ORAL ARGUMENT SCHEDULED NOVEMBER 8, 2019

No. 19-5048 & No. 19-5198

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

THE AMERICAN HOSPITAL ASSOCIATION, *et al*.,
Plaintiffs-Appellees,

v.

ALEX M. AZAR II, in his official capacity, *et al.*,
Defendants-Appellants.

On Appeal from a Final Judgment of the
U.S. District Court for the District of Columbia
(Honorable Rudolph Contreras)

BRIEF OF PLAINTIFFS-APPELLEES

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), undersigned counsel hereby certifies as follows:

Except for the following, all parties, rulings under review, and related cases are identified in the Brief for Appellants.

The Federation of American Hospitals is participating in this appeal as amicus curiae.

/s/ William B. Schultz
William B. Schultz

DISCLOSURE STATEMENT PURSUANT TO CIRCUIT RULE 26.1

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

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

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

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

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

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

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

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

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

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GLOSSARY

340B	Section 340B of the Public Health Service Act (42 U.S.C. § 256b)
ASP	Average Sales Price
CMS	Centers for Medicare & Medicaid Services (division of HHS)
GAO	U.S. Government Accountability Office
HHS	U.S. Department of Health and Human Services
MedPAC	Medicare Payment Advisory Commission
OPPS	Outpatient Prospective Payment System

STATUTES AND REGULATIONS

All applicable statutes and regulations are contained in Addendum to the Brief for Appellants.

INTRODUCTION

The Department of Health and Human Services ("HHS") drastically cut Medicare reimbursements to public and non-profit hospitals for certain drugs purchased under section 340B of the Public Health Service Act ("the 340B Program") for 2018 and 2019. Since 1992, the 340B Program has allowed community health centers and certain nonprofit hospitals ("340B hospitals") to purchase drugs ("340B drugs") at deep discounts so that they can better stretch scarce resources to provide vital services to their poor, vulnerable, and underserved communities. The recent payment cut reduced the drug reimbursement rate for these hospitals by nearly 30%, totaling $1.6 billion per year by HHS's estimate.

HHS instituted this severe cut by basing the reimbursement rate for certain outpatient drugs on acquisition costs. This decision violated the plain meaning of the applicable statutory provision governing reimbursement for outpatient drugs. The statute authorizes HHS to base reimbursement rates on acquisition costs only if HHS has statistically valid data specifically identified in the statute. Where HHS lacks that data, as the Secretary acknowledges was the case here, the statute provides that HHS must base the reimbursement rate on the average sales price of the drug ("ASP") plus 6% to account for overhead and related costs.

Although the statute authorizes the Secretary to "adjust[]" the ASP-plus-6% rate, here HHS attempted to use its adjustment authority to end-run the statutory

requirement that acquisition costs be based on statistically valid data, which was a violation of law. In doing so, HHS also unlawfully targeted 340B hospitals, undermining the 340B Program. As the district court held, "the Secretary fundamentally altered the statutory scheme established by Congress for determining . . . reimbursement rates, thereby exceeding the Secretary's authority to 'adjust' [those] rates." JA 88.

The district court's ruling holding unlawful HHS's reduction in reimbursement rates for 340B drugs should be affirmed.

STATEMENT OF THE CASE

I. Statutory Framework

A. The OPPS System and the Payment Methodology for Separately Payable Drugs

In 1997, to control Medicare expenditures for outpatient services, Congress directed the Centers for Medicare & Medicaid Services ("CMS"), an agency within HHS, to develop an Outpatient Prospective Payment System ("OPPS"). 42 U.S.C. § 1395*l*(t). Rather than paying for the reasonable expenses of such services, under the OPPS, CMS pays hospitals predetermined rates. *See generally Amgen, Inc. v. Smith*, 357 F.3d 103, 106 (D.C. Cir. 2004) (describing the history and structure of the OPPS system). To set the predetermined rates, the Secretary first creates "groups" of outpatient services. § 1395*l*(t)(2)(B). The payment rate for each service and service group is based on a "relative payment weight" that reflects the

cost of that service (or service group) in prior years relative to all the other covered services in prior years, § 1395*l*(t)(2)(C), with adjustments for the regional cost of labor and other factors, § 1395*l*(t)(2)(D)–(E). The payment weights are then converted into fees that are included on the outpatient fee schedule using a uniform multiplier. § 1395*l*(t)(3)(C)–(D). Each year, the Secretary must review various components of this system and may make revisions "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." § 1395*l*(t)(9)(A). Any annual revisions cannot cause estimated system-wide 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." § 1395*l*(t)(9)(B).

However, payment rates for specified covered outpatient drugs, which are at issue in this lawsuit, are *not* calculated using the multi-factor formula described above. HHS incorrectly states in its brief that "[t]his suit involves [OPPS] rates" that "are calculated through a formula that sets payment weights . . . based on the mean or median costs of providing such services in past years, with adjustments for regional cost variations and other specified factors." Gov't Br. at 6. In fact, since the Medicare Modernization Act was enacted in 2003,[1] payment rates for the

[1] Medicare Prescription Drug, Improvement, & Modernization Act, Pub L. No. 108-173, 117 Stat. 2066 (2003) ("Medicare Modernization Act of 2003").

drugs at issue in this lawsuit have been calculated using an entirely separate methodology set forth in paragraph (14) of the OPPS statute that exists "[a]part from reimbursement authority for general outpatient services." *Organogenesis v. Sebelius*, 41 F. Supp. 3d 14, 17 (D.D.C. 2014) (discussing the separate payment methodology in § 1395*l*(t)(14)).[2]

> The payment rates for these drugs are as follows:
>
> The amount of payment under this subsection for a specified covered outpatient drug . . .
>
> (iii) in [2006 and onward] shall be equal, subject to subparagraph (E)—
>
> > (I) to the average acquisition cost for the drug for that year . . . 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 [42 U.S.C. § 1395w-3a] as calculated and adjusted by the Secretary as necessary for purposes of this paragraph.

§ 1395*l*(t)(14)(A).[3]

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[2] As a matter of policy, HHS has long employed this separate payment methodology for "*all* separately payable drugs," not just those drugs covered by the definitional provisions in paragraph (14). Dist. Ct. Op., JA65 n.5 (emphasis in original); *see also* Gov't Mot. to Dismiss, Dkt. 15 at 6 n.1 (explaining this policy); 2013 OPPS Rule, 77 Fed. Reg. 68,210, 68,383 (Nov. 15, 2012) (same); *Organogenesis*, 41 F. Supp. 3d at 18 (same).

[3] The statute sets forth different rates for separately payable outpatient drugs for 2004 and 2005 that are not relevant here. *See* § 1395*l*(t)(14)(A)(i)-(ii).

Subclause (I) requires CMS to set rates based on the average acquisition cost of each drug if, and only if, CMS possesses specific "acquisition cost survey data." § 1395*l*(t)(14)(A)(iii)(I). To qualify, the survey data must include "a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each [drug]." § 1395*l*(t)(14)(D)(iii). It is undisputed that CMS does not have, and has never had, this data.

"[I]f hospital acquisition cost data are not available," subclause (II) requires CMS to use a statutorily defined default rate based on average sales price. § 1395*l*(t)(14)(A)(iii)(II). The default rate is ASP plus 6%. *See id.* (referring to 42 U.S.C. § 1395w-3a, which sets the payment rate at 106% of average sales price). Subclause (II) also provides that this ASP-plus-6% default rate may be "calculated and adjusted [by HHS] as necessary for purposes of this paragraph." *Id.* The meaning and limits of this "adjustment" authority are central in this case.

Reimbursement rate determinations under subclause (I) or subclause (II) are "subject to subparagraph (E)." § 1395*l*(t)(14)(A)(iii). Subparagraph (E) directs the Medicare Payment Advisory Commission ("MedPAC") to report on "adjustment" of payment rates to "take into account overhead and related expenses." § 1395*l*(t)(14)(E)(i).[4] It also authorizes HHS to "adjust" the payment rates "to take

[4] MedPAC is an independent federal commission comprised of experts in the financing and delivery of healthcare services. It advises Congress on issues

into account" any recommendations made in this report regarding these expenses. § 1395*l*(t)(14)(E)(ii). As provided in subparagraph (E), an "adjustment" to the rate otherwise determined under paragraph (14) is permissible if it seeks to "take into account overhead and related expenses." § 1395*l*(t)(14)(E)(i).

From 2006-2012, CMS set reimbursement rates for separately payable drugs using a rate of ASP plus a small fixed percentage, generally 4-6%. *See* 2013 OPPS Rule, 77 Fed. Reg. 68,210, 68,383-68,386 (Nov. 15, 2012) (recounting payment rates from prior years). CMS's variations from "ASP plus 6%" were generally intended to reflect overhead costs for providing the drugs. *See id.* For 2013, CMS formally adopted the subclause (II) default rate of ASP plus 6%, acknowledging the "continuing uncertainty about the full cost of pharmacy overhead and acquisition cost" and expressing concern that deviating from the default rate "may not appropriately account for average acquisition and pharmacy overhead cost." *Id.* at 68,386. From 2013 through 2017, CMS consistently applied the ASP-plus-6% statutory rate for all drugs paid under paragraph (14).

