubclause (I), not [S]ubclause (II), authorizes HHS to set different reimbursement rates for distinct hospital groups" based on acquisition cost, and it 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. HHS's contrary interpretation "essentially reads [S]ubclause (I) out of the statute by permitting the agency to do under [S]ubclause (II) without the requisite data what [S]ubclause (I) authorizes only with that data." Pet. App. 39a. Such an interpretation could not be upheld, whether under *Chevron* or otherwise.

Judge Pillard took direct issue with the majority's reasoning. While the majority had 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. That is especially so here, where the statutory language shows that Congress did not want HHS "just to do its best to approximate [average acquisition]

costs and then vary them by hospital groups according to its unchecked policy judgment." Pet. App. 35a. Judge Pillard also disagreed with the majority's assertion that her interpretation of the statute would render HHS's Subclause (II) "adjustment" authority superfluous, noting that her interpretation would continue to permit "adjustments" for overhead costs. See Pet. App. 36a-37a. It also ignored the far greater superfluity problem with the majority's interpretation, which would render meaningless "nearly a full column in the U.S. Code" that "specifies in detail" how HHS must conduct acquisition cost surveys. Pet. App. 39a. Judge Pillard also took issue with the majority's effort to distinguish *MCI*. As she saw it, HHS had improperly used its "adjustment" authority to make a basic and fundamental change in the statutory scheme, see Pet. App. 38a; indeed, it had adopted an interpretation 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 also responded to 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 and resulting estimates." Pet. App. 40a. As an initial matter, "concerns about the program's effects, and confidence in the agency's care in using data other than those the statute requires, cannot somehow authorize the agency to do what the statute does not." Pet. App. 41a. Nor would the majority's confidence in the data source HHS used *here* provide any "assurance for its next rulemaking," now that HHS could set rates based on acquisition cost "unmoored from the statute's express data-quality requirements." Pet. App. 42a.

In all events, Judge Pillard found the majority's policy arguments unpersuasive. 340B Hospitals, she explained, "[o]ften operat[e] at substantial losses" and thus "rely on the revenue that Medicare Part B provides in the form of standard drug-reimbursement payments that exceed those hospitals' acquisition costs." Pet. App. 42a-43a. They use these "additional resources to provide critical healthcare services to communities with underserved populations that could not otherwise afford these services." Pet. App. 43a (citation omitted). HHS's rate cut, however, "redistribute[s] funds" from these "financially strapped, public and nonprofit safety-net hospitals serving vulnerable populations—including patients without any insurance at all—to facilities and individuals who are relatively better off." *Ibid.*[13] As Judge Pillard saw it, "[i]f that is a result that Congress intended to authorize, it remains free to say so," but "the statute as it is written" does not. *Ibid.*

5. Petitioners filed a timely petition for rehearing en banc, which was denied. See Pet. App. 118a. This petition follows.

REASONS FOR GRANTING THE PETITION

The decision of the court of appeals in this case raises an issue of exceptional importance that manifestly warrants this Court's review. The court grievously erred in affirming HHS's misuse of its modest "adjustment" authority under Subclause (II) of the MMA to make wholesale changes in the method for calculating reimbursement rates for 340B Hospitals—changes that flout the requirements Congress prescribed for setting such rates. And the policy the court

[13] The funds are redistributed, rather than returned to the taxpayers, because all payment changes must be budget neutral. See 42 U.S.C. 1395*l*(t)(14)(H).

upheld on the basis of this legal error affects billions of dollars in federal prescription-drug spending, and resulted in a $1.6 billion annual hit to 340B Hospitals that depend on full Medicare reimbursements to subsidize essential healthcare services they provide to low-income communities. A legal error this serious upholding a federal agency action with consequences this grave is by itself a sufficient reason to grant review.

More fundamentally, the decision below vividly confirms the continuing need for this Court to enforce limits on *Chevron* deference, particularly as it is applied in the D.C. Circuit, to ensure that it does not give cover to federal agencies when they supplant Congress's policy judgments with their own. "Courts defer to an agency's interpretation of law when and because Congress has conferred on the agency interpretive authority over the question at issue." *City of Arlington* v. *FCC*, 569 U.S. 290, 312 (2013) (Roberts, C.J., dissenting). The MMA cannot fairly be read to confer the sweeping interpretive authority sanctioned by the court of appeals. Indeed, Congress could hardly have been clearer that HHS must set rates based on price, and not on cost, unless it can meet the stringent requirements of Subclause (I) for cost-based rates. But the court of appeals nevertheless relied on *Chevron* to conclude that HHS could decide for itself whether to adhere to those statutory requirements or instead to set cost-based rates in a different way. And it did so not based on any discretion-conferring ambiguity in Subclause (I) itself, but by seizing on the supposed ambiguity of the modest authority Congress gave the agency to "adjust" the rates it sets based on drug *prices* under Subclause (II) of the provision—the provision that applies when HHS *cannot meet* the requirements of Subclause (I) for cost-based rates.

That extreme application of *Chevron* conflicts directly with a critical limit on such deference established by this Court's decisions in *MCI Telecommunications Corp.* v. *American Telephone & Telegraph Co.*, 512 U.S. 218 (1994), and its progeny. As in that case, the agency here misused its delegated authority to make modest adjustments to statutory requirements to justify a wholesale change to the regulatory scheme Congress enacted. If left undisturbed, the decision will inevitably exert a strong and unwarranted gravitational pull in the direction of deference to agency interpretations of law in the D.C. Circuit and beyond—exacerbating separation-of-powers concerns.

Finally, there is no reason to defer review. This Court regularly grants certiorari even absent a circuit conflict when—as here—the case raises questions of fundamental importance regarding the limits of federal agency interpretive authority on matters of enormous economic and regulatory consequence. *E.g.*, *FERC* v. *Electric Power Supply Ass'n*, 136 S. Ct. 760 (2016); *Michigan* v. *EPA*, 576 U.S. 743 (2015); *Utility Air Regulatory Grp.* v. *EPA*, 573 U.S. 302 (2014); *Whitman* v. *American Trucking Ass'ns*, 531 U.S. 457 (2001); *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000); *MCI*, 512 U.S. 218.

A. The decision of the court of appeals conflicts with the limits on *Chevron* deference that this Court has established.

This Court has repeatedly held that *Chevron* deference is not a license for administrative agencies to invoke vague terms or ancillary provisions to alter the fundamental structure of a regulatory scheme. What HHS did here—relying on its narrow "adjustment" authority to circumvent a clear statutory requirement—is precisely what these precedents preclude an agency

from doing. The willingness of the court of appeals to countenance such a sharp departure from this Court's teachings on an issue of such central importance to the separation of powers is a strong reason to grant review.

1. This Court has long made clear that *Chevron* deference is "not due unless a 'court, employing traditional tools of statutory construction,' is left with an unresolved ambiguity." *Epic Systems Corp.* v. *Lewis*, 138 S. Ct. 1612, 1630 (2018) (quoting *Chevron*, 467 U.S. at 843 n.9); *SAS Inst., Inc.* v. *Iancu*, 138 S. Ct. 1348, 1358 (2018). *Chevron* therefore applies only where a statute is "*genuinely ambiguous*, 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 also *ibid.* ("when we use" the term "genuinely ambiguous," "we mean it").[14] Put another way, deference is appropriate "only when th[e] legal toolkit is empty and the interpretive question still has no single right answer." *Id.* at 2415. A "court cannot wave the ambiguity flag just because it found the [statute] impenetrable on first read." *Ibid.* The Court insists on this analytical rigor for a reason: because a statutory ambiguity is deemed to be a delegation of authority from Congress, it is imperative that a reviewing court have confidence that the authority has in fact been delegated and the agency's action is within the scope of the delegation.

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[14] *Kisor* addressed judicial deference to an agency's interpretation of its own regulation, but its reasoning applies just as strongly in the context at issue here—where an agency seeks deference for its interpretation of its organic statute. See *Kisor*, 139 S. Ct. at 2415 (explaining that the Court has adopted the "same approach" at the first step in the analysis in both contexts).

As a necessary corollary of that principle, this Court has repeatedly held that *Chevron* deference is not available whenever an agency has located a vague statutory term with a plausible definition that fits the agency's policy choice. To the contrary, agencies may not invoke "vague terms or ancillary provisions" to "alter the fundamental details of a regulatory scheme." *Whitman*, 531 U.S. at 468.

The leading case in this regard is *MCI*. That case concerned a statutory requirement that common carriers file tariffs with the FCC setting forth the rates they charge consumers. The same law authorized the FCC to "modify" any requirement of the statute. 512 U.S. at 220 (quoting 47 U.S.C. 203(b)). The FCC invoked that authority to make tariff filing optional for all non-dominant long-distance carriers (effectively, all but AT&T), but this Court struck it down. *Id.* at 225. Relying on the Latin root of the term and an analysis of dictionary definitions, the Court explained that "modify" means "to change moderately or in minor fashion," carrying a "connotation of increment or limitation." *Ibid.* That term thus 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 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 such a subtle device as permission to 'modify' rate-filing requirements." *Id.* at 231. *Chevron* was thus unable to rescue the FCC, as its interpretation had gone "beyond the meaning that the statute can bear." *Id.* at 229.

This Court's decision in *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), is of a piece. That case addressed whether the FDA, after decades of disclaiming any authority to regulate tobacco products, and in the absence of any express statutory language granting FDA such authority, could assert jurisdiction to regulate tobacco consumption. See *id.* at 125. The FDA asserted its jurisdiction by finding that nicotine is a "drug" and cigarettes are "combination products"—both of which are subject to FDA regulation. See *ibid.* Despite strong textual arguments that nicotine met the technical definition of a drug and cigarettes of a combination product, this Court rejected the FDA's claimed authority. Expressly analogizing to *MCI*, the Court explained that "Congress could not have intended to delegate a decision of such economic and political significance to an agency in so cryptic a fashion." *Id.* at 160. *Chevron* was thus again unavailable, no matter how persuasive the FDA's evidence equating nicotine to a drug. See *id.* at 159-161.

A similar analysis guided this Court in *Whitman* v. *American Trucking Ass'ns, Inc.*, 531 U.S. 457 (2001). There, the Court considered whether the EPA has authority to consider costs when setting national ambient air quality standards. The Court held that it does not, rejecting the argument that such authority could be located in EPA's responsibility to allow an "adequate margin" of safety and set standards "requisite" to protect the public health. See *id.* at 464-471 (quoting 42 U.S.C. 7409(b)(1)). Citing *MCI* and *Brown & Williamson*, the Court explained that Congress "does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes." *Id.* at 468. The Court thus found it "implausible that Congress would give to the EPA through * * * modest

words the power to determine whether implementation costs should moderate national air quality standards." *Ibid.* And because the statute was unambiguous, that "end[ed] the matter for * * * the EPA." *Id.* at 471.

The rule is clear: *Chevron* deference is not a license for agencies to "alter the fundamental details of a regulatory scheme" by invoking "vague terms or ancillary provisions." *Id.* at 468.[15] *Chevron* applies, instead, only where a statutory scheme is "genuinely ambiguous, even after a court has resorted to all the standard tools of interpretation," and concludes that Congress has conferred upon the agency interpretive authority over the question at issue. *Kisor*, 139 S. Ct. at 2414.

2. The decision of the court of appeals conflicts directly with this authority. With barely a nod to *MCI* and its progeny, the court of appeals allowed HHS to make fundamental changes to the statutory structure of the Medicare drug-reimbursement scheme solely based on the agency's vague, ancillary authority to "adjust" reimbursement rates. No amount of *Chevron* deference can justify rewriting the statute in this way.

a. Starting, as this Court always does, with the text, the MMA is unambiguous: If HHS has collected "hospital acquisition cost survey data" meeting statutory specifications, then HHS sets prescription-drug reimbursement rates based on "average acquisition cost"

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[15] This Court has often enforced the principle that vague terms or ancillary provisions cannot alter the fundamental details of a regulatory scheme. See *Gonzales* v. *Oregon*, 546 U.S. 243, 267 (2006); *Virginia Uranium, Inc.* v. *Warren*, 139 S. Ct. 1894, 1903 (2019); *Cyan, Inc.* v. *Beaver Cnty. Emps. Ret. Fund*, 138 S. Ct. 1061, 1071-1072 (2018); *Epic Sys. Corp.* v. *Lewis*, 138 S. Ct. 1612, 1626-1627 (2018); *Czyzewski* v. *Jevic Holding Corp.*, 137 S. Ct. 973, 984 (2017).

and may "vary" such rates "by hospital group." 42 U.S.C. 1395*l*(t)(14)(A)(iii)(I) (Subclause (I)). If HHS has not collected the statutorily specified data, then HHS must set prescription-drug reimbursement rates based on "average price," with such rates "calculated and adjusted" by HHS. 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II) (Subclause (II)). The text thus establishes that the collection of sufficient hospital acquisition cost survey data is critical. Only by collecting that robust data set may HHS proceed under Subclause (I)—the provision that authorizes the agency to set reimbursement rates based on acquisition cost and exercise the vast power to make "billion-dollar decisions differentiating among particular hospital groups." Pet. App. 37a.

HHS has upended that carefully designed statutory framework. Invoking its authority to "adjust[]" rates under Subclause (II), HHS now asserts that it may (as it concededly did here, see p. 9, *supra*) set reimbursement rates based on acquisition cost and vary such rates by hospital group even if it did *not* collect the hospital acquisition cost survey data required by Subclause (I). On HHS's reading of its "adjustment" authority, the requirement to collect cost survey data before setting cost-based rates has become entirely optional. That interpretation renders meaningless "nearly a full column in the U.S. Code" that "specifies in detail" how HHS must conduct acquisition cost surveys if it wishes to set differential reimbursement rates based on acquisition cost. Pet. App. 39a. Still worse, it "essentially reads [S]ubclause (I) out of the statute by permitting the agency to do under [S]ubclause (II) without the requisite data what [S]ubclause (I) authorizes only with that data." *Ibid.* HHS, in

short, has "construe[d] the statute in a way that completely nullifies textually applicable provisions meant to limit its discretion." *Whitman*, 531 U.S. at 485.

b. The court of appeals nevertheless upheld HHS's interpretation, but its decision commits critical errors and conflicts with this Court's *Chevron* jurisprudence.

As an initial matter, the decision below does not reflect the searching review for statutory clarity that this Court has required as a prerequisite to deferring under *Chevron*. See pp. 17-20, *supra*. Quite the opposite. The court acknowledged the "force" of Petitioners' argument that, under HHS's interpretation, the entirety of Subclause (I) would be rendered "meaningless," including its requirement that HHS collect statutorily specified acquisition cost survey data before it bases reimbursement rates on acquisition cost and varies rates by hospital group. Pet. App. 23a-24a. Yet the court still held that Petitioners' argument could not "carry the day under *Chevron*," apparently because the statute did not expressly forbid HHS from eviscerating Subclause (I), and "HHS's belief" that it could do so was not "unreasonable." *Ibid.* That is a far cry from the analysis this Court requires—one that empties the "legal toolkit" of "all the standard tools of interpretation," *Kisor*, 139 S. Ct. at 2414-2415, including the canon against adopting an interpretation that makes whole provisions of the statute superfluous, see, *e.g.*, *TRW Inc.* v. *Andrews*, 534 U.S. 19, 31 (2001). As a result, the court of appeals never came to grips with the question that should have controlled the outcome: did Congress delegate to HHS the power to make the requirements of Subclause (I) optional?

The court compounded that error by allowing its preference for HHS's policy outcome to shade its analysis. The court found it inconceivable that Congress would prohibit HHS from basing reimbursement rates

on acquisition costs if HHS failed to collect the statutorily required survey data, even where the "payment amounts otherwise would substantially exceed hospitals' costs" and HHS has found other "reliable cost measures." Pet. App. 24a. But that is *precisely* what the text requires. Under the law as written, HHS may set reimbursement rates based on "average acquisition cost" and "vary" such rates by "hospital group" only if it "tak[es] into account the hospital acquisition cost survey data" Congress specified. 42 U.S.C. 1395*l*(t)(14)(A)(iii)(I). If such data are "not available," HHS must base reimbursement rates on "average price," 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II)—whether or not the agency has located alternative information it finds reliable. The court below may not think it good policy that HHS may set differential reimbursement rates pegged to acquisition cost "based only on the most complete and accurate data." Pet. App. 35a. But a court's agreement with an agency's policy choice is not a proper basis for deference. See, *e.g.*, *Utility Air*, 573 U.S. at 325.

To be sure, the court of appeals purported to find a textual hook for its decision to defer to HHS—the agency's authority under Subclause (II) to "adjust" the price-based reimbursement rates under that provision "as necessary for purposes" of the statute. 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II). In the court's view, that authority justifies HHS's transformative action because one purpose of the statute is to align reimbursement rates and acquisition costs. See Pet. App. 21a-23a. And while the court of appeals acknowledged dictionary definitions that limit "adjustments" to slight changes, it held that the term "adjust" is "ambiguous as to size," which means that "under a straightforward application of *Chevron*" there may be no "limits to

what HHS could permissibly consider an 'adjustment.'" Pet. App. 29a.

That analysis runs headlong into this Court's cases. As an initial matter, HHS's "adjustment" authority is a quintessential example of a "vague" and "ancillary" provision. *Whitman*, 531 U.S. at 468. Congress buried it at the end of Subclause (II), and provided no indication (express or otherwise) that HHS could invoke it to render superfluous Subclause (I), along with the data-source standards at the heart of the statutory scheme. It is implausible that Congress would give HHS the extraordinary power to transform the statutory scheme through "such a subtle device." *MCI*, 512 U.S. at 231; see also *Brown & Williamson*, 529 U.S. at 160; *Whitman*, 531 U.S. at 468; *Gonzales* v. *Oregon*, 546 U.S. 243, 267 (2006).

That Subclause (II) permits adjustments "as necessary for purposes" of the statute does not change the analysis. It is elemental that "[n]o legislation pursues its purposes at all costs," and "[e]very statute [proposes], not only to achieve certain ends, but also to achieve them by particular means." *Freeman* v. *Quicken Loans, Inc.*, 566 U.S. 624, 637 (2012) (Scalia, J.) (internal quotation marks and citations omitted). Here, even if equating reimbursement rates to acquisition costs is one purpose of the statute, it is a purpose that Congress authorized HHS to pursue through one means and one means only—by collecting the acquisition cost survey data that Congress specified and basing reimbursement rates on that data. "Whatever effect may be accorded" the agency's "adjustment" authority, it "cannot be thought to render" the statute's "carefully designed restrictions on [HHS] discretion utterly nugatory." *Whitman*, 531 U.S. at 484.

The D.C. Circuit's insistence that the term "adjust" is "ambiguous as to size," Pet. App. 29a, likewise does

not assist. Even if "adjustments" are (as HHS believes) not always limited linguistically to minor changes, the statutory context here forecloses deference to HHS's interpretation because (as explained) it would authorize the agency to completely rework the scheme Congress designed. That is impermissible under *MCI* and its progeny, which make clear that the first step of *Chevron* is not a myopic effort to find some wiggle room in a single statutory word or phrase, but instead a contextual analysis designed to ascertain just how much authority Congress has delegated to the agency.

In all events, the term "adjust"—like the term "modify"—carries a "connotation of increment or limitation." *MCI*, 512 U.S. at 225. That is the term's ordinary meaning: a person does not "adjust" his tie when he takes it off in favor of a new one, just as a person does not "adjust" the volume when she mutes the television. (That would be still clearer if the rule of the house permitted muting the television only if the remote-holder had surveyed the room, and otherwise permitted mere adjustments as necessary.) A limited interpretation of "adjust" likewise comports (as in *MCI*) with the term's etymology[16] and dictionary definitions.[17] Other courts have had no trouble seeing that an "adjustment" is inherently limited in the same way

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[16] See *Adjust*, American Heritage Dictionary, https://ahdictionary.com/word/search.html?q=adjust (explaining that "adjust" derives from the Latin word "adiuxtare," meaning "to put close to")

[17] See, *e.g.*, *Adjust*, Cambridge Dictionary, https://dictionary.cambridge.org/dictionary/english/adjust (defining "adjust" as "to change something slightly, especially to make it more correct, effective, or suitable"); *Adjust*, Oxford University Press, Lexico.com, https://www.lexico.com/en/definition/adjust ("defining "adjust" as to "[a]lter or move (something) slightly in order to achieve the desired fit, appearance, or result").

as a "modification." See *Davis* v. *Echo Valley Condo. Ass'n*, 945 F.3d 483, 490 (6th Cir. 2019); *Amgen, Inc.* v. *Smith*, 357 F.3d 103, 117 (D.C. Cir. 2004). Yet the decision below failed to impose any "limits to what HHS could permissibly consider an 'adjustment.'" Pet. App. 29a.

3. The decision below reflects a troubling trend: "[T]he federal courts have become habituated to defer to the interpretive views of executive agencies, not as a matter of last resort but first." *Valent* v. *Comm'r of Soc. Sec.*, 918 F.3d 516, 525 (6th Cir. 2019) (Kethledge, J., dissenting). Indeed, "all too often, courts abdicate th[eir] duty [to say what the law is] by 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.); see also Kent Barnett & Christopher J. Walker, *Chevron in the Circuit Courts*, 116 Mich. L. Rev. 1, 34 (2017) (analyzing eleven years of circuit-court decisions applying *Chevron* and finding that only 30% resolved the matter at step one). "In too many cases, courts do so almost reflexively, as if doing so were somehow a virtue, or an act of judicial restraint—as if [courts'] duty were to facilitate violations of the separation of powers rather than prevent them." *Valent*, 918 F.3d at 525. This Court has often cautioned against such reflexive deference, yet the decision below shows that lower courts still fail to heed this Court's direction. Review is necessary to rein in this unfortunate tendency to flout this Court's separation-of-powers jurisprudence.

That the case comes to this Court from the D.C. Circuit makes the need for review even more pressing. That court adjudicates most matters of administrative law in the federal judiciary. Agency policymakers and agency counsel thus look to the D.C. Circuit for guidance when determining the appropriate bounds of

agency authority. If the prevailing view coming from that court is one of reflexive and capacious deference under *Chevron*, agencies will view themselves as empowered to stretch the language of their organic statutes to pursue the policy ends preferred by those who find themselves in charge, whether or not Congress shares them.

The problem is particularly acute given the statutory issue here—the breadth of agency authority to "adjust" statutory requirements. Similar provisions appear throughout the U.S. Code. See, *e.g.*, 12 U.S.C. 5627(b); 13 U.S.C. 302; 26 U.S.C. 162(l)(5)(B); 26 U.S.C. 7874(g). Under the decision below, those provisions are a license for agencies to achieve almost any policy end they desire, rather than an appropriately limited grant of residual discretion. It is essential that this Court not permit the court of appeals to effect such a vast shift in power away from the nation's lawmakers and into the hands of unaccountable administrators.

Ultimately, the decision of the court of appeals poses in stark terms the need for additional guidance from this Court as to the appropriate limits on an agency's power to interpret the meaning and scope of its statutory authority. It is no secret that members of this Court have raised concerns about whether *Chevron* deference, particularly when applied as indiscriminately as it was in this case, violates the separation of powers. See, *e.g.*, *Arlington*, 569 U.S. at 312-316 (Roberts, C.J., dissenting); *Michigan*, 576 U.S. at 760-764 (Thomas, J., concurring); *Gutierrez-Brizuela* v. *Lynch*, 834 F.3d 1142, 1149-1158 (10th Cir. 2016) (Gorsuch, J., concurring); *Kisor*, 139 S. Ct. at 2446 n.114 (Gorsuch, J., concurring in the judgment). Whatever *Chevron*'s ultimate fate, allowing the decision below to

stand as the law of the D.C. Circuit can only serve to deepen these concerns.

B. The question presented is exceptionally important.

This case presents a question of enormous importance. It addresses how HHS allocates billions of dollars annually in prescription-drug spending, and it may well determine whether 340B Hospitals can continue to provide essential services to the low-income, underserved communities that depend on them.

1. This case is exceptionally important, both to the Medicare program generally and the 340B Program in particular.

a. The issue in this case has a significant bearing on the Medicare program, which spends tens of billions of dollars annually on separately payable prescription drugs. ASPE Brief, *supra* note 3, at 13. That spending is rapidly growing, escalating from $16 billion in 2007 to $33 billion in 2017. *Ibid.* This case will determine the rules that govern that extraordinary amount of federal spending. In particular, it will determine whether HHS has the vast power to set reimbursement rates however it sees fit (subject only to arbitrary-and-capricious review), or whether HHS is instead restrained by the statutory scheme that Congress designed—one that sharply limits HHS's discretion unless HHS collects statutorily specified hospital acquisition cost survey data. As the United States has elsewhere acknowledged, "enormous monetary stakes count as a significant reason to grant certiorari." Reply Br. for Petitioners, *U.S. Dep't of Interior* v. *Kerr-McGee Oil & Gas Corp.*, No. 09-54, 2009 WL 2943389, at *9 (Sept. 11, 2009); see also, *e.g.*, *Fidelity Fed. Bank & Trust* v. *Kehoe*, 547 U.S. 1051, 1051 (2006) (Scalia, J., concurring in the denial of certiorari) ("[E]normous

potential liability, which turns on a question of federal statutory interpretation, is a strong factor in deciding whether to grant certiorari.").

