[ORAL ARGUMENT SCHEDULED FOR NOVEMBER 8, 2019]

Nos. 19-5048, 19-5198

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

AMERICAN HOSPITAL ASSOCIATION, et al.,

Plaintiffs-Appellees,

v.

ALEX M. AZAR II, Secretary of Health & Human Services, et al.,

Defendants-Appellants.

On Appeal from the United States District Court
for the District of Columbia

REPLY BRIEF FOR APPELLANTS

Of Counsel:

ROBERT P. CHARROW
General Counsel

KELLY M. CLEARY
Deputy General Counsel & Chief Legal Officer
Centers for Medicare & Medicaid Services

JANICE L. HOFFMAN
Associate General Counsel

SUSAN MAXSON LYONS
Deputy Associate General Counsel for Litigation

ROBERT W. BALDERSTON
Attorney, Office of the General Counsel
U.S. Department of Health & Human Services

JOSEPH H. HUNT
Assistant Attorney General

MARK B. STERN
ALISA B. KLEIN
LAURA E. MYRON
Attorneys, Appellate Staff
Civil Division, Room 7228
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 514-4819

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GLOSSARY

ACA	Patient Protection and Affordable Care Act
HHS	U.S. Department of Health & Human Services
HRSA	Health Resources and Services Administration
OPD	Outpatient Department
OPPS	Outpatient Prospective Payment System

INTRODUCTION

Under the Outpatient Prospective Payment System (OPPS), the Department of Health and Human Services (HHS) sets Medicare payment rates that are designed to approximate the costs incurred by efficient providers. The Medicare statute directs HHS to revise OPPS rates annually to take into account "new cost data," 42 U.S.C. § 1395*l*(t)(9)(A), and empowers HHS to make "adjustments as determined to be necessary to ensure equitable payments," *id.* § 1395*l*(t)(2)(E). The provision directly at issue here (paragraph 14) sets a default rate of 106% of average sales price for certain drugs, and explicitly provides that the rate be "calculated and adjusted by the Secretary as necessary for purposes of this paragraph," which is to compensate providers for the average acquisition cost of drugs. *Id.* § 1395*l*(t)(14)(A)(iii)(II).

In making the adjustment at issue here, the Secretary recognized that the average acquisition cost of drugs acquired by hospitals under the 340B program is significantly lower than the costs incurred by other hospitals. That differential reflects the fact that manufacturers are required, as a condition of Medicaid participation, to offer drugs at a discounted price to entities covered by the 340B program. After notice-and-comment rulemaking, HHS set the Medicare rate for drugs acquired by 340B hospitals at average sales price minus 22.5%. In doing so, HHS emphasized that it had received no comments suggesting that a different figure would better reflect the 340B hospital acquisition costs for such drugs, and that the rate was a

"conservative" measure that continues to overcompensate many 340B hospitals. 82 Fed. Reg. 52,356, 52,500, 52,502 (Nov. 13, 2017).

Having failed to take issue with the accuracy of this determination during the rulemaking, plaintiffs could not properly challenge its accuracy in court, and they do not do so. Instead, plaintiffs argue that the Medicare trust fund is required to subsidize the separate 340B program by paying covered hospitals at rates substantially higher than their average acquisition costs. On this theory, they claim that 340B hospitals are collectively owed approximately $3 billion. Plaintiffs are quite wrong, however, in asserting that HHS "unlawfully targeted 340B hospitals, undermining the 340B Program." Pl. Br. 2. Nothing in the Medicare statute requires the Secretary to fund the separate 340B program by requiring Medicare payment rates that are far in excess of the hospitals' acquisition costs. Plaintiffs' position is particularly untenable because HHS must establish OPPS payment rates in a budget-neutral manner. Thus, increased payments to 340B hospitals translate directly into reduced payments for other providers.

The Secretary's determination would survive review under any standard. It certainly does not constitute *ultra vires* action, as the district court erroneously concluded in holding that it could undertake review of the adjustment despite the Medicare statute's express bar on judicial review of OPPS rate adjustments. Plaintiffs' alternative contention that this bar does not apply to the payments at issue here rests on a misunderstanding of the relationship among the relevant statutory provisions.

ARGUMENT

A. HHS Acted Within Its Statutory Authority In Making The Challenged Payment Adjustment.

1. HHS used concededly reliable information to bring Medicare's payments more in line with costs incurred by 340B hospitals.

