[ORAL ARGUMENT NOT YET SCHEDULED]

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

OPENING BRIEF FOR APPELLANT

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28(a)(1), the undersigned counsel certifies as follows:

A. Parties and Amici

Plaintiffs-appellees in these consolidated cases are American Hospital Association; Association of American Medical Colleges; Mercy Health Muskegon; Clallam County Public Hospital No. 2; York Hospital; University of Kansas Hospital Authority; Columbus Regional Healthcare System; Copley Memorial Hospital, Inc.; East Baton Rouge Medical Center, LLC; Fayette Community Hospital, Inc.; Florida Health Sciences, Inc.; Montefiore Health System, Inc.; Northwest Medical Center; Ochsner Clinic Foundation; OSF Healthcare System; Piedmont Athens Medical Center, Inc.; Piedmont Hospital, Inc.; Piedmont Mountainside Hospital, Inc.; Piedmont Newnan Hospital, Inc.; Rush Oak Park Hospital, Inc.; Rush University Medical Center; Sarasota Memorial Hospital; Charlotte-Mecklenburg Hospital Authority; Rector and Visitors of the University of Virginia; Vanderbilt University Medical Center; Scotland Health Care System; Hackensack Meridian Health; Barnes-Jewish Hospital; Barnes-Jewish West County Hospital; Central Vermont Medical Center, Inc.; Franciscan Missionaries of Our Lady Health System, Inc.; Heartland Regional Medical Center; Missouri Baptist Medical Center; NYU Langone Health System; NYU Winthrop Hospital; Progress West Healthcare Center; Shannon Medical Center; Southwest General Health Center; Stanford Health Care; Tarrant County

Hospital District; Wooster Community Hospital Auxiliary, Inc.; University Hospitals Health System, Inc.; and University of Vermont Medical Center.

Defendant-appellant is Alex M. Azar II, in his official capacity as Secretary of Health & Human Services.

America's Essential Hospitals participated as amicus in district court.

B. Rulings Under Review

The rulings under review were entered in the lead case, *American Hospital Association v. Azar*, No. 1:18-cv-2841 (D.D.C.), by the Honorable Rosemary M. Collyer. They are the district court's September 17, 2019 opinion (Dkt. No. 31) and order (Dkt. No. 32) vacating a Medicare rule insofar as it set a particular payment rate for the 2019 year; and the district court's October 21, 2019 opinion (Dkt. No. 38) and order (Dkt. No. 39) denying the government's motion for reconsideration.

C. Related Cases

These cases were not previously before this Court. Related issues are pending before this Court in *American Hospital Association v. Azar*, Nos. 19-5048 & 19-5198 (D.C. Cir.) (oral argument heard on November 8, 2019).

As noted above, these consolidated cases involve a Medicare payment rule that governed the 2019 year. Plaintiffs recently filed new lawsuits seeking relief with respect to the Medicare payment rule that governs the 2020 year. Those suits are pending before the same judge who issued the rulings on review in these cases. *See American Hospital Association v. Azar*, No. 1:20-cv-80 (D.D.C.), and *University of Kansas Hospital Authority v. Azar*, No. 1:20-cv-75 (D.D.C.).

/s/ Alisa B. Klein
ALISA B. KLEIN

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GLOSSARY

APA	Administrative Procedure Act
E&M visits	evaluation and management office visits
HHS	U.S. Department of Health & Human Services
MedPAC	Medicare Payment Advisory Commission
OPPS	Outpatient Prospective Payment System

STATEMENT OF JURISDICTION

The hospital plaintiffs in these consolidated cases challenged Medicare reimbursement amounts that they received for certain outpatient department services, pursuant to a Medicare rate set through rulemaking for the 2019 year. The hospitals presented concrete claims to the agency and invoked the district court's jurisdiction under the Medicare provision in 42 U.S.C. § 1395ff(b)(1)(A), which incorporates by reference the judicial review provision in 42 U.S.C. § 405(g). The government contested jurisdiction on the ground that judicial review is expressly precluded by the Medicare provision that bars review of the agency's methods for controlling unnecessary increases in the volume of covered outpatient department services. *See* 42 U.S.C. § 1395*l*(t)(12)(A) (cross referencing paragraph (2)(F)).

On September 17, 2019, the district court issued an opinion that declared the challenged aspect of the rule *ultra vires*, and indicated that the rule would be vacated insofar as it set the challenged rate. *American Hospital Association v. Azar*, 410 F. Supp. 3d 142 (D.D.C.). The accompanying order directed the parties to file a joint status report discussing whether additional briefing on remedies was necessary. JA 156-57. On October 21, 2019, the district court denied the government's motion to reconsider the remedy, *American Hospital Association v. Azar*, 2019 WL 5328814 (D.D.C.), and issued a final appealable order, JA 166. The government filed a timely notice of appeal in each of the consolidated cases on December 12, 2019. This Court has appellate jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUE

Each year, through notice-and-comment rulemaking, the Department of Health & Human Services ("HHS") establishes the rates that Medicare will pay hospitals for the upcoming year under the Outpatient Prospective Payment System ("OPPS"). To control costs and protect the Medicare trust fund, the statute directs 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). The statute expressly precludes judicial review of "methods described in paragraph (2)(F)." *Id.* § 1395*l*(t)(12)(A).

In the rule at issue here, HHS determined that there was an unnecessary increase in the volume of certain outpatient department services (routine clinic visits) that could be provided just as safely, and at lower cost, in physicians' offices. HHS thus reduced the Medicare payment rate for those services for hospital outpatient departments to equal the lower rate paid for those services to physicians, who generally are compensated under a different Medicare fee schedule. The question presented is whether the district court erred in declaring that this volume-control method is *ultra vires* and therefore reviewable despite the express preclusion of judicial review, and in vacating that aspect of the rule.