Paragraph (12) of the OPPS statute precludes administrative and judicial review of certain HHS actions within the OPPS system. § 1395*l*(t)(12). Specifically, it precludes review of certain actions taken pursuant to paragraphs

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affecting the administration of the Medicare program. *See* About MedPAC, http://www.medpac.gov/-about-medpac-.

(2), (3), (5), (6), (8)(B), and (9)[5] of subsection (t). *See* § 1395*l*(t)(12)(A)–(E). Paragraph (12) has remained unchanged since 1999, although Congress has amended the OPPS statute several times since then. In 2003, when Congress added paragraphs (13) and (14), it provided that adjustments under paragraph (13) would be made "under paragraph (2)(E)," one of the paragraphs explicitly precluded under paragraph (12). § 1395*l*(t)(13)(B). For paragraph (14), however, Congress provided no cross-reference to paragraph (2) or any other indication that decisions undertaken pursuant to paragraph (14) would be precluded from review.

B. The 340B Program

Congress created the 340B Program in 1992 to provide certain hospitals and federally funded clinics caring for low-income patients (under the statute, "covered entities") with outpatient drug discounts comparable to those available to state Medicaid agencies.[6] Under that Program, manufacturers of prescription drugs, as a condition of having their outpatient drugs covered through Medicaid, are required to offer 340B hospitals and clinics outpatient drugs at or below a discounted, statutorily-determined ceiling price. In general, drug manufacturers must offer a minimum discount of between 13% and 23.1%, depending on the type of drug. *See*

[5] Subsection (t)(12)(C)'s reference to "periodic adjustments made under paragraph (6)" is a scrivener's error; it should refer to paragraph (9) instead. *See* Dist. Ct. Opp., JA80 n.13.

[6] *See* Veterans Health Care Act of 1992, Pub L. No. 102-585, § 602, 106 Stat. 4943, 4967–71 (1992) (creating section 340B of the Public Health Service Act).

42 U.S.C. §§ 256b(a)(1), 1396r-8(c)(1)(B)(i). Drugs purchased under the 340B Program include drugs that are reimbursed under the OPPS outpatient drug reimbursement system.

Congress enacted the 340B Program "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). As explained by the HHS agency responsible for administering the 340B Program, the Program furthers that objective by "lower[ing] the cost of acquiring covered outpatient drugs" from drug manufacturers, thereby generating additional resources from "health insurance reimbursements" − including reimbursements under Medicare − that are "maintained or not reduced as much as the 340B discounts or rebates."[7] In other words, under the Program, 340B hospitals receive Medicare and other insurance reimbursements that exceed the discounted price paid by these hospitals to drug manufacturers. These increased resources, in turn, enable 340B hospitals to deliver programs and services to serve vulnerable communities.

[7] Health Resources and Services Administration, Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Service Act at 14 (July 2005) ("2005 HRSA Manual"), https://docplayer.net/6345832-Hemophilia-treatment-center-manual-for-participating-in-the-drug-pricing-program-established-by-section-340b-of-the-public-health-service-act.html.

Since the 340B Program was first implemented, and consistent with the statutory design, 340B hospitals and clinics have been able to use savings generated by the Program. Recognizing the importance of financial flexibility to the operation of covered entities, Congress did not specify in the statute how funds generated through the Program must be used, *see* 42 U.S.C. § 256b, although it anticipated that participation in the Program would enable 340B hospitals and clinics to provide additional healthcare services to vulnerable communities. A 2011 report from the U.S. Government Accountability Office ("GAO") found that this is exactly what happened. Covered entities have used the additional resources to provide critical healthcare services to communities with underserved populations that could not otherwise afford these services − for instance, by increasing service locations, developing patient education programs, and providing translation and transportation services.[8]

HHS suggests that it first learned of a discrepancy between Medicare payments and acquisition costs for 340B drugs in a 2015 GAO study, and states that the challenged payment cut was a response to that revelation. *See* Gov't Br. at 10 (stating that "beginning in 2015 it became apparent that certain hospitals were routinely acquiring drugs at well below the average sales price"). But HHS has

[8] U.S. Gov't Accountability Off., GAO-11-836, Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement 17–18 (2011), http://www.gao.gov/assets/330/323702.pdf.

known about a disparity between Medicare reimbursements and acquisition costs for participants in the 340B Program since long before 2015. The 27-year-old program was *designed* to provide deep discounts to covered hospitals, with the expectation that "health insurance reimbursements" would be "maintained or not reduced as much as the 340B discounts or rebates." 2005 HRSA Manual at 14. In 2010, the HHS Office of Inspector General issued a report finding that, "in the aggregate, Medicare payments were 31 percent higher than acquisition costs among responding 340B hospitals." Office of Inspector General, Dep't of Health & Human Services, *Payment for Drugs Under the OPPS* (Oct. 22, 2010), https://oig.hhs.gov/oei/reports/oei-03-09-00420.pdf.

Recognizing the value of the 340B Program, Congress increased the categories of "covered entities" in 2010 as part of the Affordable Care Act. Originally, "covered entities" included federally-funded health centers and clinics providing services such as family planning, AIDS intervention, and hemophilia treatment, as well as public and certain not-for-profit hospitals serving a large proportion of low-income or uninsured populations. Pub L. No. 102-585, § 602; *see also* 42 U.S.C. § 256b(a)(4)(A)–(L). In 2010, Congress expanded "covered entities" to include certain children's hospitals, free-standing cancer hospitals, critical access hospitals, and sole community hospitals. *See* 42 U.S.C. § 256b(a)(4)(M)–(O). HHS characterizes the increased number of participating

340B hospitals as a "[p]erhaps unsurprising[]" byproduct of the financial benefits of the 340B Program. Gov't Br. at 12. Surprising or not, the program has expanded by express Congressional design.

II. Procedural History

A. The Proposed and Final Rules for 2018 and 2019

On July 13, 2017, CMS issued its annual Proposed OPPS Rule for Calendar Year 2018. 2018 Proposed OPPS Rule, 82 Fed. Reg. 33,558 (July 20, 2017). For drugs acquired under the 340B Program and paid pursuant to paragraph (14), CMS proposed changing the reimbursement rate from the longstanding rate of ASP plus 6% to ASP minus 22.5% – a 28.5 percentage point reduction. *Id.* at 33,564. The proposed rule for 2018 retained the ASP-plus-6% rate for all other separately payable drugs covered under paragraph (14) – *i.e.*, all outpatient drugs acquired by non-340B hospitals and certain exempted hospitals.

CMS admitted that the purpose of the reduction was to set a reimbursement rate for 340B drugs that "better represents the average acquisition cost for these drugs" paid by 340B hospitals. *Id.* at 33,634. CMS acknowledged, however, that it (and MedPAC) lacked the data required under subclause (I) of the statute to permit the use of average acquisition cost as the measurement for reimbursement. *See id.* Despite the absence of the statutorily required survey data, CMS chose to base its rate change on a MedPAC estimate that, on average, 340B hospitals "receive a

minimum discount of 22.5 percent of the ASP for drugs paid under the OPPS." *Id.* at 33,632. CMS proposed to set the reimbursement rate at the MedPAC aggregate estimate of acquisition cost, ASP minus 22.5%. Although CMS actually had taken the estimate of acquisition cost and expressed it as a percentage of ASP, it characterized the new rate as an "adjustment" of ASP, invoking its authority under subclause (II) to "adjust" the ASP-plus-6% rate. *Id.* at 33,634 (citing § 1395*l*(t)(14)(A)(iii)(II)).

CMS also admitted that its rate reduction was motivated by policy concerns with the 340B Program. Relying on a report from the General Accounting Office,[9] CMS asserted that the 340B Program was responsible for "unnecessary utilization and potential overutilization of separately payable drugs," *id.* at 33,633, although it failed to reconcile this statement with the comments it made at the time GAO issued the Report, which criticized the study and questioned its methodology.[10] Indeed, in comments to the proposed 2018 OPPS Rule, Appellees supplied data "contradict[ing] the agency's conclusion that 340B hospitals overutilize drugs,

[9] 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 (June 2015) ("2015 GAO Report"), https://www.gao.gov/assets/680/670676.pdf.

[10] *See* 2015 GAO Report at 38 (attaching HHS comments on draft version of report). HHS had pointed out that the GAO study "did not examine any patient differences in terms of outcomes or quality" and did not sufficiently account for the health status of the populations served by 340B hospitals. *Id.*

compared to non-340B hospitals," and "demonstrate[ing] that the skyrocketing cost of pharmaceuticals is the main driver of Part B drug expenditure increases," not over-utilization by 340B hospitals. AHA Comments, Dkt. No. 2-6 at 12–15.