Plaintiffs do not dispute that the purpose of the Outpatient Prospective Payment System is to set Medicare rates that compensate efficient providers for their acquisition costs. Nor do they dispute that the challenged adjustment accurately reflects their acquisition costs. They nevertheless insist that the Secretary was obliged to set Medicare rates for 340B hospitals that are far in excess of their acquisition costs, and that such hospitals are thus collectively entitled to more than $3 billion.

Plaintiffs do not take issue with the background to the rate adjustment at issue here, which is described in detail in our opening brief. Paragraph 14 requires that HHS use "average acquisition cost" for specified covered outpatient drugs, as informed by survey data, to set the Medicare rate when such data are available. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I) ("subclause I"). When such survey data are unavailable, paragraph 14 directs HHS to use average sales price plus 6% as the starting point in setting the Medicare payment rate. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) ("subclause II").[1] As explained in the 2010 Inspector General report on which

[1] The 106% average sales price formula appears in a section that is cross-referenced in subclause II. For ease of reference, we refer to that cross-referenced formula if it appeared in subclause II itself.

plaintiffs rely (Br. 10), that formula is often a good proxy for a drug's acquisition costs. For non-340B hospitals, the Inspector General found that the aggregate Medicare payment amount was only 1% higher than the drugs' acquisition costs. HHS Office of Inspector General, *Memorandum Report: Payment for Drugs Under the Hospital Outpatient Prospective Payment System* 1, 9 (Oct. 22, 2010) (OEI-03-09-00420) (2010 Inspector General Report).[2]

For 340B hospitals, in contrast, the Inspector General found that Medicare payments were 31% higher than acquisition costs. 2010 Inspector General Report at 1. The report noted that its findings were based on a limited sample of hospitals. *See id.* at 7. Those findings were later confirmed, however, in comprehensive reports issued in 2015 and 2016 by the Government Accountability Office, the Medicare Payment Advisory Commission, and the Inspector General. *See* Opening Br. 12. In its 2015 report, the Inspector General found that Medicare payments exceeded 340B ceiling prices by between 25% and 49% for 2013. HHS Office of Inspector General, *Part B Payments for 340B-Purchased Drugs* Exec. Summ., (Nov. 2015) (OEI-12-14-00030) (2015 Inspector General Report).[3] For 35 of the 500 drugs studied, the Inspector General found that the difference between the Medicare payment amount and the 340B ceiling price was so large that, in at least one quarter of 2013, "the beneficiary's

[2] https://go.usa.gov/xVg5Q
[3] https://go.usa.gov/xV2jK

coinsurance alone (i.e., 20 percent) was greater than the amount a covered entity spent to acquire the drug." *Id.* at 9.

Accordingly, in the notice-and-comment rulemaking for the OPPS rate adjustments for 2018, the agency proposed an adjusted rate for 340B hospitals of average sales price minus 22.5%. The agency adopted that rate in its final rule, explaining that it would "better, and more appropriately, reflect the resources and acquisition costs that these hospitals incur," and "lower drug costs for Medicare beneficiaries for drugs acquired by hospitals under the 340B Program." 82 Fed. Reg. 52,356, 52,362 (Nov. 13, 2017).

HHS emphasized that it had received no comments suggesting that a figure other than average sales price minus 22.5% would better reflect the hospital acquisition costs for drugs acquired by 340B providers. As the agency noted, the absence of any dispute was particularly "notable because hospitals have their own data regarding their own acquisition costs, as well as data regarding OPPS payment rates for drugs." 82 Fed. Reg. at 52,500. HHS explained that the failure of any affected hospital to object to the specific figure buttressed its conclusion that "hospitals will not be underpaid for their acquisition costs of such drugs." *Id.* Indeed, the agency emphasized, the adjusted rate is a "conservative" measure that continues to overcompensate many 340B hospitals. *Id.* at 52,502.

2. HHS acted well within its authority in making rate adjustments on the basis of the concededly accurate data.

Having failed to dispute the accuracy of the cost information during the rulemaking, plaintiffs could not dispute its accuracy in court, and they do not do so. Instead, plaintiffs argue that paragraph 14 prohibited the agency from relying on accurate data to make rate adjustments that reflect their acquisition costs.