The issue here is especially critical to providers caring for Medicare beneficiaries. Before HHS promulgated the rule at issue here, the agency had always set reimbursement rates uniformly, varying such rates between ASP+4% and ASP+6% depending on prevailing overhead costs in the market. See pp. 5-6 & n.9, *supra*. That regulatory regime provided stability to healthcare providers, including the comfort that HHS would not pay some providers more than others without engaging in a rigorous data-collection effort to determine whether such variations would be justified. But on HHS's view, it can vary rates by hospital group no matter what data it has collected. Indeed, if the decision below is left undisturbed, nothing prevents HHS from picking winners and losers in the healthcare market based on any data source HHS finds reliable. Before HHS is permitted to wield such an immense power, this Court should consider whether Congress has given it the authority to do so.

HHS's recent actions further confirm that certiorari is warranted. In response to the district court's decision in this case, HHS attempted to conduct a hospital acquisition cost survey. See 85 Fed. Reg. 86,042-86,043 (Dec. 29, 2020). The survey had glaring flaws; among them, HHS surveyed *only 340B Hospitals*, and received actual acquisition cost data from *only 7%* of the hospitals surveyed. See *id.* at 86,045; contra 42 U.S.C. 1395*l*(t)(14)(D)(iii) (requiring HHS to use "a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug"). After the court of appeals reversed the district court, HHS decided to "continue" its "current

policy" of cutting reimbursement rates for 340B Hospitals under Subclause (II). 85 Fed. Reg. at 86,054; see also *id.* at 86,052-86,054. The agency stated that, in light of "stakeholders' concerns," it would evaluate "how best to take the relevant factors into account for potentially using" survey data in the future. *Id.* at 86,052. But the agency saw no need to do so now because its Subclause (II) authority "was confirmed by the D.C. Circuit." *Id.* at 86,054. HHS has thus made clear that it sees the decision below as a license to maintain its unlawful policy, and as an excuse to avoid grappling with the difficult issues that it may face in collecting adequate data.

b. This case is important for another reason: If the decision below stands, HHS's rate cut will devastate 340B Hospitals and the communities they serve.

Tens of thousands of public and nonprofit hospitals, community health centers, and other safety-net providers participate in the 340B Program. See *Astra USA, Inc.* v. *Santa Clara Cnty., Cal.*, 563 U.S. 110, 113 (2011); OIG Report, *supra*, at 2. Those entities play a leading role in providing medical services to poor, underserved populations. See, *e.g.*, *Astra USA*, 563 U.S. at 115; U.S. Gov't Accountability Off., *GAO-21-107, Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements* 4-5 (Dec. 2020).[18] They offer vital services, including primary care, pediatrics, trauma care, obstetrics, and psychiatric services—all of which 340B Hospitals provide at a higher rate than other hospitals.

[18] https://www.gao.gov/assets/720/711209.pdf.

See, *e.g.*, Allen Dobson et al., *The Role of 340B Hospitals in Serving Medicaid and Low-income Medicare Patients* 13-16 (July 10, 2020).[19]

The role performed by 340B Hospitals carries with it a large financial burden. Because many of their patients are uninsured or underinsured, 340B Hospitals provide tens of billions of dollars annually in uncompensated care.[20] As a result, "340B hospitals operate on razor thin margins, with approximately one out of every four 340B hospitals having a negative operating margin."[21] See also Dobson, *supra*, at 3 (explaining that "[o]perating margins for 340B [disproportionate share] hospitals are significantly lower than those of non-340B hospitals"). COVID-19 has further strained that already precarious financial position. See, *e.g.*, KaufmanHall, *The Effect of COVID-19 on Hospital Financial Health* (July 2020).[22]

For 25 years, 340B Hospitals kept their commitment to low-income communities by relying on savings from the otherwise exorbitant prices of prescription

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[19] https://www.340bhealth.org/files/340B_and_Medicaid_and_Low_Income_Medicare_Patients_Report_7.10.2020_FINAL_.pdf

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

[21] 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#:~:text=For%20outpatient%20services%2C%20340B%20hospitals,between%2015%25%20and%2020%25.

[22] https://www.aha.org/system/files/media/file/2020/07/KH-COVID-Hospital-Financial-Health_FINAL.pdf.

drugs—savings made possible by the 340B Program. Those savings "support[ed] the financial stability" of hospitals that might otherwise have fallen under the weight of their perilous financial burden.[23] They allowed many 340B Hospitals to "maintain services" that are essential to their patient populations, and allowed still others to "serve more patients" and "provide services that they might not have otherwise provided."[24] The 340B Program thus served as a lifeline to the most financially vulnerable medical providers, serving the most financially vulnerable patients.

Until now. HHS's "adjusted" reimbursement rates eviscerate the federal subsidy that has kept 340B Hospitals afloat for decades. Prescription-drug reimbursement rates to 340B Hospitals are now nearly *30 percent lower*, eliminating *$1.6 billion* annually to participating providers. 82 Fed. Reg. at 52,623. Those cuts have inflicted a crushing blow on 340B Hospitals, which are already eliminating essential services at a time when a deadly pandemic continues to ravage the nation. Those cuts have likewise subverted the design of the 340B Program, which Congress created for the purpose of subsidizing medical care to the poor through above-cost insurer reimbursements. See p. 7 & n.10, *supra*. Those damaging consequences underscore the pressing need for review by this Court.

2. The Court should address this issue now. This case is an ideal vehicle for addressing the question presented. Through the course of this litigation, both the district court and the court of appeals have issued

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[23] U.S. Gov't Accountability Off., *GAO-11-836, Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 17 (Sept. 2011), https://www.gao.gov/assets/330/323702.pdf.

[24] *Id.*

thorough decisions analyzing the issue. What is more, the four judges to review it have split down the middle on the appropriate outcome, leaving this Court with the benefit of dueling, reasoned opinions. There is thus no advantage to waiting several years for the issue to arise again in the future—after billions of dollars more in harm to 340B Hospitals and the populations they serve have been inflicted.

3. Finally, the absence of a circuit conflict provides no reason to deny review over the operation of the MMA. This Court routinely grants review of important administrative law decisions notwithstanding the absence of a split. See p. 16, *supra*. And this Court has frequently granted review in splitless cases implicating the separation of powers, in recognition of their structural importance. See, *e.g.*, *Seila Law LLC* v. *Consumer Fin. Protection Bureau* (No. 19-7); *Free Enterprise Fund* v. *Public Co. Accounting Oversight Bd.* (No. 08-861); *Metropolitan Washington Airports Auth.* v. *Citizens for Abatement of Aircraft Noise, Inc.* (No. 90-906). That treatment is plainly warranted here.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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February 10, 2021

APPENDIX

APPENDIX A

Nos. 19-5048, 19-5198

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

AMERICAN HOSPITAL ASSOCIATION, et al.,
Appellees

v.

ALEX MICHAEL AZAR, II, in his official capacity as the Secretary of Health and Human Services and United States Department of Health and Human Services, Appellants

[Filed] July 31, 2020

Rehearing En Banc Denied October 16, 2020

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

OPINION

SRINIVASAN, Chief Judge:

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

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

I.

A.

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

The Department of Health and Human Services (HHS) annually establishes Part B reimbursement rates through notice-and-comment rulemaking. In setting the rates, HHS uses the "Outpatient Prospective Payment System," or OPPS. *See* 42 U.S.C. § 1395*l*(t). *See generally Am. Hosp. Ass'n v. Azar*, No. 19-5352, 964 F.3d 1230, 1233–35 (D.C. Cir. July 17, 2020). The OPPS requires HHS to fix the amounts it will pay providers for certain services before the year begins (rather than after the care has been provided). Congress moved to that prospective system to enhance HHS's ability to control Part B costs. *See* Medicare Program; Prospective Payment System for Hos-

pital Outpatient Services, 65 Fed. Reg. 18,434, 18,436–37 (Apr. 7, 2000); *Paladin Cmty. Mental Health Ctr. v. Sebelius*, 684 F.3d 527, 528–29 (5th Cir. 2012).

For most types of covered care, the Medicare statute instructs HHS to set annual OPPS reimbursement rates through a complex formula that gives the agency significant discretion. *See* 42 U.S.C. § 1395*l*(t)(2). For certain kinds of services, however, the OPPS limits that discretion and sets out a specific methodology for calculating payment rates. That is the case for certain drugs covered by Part B, known as "specified covered outpatient drugs" or SCODs.

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

Since 2006, when those two statutory pricing alternatives took effect, HHS has not had the "hospital acquisition cost survey data" contemplated by subclause (I). As a result, HHS has had to use the average price metric. *See* Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 77 Fed. Reg. 68,210, 68,385–86 (Nov. 15, 2012). The parties here agree

that, by virtue of a statutory cross-reference, a drug's default "average price" equals 106% of its "average sales price," or ASP. *See* 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) (citing 42 U.S.C. § 1395w-3a(c)). HHS calculates ASP every quarter using sales data confidentially provided by drug manufacturers.

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

B.

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

To understand HHS's reasons for reducing SCOD reimbursement rates for 340B hospitals, it is helpful to review the background of the 340B program. The program takes its name from the section of the Public

Health Service Act that authorizes it. *See* Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967–71 (1992). The program allows covered entities (including eligible hospitals) to purchase drugs from manufacturers at heavily discounted rates. *See* 42 U.S.C. § 256b(a)(4). The covered entities generally care for underserved populations, and the discounted rates enable the providers to "stretch scarce Federal resources as far as possible." H.R. Rep. No. 102-384 (II), at 12 (1992).

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

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

cial Incentives to Prescribe 340B Drugs at Participating Hospitals (June 2015), https://www.gao.gov/assets/680/670676.pdf.

When it came time to set 2018 OPPS rates, HHS decided to address the 340B-Part B payment gap. HHS believed that the gap "allow[ed] [340B] providers to generate significant profits when they administer[ed] Part B drugs." 82 Fed. Reg. at 52,494. Seeking to shrink those revenues, HHS imposed a 28.5% cut, from 106% of ASP to 77.5% of ASP, to the rates at which it would reimburse 340B hospitals for SCODs. *See id.* at 52,496. The new rate was based on a "conservative" estimate, presented by the Medicare Payment Advisory Committee, that 22.5% below ASP equaled the "average minimum discount that a 340B participating hospital receive[d]" when purchasing SCODs. *Id.* HHS estimated that its 28.5% cut to SCOD reimbursement rates for Part B hospitals would save Medicare $1.6 billion in 2018. *Id.* at 52,509. As called for by the OPPS statute, HHS did not pocket the savings, but instead redistributed them to all hospitals in a budget-neutral manner by raising other Part B reimbursement rates. *Id.* at 52,623; *see* 42 U.S.C. § 1395*l*(t)(14)(H).

By addressing the 340B-Part B payment gap, HHS hoped to mitigate "unnecessary utilization and potential overutilization of [Part B] drugs." Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 33,558, 33,633 (July 20, 2017). HHS cited a GAO study which found that 340B hospitals prescribed more drugs than other hospitals, a disparity unexplained by salient distinctions between the hospitals or their patient populations. *Id.* at 52,494. HHS also sought to reduce the disproportionate coinsurance payments

borne by Medicare Part B beneficiaries (mostly elderly patients) for 340B SCODs: because the amount of a patient's coinsurance payment is a fixed percentage of the medical bill as measured by the OPPS payment level, and because the latter amount for SCODs exceeded 340B hospitals' actual costs to obtain the drugs, patients' out-of-pocket coinsurance payments for SCODs became inflated, sometimes even exceeding a hospital's costs to acquire the drugs. *See id.*

Ultimately, HHS found it "inappropriate for Medicare to subsidize other activities" by 340B hospitals—as laudable as those activities may be—"through Medicare payments for [Part B] drugs." *Id.* at 52,495. In order to "better and more appropriately reflect the resources and acquisition costs that [340B] hospitals incur," HHS acted to close the Part B-340B gap. *Id.* (formatting modified). HHS relied on its authority to "adjust" the average price metric under subclause (II) of the statute:

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

Id. at 52,499.

C.

The plaintiffs here are three hospitals and three hospital associations, to whom we will refer collectively as the Hospitals. On November 13, 2017, the day HHS published the rule reducing 340B reim-

bursement rates for SCODs, the Hospitals brought a challenge to HHS's action. *See Am. Hosp. Ass'n v. Hargan*, 289 F. Supp. 3d 45, 50 (D.D.C. 2017). The district court dismissed the suit on the ground that the Hospitals had yet to present a concrete claim for payment to HHS, as required by statute. *See id.* at 47. We affirmed. *Am. Hosp. Ass'n v. Azar*, 895 F.3d 822, 828 (D.C. Cir. 2018).

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

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

II.

We must first address a threshold challenge to our jurisdiction. The government asserts that paragraph 1395*l*(t)(12) of the OPPS statute,

1395*l*(t)(12), precludes judicial review of HHS's adjustments to SCOD rates. The district court disagreed, and so do we. Unable to find "clear and convincing evidence that Congress intended" that result, as would be required to overcome the "strong presumption that Congress intends judicial review of administrative action," we conclude that the challenged rate adjustment is subject to judicial review. *Amgen, Inc. v. Smith*, 357 F.3d 103, 111 (D.C. Cir. 2004) (quoting *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 670, 106 S.Ct. 2133, 90 L.Ed.2d 623 (1986)).

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

The first provision, subparagraph (12)(A), bars review of the "development of the classification system under paragraph (2), including the establishment of groups and relative payment weights for covered OPD [outpatient department] services, of wage adjustment factors, other adjustments, and methods described in paragraph (2)(F)." 42 U.S.C. § 1395*l*(t)(12)(A); *see also Am. Hosp. Ass'n*, No. 19-5352, 964 F.3d at 1237–38. The second provision, subparagraph (12)(C), bars review of "periodic adjustments made under paragraph ([9])." *Id.* § 1395*l*(t)(12)(C). (While the provision in fact refers to "paragraph (6)," all agree that the reference contains a scrivener's error and that Congress in fact intended to refer to paragraph (9).) The reach of subparagraphs (12)(A)

and (12)(C) turns on the scope of the provisions they cross-reference: paragraphs (2) and (9), respectively.

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

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

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

SCOD payments "shall be equal" to one of those two options. *Id.* § 1395*l*(t)(14)(A)(iii).

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

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

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

Our analysis of the text draws support from Congress's history of amendments to the OPPS statute. When adding new provisions to subsection 1395*l*(t), Congress has tended to say expressly when it wishes to preclude judicial review of decisions made under an added provision. In 1999, Congress added paragraphs (5), (6), and (7) to subsection (t). In the same legislation, Congress also added clause (E) to paragraph (12), which provided that certain "determination[s]" made under paragraphs (5) and (6), but not any decisions under paragraph (7), would not be judicially reviewable. *See* Pub. L. No. 106-113, § 201(d), 113 Stat. 1501 (1999). In 2015, Congress included a preclusion-of-judicial-review provision directly within the newly added paragraph (21), rather than amending paragraph (12). *See* Pub. L. No. 114-74, § 603, 129 Stat. 584, 598 (2015). By contrast, when Congress added paragraph (14) in 2003, it did so without any indication of an intention to preclude judicial review of SCOD rate-setting decisions.

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

ment rate, when HHS does so, it exercises authority located not in (14) but in paragraphs (2) and (9).

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

First, Congress on several occasions has specifically noted, directly in the statutory text, that certain OPPS-related decisions fall under paragraph (2). When Congress authorized HHS to make "outlier adjustments" and "pass-through payments," it fleshed out how those actions would work in paragraphs (5) and (6) respectively, but lodged the authority to make the adjustments in the newly added subparagraph (2)(E). *See* 42 U.S.C. § 1395*l*(t)(2)(E). When Congress added paragraphs (13) and (18), which address adjustments for rural and cancer hospitals, respectively, it similarly provided that those adjustments would fall under subparagraph (2)(E). 42 U.S.C. § 1395*l*(t)(13)(B) ("the Secretary shall provide for an appropriate adjustment under paragraph (2)(E)"); *id.* § 1395*l*(t)(18)(B) ("the Secretary shall ... provide for an appropriate adjustment under paragraph (2)(E)"). But when Congress added the SCOD reimbursement provisions of paragraph (14) in 2003, it included no such language referencing paragraph (2).

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

equitable-adjustment authority to change the rates. But it does not appear HHS may make such adjustments to SCOD rates.

As a matter of statutory text, paragraph (14) provides its own authorizations for HHS to adjust SCOD rates. Subclause (I) of paragraph (14), which sets out the average-acquisition-cost formula, says that the Secretary "may vary [the calculated reimbursement rate] by hospital group." 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I). Subclause (II), which requires SCOD reimbursement to reflect a drug's average price, allows the Secretary to "calculate[ ] and adjust[ ] [the average price metric] as necessary for purposes of this paragraph." *Id.* § 1395*l*(t)(14)(A)(iii)(II). And both the average-acquisition-cost and average-price formulas are "subject to subparagraph (E)," which authorizes the Secretary to "adjust" SCOD payments to account for "overhead and related expenses, such as pharmacy services and handling costs." *Id.* § 1395*l*(t)(14)(E). It would be odd for Congress in paragraph (14) to provide HHS with those specific authorities to "adjust" SCOD rates if HHS nonetheless has the general authority to adjust those rates as it sees fit under paragraph (2) or (9).

HHS's longstanding practice, and the 2018 and 2019 Rules at issue here, corroborate that understanding. HHS has never purported to use its paragraph (2) or (9) authorities either to set SCOD rates or to deviate from the default "average price" rate set out in subclause (II). And it did not do so here. Instead, in the 2018 Rule, HHS grounded its action in in the "calculate and adjust" provision of paragraph (14), subclause (II). 82 Fed. Reg. at 52,499–500. The government claims that HHS invoked its paragraph (9) authority in the 2018 Rule's preamble. But the preamble stated only that the Rule would "describe

[that] and various other statutory authorities in the relevant sections of this final rule." *Id*. at 52,362. And in the section of the Rule explaining HHS's statutory authority to make the 340B-related reduction to SCOD rates, there is no reference to paragraph (9). *See id.* at 52,496, 52,499–502.

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

Third, paragraph (14) operates as a standalone payment regime for all practical purposes. The statute contemplates that HHS will set SCOD payment rates in a vacuum, without taking into account other OPPS rate-setting decisions. SCOD rates are not set through relative weighting with rates for other reimbursable care. And if HHS changes the payment weights for other APCs, SCOD prices need not change because SCOD rates are unaffected by the statute's budget-neutrality requirement. Recall that SCOD rates must equal either average acquisition cost or average price. Although subparagraph (14)(H) requires that "[a]dditional expenditures resulting from this paragraph" be "taken into account" for overall budget neutrality for the OPPS, that language

recognizes that the expenditures "resulting" from the application of paragraph (14) will be calculated first, irrespective of other adjustments made to other OPPS payments. 42 U.S.C. § 1395*l*(t)(14)(H). Only then are those set-in-stone numbers put into the budget-neutrality calculator.

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

The government lastly relies on subparagraph (14)(H), reading that provision to indicate that setting of SCOD rates is an exercise of paragraph (9)'s annual-adjustment authority. Subparagraph (14)(H), enacted along with the rest of paragraph (14) in 2003, requires that SCOD payments be counted for budget-neutrality purposes in years after 2005, but specifies that the payments "shall *not* be taken into account" for budget-neutrality purposes in 2004 and 2005. 42 U.S.C. § 1395*l*(t)(14)(H) (emphasis added); *see also id.* § 1395*l*(t)(9)(B). According to the government, the specification that SCOD payments would not be subject to budget neutrality in 2004 and 2005 suggests that budget neutrality otherwise applies, which would be the case if SCOD rate-setting were an exercise of paragraph (9) authority (given that all paragraph (9) adjustments must be budget neutral, *see id.* § 1395*l*(t)(9)(B)).

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

To sum up: subparagraphs (12)(A) and (12)(C) do not, by their terms, clearly cover HHS's decision to cut SCOD reimbursement to 340B hospitals. While the government argues that SCOD rate-setting is merely a species of general OPPS rate-setting under paragraphs (2) and (9), and that Congress thus intended SCOD payment decisions to be similarly insulated from review, that account, at a minimum, is not *clearly* correct. As a result, the government has failed to "overcom[e] the strong presumption that Congress did not mean to prohibit" our review. *Bowen*, 476 U.S. at 672, 106 S.Ct. 2133.

III.

Proceeding to the merits, the sole question before us is whether HHS had statutory authority to impose its 28.5% cut to SCOD reimbursement rates for 340B

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

On that issue of statutory interpretation, HHS is entitled to *Chevron* deference, which it has invoked here (although it did not do so expressly until a post-argument letter submitted to the Court). *See Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984). When an agency "interpret[s] a statute it is charged with administering in a manner (and through a process) evincing an exercise of its law-making authority," that interpretation is entitled to *Chevron* treatment, and the agency cannot forfeit *Chevron*'s applicability. *SoundExchange, Inc. v. Copyright Royalty Board*, 904 F.3d 41, 54–55 (D.C. Cir. 2018). HHS established SCOD reimbursement rates for 340B hospitals through notice-and-comment rulemaking and explained why it "believe[d] that [its] proposal [was] within [its] statutory authority to promulgate." 82 Fed. Reg. at 52,499. HHS's understanding of its statutory authority thus is entitled to *Chevron* deference. *See Am. Hosp. Ass'n*, No. 19-5352, 964 F.3d at 1239; *Tenet HealthSystems HealthCorp. v. Thompson*, 254 F.3d 238, 248 (D.C. Cir. 2001); *see also Barnhart v. Walton*, 535 U.S. 212, 222, 122 S.Ct. 1265, 152 L.Ed.2d 330 (2002).

Under *Chevron*, we first ask whether "Congress has directly spoken to the precise question at issue." *Chevron*, 467 U.S. at 842, 104 S.Ct. 2778. Here, the "precise question at issue" is whether HHS's adjustment authority in subclause (II) encompasses a reduction to SCOD reimbursement rates aimed at bringing reimbursements to 340B hospitals into line with their actual costs to acquire the drugs. If the statute does not directly foreclose HHS's understanding, we defer to the agency's reasonable interpretation. *See id.* at 844, 104 S.Ct. 2778. We conclude that HHS's interpretation of subclause (II) is not directly foreclosed and is reasonable.

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

Much is undisputed about HHS's application of subclause (II)'s adjustment authority to reduce SCOD payment rates to 340B hospitals. First, HHS properly found that the "hospital acquisition cost data" contemplated by subclause (I) was unavailable, such that HHS needed to determine payment rates in accord-

ance with subclause (II)'s fallback reliance on average drug prices. Second, 340B hospitals obtain SCODs at substantially lower cost than other providers, such that reimbursing those hospitals at the same rate as other providers would give sizable revenues to the hospitals. Third, HHS's 28.5% SCOD rate reduction for 340B hospitals is a fair, or even conservative, measure of the reduction needed to bring payments to those hospitals into parity with their costs to obtain the drugs. *See* 82 Fed. Reg. at 52,500. Fourth, absent the reduction, at least some Medicare beneficiaries served by 340B hospitals (generally underserved populations) would pay out-of-pocket copayments for the drugs that substantially exceed the normal copay share of providers' cost to obtain the drugs—with beneficiaries' copayments sometimes exceeding 340B hospitals' *full* cost to purchase the drugs. And fifth, the roughly $1.6 billion in savings from reducing SCOD reimbursement payments to 340B hospitals is not kept by the agency but is redistributed to all providers as additional reimbursement payments for other services. *See generally* pp. 822–23, *supra*.

That is the backdrop against which we consider whether HHS permissibly understood its subclause (II) adjustment authority to encompass its reduction to reimbursement payments to 340B hospitals for SCODs. Was HHS obligated to continue reimbursing 340B hospitals for SCODs in amounts substantially exceeding their costs to obtain the drugs, with the resulting effects that concerned the agency on out-of-pocket copayments owed by Medicare beneficiaries? We think the agency was not compelled to continue doing so.

The central question is whether HHS permissibly conceived of the "purposes of this paragraph," i.e., paragraph (14), in exercising its subclause (II) au-

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

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

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

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

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

eas"); *id.* § 1395*l*(t)(18)(B) (same for cancer hospitals).

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

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

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

subclause (II) to approximate drug acquisition costs. Our dissenting colleague, too, stresses the same point. Dissenting Op. 836–37.