PERTINENT STATUTES AND REGULATIONS

Pertinent provisions are reproduced in the addendum to this brief.

STATEMENT OF THE CASE

I. Statutory And Regulatory Background

A. The Medicare Outpatient Prospective Payment System

The Medicare program provides federally funded medical insurance for the elderly and persons who are disabled. *Amgen, Inc. v. Smith*, 357 F.3d 103, 107 (D.C. Cir. 2004). Part A provides insurance coverage for inpatient hospital care, home health care, and hospice services. Part B is a voluntary program that provides supplemental coverage for other types of care, including outpatient hospital care. *Id.* at 105-06.

Before 1997, the Medicare program paid for hospital outpatient department services based on the reasonable costs actually incurred by the hospital. By the late 1990s, sharp increases in the cost of medical care and demographic changes in the population threatened the Medicare trust fund with insolvency. H.R. Rep. No. 106-436, at 33 (1999). The Balanced Budget Act of 1997 made major revisions in Medicare payment policies in an attempt to save Medicare and reduce its escalating costs. *Id.* As relevant here, the Act directed the Secretary to establish an Outpatient Prospective Payment System under which hospitals are reimbursed based on predetermined rates for outpatient department services. The rates are revised each

year through notice-and-comment rulemaking, and published before they go into effect.

The 1997 legislation included three principal mechanisms to control Medicare costs for hospital outpatient department services. First, to encourage hospital efficiency, the 1997 legislation directed the Secretary to base the Medicare payment amount on the median cost for a service. 42 U.S.C. § 1395*l*(t)(2)(C). To that end, the Secretary establishes classifications for covered services (or groups of covered services that are comparable clinically and in terms of cost), *id.* § 1395*l*(t)(2)(A)-(B); establishes relative payment weights for each classification based on historical data regarding the median cost of the service (or group of services) within the classification, *id.* § 1395*l*(t)(2)(C); and uses a multiplier known as the conversion factor to translate the relative payment weights into dollar amounts, *id.* § 1395*l*(t)(3)(C). The Secretary then adjusts the payment amounts, in budget-neutral manner, to account for regional differences in labor costs and other specified variations. *Id.* § 1395*l*(t)(2)(D) (wage adjustments); *id.* § 1395*l*(t)(2)(E) (other adjustments).

Second, the 1997 legislation required that total prospective payment amounts be no greater than the amounts that would have been paid under a "reasonable cost" approach. 42 U.S.C. § 1395*l*(t)(3)(A), (C). The legislation established a complex formula for calculating increases in this baseline amount, to reflect, among many other factors, population growth, demographic changes and inflation. *Id.* Under the

formula, an increased volume of services generally results in an increase to the baseline.

In any fiscal year, total prospective payments may not exceed the adjusted baseline amount. Thus, although the Secretary is required to make annual updates to payment classifications, relative payment weights, and other components of the prospective payment system in order to reflect changes in technology, medical practice, cost data and other areas, those adjustments must be budget neutral, *i.e.*, they may not cause the estimated amount of expenditures for the year to increase or decrease. 42 U.S.C. § 1395*l*(t)(9)(A)-(B).

Third, the 1997 legislation separately addressed the need to limit unnecessary increases in the volume of covered hospital outpatient department services. As noted above, the budget-neutrality requirement does not prevent such unnecessary increases in volume. Accordingly, the statute directed 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)"). The statute expressly precludes judicial review of (*inter alia*) "methods described in paragraph (2)(F)." *Id.* § 1395*l*(t)(12)(A).

B. Unnecessary Increases In The Volume Of Routine Clinic Visits At Hospital Outpatient Departments

This litigation involves a volume-control method that HHS developed pursuant to its paragraph (2)(F) authority, and implemented as part of the OPPS rule for the

2019 year. Hospital outpatient department services have long been the fastest growing sector of Medicare payments. For many years, the Medicare Payment Advisory Commission ("MedPAC")—an independent agency charged with producing reports on the Medicare program—has expressed concern that a significant part of this increase has been unnecessary. MedPAC has explained that much of this unnecessary increase is attributable to the fact that Medicare pays a higher rate when services are provided by a hospital outpatient department than it pays when the same services are performed in freestanding physicians' offices, which are governed by a different Medicare fee schedule. As discussed below, MedPAC has found that this payment differential created a financial incentive to shift services from physicians' offices (where they are reimbursed at a lower Medicare rate) to hospital outpatient departments (where they are reimbursed at a higher Medicare rate).

In 2014, for example, MedPAC reported that Medicare payment rates for "evaluation and management (E&M) office visits"—essentially routine clinic visits—were much higher in hospital outpatient departments than in physicians' offices, and that hospital outpatient departments had increased their volume of those services while physicians' offices had seen a decrease. *Report to the Congress: Medicare Payment Policy* 42 (Mar. 2014), https://go.usa.gov/xdCzV. MedPAC later reported that the volume of outpatient department services per beneficiary grew by 47% from 2005 to 2015, and that one-third of the growth in outpatient volume from 2014 to 2015 was due to an increase in the number of E&M visits billed as outpatient services. *Report to*

the Congress: Medicare Payment Policy 69 (Mar. 2017), https://go.usa.gov/xdCzG. From 2012 to 2015, outpatient E&M services per beneficiary grew by 22%, compared with a 1% decline in physician office-based visits. *Id.* at 70.

