[ORAL ARGUMENT SCHEDULED FOR APRIL 17, 2020]

Nos. 19-5352, 19-5353, 19-5354

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, in his official capacity as Secretary of Health & Human Services,

Defendant-Appellant.

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

REPLY BRIEF FOR APPELLANT

Of Counsel:

ROBERT P. CHARROW
General Counsel

BRIAN R. STIMSON
Principal Deputy General Counsel

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
Attorneys, Appellate Staff
Civil Division, Room 7235
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 514-1597
alisa.klein@usdoj.gov

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GLOSSARY

CMS	Centers for Medicare & Medicaid Services
HHS	U.S. Department of Health & Human Services
OPPS	Outpatient Prospective Payment System

SUMMARY OF ARGUMENT

To protect the Medicare trust fund, Congress directed the Secretary of Health & Human Services ("HHS") to develop a method for controlling unnecessary increases in the volume of covered outpatient department services. 42 U.S.C. § 1395*l*(t)(2)(F) ("paragraph (2)(F)"). To ensure that such volume-control methods could be implemented without delay, Congress expressly precluded judicial review of "methods described in paragraph (2)(F)." *Id.* § 1395*l*(t)(12)(A).

Our opening brief showed that the volume-control method at issue here falls well within HHS's paragraph (2)(F) authority and is certainly not *ultra vires*. As detailed in the final rule, HHS found that there has been an unnecessary increase in the volume of particular outpatient department services—routine clinic visits—which have shifted over time from freestanding physicians' offices to hospital outpatient departments. HHS found that this shift was induced by the higher rate that Medicare pays under the Outpatient Prospective Payment System ("OPPS"), and that the increase in the volume of outpatient services is unnecessary because beneficiaries can safely receive these routine services in freestanding physicians' offices. Thus, as a volume-control method, HHS reduced the OPPS rate for routine clinic visits to bring it in line with the rate paid under the physician fee schedule.

Plaintiffs assert that HHS never made the predicate findings required by paragraph (2)(F), and instead asserted "freewheeling" authority "to create any kind of payment scheme it likes." Pl. Br. 20. To support this contention, plaintiffs emphasize

that the total volume of "clinic services" does not change when these services are shifted from freestanding physicians' offices to outpatient departments. Pl. Br. 45.

Plaintiffs fundamentally misunderstand the statute. Paragraph (2)(F) directs HHS to control an unnecessary increase in the volume of *outpatient department* services. Services provided by freestanding physicians' offices are not outpatient department services. Whether the total volume of services is lowered has no bearing on the agency's responsibilities under paragraph (2)(F). HHS found: (1) a shift in routine visits from freestanding physicians' offices to outpatient departments; (2) that the shift was induced by the higher payment rate for outpatient services; (3) that the shift was unnecessary; and (4) that equalizing payments would be an effective method of volume control. *See* 83 Fed. Reg. 58,818, 59,006-14 (Nov. 21, 2018). Plaintiffs offer no sound reason for questioning the adequacy of these findings.

Plaintiffs cannot circumvent the statute's preclusion of review of "methods described in paragraph (2)(F)," 42 U.S.C. § 1395*l*(t)(12)(A), by asserting that the challenged volume-control method is *ultra vires*. The *ultra vires* doctrine does not permit a court to disregard an express preclusion of review, and in any event requires a showing that the challenged action is "contrary to a specific prohibition in the statute that is clear and mandatory." *DCH Regional Medical Center v. Azar*, 925 F.3d 503, 509 (D.C. Cir. 2019). Although plaintiffs claim that there is "clear statutory text prohibiting [HHS] from decreasing payment rates for clinic services in a non-budget-neutral manner," Pl. Br. 28, they quote no such prohibition, which is nonexistent.

Furthermore, HHS's interpretation of paragraph (2)(F) is plainly reasonable and would be sustained under the usual *Chevron* framework if review were not barred.