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

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

The Hospitals submit that "[t]he purpose of paragraph (14) is to establish the rate for separately payable drugs." Appellees' Br. 42–43. That may be true at a high level of generality—indeed, the title of paragraph (14) is "Drug APC payment rates"—but it is unhelpful to the Hospitals for our purposes. After all, HHS's rate reduction for payments to 340B hospitals does "establish the rate for separately payable drugs."

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

The Hospitals' reading of subclause (II)'s adjustment authority as addressed to overhead costs, it bears noting, would necessarily mean that the purpose of granting that authority is to enable bringing ASP closer to drug acquisition costs—precisely what the Hospitals otherwise say the agency cannot aim to do when exercising its subclause (II) authority. But under the Hospitals' evident understanding, the agency can try to get ASP closer to actual costs only

to the extent of taking into account overhead costs, without going further to bring ASP all the way into alignment with acquisition costs. That half-measure understanding of subclause (II)'s adjustment authority is incompatible with its broad terms, which speak generally to the "purposes" of paragraph (14), including, in particular, approximating drug acquisition costs.

Our dissenting colleague nonetheless endorses the Hospitals' suggestion that subclause (II)'s adjustment authority, while framed generally, should be read as focused on overhead costs. Dissenting Op. 836–38. Our colleague briefly suggests that there may be no redundancy between subclause (II) and subparagraph (14)(E) under that reading because, she posits, the two provisions both allow for adjustments to account for overhead costs, but at different times, with (14)(E) in the nature of a time-limited, naturally-expiring allowance and subparagraph (II) an ensuing, ongoing one. *Id.* at 836–37. Again, though, if the provisions were designed to cover the same terrain (even if at different times), one would expect them to use similar language in defining the territory, which they conspicuously do not. And at any rate, the statutory text confirms that the provisions are designed to work side-by-side contemporaneously, not at different times: Congress rendered subclause (II)'s provisions expressly "subject to paragraph (E)," such that the agency, when acting under subclause (II), could make adjustments to ASP *both* under that provision's own, broadly-framed adjustment authority *and* under subparagraph (14)(E)'s more specific authority addressed to overhead costs. 42 U.S.C. § 1395*l*(t)(14)(A).

Our dissenting colleague ultimately allows that the Hospitals' overhead-costs interpretation of subclause

(II)'s adjustment authority means that the provision may reiterate—i.e., make "double sure"—subparagraph (14)(E)'s express authority to account for overhead costs. Dissenting Op. 837. But our colleague still believes that the Hospitals' reading of the statute is unambiguously compelled at *Chevron* step one. *Id.* at 834–35. In her evident view, any superfluity occasioned by that reading is less substantial than the superfluity occasioned by the agency's reading. *Id.* at 838–39. But even assuming there is a reliable metric for comparing degrees of superfluity across readings in that fashion, that kind of comparison is not the stuff of a *Chevron* step one resolution. Rather, when competing readings of a statute would each occasion their own notable superfluity, that manifests the kind of statutory ambiguity that *Chevron* permits the agency to weigh and resolve. *See National Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 666, 127 S.Ct. 2518, 168 L.Ed.2d 467 (2007); *Peter Pan Bus Lines, Inc. v. Fed. Motor Carrier Safety Admin.*, 471 F.3d 1350, 1354 (D.C. Cir. 2006) ("[S]ection 13902 contains surplusage under either reading and, as a result, we cannot say that either proffered construction reflects the Congress's unambiguously expressed intent.").

The Hospitals separately suggested in oral argument that subclause (II)'s adjustment authority could pertain to improving the accuracy of the sales-price metric specifically for hospitals (as opposed to other providers). ASP reflects sales prices to all manner of medical providers, including pharmacies, clinics, independent physician practices, and the like. *See* 42 U.S.C. § 1395w-3a(c). As the Hospitals see it, HHS can adjust ASP to arrive at a metric that better reflects the prices paid by hospitals alone. But nothing in subclause (II)'s general adjustment authority sug-

gests that it is so narrowly focused. And in any event, to the extent HHS might adjust ASP to more accurately reflect prices paid by hospitals, it is unclear whether there would then remain any appreciable difference between such a hospital-specific ASP and hospital acquisition costs. Yet the Hospitals' whole point is that HHS cannot rely on its subclause (II) adjustment authority to approximate acquisition costs.

Especially in view of the Hospitals' inability to present an interpretation of HHS's subclause (II) adjustment authority that would give it meaningful independent content, we cannot conclude that the statute forecloses HHS from reducing SCOD reimbursement rates for 340B hospitals with the object of bringing payments into alignment with acquisition costs. Rather, in the specific circumstances of this case, HHS permissibly read the statute to allow it to implement the 340B payment reduction. Although subclause (I) calls for the "average acquisition cost" payment metric to "tak[e] into account" subparagraph (D)'s survey data, here, HHS relied on data of undisputed reliability. Moreover, the agency acted on that data in a cautious way, adopting a "conservative, lowerbound estimate" of the 340B discount's size. 82 Fed. Reg. at 52,504 (quotation marks omitted). In those circumstances, HHS reasonably concluded that it need not continue subsidizing 340B providers with Part B (i.e. taxpayer) funds and Medicare beneficiaries' copayments. We of course do not consider the wisdom of that decision as a policy matter in the first instance, but only whether the agency had statutory authority to reach it. *See Chevron*, 467 U.S. at 845, 104 S.Ct. 2778. We conclude that the agency's decision rests on a permissible understanding of its statutory authority.

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

The Hospitals point to our decision in *Amgen*, which considered an "adjustment" under HHS's subparagraph (2)(E) authority to make equitable adjustments. In the course of upholding the challenged adjustment, we observed that "similar limits inhere in the term 'adjustments' to those the Supreme Court found in the word 'modify'" in *MCI Telecomms. Corp v. Am. Tel. & Tel. Co.*, 512 U.S. 218, 225, 114 S.Ct. 2223, 129 L.Ed.2d 182 (1994). *Amgen*, 357 F.3d at 117. And the *MCI* Court stated that "modify" means "to change moderately or in minor fashion." *MCI*, 512 U.S. at 225, 114 S.Ct. 2223. But we do not read *Amgen* to prescribe that "adjust" in the OPPS statute refers only to minor changes. To the contrary, *Amgen* explained that it "ha[d] no occasion to engage in line drawing to determine when 'adjustments' cease being 'adjustments.'" 357 F.3d at 117. Even if there are limits to what HHS could permissibly consider an "adjustment," that line has not been crossed here,

where the agency acted on a conservative estimate drawn from data of undisputed reliability.

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

Congress, however, was not silent about HHS's adjustment power in subclause (II). Whereas subclause (I) does not grant HHS any general authority to adjust reimbursement rates, subclause (II) affirmatively grants HHS general adjustment authority for deployment "as necessary for purposes of" paragraph (14). And as explained, HHS reasonably believes that a central purpose of paragraph (14) is to accurately reimburse hospitals for their acquisition costs. There is no reason to think that HHS's general adjustment authority when acting under subclause (II) excludes the more focused license to vary rates by hospital group when acting under subclause (I). In particular, the Hospitals provide no reason why, if HHS knows that a certain group of hospitals has far lower (or far

higher) costs than others, Congress would want to preclude HHS from acting on that information in a suitably tailored fashion when exercising its adjustment authority under subclause (II). At a minimum, the statute does not clearly preclude HHS from adjusting the SCOD rate in a focused manner to address problems with reimbursement rates applicable only to certain types of hospitals. That is enough to reject the Hospitals' argument under *Chevron*.

* * * * *

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

So ordered.

PILLARD, Circuit Judge, dissenting in part:

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

The statute sets forth two alternative bases for HHS's calculation of the relevant reimbursement rates: It may set those rates under subclause (I) based on average acquisition cost (reflecting the average cost that hospitals actually incurred in purchasing the drug), or under subclause (II) based on average sales price (reflecting the average price, updated quarterly, at which manufacturers sold the drug to most purchasers, not limited to hospitals). *See* 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I)-(II). When the two

subclauses at issue here are read together, the conclusion is unavoidable that HHS may institute its large reductions, tailored for a distinct hospital group, only under subclause (I), which requires the agency to take into account specific data undisputedly absent here.

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

* * *

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

> (I) to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on the volume of covered [outpatient department] services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D); or
>
> (II) if hospital acquisition cost data are not available, the average price for the drug in the year established under section 1395u(o) of this title, section 1395w-3a of this title, or section 1395w-3b of this title, as the case may be, as

> calculated and adjusted by the Secretary as necessary for purposes of this paragraph.

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

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

The two subclauses operate as alternatives: Subclause (I) lays out what the agency may do when it has collected and taken into account the "hospital acquisition cost survey data under subparagraph (D)," whereas subclause (II) lays out what the agency may do "if the hospital acquisition cost data are not available." *Id*. § 1395*l*(t)(14)(A)(iii). If the agency has that data, it may set reimbursement rates based on the "average acquisition cost for the drug for that year," and "vary by hospital group" any reimbursement rates. *Id*. § 1395*l*(t)(14)(A)(iii)(I). But "if hospital acquisition cost data are not available," *id*. § 1395*l*(t)(14)(A)(iii)(II), the agency must set reimbursement amounts under subclause (II) by resort to what it has previously called the "statutory default" rate for a given drug in a given year, *see, e.g.*, 2013 OPPS Rule,

2012). That statutory default rate is the drug's average sales price charged to hospitals, clinics, pharmacies, and other providers, drawn from data that drug manufacturers submit to HHS every quarter. *See id.* §§ 1395w-3a(c), 1396r-8(b)(3)(A)(iii). Subclause (II) provides for the average sales price to be "adjusted ... as necessary for purposes of this paragraph" but, unlike subclause (I), grants no authority to vary the reimbursement rates by hospital group. *Id.* § 1395*l*(t)(14)(A)(iii)(II).

As everyone agrees, HHS has never collected the "hospital acquisition cost data" that the statute contemplates, so must proceed under its subclause (II) authority to set reimbursement rates for the 2018 and 2019 OPPS rules. *See, e.g.*, HHS Br. 9; 2018 Proposed OPPS Rule, 82 Fed. Reg. 33,558, 33,634 (proposed July 20, 2017). The question before us is whether the agency may set and vary by hospital group SCOD reimbursement rates in the manner that subclause (I) authorizes, without collecting and considering the data that subclause (I) specifies, by invoking its authority under subclause (II) to adjust the average-sales-price-based reimbursement rate and, in effect, simply deem that to be a rate reflecting hospitals' average acquisition cost. The majority concludes that the agency's circumvention of subclause (I) in this manner is a permissible construction of the statute for several reasons, none of which I find persuasive.

First, the majority argues, based primarily on the text of subclause (I) and other provisions in the OPPS statute, that Congress' "primary goal is to reimburse providers for their acquisition costs." Maj. Op. at 830. But the statute's overarching goal is not its only goal, to be achieved however the agency sees fit. When it comes to Medicare Part B payments for SCODs, par-

agraph (14) specifically tells us when and how Congress intended HHS to pursue acquisition-cost-based reimbursement. Only subclause (I), not subclause (II), authorizes HHS to set different reimbursement rates for distinct hospital groups—rather than a uniform, drug-by-drug "average price for the drug in the year," 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II)—and to do so only by taking into account the different acquisition costs identified in the robust, hospital-specific data that Congress required the agency to collect.

The majority finds it inconceivable that Congress would require the same sales-price-based reimbursement rate for all types of hospitals when hospitals' acquisition costs vary widely. *See, e.g.*, Maj. Op. at 831. But in authorizing the average-sales-price methodology, which takes account of most discounts and rebates that purchasers receive, Congress was attuned to the many factors rendering non-uniform the amounts different hospitals actually pay for the same drugs. Given Congress' awareness that various hospitals—not only 340B hospitals—pay more or less than others, I see nothing inconceivable about Congress requiring disparities in reimbursement rates to certain types of hospitals to be identified and acted upon based only on the most complete and accurate data.

If Congress wanted HHS, in the absence of subclause (I)'s hospital-specific data regarding average acquisition costs, just to do its best to approximate those costs and then vary them by hospital groups according to its unchecked policy judgment, it easily could have written the statute to say so. Instead, subclause (II) mandates that the base reimbursement rate "shall be equal" to the specified drug's statutory default rate premised on average sales price, subject to adjustments, and entirely omits the authority

granted in subclause (I) to "vary by hospital group" the pricing data or resultant rate. 42 U.S.C. § 1395*l*(t)(14)(A)(iii). I cannot discern in the statute any congressional intention that the adjustment authority be used to set markedly different prices for different hospital groups. I would instead affirm the district court's conclusion that HHS "cannot fundamentally rework the statutory scheme—by applying a different methodology than the provision requires—to achieve under sub[clause] (II) what [it] could not do under sub[clause] (I) for lack of adequate data." *Am. Hosp. Ass'n v. Azar*, 348 F. Supp. 3d 62, 82 (D.D.C. 2018).

Second, the majority reasons that this data-sensitive reading of the two subclauses cannot be correct because it "renders subclause (II)'s adjustment authority superfluous." Maj. Op. at 831. But the Hospitals' reading of the subclause (II) adjustment authority as primarily cross-referencing incremental modifications like the overhead-cost adjustment described in subparagraph (E) does not make the former altogether redundant. As the Hospitals explain, subparagraph (E) authorized adjustments for overhead with reference to a one-time, 2005 MedPAC report, whereas subclause (II)'s authority to make "adjust[ments] ... as necessary for purposes of this paragraph," 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II), encompasses "adjustments" for overhead in the same manner on an ongoing basis. *See* Hospitals Br. 5-6, 49.

In any event, reading section 1395*l*(t)(14) to contain overlapping references to a limited adjustment authority—making "double sure" the point is made—does not create the kind of superfluity that renders a statute ambiguous. *Mercy Hosp., Inc. v. Azar*, 891 F.3d 1062, 1068 (D.C. Cir. 2018) (quoting *Fla. Health Scis. Ctr., Inc. v. HHS*, 830 F.3d 515, 520

(D.C. Cir. 2016)). As we have recognized with respect to the Medicare statute, a "little overlap, either by accident or design, is to be expected in any complex statutory scheme with interdependent provisions" and does not alone create ambiguity. *Id*. The fact that average price data lumps together pharmaceutical sales to hospitals from sales to non-hospital providers seems to explain Congress' clear decision to omit from subclause (II) the authority in subclause (I) to vary reimbursement by hospital group. Without subclause (I)'s hospital-specific cost data, billion-dollar decisions differentiating among particular hospital groups could rest on significantly less exact information.

Moreover, to the extent that past agency practice bears on the question of statutory construction before us, it only confirms the Hospitals' reading that the agency's subclause (II) adjustment authority references overhead adjustments like those contemplated by subparagraph (E). As the agency described at length in 2012, during the preceding six years HHS had made no adjustments to its estimate of average sales prices other than occasional small tweaks to account for overhead costs (and, in any case, purported to rely only on its subclause (I) authority). *See* 2013 OPPS Rule, 77 Fed. Reg. at 68,383-86 (explaining the agency's methodology year by year over this period); *see also* 2016 OPPS Rule, 80 Fed. Reg. 70,298, 70,439 (Nov. 13, 2015) (providing a similar summary of the agency's past methodology); Hospitals Br. 49 ("[W]hen HHS previously made adjustments to the ASP-plus-6% rate, it explained at the time that it was doing so to account for estimates of overhead."). Indeed, the focus of the agency in those years was on collecting more accurate overhead-cost data to better tailor its adjustments. *See, e.g.*, 2013 OPPS Rule,

years before the two challenged rules at issue, the agency simply adopted the statutory default rate of 106% of the average sales price under subclause (II) without making any adjustments at all. *See* 2018 OPPS Rule, 82 Fed. Reg. 52,362, 52,490 (Nov. 13, 2017).

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

The Hospitals' limited reading of the adjustment authority that subclause (II) confers is supported by our previous caution that the term "adjustment" in this statute—like the term "modify" at issue in *MCI Telecommunications Corp. v. AT&T Co.*, 512 U.S. 218, 225, 114 S.Ct. 2223, 129 L.Ed.2d 182 (1994), which the Court held "means to change moderately or in minor fashion"—cannot permit "basic and fundamental changes in the scheme." *Amgen, Inc. v. Smith*, 357 F.3d 103, 117 (D.C. Cir. 2004) (quoting *MCI*, 512 U.S. at 225, 114 S.Ct. 2223). The majority distinguishes *Amgen* by quoting our observation there that we had "no occasion to engage in line drawing to determine when 'adjustments' cease being 'adjustments.'" *Id*. But that observation made eminent sense in a dispute "involving only the payment amount for a single drug," and we went on to warn that a "more substantial departure from the default amounts would, at some point, violate the Secretary's obliga-

tion to make such payments and cease to be an 'adjustment.'" *Id*. (alteration omitted). Given the scale and segmentation of the rate cut at issue—reducing SCOD reimbursements by nearly a third, thereby eliminating $1.6 billion annually in reimbursements to many of the most financially vulnerable hospitals in the Medicare program—I disagree that, "[e]ven if there are limits to what HHS could permissibly consider an 'adjustment,' that line has not been crossed here." Maj. Op. at 834.

Not only is the majority wrong to reject the Hospitals' reading as creating unexplained surplusage, *see* Maj. Op. at 831–33, but the superfluity concerns cut decisively the other way. As discussed above, the majority essentially reads subclause (I) out of the statute by permitting the agency to do under subclause (II) without the requisite data what subclause (I) authorizes only with that data. The majority also renders superfluous the entirety of subparagraph (D). *See* 42 U.S.C. § 1395*l*(t)(14)(D). That subparagraph, occupying nearly a full column in the U.S. Code, specifies in detail how the "[a]cquisition cost survey for hospital outpatient drugs" is to be conducted, first by the Government Accountability Office (GAO) and later by HHS, after that agency has "tak[en] into account" the Comptroller General's "recommendations" as to the "frequency and methodology of subsequent surveys." *Id*. § 1395*l*(t)(14)(D)(i)-(ii). Subparagraph (D) further includes a provision dealing with "survey requirements," mandating that the GAO and HHS surveys "shall have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug." *Id*. § 1395*l*(t)(14)(D)(iii). And a later clause details how acquisition-cost variations by hospital group are to be

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

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

Finally, the majority repeatedly justifies its reading by reference to the policy benefits of the agency's rate reductions and the reasonableness of the agency's alternative data and resulting estimates. *See, e.g.*, Maj. Op. at 828, 829, 830, 831, 832–33. The majority views it as relevant "backdrop," for example, that one result of the agency's proposed cuts will be to lower copayments for Medicare beneficiaries served by 340B hospitals, and to avoid the prospect of any beneficiary possibly paying more in a copayment than the hospital paid to buy the prescribed drugs. *Id.* at 829; *but see* HHS Off. of Inspector Gen., OEI-12-14-00030, Part B Payments for

340B-Purchased Drugs 9 n.26 (Nov. 2015) (OIG Report) (noting that 340B hospitals "may waive all or part of the beneficiary's coinsurance"). And the majority notes HHS's worries that 340B hospitals might overprescribe drugs that bring reimbursement revenue. *See* Maj. Op. at 822–23; *but see* U.S. Gov't Accountability Off., GAO-15-442, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals 31 (June 2015) (noting HHS's view that "higher spending for Part B drugs at 340B hospitals" might "lead to better clinical outcomes" for patients served by those safety-net hospitals, who often are in "meaningful[ly]" poorer health than other patients). The majority also expresses confidence that the agency examined "data of undisputed reliability," Maj. Op. at 833, "acted on that data in a cautious way," *id*., and implemented a "fair, or even conservative, measure of the reduction needed to bring payments to those hospitals in parity with their costs to obtain the drugs," *id*. at 829. "In those circumstances," the majority declares, "HHS reasonably concluded that it need not continue subsidizing 340B providers with Part B (i.e. taxpayer) funds and Medicare beneficiaries' copayments." *Id*. at 833.

Those circumstances would perhaps be relevant were this a challenge to the agency's rules as arbitrary and capricious. But concerns about the program's effects, and confidence in the agency's care in using data other than those the statute requires, cannot somehow authorize the agency to do what the statute does not. As the Supreme Court has held, an "agency has no power to 'tailor' legislation to bureaucratic policy goals by rewriting unambiguous statutory terms." *Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302, 325, 134 S.Ct. 2427, 189 L.Ed.2d 372

(2014). And, unmoored from the statute's express data-quality requirements, the asserted reliability of the quite different data HHS gathered here provides no assurance for its next rulemaking. Whether HHS's actions might have perceptible policy advantages does not affect whether the statute authorizes what the agency has done.

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

The challenged rules took a major bite out of 340B hospitals' funding. Often operating at substantial

losses, 340B hospitals rely on the revenue that Medicare Part B provides in the form of standard drug-reimbursement payments that exceed those hospitals' acquisition costs. 340B hospitals "have used the additional resources to provide critical healthcare services to communities with underserved populations that could not otherwise afford these services." Hospitals Br. 9 (citing GAO Report at 17-18); *see also Cares Cmty. Health v. HHS*, 944 F.3d 950, 955 (D.C. Cir. 2019). Although stakeholders have debated "whether statutory changes should be made to enable Medicare and/or Medicaid to share in these savings," OIG Report 2, Congress has not made any such change. And, as written, subparagraph (E) does not empower the Secretary to "adjust" away from 340B hospitals substantial annual revenue they garner under the separate, unchallenged 340B statute to provide care to underserved communities.

The net effect of HHS's 2018 and 2019 OPPS rules is to redistribute funds from financially strapped, public and nonprofit safety-net hospitals serving vulnerable populations—including patients without any insurance at all—to facilities and individuals who are relatively better off. If that is a result that Congress intended to authorize, it remains free to say so. But because the statute as it is written does not permit the challenged rate reductions, I respectfully dissent.

APPENDIX B

No. 18-CV-2084

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, et al., Plaintiffs,

v.

ALEX M. AZAR II, United States Secretary of Health and Human Services, et al., Defendants.

[Filed] December 27, 2018

MEMORANDUM OPINION

DENYING DEFENDANTS' MOTION TO DISMISS; GRANTING PLAINTIFFS' MOTION FOR A PERMANENT INJUNCTION; DENYING AS MOOT PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

RUDOLPH CONTRERAS, United States District Judge

I. INTRODUCTION

This action concerns whether the Department of Health and Human Services ("HHS") acted lawfully when it reduced Medicare payments worth billions of dollars to private institutions, to correct what it views as a fundamental misalignment of Medicare programs. Plaintiffs, a group of hospital associations and non-profit hospitals,[1] contend that HHS exceeded its

[1] The hospital association Plaintiffs ("Association Plaintiffs") are the American Hospital Association ("AHA"), the Association of American Medical Colleges ("AAMC"), and America's Essential Hospitals ("AEH"). Compl. ¶¶ 4–9. The non-profit hospital Plaintiffs ("Hospital Plaintiffs") are the Henry Ford Health System ("Henry Ford"), Northern Light Health ("Northern Light")—formerly Eastern Maine Healthcare Systems—and

statutory authority when it cut Medicare reimbursement rates for certain outpatient pharmaceutical drugs by nearly 30%. Defendants, HHS and its Secretary, contend that the rate adjustment was statutorily authorized and necessary to close the gap between the discounted rates at which Plaintiffs obtain the drugs at issue—through Medicare's "340B Program"—and the higher rates at which Plaintiffs were previously reimbursed for those drugs under a different Medicare framework.

Presently before this Court are Plaintiffs' motion for a preliminary or permanent injunction and Defendants' motion to dismiss. Among other relief, Plaintiffs ask the Court to vacate the Secretary's rate reduction, require the Secretary to apply previous reimbursement rates for the remainder of this year, and require the Secretary to pay Plaintiffs the difference between the reimbursements they have received this year under the new rates and the reimbursements they would have received under the previous rates. Defendants contest the Court's ability to hear the case, arguing that Congress has shielded the Secretary's action from judicial review, that the Secretary's boundless discretion precludes review, and that Plaintiffs' failure to exhaust their administrative remedies is fatal. Defendants also argue that the Secretary's action was well within his statutory authority.

For the reasons stated below, the Court concludes that it has jurisdiction to provide relief in this case and that Plaintiffs are entitled to such relief. While in

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Fletcher Hospital, Inc., doing business as Park Ridge Health ("Park Ridge"). Compl. ¶¶ 10–18; Notice of Party Name Change at 1, ECF No. 21 (stating that Eastern Maine Healthcare Systems has changed its name to Northern Light Health).

certain circumstances the Secretary could implement the rate reduction at issue here, he did not have statutory authority to do so under the circumstances presented. Moreover, because the parties have fully and vigorously debated the merits of Plaintiffs' claims, which turn on questions of law, not fact, the Court concludes that further merits briefing would be redundant and inefficient. However, while Plaintiffs are entitled to *some* relief, the potentially drastic impact of this Court's decision on Medicare's complex administration gives the Court pause. Accordingly, the Court grants Plaintiffs' motion for a permanent injunction and orders supplemental briefing on the question of a proper remedy.