CMS also stated that the payment cut would advance the policy objective of "allow[ing] Medicare beneficiaries (and the Medicare program) to pay less when hospitals participating in the 340B Program furnish drugs to Medicare beneficiaries that are purchased under the 340B Program" because of the "inextricable link" between the Medicare payment rate and Medicare beneficiaries' 20% cost-sharing obligation. 2018 Proposed OPPS Rule, 82 Fed. Reg. at 33,633. CMS failed to acknowledge that most Medicare beneficiaries have supplemental coverage (including Medicaid for those with the lowest incomes) that reduces or entirely covers their copayments, limiting the potential benefit from any copayment reduction. CMS also failed to mention that the OPPS Rule would cause concomitant increases in out-of-pocket costs of drugs for some beneficiaries in non-340B hospitals and for other OPPS services. *See* AHA Comments, Dkt. No. 2-6 at 12; AEH Comments, Dkt. No. 2-8 at 10; Henry Ford Comments, Dkt. No. 2-9 at 2.

CMS's proposal was reviewed by its Advisory Panel on Hospital Outpatient Payment, which advised CMS not to adopt the change, recommending instead that CMS collect additional data "on the potential impact of revising the payment rate,"

including the "potential impact on 340B hospitals."[11] Numerous parties − including Appellees − submitted comments opposing the Proposed Rule. These comments explained that CMS's policy justifications for the rate reduction were misguided. The comments highlighted the likely impact of the reduction on 340B covered entities' ability to provide critical healthcare programs to their communities, including underserved patients. And the comments presented detailed arguments that HHS lacked statutory authority to use a cost-based approach to calculate the reimbursement rate or to so drastically reduce the rate and undercut the 340B Program.[12]

On November 1, 2017, CMS issued a final rule adopting the near-30% reduction for 340B hospitals (with certain exemptions). CMS, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 52,356, 52,493–52,511 (Nov. 13, 2017) ("2018 OPPS Rule"). In the 2018 OPPS Rule, CMS estimated that the total impact of the payment reduction on 340B hospitals in 2018 would be $1.6 billion. *Id.* at 52,623. CMS *did not* change the payment rate under

[11] CMS, Advisory Panel on Hospital Outpatient Payment: Recommendations at 2 (Aug. 21, 2017), https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/Downloads/2017-08-21-Panel-Recommendations.pdf.

[12] *See* AHA Comments, Dkt. No. 2-6 at 6–12; AAMC Comments, Dkt. No. 2-7 at 2–3; AEH Comments, Dkt. No. 2-8 at 4–12; Henry Ford Comments, Dkt. No. 2-9 at 1–3; Northern Light Health (then "EMHS") Comments, Dkt. No. 2-10 at 1–2; Park Ridge Comments, Dkt. No. 2-11 at 2–3.

paragraph (14) generally; it continued to use the ASP-plus-6% payment rate for drugs paid under that paragraph, with only 340B hospitals carved out.

On November 21, 2018, CMS issued a regulation for calendar year 2019 setting reimbursement for 340B drugs at ASP minus 22.5%, just as it had done for calendar year 2018. CMS, Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 83 Fed. Reg. 58,818, 58,979–81 (Nov. 21, 2018) ("2019 OPPS Rule").

B. The Prior Litigation and the District Court's Ruling

On November 13, 2017, Appellees filed a complaint and a motion for a preliminary injunction seeking to vacate the 2018 Rule. *Am. Hosp. Ass'n v. Hargan*, Civ. Action No. 1:17-cv-2447 (RC) (D.D.C. filed Nov. 13, 2017). On December 29, 2017, the district court granted the government's motion to dismiss on the ground that the court would not have jurisdiction until the Secretary had denied a specific claim for reimbursement, which could not occur until the rule went into effect on January 1, 2018. *Am. Hosp. Ass'n v. Hargan*, 289 F. Supp. 3d 45 (D.D.C. 2017). This Court affirmed on the same basis. *Am. Hosp. Ass'n v. Azar,* 895 F.3d 822 (D.C. Cir. 2018).

Once they had presented claims for reimbursement under the 2018 rule, which were uniformly reimbursed at the lower rate, Appellees filed this lawsuit,

again seeking to invalidate the methodology that HHS used in its 2018 OPPS rule. Complaint, JA 12–35. At the same time, Appellees filed a motion seeking a preliminary and permanent injunction enjoining the 2018 rule and requiring HHS to reimburse 340B hospitals for the difference between what they had received under the 2018 OPPS rule and what they were entitled to receive under a correct application of the law. Pls.' Mot. for Prelim. & Permanent Inj., Dkt. No. 2.

On December 27, 2018, the district court granted Plaintiffs' motion for a permanent injunction and held unlawful the reduced rate for 340B drugs in the 2018 OPPS Rule on the grounds that it exceeded the Secretary's authority under § 1395*l*(t)(14)(A)(iii)(II). JA 60–96; *Am. Hosp. Ass'n v. Azar,* 348 F. Supp. 3d 62 (D.D.C. 2018). The court declined to apply its injunction to the 2019 OPPS Rule because Plaintiffs had not yet "presented the Secretary with a concrete claim for reimbursement under the 2019 rule." JA 94 n.25.

Once the 2019 OPPS Rule had become effective, Appellees presented claims and filed a supplemental complaint to challenge that Rule as well. JA 102–26. On May 6, 2019, the district court granted Appellees' motion for a permanent injunction with respect to the 2019 OPPS Rule and held it unlawful. JA 136–41; *Am. Hosp. Ass'n v. Azar*, 385 F. Supp. 1, 6–10 (D.D.C. 2019). The district court then remanded to HHS to give it "the first crack at crafting appropriate remedial

measures," JA 131, and directed the parties to submit a status report on August 5, 2019 regarding the agency's progress. JA 151.

On June 1, 2019, HHS filed a motion seeking immediate entry of final judgment to facilitate this appeal, which the district court granted on July 10, 2019. JA 152–57; *Am. Hosp. Ass'n v. Azar*, 2019 WL 3037306 (D.D.C. July 10, 2019). HHS filed a notice of appeal the next day. JA 158–59. This Court ordered an expedited briefing schedule, which Appellees had requested based on their view that HHS would be required to "stop paying the claims at an illegal rate soon after this Court issues its decision, if that decision is favorable to Appellees." Appellees' Consent Mot. to Expedite Briefing, Doc. #1798888, at 9 (July 24, 2019).

SUMMARY OF ARGUMENT

The Secretary's almost 30% reduction in Medicare reimbursement for 340B drugs used in an outpatient setting was contrary to the Medicare statute, which does not preclude judicial review of the Secretary's decision.

This Court has emphasized the "strong presumption that Congress intends judicial review of administrative action," and specifically of administrative actions under the OPPS statute. *Amgen, Inc. v. Smith*, 357 F.3d 103, 111 (D.C. Cir. 2004) (citation omitted). The presumption can only be overcome by "clear and convincing evidence that Congress intended to preclude the suit." *Id.* Paragraph (12), the preclusion provision of the OPPS statute, lists the paragraphs of the

statute that are precluded, but paragraph (14), the authority that the Secretary relied on for the reduction at issue here, is not among them. Paragraphs (12)(A) and (12)(C), the provisions on which HHS relies, apply to preclude judicial review of adjustments made under paragraphs (2) and (9), respectively, but not paragraph (14). In its rulemaking notices, HHS never suggested that the challenged payment cut was made pursuant to either paragraph (2) or (9), and in any event HHS could not have relied on either of those paragraphs as authority for the decision challenged here. HHS decisions establishing reimbursements rates for separately payable drugs must be set under the separate system that Congress established under paragraph (14).

Even if Congress had precluded HHS decisions under paragraph (14), judicial review is appropriate here under the well-established exception for review of agency actions that are *ultra vires*. *See Amgen*, 357 F.3d at 112–13; *DCH Regional Med. Ctr. v. Azar*, 925 F.3d 503, 508–09 (D.C. Cir. 2019).

On the merits, this is a straightforward case of statutory construction. In paragraph (14) of the OPPS statute, Congress provided the Secretary two options for reimbursing covered outpatient drugs, and explicitly identified the circumstances under which each could be used. Under subclause (I) of section 1395*l*(t)(14)(A)(iii), HHS must base rates on the average acquisition cost, but only if the Secretary has the hospital acquisition cost survey data specified in paragraph

(14)(D). HHS admits that it does not have this data, and it did not purport to use subclause (I) to set the rates at issue here. If survey data are not available, the Secretary must use subclause (II) of the statute, which directs HHS to pay the statutory default rate of ASP plus 6%, as calculated and adjusted for purposes of paragraph (14).

HHS admitted that the purpose of the reduction of the rates at issue here was to set reimbursement at a rate that "better represents the average acquisition cost for these drugs." 2018 OPPS Rule, 82 Fed. Reg. at 52,496. Thus, HHS purported to use its adjustment authority under subclause (II) to nullify the specific statutory requirements for using acquisition costs in subclause (I). This was unlawful because it effectively repealed the requirement to use hospital acquisition cost survey data in order to set reimbursement at acquisition costs.

In addition, under subclause (II), any change in the ASP-plus-6% rate must be an adjustment of that rate. As HHS acknowledges, the challenged rate change was an approximation of acquisition costs; it was not an adjustment of the ASP-plus-6% default rate.

HHS's policy justifications also do not support such a so-called adjustment. HHS may disagree with the policy goal of the 340B program, which is to generate resources for facilities that serve vulnerable communities by allowing them to

acquire drugs at a cost lower than they are reimbursed, but HHS may not override Congress's clear mandate. Only Congress can make such a change.