That is plainly not the case. Subclause II authorizes the Secretary to adjust—"as necessary for purposes of" paragraph 14—the 106% average sales price formula that provides the starting point for the Medicare Part B payment amount for specified covered outpatient drugs. That is precisely what the Secretary did.

Plaintiffs are obliged to acknowledge that subclause II authorizes HHS to adjust the 106% average sales price rate "as necessary for purposes of" paragraph 14. Pl. Br. 42. They suggest, however, that the adjustment does not further those purposes because "[t]he purpose of paragraph (14) is to establish the rate for separately payable drugs." Pl. Br. 42-43. It is unclear what plaintiffs mean by this opaque assertion. The adjustment did establish the rate for the drugs at issue here, and it did so in the manner that advances paragraph 14's overarching purpose to compensate efficient providers for their acquisition costs.

Plaintiffs' observation that subclause I requires HHS to use "statistically significant acquisition cost data" when basing the Medicare rate on survey data, Pl. Br. 40, and to use a "large sample" of hospitals to "ensure that any estimate of

acquisition costs was rigorous," Pl. Br. 41, is beside the point. Although plaintiffs intimate that the data on which HHS relied was not "rigorous," *id.*, no hospital argued in the rulemaking that the cost-ceiling information on which HHS relied was inaccurate or unreliable. On the contrary, the agency's finding that the adjusted rate is a conservative measure that continues to overcompensate 340B hospitals was uncontested.

Plaintiffs are on no firmer ground in urging that the authority to make adjustments under subclause II is confined to "overhead costs." Pl. Br. 49. The statutory authority to make adjustments for overhead costs is in a separate provision that supplements both subclause I and subclause II. *See* 42 U.S.C. § 1395*l*(t)(14)(A)(iii) (making the instructions in subclauses I and II "subject to subparagraph (E)"); *id.* § 1395*l*(t)(14)(E) ("Adjustment in payment rates for overhead costs"). That separate provision, which reflects the difficulty of allocating overhead costs to particular drugs, does not in any way diminish the agency's express authority to adjust the formula in subclause II as necessary for purposes of paragraph 14.

Plaintiffs' insistence that 340B hospitals should receive payments far above their acquisition costs is particularly untenable because of the consequences for other providers and Medicare beneficiaries. Plaintiffs do not dispute that rates established under paragraph 14 are subject to the OPPS statute's budget neutrality requirement. Although paragraph 14(H) exempted payments under paragraph 14 from the budget

neutrality requirement for the 2004 and 2005 years, there is no such exemption for future years.

Nor do plaintiffs deny that inflated Medicare payments for 340B hospitals result in increased copayments for Medicare beneficiaries, whose 20% copayments are tied to the Medicare payment amount. Plaintiffs wrongly state (Br. 13) that HHS failed to acknowledge that many Medicare beneficiaries have supplemental private coverage that reduces or covers their copayments. In fact, HHS specifically addressed that point in the rulemaking. *See* 82 Fed. Reg. at 52,497-98, 52,504. HHS also noted comments indicating that significant numbers of Medicare beneficiaries do not have supplemental coverage and that, for a drug that is paid at $10,000 per month, the adjustment would save a beneficiary approximately $500 a month, which may be the difference between getting treatment and foregoing treatment due to financial reasons. *See id.* at 52,497-98. Moreover, HHS noted that even with respect to beneficiaries with supplemental coverage, the premiums would likely decrease if the Medicare payments to 340B hospitals decreased. *See id.* at 52,498.

Plaintiffs declare that the payment reduction for 340B hospitals caused "concomitant increases" in copayments for other Medicare beneficiaries, Pl. Br. 13, because the savings that resulted from the payment reduction were redistributed in the form of a 3.2% increase in Medicare payment rates for non-drug items and services. However, those rate increases were comparatively small and diffuse because they were spread out across all other services within the OPPS, whereas, before the

rate adjustment at issue here, beneficiaries whose drugs were acquired by 340B hospitals were vastly overpaying for such drugs. Indeed, the Inspector General found that the beneficiary's coinsurance alone could be greater than the entire amount that a 340B hospital spent to acquire the drug. *See* 2015 Inspector General Report at 9. Moreover, as one commenter emphasized, the coinsurance savings that result from the rate adjustment at issue here are particularly significant for cancer patients, because drug cost is an important component of overall outpatient cancer care costs. 82 Fed. Reg. at 52,497. The agency thus reasonably determined that the payment adjustment here would protect the interests of Medicare beneficiaries as well as promoting equity among Medicare providers.