Plaintiffs' alternative argument—which the district court did not adopt—is equally unpersuasive. They contend that section 603 of the Bipartisan Budget Act of 2015 unambiguously exempted them from the Secretary's paragraph (2)(F) authority. But section 603 has no bearing on the issues here. Congress enacted section 603 to address a specific problem: hospitals were buying up freestanding physicians' offices in order to bill Medicare at the higher OPPS rate. To stem that tide, section 603 removed from the OPPS altogether those off-campus outpatient departments established after section 603 was enacted. Such newly established off-campus outpatient departments are paid at a different rate for *all* of the services they provide. Plaintiffs do not fall into that category. Plaintiffs instead represent preexisting off-campus outpatient departments. These remain under the OPPS and continue to receive the standard OPPS payment for most types of services, such as emergency services, x-rays, drugs, and medical supplies. And because they remain subject to the OPPS, they are subject to the volume-control authority in paragraph (2)(F), which the Secretary exercised with respect to one particular type of service—routine clinic visits. Nothing in the text of section 603 gave preexisting off-campus outpatient departments special OPPS privileges or immunities that other outpatient departments do not enjoy.

ARGUMENT

A. Contrary To Plaintiffs' Premise, HHS Found An Unnecessary Increase In The Volume Of Routine Clinic Visits At Off-Campus Hospital Outpatient Departments

The statute that governs the Outpatient Prospective Payment System precludes judicial review of "methods described in paragraph (2)(F)," 42 U.S.C. § 1395*l*(t)(12)(A): that is, methods "for controlling unnecessary increases in the volume of covered [outpatient department] services," *id.* § 1395*l*(t)(2)(F). Plaintiffs' attack on the volume-control method at issue here rests on the mistaken premise that HHS never made the findings required by paragraph (2)(F). They wrongly assert that HHS did not "act in response to an 'increase' in the volume of outpatient services, let alone an 'unnecessary' one." Pl. Br. 44.

As detailed in the final rule, HHS made several critical findings. First, it found that there has been a substantial increase in the volume of routine clinic visits at outpatient departments. Second, it found that this increase in volume resulted from the shift of these routine clinic services from freestanding physicians' offices to outpatient departments. Third, it found that this shift was due in significant part to the fact that Medicare pays more for routine clinic visits at outpatient departments than it pays for the same visits at freestanding physicians' offices. And fourth, HHS found that this increase in the volume of outpatient department services was unnecessary because these routine clinic services can safely be provided at freestanding physicians' offices. *See* 83 Fed. Reg. 58,818, 59,006-14 (Nov. 21, 2018).

Accordingly, as a method of volume control, HHS reduced the payment rate for routine clinic visits for off-campus outpatient departments to equal the rate paid to physicians for the same services. As the agency explained, "capping the OPPS payment at the [physician fee schedule]-equivalent rate" is "an effective method to control the volume of these unnecessary services because the payment differential that is driving the site-of-service decision will be removed." *Id.* at 59,009.

Plaintiffs offer no plausible basis for their contention that there is a "fundamental mismatch between the issue that [HHS] sought to address and the statute it invoked to do so." Pl. Br. 45. Plaintiffs argue that the substantial shift in routine clinic services from freestanding physicians' offices to outpatient departments did not change the total volume of "clinic services." *Id.* But the point of paragraph (2)(F) is not to regulate the total volume of "clinic services." Instead, paragraph (2)(F) directs the Secretary to control unnecessary increases in the volume of *outpatient department* services. Services provided by freestanding physicians' offices are not outpatient department services. And, as plaintiffs recognize, HHS found that the increased volume of outpatient department services was unnecessary, because beneficiaries "can safely receive" these routine clinic services in freestanding physicians' offices. Pl. Br. 45 (quoting 83 Fed. Reg. at 59,010).

Plaintiffs' insistence that HHS failed to make the findings required by paragraph (2)(F) is premised on this basic misunderstanding of this statutory provision. That misunderstanding, in turn, underlies their claim that HHS has

interpreted paragraph (2)(F) to give it "freewheeling authority" to "create any kind of payment scheme it likes." Pl. Br. 20. It likewise underlies their assertions that HHS "claims a sub-sub-sub provision of the Medicare Act implicitly permits the agency to upend the longstanding Medicare reimbursement scheme, and to replace it with the scheme of its choice." Pl. Br. 1.