ARGUMENT

I. The OPPS Statute Does Not Preclude Review of the Rate Change at Issue in This Case.

This Court has emphasized the "strong presumption that Congress intends judicial review of administrative action," and specifically of administrative actions under the OPPS statute. *Amgen*, 357 F.3d at 111 (citation omitted). "Even where . . . a statutory provision expressly prohibits judicial review, the presumption applies to dictate that such a provision be read narrowly." *Am. Clinical Lab. Ass'n v. Azar*, 931 F.3d 1195, 1204 (D.C. Cir. 2019). The presumption can only be overcome by "clear and convincing evidence that Congress intended to preclude the suit." *Amgen*, 357 F.3d at 111.

HHS asserts, without qualification, that "[t]he Medicare statute expressly precludes judicial review of HHS's adjustments to OPPS rates." Gov't Br. at 1. But in fact the statute's preclusion provision – paragraph (12) – operates *selectively*. The OPPS statute contains 22 paragraphs, and paragraph (12) states that there shall be no administrative or judicial review of actions under six of them: paragraphs (2), (3), (5), (6), (8)(B), and (9). *See* § 1395*l*(t)(12)(A)–(E). Paragraph (12) does not preclude judicial review of actions under paragraph (14), which is the paragraph pursuant to which the challenged rate change was made.

In 1999 Congress added three additional paragraphs to the OPPS statute and simultaneously amended paragraph (12) to expressly preclude review of decisions under two of the three. § 1395*l*(t)(12)(E) (precluding judicial review of decisions under paragraphs (5) and (6) but not paragraph (7)).[13] Similarly, in 2015 Congress added paragraph (21) to the OPPS statute and expressly precluded administrative and judicial review of certain determinations under that paragraph. *See* § 1395*l*(t)(21)(E).[14] But when Congress enacted paragraph (14) in 2003 to create a separate payment methodology for specified covered outpatient drugs, it did *not* add a corresponding preclusion provision to paragraph (12), nor did it in any way indicate that payment amount determinations under paragraph (14) were subject to preclusion. Similarly, there are numerous other paragraphs of the OPPS statute for which Congress did not preclude judicial review. These are meaningful choices.

HHS's view is that there is no "evident need for judicial oversight of OPPS rates, because Congress regularly intervenes to revise the OPPS provisions." Gov't Br. at 35. HHS has it exactly backwards: the fact that Congress regularly revises the OPPS statute makes it all the more notable that Congress has not expressly precluded review of decisions under many paragraphs of the OPPS statute,

[13] Consol. Appropriations Act, 2000, Pub. L. No. 106-113, App'x F, § 201(d), 113 Stat. 1501, 1501A-339 (1999).

[14] Bipartisan Budget Act of 2015, Pub. L. No. 114-74, § 603, 129 Stat. 584, 597–98 (2015).

including paragraph (14). Congress could have chosen to preclude review of *all* determinations within the OPPS system, but it clearly did not do so. Instead it specified which agency decisions are shielded from review, and payment rate determinations under paragraph (14) are not among them. Paragraph (14) is also not among the specific provisions of the statute that HHS's regulation identifies as precluded from judicial review. *See* 42 C.F.R. § 419.60.

Relying on paragraph (12), but without quoting or discussing its text, HHS asserts that "the Medicare statute expressly precludes review of OPPS adjustments, including adjustments under paragraph 14." Gov't Br. at 22 (header formatting omitted). But HHS cannot even settle on *which* provision of paragraph (12) supplies "clear and convincing evidence that Congress intended to preclude" review of payment determinations under paragraph (14), a telling sign that preclusion here is not clear, much less convincing. In the prior litigation challenging the 2018 OPPS Rule before it went into effect, HHS relied on paragraphs (12)(A) and (12)(E) in the district court and in its brief on appeal. At oral argument on appeal, HHS invoked preclusion under paragraph (12)(C) for the first time. In the present lawsuit, HHS asked the district court to find preclusion under paragraphs (12)(A), (12)(C), *and* (12)(E). Now, HHS invokes paragraphs (12)(A) and (12)(C), which it broadly characterizes as "preclud[ing] judicial

review of the Secretary's adjustments to prospective payment amounts." Gov't Br. at 7.

As we demonstrate below, neither paragraph (12)(A) nor paragraph (12)(C) precludes review of payment amount determinations under paragraph (14). And HHS's policy arguments for finding preclusion are inapt.

A. Review is not precluded under paragraph (12)(A).

Paragraph (12)(A) of the OPPS statute precludes judicial review of:

> [T]he 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).

§ 1395*l*(t)(12)(A). Paragraph (12)(A), by its terms, precludes review only of actions that HHS takes "under paragraph (2)," *id.*, not actions that it takes under paragraph (14). In *Amgen*, this Court held that the "other adjustments" for which review is precluded under paragraph (12)(A) are the "other adjustments" referenced in paragraph (2)(E)—*i.e.*, "other adjustments as determined to be necessary to ensure equitable payments." 357 F.3d at 113 (quoting 42 U.S.C. § 1395*l*(t)(2)(E)). HHS appears to be arguing that review is precluded because the exercise of paragraph (14) authority at issue in this case was *also* an equitable adjustment under paragraph (2)(E). *See* Gov't Br. at 22–23.

But the challenged payment cut in this case was *not* an equitable adjustment under paragraph (2)(E). That is clear from the relevant passages of the 2018 and

2019 OPPS Rules, which did not cite paragraph (2)(E), did not invoke authority to make equitable adjustments, and did not include a "determin[ation]" that the severe cuts to the 340B Program would be "equitable." 2018 OPPS Rule, 82 Fed. Reg. at 52,506–07; 2019 OPPS Rule, 83 Fed. Reg. at 58,979–81. In contrast, other, unrelated portions of the 2018 and 2019 OPPS Rules *did* invoke the Secretary's authority to make "equitable" adjustments under paragraph (2)(E). *See, e.g.*, 2018 OPPS Rule, 82 Fed. Reg. at 52,421 (equitably adjusting payment for rare retinal procedure); 2019 OPPS Rule, 83 Fed. Reg. at 58,892–93 (equitably adjusting payments for certain new technology procedures). Similarly in *Amgen*, HHS had "*claim[ed]* to [be] act[ing] pursuant to the authority in § (t)(2)(E) to make 'adjustments . . . to ensure equitable payments.'" 357 F.3d at 107 (emphasis added). Paragraph (14) established a specific methodology for setting reimbursements for separately payable outpatient drugs and a standard for making adjustments to those payments. The Secretary could not, and in fact did not, bypass paragraph (14), by purporting to use his equitable adjustment authority under paragraph (2)(E). *See* 2018 OPPS Rule, 82 Fed. Reg. at 52,506–07.

For some amendments to the OPPS statute, Congress placed a new set of HHS actions under the umbrella of paragraph (2)(E), thereby subjecting them to preclusion under paragraph (12)(A). For example, in 1999, when it added paragraphs (5), (6), and (7), to the OPPS statute, Congress amended paragraph

(2)(E) to require that the Secretary establish the adjustments and payments "under paragraph (5)" and "under paragraph (6)" (but not under paragraph (7)). § 1395*l*(t)(2)(E).[15] HHS action under paragraphs (5) and (6) is thus precluded from review, but HHS action under paragraph (7) is not.[16]

Similarly, when Congress added paragraphs (13) (adjustment for rural hospitals) and (18) (adjustment for cancer hospitals), it expressly provided that HHS's payment adjustments under those paragraphs would occur "under paragraph (2)(E)," thereby subjecting them to preclusion under paragraph (12)(A). § 1395*l*(t)(13)(B), (t)(18)(B). In short, Congress made clear that actions taken under these new provisions were "under paragraph (2)(E)" and therefore within paragraph (12)(A)'s ambit as actions taken "under paragraph (2)." In contrast, when it added paragraph (14) to the OPPS statute in 2003, Congress did not reference paragraph (2)(E) or suggest in any way that adjustments under paragraph (14) are equitable adjustments under that paragraph. Notably, paragraphs (13) and (14) were added at the same time.[17] Congress identified adjustments pursuant to

[15] Consol. Appropriations Act, App'x F, Sec. 1, § 201(c), 113 Stat. 1501, 1501A-339 (1999).

[16] To make its intent clear, Congress at the same time added a new preclusion provision to paragraph (12), specifically precluding actions under paragraphs (5) and (6). *See* 42 U.S.C. § 1395*l*(t)(12)(E) (precluding review of actions taken "under paragraph (5)" and "under paragraph (6)").

[17] Medicare Modernization Act of 2003, § 411(b) (adding paragraph (13)); § 621(a)(1) (adding paragraph (14)).

paragraph (13) as occurring "under paragraph (2)(E)," but not adjustments pursuant to paragraph (14).

There is plainly not clear and convincing evidence that review of such actions is precluded by paragraph (12)(A).