II. BACKGROUND AND PROCEDURAL HISTORY

A. Medicare

Medicare is a federal health insurance program for the elderly and disabled, established by Title XVIII of the Social Security Act. *See* 42 U.S.C. §§ 1395–1395*lll*. Medicare Part A provides insurance coverage for inpatient hospital care, home health care, and hospice services. *Id.* § 1395c. Medicare Part B provides supplemental coverage for other types of care, including outpatient hospital care. *Id.* §§ 1395j, 1395k. HHS's Outpatient Prospective Payment System ("OPPS"), which directly reimburses hospitals for providing outpatient services and pharmaceutical drugs to Medicare beneficiaries, is a component of Medicare Part B. *See id.* at 1395*l*(t). OPPS requires "payments for outpatient hospital care to be made based on predetermined rates." *Amgen, Inc. v. Smith*, 357 F.3d 103, 106 (D.C. Cir. 2004). Under this system, HHS—through the Centers for Medicare and Medicaid Services ("CMS")—sets annual OPPS reimbursement rates prospectively, before a given year,

rather than retroactively based on covered hospitals' actual costs during that year.[2]

B. The 340B Program

In 1992, Congress established what is now commonly referred to as the "340B Program." Veterans Health Care Act of 1992, Pub L. No. 102-585, § 602, 106 Stat. 4943, 4967–71. The 340B Program allows participating hospitals and other health care providers ("covered entities") to purchase certain "covered outpatient drugs" from manufacturers at or below the drugs' "maximum" or "ceiling" prices, which are dictated by a statutory formula and are typically significantly discounted from those drugs' average manufacturer prices. *See* 42 U.S.C. § 256b(a)(1)–(2).[3] Put more simply, this Program "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health care facilities." *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 113, 131 S.Ct. 1342, 179 L.Ed.2d 457 (2011). It is intended to enable covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992); *see also* Medicare Program: Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs ("2018 OPPS Rule"), 82 Fed. Reg. 52,356, 52,493 & 52,493 n.18 (Nov. 13, 2017) (codified at 42 C.F.R. pt. 419).[4] Im-

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[2] CMS is a component of HHS and is overseen by the Secretary. *See* HHS Organizational Chart, HHS (Nov. 14, 2018), https://www.hhs.gov/about/agencies/orgchart/index.html.

[3] The manufacturers must offer these discounts as a condition of their participation in the Medicaid program. *Id.* § 256b(a)(3).

[4] While the regulations setting 340B drug reimbursement rates, including the 2018 OPPS Rule, are technically issued by CMS,

portantly, and as discussed in greater detail below, the 340B Program allows covered entities to purchase certain drugs at steeply discounted rates, and then seek reimbursement for those purchases under Medicare Part B at the rates established by OPPS.

C. Medicare Reimbursement Rates for 340B Drugs

The statutory provision governing OPPS, codified at 42 U.S.C. § 1395*l*(t), imposes the framework by which HHS must set prospective Medicare reimbursement rates. Among other requirements under that provision, HHS must determine how much it will pay for "specified covered outpatient drugs" ("SCODs") provided by hospitals to Medicare beneficiaries. 42 U.S.C. § 1395*l*(t)(14)(A). SCODS are a subset of "separately payable drugs," which are not bundled with other Medicare Part B outpatient services and are therefore reimbursed on a drug-by-drug basis. *See id.* § 1395*l*(t)(14)(B). And as noted, the 340B Program covers certain separately payable drugs, some of which are SCODs and some of which are not. 82 Fed. Reg. at 52,496; Defs.' Mot. to Dismiss ("Defs.' Mot.") at 5, ECF No. 14.

Congress has authorized two potential methodologies for setting SCOD rates.[5] First, if HHS has cer-

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see 82 Fed. Reg. at 52,356, for simplicity's sake the Court will refer to them as HHS regulations.

[5] While not all separately payable drugs qualify as SCODs, to which the payment methodologies of § 1395*l*(t)(14)(A) apply, "[HHS] applies these statutory payment methodologies to *all* separately payable drugs, even those that are *not* SCODS." Defs.' Mot. at 6 n.1 (citing 77 Fed. Reg. at 68,383); *see also* 82 Fed. Reg. at 52,509 (stating that the rate reduction will apply to "separately payable Part B drugs ... that are acquired through the 340B Program"). Thus, the methodology at issue here applies to all 340B drugs, not just SCODS covered by the 340B

tain "hospital acquisition cost survey data," it must set the reimbursement rate for each SCOD according to "the *average acquisition cost* for the drug for that year ... as determined by the Secretary taking into account" the survey data. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I) (emphasis added). Second, if the survey data is not available, each SCOD's reimbursement rate must be set equal to "the *average price* for the drug in the year established under ... section 1395w-3a ... as calculated and adjusted by the Secretary as necessary for purposes of this paragraph." *Id.* § 1395*l*(t)(14)(A)(iii)(II) (emphasis added). Section 1395w-3a, in turn, provides that a given drug's default reimbursement rate is the average sales price ("ASP") of the drug plus 6%.[6] *Id.* § 1395w-3a(b)(1)(A)–(B); *see also* Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs ("2012 OPPS Rule"), 77 Fed. Reg. 68,210, 68,387 (Nov. 15, 2012) (codified at 42 C.F.R. pt. 419) (adopting a reimbursement rate of ASP plus 6% for covered drugs in light of the "continuing uncertainty about the full

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Program. This "is a policy choice rather than a statutory requirement." Defs.' Mot. at 6 n.1 (quoting 77 Fed. Reg. at 68,383). Because neither party raises the question of whether the Secretary's statutory authority to alter reimbursement rates for SCODs also governs the Secretary's "policy choice" to apply the same rates to non-SCOD, separately payable drugs, the Court will not address that question here.

[6] Both parties seem to agree that § 1395w-3a sets a default payment rate of 106% of a given drug's volume-weighted average sales price, and that this rate is the presumptive reimbursement rate under § 1395*l*(t)(14)(A)(iii)(II). *See* Defs.' Mot. at 6; Pls.' Mem. Supp. Mot. Prelim. & Permanent Inj. ("Pls.' Mem.") at 3–4, ECF No. 2-1; 82 Fed. Reg. at 52,501 (acknowledging ASP plus 6% as the "statutory benchmark").

cost of pharmacy overhead and acquisition cost" and the concern that deviating from the default rate "may not appropriately account for average acquisition and pharmacy overhead cost ....").

D. The 340B-Medicare Payment Gap

As explained above, hospitals participating in the 340B Program purchase 340B drugs at steeply discounted rates, and when those hospitals prescribe the 340B drugs to Medicare beneficiaries they are reimbursed by HHS at OPPS rates. Before 2018, the relevant OPPS rate for 340B drugs was ASP plus 6%. *See, e.g.*, 77 Fed. Reg. at 68,387. This rate resulted in a significant gap between what hospitals paid for 340B drugs and what they received in Medicare reimbursements for those drugs, because the 340B Program allowed participating hospitals to buy the drugs at a far lower rate than ASP plus 6%. *See* 82 Fed. Reg. at 52,495 (citing an Office of Inspector General report finding that this margin "allowed covered entities to retain approximately $1.3 billion in 2013"). Plaintiffs allege that the revenues derived from this payment gap have "helped [Plaintiffs] provide critical services to their communities, including underserved populations in those communities." Pls.' Mem. Supp. Mot. Prelim. & Permanent Inj. ("Pls.' Mem.") at 31 (citing Aff. of Tony Filer ("Northern Light Aff.") ¶ 13, Pls.' Mot. Prelim. & Permanent Inj. ("Pls.' Mot.") Ex. V, ECF No. 2-25; Aff. of Robin Damschroder ("Henry Ford Aff.") ¶¶ 15–18, Pls.' Mot. Ex. W, ECF No. 2-26; Aff. of Wendi Barber ("Park Ridge Aff.") ¶¶ 15–17, Pls.' Mot. Ex. X, ECF No. 2-27), ECF No. 2-1. They further allege that the narrowing of this gap "threatens these critical services" because Plaintiffs may be unable to fund the services with lower reimbursement amounts. *Id.* (citing Northern Light Aff. ¶¶ 14–19; Henry Ford Aff. ¶¶ 19–20; Park

Ridge Aff. ¶¶ 18–19).

E. The 2018 OPPS Rule

In mid-2017, HHS proposed reducing the Medicare reimbursement rates for SCODs and other separately payable drugs acquired through the 340B Program from ASP plus 6% to ASP minus 22.5%. Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 33,558, 33,634 (Jul. 20, 2017) (codified at 42 C.F.R. pt. 419). HHS provided a detailed explanation of why it believed this rate reduction was necessary. First, HHS noted that several recent studies have confirmed the large "profit" margin created by the difference between the price that hospitals pay to acquire 340B drugs and the price at which Medicare reimburses those drugs. *See id.* at 33,632–33. Second, HHS stated that because of this "profit" margin, HHS was "concerned that the current payment methodology may lead to unnecessary utilization and potential overutilization of separately payable drugs." *Id.* at 33,633. It cited, as an example of this phenomenon, a 2015 Government Accountability Office Report finding that Medicare Part B drug spending was substantially higher at 340B hospitals than at non-340B hospitals. *Id.* at 33,632–33. The data indicated that "on average, beneficiaries at 340B ... hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at the other non-340B hospitals in GAO's analysis." *Id.* at 33,633. Third, HHS expressed concern "about the rising prices of certain drugs and that Medicare beneficiaries, including low-income seniors, are responsible for paying 20 percent of the Medicare payment rate for these drugs," rather than the lower 340B rate paid by the covered hospitals.

Thus, HHS concluded that lowering the Medicare reimbursement rates for 340B Program drugs would "make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs[,] while recognizing the intent of the 340B program to allow covered entities, including eligible hospitals to stretch scarce resources while continuing to provide access to care." *Id.* HHS, however, did not have the data necessary to "precisely calculate the price paid by 340B hospitals for [any] particular covered outpatient drug." *Id.* at 33,634. For that reason, HHS estimated 340B hospitals' drug acquisition costs based on those hospitals' average 340B discount. *See id.* Specifically, HHS proposed applying the average 340B discount estimated by the Medicare Payment Advisory Commission ("MedPAC")—22.5% of a covered drug's average sales price—to govern the 340B drug reimbursement rates. *See id.* HHS believed that MedPAC's estimate was appropriate and, in fact, conservative because the "actual average discount experienced by 340B hospitals is likely much higher than 22.5[%]." *Id.*

In addition to explaining its rationale and methodology for reducing the 340B reimbursement rates to ASP minus 22.5%, HHS stated its purported statutory basis for taking that action. Because HHS did not "have hospital acquisition cost data for 340B drugs," 82 Fed. Reg. at 33,634, it could not invoke its express authority under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I) to set rates according to the drugs' average acquisition costs. Instead, HHS invoked its authority under § 1395*l*(t)(14)(A)(iii)(II), "which states that if hospital acquisition cost data are not available, the payment for an applicable drug shall be the average price for the drug ... as calculated and adjusted by the Secretary as necessary." 82 Fed. Reg. at 33,634. HHS

would thus "adjust the applicable payment rate as necessary" for separately payable drugs acquired under the 340B program, "to ASP minus 22.5[%]." *Id.* HHS stated that the adjustment was necessary because ASP minus 22.5% "better represents the average acquisition cost for [340B] drugs and biologicals." *Id.*

Plaintiffs strongly opposed the proposed 2018 340B reimbursement rates, and they voiced their opposition in comments to the proposed rule. Plaintiffs argued primarily that HHS did not have the legal authority to change the 340B reimbursement rates in the manner proposed, and that reducing reimbursement rates by nearly 30% would severely impact covered entities' ability to provide critical healthcare programs to their communities, particularly to their underserved patients. *See generally* AHA Comments, Pls.' Mot. Ex. C, ECF No. 2-6; AAMC Comments, Pls.' Mot. Ex. D, ECF No. 2-7; AEH Comments, Pls.' Mot. Ex. E, ECF No. 2-8; Henry Ford Comments, Pls.' Mot. Ex. F, ECF No. 2-9; Northern Light Comments, Pls.' Mot. Ex. G, ECF No. 2-9.

Nevertheless, in November 2017, HHS adopted the proposed 340B reimbursement rate reduction. *See* 82 Fed. Reg. at 52,362. In issuing its final rule, HHS responded to Plaintiffs' arguments about its authority to change Medicare reimbursement rates for 340B drugs. *See id.* at 52,499. HHS argued that the Secretary's authority under § 1395*l*(t)(14)(A)(iii)(II) to "calculate and adjust" drug payments "as necessary for purposes of this paragraph" gave the Secretary broad discretion, including discretion to adjust Medicare payment rates according to whether or not certain drugs were acquired at a significant discount. *Id.* HHS also disagreed with commenters that the authority to "calculate and adjust" drug rates as neces-

sary was limited to "minor changes"; it saw "no evidence in the statute to support that position." *Id.* at 52,500. Accordingly, HHS used its purported authority "to apply a downward adjustment that is necessary to better reflect acquisition costs of [340B] drugs." *Id.* The 340B reimbursement rates dictated by this rule, and its ASP minus 22.5% methodology, became effective on January 1, 2018. *Id.* at 52,356.

F. Procedural History

In late 2017, Plaintiffs raised an Administrative Procedure Act ("APA") challenge to the 2018 OPPS Rule's 340B provisions. *See generally* Compl., *Am. Hosp. Ass'n v. Hargan ("AHA I")*, No. 17-2447, ECF No. 1 (D.D.C.). However, this Court dismissed the action because Plaintiffs failed "to present any concrete claim for reimbursement to the Secretary for a final decision[,]" which is "a fundamental jurisdictional impediment to judicial review under 42 U.S.C. § 405(g)." *AHA I v. Hargan*, 289 F.Supp.3d 45, 55 (D.D.C. 2017).[7] Both parties agree that Plaintiffs have now presented reimbursement claims covered by the 2018 OPPS Rule, Defs.' Mot. at 15 n.6; Pls.' Mem. at 11–12, and Plaintiffs have re-filed suit asserting nearly identical challenges to the rule, *see generally* Compl., ECF No. 1.

Plaintiffs allege that the Secretary's reimbursement rate reduction for 340B drugs violates the APA and the Social Security Act because it is "arbitrary and capricious and contrary to law, and in excess of the Secretary's authority under the Medicare provisions of the Social Security Act." Compl. ¶¶ 68–69 (citing 42 U.S.C. §§ 405(g), 1395ii, 1395*l*(t)(14)(A)(iii);

[7] This decision was recently affirmed by the D.C. Circuit. *See Am. Hosp. Ass'n v. Azar ("AHA II")*, 895 F.3d 822, 828 (D.C. Cir. 2018).

5 U.S.C. § 706(2)). In conjunction with filing their complaint, Plaintiffs have moved for either a preliminary injunction or a permanent injunction under Rule 65 of the Federal Rules of Civil Procedure. Pls.' Mot. at 1, ECF No. 2. Plaintiffs request that this Court direct the Secretary to:

> [S]trike the changes in the payment methodology for 340B drugs from the OPPS Rule and use the methodology used in calendar year 2017 for all future 340B Program payments in 2018; pay the Hospital Plaintiffs and all provider members of the Association Plaintiffs the difference between the payments for 340B drugs that they received under the 2018 OPPS Rule and the payments they would have received under the 2017 OPPS Rule; and conform the payment methodology that they use for 340B drugs in calendar year 2019 and subsequent years to the requirements of the Social Security Act, and specifically not to use acquisition cost to calculate payment rates unless Defendants have complied with 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I).

Pls.' Mem. at 35. The government has opposed Plaintiffs' motion and filed a motion to dismiss the action pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). *See generally* Defs.' Mot. The parties' motions are fully briefed and ripe for this Court's consideration.

III. LEGAL STANDARDS

A. Federal Rule of Civil Procedure 12(b)(1)

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(1) "presents a threshold challenge to the Court's jurisdiction." *Curran v. Holder,* 626 F.Supp.2d 30, 32 (D.D.C. 2009) (quoting *Agrocom-*

plect, AD v. Republic of Iraq, 524 F.Supp.2d 16, 21 (D.D.C. 2007)). "It is to be presumed that a cause lies outside [the federal courts'] limited jurisdiction, and the burden of establishing the contrary rests upon the party asserting jurisdiction." *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377, 114 S.Ct. 1673, 128 L.Ed.2d 391 (1994) (citing *McNutt v. Gen. Motors Acceptance Corp.*, 298 U.S. 178, 182–83, 56 S.Ct. 780, 80 L.Ed. 1135 (1936); *Turner v. Bank of N.A.*, 4 U.S. (4 Dall.) 8, 11, 1 L.Ed. 718 (1799)). In determining whether the plaintiff has met this burden, a court must accept "the allegations of the complaint as true," *Banneker Ventures, LLC v. Graham*, 798 F.3d 1119, 1129 (D.C. Cir. 2015), and "construe the complaint 'liberally,' granting the plaintiff 'the benefit of all inferences that can be derived from the facts alleged,'" *Barr v. Clinton*, 370 F.3d 1196, 1199 (D.C. Cir. 2004) (quoting *Kowal v. MCI Commc'ns Corp.*, 16 F.3d 1271, 1276 (D.C. Cir.1994)). However, "the [p]laintiff's factual allegations in the complaint ... will bear closer scrutiny in resolving a 12(b)(1) motion than in resolving a 12(b)(6) motion for failure to state a claim." *Grand Lodge of Fraternal Order of Police v. Ashcroft*, 185 F.Supp.2d 9, 13–14 (D.D.C. 2001) (internal quotation marks omitted) (citing 5A Charles A. Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1350).

The Court must confirm its jurisdiction for each type of claim brought before it, including APA challenges. Indeed, while the "APA generally establishes a cause of action for those suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action," the "APA does not apply ... to the extent that ... statutes preclude judicial review." *Tex. All. for Home Care Servs. v. Sebelius*, 681 F.3d 402, 408 (D.C. Cir. 2012) (internal quotation

marks omitted) (quoting 5 U.S.C. § 701(a)(1); *Koretoff v. Vilsack*, 614 F.3d 532, 536 (D.C. Cir. 2010)). Similarly, courts lack jurisdiction over claims brought under the Social Security Act until the claimants have exhausted their administrative remedies and received final decisions from the Secretary regarding the issues underlying those claims. 42 U.S.C. § 405(g).

B. Federal Rule of Civil Procedure 12(b)(6)

The Federal Rules of Civil Procedure require that a complaint contain "a short and plain statement of the claim" to give the defendant fair notice of the claim and the grounds upon which it rests. Fed. R. Civ. P. 8(a)(2); *accord Erickson v. Pardus*, 551 U.S. 89, 93, 127 S.Ct. 2197, 167 L.Ed.2d 1081 (2007) (per curiam). A motion to dismiss under Rule 12(b)(6) does not test a plaintiff's ultimate likelihood of success on the merits; rather, it tests whether a plaintiff has properly stated a claim. *See Scheuer v. Rhodes*, 416 U.S. 232, 236, 94 S.Ct. 1683, 40 L.Ed.2d 90 (1974), *abrogated on other grounds by Harlow v. Fitzgerald*, 457 U.S. 800, 102 S.Ct. 2727, 73 L.Ed.2d 396 (1982). A court considering such a motion presumes that the complaint's factual allegations are true and construes them liberally in the plaintiff's favor. *See, e.g.*, *United States v. Philip Morris, Inc.*, 116 F.Supp.2d 131, 135 (D.D.C. 2000).

To survive a motion to dismiss, a complaint need not contain all elements of a prima facie case. *See Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 511–14, 122 S.Ct. 992, 152 L.Ed.2d 1 (2002); *Bryant v. Pepco*, 730 F.Supp.2d 25, 28–29 (D.D.C. 2010). However, the "complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009) (quoting

Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007)). This means that a plaintiff's factual allegations "must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Twombly*, 550 U.S. at 555, 127 S.Ct. 1955 (citations omitted). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements," are therefore insufficient to withstand a motion to dismiss. *Iqbal*, 556 U.S. at 678, 129 S.Ct. 1937. A court need not accept a plaintiff's legal conclusions as true, *see id.*, nor must a court presume the veracity of legal conclusions couched as factual allegations, *see Twombly*, 550 U.S. at 555, 127 S.Ct. 1955.

C. Administrative Procedure Act

The APA governs the conduct of federal administrative agencies. *See* 5 U.S.C. §§ 101–913. It permits a court to "compel agency action unlawfully withheld or unreasonably delayed," *id.*§ 706(1), and to "hold unlawful and set aside agency action, findings, and conclusions found to be ... arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," *id.*§ 706(2)(A). It provides for judicial review of a "final agency action for which there is no other adequate remedy in a court[,]" *id.* § 704, except when "statutes preclude judicial review" or the "agency action is committed to agency discretion by law[,]" *id.* § 701(a).

IV. ANALYSIS

By and large, the Secretary's arguments for dismissal concern whether this Court has jurisdiction to hear Plaintiffs' allegations. First, the Secretary argues that Plaintiffs' failure to exhaust their adminis-

trative remedies forecloses judicial review. Second, the Secretary argues that certain Medicare provisions preclude the Court's review. Third, the Secretary argues that the decision to reduce 340B drug reimbursement rates was "committed to agency discretion by law," and therefore outside the scope of APA review. Fourth, the Secretary argues that he had clear statutory authority to "adjust" 340B drug reimbursement rates. The Court addresses each argument in turn and concludes that the potential jurisdictional obstacles are not fatal here, and that the Secretary's action exceeded his authority to "adjust" rates. Accordingly, Plaintiffs are entitled to relief, to be determined after the Court considers the parties' supplemental briefing.

A. Plaintiffs Need Not Exhaust Their Administrative Remedies

The Secretary argues that the Court lacks jurisdiction because Plaintiffs failed to exhaust their administrative remedies prior to filing suit. In evaluating this argument, the Court must consider the mechanism by which Plaintiffs have brought this suit. Plaintiffs assert their claims under a specific Social Security Act provision, 42 U.S.C. § 405(g),[8] which is the proper provision by which to raise an APA chal-

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[8] This provision states, in relevant part, that:

> Any individual, after any *final decision* of the [Secretary] made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action commenced within sixty days after the mailing to him of notice of such decision or within such further time as the Commissioner of Social Security may allow. Such action shall be brought in the district court of the United States ....

42 U.S.C. § 405(g) (emphasis added).

lenge to a Medicare-related agency action. 42 U.S.C. §§ 405(h),[9] 1395ii; *Heckler v. Ringer*, 466 U.S. 602, 615, 104 S.Ct. 2013, 80 L.Ed.2d 622 (1984); *Am. Hosp. Ass'n v. Azar ("AHA II")*, 895 F.3d 822, 825 (D.C. Cir. 2018). And as noted, judicial review of a claim brought under § 405(g) is foreclosed until the claimants have exhausted their administrative remedies and received a final decision from the Secretary. 42 U.S.C. § 405(g); *Mathews v. Eldridge*, 424 U.S. 319, 328, 96 S.Ct. 893, 47 L.Ed.2d 18 (1976); *AHA II*, 895 F.3d at 826. Although the concept of "exhaustion" exists under typical administrative law principles, the Supreme Court has explained that § 405(h)'s channeling mechanism imposes an even more exact-

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[9] This provision states that:

> The findings and decision of the [Secretary] after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency *except as herein provided*. No action against the United States, the [Secretary], or any officer or employee thereof shall be brought under section 1331 or 1346 [federal defendant jurisdiction] of title 28 to recover on any claim arising under this subchapter.

42 U.S.C. § 405(h) (emphasis added). The Supreme Court has interpreted § 405(h) to require that Medicare claims be pursued through the special review system laid out in § 405(g), rather than through other judicial mechanisms that may otherwise be available. *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 8–15, 120 S.Ct. 1084, 146 L.Ed.2d 1 (2000). 42 U.S.C. § 1395ii expressly applies § 405(h) to claims arising under the Medicare provisions of the Social Security Act, and the D.C. Circuit has reasoned that "expressly incorporating the judicial-review bar in § 405(h) also effectively incorporates the exception 'herein provided' in § 405(g)." *Am. Hosp. Ass'n v. Azar ("AHA II")*, 895 F.3d 822, 825 (D.C. Cir. 2018) (citing *United States v. Blue Cross & Blue Shield of Ala., Inc.*, 156 F.3d 1098, 1103 (11th Cir. 1998)).

ing exhaustion requirement. *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 12, 120 S.Ct. 1084, 146 L.Ed.2d 1 (2000) ("[T]he bar of § 405(h) reaches beyond ordinary administrative law principles of 'ripeness' and 'exhaustion of administrative remedies'...."). Indeed, § 405(h) "demands the 'channeling' of virtually all legal attacks through the agency." *Id.* at 13, 120 S.Ct. 1084.