MedPAC concluded that this growth was due, in part, to hospitals purchasing freestanding physician practices and converting the billing from the lower paying physician fee schedule to the higher paying OPPS. *Report to the Congress: Medicare Payment Policy* 69 (Mar. 2014). In 2015, Congress intervened to reduce the incentive for hospitals to continue acquiring freestanding physician practices. In section 603 of the Bipartisan Budget Act of 2015, Pub. L. No. 114-74, 129 Stat. 584, 597-98, Congress provided that newly established off-campus outpatient departments would not receive payment under the OPPS. *See* 42 U.S.C. § 1395*l*(t)(21); *see also* 42 C.F.R. § 413.65(a)(2) (defining an "off-campus" outpatient department as a facility separated by a specified distance (or more) of the hospital with which it is affiliated). That amendment applied to all services that a newly established off-campus outpatient department provides—not just to evaluation and management services.[1]

The amendment did not affect preexisting off-campus outpatient departments, which continued to receive payment under the OPPS and thus remained subject to the agency's general volume-control authority. Growth in outpatient department

[1] In 2016, Congress provided that certain hospitals that were "mid-build" at the time section 603 was enacted would continue to receive payment under the OPPS. 21st Century Cures Act, Pub. L. No. 114-255, § 16001, 130 Stat. 1033, 1324 (2016).

services continued and, in its 2018 report, MedPAC found that the Medicare program spent $1.8 billion more in 2016 than it would have spent if the payment rates for evaluation and management services at outpatient departments were the same as the rates for freestanding physician office rates. *Report to the Congress: Medicare Payment Policy* 73 (Mar. 2018), https://go.usa.gov/xdCzu. MedPAC emphasized these routine clinic visits to outpatient departments had increased by 43.8% (or an average of 7.5% per year) between 2011 and 2016, whereas visits in freestanding offices rose by only 0.4%. *Id.*

C. The 2019 And 2020 OPPS Rules

In the rulemaking for the 2019 year, HHS exercised its paragraph (2)(F) authority to control unnecessary increases in the volume of covered outpatient department services. HHS determined that the growth of routine clinic visits at off-campus hospital outpatient departments was due to the differential between the OPPS payment rate and the lower Medicare rate paid under the physician fee schedule. HHS explained that "these services could likely be safely provided in a lower cost setting," *i.e.*, at physician offices. 83 Fed. Reg. 37,046, 37,142 (July 31, 2018). HHS concluded that "capping the OPPS payment at the [physician fee schedule]-equivalent rate would be 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." 83 Fed. Reg. 58,818, 59,009 (Nov. 21, 2018). HHS thus reduced the Medicare payment rate for routine clinic visits for off-campus outpatient

departments to equal the rate paid to physicians for the same services, and indicated that the rate reduction would be phased in over two years. *Id.* at 59,014.

For the 2019 year, HHS estimated that this volume-control method would result in savings of approximately $300 million to Medicare, and would reduce the copayments that Medicare beneficiaries make by approximately $80 million. 83 Fed. Reg. at 59,014. For the 2020 year, HHS estimated that this volume-control method would result in savings of approximately $640 million to Medicare, and would reduce the copayments that Medicare beneficiaries make by approximately $160 million. 84 Fed. Reg. 61,142, 61,369 (Nov. 12, 2019).

II. District Court Proceedings

Plaintiffs in these consolidated actions are hospital associations and certain member hospitals. The district court declared that the rate reduction for routine clinic visits at off-campus outpatient departments was *ultra vires*, and vacated that aspect of the 2019 OPPS rule. *American Hospital Association v. Azar*, 410 F. Supp. 3d 142 (D.D.C. 2019).

The district court concluded that it could review plaintiffs' claims notwithstanding the Medicare statute's express preclusion of judicial review of "methods described in paragraph (2)(F)" for "controlling unnecessary increases in the volume of covered [outpatient department] services." 42 U.S.C. § 1395*l*(t)(12)(A) (cross-referencing paragraph (2)(F)). The district court acknowledged that "paragraph (t)(12)(A) plainly shields a 'method' to control volume in outpatient

departments from judicial review." 410 F. Supp. 3d at 153. And the court did not question HHS's determination that "capping the OPPS payment at the [physician fee schedule]-equivalent rate would be 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." 83 Fed. Reg. at 58,009.

Nonetheless, the district court declared that it could review the method adopted by HHS because, in the court's view, the chosen method was outside the agency's statutory authority. The court inferred from other aspects of the OPPS scheme that a volume-control method cannot include "service-specific, non-budget-neutral cuts." 410 F. Supp. 3d at 156. The court stated that "Congress established an elaborate statutory scheme which spelled out each step for determining the amount of payment for [outpatient-department] services," *id.*, and generally required that rate adjustments be budget neutral, *id.* at 158. Declaring that Congress does not "hide elephants in mouseholes," the court opined that paragraph (2)(F) does not allow HHS to rely on service-specific, non-budget neutral rate cuts as a method of volume control. *Id.* (quotation marks omitted).

The district court vacated the reduced rate for routine clinic visits in the 2019 rule, 410 F. Supp. 3d at 161, and denied the government's motion to reconsider the remedy and remand without vacatur or to stay the vacatur pending appeal, *American Hospital Association v. Azar*, 2019 WL 5328814 (D.D.C. Oct. 21, 2019). Plaintiffs have since filed new lawsuits seeking the same relief with respect to the rate reduction in

the 2020 OPPS rule, which went into effect on January 1, 2020. *See* 84 Fed. Reg. 61,619 (Nov. 13, 2019); *see American Hospital Association v. Azar*, No. 1:20-cv-80 (D.D.C.), and *University of Kansas Hospital Authority v. Azar*, No. 1:20-cv-75 (D.D.C.).

SUMMARY OF ARGUMENT

To control costs and protect the Medicare trust fund, the statute that governs the Outpatient Prospective Payment System directs 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). The statute expressly precludes judicial review of "methods described in paragraph (2)(F)." *Id.* § 1395*l*(t)(12)(A).