As the rule makes plain, however, pursuant to the specific authority in paragraph (2)(F), HHS simply reduced the OPPS rate for routine clinic visits as a calibrated response to the payment differential that was driving an unnecessary increase in the volume of those outpatient services. Plaintiffs' extravagant rhetoric does not alter the limited, targeted nature of the rule, which in no respect threatens to "upend the longstanding Medicare reimbursement scheme." Pl. Br. 1.

B. The Statute's Express Preclusion Of Judicial Review Bars This Suit

Congress expressly precluded judicial review of "methods described in paragraph (2)(F)." 42 U.S.C. § 1395*l*(t)(12)(A). That should be the end of this case. As explained above, HHS made the findings required under paragraph (2)(F), and adopted a method that is tailored to control the unnecessary increase in the volume of routine clinic services at outpatient departments. And as this Court recognized in *DCH Regional Medical Center v. Azar*, 925 F.3d 503, 509 (D.C. Cir. 2019), the doctrine of *ultra vires* review does not allow a court to disregard an express preclusion of judicial review.

Nor have plaintiffs demonstrated the prerequisite for *ultra vires* review, which requires a showing that the challenged agency action is "contrary to a specific prohibition in the statute that is clear and mandatory." *DCH*, 925 F.3d at 509. Plaintiffs assert that there is an "obvious violation of a clear statutory command," Pl. Br. 28 (quoting *DCH*, 925 F.3d at 510). But plaintiffs decline to indicate what the clear command might be. Plaintiffs disparage our opening brief for being "sparse on words." Pl. Br. 1. But in their 12,997 words they never identify what, by their account, is the "clear statutory text prohibiting" HHS's volume-control method. Pl. Br. 28. The failure is unsurprising since there is no such prohibition.

Plaintiffs' argument boils down to the assertion that the broad grant of volume-control authority in paragraph (2)(F) should be interpreted narrowly, based on inferences they seek to draw from other OPPS provisions. That is not *ultra vires* review. *See DCH*, 925 F.3d at 509 (emphasizing that an *ultra vires* argument "is essentially a Hail Mary pass—and in court as in football, the attempt rarely succeeds") (citation omitted). Plaintiffs' reliance on *Southwest Airlines Co. v. TSA*, 554 F.3d 1065 (D.C. Cir. 2009), and *COMSAT Corp. v. FCC*, 114 F.3d 223 (D.C. Cir. 1997), is misplaced. As in *DCH,* those cases "involved a far more obvious legal error than anything arguably present here." *DCH*, 925 F.3d at 510. "In *COMSAT*, the agency was authorized to collect fees only for 'rulemaking proceedings or changes in law,' yet it sought to collect fees for concededly different activities." *Id.* (quoting 114 F.3d at 225). "Likewise, in *Southwest Airlines*, the agency was authorized to collect certain fees

only for screening 'passengers and property,' yet it sought to collect those fees for screening non-passengers." *Id.* (quoting 554 F.3d at 1070-71). "Nothing remotely analogous is present here." *Id.*[1]

C. Plaintiffs' Various Attempts To Narrow Paragraph (2)(F) Would, In Any Event, Fail Under The *Chevron* Framework

In any event, plaintiffs' various proposals to narrow the text of paragraph (2)(F) would fail under the familiar *Chevron* framework. Plaintiffs' opening gambit—that the government "forfeited" the argument for *Chevron* deference, Pl. Br. 55—is difficult to comprehend. The government argued for *Chevron* deference below, *see e.g.,* Dkt. No. 21 at 13-14, Case No. 1:18-cv-2841, and the district court agreed that the *Chevron* framework applied. *See American Hospital Association v. Azar*, 410 F. Supp. 3d 142, 151-52 (D.D.C. 2019). That is unsurprising, because it is well settled that HHS's interpretation of the Medicare statute is entitled to *Chevron* deference. *See, e.g.*, *Baystate*