Section 405(g)'s review channeling mechanism contains two elements. First, the provision contains a jurisdictional, non-waivable "requirement that a claim for benefits shall have been presented to the Secretary." *Eldridge*, 424 U.S. at 328, 96 S.Ct. 893. Second, the provision contains a non-jurisdictional "requirement that the administrative remedies prescribed by the Secretary be exhausted." *Id.* This requirement may be waived by the agency or a court.[10] *See id.* at 330, 96 S.Ct. 893. Together, these requirements serve the practical purpose of "assur[ing] the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes." *Ill. Council*, 529 U.S. at 13, 120 S.Ct. 1084. Because, as noted, both parties agree that Plaintiffs have satisfied § 405(g)'s presentment requirement, the Court must consider whether Plaintiffs may be excused from exhausting their administrative remedies.

"A court may waive the exhaustion requirements

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[10] In arguing that Plaintiffs must fully exhaust their administrative remedies, the Secretary notes that the Social Security Act provides an "abbreviated review process" by which a claimant may request expedited judicial review. Defs.' Mot. at 27 (citing 42 U.S.C. § 1395ff(b)(2)(A); 42 C.F.R. § 405.990). However, the Secretary does not explain why that provision would prevent a court from waiving 42 U.S.C. § 405(g)'s exhaustion requirement when appropriate, nor does the Secretary cite case law establishing that principle.

of § 405(g) when: (1) the issue raised is entirely collateral to a claim for payment; (2) plaintiffs show they would be irreparably injured were the exhaustion requirement enforced against them; [or] (3) exhaustion would be futile." *Triad at Jeffersonville I, LLC v. Leavitt,* 563 F.Supp.2d 1, 16 (D.D.C. 2008) (citing *Bowen v. City of New York*, 476 U.S. 467, 483–85, 106 S.Ct. 2022, 90 L.Ed.2d 462 (1986)); *see also Tataranowicz v. Sullivan*, 959 F.2d 268, 274 (D.C. Cir. 1992). In such situations, a "district court may, in its discretion, excuse exhaustion if 'the litigant's interests in immediate judicial review outweigh the government's interests in the efficiency or administrative autonomy that the exhaustion doctrine is designed to further.'" *Avocados Plus Inc. v. Veneman,* 370 F.3d 1243, 1247 (D.C. Cir. 2004) (quoting *McCarthy v. Madigan,* 503 U.S. 140, 146, 112 S.Ct. 1081, 117 L.Ed.2d 291 (1992)).

Here, Plaintiffs rely solely on what they claim is the futility of exhausting their administrative remedies. "Futility may serve as a ground for excusing exhaustion, either on its own or in conjunction with [the] other factors ...." *Nat'l Ass'n for Home Care & Hospice, Inc. v. Burwell*, 77 F.Supp.3d 103, 110 (D.D.C. 2015); *see also Tataranowicz*, 959 F.2d at 274 (waiving the plaintiffs' § 405(g) exhaustion requirement as futile, without recourse to other factors). That said, the ordinary standard for futility in administrative law cases is inapplicable in Medicare cases. *See Weinberger v. Salfi*, 422 U.S. 749, 766, 95 S.Ct. 2457, 45 L.Ed.2d 522 (1975) (stating that § 405(g) is "more than simply a codification of the judicially developed doctrine of exhaustion, and may not be dispensed with merely by a judicial conclusion of futility"). Instead, the Court must consider whether judicial resolution of the issue will interfere with the

agency's efficient functioning, deny the agency the ability to self-correct, or deprive the Court of the benefits of the agency's expertise and an adequate factual record. *Tataranowicz*, 959 F.2d at 275 (citing *Salfi*, 422 U.S. at 765, 95 S.Ct. 2457).

Applying these principles, the futility of requiring Plaintiffs to exhaust their administrative remedies in this case is readily apparent. The Secretary does not argue that proceeding with Plaintiffs' lawsuit would somehow "interfere with the agency's efficient functioning."[11] Nor does the Secretary contend that this dispute must be resolved based on facts that would be more fully developed through the administrative process. Indeed, as the Secretary recognizes, Plaintiffs' claim "raises pure legal questions regarding the scope of the Secretary's statutory authority ...." Defs.' Mot. at 28 n.10. Finally, there is no reason to believe that the agency might overturn the regulation, should Plaintiffs be given additional opportunities to raise their arguments through the administrative process. In the notice and comment proceedings, HHS specifically considered and rejected the arguments that Plaintiffs now raise here. *See* 82 Fed. Reg. at 52,499–502 (asserting that the Secretary could reduce SCOD reimbursement rates pursuant to the Secretary's authority to "adjust" reimbursement rates under 42 U.S.C § 1395*l*(t)(14)(A)(iii)(II), and rejecting Plaintiffs' claims to the contrary). Moreover, HHS's proposed 2019 OPPS Rule continues to reimburse 340B drugs at ASP minus 22.5%, indicating HHS's commitment to its position here. Medicare Program:

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[11] In fact, Plaintiffs assert, and the Secretary does not contest, that clarity regarding the 340B reimbursement rates will *improve* the agency's efficiency by resolving a large portion of the agency's administrative appeal workload raising the same issues addressed by this opinion. *See* Pls.' Mem. Ex. T at 2 n.2.

Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs ("Proposed 2019 OPPS Rule"), 83 Fed. Reg. 37,046, 37,122 (July 31, 2018) (to be codified at 42 C.F.R. pt. 419).

In fact, as Plaintiffs point out and the Secretary does not dispute, because the 2018 OPPS Rule is final, it appears that no administrative review body would even have authority to alter or deviate from its requirements, due to the Rule's binding nature on HHS. Indeed, HHS regulations provide that "[a]ll laws *and regulations* pertaining to the Medicare and Medicaid programs ... are binding on ALJs and attorney adjudicators, and the [Medicare Appeals] Council." 42 C.F.R. § 405.1063(a) (emphasis added); *see also* HHS Expedited Access to Judicial Review Ruling at 6, ECF No. 19-1 (stating that "neither the ALJ nor the [Medicare Appeals] Council has the authority to find the 2018 OPPS Rule invalid").

When faced with similar circumstances, the Supreme Court and other courts in this jurisdiction have waived the Social Security Act's exhaustion requirement.[12] *See Mathews v. Diaz*, 426 U.S. 67, 76–77, 96 S.Ct. 1883, 48 L.Ed.2d 478 (1976) (treating, for jurisdictional purposes, the Secretary's "stipulat[ion] that no facts were in dispute, that the case was ripe for disposition by summary judgment, and that the only issue before the District Court was the constitutionality of the statute ... as tantamount to a

[12] Because the Court concludes that Plaintiffs' exhaustion of their administrative remedies here would be futile, it need not consider Plaintiffs' argument that they *have* exhausted their administrative remedies with respect to certain claims for reimbursement. *See* Pls.' Opp'n Defs.' Mot. ("Pls.' Opp'n") at 11–12, ECF No. 16.

decision denying the application and as a waiver of the exhaustion requirements" because the "constitutional question [was] beyond the Secretary's competence"); *Tataranowicz*, 959 F.2d at 274 (excusing exhaustion requirement on futility grounds where "the Secretary g[ave] no reason to believe that the agency machinery might accede to plaintiffs' claims"); *Nat'l Ass'n for Home Care & Hospice*, 77 F.Supp.3d at 112 (excusing exhaustion requirement on futility grounds because plaintiff's "statutory claim—that the Secretary exceeded her authority under the [Affordable Care Act] in promulgating [a rule]—[was] a purely legal challenge to the agency's established interpretation of the Medicare Act"); *Hall v. Sebelius*, 689 F.Supp.2d 10, 23–24 (D.D.C. 2009) (stating that "exhaustion may be excused where 'an agency has adopted a policy or pursued a practice of general applicability that is contrary to the law'" (quoting *DL v. District of Columbia,* 450 F.Supp.2d 11, 17 (D.D.C. 2006)). The Court does the same here. Because Plaintiffs have presented claims for reimbursement to the Secretary under the 2018 OPPS Rule, and because Plaintiffs' exhaustion of their administrative remedies would be futile, the Court waives Plaintiffs' exhaustion requirement and exercises its subject matter jurisdiction under 42 U.S.C. § 405(g).

B. This Court Is Not Precluded From Evaluating Plaintiffs' *Ultra Vires* Claim

The Secretary also argues that the Court is precluded by certain Medicare provisions from hearing Plaintiffs' suit. Again, the precise mechanism by which Plaintiffs have brought this suit is key to the Court's analysis. Although, as discussed above, this Court has jurisdiction under § 405(g) to hear Plaintiffs' action, Plaintiffs ultimately seek relief not under

§ 405(g), but under the APA. *See* Compl. ¶¶ 68–69. And under the APA, litigants may seek review of agency action, "except to the extent that [a] statute[ ] preclude[s] judicial review." 5 U.S.C. § 701(a)(1).

"There is a 'strong presumption that Congress intends judicial review of administrative action.'" *Amgen*, 357 F.3d at 111 (quoting *Bowen v. Mich. Acad. of Family Physicians,* 476 U.S. 667, 670, 106 S.Ct. 2133, 90 L.Ed.2d 623 (1986)). This presumption weighs "particularly strong[ly]" in favor of "judicial review of agency action taken in excess of delegated authority," as alleged here. *Id.* at 111–12 (citing *Leedom v. Kyne,* 358 U.S. 184, 190, 79 S.Ct. 180, 3 L.Ed.2d 210 (1958); *Aid Ass'n for Lutherans v. USPS*, 321 F.3d 1166, 1173 (D.C. Cir. 2003)). To overcome the presumption, there must be "'clear and convincing evidence' of a contrary legislative intent." *Abbott Labs. v. Gardner*, 387 U.S. 136, 141, 87 S.Ct. 1507, 18 L.Ed.2d 681 (1967) (quoting *Rusk v. Cort*, 369 U.S. 367, 380, 82 S.Ct. 787, 7 L.Ed.2d 809 (1962)), *overruled on other grounds by Califano v. Sanders,* 430 U.S. 99, 107, 97 S.Ct. 980, 51 L.Ed.2d 192 (1977). This analysis requires that the Court look to the statute's "express language ... the structure of the statutory schemes, its objectives, its legislative history, and the nature of the administrative action involved." *Block v. Cmty. Nutrition Inst.*, 467 U.S. 340, 345, 104 S.Ct. 2450, 81 L.Ed.2d 270 (1984).

The Secretary contends that three Medicare provisions preclude this Court's review of Plaintiffs' suit: 42 U.S.C. § 1395*l*(t)(12)(A), (t)(12)(C), and (t)(12)(E). Defs.' Mot. at 17. Subsection (t)(12)(A) states:

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

42 U.S.C. § 1395*l*(t)(12)(A) (emphasis added). Subsection (t)(12)(C) states that "[t]here shall be no administrative or judicial review under section 1395ff of this title, 1395*oo* of this title, or otherwise of ... *periodic adjustments* made under paragraph [9]."[13] *Id.* § 1395*l*(t)(12)(C) (emphasis added). And subsection (t)(12)(E) states:

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

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[13] Both parties agree that because of a scrivener's error, subsection (t)(12)(C) explicitly refers to "periodic adjustments made under paragraph [(t)](6)" but should refer to subsection (t)(9). *See* Defs.' Mot. at 6 n.2; Pls.' Opp'n Defs.' Mot. ("Pls.' Opp'n") at 7 n.6, ECF No. 16. Subsection (t)(9) requires that "[t]he Secretary ... review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph [(t)](2)." *Id.*§ 1395(t)(9)(A).

Id. § 1395*l*(t)(12)(E) (emphasis added).

It is uncontested that none of these subsections explicitly preclude judicial review of rate adjustments made under subsection (t)(14). *See* Pls.' Opp'n Defs.' Mot. ("Pls.' Opp'n") at 3, ECF No. 16. And Plaintiffs argue that without this explicit reference, there is no "clear and convincing evidence" that subsection (t)(12) is intended to preclude judicial review of the subsection (t)(14) rate adjustment at issue here. *Id.* a 3–4. The Secretary, on the other hand, argues that the separately payable drugs addressed by subsection (t)(14) fall within the OPPS payment "classification system" established under subsection (t)(2). Defs.' Mot. at 19. Therefore, according to the Secretary, adjustments to those drugs' reimbursement rates are "adjustments" described in subsection (t)(2), made to the agency's "fee schedule amount associated with particular ... drugs," review of which are precluded by subsections (t)(12)(A) and (t)(12)(E). *Id.* at 19–21; Reply Supp. Defs.' Mot. ("Defs.' Reply") at 4–5, ECF No. 20. The Secretary further argues that in finalizing the 2018 OPPS Rule, the Secretary explicitly invoked his subsection (t)(9) authority to periodically revise relative payment rates, review of which is precluded by subsection (t)(12)(C). Defs.' Mot. at 20 (citing 82 Fed. Reg. at 52,356); Defs.' Reply at 7–8.

The parties' preclusion arguments notwithstanding, because Plaintiffs claim that the Secretary acted in excess of his statutory authority—that he acted *ultra vires*—the Court need not resolve the parties' conflicting interpretations of subsection (t)(12). "[T]he case law in this circuit is clear that judicial review is available when an agency acts *ultra vires*." *Aid Ass'n for Lutherans*, 321 F.3d at 1173 (citing *Chamber of Commerce v. Reich*, 74 F.3d 1322, 1327–28 (D.C. Cir. 1996)). Thus, "the APA's stricture barring judicial

review 'to the extent that statutes preclude judicial review,' 'does not repeal the review of *ultra vires* actions' ...." *Id.* (quoting 5 U.S.C. § 701(a)(1); *Dart v. United States*, 848 F.2d 217, 224 (D.C. Cir. 1988)). Put simply, if the Secretary's 340B drug reimbursement rate reduction was an "adjustment" under subsection (t)(14), review of that adjustment is arguably precluded by subsection (t)(12). But if the Secretary's action was not an "adjustment," the Court may review it. *See Amgen*, 357 F.3d at 112 (section 1395*l*(t)(12)(A) prevents "review only of those 'other adjustments' that the Medicare Act authorizes the Secretary to make; in other words, the preclusion on review of 'other adjustments' extends no further than the Secretary's statutory authority to make them.").

Accordingly, to determine whether Plaintiffs raise an *ultra vires* claim falling outside the scope of subsection (t)(12)'s preclusion provisions, the Court must consider that claim's merits. *See id.* at 113 ("[T]he determination of whether the court has jurisdiction is intertwined with the question of whether the agency has authority for the challenged action, and the court must address the merits to the extent necessary to determine whether the challenged agency action falls within the scope of the preclusion on judicial review."); *Organogenesis Inc. v. Sebelius*, 41 F.Supp.3d 14, 20–21 (D.D.C. 2014) ("[I]f Apligraf qualifies as a SCOD, this Court may hear the case under the *ultra vires* doctrine of review," but "if Apligraf does not qualify as a SCOD, 42 U.S.C. § 1395*l*(t)(12)(A) precludes this Court's review."); *cf. COMSAT Corp. v. FCC*, 114 F.3d 223, 226–27 (D.C. Cir. 1997) (in determining whether a statutory provision precluded judicial review of an agency action, noting that such a determination "merges consideration of the legality of the [agency]'s action with consideration of th[e]

court's jurisdiction in cases in which the challenge to the [agency]'s action raises the question of the [agency]'s authority to enact a particular amendment. Where, as here, we find that the [agency] has acted outside the scope of its statutory mandate, we also find that we have jurisdiction to review the [agency]'s action."). Because the Court concludes, as explained below, that the Secretary exceeded his authority under the Medicare provisions of the Social Security Act, the Court also necessarily concludes that subsection (t)(12) does not preclude judicial review of Plaintiffs' claims.

C. HHS's 340B Reimbursement Rate Reduction Was *Ultra Vires*

Having waded through the potential impediments to its jurisdiction, the Court may consider Plaintiffs' core allegation; that the Secretary acted *ultra vires* in "adjusting" the 340B drug reimbursement rates from ASP plus 6% to ASP minus 22.5%. "To challenge agency action on the ground that it is *ultra vires*, [a plaintiff] must show a 'patent violation of agency authority.'" *Fla. Health Scis. Ctr., Inc. v. Sec'y of HHS*, 830 F.3d 515, 522 (D.C. Cir. 2016) (quoting *Indep. Cosmetic Mfrs. & Distribs., Inc. v. U.S. Dep't of Health, Educ. & Welfare*, 574 F.2d 553, 555 (D.C. Cir. 1978)). "A violation is 'patent' if it is '[o]bvious' or 'apparent.'" *Id.* (quoting Black's Law Dictionary (10th ed. 2014)). "Such ultra vires review is 'quite narrow.'" *H. Lee Moffitt Cancer Center & Research Inst. Hosp., Inc. v. Azar*, 324 F.Supp.3d 1, 11 (D.D.C. 2018) (quoting *Mittleman v. Postal Regulatory Comm'n*, 757 F.3d 300, 307 (D.C. Cir. 2014)).

Plaintiffs' *ultra vires* argument here turns on the scope of the Secretary's discretion under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) to alter the statutory benchmark drug reimbursement rates. As noted, under

that provision, a given drug's reimbursement rate "shall be equal ... [to] the average price for the drug in the year established under ... section 1395w-3a of this title ... *as calculated and adjusted by the Secretary as necessary for purposes of this paragraph*." *Id.* (emphasis added). And the parties agree that § 1395w-3a sets a default payment rate of ASP plus 6%, which HHS implemented for several years preceding the 2018 OPPS Rule. Defs.' Mot. at 6; Pls.' Mem. at 3–4; 77 Fed. Reg. at 68,387.

Thus, the principle dispute among the parties is whether the Secretary acted within his authority to "calculate[ ] and adjust[ ]" the statutory benchmark rate of ASP plus 6% when he reduced that rate to ASP minus 22.5% based on his estimation of 340B hospitals' drug acquisition costs, rather than the drugs' average sales prices. 82 Fed. Reg. at 52,496. The Secretary argues that the authority to "adjust" reimbursement rates is essentially a plenary power to change rates according to any methodology, so long as the rates are expressed as a function of average drug prices. *See* Defs.' Mot. at 34. This argument relies on the premise that the statute's text does not impose any limits on the Secretary's authority to adjust rates. *See id.* at 31. This is plainly wrong.

In fact, the statute's plain text *does* limit the Secretary's "adjust[ment]" authority. The D.C. Circuit held as much under nearly identical circumstances in *Amgen*. In that case, the Circuit considered the Secretary's authority to adjust reimbursement rates under a different, but related, Medicare provision: 42 U.S.C. § 1395*l*(t)(2)(E). *Amgen*, 357 F.3d at 107. Like subsection (t)(14)(A)(iii)(II), subsection (t)(2)(E) authorizes the Secretary to make "adjustments" to certain hospital reimbursement rates "to ensure equitable payments" under the OPPS scheme.

1395*l*(t)(2)(E).[14] In addressing the *Amgen* plaintiff's claim that the Secretary exceeded his adjustment authority under subsection (t)(2)(E), the Circuit observed that "[l]imitations on the Secretary's equitable adjustment authority *inhere in the text* of § (t)(2)(E)." *Amgen*, 357 F.3d at 117 (emphasis added). Indeed, because the statute "only authorizes 'adjustments,'" it could not be read to permit "total elimination or severe restructuring of the statutory scheme." *Id.* Though the relatively insignificant rate reduction at issue in *Amgen* was not *ultra vires*, the Circuit concluded that because "the term 'adjustments'" did not "encompass the power to make 'basic and fundamental changes in the [statutory] scheme' ... a more substantial departure from the default amounts would, at some point ... cease to be an 'adjustment[ ].'" *Id.* (quoting *MCI Telecomms. Corp. v. Am. Tel. & Tel. Co.*, 512 U.S. 218, 225, 114 S.Ct. 2223, 129 L.Ed.2d 182 (1994)).

Amgen's logic applies equally here. First, "identical words and phrases within the same statute should normally be given the same meaning." *Powerex Corp. v. Reliant Energy Servs., Inc.*, 551 U.S. 224, 232, 127 S.Ct. 2411, 168 L.Ed.2d 112 (2007). Thus, because Congress did not intend for the term "adjust" to confer unbridled authority in the context of subsection (t)(2)(E), there is good reason to believe that Congress did not intend to confer such authority in the context of subsection (t)(14)(A)(iii)(II). But more fundamen-

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[14] This subsection states:

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

tally, the structure of subsection (t)(14)(A)(iii)(II) necessitates this conclusion. That provision commands that SCOD reimbursement rates "shall" be set "equal" to a rate specified in certain other statutory provisions; here, each drug's average sales price plus 6%. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II). This clear directive is qualified only by the Secretary's authority to "adjust" those rates. *Id.* Notably, the Medicare subsection at issue in *Amgen* followed this very same structure by articulating a clear requirement and then qualifying that requirement with the modest authority to adjust rates. Thus, like in *Amgen*, the language and structure of subsection (t)(14)(A)(iii)(II) make clear that the Secretary may not make "basic and fundamental changes" under the purported auspices of making mere "adjustments" to the rates statutorily imposed by that subsection.[15] *See Amgen*, 357 F.3d at 117; *cf. Railway Labor Execs.' Ass'n v. Nat. Mediation Bd.*, 29 F.3d 655, 669 (D.C. Cir. 1994) (en banc) ("[I]t goes without saying that the bald assertion of power by [an] agency cannot legitimize it.").

Amgen also answers another critical question: whether an abuse of the Secretary's adjustment authority might form the basis of an *ultra vires* action.

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[15] In addition to arguing that § 1395*l*(t)(14)(A)(iii)(II)'s plain text imposes no limitation on the Secretary's adjustment authority, the Secretary argues that had Congress wished to limit that authority, it would have done so explicitly, as it did in the same subsection with respect to 2004 and 2005 payment rates. Defs.' Mot. at 31 (citing 42 U.S.C. § 1395*l*(t)(14)(A)(i)–(ii)). This argument is essentially an all or nothing proposition; Congress either imposes rigid instructions or it grants unbridled authority. As discussed, the Court believes that Congress acted with more nuance here. In granting the Secretary authority to "adjust" the statutory benchmark rate, Congress provided leeway for the Secretary to alter and even reduce that benchmark, but not leeway to toss it aside entirely.

That is to say, whether a court could find, under some set of circumstances, that the Secretary has "patent[ly]" violated his authority to "adjust" payment rates. *Fla. Health Scis. Ctr.*, 830 F.3d at 522. *Amgen* suggests that such a finding is possible. The D.C. Circuit explained that, although the Secretary's equitable adjustment authority permitted "the adjustment of OPPS payments otherwise set by the Medicare Act," it did not "give the Secretary the absurdly broad power to make drastic adjustments, such as the elimination of the entire pass-through program, and term it an 'equitable adjustment,' thereby undermining the mandatory nature of the pass-through payment system *while evading judicial review*." *Amgen, Inc.*, 357 F.3d at 117 (emphasis added). Rather, if the Secretary makes "basic and fundamental changes in the scheme ... the Secretary would, in that event, exceed his statutory authority [to make adjustments] under § (t)(2)(E) [and] *the preclusion on judicial review in § (t)(12)(A) would not apply*." *Id.* (emphasis added). In other words, judicial review would be permitted because the Secretary's purported "adjustment" would be, in fact, an *ultra vires* act (i.e. a patent violation of his authority).

The question for the Court, then, is whether the change at issue here—reducing the default 340B drug reimbursement rate of ASP plus 6% to ASP minus 22.5%—is so substantial as to be a patent violation of the Secretary's § (t)(14)(A)(iii)(II) adjustment authority. Although similar arguments have been raised in this jurisdiction, no court has held that the Secretary acted outside of his authority to make "adjustments" to any Medicare reimbursement rates. For example, in *Amgen*, the D.C. Circuit had "no occasion to engage in line drawing to determine when 'adjustments' cease being 'adjustments'" because the rate adjust-

ment at issue there involved "only the payment amount for a single drug, [which] does not work 'basic and fundamental changes in the scheme' Congress created in the Medicare Act ...." *Amgen, Inc.*, 357 F.3d at 117 (quoting *MCI*, 512 U.S. at 225, 114 S.Ct. 2223). Likewise, in other cases, courts have found that payment reductions of 0.2% and 2.9% were not significant enough to warrant a finding that the Secretary exceeded his adjustment authority. *See Shands Jacksonville Med. Ctr. v. Burwell*, 139 F.Supp.3d 240, 260 (D.D.C. 2015) (citing *Adirondack Med. Ctr. v. Sebelius*, 740 F.3d 692, 700 (D.C. Cir. 2014)).