B. Review is not precluded under paragraph (12)(C).

HHS also invokes subsection (t)(12)(C) of the Medicare Act, which precludes review of "periodic adjustments made under paragraph [9][18]." § 1395*l*(t)(12)(C). Adjustments under paragraph (9) are separate and apart from agency action under paragraph (14) such as the payment reduction at issue in this case. When Congress directed CMS to switch from a system based on reasonable costs for the payment of outpatient department services to a system where the payments were established prospectively based on historical data, it instructed CMS in paragraph (2) to develop a classification system for covered services, specifying, for example, that the Secretary: (1) "may establish groups of covered OPD services" (subparagraph (B)); (2) "shall . . . establish relative payment weights" (subparagraph (C)); (3) "shall determine a wage adjustment factor" (subparagraph (D)); and (4) "shall establish . . . other adjustments as determined to be necessary to ensure equitable payments" (subparagraph (E)).

[18] As noted above, paragraph (12)(C) contains a scrivener's error and should refer to paragraph (9). *See supra* note 5.

After the system has been established, Congress in paragraph (9) directed HHS to "review not less often than annually" the elements of the classification system, *i.e.*, "the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2)," and to "revise" them "to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors." 42 U.S.C. § 1395*l*(t)(9)(A). In other words, after CMS used its authority under paragraph (2)(B)–(E) to establish groups, relative payment weights, wage and other adjustments, paragraph (9) requires it to update those factors at least annually.[19]

This exercise bears no relationship to the setting of reimbursement rates under paragraph (14). Reimbursement rates under paragraph (14) are fixed according to the average acquisition cost or average sales price of a particular drug, with an addition to cover overhead. *See* § 1395*l*(t)(14)(A)(iii)(I)–(II), (t)(14)(E)(ii). Payments for the outpatient drugs covered under paragraph (14) are set exclusively under paragraph (14), and once they are set, paragraph (14) determines the payment for each separately payable drug used in connection with an outpatient service. None of the factors that bear on the adjustments that HHS must make under paragraph (9)(A), such as regional labor costs and the relative costs of other

[19] Thus the "other adjustments" referenced in paragraph (9) are the "other adjustments in paragraph (2)(E) – *i.e.*, equitable adjustments – which HHS did not and could not have invoked when it make the payment reduction at issue here. *See supra* at 23–26.

services, has any relevance to reimbursement rates for drugs covered by paragraph (14).

Given that payment rate determinations under paragraph (14) are separate from adjustments under paragraph (9)(A), it is unsurprising that HHS did not invoke its authority under paragraph (9) in making the payment cuts at issue in this case. Rather, HHS specifically invoked its authority under paragraph (14). 2018 OPPS Rule, 82 Fed. Reg. at 52,506–07; 2019 OPPS Rule, 83 Fed. Reg. at 58,979–81.[20]

Although it does not make this claim in the preclusion argument in its brief, in a cryptic footnote in the background section, HHS asserts that "adjustments made under paragraph 14, which is at issue here, are a subset of the adjustments made under paragraph 9." Gov't Br. at 7 n.1. But setting drug payment amounts under paragraph (14) is not the same as, or an example of, the annual revisions of

[20] In the executive summary sections of the 2018 OPPS Rule and the 2019 OPPS Rule, HHS referenced paragraph (9)(A) among other statutory authorities. But in neither 2018 nor 2019 did HHS purport to be identifying paragraph (9)(A) as the authority for the *entire* rule, which in both cases were hundreds of pages long. Rather, after referencing paragraph (9)(A) and other statutory authorities, HHS explained: "We describe these *and various other statutory authorities* in the relevant sections of this final rule with comment period." 2018 OPPS Rule, 82 Fed. Reg. at 52,362 (emphasis added); 2019 OPPS Rule, 83 Fed. Reg. at 58,820 (same). HHS then specifically invoked paragraph (9)(A) in many sections of the two rules, but not in the sections instituting the cuts to the 340B Program. In those sections, HHS invoked only its authority under paragraph (14). *See* 2018 OPPS Rule, 82 Fed. Reg. at 52,506-07; 2019 OPPS Rule, 83 Fed. Reg. at 58,979–81.

components of the OPPS system that the Secretary must undertake pursuant to paragraph (9). If HHS calculates payment rates under paragraph (14) using the ASP methodology, and in doing so, "adjust[s]" that rate "as necessary for purposes of this paragraph," § 1395*l*(t)(14)(A)(iii)(II), that adjustment is integral to the determination of the payment rate for a drug under paragraph (14). Indeed, such an adjustment is expressly "for purposes of *this paragraph*," *id.* (emphasis added), not for purposes of paragraph (9). In no sense is such an adjustment a "subset" of the adjustments contemplated under paragraph (9). *See* Gov't Br. at 7 n.1.

As HHS points out, paragraph (14)(H) cross-references paragraph (9), Gov't Br. at 7 n.1, but that cross-reference does not support HHS's position that adjustments made under paragraph (14) are a "subset" of the adjustments made under paragraph (9). Although HHS does not rely on paragraph (14)(H) in support of its preclusion argument and did not advance it below, we address it here in anticipation that HHS may make the argument in its reply.

Paragraph (14)(H) states that "[a]dditional 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." § 1395*l*(t)(14)(H).[21] Paragraph (14)(H)

[21] Similarly, paragraph (9)(B), which requires adjustments under 9(A) to be budget neutral, provides that, for 2004 and 2005, the Secretary shall not make a budget neutrality adjustment to counteract any expenditures resulting from revisions under

applies *after* expenditures under paragraph (14) have been calculated, including any adjustments to the average sales price under paragraph (14)(A)(iii)(II). Once those expenditures are calculated, they become an input that the Secretary must "take into account" when making annual revisions under paragraph (9).

As noted above, paragraph (9)(A) requires that HHS review and revise various components of the OPPS system each year, including the "relative payment weights, and the wage and other adjustments described in paragraph (2)." § 1395*l*(t)(9)(A). The revisions must "take into account" various pieces of information, such as "changes in technology, the addition of new services, new cost data, and other relevant information and factors." *Id.* When making any revisions under paragraph (9)(A), HHS must ensure that the estimated total amount of Medicare expenditures does not increase or decrease from what it is estimated to be without the revisions. *Id.* § 1395*l*(t)(9)(B).

Paragraph (14)(H) states that any expenditures resulting from paragraph (14) must be among the information that HHS takes into account when making adjustments under paragraph (9)(A) (which, in turn, must be budget-neutral pursuant to paragraph (9)(B)). In other words, the statute envisions a two-step process. First, HHS must set the payment amount for separately covered drugs

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paragraph (9)(A) "that would not have been made but for the application of paragraph (14)." 42 U.S.C. § 1395*l*(t)(9)(B).

under paragraph (14), which may involve an adjustment to the default rate of ASP plus 6%. Paragraph (14) determines the amount of payment for separately payable drugs, and that payment amount is never affected by paragraph (9). Second, once that payment amount is set, HHS must factor the resulting expenditures into the annual revisions to components of the OPPS system that it makes under paragraph (9). Judicial review of paragraph (9) adjustments is precluded, but review of the payment rate under paragraph (14) is not.

Thus, adjustments to drug payment amounts under paragraph (14) are not "a subset of the adjustments made under paragraph 9," Gov't Br. at 7 n.1 (emphasis added), such that they would be subject to preclusion under paragraph (12)(C). There is certainly no clear and convincing evidence that Congress intended to preclude review of determinations under paragraph (14) in such an indirect fashion.

C. HHS's policy arguments for preclusion are inapt.

HHS argues that "the difficulty of devising an appropriate remedy underscores why the Medicare statute expressly precludes judicial review of OPPS adjustments and other aspects of the outpatient prospective payment system." Gov't Br. at 34. HHS is wrong that devising an appropriate remedy would be prohibitively difficult, as demonstrated by HHS's own prior decisions to remedy illegal conduct and its statements in this case. But regardless, HHS's concerns

about devising a remedy do not bear on whether Congress has spoken clearly in the text of the statute to preclude this lawsuit.

First, HHS has recognized in this litigation that a retrospective remedy would be feasible. In the context of opposing injunctive relief in the first lawsuit, HHS took the position that any harm from the cuts to the 340B program was not irreparable because "Plaintiffs' alleged economic loss here would be recoverable if the Court were to enter final judgment in their favor." Mem. in Supp. of Defs.' Mot. to Dismiss and in Opp'n to Pls.' Mot. for Prelim. Inj., *Am. Hosp. Ass'n v. Hargan*, No. 17-cv-2447, Dkt. No. 18 at 49 (D.D.C., filed Dec. 1, 2017). Moreover, in its proposed OPPS Rule for 2020, HHS has put forward for public comment a specific, feasible remedy mechanism for underpayments in 2018 and 2019 that "would utilize our Medicare contractors to make one payment to each affected hospital." 2020 Proposed OPPS Rule, 84 Fed. Reg. 39,398, 39,505 (Aug. 9, 2019). Based on its view that such a remedy would need to budget neutral, HHS solicited comments on how to accomplish budget neutrality, and raised the possibility that it could be done "with a *prospective* approach" so that there would be no recoupment of past payments. *Id.* (emphasis added). Simply put, HHS knows how to remedy the violation at issue in this case, and even if it has authority to make the remedy budget neutral, doing so would not cause a system-wide disruption as claimed in the HHS brief.