[1] Plaintiffs incorrectly suggest (Br. 17-18) that this Court in *DCH* disregarded a jurisdictional holding in *Amgen v. Smith*, 357 F.3d 103 (D.C. Cir. 2004). The discussion of *ultra vires* review in *Amgen* was dicta because it had no effect on the judgment. Although plaintiffs argue (Br. 18) that "the Court in *Amgen* was required to decide the 'threshold issue' of its own jurisdiction before reaching the merits of the parties' claims," *Amgen* said no such thing, which would have been at odds with the state of the law at the time. *See, e.g., Kramer v. Gates*, 481 F.3d 788, 791 (D.C. Cir. 2007) (noting that the Supreme Court's 1998 decision in *Steel Co. v. Citizens for a Better Environment,* 523 U.S. 83 (1998), "explicitly recognized the propriety of addressing the merits where doing so made it possible to avoid a doubtful issue of *statutory* jurisdiction") (citing *Steel Co.*, 523 U.S. at 96-97 & n.2). *Cf. Kaplan v. Central Bank of the Islamic Republic of Iran*, 896 F.3d 501, 511 (D.C. Cir. 2018) (declining to decide whether subsequent Supreme Court precedent called the vitality of *Kramer*'s distinction into question).

Franklin Med. Ctr. v. Azar, __ F.3d __, No. 18-5264, 2020 WL 625214, at *6 (D.C. Cir. Feb. 11, 2020); *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 417-20 (1993). Plaintiffs rely (Br. 56) on *Smith v. Berryhill*, 139 S. Ct. 1765, 1778 (2019), but that case involved only the scope of the Social Security Act's judicial-review provision, whereas this case involves the substantive volume-control authority in paragraph (2)(F). Plaintiffs also assert that HHS's interpretation is inconsistent with its prior statements, but the district court correctly rejected that assertion for reasons discussed below. *See infra* pp.11-12.

1. Paragraph (2)(F) does not limit HHS to developing an "analytical mechanism" for determining whether there has been an unnecessary increase in volume

Plaintiffs' primary argument—not accepted by the district court—is that paragraph (2)(F) cannot "be read to permit CMS to address service volume directly." Pl. Br. 31. They urge that paragraph (2)(F) merely "permits CMS to adopt an analytical mechanism for *determining* whether there is an unnecessary increase in volume[.]" *Id.*

That argument is flatly at odds with the text of paragraph (2)(F), which says: "[T]he Secretary shall develop a method for controlling unnecessary increases in the volume of covered [outpatient department] services." That is an instruction to control volume directly.

Plaintiffs are equally wrong to assert that the OPPS statute makes an adjustment to the conversion factor the exclusive method of volume control. *See* Pl.

Br. 31. As our opening brief explained (Br. 4), the conversion factor is a multiplier used to translate the relative payment weights into dollar amounts. 42 U.S.C. § 1395*l*(t)(3)(C). Although the statute provides that HHS "may" make an adjustment to the conversion factor as a volume-control method, the text makes clear that adjusting the conversion factor—which has the effect of cutting OPPS rates across-the-board—is a secondary response that the Secretary may employ if the volume of OPPS services increases notwithstanding volume-control methods that HHS develops under paragraph (2)(F). Thus, the statute provides that, if "the Secretary determines under methodologies described in paragraph (2)(F) that the volume of services paid for under this subsection increased *beyond amounts established through those methodologies*," then "the Secretary may appropriately adjust the update to the conversion factor." 42 U.S.C. § 1395*l*(t)(9)(C) (emphasis added). Similarly, the 1997 conference report on which plaintiffs seek to rely explained that, if the Secretary "determined that the volume of services paid for under this subsection increased beyond amounts established through those methodologies, the Secretary would be authorized to adjust the update to the conversion factor." Pl. Br. 38 (quoting H.R. Rep. No. 105-217, at 784 (1997)) (emphasis omitted).

Nor would it make any sense to penalize all outpatient departments with an across-the-board rate cut, when, as here, the unnecessary increase in volume concerns only a particular type of service (routine clinic visits). Plaintiffs argue that this Court must ignore such "policy rationales," Pl. Br. 42, emphasizing that "an agency may not

rewrite clear statutory terms to suit its own sense of how the statute should operate." *Id.* (quoting *Utility Air Regulatory Group v. EPA*, 573 U.S. 302, 328 (2014)). Here, however, the plain text and sound policy are in alignment. It is plaintiffs that are urging the Court to impose constraints that do not appear in the text of paragraph (2)(F). And, to the extent that plaintiffs attempt to supply their own policy rationale for their position, it is unpersuasive, since there is nothing "draconian" about a volume-control method that is tailored to the very services that account for the unnecessary increase in volume. Pl. Br. 43.