But the circumstances here are quite different than those previously presented in this jurisdiction. The Secretary's rate adjustment at issue here does not affect a single drug or even a handful of drugs, but rather potentially thousands of pharmaceutical products found in the 340B Program. *See* 82 Fed. Reg. at 52,494 (discussing the number of 340B "covered products" available to 340B covered entities). Moreover, the changes that the Secretary imposed are not modest. Indeed, by changing the formula from the statutory default of ASP plus 6% to ASP minus 22.5%, the Secretary is imposing a nearly 30% reduction from the formula that Congress expressly set as the standard. When viewed together, the rate reduction's magnitude and its wide applicability inexorably lead to the conclusion that the Secretary fundamentally altered the statutory scheme established by Congress for determining SCOD reimbursement rates, thereby exceeding the Secretary's authority to "adjust[ ]" SCOD rates under § (t)(14)(A)(iii)(II).

In attempting to justify this drastic departure from the statutorily mandated rates, the Secretary argues that because § (t)(14)(A)(iii) "itself identifies 'acquisition cost[s]' as a valid reference point for drug pay-

ments," the Secretary must necessarily have been within his authority to adjust 340B reimbursement rates to achieve that goal. *Id.* at 29, 33. It is true that § (t)(14)(A)(iii) authorizes the Secretary to set reimbursement rates at levels consistent with hospitals' acquisition costs for those drugs. 42 U.S.C. 1395*l* § (t)(14)(A)(iii)(I). But that authorization is found in subsection *(I)*, which requires the Secretary to consider certain hospital acquisition cost survey data. *Id.*

Here, the Secretary eschewed the use of subsection (I) because the required acquisition cost data was not available. 82 Fed. Reg. at 52,496. And the statutory scheme is clear that if the Secretary does not have that data, he must calculate reimbursement rates by reference to the drugs' *average sales prices*. 42 U.S.C. § (t)(14)(A)(iii)(II). While the Secretary is permitted to make "adjust[ments]" to those rates for whatever reasons he deems "necessary," adjustments are all he can make.[16] *Id.* He cannot fundamentally rework the statutory scheme—by applying a different methodology than the provision requires—to achieve under subsection (II) what he could not do under subsection (I) for lack of adequate data.[17] Indeed, the Secretary's

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[16] The Secretary argues that subsection (II) cannot mandate a reimbursement rate "based strictly on ASP" because that interpretation would render the Secretary's adjustment authority meaningless. Defs.' Mot. at 29. The Court's holding is not so rigid; it agrees that the Secretary has *some* authority to deviate from the statutory benchmark of ASP plus 6%. The Court merely holds that if an adjustment is sufficiently large and entirely de-coupled from the methodology imposed by subsection (II), it may exceed the Secretary's statutory authority and cease to be an "adjustment."

[17] Because the Court concludes that the Secretary's rate reduction is unsupported by the statute's unambiguous text, the Court need not address whether the Secretary's statutory inter-

admission that he sought to mimic the result of subsection (I)—by setting rates designed to approximate *acquisition costs*—under the authority of subsection (II)—which dictates that rates approximate *average sales prices*—only further supports the notion that the Secretary's purported adjustments were, in fact, fundamental changes in the statutory scheme.[18] *See* 82 Fed. Reg. at 52,500 (stating that the Secretary is "using [his] authority [under § (t)(14)(A)(iii)(II)] to apply a downward adjustment that is necessary to better reflect acquisition costs of those drugs"). Congress could very well have chosen to treat Medicare reimbursements for 340B drugs differently than reimbursements for other separately payable drugs, but it did not do so. To the extent the Secretary disagrees on policy grounds with Congress's decision, *see, e.g.*, 82 Fed. Reg. at 52,495 ("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 Secretary may either collect the data necessary to set payment rates based on acquisition costs, or he may raise his disagreement with Congress, but he may not end-run Congress's clear mandate.

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pretation is entitled to deference under *Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837, 842–43, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984). *See* Defs.' Mot. at 28.

[18] The Secretary urges the Court to take into account the rate reduction's "context," and consider that it will allow Medicare beneficiaries to "share in the program savings realized by hospitals and other covered entities that participate in the 340B Program." Defs.' Mot. at 32 (quoting 82 Fed. Reg. at 52,495). The Court does not dispute the Secretary's policy reasons for seeking to reduce 340B reimbursement rates. But a noble goal does not excuse the Secretary's *ultra vires* action taken in pursuit of that goal.

For these reasons, the Court concludes that the Secretary acted *ultra vires*.[19] This conclusion carries two implications. First, the Court's conclusion means that 42 U.S.C. § 1395*l*(t)(12), which ordinarily proscribes judicial review of the Secretary's OPPS reimbursement rate determinations, presents no barrier in this case.[20] Therefore, the Secretary's Federal Rule

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[19] Accordingly, the Court declines to address Plaintiffs' alternative arguments that (1) the Secretary's adjustment authority is limited to the consideration of hospitals' overhead costs, Pls.' Mem. at 26–27; (2) the Secretary's action was *ultra vires* because it improperly treats certain providers differently than others, *id.* at 27–28; and (3) the Secretary's action was *ultra vires* because it undermines the purpose of the 340B program, *id.* at 28–30.

[20] The Secretary also argues that, even if § 1395*l*(t)(12) does not preclude judicial review, any payment adjustment under § 1395(t)(14)(A)(iii)(II) is committed to agency discretion by law, and is therefore unreviewable by this Court. Defs.' Mot. at 25–26; *see also* 5 U.S.C. § 701(a)(2) (stating that an agency action may not be challenged under the APA if it "is committed to agency discretion by law"). Again, the provision at issue requires the Secretary to set SCOD payment rates at "the average price for the drug ... *as calculated and adjusted by the Secretary as necessary for purposes of this paragraph*." 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) (emphasis added). In raising his "agency discretion by law" argument, the Secretary focuses on the part of the statute that reads "as necessary for the purposes of this paragraph." Defs.' Mot. at 25–26. According to him, this language leaves the court without any "meaningful standard against which to judge the agency's exercise of discretion." *Id.* at 25 (quoting *Heckler v. Chaney*, 470 U.S. 821, 830, 105 S.Ct. 1649, 84 L.Ed.2d 714 (1985)). But this argument can only carry force to the extent that one understands the Secretary's 340B rate reduction to be an "adjustment." That is, a court may not inquire into the "necessity" of an "adjustment" made by the Secretary, but that does not prevent the Court from inquiring into whether the Secretary's actions were, in fact, an "adjustment" or something more. Because, as described above, the Secretary's actions did not constitute an "adjustment" for purposes of the

12(b)(1) motion to dismiss for lack of subject matter jurisdiction must fail. Second, the Court's conclusion means that Plaintiffs have adequately alleged a claim for relief under the APA, thereby defeating the Secretary's Federal Rule 12(b)(6) motion to dismiss.

D. Disposition

Having resolved that this Court has jurisdiction over this matter and that, on the merits, the Secretary's action was *ultra vires*, the Court must now consider the proper way forward. Plaintiffs urge the Court to "[a]dvanc[e] a decision on the merits" under Federal Rule of Civil Procedure 65(a)(2). Pls.' Mem. at 34. Rule 65(a)(2) states that "[b]efore or after beginning [a] hearing on a motion for a preliminary injunction, the court may advance the trial on the merits and consolidate it with the hearing." Fed. R. Civ. P. 65(a)(2); *accord Teva Pharm. USA, Inc. v. FDA*, 398 F.Supp.2d 176, 181 n.1 (D.D.C. 2005) ("This type of consolidation is a procedural tool designed to conserve the resources of the Court and the parties by avoiding duplicative efforts." (citing *NOW v. Operation Rescue,* 747 F.Supp. 760, 768 (D.D.C. 1990))), *vacated on other grounds by*441 F.3d 1 (D.C. Cir. 2006). In determining whether a decision on the merits is appropriate, a court must consider whether, at this stage, "the record is sufficient for a determination on the merits under the summary judgment standard, or, where reliance on the record is unnecessary, under the motion to dismiss standard." *March for Life v. Burwell*, 128 F.Supp.3d 116, 124 (D.D.C. 2015). Both parties contend that the record is suffi-

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statute, the Secretary's argument presents no barrier to this Court's review. *See Amgen*, 357 F.3d at 117 (interpreting the statutory scheme to impose limitations on the Secretary's authority to "adjust" reimbursement rates).

cient for a determination on the merits here, and the Court agrees.

The Secretary has had every opportunity and incentive to argue the merits of Plaintiffs' claim, and he was aware that the Court may enter judgment on the merits at this stage. Indeed, the Secretary urged this Court to decide this case on the merits, asserting that "[b]ecause Plaintiffs' APA claims raise pure legal questions regarding the scope of the Secretary's statutory authority, the Court may reach the merits of those claims on a Rule 12(b)(6) motion."[21] Defs.' Mot. at 28 n.10. This, of course, is true. Plaintiffs' Complaint "actually presents no [disputed] factual allegations, but rather only arguments about the legal con-

[21] Even if the parties had not been on notice of the Court's inclination to render a decision on the merits, summary judgment would likely still be appropriate under Federal Rule of Civil Procedure 56. *See* Fed. R. Civ. P. 56(f)(3) (stating that a court may "consider summary judgment on its own after identifying for the parties material facts that may not be genuinely in dispute."). It is generally understood that "'[a] district court may grant summary judgment without notice if' ... the losing party has had a full and fair opportunity to present arguments and ... the parties have no genuine dispute as to a material fact." *Koninklijke Philips Elecs. N.V. v. Cardiac Sci. Operating Co.*, 590 F.3d 1326, 1332 (Fed. Cir. 2010) (quoting *United States v. Grayson*, 879 F.2d 620, 625 (9th Cir. 1989)); *accord Colbert v. Potter*, 471 F.3d 158, 168 (D.C. Cir. 2006) (stating that summary judgment, even if entered erroneously, constitutes harmless error "[w]hen a nonmoving party could not have produced any 'evidence sufficient to create a substantial question of fact material to the governing issues of the case'" (quoting *Holy Land Found. for Relief & Dev. v. Ashcroft*, 333 F.3d 156, 165 (D.C. Cir. 2003)). In this case, the Secretary vigorously argued the merits of Plaintiffs' claim and conceded that there can be no genuine dispute of any material fact, as the case involves a pure question of law.

clusion to be drawn about the agency action." *Marshall Cty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993); *see also* Defs.' Mot. at 28 n.10 ("[I]t is unnecessary for the Court to consider the administrative record in evaluating Plaintiffs' claim, since the claims present pure questions of statutory interpretation."); Defs.' Reply at 3 n.2 ("Defendant's motion ... does not depend upon the contents of any documents other than the final rule challenged by plaintiffs and other judicially noticeable materials."). Thus, "the sufficiency of the complaint is the question on the merits, and there is no real distinction in this context between the question presented on a 12(b)(6) motion and a motion for summary judgment." *Marshall Cty.*, 988 F.2d at 1226; *see also March for Life*, 128 F.Supp.3d at 124 ("Where a plaintiff's complaint properly states a claim, summary judgment is the appropriate method by which to resolve the merits of a dispute regarding federal agency action 'because the ... regulation's validity is a question of law.'" (quoting *Lederman v. United States,* 89 F.Supp.2d 29, 33 (D.D.C. 2000), *on recons. in part*, 131 F.Supp.2d 46 (D.D.C. 2001))).

Consequently, in their briefing, both parties argued at length about the Secretary's authority to implement the Medicare rate reduction at issue. Moreover, the Secretary did not oppose, or even address, Plaintiffs' request that the Court render a judgment on the merits. And the Secretary gave no reason to believe that he might present different or additional legal arguments at some later stage in the litigation.[22] As discussed above, having considered the

[22] This Court held oral argument in *AHA I*, which involved the same parties, the same procedural posture, and substantially similar claims raised by Plaintiffs against the Secretary. *See AHA I*, 289 F.Supp.3d at 50; Min. Entry, Dec. 21, 2017, *AHA I*,

parties' arguments, the Court concludes that the Secretary exceeded his authority under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) in setting the 340B drug reimbursement rates in the 2018 OPPS Rule. Because the Secretary had every opportunity and every reason to present his merits arguments, because he did present those arguments, and because there is no reason to believe that a more developed record in the future could lead to any other outcome than the one reached today, the Court will enter judgment in favor of Plaintiffs.[23]

E. Remedies

The typical remedy for an agency rule promulgated contrary to law is to vacate the rule. *See Humane Soc'y of U.S. v. Zinke*, 865 F.3d 585, 614 (D.C. Cir.

No. 17-2447 (noting that the Court heard oral argument on that date); Pls.' Mem. at 2 (conceding that *AHA I* concerned a "substantively identical challenge"); Defs.' Mot. at 15 (same). During that argument the Court asked the Secretary's counsel whether there was any reason why the Court should not enter judgment at this stage in the proceedings, and counsel could identify none apart from his general desire for a "second bite at the apple." The Court sees no reason to grant the Secretary a "second bite" when there is no evidence that the second bite would be any different than the first. The Court also declines to hear oral argument on the parties' motions at this stage because it believes that oral argument would "be of no meaningful assistance in rendering a final decision[,]" in light of the *AHA I* oral argument and the clear, thorough briefing in *AHA I* and this case. *Owen-Williams v. BB & T Inv. Servs., Inc.*, 797 F.Supp.2d 118, 126 (D.D.C. 2011); *see also* LCvR 7(f) (stating that the decision to conduct an oral argument "shall be within the discretion of the Court").

[23] Because the Court has consolidated Plaintiffs' preliminary injunction motion with a decision on the merits, the Court "need not decide the preliminary injunction." *Pharm. Research & Mfrs. of Am. v. HHS*, 43 F.Supp.3d 28, 34 (D.D.C. 2014).

2017) (citing *Sugar Cane Growers Co-op. of Fla. v. Veneman*, 289 F.3d 89, 97 (D.C. Cir. 2002)); *St. Lawrence Seaway Pilots Ass'n, Inc. v. U.S. Coast Guard*, 85 F.Supp.3d 197, 208 (D.D.C. 2015). As noted, Plaintiffs seek that relief and its logical consequences, including that the Court require HHS to apply the 2017 OPPS drug reimbursement methodology—ASP plus 6%—to 340B drug payments made for the remainder of 2018,[24] and pay the Hospital Plaintiffs, and all 340B Program participants who are members of the Association Plaintiffs, the difference between the 340B drug payments that they have received under the 2018 OPPS Rule and the higher payments that they would have received under the 2017 OPPS Rule.[25] Pls.' Mot. at 1–2. In other words, Plaintiffs seek retroactive Medicare Part B payments and a reallocation of those payments going forward. Plaintiffs' complaint also seeks declaratory relief. Compl. at 23. In determining whether to provide these remedies, the Court must consider "'the seriousness of the ... deficiencies' of the [agency's] action" and "the disruptive consequences of vacatur." *Heartland Reg'l Med. Ctr. v. Sebelius,* 566 F.3d 193, 197 (D.C. Cir. 2009) (first alteration in original) (quoting *Fox Television*

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[24] Considering the timing of the Court's Order, this first remedy is likely to have little impact compared to the second remedy.

[25] Plaintiffs also ask this Court to enjoin the Secretary and HHS from incorporating the payment methodology challenged here into the HHS rule setting 2019 340B drug reimbursement rates. *See* Pls.' Mem. at 35; Compl. at 24. However, Plaintiffs' complaint does not explicitly challenge the 2019 rule, and Plaintiffs have once again failed to show that they have presented the Secretary with a concrete claim for reimbursement under the 2019 rule, as required by 42 U.S.C. § 405(g). *See Eldridge*, 424 U.S. at 328, 96 S.Ct. 893. This Court is thus foreclosed from reviewing the 2019 rule, and it declines to impose injunctive relief concerning that rule. *AHA II*, 895 F.3d at 828.

Stations, Inc. v. FCC, 280 F.3d 1027, 1048–49 (D.C. Cir. 2002)).

Here, vacatur and the other relief sought by Plaintiffs are likely to be highly disruptive. An important component of the Medicare Part B scheme is its budget neutrality requirement. *See* 42 U.S.C. § 1395*l*(t)(9)(B) (stating that OPPS payment "adjustments for a year may not cause the estimated amount of expenditures ... for the year to increase or decrease from the estimated amount of expenditures ... that would have been made if the adjustments had not been made"). And the Secretary claims that this requirement applies to the 340B drug reimbursements at issue here. Defs.' Mot. at 5, 14; *see also* 82 Fed. Reg. at 52,623 ("[W]e are implementing this payment reduction in a budget neutral manner within the OPPS").

Under the budget neutrality requirement, reducing 2018 340B reimbursement rates allowed the Secretary to increase reimbursements for other drugs and services covered under Medicare Part B; increasing 340B reimbursement rates would likewise require the Secretary to reduce reimbursements elsewhere in the program. For instance, in finalizing the 2018 OPPS Rule, the Secretary stated that "the reduced payments for separately payable drugs purchased through the 340B Program w[ould] increase payment rates for other non-drug items and services paid under the OPPS by an offsetting aggregate amount." 82 Fed. Reg. at 52,623. The Secretary could thus "increase OPPS payment rates for non-drug items and services by approximately 3.2[%]." *Id.* The retroactive OPPS payments that Plaintiffs seek here would presumably require similar offsets elsewhere; a quagmire that may be impossible to navigate considering the volume of Medicare Part B payments made in

2018.

The D.C. Circuit and other circuits have recognized the "havoc that piecemeal review of OPPS payments could bring about" in light of the budget neutrality requirement. *Amgen*, 357 F.3d at 112 (citing *Am. Soc'y of Cataract & Refractive Surgery v. Thompson*, 279 F.3d 447, 454 (7th Cir. 2002) (noting the "disruptive" impact of requiring Medicare Part B payment adjustments); *Skagit Cty. Pub. Hosp. Dist. No. 2 v. Shalala*, 80 F.3d 379, 386–87 (9th Cir. 1996)); *see also Paladin Cmty. Mental Health Ctr. v. Sebelius*, 684 F.3d 527, 531 n.3 (5th Cir. 2012) ("Judicial determinations forcing the Secretary to retroactively alter payment rates for various covered services—e.g., payment rates that are adjusted annually and are required to remain budget neutral—would likely wreak havoc on the already complex administration of Medicare Part B's outpatient prospective payment system." (citation omitted)). In the interest of avoiding that havoc, and because neither party thoroughly addressed the question of remedies in their briefs,[26] the Court will order supplemental briefing on this issue.

V. CONCLUSION

For the foregoing reasons, Plaintiffs' Motion for a

[26] The Secretary argues that the potential disruption caused by judicial intervention motivated Congress to preclude judicial review of OPPS payment adjustments. Defs.' Mot. at 40–41. The Secretary does not, however, address how that disruption may be mitigated in the event of a decision for Plaintiffs. And Plaintiffs make the conclusory argument that the disruption would be offset by gains resulting from the lawful implementation of Medicare Part B. Pls.' Opp'n at 10–11. While a noble sentiment, this does not bring the Court any closer to understanding how to provide Plaintiffs with relief without wreaking havoc on the system.

Preliminary Injunction (ECF No. 2) is **DENIED AS MOOT**, the Secretary's Motion to Dismiss (ECF No. 14) is **DENIED**, and Plaintiffs' Motion for a Permanent Injunction (ECF No. 2) is **GRANTED**, insofar as Plaintiffs are entitled to equitable relief. Fashioning that relief, however, requires supplemental briefing from the parties addressing the relief's proper scope and implementation. Consequently, it is **HEREBY ORDERED** that:

1. The parties shall provide supplemental briefing on the appropriate remedy, limited to no more than 25 pages per brief, within 30 days of this Memorandum Opinion's issuance; and
2. The parties shall respond to those briefs, limited to no more than 15 pages per response, within 14 days after the supplemental briefs are filed.

An order consistent with this Memorandum Opinion is separately and contemporaneously issued.

APPENDIX C

No. 18-CV-2084

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, et al., Plaintiffs,

v.

ALEX M. AZAR II, United States Secretary of Health and Human Services, et al., Defendants.

[Filed] May 6, 2019

MEMORANDUM OPINION

GRANTING IN PART PLAINTIFFS' MOTION FOR A PERMANENT INJUNCTION; REMANDING THE 2018 AND 2019 OPPS RULES TO HHS

RUDOLPH CONTRERAS, United States District Judge

I. INTRODUCTION

This Court previously held that the Department of Health and Human Services ("HHS") exceeded its statutory authority when it reduced the 2018 Medicare reimbursement rate for certain pharmaceutical drugs—those covered by the "340B Program"—by nearly 30%. In that decision, the Court asked the parties to provide supplemental briefing regarding the appropriate remedy. That briefing is now ripe for the Court's consideration. Plaintiffs, a group of hospital associations and non-profit hospitals,[1] have also

[1] The hospital association Plaintiffs are the American Hospital Association ("AHA"), the Association of American Medical Colleges ("AAMC"), and America's Essential Hospitals ("AEH"). *See* Suppl. Compl. ¶¶ 5–10, ECF No. 39. The non-profit hospital Plaintiffs are the Henry Ford Health System ("Henry Ford Hos-

filed a supplemental complaint raising a new claim. They contend that HHS once again exceeded its statutory authority when it implemented the same 340B reimbursement rate for 2019 that the Court held was unlawfully implemented in 2018.[2]

For the reasons stated below, the Court concludes that HHS's 2019 340B reimbursement rate is unlawful, for the same reasons that the 2018 rate was unlawful. The Court also concludes that, despite the fatal flaw in the agency's rate adjustments, vacating HHS's 2018 and 2019 rules is not the best course of action, given the havoc vacatur may wreak on Medicare's administration. Rather, the Court will remand the two rules to the agency, giving it the first crack at crafting appropriate remedial measures. The Court expects HHS to resolve this issue promptly.

II. BACKGROUND

This Court's most recent opinion contains a detailed discussion of this case's background and procedural history, and the relevant statutes and regulations. *See Am. Hosp. Assoc. v. Azar ("AHA")*, 348 F. Supp. 3d 62, 66–72 (D.D.C. 2018). The Court will briefly summarize the relevant background here.

Medicare is a federal health insurance program for the elderly and disabled, established by Title XVIII of the Social Security Act. *See* 42 U.S.C. §§ 1395–1395*lll*.[3] Medicare Part A provides coverage for inpa-

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pital"), Northern Light Health ("Northern Light"), and Park Ridge Health ("Park Ridge"). *See id.* ¶¶ 11–19.

[2] Plaintiffs assert their claims against both HHS and the Secretary of Health and Human Services. *See* Suppl. Compl. ¶¶ 20–21. The Court will refer to HHS and the Secretary interchangeably.

[3] These provisions are commonly known as the "Medicare Act."

tient hospital care, home health care, and hospice services. *Id.* § 1395c. Medicare Part B provides supplemental coverage for other types of care, including outpatient hospital care. *Id.* §§ 1395j, 1395k. HHS's Outpatient Prospective Payment System ("OPPS"), which directly reimburses hospitals for outpatient services and pharmaceutical drugs provided to Medicare beneficiaries, is a component of Medicare Part B. *See id.* at 1395*l*(t). OPPS requires "payments for outpatient hospital care to be made based on predetermined rates." *Amgen, Inc. v. Smith*, 357 F.3d 103, 106 (D.C. Cir. 2004). Under this system, the Secretary—through the Centers for Medicare and Medicaid Services ("CMS")—sets annual OPPS reimbursement rates prospectively, before a given year, rather than retroactively based on covered hospitals' actual costs during that year.[4]

Medicare Part B reimburses, among other products and services, "specified covered outpatient drugs" ("SCODs") provided by hospitals to Medicare beneficiaries. 42 U.S.C. § 1395*l*(t)(14)(A). SCODS are a subset of "separately payable drugs," which are not bundled with other Medicare Part B outpatient services, and are therefore reimbursed on a drug-by-drug basis. *See id.* § 1395*l*(t)(14)(B). Congress has authorized two potential methodologies for setting SCOD rates. First, if the Secretary has certain "hospital acquisition cost survey data," he must set the reimbursement rate for each SCOD according to "the *average acquisition cost* for the drug for that year ... as determined by the Secretary taking into account" the

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The Court will refer to them as such.