In the rule at issue here, HHS determined that there was an unnecessary increase in the volume of certain routine hospital outpatient services that could be provided just as safely, and at lower cost, in physicians' offices, where services are reimbursed under a different Medicare fee schedule. Accordingly, HHS exercised its paragraph (2)(F) authority to reduce the OPPS payment rate for such services, so as to bring that rate into parity with the lower rate that Medicare pays physicians for the same services.

The district court did not question HHS's determination that "capping the OPPS payment at the [physician fee schedule]-equivalent rate would be 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." 83 Fed. Reg.

58,818, 58,009 (Nov. 21, 2018). Nonetheless, the district court declared this volume-control method *ultra vires* and vacated that aspect of the OPPS rule.

The district court's ruling rests on a misunderstanding of the nature of *ultra vires* review, as well as a misunderstanding of the OPPS provisions on which the court relied. The court did not suggest that the volume-control method at issue here 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), which is a prerequisite to finding an agency action *ultra vires*. Instead, the court drew inferences from a series of OPPS provisions. That is not *ultra vires* review, and, moreover, the inferences drawn by the district court were unwarranted. The agency's contrary understanding of the statute it is charged with administering is correct and, at a minimum, reasonable, and thus would be properly be upheld under the *Chevron* framework if Congress had not precluded judicial review outright.

STANDARD OF REVIEW

The district court's decision rests on issues of law that are subject to de novo review in this Court. *See, e.g.*, *Florida Health Sciences Center, Inc. v. Secretary of HHS*, 830 F.3d 515, 518 (D.C. Cir. 2016).

ARGUMENT

THE METHOD USED BY HHS TO CONTROL UNNECESSARY INCREASES IN THE VOLUME OF MEDICARE-COVERED OUTPATIENT SERVICES IS NOT *ULTRA VIRES*

A. The Volume-Control Method Used By HHS Does Not Contravene Any Specific Statutory Prohibition

Each year, through notice-and-comment rulemaking, the Department of Health & Human Services sets the rates that Medicare will pay hospitals for covered outpatient services under the Outpatient Prospective Payment System. To control costs and protect the Medicare trust fund, the OPPS statute directs 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), and explicitly precludes judicial review of (*inter alia*) "methods described in paragraph (2)(F)," *id.* § 1395*l*(t)(12)(A).

In developing the OPPS rule for the 2019 year, HHS determined that there was an unnecessary increase in the volume of certain outpatient services—routine clinic visits—that could be provided just as safely, and at lower cost, in physicians' offices, where services are reimbursed under a different Medicare fee schedule. 83 Fed. Reg. 58,818, 59,004-14 (Nov. 21, 2018). Accordingly, HHS reduced the Medicare payment rate for those services for outpatient departments to equal the lower rate paid to physicians for the same services, and indicated that the rate reduction would be phased in over two years. *Id.* at 59,014. For the 2019 year, HHS estimated that this volume-control method would result in savings of approximately $300 million to Medicare, and would reduce the copayments that Medicare beneficiaries make by

approximately $80 million. *Id.* For 2020, HHS estimated that this volume-control method would result in savings of approximately $640 million to Medicare, and would reduce the copayments that Medicare beneficiaries make by approximately $160 million. 84 Fed. Reg. 61,142, 61,369 (Nov. 12, 2019).

HHS adopted this method for curbing unnecessary increases in volume in response to several studies issued by the Medicare Payment Advisory Commission, which is the independent agency that is charged with producing reports on the Medicare program. MedPAC's findings traced the unnecessary increase in the volume of covered outpatient services that resulted from the higher rate that Medicare pays when routine clinic services are provided by a hospital outpatient department, rather than in a freestanding physician's office. *See supra* pp. 6-8.

The district court did not question the accuracy of these findings. Nor did the court question HHS's determination that "capping the OPPS payment at the [physician fee schedule]-equivalent rate would be 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." 83 Fed. Reg. at 58,009.

That should have marked the culmination of the district court's analysis. Instead, the court concluded that it could review the agency's method on the ground that it was *ultra vires*. That ruling reflects a basic misunderstanding of the nature of *ultra vires* review. It also reflects a misunderstanding of the OPPS provisions on which the court relied, as discussed in Part B below.

On its face, the broad preclusion of judicial review of the agency actions described in section 1395*l*(t)(12) contains no exceptions. The OPPS statute provides that "[t]here shall be no administrative or judicial review under section 1395ff of this title, 1395oo of this title, or otherwise of" various agency actions including "methods described in paragraph (2)(F)" for controlling unnecessary increase in the volume of covered outpatient department services.

In *Amgen, Inc. v. Smith*, 357 F.3d 103 (D.C. Cir. 2004), this Court stated, in dicta, that it would construe the OPPS bar on judicial review to allow limited review of claims of *ultra vires* action, but this Court has never applied that reasoning to invalidate any OPPS rate. And in *DCH Regional Medical Center v. Azar*, 925 F.3d 503, 509 (D.C. Cir. 2019), this Court 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."

Neither of those conditions is satisfied in this case. The preclusion of judicial review in OPPS statute is express, not implied. And the district court did not suggest that the agency's method was "contrary to a specific prohibition in the statute that is clear and mandatory."

The district court instead conducted an analysis not meaningfully different from review under the Administrative Procedure Act ("APA") to determine whether an agency action is "contrary to law." The court inferred (incorrectly) from various

other statutory provisions that the method employed by HHS is not the type of method that falls within the broad grant of statutory authority. If review of this kind were permissible, the statutory preclusion of judicial review would be largely nullified. Inferring restrictions from a variety of statutory provisions may be appropriate when a court engages in APA review. But such reasoning cannot support a conclusion that agency action is *ultra vires*.