Plaintiffs' assertion (Br. 39-40) that HHS previously concluded that a reduction in the conversion factor is the exclusive volume-control method is baseless. As plaintiffs acknowledge (Br. 40 n.6), the district court rejected this contention, and for good reason. Even a cursory look at the passages plaintiffs cite shows that HHS did not describe an adjustment to the conversion factor as the exclusive means of volume control. In the passage from the 1998 rulemaking (63 Fed. Reg. 47,552, 47,586 (Sept. 8, 1998)), HHS considered three methods that would have adjusted the conversion factor and concluded that two would have required legislation because they would modify the Sustainable Growth Rate that Congress had imposed by statute. In the passage from the 2001 rulemaking (66 Fed. Reg. 59,856, 59,908 (Nov. 30, 2001)), HHS simply described various statutory provisions that pertain to updating the conversion factor. And in the passage from the 2007 rulemaking (72 Fed. Reg. 66,580, 66,610 (Nov. 27, 2007)), HHS noted that it had used the packaging of services

as a volume-control method, which belies plaintiffs' contention that HHS regarded an adjustment to the conversion factor as the exclusive volume-control method.[2]

2. Paragraph (2)(F) does not bar HHS from making "non-budget-neutral cuts to specific services" as a method of volume control

As a fallback to their contention that paragraph (2)(F) precludes HHS from addressing volume control directly, plaintiffs assert the position adopted by the district court. They declare that, "even assuming for the sake of argument that Subsection (t)(2)(F) could be read to permit [HHS] to address service volume directly," Pl. Br. 31, it does not allow HHS "to make non-budget-neutral cuts to specific services." Pl. Br. 32.

Like their primary argument, plaintiffs' fallback has no anchor in the statutory text on which they rely. They note that paragraph (2) is titled "System requirements," and emphasize that paragraph (2) begins with the phrase "[u]nder the payment system." Pl. Br. 31-32. From these observations, they appear to infer that the various subsections of paragraph (2)—which they describe derisively as "sub-sub-sub" provisions of the Medicare statute, Pl. Br. 1-2, do not allow HHS to adjust the "amount of payment" determined under the formulas set forth in subsequent paragraphs. Pl. Br. 32.

[2] As plaintiffs recognize, the packaging of services is a method of "encouraging efficient delivery of services." Pl. Br. 40. Packaging was thus implemented in a budget-neutral manner. *See* 72 Fed. Reg. at 66,615. The agency indicated that it would consider other options if packaging and bundling were not sufficient to control unnecessary increases in volume. *See id.* at 66,614.

That line of argument replicates the argument that this Court rejected in *Amgen, Inc. v. Smith*, 357 F.3d 103 (D.C. Cir. 2004). Paragraph (2)'s title "System requirements," and the introductory phrase "[u]nder the payment system," refer to the OPPS generally, which is the payment system that paragraph (1) instructed HHS to establish. The various subsections of paragraph (2) set forth overarching requirements for that payment system and, as this Court recognized in *Amgen*, they qualify the payment formulas that follow. The subsection at issue in *Amgen* was paragraph (2)(E), which in relevant part authorizes the Secretary to adjust payment rates as necessary to ensure equitable payments. The plaintiff in *Amgen* argued that paragraph (2)(E) did not permit HHS to eliminate a supplemental payment that was required under the formula set out in paragraph (6). This Court rejected that argument, recognizing that paragraph (2)(E) gives HHS authority to adjust the payment amounts that result from the payment formulas that follow. *See Amgen*, 357 F.3d at 208.

Paragraph (2)(F) is structurally parallel to paragraph (2)(E) and, like paragraph (2)(E), it qualifies the payment formulas that follow. Given *Amgen*'s holding, it is unclear why plaintiffs disparage paragraph (2)(F) as a "sub-sub-sub provision of the Medicare Act." Pl. Br. 1-2. Plaintiffs make no serious attempt to reconcile their position with the holding of *Amgen*. In a footnote, they observe that *Amgen* "addressed the proper interpretation of Subsection (t)(2)(E), which permits CMS to make equitable adjustments to payment rates in a budget-neutral manner."