Second, it should come as no surprise that HHS is eminently capable of remedying past reimbursements that are determined to have been unlawful, since HHS has done so in the past. For example, in *Cape Cod Hospital v. Sebelius*, 630 F.3d 203 (D.C. Cir. 2011), this Court invalidated portions of a regulation on the grounds that HHS had incorrectly implemented a statutory provision regarding how certain wage indices should be calculated going back several years. The Court remanded to CMS to explain why it had not undone all of its prior errors, and if it could not provide an explanation beyond its desire for finality, the Court ordered CMS to recalculate the payments due to hospitals that removed all of the prior errors. *Id.* at 216. CMS ultimately paid hospitals corrected amounts going back several years. *See, e.g.*, Rich Daly, *CMS may owe $3 billion; Payments to settle lawsuits in Medicare pay deals*, MODERN HEALTHCARE (Apr. 14, 2012), https://www.modernhealthcare.com/article/20120414/MAGAZINE/304149931/cms-may-owe-3-billion. Similarly, in *Shands Jacksonville Medical Center, Inc. v. Azar*, 366 F. Supp. 3d 32 (D.D.C. 2018), after litigation challenging a reduction in reimbursements for inpatient hospital services of 0.2 percent over a three-year period, HHS "adopt[ed] a one-time 0.6 percent rate increase for FY 2017 to address the effect of the 0.2 percent reduction to the rates in effect for FY 2014, FY 2015, and FY 2016." *Id.* at 39 (internal quotation marks and citation omitted).

HHS is perfectly capable of crafting a remedy to redress past underpayments in the context of a prospective payment system.

Third, even if HHS is correct that adjustments under paragraph (14) must be budget neutral, *retroactive* expenditures that fix a prior, improper underpayment need not be budget neutral. The budget neutrality requirement in paragraph (9), by its terms, applies only to "adjustments" that might otherwise impact the "*estimated* amount of expenditures under [Medicare] for [a] year." § 1395*l*(t)(9)(B) (emphasis added). The reference to "estimated" annual expenditures makes clear that paragraph (9)(B) is speaking of the forward-looking adjustments identified in paragraph (9)(A), not backward-looking remedial payments. *See* Federation of American Hospitals Amicus Br. at 14 ("The law does not permit post-hoc reconciliation or recoupment to achieve budget neutrality after payments are made to providers."). Moreover, HHS has previously made retroactive adjustments on its own initiative without "suggest[ing] any conflict between that retroactive adjustment and budget neutrality." *H. Lee Moffitt Cancer Ctr. & Research Inst. Hosp., Inc. v. Azar*, 324 F. Supp. 3d 1, 15 (D.D.C. 2018). As Judge Kelly noted in *H. Lee Moffitt*, "if HHS can correct its own administrative error by means of a retroactive adjustment, surely it can comply with a congressional[] mandate[] . . . by means of a retroactive adjustment." *Id.* at 16.

Finally, HHS's policy arguments about the difficulty of a remedy are ultimately beside the point. Holding a lawsuit to be precluded is appropriate only in the face of "clear and convincing evidence" that that was Congress's intent. *Amgen*, 357 F.3d at 111. There is no such clear and convincing evidence in the OPPS statute that Congress intended to preclude drug payment determinations under paragraph (14); that is the end of the inquiry.

II. Even if Preclusion Applied to Paragraph (14), the District Court Correctly Held that the Secretary's Decision Is Reviewable Under this Court's *Ultra Vires* Doctrine.

Even if paragraph (12)'s preclusion provisions applied to adjustments under paragraph (14) (and, as demonstrated above, they do not), the district court correctly held that judicial review is not precluded in this case because the Secretary had no authority to make the adjustments at issue here.

In *Amgen*, after holding that paragraph (12)(A) of the OPPS statute precluded judicial review of HHS's decision to use its equitable adjustment authority under paragraph 2(E), this Court held that the preclusion provision prevents review *only* of those adjustments that the OPPS statute authorizes the Secretary to make, and proceeded to review the merits of Amgen's claims. 357 F.3d at 112, 117. As this Court explained, "[t]he presumption is particularly strong that Congress intends judicial review of agency action" that exceeds the agency's authority under a statute. *Id.* at 111–12.

In *DCH Regional Medical Center v. Azar*, 925 F.3d 503 (D.C. Cir. 2019), this Court reviewed an HHS decision under a different section of the Medicare Act and stated that *ultra vires* review is permitted when: "(i) the statutory preclusion of review is implied rather than express; (ii) there is no alternative procedure for review of the statutory claim; and (iii) the agency plainly acts in excess of its delegated powers and contrary to a specific prohibition in the statute that is clear and mandatory." *Id.* at 509 (citation omitted). The principal case on which *DCH Regional Medical Center* relies, *Board of Governors of Federal Reserve System v. MCorp Finanical, Inc.*, 502 U.S. 32 (1991), adopted a more permissive test for judicial review, and held that review under the *Leedom v. Kyne* doctrine is permitted where preclusion would deprive the litigant of a "meaningful and adequate opportunity for judicial review" and where there is a lack of "clarity of the congressional preclusion of review [provision]." *MCorp*, 502 U.S. at 43–44; *see also Leedom v. Kyne*, 358 U.S. 184 (1958).

Under any of these tests, the *ultra vires* exception applies here. First, any preclusion here would be implied rather than express, and certainly lacks clarity as to its applicability to the Secretary's decision in this case. As explained above, the statutory preclusion provisions upon which HHS relies preclude review of adjustments under paragraphs (2) and (9), but not paragraph (14). *See* §§ I.A & I.B, *supra*. If there is preclusion here, it is certainly not express or clear from the text of

paragraph (12). Second, there is no alternative procedure for review of the Appellee's statutory claim, and HHS does not argue otherwise. *See* Gov't Br. at 23-24.

Third and finally, as we demonstrate below and as the district court found, in implementing the rate cut at issue here while purporting to rely on its "adjustment" authority under paragraph (14), HHS acted in excess of its delegated powers and contrary to a specific prohibition in the Medicare statute that is clear and mandatory. As the district court stated, "[w]hile the Secretary is permitted to make 'adjust[ments]' . . . [h]e cannot fundamentally rework the statutory scheme – by applying a different methodology than the provision requires – to achieve under [one provision] what he could not do under [another provision] for lack of adequate data." JA 88–89. As the *Amgen* court explained, "a more substantial departure from the default amounts [will], at some point, violate the Secretary's statutory obligation . . . and cease to be an 'adjustment.'" 357 F.3d at 117. For all of the reasons set forth below with respect to the merits, the district court correctly found that the Secretary's actions were *ultra vires*.

III. The Near-30% Reduction in Reimbursements for Outpatient Drugs Violated HHS's Adjustment Authority Under the OPPS Statute.

HHS's repeated statements (Gov't Br. at 1, 2, 3, 20, 21, 22, 24, 29, 30) that Congress directed it to use acquisition costs to set reimbursement for separately payable outpatient drugs ignore the plain language of the statute and the clear

directions that Congress gave the agency. While HHS is correct that Congress directed the agency to use acquisition costs in specified circumstances, it ignores the statutory language that establishes a methodology for calculating those costs and directs the Secretary to use a different methodology based on ASP if the required data for using acquisition costs are not available. HHS's basic argument is that it can ignore requirements in the statute for calculating acquisition costs and use its authority to adjust average sales price plus overhead to devise its own methodology to estimate acquisition costs. HHS describes a statute that Congress could have written if it had intended to give HHS complete discretion to estimate acquisition costs, but that is not the statute that Congress wrote. HHS's adjustment challenged here effectively repeals a provision of the statute to advance its preferred policy. In addition, a reduction of the magnitude at issue and for the purposes identified by HHS is not an "adjustment" to "average sales price" under the statute. Finally, HHS had no authority to undermine the 340B Program by reducing drug payments only for certain providers.

A. The Secretary cannot set payment amounts based on acquisition costs using his statutory authority to "adjust" ASP.

The OPPS statute identifies two payment methodologies for payments of covered outpatient drugs in two separate subclauses of section 1395*l*(t)(14)(A)(iii). Under subclause (I), the payment is:

> the average acquisition cost for the drug for that year . . . as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D).

Subparagraph (D) requires that the survey data must be based on "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." § 1395*l*(t)(14)(D)(iii) (emphasis added). The Secretary admits that the required survey data are not available and never have been, and thus HHS did not use subclause (I) to set the payment rate. Gov't Br. at 9.

Recognizing that the required acquisition cost data might not be available, Congress provided a second payment methodology in subclause (II), which provides:

> if hospital acquisition cost data are not available, the average price for the drug in the year established under [42 U.S.C. § 1395w-3a] as calculated and adjusted by the Secretary as necessary for purposes of this paragraph.