[4] CMS is a component of HHS and is overseen by the Secretary. *See* HHS Organizational Chart, HHS (Nov. 14, 2018), https://www.hhs.gov/about/agencies/orgchart/index.html.

survey data. *Id.* § 1395*l*(t)(14)(A)(iii)(I) (emphasis added). Second, if the survey data is not available, each SCOD's reimbursement rate must be set equal to "the *average [sales] price* [("ASP")] for the drug in the year established under ... section 1395w-3a ... as calculated and adjusted by the Secretary as necessary for purposes of this paragraph." *Id.* § 1395*l*(t)(14)(A)(iii)(II) (emphasis added). Section 1395w-3a, in turn, provides that a given drug's default reimbursement rate is the average sales price ("ASP") of the drug plus 6%.[5]

The Secretary applies the same methodologies used to set SCOD reimbursement rates to set rates for separately payable drugs covered by the "340B Program."[6] *See* Veterans Health Care Act of 1992,

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[5] While subsection (t)(14)(A)(iii)(II) provides two additional bases for calculating reimbursement rates—section 1395u(*o*) and section 1395w-3b—both parties agree that the default rate for purposes of the drugs at issue here is the rate established by section 1395w-3a. *See* Defs.' Mot. to Dismiss at 6, ECF No. 14; Pls.' Mem. Supp. Mot. Prelim. & Permanent Inj. at 3–4, ECF No. 2-1; Medicare Program: Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs ("2018 OPPS Rule"), 82 Fed. Reg. 52,356, 52,501 (Nov. 13, 2017) (codified at 42 C.F.R. pt. 419) (acknowledging ASP plus 6% as the "statutory benchmark").

[6] Not all 340B drugs qualify as SCODs, to which the payment methodologies of § 1395*l*(t)(14)(A) expressly apply. The Secretary, however, "applies these statutory payment methodologies to *all* separately payable drugs, even those that are *not* SCODS." Defs.' Mot. to Dismiss at 6 n.1, ECF No. 6 (citing Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 77 Fed. Reg. 68,210, 68,383 (Nov. 15, 2012) (codified at 42 C.F.R. pt. 419)); *see also* 82 Fed. Reg. at 52,509 (stating that the rate reduction will apply to "separately payable Part B drugs ... that are acquired through

Pub L. No. 102-585, § 602, 106 Stat. 4943, 4967–71. The 340B Program "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health care facilities." *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 113, 131 S.Ct. 1342, 179 L.Ed.2d 457 (2011); *see also* 42 U.S.C. § 256b(a)(1)–(2).[7] The statutory provisions that establish those price ceilings are independent from the statutory provisions that establish Medicare reimbursement rates. Put another way, the 340B Program caps the prices that eligible providers pay for covered drugs, but Medicare Part B sets the reimbursement rates those providers receive for prescribing covered drugs to Medicare beneficiaries. Until recently, there was a significant spread between 340B prices and Medicare reimbursement rates. 340B Program participants could purchase drugs at steeply discounted rates under the Program, then seek reimbursement for those purchases at the higher Medicare Part B rates established by OPPS. The Secretary's attempt to narrow the spread triggered this litigation.

In mid-2017, the Secretary proposed reducing reimbursement rates for SCODs and other 340B drugs, from ASP plus 6% to ASP minus 22.5%. Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg.

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the 340B Program"). The methodology at issue here thus applies to all 340B drugs. This "is a policy choice rather than a statutory requirement." Defs.' Mot. to Dismiss at 6 n.1 (quoting 77 Fed. Reg. at 68,383).

[7] The Program is intended to enable providers "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992); *see also* 82 Fed. Reg. at 52,493 & 52,493 n.18.

33,558, 33,634 (Jul. 20, 2017) (codified at 42 C.F.R. pt. 419). The Secretary asserted that this change was necessary to "make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs[,] while recognizing the intent of the 340B program to allow covered entities, including eligible hospitals, to stretch scarce resources while continuing to provide access to care." *Id.* at 33,633.

The Secretary's statutory authority to reduce the 2018 340B rate was limited by the data available to him. Because he did not "have hospital acquisition cost data for 340B drugs," 82 Fed. Reg. at 33,634, he could not invoke his express authority under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I) to set rates according to the drugs' average acquisition costs. Instead, he invoked subsection (t)(14)(A)(iii)(II), which allows him to set rates according to the drugs' average sales prices, "as calculated and adjusted by the Secretary as necessary." 82 Fed. Reg. at 33,634. The Secretary proposed to "adjust the applicable payment rate as necessary" for separately payable 340B drugs, "to ASP minus 22.5[%]." *Id.* According to the Secretary, the adjustment was necessary because ASP minus 22.5% was the average 340B discount estimated by the Medicare Payment Advisory Commission ("MedPAC"), and thus "better represents the average acquisition cost for [340B] drugs and biologicals." *Id.* Plaintiffs objected to this adjustment, but the Secretary rejected their objections and adopted the proposal. *See* Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs ("2018 OPPS Rule"), 82 Fed. Reg. 52,356, 52,362 (Nov. 13, 2017) (codified at 42 C.F.R. pt. 419). HHS reimbursed 340B drugs at ASP minus 22.5%

throughout 2018.

Having failed to defeat the 2018 340B rate adjustment during the notice and comment period, Plaintiffs challenged the 2018 OPPS Rule in this Court. *See AHA*, 348 F. Supp. 3d at 71–72. They argued that the Secretary exceeded his statutory authority in setting the 2018 340B rate, in violation of the Administrative Procedure Act ("APA") and the Social Security Act. *See id.* at 71. This Court agreed. It held that the Secretary violated subsection (t)(14)(A)(iii)(II)'s plain text when he invoked that provision to "adjust" 340B rates downward by 30%, based not on the drugs' average sales prices—as dictated by the statutory text—but on the drugs' estimated acquisition costs. *See id.* at 79–83. The Court ordered the parties to provide supplemental briefing on the proper remedy. *See id.* at 86.

The Secretary has continued to apply the same 340B rate in 2019. *See* Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs ("2019 OPPS Rule"), 83 Fed. Reg. 58,818, 58,979 (Nov. 21, 2018) (codified at 42 C.F.R. pt. 419). And in adopting that rate, the Secretary incorporated by reference his rationale for adopting the 2018 340B rate, the rationale that this Court later held was contrary to law. *See id.* at 58,981 (referring commenters to the Secretary's "detailed response regarding [his] statutory authority to require payment reductions for [340B drugs] in the CY 2018 OPPS/ASC final rule").

Plaintiffs have filed a supplemental complaint, *see* Suppl. Compl., ECF No. 39, and moved to permanently enjoin the 2019 OPPS Rule, *see* Pls.' Mot. Permanent Inj. Covering 2019 OPPS Rule ("Pls.' Mot. Inj."), ECF No. 35. That motion, and the parties' remedies

briefing, is now ripe for the Court's review. The Court will first consider Plaintiffs' motion to enjoin the 2019 OPPS Rule, then the parties' remedies briefing. It grants Plaintiffs' motion in part, and remands both the 2018 and 2019 OPPS Rules to HHS, giving the Secretary the first crack at crafting an appropriate remedy.

III. MOTION FOR PERMANENT INJUNCTION

Rather than fully briefing Plaintiffs' motion to enjoin the 2019 OPPS Rule, the parties have elected to incorporate by reference their arguments regarding the 2018 OPPS Rule.[8] Plaintiffs proffer that "[f]or all of the reasons that the Court has already articulated with respect to the 2018 OPPS Rule, the 2019 OPPS Rule is *ultra vires* and unlawful."[9] Pls.' Mot. Inj. at 2. Defendants respond that their arguments for denying Plaintiffs' challenge to the 2018 OPPS Rule "provide ample bases for rejecting" Plaintiffs' challenge to the

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[8] In evaluating Plaintiffs' challenge to the 2018 OPPS Rule, the Court consolidated the parties' pleading-stage briefing with a decision on the merits. *See AHA*, 348 F. Supp. 3d at 83–85. The Court does the same here. This case raises pure questions of law that do not turn on the administrative record or any other facts that may emerge at the summary judgment stage. *See id.* Proceeding to summary judgment, rather than reaching a decision now, would thus be redundant and unnecessary. *See Marshall Cty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993). Neither party contests this approach.

[9] Plaintiffs' challenge is grounded in the APA. The APA provides for judicial review of a "final agency action for which there is no other adequate remedy in a court[,]" 5 U.S.C. § 704, except when "statutes preclude judicial review" or the "agency action is committed to agency discretion by law[,]" *id.* § 701(a). The APA permits a court to "hold unlawful and set aside agency action, findings, and conclusions found to be ... arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id.* § 706(2)(A).

2019 OPPS Rule. Defs.' Opp'n Pls.' Mot. Inj. at 1, ECF No. 42. Recognizing that the Court "rejected those arguments in the context of the 2018 OPPS Rule," Defendants "respectfully request that the Court reconsider its conclusion." *Id.* at 2. The Court declines Defendants' invitation. It enjoins the 2019 OPPS Rule for the same reason that it enjoined the 2018 OPPS Rule. In the interest of thoroughness, the Court will briefly summarize that reasoning.

First, Plaintiffs have sufficiently exhausted their administrative remedies, such that they may challenge the 2019 OPPS Rule in federal court. To seek judicial review, a plaintiff challenging a Medicare-related agency action must satisfy two requirements established by 42 U.S.C. § 405(g). *See Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 12–15, 120 S.Ct. 1084, 146 L.Ed.2d 1 (2000). First, a jurisdictional, non-waivable "requirement that a claim for benefits shall have been presented to the Secretary." *Mathews v. Eldridge*, 424 U.S. 319, 328, 96 S.Ct. 893, 47 L.Ed.2d 18 (1976). Second, a non-jurisdictional "requirement that the administrative remedies prescribed by the Secretary be exhausted." *Id.* This second requirement may be waived by the agency or a court. *See id.* at 330, 96 S.Ct. 893. Together, the two requirements serve the practical purpose of "assur[ing] the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes." *Ill. Council*, 529 U.S. at 13, 120 S.Ct. 1084.

Plaintiffs satisfied § 405(g)'s first, non-waivable requirement when Henry Ford Hospital presented HHS with two claims for reimbursement for 340B drugs prescribed under the 2019 OPPS Rule. *See* ECF Nos. 34–1 & 34-2. In response, HHS dutifully applied the 2019 340B reimbursement rate chal-

lenged by Plaintiffs: ASP minus 22.5%.[10] *Id.* Defendants do not contest that Henry Ford Hospital's 2019 claims satisfy § 405(g)'s presentment requirement.

Plaintiffs need not satisfy § 405(g)'s second requirement, that they fully exhaust the administrative process, because exhaustion would be futile. As this Court previously noted, plaintiffs need not exhaust their administrative remedies when "(1) the issue raised is entirely collateral to a claim for payment; (2) plaintiffs show they would be irreparably injured were the exhaustion requirement enforced against them; [or] (3) exhaustion would be futile." *AHA*, 348 F. Supp. 3d at 75 (alteration in original) (quoting *Triad at Jeffersonville I, LLC v. Leavitt,* 563 F. Supp. 2d 1, 16 (D.D.C. 2008)); *see also Tataranowicz v. Sullivan*, 959 F.2d 268, 274 (D.C. Cir. 1992). In such circumstances, a "district court may, in its discretion, excuse exhaustion if 'the litigant's interests in immediate judicial review outweigh the government's interests in the efficiency or administrative autonomy that the exhaustion doctrine is designed to further.'" *Avocados Plus Inc. v. Veneman,* 370 F.3d 1243, 1247 (D.C. Cir. 2004) (quoting *McCarthy v. Madigan,* 503 U.S. 140, 146, 112 S.Ct. 1081, 117 L.Ed.2d 291 (1992)). More specifically, the court must consider whether judicial resolution of the issue will interfere

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[10] Henry Ford Hospital technically presented its claims to a Medicare administrative contractor (also known as a "fiscal intermediary"), which processes reimbursements on behalf of HHS. *See* 42 C.F.R. § 424.32. "If dissatisfied with the contractor's initial determination, the hospital then may pursue within HHS various other avenues for redetermination, reconsideration, hearings, and appeals." *American Hospital Association v. Azar*, 895 F.3d 822, 824 (D.C. Cir. 2018) (citing 42 U.S.C. § 1395ff; 42 C.F.R. § 405.904); *see also* Pls.' Mem. Supp. Mot. Prelim. & Permanent Inj. at 11, ECF No. 2-1 (describing the Secretary's four-level administrative appeal process).

with the agency's efficient functioning, deny the agency the ability to self-correct, or deprive the Court of the benefits of the agency's expertise and an adequate factual record. *See Tataranowicz*, 959 F.2d at 275 (citing *Weinberger v. Salfi*, 422 U.S. 749, 765, 95 S.Ct. 2457, 45 L.Ed.2d 522 (1975)).

As with Plaintiffs' challenge to the 2018 OPPS Rule, *see AHA*, 348 F. Supp. 3d at 75–76, it would be futile for Plaintiffs to exhaust their administrative remedies here, because their challenge raises pure questions of law that cannot be decided through the administrative process. Plaintiffs argue that the Secretary lacked statutory authority to set the 2019 340B reimbursement rate at ASP minus 22.5%. *See* Pls.' Mot. Inj. at 2. The Court does not need a factual record to decide that question. And no administrative body has authority to rule in Plaintiffs' favor, even if Plaintiffs are correct on the law. *See* 42 C.F.R. § 405.1063(a) (stating that "[a]ll laws and regulations pertaining to the Medicare and Medicaid programs ... are binding on ALJs and attorney adjudicators, and the [Medicare Appeals] Council"); HHS Expedited Access to Judicial Review Ruling at 6, ECF No. 19-1 (stating that "neither the ALJ nor the [Medicare Appeals] Council has the authority to find the 2018 OPPS Rule invalid"). Plus, it is unlikely that further administrative appeals would cause the Secretary to rethink his position that he has authority to "adjust" 340B rates from ASP plus 6% to ASP minus 22.5%, based on the drugs' estimated acquisition costs. *See Tataranowicz*, 959 F.2d at 275. Even after this Court held the 2018 OPPS Rule unlawful, the Secretary left the identical 2019 OPPS Rule in place. Thus, because Plaintiffs have presented claims for reimbursement to the Secretary under the 2019 OPPS Rule, and because Plaintiffs' exhaustion of their administrative

remedies would be futile, the Court waives Plaintiffs' exhaustion requirement and exercises its subject matter jurisdiction under 42 U.S.C. § 405(g).

Second, on the merits, the Secretary acted *ultra vires* in setting the 2019 340B reimbursement rate. *Ultra vires* review "is 'quite narrow.'" *H. Lee Moffitt Cancer Ctr. & Research Inst. Hosp., Inc. v. Azar*, 324 F. Supp. 3d 1, 11 (D.D.C. 2018) (quoting *Mittleman v. Postal Regulatory Comm'n*, 757 F.3d 300, 307 (D.C. Cir. 2014)). To successfully mount an *ultra vires* challenge, a plaintiff "must show a 'patent violation of agency authority.'" *AHA*, 348 F. Supp. 3d at 79 (quoting *Fla. Health Scis. Ctr., Inc. v. Sec'y of HHS*, 830 F.3d 515, 522 (D.C. Cir. 2016)). "A violation is 'patent' if it is '[o]bvious' or 'apparent.'" *Fla. Health Scis. Ctr.*, 830 F.3d at 522 (quoting Black's Law Dictionary (10th ed. 2014)). The Secretary's violation here is apparent.

The Secretary set the 2019 340B rate using his authority under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) ("subsection II"). *See* 83 Fed. Reg. at 58,981 (incorporating the 2018 OPPS Rule's discussion of the Secretary's authority to reimburse 340B drugs at ASP minus 22.5%). Under that provision, a given drug's reimbursement rate "shall be equal ... [to] the *average [sales] price for the drug* in the year established under ... section 1395w-3a of this title ... as calculated and adjusted by the Secretary as necessary for purposes of this paragraph." *Id.* (emphasis added). This Court previously held, based on the D.C. Circuit's decision in *Amgen*, that subsection II's plain text limits the Secretary's authority to adjust rates.[11] *See AHA*,

[11] In *Amgen*, the Circuit considered the Secretary's authority to adjust reimbursement rates under a different, but related, Medicare provision: 42 U.S.C. § 1395*l*(t)(2)(E). *See Amgen*, 357 F.3d at 107. Like subsection (t)(14)(A)(iii)(II), subsection (t)(2)(E) au-

348 F. Supp. 3d at 79–81. Adopting the Circuit's reasoning, the Court concluded that "because the term adjustments" does not "encompass the power to make basic and fundamental changes in the [statutory] scheme ... a more substantial departure from the default amounts would, at some point ... cease to be an adjustment[ ]." *Id.* at 80 (internal quotation marks omitted) (quoting *Amgen*, 357 F.3d at 117). Put simply, because subsection II "only authorizes adjustments," it cannot not be read to permit the "total elimination or severe restructuring of the statutory scheme." *Id.* (quoting *Amgen*, 357 F.3d at 117). To do so would be *ultra vires.*

In "adjusting" the 2019 340B rate under subsection II, the Secretary made basic and fundamental changes to the statutory scheme. The rate covers reimbursement for potentially thousands of pharmaceutical products. *See* 82 Fed. Reg. at 52,494 (discussing the number of 340B "covered products" available to 340B Program participants). The Secretary expressly based that rate on the products' estimated acquisition costs. *See* 82 Fed. Reg. at 52,496, 52,500. That methodology—setting a drug's rate based on its acquisition

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thorizes the Secretary to make "adjustments" to certain hospital reimbursement rates "as determined to be necessary to ensure equitable payments" under the OPPS scheme. 42 U.S.C. § 1395*l*(t)(2)(E). In addressing the *Amgen* plaintiff's claim that the Secretary exceeded his adjustment authority under subsection (t)(2)(E), the Circuit observed that "[l]imitations on the Secretary's equitable adjustment authority inhere in the text of § (t)(2)(E)." *Amgen*, 357 F.3d at 117. Thus, though the slight adjustment at issue in *Amgen* was not *ultra vires*, the Circuit left open the possibility that an adjustment of much greater magnitude could, in fact, "cease to be an 'adjustment[ ]'" at all. *Id.* (alteration in original) (quoting *MCI Telecomms. Corp. v. Am. Tel. & Tel. Co.*, 512 U.S. 218, 225, 114 S.Ct. 2223, 129 L.Ed.2d 182 (1994)).

cost—is contained in a Medicare subsection on which the Secretary could not rely, because he did not gather the necessary data—he did not have the "hospital acquisition cost survey data under subparagraph (D)." 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I) ("subsection I"). The subsection on which the Secretary did rely sets a drug's rate based on its average sales price, rather than its acquisition cost. *See id.* § (t)(14)(A)(iii)(II) ("subsection II").[12] The Secretary thus "adjusted" the 2019 340B rate using a methodology entirely decoupled from that established by the Medicare subsection on which he relied. Not to mention, the rate adjustment is not modest; it is a nearly 30% reduction from the default statutory formula. "When viewed together, the rate reduction's magnitude and its wide applicability inexorably lead to the conclusion that the Secretary fundamentally altered the statutory scheme established by Congress for determining SCOD reimbursement rates, thereby exceeding the Secretary's authority to 'adjust[ ]' SCOD rates under § (t)(14)(A)(iii)(II)."[13] *AHA*, 348 F. Supp. 3d at 81 (al-

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[12] Again, subsection II allows the secretary to set each 340B drug's reimbursement rate equal to "the average price for the drug in the year established under ... section 1395w-3a ... as calculated and adjusted by the Secretary as necessary for purposes of this paragraph." 42 U.S.C. § (t)(14)(A)(iii)(II).

[13] The Secretary argues that his "adjustment" of the 2019 340B reimbursement rate is shielded by 42 U.S.C. § 1395*l*(t)(12). That provision precludes judicial review of certain types of Medicare rate adjustments. *See, e.g.*, 42 U.S.C. § 1395*l*(t)(12)(C) (barring judicial review of "periodic adjustments made under paragraph [(t)(9)]"). However, "the preclusion on review of" those adjustments "extends no further than the Secretary's statutory authority to make them." *Amgen*, 357 F.3d at 112. In other words, if the Secretary makes an "adjustment" within that term's meaning, subsection (t)(12) bars a court from reviewing the reasons underlying that adjustment. But if the Secretary's action is so extreme that it ceases to be an "adjustment," a court may re-

teration in original).

IV. REMEDIES

Having concluded that both the 2018 and 2019 340B reimbursement rates were unlawful, the Court must determine how to "unscramble the egg," so to speak. Determining the proper remedy is no easy task, given Medicare's complexity. The parties, unsurprisingly, take wildly divergent positions on this

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view and strike down that action. *See id.* at 112–14; *AHA*, 348 F. Supp. 3d at 78–79; *Organogenesis Inc. v. Sebelius*, 41 F. Supp. 3d 14, 20–21 (D.D.C. 2014). Here, because the Secretary exceeded his statutory authority to make an "adjustment" under subsection (t)(14)(A)(iii)(II), subsection (t)(12) does not preclude the Court from reviewing that action. *Cf. H. Lee Moffitt Cancer Ctr. & Research Inst. Hosp., Inc. v. Azar*, 324 F. Supp. 3d 1, 11–12 (D.D.C. 2018) (holding that the court would have jurisdiction, "under *ultra vires* review," to hear the plaintiff's claim that the agency was statutorily required to make an adjustment under subsection (t)(2)(E)). The Court thus need not determine whether subsection (t)(12) would preclude review of a lawful adjustment made under subsection (t)(14).

The Secretary also argues that his adjustment is "committed to agency discretion by law," and is thus unreviewable under the APA. 5 U.S.C. § 701(a)(2). That argument fails for the same reason that the Secretary's statutory preclusion argument fails. A matter is committed to agency discretion when "the statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion." *Heckler v. Chaney*, 470 U.S. 821, 830, 105 S.Ct. 1649, 84 L.Ed.2d 714 (1985). The D.C. Circuit indicated in *Amgen*, however, that the statute at issue here *does* impose a meaningful standard: The Secretary may not use his adjustment authority to make fundamental changes to the statutory scheme. *See Amgen*, 357 F.3d at 117. "[A] court may not inquire into the 'necessity' of an 'adjustment' made by the Secretary, but that does not prevent the Court from inquiring into whether the Secretary's actions were, in fact, an 'adjustment' or something more." *AHA*, 348 F. Supp. 3d at 83 n.20.

issue. Plaintiffs seek injunctive relief. *See* Pls.' Suppl. Remedies Br. ("Pls.' Remedy Br.") at 10–11, ECF No. 32. They ask this Court to (1) order the Secretary to pay Plaintiffs "the difference between the amount they received [under the 2018 and 2019 OPPS Rules] and the amount to which they are entitled (based on the ASP plus 6% methodology)"; and (2) order that Plaintiffs that have not yet received reimbursement for 340B drugs prescribed in 2018 and 2019 be paid "the amount they would have received under the 2017 OPPS rule."[14] *Id.* Defendants, on the other hand, ask this Court to remand the 2018 and 2019 OPPS Rules to HHS, without vacating the rules or imposing specific duties on the agency. *See* Defs.' Remedy Br. at 1–2, ECF No. 31.

The parties' briefing raises two questions regarding the appropriate remedy. First, should the Court issue an injunction or remand the issue to the agency? Second, if remand is appropriate, should the Court vacate the 2018 and 2019 OPPS Rules? Having reviewed the parties' briefing and the relevant case law, the Court concludes that remand without vacatur is most appropriate.

A. Remand is Appropriate

Remand, rather than an injunction, is the better course of action here. As Defendants note, "[w]hen a district court reverses agency action and determines that the agency acted unlawfully, ordinarily the appropriate course is simply to identify a legal error and

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[14] Plaintiffs' remedies briefing does not specifically discuss the 2019 OPPS Rule. However, in their motion for a permanent injunction, Plaintiffs ask this Court to (1) require the Secretary to amend the 2019 rule and implement a 340B rate of ASP plus 6%, and (2) "implement the same retrospective remedy that [P]laintiffs have proposed for 2018." Pls.' Mot. Inj. at 3–4.

then remand to the agency, because the role of the district court in such situations is to act as an appellate tribunal." *N. Air Cargo v. USPS*, 674 F.3d 852, 861 (D.C. Cir. 2012) (citing *PPG Indus., Inc. v. United States*, 52 F.3d 363, 365 (D.C. Cir. 1995)). Thus, when a plaintiff brings an APA claim "to set aside an unlawful agency action ... it is the prerogative of the agency to decide in the first instance how best to provide relief." *Bennett v. Donovan*, 703 F.3d 582, 589 (D.C. Cir. 2013) (citing *N. Air Cargo*, 674 F.3d at 861). Indeed, in certain circumstances, "to order the agency to take specific actions is reversible error." *Flaherty v. Pritzker*, 17 F. Supp. 3d 52, 57 (D.D.C. 2014) (citing *Cty. of Los Angeles v. Shalala*, 192 F.3d 1005 (D.C. Cir. 1999)). If the plaintiffs are "dissatisfied with [the agency's] remedy [on remand], they would always have the option to seek review" of that remedy under the APA. *Bennett*, 703 F.3d at 589 (citing 5 U.S.C. § 706(2)(A)).