In failing to give effect to the statutory limit on its jurisdiction, the district court's ruling frustrated Congress's intent to ensure that methods to reduce the volume of unnecessary services can be implemented expeditiously, without the delay that is attendant to litigation. *Cf. Texas Alliance for Home Care Services v. Sebelius*, 681 F.3d 402, 409 (D.C. Cir. 2012) (explaining that another Medicare preclusion of review provision "manifest[s] the Congress's intent to proceed with these initial administrative processes without risk of litigation blocking the execution of the program") (quotation marks omitted). The district court's order has delayed the volume-control method that HHS adopted, and shifted to the Medicare trust fund the administrative costs of recouping the overpayments to hospital outpatient departments. Furthermore, the district court is poised to do the same with respect to the rule for the 2020 year—which will greatly compound the harms that Congress sought to avoid by expressly precluding judicial review. *See American Hospital Association v. Azar*, 2019 WL 6841719 (D.D.C. Dec. 16, 2019); *see also American Hospital*

Association v. Azar, No. 1:20-cv-80 (D.D.C.); *University of Kansas Hospital Authority v. Azar*, No. 1:20-cv-75 (D.D.C.).

B. The District Court's Inferences Rest On A Basic Misunderstanding Of The OPPS Scheme

Because the district court fundamentally misunderstood the nature of *ultra vires* review, it is unnecessary to consider the correctness of its inferential analysis. Were the Court to do so, it is equally clear that the district court misunderstood the OPPS provisions on which it relied. By contrast, HHS's interpretation of the statute that it is charged with administering is reasonable and entitled to *Chevron* deference.

The district court stated that "Congress established an elaborate statutory scheme which spelled out each step for determining the amount of payment for [outpatient department] services," 410 F. Supp. 3d at 156, and generally required that rate adjustments be budget neutral, *id.* at 158. From these observations, the court inferred that HHS's authority to establish methods for volume-control does not encompass service-specific, non-budget neutral rate cuts. *Id.* at 156. The court noted, for example, that Medicare payment rates under the OPPS are generally based on the average cost of providing a service, *id.* at 146-47, and declared that the rate-reduction at issue here "would supersede Congress' carefully crafted relative payment system by severing the connection between a service's payment rate and its relative resource use," *i.e.*, cost. *Id.* at 158. The court declared that "[t]here is no reason to think that Congress with one hand granted [HHS] the authority to upend such a 'basic principle'

of the Outpatient Prospective Payment System while working with the other to preserve it." *Id.* at 158-59.

That reasoning fails to appreciate that the general rules that govern OPPS payment rates are expressly qualified by other grants of authority. The statute specifically directs HHS to develop methods for controlling unnecessary increases in the volume of covered outpatient department services. 42 U.S.C. § 1395*l*(t)(2)(F). Nothing in that language suggests that the Secretary cannot seek to control the unnecessary increases in the volume of routine visits at outpatient departments by addressing a payment differential that skews the market—with adverse effects on Medicare beneficiaries in the form of increased copayments and on the Medicare trust fund. The district court could not deny that the agency's method would indeed "be 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." 83 Fed. Reg. at 59,009.

The district court's assumption that cost considerations for hospital outpatient departments trump all other statutory provisions and equitable considerations is unfounded, as illustrated by this Court's holding in *Amgen*. In that case, HHS eliminated a supplemental payment for one drug because of "the availability of the clinically similar yet cheaper" alternative, reasoning that it was not "an equitable or efficient use of Medicare funds to pay for these two functionally equivalent products at greatly different rates." 357 F.3d at 108. This Court upheld the rate reduction as a

permissible exercise of HHS's paragraph (2)(E) authority to adjust payment rates "as determined to be necessary to ensure equitable payments"—even though that rate reduction severed the connection between the payment rate for Amgen's product and the product's cost. Here, too, the general rules that govern OPPS payment rates are qualified by HHS's explicit authority under paragraph (2)(F) to develop methods to control unnecessary increases in the volume of covered outpatient department services, and the agency properly exercised that explicit grant of authority.

In a variant on the same reasoning, the district court noted that Congress generally "required that adjustments to the Outpatient Prospective Payment System be made in a budget-neutral fashion," 410 F. Supp. 3d at 158, yet imposed no such constraint on the volume-control methods developed under paragraph (2)(F), *see id.* at 159. The court inferred from "how pervasively the statute requires budget neutrality in the Outpatient Prospective Payment System" that Congress could not have intended to allow HHS to use a service-specific, non-budget neutral rate reduction as a method of controlling unnecessary increases in volume. *Id.* The court drew the wrong inference from this statutory structure. The requirement of budget neutrality is not designed to limit unnecessary increases in the volume of outpatient department services, which is why Congress separately empowered HHS to do so in paragraph (2)(F). As the district court itself recognized, Congress gave HHS the volume-control authority because it was "[c]oncerned that fee schedule limits would

not adequately limit increases in *overall* expenditures," *id.* at 147 (emphasis added), an issue the budget-neutrality requirement does not address.

The district court also noted that, under paragraph (9)(C), "[i]f 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 otherwise applicable in a subsequent year." 410 F. Supp. 3d at 147. The court inferred that an adjustment to the conversion factor is the only permissible form of rate adjustment that HHS may use to control unnecessary increases in volume. But by its terms, this paragraph (9)(C) authority is permissible: HHS "may" adjust the conversion factor—which would have the effect of reducing Medicare payment rates across-the-board—under specified circumstances. Paragraph (9)(C) does not make an adjustment to the conversion factor the exclusive volume-control method. And here, HHS was not addressing an across-the-board unnecessary increase in the volume of covered outpatient department services, but an unnecessary increase in the volume of particular outpatient department services: the routine clinic services that can be provided just as safely, and at lower cost, in a freestanding physician's office. Nothing in the statute compels HHS to penalize all outpatient

departments (by adjusting the conversion factor) in order to control unnecessary increases in the volume of particular services.[2]

CONCLUSION

The judgment of the district court should be reversed.