B. The 340B Program And Medicare Program Are Distinct, And No Statute Requires Medicare To Overpay 340B Hospitals.

Plaintiffs get matters backwards when they urge that "HHS abused its adjustment authority by specifically targeting non-exempt 340B hospitals." Pl. Br. 50. The 340B program and Medicare programs are separate programs, and no statute requires Medicare to overpay 340B hospitals.

As plaintiffs note (Br. 7 & n.6), Congress created the 340B program through a provision of the Veterans Health Care Act of 1992 that amended the Public Health Service Act. Section 340B requires drug manufacturers, as a condition of Medicaid participation, to sell drugs at discounted prices to providers known as "covered entities," including, for example, federally qualified health centers. *See* 42 U.S.C.

§ 256b. The statutory provisions that govern the 340B program make no reference to Medicare payments, nor is there any requirement that drugs acquired through the 340B program be used for Medicare beneficiaries.

The 340B program is not administered by HHS's Centers for Medicare & Medicaid Services, but by a different HHS component, the Health Resources and Services Administration (HRSA). And, contrary to plaintiff's assertion, HRSA's 340B manual makes no reference to "reimbursements under Medicare." Pl. Br. 8. On the page that plaintiffs cite (Br. 8 n.7), the manual refers to covered entities that "apply for grants and bill private health insurance."

Plaintiffs' observation (Br. 10, 52-53) that Congress expanded the categories of entities eligible to participate in the 340B program when it enacted the Patient Protection and Affordable Care Act (ACA), has nothing to do with the issues in this case. The ACA's amendments made no reference to Medicare. And, in any event, most of the entities that became eligible for the 340B program by virtue of the ACA's amendments are unaffected by the payment adjustment at issue here, either because they do not receive payment under OPPS or because HHS exempted them from the payment adjustment. *See* 82 Fed. Reg. at 52,362, 52,494-95, 52,506-07 (explaining that critical access hospitals are paid under a different scheme outside OPPS, and that rural sole community hospitals, children's hospitals, and prospective-payment-system-exempt cancer hospitals are exempt from the payment adjustment).

Plaintiffs nevertheless argue that Medicare must overpay 340B hospitals unless HHS gathers the survey data described in subclause I. Plaintiffs emphasize that "subclause (I) expressly allows the Secretary to vary payment amounts by hospital group." Pl. Br. 50.[4] And they argue that, by negative implication, subclause II does not give HHS that authority. *See id.* at 50 (stating that "there is no such authority under subclause (II)").

That *expressio unius* argument is a variant on plaintiffs' central theme, and it fails for the reasons discussed in our opening brief (Br. 31-32). Paragraph 14 does not state that HHS may vary Medicare's payment amounts by hospital group "only" when HHS sets rates under subclause I. As HHS explained, it is generally empowered to adjust drug prices "as necessary" for the overall purposes of paragraph 14, and there is nothing in paragraph 14 to indicate that it is foreclosed from varying Medicare payment for a drug when, as here, a particular group of hospitals acquires the drug at a substantially lower acquisition cost. 82 Fed. Reg. at 52,500. The agency's conclusion echoed this Court's reasoning in *Adirondack Medical Center v. Sebelius*, 740

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[4] Subclause I provides that the Medicare payment amount shall be equal 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] services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D).

42 U.S.C. § 1395*l*(t)(14)(iii)(I) (emphasis added).

F.3d 692 (D.C. Cir. 2014), where the Court emphasized that "Congress generally knows how to use the word 'only' when drafting laws." *Id.* at 697. The "*expressio unius* canon is a 'feeble helper in an administrative setting, where Congress is presumed to have left to reasonable agency discretion questions that it has not directly resolved.'" *Id.* "And when countervailed by a broad grant of authority contained within the same statutory scheme, the canon is a poor indicator of Congress'[s] intent." *Id.*

HHS's interpretation of the statutes that it is charged with administering is thus correct and, at a minimum, reasonable. If there were any doubt on the matter, it is removed by the amendment to § 1395*l*(t) that Congress enacted in October 2018. Although that amendment added a new paragraph 22 that addressed the payment rates for opioids, Congress conspicuously declined to amend paragraph 14—even though HHS had already established the reduced payment rate for drugs acquired by 340B hospitals for the 2018 year and announced its proposal to do the same for 2019. *See* Pub. L. No. 115-271, § 6082, 132 Stat. 3992, 3992-93 (Oct. 24, 2018).