At least one other court in this jurisdiction has followed this course under similar circumstances. *See Moffitt Cancer Ctr.*, 324 F. Supp. 3d at 19. In *Moffitt Cancer Center*, the plaintiff challenged the Secretary's decision *not* to make an OPPS rate adjustment under 42 U.S.C. § 1395*l*(t)(2)(E), arguing that the adjustment was required by statute. *Id.* at 10–11. The plaintiff sought an order requiring HHS to (1) vacate and amend a particular rule, and (2) "adjust [the plaintiff's] payments ... accordingly." *Id.* at 18–19. The court agreed with the plaintiff on the merits, holding that the statute unambiguously required the Secretary to raise the plaintiff's OPPS rates under subsection (t)(2)(E). *See id.* at 13–14. But the court declined to grant the specific relief sought. *See id.* at 19. Instead, it "simply remand[ed] to HHS so that it c[ould] consider and adopt an 'appropriate adjust-

ment.'" *Id.* The Court will take the same approach here.

Plaintiffs' arguments for injunctive relief are unpersuasive, and the case law weighs against them. Plaintiffs note that there are multiple ways for HHS to remediate its underpayments, some more complicated than others. *See* Pls.' Remedy Br. at 2–4, 7–8. This discussion illustrates why remand is best: Injunctive relief is typically appropriate when "there is 'only one rational course' for the [a]gency to follow upon remand." *Berge v. United States*, 949 F. Supp. 2d 36, 43 (D.D.C. 2013) (quoting *Am. Fed'n of Gov't Emps., AFL-CIO v. Fed. Labor Relations Auth.*, 778 F.2d 850, 862 n.19 (D.C. Cir. 1985)). As the parties' briefing makes clear, HHS has multiple courses on remand, including Plaintiffs' proposed mechanism.[15] Plaintiffs also note "recent examples of cases in which HHS has paid hospitals to compensate for past underpayments." Pls.' Remedy Br. at 4–7. But in each of those cases, the agency reached its own decision on remand; the courts did not grant injunctive relief. *See Cape Cod Hosp. v. Sebelius*, 630 F.3d 203, 216 (D.C. Cir. 2011); *Moffitt Cancer Ctr.*, 324 F. Supp. 3d at 18–19; *Shands Jacksonville Med. Ctr. v. Burwell*, 139 F. Supp. 3d 240, 267–71 (D.D.C. 2015). Finally, Plaintiffs express concern that the Secretary may use remand to "further delay resolution of this matter" or

[15] For example, HHS indicates that it could potentially adjust reimbursement rates in future years to make up for its underpayments in 2018 and 2019. *See* Defs.' Remedy Br. at 11. Or, it also indicates that it could amend the 2018 and 2019 OPPS Rules, and issue retroactive payments accordingly. *See id.* And as discussed below, there is some question as to whether the agency's actions must be budget neutral. The path forward is not sufficiently clear cut that this Court should chart it in the first instance.

even deny relief altogether. Pls.' Resp. Br. Remedies ("Pls.' Resp.") at 1, ECF No. 37. But the Court will retain jurisdiction over this matter, and the Court may reconsider the remedy if the agency fails to fulfill its responsibilities in a prompt manner. In short, Plaintiffs have provided no sound reason or case law to support deviating from the normal course in this jurisdiction under these circumstances: remand.

B. Vacatur is not Warranted

While it is a close question, the Court concludes that it is best to remand the 2018 and 2019 OPPS Rules without vacating them. In deciding whether vacatur is warranted, the Court turns to the standard articulated by the D.C. Circuit in *Allied-Signal, Inc. v. U.S. Nuclear Regulatory Commission*, 988 F.2d 146, 150–51 (D.C. Cir. 1993).[16] Under this standard, the Court must weigh "the seriousness of the [agency] order's deficiencies (and thus the extent of doubt whether the agency chose correctly) and the disruptive consequences of an interim change that may itself be changed." *Id.* (quoting *Int'l Union, United Mine Workers of Am. v. Fed. Mine Safety & Health Admin.*, 920 F.2d 960, 967 (D.C. Cir. 1990)). "There is no rule requiring either the proponent or opponent of vacatur to prevail on both factors." *Shands*, 139 F. Supp. 3d at 270 (listing cases). "[R]esolution of the question turns on the Court's assessment of the overall equities and practicality of the alternatives." *Id.*

Plaintiffs state that they "are not urging this Court to vacate the portions of the 2018 OPPS Rule that the Court held unlawful." Pls.' Resp. at 2.[17] Yet, Plaintiffs

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[16] Both parties agree that this standard is applicable. *See* Defs.' Remedy Br. at 5; Pls.' Resp. at 2.

[17] This may be an eleventh-hour strategic decision. Perhaps Plaintiffs have decided that vacatur will increase the likelihood

also argue that the *Allied-Signal* factors weigh in favor of vacatur. *See* Pls.' Remedy Br. at 7 n.6; Pls. Resp. at 2. And their supplemental complaint expressly seeks vacatur. *See* Suppl. Compl. at 24 (asking this Court to "strike the changes in the payment methodology for section 340B drugs from the 2018 and 2019 OPPS Rules"). Regardless, the Court concludes that the *Allied-Signal* factors weigh, ever so slightly, against vacatur.

The Secretary's deficiencies here were substantial. He patently violated the Medicare Act's text. Unlike cases in which the agency's decision may have been lawful, but was inadequately explained, *see Am. Great Lakes Ports Ass'n v. Zukunft*, 301 F. Supp. 3d 99, 103 (D.D.C. 2018), no amount of reasoning on remand will allow the Secretary to re-implement the 340B rates in the same manner, *see Shands*, 139 F. Supp. 3d at 268 (holding that the first *Allied-Signal* factor weighed in favor of vacatur where the "flaw in the notice and comment process was substantial," and the court was not convinced that HHS would be able to justify its decision on remand). Rather, the Secretary would need to justify those rates under a different statutory provision—a nearly impossible task, given the Secretary's lack of relevant data. The Secretary argues that "there remains some 'doubt about whether the agency chose correctly,'" given that the D.C. Circuit could reverse this Court's decision on appeal. Defs.' Remedy Br. at 5 (quoting *Allied-Signal*, 988 F.2d at 150). That may be true. But the Secretary cites no case in which a court considered the losing party's potential success on appeal in determining the

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that HHS corrects its underpayments in a budget neutral manner, clawing back payments made to Plaintiffs for other Medicare-related services. *See* Pls.' Resp. at 10–11.

proper trial-level remedy. Possible success on appeal would weigh against vacatur in every case, given that reversal is always a possibility. The Court will not consider it here. The first *Allied-Signal* factor thus weighs in favor of vacatur.

On the other hand, vacatur would likely be highly disruptive. If the Court were to vacate the 2018 and 2019 OPPS Rules, it could order the Secretary to reinstate the rule previously in effect—the 2017 OPPS Rule—or leave it to the Secretary to issue new rules. *See Am. Great Lakes Ports*, 301 F. Supp. 3d at 103–04; *Oceana, Inc. v. Evans*, 389 F. Supp. 2d 4, 6 (D.D.C. 2005). Under either scenario, 340B reimbursement rates would presumably be higher than ASP minus 22.5%. While those higher rates would address Plaintiffs' harm, they would raise the following potentially serious administrative problems.

In general, OPPS payments must remain budget neutral, which could throttle the Secretary's ability to retroactively adjust reimbursement rates in the event of vacatur. *See, e.g.*, 42 U.S.C. § 1395*l*(t)(9)(B) (stating that OPPS rate "adjustments for a year may not cause the estimated amount of expenditures ... for the year to increase or decrease from the estimated amount of expenditures ... that would have been made if the adjustments had not been made"); *id. § 1395l*(t)(14)(H) (stating that "[a]dditional expenditures resulting from" subsection (t)(14), after 2005, "shall be taken into account" in "establishing the conversion, weighting, and other adjustment factors" under subsection (t)(9)). Budget neutrality dictates that any increase in spending on certain aspects of Medicare Part B must be offset by decreases elsewhere in the program. *See Cape Cod*, 630 F.3d at 206 (noting that budget neutrality required the Secretary to implement a rate adjustment "in a manner that

would have no effect on the annual total of Medicare payments made to all hospitals throughout the country for inpatient services").

The Secretary issued the 2018 and 2019 340B rates according to this principle: Because he decreased reimbursement rates for 340B drugs, he increased rates for other Medicare Part B products and services. *See* 82 Fed. Reg. at 52,623 (stating that HHS implemented the 340B "payment reduction in a budget neutral manner within OPPS," allowing HHS to "increase OPPS payment rates for non-drug items and services by approximately 3.2[%]"). Thus, if the Secretary were to retroactively raise the 2018 and 2019 340B rates, budget neutrality would require him to retroactively lower the 2018 and 2019 rates for other Medicare Part B products and services. And because HHS has already processed claims under the previous rates, the Secretary would potentially be required to recoup certain payments made to providers; an expensive and time-consuming prospect. *See* Decl. of Elizabeth Richter ¶¶ 5–9, ECF No. 31-1 (estimating that recoupment would take a year, require between $25 and $30 million in administrative costs, and adversely impact Medicare beneficiaries who would owe different amounts under their cost-sharing obligations).

The parties, and the Federation of American Hospitals,[18] strongly debate whether the Secretary's re-

[18] The Federation of American Hospitals filed an amicus brief on behalf of "more than 1,000" non-340B hospitals, addressing remedies. *See* Unopposed Mot. Leave File Amicus Curiae Br. at 1–2, ECF No. 33. The Federation also seeks leave to respond to the parties' briefing on this issue. *See* Mot. Leave File Amicus Curiae Br. at 1, ECF No. 40. Because the Court finds the Federation's briefing helpful, it exercises its "inherent authority" to allow the Federation's participation as amicus curiae. *Jin v.*

medial rate adjustments must be budget neutral. *See* Pls.' Remedy Br. at 8–10; Defs.' Remedy Br. at 7–9; Amicus Br. at 4–7, ECF No. 38. Some courts in this jurisdiction have hypothesized, without concluding, that HHS's remedial adjustments need not be budget neutral. *See Moffitt Cancer Ctr.*, 324 F. Supp. 3d at 15–16. The D.C. Circuit, on the other hand, has suggested the opposite, *see Amgen*, 357 F.3d at 112 (noting that "judicially mandated changes in one [OPPS] payment rate would affect the aggregate impact of the Secretary's decisions by requiring offsets elsewhere, and thereby interfere with the Secretary's ability to ensure budget neutrality in each fiscal year"), although it does not appear to have definitively weighed in. At this stage, it suffices to say that the uncertainty surrounding this issue all but guarantees its resolution would be highly disruptive, should the Court vacate the 2018 and 2019 OPPS Rules.[19]

Relatedly, the presumption against retroactive rulemaking would also complicate vacatur, given that vacatur would force the Secretary to retroactively issue rules for 2018 and 2019. *See* Pls.' Response at 10. Under this presumption, "a statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules unless that power is conveyed

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Ministry of State Sec., 557 F. Supp. 2d 131, 136 (D.D.C. 2008) (quoting *Smith v. Chrysler Fin. Co., LLC*, No. Civ. A. 00-6003, 2003 WL 328719, at *8 (D.N.J. Jan. 15, 2003)). The Court will consider the Federation's response brief.

[19] Budget neutrality is likely to cause disruption regardless of whether the Court vacates the 2018 and 2019 OPPS Rules. But remand without vacatur will allow the agency more flexibility to determine the least disruptive means of correcting its underpayments to Plaintiffs, including possibly making remedial payments in a non-budget neutral manner.

by Congress in express terms." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208, 109 S.Ct. 468, 102 L.Ed.2d 493 (1988). "Even where some substantial justification for retroactive rulemaking is presented, courts should be reluctant to find such authority absent an express statutory grant." *Id.* at 208–09, 109 S.Ct. 468.

Other courts grappling with this issue in the Medicare context have found that it weighs against vacatur. For instance, in *Shands*, another court in this jurisdiction considered whether to vacate an HHS rule reducing a particular reimbursement rate by 0.2% without adequate explanation. *See Shands*, 139 F. Supp. 3d at 263, 269. There, as here, it was "unclear whether the presumption against retroactive rulemaking would apply" if HHS were required to issue a new rule upon vacatur. *Id.* at 269. The Court held that the presumption's applicability weighed against vacatur, because it would impact the agency's ability to navigate the proper remedial action. *See id.*; *cf. Heartland Reg'l Med. Ctr. v. Sebelius*, 566 F.3d 193, 198 (D.C. Cir. 2009) ("[W]e think it sufficient for the purpose of the second *Allied–Signal* factor that vacatur of the rural location requirement would have raised substantial doubt about HHS's ability to recoup payments it made for years prior to reinstatement of that requirement."); *Am. Great Lakes Ports*, 301 F. Supp. 3d at 104 (holding that vacatur was inappropriate where "it would appear that the Coast Guard would be unable to reinstate the 2016 rates through a properly justified new rule due to the presumption against retroactive rulemaking"). The same concern applies here: The Secretary may not be able to retroactively adjust 340B payments, at least not in a budget neutral manner, should the 2018 and 2019 OPPS Rules be vacated. Any attempt to do so would

almost certainly trigger litigation. *See* Amicus Br. at 10 (asking this Court to determine that the Secretary "lacks authority to recoup any or all of the 3.2[%] budget neutrality adjustment" made in the 2018 OPPS Rule). Remand may allow the agency to avoid the issue altogether.[20]

It is true that, as Plaintiffs note, courts most commonly remand without vacatur agency decisions that suffer from procedural, rather than substantive, deficiencies. *See, e.g. Am. Great Lakes Ports*, 301 F. Supp. 3d at 104. But Plaintiffs cite no case law indicating that remand without vacatur is *never* appropriate for agency decisions suffering from severe deficiencies. Nor could they. *See North Carolina v. EPA*, 550 F.3d 1176, 1177–78 (D.C. Cir. 2008) (per curiam) (remanding an agency rule without vacatur, despite "more than several fatal flaws in the rule" (quoting *North Carolina v. EPA*, 531 F.3d 896, 901 (D.C. Cir. 2008) (per curiam))); *Shands*, 139 F. Supp. 3d at 270 (remanding the Secretary's rate reduction without vacatur, despite the action's serious deficiencies); *cf. Fertilizer Inst. v. EPA*, 935 F.2d 1303, 1312 (D.C. Cir. 1991) ("[W]hen equity demands, an unlawfully promulgated regulation can be left in place while the agency provides the proper procedural remedy."). Given the "complex prospective payment system" at issue

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[20] For instance, the Secretary may be able to raise 340B rates in future years to compensate for the 2018 and 2019 underpayments. *See Shands Jacksonville Med. Ctr., Inc. v. Azar,* 366 F.Supp.3d 32, 57-58 (D.D.C. 2018) (affirming the Secretary's decision to implement a one-time, prospective rate increase to address underpayments in previous years). The Federation of American Hospitals contends that the Medicare Act does not authorize this type of prospective remedial adjustment in a budget neutral manner. *See* Amicus Br. at 9–10. But the Court need not decide that at this stage.

here, *Amgen*, 357 F.3d at 112, the Court concludes that vacating the 2018 and 2019 OPPS Rules would do more harm than good, despite the fatal flaws in the Secretary's 340B rate adjustments.

V. CONCLUSION

For the foregoing reasons, the Court concludes that the 340B drug reimbursement rate contained in the 2019 OPPS Rule is unlawful, because it was implemented in contravention of the Medicare Act's plain text. That said, the Court declines to grant the injunctive relief requested by Plaintiffs. Instead, the Court remands the 2018 and 2019 OPPS Rules to the Secretary without vacatur. Thus, Plaintiffs' Motion for a Permanent Injunction (ECF No. 35) is **GRANTED IN PART**, and Defendants' Motion to Dismiss (ECF No. 42) is **DENIED**. On or before **August 5, 2019**, the parties shall submit a status report regarding the agency's progress on remand to remedy the issues raised in this litigation concerning the 2018 and 2019 OPPS Rules. The Court expects that the agency will act expeditiously to resolve these issues. An order consistent with this Memorandum Opinion is separately and contemporaneously issued.

APPENDIX D

No. 18-CV-2084

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, et al., Plaintiffs,

v.

ALEX M. AZAR II, United States Secretary of Health and Human Services, et al., Defendants.

[Filed] July 10, 2019

MEMORANDUM OPINION

GRANTING DEFENDANTS' MOTION FOR ENTRY OF FINAL JUDGMENT; DENYING AS MOOT PLAINTIFFS' MOTION FOR A FIRM DATE

RUDOLPH CONTRERAS, United States District Judge

I. BACKGROUND[1]

On May 6, 2019, this Court held that the Department of Health and Human Services ("HHS") exceeded its statutory authority when it reduced the 2019 Medicare reimbursement rate for pharmaceutical drugs covered by the "340B Program" by nearly 30%. *See Am. Hosp. Ass'n v. Azar ("AHA II")*, No. CV 18-2084 (RC), 2019 WL 1992868 (D.D.C. May 6, 2019). This holding followed the Court's December

[1] Because the December 2018 Opinion and May 2019 Opinion contain extensive discussion of the relevant background, procedural history, and the relevant statutes and regulation, *see AHA II*, 2019 WL 1992868 at *1–4; *AHA I*, 348 F. Supp. 3d at 66–72, and because the instant order addresses the remedy and not the merits in this dispute, the Court will not recapitulate the facts previously reported in detail.

2018 conclusion that HHS exceeded its statutory authority in reducing the 2018 Medicare reimbursement rate. *See Am. Hosp. Ass'n v. Azar ("AHA I")*, 348 F. Supp. 3d 62, 79–83 (D.D.C. 2018). In *AHA II*, this Court also specified the remedy for the agency's unlawful rate adjustments: remand of both the 2018 and 2019 rules to the agency, without vacatur. *AHA II*, 2019 WL 1992868 at *7–10. In specifying the remedy, the Court stated that it would "retain jurisdiction over this matter" so that it could "reconsider the remedy if the agency fails to fulfill its responsibilities in a prompt manner." *Id.* at *7.

Both parties soon filed further motions. Plaintiffs moved for a firm date by which Defendants must propose a remedy to the Court. Pls.' Mot. for Firm Date, ECF No. 51 ("Pls.' Mot."). Defendants moved for reconsideration of the May 6, 2019 Order and requested entry of final judgment pursuant to Federal Rule of Civil Procedure Rule 58(a), contending that the Court's retention of jurisdiction was "clear error." Defs.' Mot. for Recons., Entry of Final J., and Expedited Briefing, ECF No. 54 ("Defs.' Mot."). In this motion, Defendants also argue that entry of final judgment is necessary for expeditious review on the merits in the D.C. Circuit. *Id.* at 1. These motions are ripe for the Court's consideration. For the reasons stated below, the Court will grant Defendant's motion for entry of final judgment and dismiss as moot Plaintiff's motion for a firm date.

II. ANALYSIS

Defendants ask this Court to revisit the remedy specified in the May 6, 2019 Order, ECF No. 49, specifically requesting that the Court, first, reconsider its retention of jurisdiction following remand to HHS and, second, enter final judgment. Defs.' Mot. 1. Defendants argue that the Court has both the authority

and the imperative to reconsider the May 6 Order. The Court agrees.

A court has authority to reconsider an interlocutory order like the May 6 Order "at any time before the entry of judgment adjudicating all the claims and the rights and liabilities of all the parties." *Lewis v. District of Columbia*, 736 F. Supp. 2d 98, 101 (D.D.C. 2010) (quoting Fed. R. Civ. P. 54(b)); *see also Bayshore Cmty. Hosp. v. Azar*, 325 F. Supp. 3d 18, 22 (D.D.C. 2018) (quoting *Ofisi v. BNP Paribas, S.A.*, 285 F. Supp. 3d 240, 243 (D.D.C. 2018)). "Relief under Rule 54(b) is available 'as justice requires,' a standard that reflects the flexibility afforded courts under the rule." *Bayshore Cmty. Hosp.*, 325 F. Supp. 3d at 22 (quoting *Cobell v. Jewell*, 802 F.3d 12, 25 (D.C. Cir. 2015) (internal quotation mark omitted)). For a court to grant a motion for reconsideration of an interlocutory order, the movant must generally demonstrate: "(1) an intervening change in the law; (2) the discovery of new evidence not previously available; or (3) a clear error in the first order." *Zeigler v. Potter*, 555 F. Supp. 2d 126, 129 (D.D.C. 2008), *aff'd*, No. 09-5349, 2010 WL 1632965 (D.C. Cir. Apr. 1, 2010) (quoting *Keystone Tobacco Co. v. U.S. Tobacco Co.*, 217 F.R.D. 235, 237 (D.D.C. 2003)).

Here, Defendants argue that the Court's retention of jurisdiction upon remand to HHS constitutes clear error. They contend that the proper remedy is remand to the agency—and remand alone. *See* Defs.' Mot. at 2. Defendants aver that this is an open and shut issue: because this Court reviewed the agency's action and found that the agency made an error of law, "the court's inquiry is at an end: the case must be remanded to the agency for further action consistent with the correct legal standards." *Id.* (quoting *Palisades Gen. Hosp. Inc. v. Leavitt*, 426 F.3d 400,

403 (D.C. Cir. 2005)). Plaintiffs counter with a different view of what remand requires, asserting that this Court nonetheless has *discretion* in certain circumstances to retain jurisdiction. Pls.' Opp'n Defs.' Mot. 3, ECF No. 56. Thus, even Plaintiffs acknowledge that, although the Court may retain jurisdiction over this case, it is not *required* to do so. The Court thus reconsiders the issue and determines that it should not exercise its discretion in that fashion.

As a general matter, Plaintiffs are correct that the Court has discretion to retain jurisdiction, and it aligns with other courts in this Circuit in "recogniz[ing] that it has the discretion to retain jurisdiction over a case pending completion of a remand and to order the filing of progress reports." *Baystate Med. Ctr. v. Leavitt*, 587 F. Supp. 2d 37, 41 (D.D.C. 2008) (citing *Cobell*, 240 F.3d at 1109). But "this discretion is typically reserved for cases alleging unreasonable delay of agency action or failure to comply with a statutory deadline, or for cases involving a history of agency noncompliance." *Id.* (citing *Cobell,* 240 F.3d at 1109). In the instant case, there is no evidence of unreasonable agency delay or noncompliance on par with the decades-long recalcitrance evidenced in cases such as *Cobell*. And in such instances, "[t]he norm is to vacate agency action that is held to be arbitrary and capricious and remand for further proceedings consistent with the judicial decision, without retaining oversight over the remand proceedings." *Baystate Med. Ctr.*, 587 F. Supp. 2d at 41. Here, of course, the Court concluded that vacatur was inappropriate, *see AHA II*, 2019 WL 1992868 at *7, so its retention of jurisdiction cuts against this norm.

Moreover, pragmatic considerations call for reconsideration of the Court's original stance. Both parties

wish to resolve the dispute expeditiously. And this Court is sympathetic to Defendants' argument that retention of oversight over remand to the agency "calls into question the finality of the remand order" and thereby risks delaying the ability to appeal to the D.C. Circuit. Defs.' Mot. 3. Although Plaintiffs would prefer that this Court retain jurisdiction and resolve the merits and the remedy at once, Defendants correctly note in a separate filing that the Administrative Procedure Act does not permit this Court to review a *proposed* rule before it is final. Defs.' Opp'n Pls.' Mot. 4–5, ECF No. 53 (discussing 5 U.S.C. § 704 and associated case law). Accordingly, retention of jurisdiction risks delaying prompt resolution of this suit, pending a final agency rule. To afford the parties the opportunity for expedited review by the D.C. Circuit, this Court will grant Defendants' motion for entry of final judgment. This resolution moots Plaintiffs' motion for a firm date.

III. CONCLUSION

For the foregoing reasons, Defendants' motion for reconsideration and motion for entry of final judgment is **GRANTED** and Plaintiffs' motion for entry of a firm date is **DENIED** as moot. An order consistent with this Memorandum Opinion is separately and contemporaneously issued.

APPENDIX E

Nos. 19-5048, 19-5198

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

AMERICAN HOSPITAL ASSOCIATION, et al.,
Appellees

v.

ALEX MICHAEL AZAR, II, in his official capacity as the Secretary of Health and Human Services and United States Department of Health and Human Services, Appellants

[Filed] October 16, 2020

Before: SRINIVASAN, Chief Judge, and HENDERSON, ROGERS, TATEL, GARLAND, MILLETT, PILLARD, WILKINS, KATSAS, RAO*, and WALKER, Circuit Judges.

ORDER

Upon consideration of appellees' petition for rehearing en banc, and the absence of a request by any member of the court for a vote, it is

ORDERED that the petition be denied.

Per Curiam

FOR THE COURT:

Mark J. Langer, Clerk

BY: /s/
Michael C. McGrail
Deputy Clerk

* Circuit Judge Rao did not participate in this matter.

APPENDIX F

42 USCA § 1395*l* provides in pertinent part:

Payment of benefits

* * *

(t) Prospective payment system for hospital outpatient department services

* * *

(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 services 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.

* * *