Respectfully submitted,

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[2] The district court did not adopt plaintiffs' alternative argument, that section 603 of the Bipartisan Budget Act of 2015—which excluded certain newly established outpatient departments from the OPPS—implicitly barred HHS from using its general paragraph (2)(F) authority to control an unnecessary increase in the volume of covered services at outpatient departments that continue to receive payment under the OPPS. If plaintiffs renew this line of argument on appeal, we will address it in our reply brief.

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 4,790 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
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CERTIFICATE OF SERVICE

I hereby certify that on January 23, 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
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ADDENDUM

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42 U.S.C. § 1395*l*(t) (excerpts) .... Add. 1

42 U.S.C. § 1395*l*(t) Prospective Payment System for Hospital Outpatient Department Services

(1) Amount of payment

(A) In general

With respect to covered OPD services (as defined in subparagraph (B)) furnished during a year beginning with 1999, the amount of payment under this part shall be determined under a prospective payment system established by the Secretary in accordance with this subsection.

(B) Definition of covered OPD services

For purposes of this subsection, the term "covered OPD services"--

(i) means hospital outpatient services designated by the Secretary;

(ii) subject to clause (iv), includes inpatient hospital services designated by the Secretary that are covered under this part and furnished to a hospital inpatient who (I) is entitled to benefits under part A but has exhausted benefits for inpatient hospital services during a spell of illness, or (II) is not so entitled;

(iii) includes implantable items described in paragraph (3), (6), or (8) of section 1395x(s) of this title;

(iv) does not include any therapy services described in subsection (a)(8) or ambulance services, for which payment is made under a fee schedule described in section 1395m(k) of this title or section 1395m(l) of this title and does not include screening mammography (as defined in section 1395x(jj) of this title), diagnostic mammography, personalized prevention plan services (as defined in section 1395x(hhh)(1) of this title), or preventive services described in subparagraphs (A) and (B) of section 1395x(ddd)(3) of this title that are appropriate for the individual and, in the case of such services described in subparagraph (A), are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population; and

(v) does not include applicable items and services (as defined in subparagraph (A) of paragraph (21)) that are furnished on or after January 1, 2017, by an off-campus outpatient department of a provider (as defined in subparagraph (B) of such paragraph).

(2) System Requirements

Under the payment system—

(A) the Secretary shall develop a classification system for covered OPD services;

(B) the Secretary may establish groups of covered OPD services, within the classification system described in subparagraph (A), so that services classified within each group are comparable clinically and with respect to the use of resources and so that an implantable item is classified to the group that includes the service to which the item relates;

(C) the Secretary shall, using data on claims from 1996 and using data from the most recent available cost reports, establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B)) based on median (or, at the election of the Secretary, mean) hospital costs and shall determine projections of the frequency of utilization of each such service (or group of services) in 1999;

(D) subject to paragraph (19), the Secretary shall determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner;

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

(F) the Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services;

(G) the Secretary shall create additional groups of covered OPD services that classify separately those procedures that utilize contrast agents from those that do not; and

(H) with respect to devices of brachytherapy consisting of a seed or seeds (or radioactive source), the Secretary shall create additional groups of covered OPD services that classify such devices separately from the other services (or group of services) paid for under this subsection in a manner reflecting the number, isotope, and radioactive intensity of such devices furnished, including separate groups for palladium-103 and iodine-125 devices and for stranded and non-stranded devices furnished on or after July 1, 2007.

For purposes of subparagraph (B), items and services within a group shall not be treated as "comparable with respect to the use of resources" if the highest median cost (or mean cost, if elected by the Secretary under subparagraph (C)) for an item or service within the group is more than 2 times greater than the lowest median cost (or mean cost, if so elected) for an item or service within the group; except that the Secretary may make exceptions in unusual cases, such as low volume items and services, but may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 360bb of Title 21.

(3) Calculation of base amounts

(A) Aggregate amounts that would be payable if deductibles were disregarded

The Secretary shall estimate the sum of--

(i) the total amounts that would be payable from the Trust Fund under this part for covered OPD services in 1999, determined without regard to this subsection, as though the deductible under subsection (b) did not apply, and

(ii) the total amounts of copayments estimated to be paid under this subsection by beneficiaries to hospitals for covered OPD services in 1999, as though the deductible under subsection (b) did not apply.

(B) Unadjusted copayment amount

(i) In general

For purposes of this subsection, subject to clause (ii), the "unadjusted copayment amount" applicable to a covered OPD service (or group of such services) is 20 percent of the national median of the charges for the service (or services within the group) furnished during 1996, updated to 1999 using the Secretary's estimate of charge growth during the period.

(ii) Adjusted to be 20 percent when fully phased in

If the pre-deductible payment percentage for a covered OPD service (or group of such services) furnished in a year would be equal to or exceed 80 percent, then the unadjusted copayment amount shall be 20 percent of amount determined under subparagraph (D).

(iii) Rules for new services

The Secretary shall establish rules for establishment of an unadjusted copayment amount for a covered OPD service not furnished during 1996, based upon its classification within a group of such services.

(C) Calculation of conversion factors

(i) For 1999

(I) In general

The Secretary shall establish a 1999 conversion factor for determining the medicare OPD fee schedule amounts for each covered OPD service (or group of such services) furnished in 1999. Such conversion factor shall be established on the basis of the weights and frequencies described in paragraph (2)(C) and in such a manner that the sum for all services and groups of the products (described in subclause (II) for each such service or group) equals the total projected amount described in subparagraph (A).