In short, the challenged payment adjustment would properly be upheld even if judicial review were not expressly precluded by the Medicare statute. Furthermore, as explained below, plaintiffs' attempt to circumvent the statute's express preclusion of review is unavailing.

C. The Medicare Statute Expressly Precludes Review Of OPPS Adjustments, Including Adjustments Under Paragraph 14.

1. As the foregoing discussion makes clear, the district court erred in concluding that review was available because the agency actions at issue were *ultra vires*. As our opening brief explained, this Court has never invalidated any OPPS rate as *ultra vires*, and the Court recently clarified that *ultra vires* review is permitted only when "the statutory preclusion of review is implied rather than express" and "the agency plainly acts in excess of its delegated powers and contrary to a specific prohibition in the statute that is clear and mandatory." *DCH Reg'l Med. Ctr. v. Azar*, 925 F.3d 503, 509-10 (D.C. Cir. 2019).

Neither of those conditions is met here. Plaintiffs cannot seriously contend that the Medicare preclusion of review provision is "implied rather than express," Pl. Br. 36, as those terms were used in *DCH Regional*. In explaining what was meant by "implied," this Court referred to a case in which "the putative bar on district-court review was 'implied' from the 'silence' of a statute permitting review in the courts of appeals." *DCH Regional*, 925 F.3d at 509. Here, by contrast, paragraph 12 explicitly provides that "[t]here shall be no administrative or judicial review under section 1395ff of this title, 1395oo of this title, or otherwise of" specified agency actions. 42 U.S.C. § 1395*l*(t)(12) ("Limitation on review"). The statutory preclusion is thus express, not implied.

Nor is this a case in which "the agency plainly acts in excess of its delegated powers and contrary to a specific prohibition in the statute that is clear and mandatory." *DCH Regional*, 925 F.3d at 509-10. On the contrary, the challenged adjustment would properly be upheld even if it were reviewed under the standards of the Administrative Procedure Act, rather than for the "extreme" error that must be shown if an agency action is to be deemed *ultra vires*. *Id.* at 509.

2. a. Plaintiffs offer the alternative argument that rate adjustments made under paragraph 14 are wholly exempt from § 1395*l*(t)'s bar on judicial review of adjustment determinations. This argument fundamentally misunderstands the interaction of the paragraphs of § 1395*l*(t) that collectively govern the Outpatient Prospective Payment System.

Paragraph 2 establishes "[s]ystem requirements" for the entire OPPS, which include the development of a classification system for covered outpatient department services. "In implementing this system, the Secretary groups outpatient services into classifications called Ambulatory Payment Classifications ("APCs"). 42 U.S.C. § 419.31." *Amgen, Inc. v. Scully*, 234 F. Supp. 2d 9, 11 (D.D.C. 2002), *aff'd on other grounds sub nom. Amgen, Inc. v. Smith*, 357 F.3d 103 (D.C. Cir. 2004).[5] Under paragraph 2, HHS classifies covered services into groups, 42 U.S.C. § 1395*l*(t)(2)(A), establishes relative payment weights for covered services, *id.* § 1395*l*(t)(2)(C), and, in a

[5] The terms "ambulatory" and "outpatient" are used interchangeably in the statute and regulations.

budget-neutral manner, makes various adjustments including "adjustments as determined to be necessary to ensure equitable payments," *id.* § 1395*l*(t)(2)(E).

Under paragraph 9, HHS periodically revises these groups, relative payment rates, and adjustments in a budget-neutral manner, to take into account (*inter alia*) new cost data. *Id.* § 1395*l*(t)(9). HHS makes the revisions required by paragraph 9 through annual notice-and-comment rulemaking, as illustrated by the rules at issue here.