§ 1395*l*(t)(14)(A)(iii)(II). This is the authority that the Secretary identified in the 2018 and 2019 OPPS Rules to set the payment rate for covered drugs. And for the near-30% reduction in reimbursements for drugs acquired under the 340B Program, HHS purported to rely on its authority to "calculate[] and adjust[]" average sales price. HHS does not deny that its goal in setting prices for 340B drugs was to approximate acquisition costs, and in fact candidly explains that its objective in reducing payments on 340B purchased drugs was to "better align"

those payments "with hospital *acquisition costs*." 2018 OPPS Rule, 82 Fed. Reg. at 52,498 (emphasis added). CMS then proceeded to rely on *estimates* of *aggregate* acquisition costs compiled by MedPAC, rather than use statistically significant acquisition cost data for each drug as required by subclause (I). *See id.* at 52,496. CMS expressed that aggregated acquisition cost estimate as a percentage of ASP—ASP minus 22.5 percent—and then stated that it was "adjusting" ASP by that amount.[22]

HHS's interpretation of the statute would effectively repeal subclause (I) and give it unlimited discretion to establish the reimbursement rate under subclause (II). As the district court held, "[the Secretary] cannot fundamentally rework the statutory scheme—by applying a different methodology than the provision requires---to achieve under sub[clause] (II) what he could not do under sub[clause] (I) for lack of adequate data." JA 88–89.[23]

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[22] MedPAC stated that this estimate was based on approximations of other metrics, such as average manufacturer price (to which MedPAC did not have access) and best price. *See* MedPAC, *Overview of the 340B Drug Pricing Program*, at App. A (May 2015), http://www.medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf.

[23] Similarly, the Government Accountability Office has concluded that the Secretary's adjustment authority does not allow HHS to establish reimbursement rates based on acquisition costs under subclause (II). 2015 GAO Report at 29 ("Medicare uses a statutorily defined formula to pay hospitals at set rates for drugs, *regardless of their costs for acquiring them, which CMS cannot alter based on hospitals' acquisition costs*" (emphasis added)).

If Congress had intended to give CMS broad discretion to estimate acquisition cost by any means, it would not have enacted the subclause (I) data requirement. Instead it would have given CMS flexibility to use whatever data were available to arrive at what it determined was a reasonable estimate of acquisition cost. It quite clearly did no such thing. Indeed, subclause (I)'s structure reflects Congress's clear concern about how the Secretary might use acquisition costs in setting the reimbursement rates for separately payable drugs. In order to ensure that any estimate of acquisition costs was rigorous, subclause (I) requires that acquisition costs be based on data specified in paragraph (14)(D) − *i.e.*, surveys of hospitals that take into account recommendations of the Comptroller General and that "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." § 1395*l*(t)(14)(D)(iii).

If such data are not available, the Secretary may not use acquisition costs and must set the price for separately payable drugs using the methodology in subclause (II). As the district court stated, "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." JA 89.

HHS argues that, because subclause (I) does not include the word "only," the rigorous data requirement in subclause (I) does not limit HHS's authority to set payment rates based on average acquisition costs. According to HHS, the district court's interpretation of subclause (I) replicates the type of *expressio unius* argument that this Court rejected in *Adirondack Medical Center v. Sebelius*, 740 F.3d 692 (D.C. Cir. 2014). Gov't Br. at 31–32. This argument does not survive a textual analysis of the statute.

First, by including the phrase "if hospital acquisition cost data are not available" in subclause (II), Congress *explicitly* limited the use of acquisition costs to determine drug reimbursement to when the survey data are available, as required under subclause (I). Appellees and the district court are not reading the word "only" into the statute. Congress created that limitation.

Second, HHS argues that its authority to "adjust[]" average sales price in subclause (II) overrides the limitation in subclause (I) regarding acquisition cost. As the district court noted, JA 88–89, while subclause (II) authorizes the Secretary to adjust the default rate of ASP plus 6 percent, HHS cannot use this authority to rework the statutory scheme and achieve under subclause (II) what it could not achieve under subclause (I) for lack of data. Moreover, the Secretary's "adjustment" authority extends only to adjustments "as necessary for purposes of this paragraph." § 1395*l*(t)(14)(A)(iii)(II). The purpose of paragraph (14) is to

establish the rate for separately payable drugs, but the statutory text is clear that average acquisition costs may not be used unless they meet the standards established by the statute.

HHS puts forth various policy justifications for the near-30% reduction in payments for 340B drugs, Gov't Br. at 26–29, and Appellees dispute those policy rationales, as noted in comments to the 2018 and 2019 OPPS Rules. *See supra* note 12 and accompanying text. But regardless, those policy goals cannot support an "adjustment" of average sales price that was not designed to accurately adjust the market-based sales price formula required by subclause (II), but was instead was designed to equal the minimum discount of drugs established for certain 340B hospitals under the 340B program, a different statutory regime. Such decisions belong to Congress. *Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302, 325 (2014) ("An agency has no power to 'tailor' legislation to bureaucratic policy goals by rewriting unambiguous statutory terms.").

Finally, HHS cannot rely on its authority to make equitable adjustments under subsection (t)(2)(E) or to periodically adjust OPPS rates in light of new cost data under subsection (t)(9)(A), as it attempts to do in its brief. *See, e.g.*, Gov't Br. at 31 (characterizing the challenged payment cuts as "a quintessential exercise of HHS's authority to make adjustments as necessary to make Medicare payments equitable"); *id.* at 32 (invoking "HHS's broad authority . . . to periodically adjust

OPPS rates in light of 'new cost data.'" (quoting § 1395*l*(t)(9)(A))). The adjustment at issue was made pursuant to subsection (t)(14), not subsection (t)(2)(E) or (t)(9)(A). 2018 OPPS Rule, 82 Fed. Reg. at 52,506–07; 2019 OPPS Rule, 83 Fed. Reg. at 58,979–81. In judging whether a rulemaking was lawful, a court must "look to what the agency said at the time of the rulemaking—not to its lawyers' post-hoc rationalizations." *Council for Urological Interests v. Burwell*, 790 F.3d 212, 222 (D.C. Cir. 2015). That is because of the basic precept of administrative law that "[a] reviewing court . . . must judge the propriety of agency action solely by the grounds invoked by the agency. If those grounds are inadequate or improper, the court is powerless to affirm the administrative action by substituting what it considers to be a more adequate or proper basis." *Id.* (quoting *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947)). HHS did not invoke paragraphs (2)(E) or (9)(A) in making the payment cuts at issue here, and it cannot rely on them now.

Even if the Secretary had invoked subsection (t)(2)(E) or (t)(9)(A), he had no authority to adjust drug reimbursement rates pursuant to either of those provisions. Both paragraphs (2)(E) and (9)(A) permit the Secretary to make adjustments with respect to services for which the payment rate is calculated under paragraph (2), not under paragraph (14). Paragraph (14) establishes a specific reimbursement methodology and a standard for making adjustments for outpatient

drugs. The Secretary could not bypass the specific methodology in paragraph (14) by simply setting reimbursement rates for covered drugs at any rate he chose and characterizing the rate as the product of an equitable adjustment under paragraph (2)(E). *Cf. Am. Hosp. Ass'n v. Azar*, 2019 WL 4451984, at *11 (D.D.C. Sept. 17, 2019) (rejecting HHS argument that, "in a single sentence Congress granted it parallel authority to set payment rates in its discretion" that "would supersede" authority Congress "carefully crafted" elsewhere in the OPPS statute).

Similarly, paragraph (14) sets forth a specific process by which the Secretary can consider acquisition cost when setting payment rates for specified covered drugs. The Secretary could not bypass that entire process by relying on his authority under paragraph (9)(A) to adjust payment rates for *other* covered services based on "new cost data." Paragraph (9) expressly sets forth the items that it requires the Secretary to review and revise based on new cost data and other information: "the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2)." § 1395*l*(t)(9)(A). Drug payment amounts under paragraph (14) are not among them.

B. The almost 30% reduction was not an "adjustment" of the average sales price.

Under subclause (II), the statutory provisions on which the Secretary relied, reimbursement for separately payable drugs in any year after 2005 must be equal to "the average price for the drug in the year . . . *as calculated and adjusted* by the

Secretary as necessary for purposes of this paragraph." § 1395*l*(t)(14)(A)(iii)(II) (emphasis added). The district court correctly held that HHS's near-30% reduction in payments was not an "adjustment" to ASP because it was "sufficiently large and entirely de-coupled from the methodology imposed by sub[clause] (II)." JA 88 n.16.

Although the statutory term "adjust" authorizes the Secretary to make changes, these changes must be supported by a legitimate rationale, incremental and limited. In *Amgen*, this Court held that the Secretary's authority to "make . . . adjustments" to payments under a different part of the OPPS system, § 1395*l*(t)(2)(E), was constrained by the "limitations" that "inhere" in the word "adjustments." 357 F.3d at 117. The Court found those "inhere[nt]" "limitations" to be similar to those the U.S. Supreme Court placed on the word "modify" in *MCI Telecommunications Corp. v. AT&T*, 512 U.S. 218, 225 (1994). In *MCI*, the Supreme Court held that "'modify' . . . has a connotation of *increment or limitation*," 512 U.S. at 225 (emphasis added), and that "every dictionary we are aware of says that 'to modify' means to *change moderately or in minor fashion*." *Id.* (emphasis added) (citing dictionary definitions of modify). *See also id.* at 227-28 ("'Modify,' in our view, connotes moderate change."). Thus, in *Amgen* this Court held that the term "adjustments" does not encompass the power to make basic and fundamental changes in the statutory scheme. 357 F.3d at 117.