(II) Product described

The Secretary shall determine for each service or group the product of the medicare OPD fee schedule amounts (taking into account appropriate adjustments described in paragraphs (2)(D) and (2)(E)) and the estimated frequencies for such service or group.

(ii) Subsequent years

Subject to paragraph (8)(B), the Secretary shall establish a conversion factor for covered OPD services furnished in subsequent years in an amount equal to the conversion factor established under this subparagraph and applicable to such services furnished in the previous year increased by the OPD fee schedule increase factor specified under clause (iv) for the year involved.

(iii) Adjustment for service mix changes

Insofar as the Secretary determines that the adjustments for service mix under paragraph (2) for a previous year (or estimates that such adjustments for a future year) did (or are likely to) result in a change in aggregate payments under this subsection during the year that are a result of changes in the coding or classification of covered OPD services that do not reflect real changes in service mix, the Secretary may adjust the conversion factor computed under this subparagraph for subsequent years so as to eliminate the effect of such coding or classification changes.

(iv) OPD fee schedule increase factor

For purposes of this subparagraph, subject to paragraph (17) and subparagraph (F) of this paragraph, the "OPD fee schedule increase factor" for services furnished in a year is equal to the market basket percentage increase applicable under section 1395ww(b)(3)(B)(iii) of this title to hospital discharges occurring during the fiscal year ending in such year, reduced by 1 percentage point for such

factor for services furnished in each of 2000 and 2002. In applying the previous sentence for years beginning with 2000, the Secretary may substitute for the market basket percentage increase an annual percentage increase that is computed and applied with respect to covered OPD services furnished in a year in the same manner as the market basket percentage increase is determined and applied to inpatient hospital services for discharges occurring in a fiscal year.

(D) Calculation of medicare OPD fee schedule amounts

The Secretary shall compute a medicare OPD fee schedule amount for each covered OPD service (or group of such services) furnished in a year, in an amount equal to the product of--

(i) the conversion factor computed under subparagraph (C) for the year, and

(ii) the relative payment weight (determined under paragraph (2)(C)) for the service or group.

(E) Pre-deductible payment percentage

The pre-deductible payment percentage for a covered OPD service (or group of such services) furnished in a year is equal to the ratio of--

(i) the medicare OPD fee schedule amount established under subparagraph (D) for the year, minus the unadjusted copayment amount determined under subparagraph (B) for the service or group, to

(ii) the medicare OPD fee schedule amount determined under subparagraph (D) for the year for such service or group.

(F) Productivity and other adjustment

After determining the OPD fee schedule increase factor under subparagraph (C)(iv), the Secretary shall reduce such increase factor--

(i) for 2012 and subsequent years, by the productivity adjustment described in section 1395ww(b)(3)(B)(xi)(II) of this title; and

(ii) for each of 2010 through 2019, by the adjustment described in subparagraph (G).

The application of this subparagraph may result in the increase factor under subparagraph (C)(iv) being less than 0.0 for a year, and may result in payment rates under the payment system under this subsection for a year being less than such payment rates for the preceding year.

(G) Other adjustment

For purposes of subparagraph (F)(ii), the adjustment described in this subparagraph is--

(i) for each of 2010 and 2011, 0.25 percentage point;

(ii) for each of 2012 and 2013, 0.1 percentage point;

(iii) for 2014, 0.3 percentage point;

(iv) for each of 2015 and 2016, 0.2 percentage point; and

(v) for each of 2017, 2018, and 2019, 0.75 percentage point.

(4) Medicare payment amount

The amount of payment made from the Trust Fund under this part for a covered OPD service (and such services classified within a group) furnished in a year is determined, subject to paragraph (7), as follows:

(A) Fee schedule adjustments

The medicare OPD fee schedule amount (computed under paragraph (3)(D)) for the service or group and year is adjusted for relative differences in the cost of labor and other factors determined by the Secretary, as computed under paragraphs (2)(D) and (2)(E).

(B) Subtract applicable deductible

Reduce the adjusted amount determined under subparagraph (A) by the amount of the deductible under subsection (b), to the extent applicable.

(C) Apply payment proportion to remainder

The amount of payment is the amount so determined under subparagraph (B) multiplied by the pre-deductible payment percentage (as determined under paragraph (3)(E)) for the service or group and year involved, plus the amount of any reduction in the copayment amount attributable to paragraph (8)(C).

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(9) Periodic Review and Adjustments Components of Prospective Payment System

(A) Periodic Review—The Secretary shall review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) 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. The Secretary shall consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the groups and weights. Such panel may use data collected or developed by entities and organizations (other than the Department of Health and Human Services) in conducting such review.

(B) Budget Neutrality Adjustment—If the Secretary makes adjustments under subparagraph (A), then the adjustments for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made. In determining adjustments under the preceding sentence for 2004 and 2005, the Secretary shall not take into account under this subparagraph or paragraph (2)(E) any expenditures that would not have been made but for the application of paragraph (14).

(C) Update Factor—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, the Secretary may appropriately adjust the update to the conversion factor otherwise applicable in a subsequent year.

****

(12) Limitation on Review—There shall be no administrative or judicial review under section 1395ff of this title, 1395oo of this title, or otherwise of—

(A) the development of the classification system under paragraph (2), including the establishment of groups and relative payment weights for covered OPD services, of wage adjustment factors, other adjustments, and methods described in paragraph (2)(F);

(B) the calculation of base amounts under paragraph (3);

(C) periodic adjustments made under paragraph (6);

(D) the establishment of a separate conversion factor under paragraph (8)(B); and

(E) the determination of the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applicable percentage under paragraph (5) or the determination of insignificance of cost, the duration of the additional payments, the determination and deletion of initial and new categories (consistent with subparagraphs (B) and (C) of paragraph (6)), the portion of the Medicare OPD fee schedule amount associated with particular devices, drugs, or biologicals, and the application of any pro rata reduction under paragraph (6).