In paragraph 12, Congress broadly precluded judicial review of HHS's determinations regarding components of the OPPS. Paragraph 12(A) precludes review of classifications and adjustments made under paragraph 2. And paragraph 12(C) precludes review of periodic adjustments made under paragraph 9.[6]

Paragraph 14 does not, as plaintiffs' analysis suggests, establish a standalone payment regime. Paragraph 14 provides instructions to HHS about how to exercise its paragraph 2 and 9 authority when setting and revising payments with respect to specified covered outpatient drugs. When Congress added paragraph 14 in 2003, it made clear that it was adding a new payment methodology—titled "Drug APC Payment Rates"—within the overall ambulatory payment classification system described in paragraph 2(A). Indeed, a drug is not eligible for payment under paragraph 14 unless it is a drug "for which a separate ambulatory payment

[6] The text of paragraph 12(C) precludes review of the "periodic adjustments made under paragraph (6)," but everyone agrees that this reference to paragraph 6 was a scrivener's error that should have been a reference to paragraph 9. *See* Pl. Br. 7 n.5.

classification group (APC) has been established." 42 U.S.C. § 1395*l*(t)(14)(B)(i). The ambulatory payment classification system described in paragraph 2(A) applies to "covered OPD services," and the specified covered outpatient drugs eligible for payment under paragraph 14(A) are, by definition, "furnished as part of a covered OPD service." *Id.* § 1395*l*(t)(14)(A). Therefore, action taken under paragraph 14 is necessarily action taken under paragraph 2, and review is precluded by paragraph 12(A).

Review is likewise precluded by paragraph 12(C), which precludes review of the periodic rate adjustments made under paragraph 9. The statutory cross-references underscore the applicability of the preclusion provision. Paragraph 14(H) specifically cross-references paragraph 9, and paragraph 9(B) likewise cross-references paragraph 14.[7]

At bottom, plaintiffs' attempt to evade the statutory preclusion rests on the mistaken premise that the Court should review the instructions in paragraph 14 as if they established a standalone reimbursement scheme that does not form part of the broader system of classifications and adjustments made under paragraph 2. *See* Pl.

[7] In district court, we explained that review is also precluded under paragraph 12(E), which precludes review of "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)." Although plaintiffs incorrectly argued that the "under paragraph (6)" language modifies all of the preceding language, it is unnecessary to address that issue because review is independently precluded under paragraph 12(A) and (C).

Br. 23. Paragraph 14 does not establish a standalone payment regime: it provides instructions to HHS about how to exercise its paragraph 2 and 9 authority when setting payments with respect to specified covered outpatient drugs. It is thus immaterial that, as plaintiffs note (Br. 7, 21), paragraph 12 does not itself explicitly cross-reference paragraph 14.

Plaintiffs again misunderstand the interaction of the relevant provisions when they incorrectly declare that "HHS did not invoke its authority under paragraph (9) in making" the adjustments at issue here. Pl. Br. 28. The very purpose of the rulemakings at issue was to make the periodic adjustments to OPPS that are required by paragraph 9, and the preamble to the rules explicitly invoked Secretary's authority under "section 1833(t)(9)(A)," that is, paragraph 9(A). *See* 82 Fed. Reg. at 52,361-62; *see also* 83 Fed. Reg. 58,818, 58,820 (Nov. 21, 2018) (same).

b. Plaintiffs are equally wide of the mark in urging (Br. 31-35) that the policy considerations that underlie the statutory preclusion of review are inapt. As this Court recognized in *Amgen, Inc. v. Smith*, 357 F.3d 103, 112 (D.C. Cir. 2004), the bar on review is "unsurprising" in light of the budget-neutrality requirement for OPPS adjustments. Absent that bar, "[r]eview could result in the retroactive ordering of payment adjustments after hospitals have already received their payments for the year," and "judicially mandated changes in one payment rate would affect the aggregate impact of the Secretary's decisions by requiring offsets elsewhere." *Id.*

Plaintiffs do not and could not contend that payments under paragraph 14 are exempt from the requirement of budget neutrality. As noted above, although paragraph 14(H) exempted such payments from paragraph 9's budget-neutrality mandate for the 2004 and 2005 years, there is no such exemption for subsequent years. Likewise, although paragraph 9(B) exempted from its budget-neutrality mandate the payments made under paragraph 14 for the 2004 and 2005 years, it provided no such exemption for subsequent years. Accordingly, HHS redistributed the $1.6 billion in annual savings from the rate adjustments at issue here, resulting in a 3.2% increase in the Medicare payment rates for non-drug items and services for the 2018 and 2019 years. *See* Opening Br. 15-16.

Plaintiffs instead argue that the $3 billion that 340B hospitals seek for the 2018 and 2019 years should be exempt from the statute's budget-neutrality requirement because such payments would be "backward-looking remedial payments." Pl. Br. 34. Even if plaintiffs were correct that some exception to budget neutrality could apply, the general applicability of the budget-neutrality requirement to paragraph 14 rates underscores the error of their contention that adjustments to rates under paragraph 14 are exempt from the bar on judicial review.