As the district court correctly found, "*Amgen*'s logic applies equally here." JA 85. Because "identical words and phrases within the same statute should normally be given the same meaning" and because "Congress did not intend for the term 'adjust' to confer unbridled authority in the context of subsection (t)(2)(E)," this Court's analysis in *Amgen* demonstrates "that Congress did not intend to confer such authority in the context of subsection (t)(14)(A)(iii)(II)." *Id.* (citing *Powerex Corp. v. Reliant Energy Servs., Inc.*, 551 U.S. 224, 232 (2007)).

The structure of subsection (t)(14)(A)(iii)(II) "necessitates this conclusion," as the district court further explained. *Id.* The provision requires reimbursement rates for separately payable drugs to be equal to a rate specified in another statutory provision, ASP plus 6%. "This clear directive is qualified only by the Secretary's authority to 'adjust' those 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." JA 85–86 (citing *Amgen*, 357 F.3d at 117).[24] Dictionary definitions of "adjust" confirm the

[24] *Amgen* itself involved a rate change for a single drug product made by a single company that quite clearly "[did] not work basic and fundamental changes in the scheme Congress created in the Medicare Act." 357 F.3d at 117 (citation & internal quotations omitted).

limits inherent in the word that this Court set forth in *Amgen*.[25] The near-30% rate reduction at issue here is a dramatic departure from the ASP-plus-6% statutory rate that cannot possibly be viewed as a "minor" or "slight" change.

Moreover, an "adjustment" must be tethered to the thing being adjusted, and in no sense was the payment rate that HHS set conceptually related to average sales price. HHS was explicit that it set the payment rate for drugs purchased under the 340B Program to approximate acquisition cost. The mere fact that it expressed the resulting rate as a percentage of ASP does not mean that it arrived at that rate by "adjusting" ASP. The large size of the reduction also is evidence that tethering the new reimbursement rate to ASP was a pretext for setting the rate based on acquisition cost, which HHS admits is what it was doing.

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[25] *Adjust*, Oxford Dictionaries, https://en.oxforddictionaries.com/definition/adjust (defining "adjust" to mean "alter or move (something) *slightly* in order to achieve the desired fit, appearance, or result." (emphasis added); *Adjust*, Cambridge Dictionary, https://dictionary.cambridge.org/dictionary/english/adjust ("to change something *slightly*, especially to make it more correct, effective, or suitable") (emphasis added); *Adjust*, Collins English Dictionary (12th ed. 2014) ("to alter *slightly*, esp. to achieve accuracy; regulate") (emphasis added); *Adjust*, Longman Dictionary, https://www.ldoceonline.com/dictionary/adjust ("to gradually become familiar with a new situation"; "to change or move something *slightly* to improve it or make it more suitable for a particular purpose") (emphasis added); *Adjust*, Merriam-Webster, https://www.merriam-webster.com/dictionary/adjust (defining "adjust" for English language learners to mean "to change (something) *in a minor way* so that it works better.") (emphasis added).

Paragraph (14) also provides guidance as to how Congress envisioned HHS would use its authority to "adjust[]" ASP "as necessary for purposes of this paragraph." § 1395*l*(t)(14)(A)(iii)(II). Paragraph (14)(E) authorizes an "[a]djustment in payment rates *for overhead costs*." § 1395*l*(t)(14)(E) (emphasis added). It makes sense to look to subparagraph (E) for evidence of what "adjustments" Congress was envisioning not only because of subclause (II)'s reference to adjustments "as necessary *for purposes of this paragraph*," but also because paragraph (14)(A) explains that the calculation of payment for separately payable drugs is "subject to subparagraph (E)." § 1395*l*(t)(14)(A)(iii). Indeed, when 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. *See, e.g.*, 2013 OPPS Rule, 77 Fed. Reg. at 68,383–86 (adjusting payment rate under subclause (II) from ASP+4% to ASP+6%). That type of incremental modification, which is tethered to the ASP-plus-6% rate and is designed to make it more accurately reflect factors not captured by ASP alone, is an appropriate "adjustment" given the text and structure of the statute. A replacement of ASP plus 6% with an estimate of acquisition cost, resulting in a rate change of almost 30%, is not.

C. CMS has no authority to treat 340B providers differently or to reverse a Congressional mandate regarding the 340B Program.

When HHS calculated the payment rate under paragraph (14) in 2018 and 2019 for covered outpatient drugs in general, it maintained the ASP-plus-6% rate

that it had paid in previous years. *See* 2018 OPPS Rule, 82 Fed. Reg. at 52,490–91. It was *only* for hospitals participating in the 340B Program that HHS reduced the payment rate to ASP minus 22.5%, purporting to use its authority to adjust ASP. *Id.* at 52,509–10. HHS abused its adjustment authority by specifically targeting non-exempt 340B hospitals.

Paragraph (14) requires HHS to set payment rates on a drug-by-drug basis, and subclause (II) provides no authority for HHS to set special rules for particular hospitals or classes of hospitals. *See* § 1395*l*(t)(14)(A) (setting forth how to calculate "[t]he amount of payment under this subsection *for a specified covered outpatient drug*" (emphasis added)). Subclause (II) envisions that HHS will calculate a drug-by-drug payment rate, using "the average price *for the drug* in the year." § 1395*l*(t)(14)(A)(iii)(II) (emphasis added). The methodology in subclause (II) allows HHS to establish a single payment amount that applies to *all* hospitals. Notably, subclause (I) expressly allows the Secretary to vary payment amounts by hospital group, *see* § 1395*l*(t)(14)(A)(iii)(I), but there is no such authority under subclause (II). There is no indication in paragraph (14) that HHS's authority to "adjust[]" the default rate under subclause (II) "as necessary for purposes of this paragraph" encompasses the sort of differential treatment that HHS undertook here.

Compounding the problem of HHS's selective targeting of 340B hospitals is that the reduced rate undermines the basic purposes of the 340B Program. Under that Program, eligible hospitals and clinics – *i.e.*, those that serve a disproportionately large share of persons who cannot afford care – receive drug price discounts from pharmaceutical companies. As the HHS agency responsible for the 340B Program has recognized, the Program's purpose is for insurance reimbursements for those drugs (which includes reimbursements from Medicare, a government insurance program) to generate additional resources that these hospitals can use to serve their communities, including underserved populations in those communities. 2005 HRSA Manual at 14 (noting that the Program furthers its legislative purpose by "lower[ing] the cost of acquiring covered outpatient drugs" from drug manufacturers, thereby generating additional resources from "health insurance reimbursements" that are "maintained or not reduced as much as the 340B discounts or rebates").

Nothing in the text, structure, or legislative history of the OPPS drug reimbursement provisions, or in HHS's interpretation of those provisions between 2003 and 2017, suggests that Congress intended to give HHS authority through the OPPS system to "align" 340B drug prices with Medicare reimbursements for those drugs, as HHS seeks to do in this case. Thus, CMS's rate reduction amounts to an impermissible attempt by the Secretary "to reconfigure" both Congress's statutory

340B scheme *and* the OPPS drug reimbursement scheme. *Howard v. Pritzker*, 775 F.3d 430, 432 (D.C. Cir. 2015); *see also Can-Am Plumbing, Inc. v. NLRB*, 321 F.3d 145, 154 (D.C. Cir. 2003) (holding that an agency must apply a statute "insofar as possible, in a manner that minimizes the impact of its actions on the policies of . . . [an]other statute") (citation omitted). Indeed, CMS forthrightly acknowledged that its rate reduction was a frontal attack on the congressional purposes behind the 340B Program. *See* 2018 OPPS Rule, 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.").

HHS has justified its efforts to "align" 340B drug prices and reimbursements to 340B hospitals by invoking its policy concerns regarding the effects of the 340B Program on drug utilization and Medicare beneficiaries. Gov't Br. at 26–29; 2018 OPPS Rule, 82 Fed. Reg. at 52,497. Even if those concerns were well-founded, and as discussed above they are not, *see supra* at 12–14, they do not give HHS license to subvert Congressional intent embodied in the 340B Program.

Finally, Congress's intent in the OPPS law to leave operation of the 340B Program undisturbed was confirmed by its decision in the Affordable Care Act to significantly expand the number of 340B hospitals. *See supra* at 10–11 (discussing addition of new categories of covered entities in 2010). This endorsement of the

340B Program is inconsistent with the conclusion that Congress intended to allow HHS to dramatically cut back the Program through the kind of reimbursement rate reduction at issue here.

As the district court stated, "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." JA 89.

CONCLUSION

The judgment of the district court should be affirmed.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH FEDERAL RULE OF APPELLATE PROCEDURE 32(a)

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 12,411 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and D.C. Circuit Rule 32(e)(1).

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

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CERTIFICATE OF SERVICE

Pursuant to D.C. Circuit Rule 25(c), I hereby certify that on September 24, 2019, I caused the foregoing to be electronically filed with the Court using the CM/ECF system. All parties to the case have been served through the CM/ECF system.

/s/ William B. Schultz
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