Pl. Br. 44 n.8 (emphasis omitted). They declare that, "[i]f anything, *Amgen* suggests that where CMS seeks to make changes in payment rates based on its view of the value of different services, it must do so in a budget neutral manner." *Id.* But paragraph (2)(E) explicitly provides that equitable adjustments shall be made "in a budget-neutral manner." 42 U.S.C. § 1395*l*(t)(2)(E). There is no such requirement in paragraph (2)(F), which is unsurprising because volume-control methods provide a way to "limit increases in *overall* expenditures." *American Hospital Ass'n*, 410 F. Supp. 3d at 147 (emphasis added).

Whereas plaintiffs give short shrift to the holding of *Amgen*—which involved a parallel OPPS provision—they incorrectly assert that "*Hays v. Sebelius*, 589 F.3d 1279 (D.C. Cir. 2009), is directly on point." Pl. Br. 54. *Hays* involved an overarching Medicare provision that applies to Parts A and B, which states that no payment may be made "for any expenses incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). This Court concluded that the phrase "reasonable and necessary" modifies "items and services" rather than "expenses," and thus held that this provision requires Medicare to cover the full cost of items and services that are reasonable and necessary, even if a less costly alternative is available. 589 F.3d at 1281-83.

By contrast, the word "unnecessary" in paragraph (2)(F) of the OPPS statute modifies the phrase "increases in the volume of covered [outpatient department]

services." And as already explained, the challenged rule is a calibrated response to the payment differential that was driving an unnecessary increase in the volume of routine clinic services at outpatient departments.

D. Section 603 Of The Bipartisan Budget Act of 2015 Did Not Exempt Plaintiffs From Paragraph (2)(F)

Plaintiffs argue in the alternative that section 603 of the Bipartisan Budget Act of 2015 exempted them from the Secretary's volume-control authority in paragraph (2)(F) of the OPPS statute. There is no such exemption.

Congress enacted section 603 to address a particular problem: hospitals were buying up freestanding physician practices and converting the billing from the physician fee schedule to the higher outpatient department rate, "without a change in either the physical location or a change in the acuity of the patients seen." 83 Fed. Reg. at 59,008; *see also, e.g.*, Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy* 69-70 (Mar. 2017), https://go.usa.gov/xdCzG; U.S. Gov't Accountability Office, GAO-16-189, *Increasing Hospital-Physician Consolidation Highlights Need for Payment Reform* (Dec. 2015), https://go.usa.gov/xdpQV.

To curb that practice, section 603 removed from the OPPS those off-campus outpatient departments that would be established after section 603 was enacted. *See* Bipartisan Budget Act of 2015, Pub. L. No. 114-74, § 603, 129 Stat. 584, 597-98, codified at 42 U.S.C. § 1395*l*(t)(1)(B)(v), (21). (The following year, Congress clarified that this exclusion from the OPPS did not apply to certain hospitals that were "mid-

build" at the time section 603 was enacted. *See* 21st Century Cures Act, Pub. L. No. 114-255, § 16001, 130 Stat. 1033, 1324 (2016).)

As a result of these amendments to the Medicare statute, newly established off-campus outpatient departments (sometimes referred to as "non-excepted provider based departments") are paid at the physician fee schedule rate for *all* of the services they provide.[3] In other words, these facilities were removed from the OPPS altogether. Congress thus reduced "the incentive that hospitals would otherwise have going forward to purchase physician's offices." Pl. Br. 51.

By contrast, preexisting off-campus outpatient departments (sometimes referred to as "excepted provider based departments") remain under the OPPS. These facilities continue to receive the standard OPPS payment amount for emergency department visits, observation services, x-rays, cardiac catheterizations and thousands of other procedures usually paid under the OPPS. Because preexisting off-campus outpatient departments remain under the OPPS, they also remain subject to the specific OPPS volume-control authority in paragraph (2)(F). In the rule at issue here, HHS exercised that paragraph (2)(F) with respect to a particular outpatient

[3] Section 603 provided that newly established off-campus outpatient departments would be paid under a different payment system to be selected by HHS, and expressly precluded judicial review of the determination of the applicable payment system. 42 U.S.C. § 1395*l*(t)(21)(C), (E). Under the payment system that HHS adopted, the newly established off-campus outpatient departments receive payment at a rate that approximates the rate that would have been paid under the physician fee schedule. 81 Fed. Reg. 79,562, 79,726 (Nov. 14, 2016).

department service—routine clinic visits—based on the finding that there has been an unnecessary increase in the volume of those outpatient department services.