In any event, plaintiffs' assertion that the budget-neutrality requirement does not apply to "backward-looking remedial payments," Pl. Br. 34, turns *Amgen*'s reasoning on its head. As *Amgen* emphasized, Congress precluded judicial review of OPPS payment adjustments because "judicially mandated changes in one payment

rate would affect the aggregate impact of the Secretary's decisions by requiring offsets elsewhere." *Amgen*, 357 F.3d at 112. In other words, the budget-neutrality requirement is a central reason for the preclusion of review. And because judicial review is precluded, there can be no court-ordered remedy to make Medicare payments in violation of the budget-neutrality mandate.

Plaintiffs make no attempt to reconcile their argument with this aspect of *Amgen*'s reasoning. Instead, they rely on this Court's decision in *Cape Cod Hospital v. Sebelius*, 630 F.3d 203 (D.C. Cir. 2011). That case, however, involved the implementation of a budget-neutrality requirement, not an argument that such a requirement may be ignored. *See id.* at 216 (explaining that the Court would remand for HHS "either to explain why reversing all prior rural-floor budget-neutrality adjustments was unnecessary to achieve budget neutrality in 2008," or, if the agency "can provide no explanation beyond the finality concern we have rejected here, to recalculate the payments due the hospitals under a formula that removes the effects of the prior rural-floor budget-neutrality adjustments").[8]

[8] The district court cases that plaintiffs cite are likewise inapposite. *Shands Jacksonville Medical Center, Inc. v. Azar*, 366 F. Supp. 3d 32 (D.D.C. 2018), did not involve a statutory budget-neutrality requirement. *See id.* at 62 ("In certain areas, the Medicare Act does require budget neutrality. This, however, is not one of them.") (citations omitted). And in *H. Lee Moffitt Cancer Center & Research Institute Hospital, Inc. v. Azar*, 324 F. Supp. 3d 1, 19 (D.D.C. 2018), the court did not order additional payments but instead remanded so that HHS could consider and adopt an appropriate adjustment for the year at issue.

The district court here recognized that the "retroactive OPPS payments that [p]laintiffs 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." *American Hosp. Ass'n v. Azar*, 348 F. Supp. 3d 62, 86 (D.D.C. 2018). The court denied plaintiffs' request for an injunction and instead remanded to HHS to devise a remedy. JA144 (concluding that "Plaintiffs' arguments for injunctive relief are unpersuasive"). Plaintiffs did not appeal the denial of an injunction. And in the current rulemaking proceedings, HHS has made clear that budget neutrality has to be taken into account if it were ultimately determined that 340B hospitals are entitled to additional payments. *See* 84 Fed. Reg. 39,398, 39,504 (Aug. 9, 2019).[9]

[9] HHS also has begun the process of collecting the survey data from 340B hospitals that, under the district court's own reasoning, will permit HHS to base the Medicare payment amount on the average acquisition costs for drugs acquired by 340B hospitals. *See* 84 Fed. Reg. 51,590 (Sept. 30, 2019); *see also* https://go.usa.gov/xVeCu (supporting statements).

CONCLUSION

The judgment of the district court should be reversed.

Respectfully submitted,

JOSEPH H. HUNT
Assistant Attorney General

MARK B. STERN
ALISA B. KLEIN
s/ Laura E. Myron
LAURA E. MYRON
Attorneys, Appellate Staff
Civil Division, Room 7228
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 514-4819
laura.e.myron@usdoj.gov

Of Counsel:

ROBERT P. CHARROW
General Counsel

KELLY M. CLEARY
Deputy General Counsel & Chief Legal Officer, Centers for Medicare & Medicaid Services

JANICE L. HOFFMAN
Associate General Counsel

SUSAN MAXSON LYONS
Deputy Associate General Counsel for Litigation

ROBERT W. BALDERSTON
Attorney, Office of the General Counsel
U.S. Department of Health & Human Services

October 2019

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 4,796 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word 2016 in Garamond 14-point font, a proportionally spaced typeface.

s/ Laura E. Myron
LAURA E. MYRON

CERTIFICATE OF SERVICE

I hereby certify that on October 11, 2019, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

s/ Laura E. Myron
LAURA E. MYRON