****

(21) Services furnished by an off-campus outpatient department of a provider

(A) Applicable items and services

For purposes of paragraph (1)(B)(v) and this paragraph, the term "applicable items and services" means items and services other than items and services furnished by a dedicated emergency department (as defined in section 489.24(b) of title 42 of the Code of Federal Regulations).

(B) Off-campus outpatient department of a provider

(i) In general

For purposes of paragraph (1)(B)(v) and this paragraph, subject to the subsequent provisions of this subparagraph, the term "off-campus outpatient department of a provider" means a department of a provider (as defined in section 413.65(a)(2) of title 42 of the Code of Federal Regulations, as in effect as of November 2, 2015) that is not located--

(I) on the campus (as defined in such section 413.65(a)(2)) of such provider; or

(II) within the distance (described in such definition of campus) from a remote location of a hospital facility (as defined in such section 413.65(a)(2)).

(ii) Exception

For purposes of paragraph (1)(B)(v) and this paragraph, the term "off-campus outpatient department of a provider" shall not include a department of a provider (as so defined) that was billing under this subsection with respect to covered OPD services furnished prior to November 2, 2015.

(iii) Deemed treatment for 2017

For purposes of applying clause (ii) with respect to applicable items and services furnished during 2017, a department of a provider (as so defined) not described in such clause is deemed to be billing under this subsection with respect to covered OPD services furnished prior to November 2, 2015, if the Secretary received from the provider prior to December 2, 2015, an attestation (pursuant to section 413.65(b)(3) of title 42 of the Code of Federal Regulations) that such department was a department of a provider (as so defined).

(iv) Alternative exception beginning with 2018

For purposes of paragraph (1)(B)(v) and this paragraph with respect to applicable items and services furnished during 2018 or a subsequent year, the term "off-campus outpatient department of a provider" also shall not include a department of a provider (as so defined) that is not described in clause (ii) if--

(I) the Secretary receives from the provider an attestation (pursuant to such section 413.65(b)(3)) not later than December 31, 2016 (or, if later, 60 days after December 13, 2016), that such department met the requirements of a department of a provider specified in section 413.65 of title 42 of the Code of Federal Regulations;

(II) the provider includes such department as part of the provider on its enrollment form in accordance with the enrollment process under section 1395cc(j) of this title; and

(III) the department met the mid-build requirement of clause (v) and the Secretary receives, not later than 60 days after December 13, 2016, from the chief executive officer or chief operating officer of the provider a written certification that the department met such requirement.

(v) Mid-build requirement described

The mid-build requirement of this clause is, with respect to a department of a provider, that before November 2, 2015, the provider had a binding written agreement with an outside unrelated party for the actual construction of such department.

(vi) Exclusion for certain cancer hospitals

For purposes of paragraph (1)(B)(v) and this paragraph with respect to applicable items and services furnished during 2017 or a subsequent year, the term "off-campus outpatient department of a provider" also shall not include a department of a provider (as so defined) that is not described in clause (ii) if the provider is a hospital described in section 1395ww(d)(1)(B)(v) of this title and--

(I) in the case of a department that met the requirements of section 413.65 of title 42 of the Code of Federal Regulations after November 1, 2015, and before December 13, 2016, the Secretary receives from the provider an attestation that such department met such requirements not later than 60 days after such date; or

(II) in the case of a department that meets such requirements after such date, the Secretary receives from the provider an attestation that such department meets such requirements not later than 60 days after the date such requirements are first met with respect to such department.

(vii) Audit

Not later than December 31, 2018, the Secretary shall audit the compliance with requirements of clause (iv) with respect to each department of a provider to which such clause applies. Not later than 2 years after the date the Secretary receives an attestation under clause (vi) relating to compliance of a department of a provider with requirements referred to in such clause, the Secretary shall audit the compliance with such requirements with respect to the department. If the Secretary finds as a result of an audit under this clause that the applicable requirements were not met with respect to such department, the department shall not be excluded from the term "off-campus outpatient department of a provider" under such clause.

(viii) Implementation

For purposes of implementing clauses (iii) through (vii):

(I) Notwithstanding any other provision of law, the Secretary may implement such clauses by program instruction or otherwise.

(II) Subchapter I of chapter 35 of Title 44 shall not apply.

(III) For purposes of carrying out this subparagraph with respect to clauses (iii) and (iv) (and clause (vii) insofar as it relates to clause (iv)), $10,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title, to remain available until December 31, 2018. For purposes of carrying out this subparagraph with respect to clause (vi) (and clause (vii) insofar as it relates to such clause), $2,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title, to remain available until expended.

(C) Availability of payment under other payment systems

Payments for applicable items and services furnished by an off-campus outpatient department of a provider that are described in paragraph (1)(B)(v) shall be made

under the applicable payment system under this part (other than under this subsection) if the requirements for such payment are otherwise met.

(D) Information needed for implementation

Each hospital shall provide to the Secretary such information as the Secretary determines appropriate to implement this paragraph and paragraph (1)(B)(v) (which may include reporting of information on a hospital claim using a code or modifier and reporting information about off-campus outpatient departments of a provider on the enrollment form described in section 1395cc(j) of this title).

(E) Limitations

There shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise of the following:

(i) The determination of the applicable items and services under subparagraph (A) and applicable payment systems under subparagraph (C).

(ii) The determination of whether a department of a provider meets the term described in subparagraph (B).

(iii) Any information that hospitals are required to report pursuant to subparagraph (D).

(iv) The determination of an audit under subparagraph (B)(vii).

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