Contrary to plaintiffs' contention, nothing in section 603 exempted them from the Secretary's paragraph (2)(F) authority, or provided a "guarantee" (Br. 48) that they would be reimbursed for every service at the OPPS rate, regardless of whether there was an unnecessary increase in volume of a particular service. There is no such guarantee in the statute, which simply leaves preexisting off-campus outpatient departments subject to the same OPPS provisions that govern outpatient departments generally. The amendments made by section 603, which are codified in 42 U.S.C. § 1395*l*(t)(1)(B)(v), (21), did not in any way restrict the Secretary's authority under paragraph (2)(F) with respect to facilities that remain subject to the OPPS.

Likewise, section 603 did not purport to determine whether an increase in volume of a particular type of outpatient service was "necessary." Pl. Br. 46. Congress left that fact-specific determination to the Secretary to make through rulemaking under paragraph (2)(F), which section 603 did not amend. Although plaintiffs proclaim (Br. 46) that "Congress Unambiguously Provided In Section 603 That Excepted Off-Campus [Provider Based Departments] Must Be Paid At OPPS Rates," they again fail to quote any statutory text that says such a thing.[4]

[4] Based on the 2015 GAO report, plaintiffs state that HHS acknowledged that "Section 603 is best read to require CMS to pay excepted off-campus [provider based departments] for their services at OPPS rates," regardless of whether there is an

Plaintiffs once more battle a straw man when they declare that section 603 did not "leave the treatment of existing facilities to the agency's whims." Pl. Br. 52. The agency did not claim that it could change the payment rate for off-campus outpatient facilities at its whim. The agency exercised the volume-control authority in paragraph (2)(F) of the OPPS statute, after making the predicate findings that there was an unnecessary increase in the volume of a particular type of outpatient service (routine clinic visits).

Contrary to plaintiffs' suggestion, the 2016 House report did not speak of a "guarantee" that preexisting off-campus facilities would receive the OPPS rate for every service they provide. In the passage that plaintiffs quote (Pl. Br. 48), the House report simply stated, as a descriptive matter, that preexisting off-campus facilities "continue to receive the higher payment rates that apply to an outpatient department on the campus of a hospital," H.R. Rep. No. 114-604, pt. 1, at 20 (2016). That description was accurate at the time and remains so today for nearly every type of service these facilities provide. It is equally clear, however, that such "grandfathered" facilities, *id.* at 10, remain subject to the entirety of the OPPS, which includes the volume-control authority in paragraph (2)(F). Nothing in section 603 gave preexisting

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unnecessary increase in the volume of a particular service. Pl. Br. 49-50 & n.10. However, the GAO recognized that HHS had provided only "technical comments" on a draft of the report. U.S. Gov't Accountability Office, GAO-16-189, *Increasing Hospital-Physician Consolidation Highlights Need for Payment Reform* 17 (Dec. 2015), https://go.usa.gov/xdpQV.

off-campus outpatient departments special OPPS privileges or immunities that other outpatient departments do not enjoy. Plaintiffs may "wish[] that Congress had resolved the issue differently," Pl. Br. 54, but that is not license to disregard the actual text of section 603.

CONCLUSION

The judgment of the district court should be reversed.

Respectfully submitted,

JOSEPH H. HUNT
Assistant Attorney General

MARK B. STERN
/s/ Alisa B. Klein
ALISA B. KLEIN
Attorneys, Appellate Staff
Civil Division, Room 7235
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 514-1597
alisa.klein@usdoj.gov

Of Counsel:

ROBERT P. CHARROW
General Counsel

BRIAN R. STIMSON
Principal Deputy General Counsel

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

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 4,677 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/ Alisa B. Klein
ALISA B. KLEIN

CERTIFICATE OF SERVICE

I hereby certify that on March 11, 2020, 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/ Alisa B. Klein
ALISA B. KLEIN