[ORAL ARGUMENT HAS NOT BEEN SCHEDULED]

No. 19-5352
(Consolidated with Nos. 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 and Human Services,

Defendant-Appellant.

On Appeal From a Final Judgment of the United States District Court for the District of Columbia (Collyer, J.)

BRIEF OF DIGESTIVE HEALTH PHYSICIANS ASSOCIATION, LARGE UROLOGY GROUP PRACTICE ASSOCIATION, AND THE ORTHOFORUM AS *AMICI CURIAE* IN SUPPORT OF DEFENDANT-APPELLANT AND REVERSAL

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CORPORATE DISCLOSURE STATEMENT AND CONSENT TO FILE

Pursuant to Federal Rule of Appellate Procedure 26.1 and D.C. Circuit Rule 26.1, *amici curiae* state as follows:

1. Digestive Health Physicians Association has no parent corporation, and no publicly traded company owns 10% or more of its stock.
2. Large Urology Group Practice Association has no parent corporation, and no publicly traded company owns 10% or more of its stock.
3. The OrthoForum has no parent corporation, and no publicly traded company owns 10% or more of its stock.

Amici curiae are trade associations representing approximately 350 independent physician practices made up of nearly 8,000 physicians in the fields of gastroenterology, urology, orthopaedic surgery, pathology, and radiation oncology.

Pursuant to Federal Rule of Appellate Procedure 29(a)(2) and D.C. Circuit Rule 29(b), *amici curiae* state that all parties to this proceeding have consented to the filing of this brief.

TABLE OF CONTENTS

CORPORATE DISCLOSURE STATEMENT AND CONSENT TO FILE i

TABLE OF AUTHORITIES iv

GLOSSARY vi

STATEMENT OF INTEREST OF *AMICI CURIAE* 1

ARGUMENT 2

I. THE SECRETARY ACTED WITHIN HIS DISCRETION—AND CERTAINLY DID NOT COMMIT THE KIND OF EXTREME AGENCY ERROR NECESSARY TO SUSTAIN AN *ULTRA VIRES* CHALLENGE—WHEN HE ESTABLISHED A RATE CAP AS A METHOD FOR CONTROLLING UNNECESSARY INCREASES IN THE VOLUME OF CLINIC VISIT SERVICES 5

A. Congress Granted the Secretary Significant Discretion to "Develop a Method for Controlling Unnecessary Increases in the Volume of Covered [Outpatient Department] Services." 6

1. The Secretary's Mandate Encompasses the Authority to Reduce Financial Incentives that are Driving Unnecessary Increases in Volume 7

2. The District Court's Reliance on Implicit Limitations on the Secretary's Authority is Not Enough to Satisfy *Ultra Vires* Review, and in Any Event, the Court's Construction Violates the Text and Structure of the Medicare Act 9

B. The District Court Did Not Identify Any Factual Error in the Secretary's Finding that There Was an Unnecessary Increase in the Volume of Clinic Visit Services 14

1. The Volume of Clinic Visit Services Provided at Off-Campus Outpatient Departments Has Increased Dramatically Over the Years, Costing the Medicare Program and Its Beneficiaries Billions of Dollars in Unnecessary Expenses 16

2. Independent Physician Practices Are Equipped to Provide the Same Covered Services to Patients at a Lower Cost, Which Further Shows the Increase in Volume at Off-Campus Outpatient Departments Was Unnecessary 19

II. NOTHING IN THE BIPARTISAN BUDGET ACT OF 2015 ALTERED THE SECRETARY'S EXISTING AUTHORITY TO CONTROL UNNECESSARY INCREASES IN VOLUME AT OFF-CAMPUS OUTPATIENT DEPARTMENTS 21

A. Section 603 of the Bipartisan Budget Act Was Aimed at Eliminating the Proliferation of New Off-Campus Outpatient Departments, Not Controlling Unnecessary Increases in the Volume of Services at Existing Outpatient Departments 23

B. It Cannot be that the Secretary is Now Powerless to Prevent Unnecessary Increases in the Volume of Services at Certain Off-Campus Outpatient Departments 24

CONCLUSION 27

CERTIFICATE OF COMPLIANCE 28

CERTIFICATE OF SERVICE 29

TABLE OF AUTHORITIES

Cases

Am. Hosp. Ass'n v. Azar,
410 F. Supp. 3d 142 (D.D.C. 2019) ... 9-13, 22

Children's Hosp. Ass'n of Tex. v. Azar,
933 F.3d 764 (D.C. Cir. 2019) ... 8

**DCH Reg'l Med. Ctr. v. Azar*,
925 F.3d 503 (D.C. Cir. 2019) ... 6, 8-9, 14-15, 19, 22, 27

United States v. Project on Gov't Oversight,
616 F.3d 544 (D.C. Cir. 2010) ... 14

Whitman v. Am. Trucking Ass'ns, Inc.,
531 U.S. 457 (2001) ... 13

Statutes

42 U.S.C. § 1395l(t) ... 23, 25

42 U.S.C. § 1395l(t)(1)(B) ... 23

42 U.S.C. § 1395l(t)(1)(B)(v) ... 22-23

*42 U.S.C. § 1395*l*(t)(2)(F) ... 4, 6-14, 22, 24, 26

42 U.S.C. § 1395l(t)(3)(C)(ii) ... 26

42 U.S.C. § 1395*l*(t)(9)(C) ... 6, 10-14, 26

*42 U.S.C. § 1395*l*(t)(12)(A) ... 4, 8-9, 27

42 U.S.C. § 1395l(t)(21)(A) ... 23

42 U.S.C. § 1395l(t)(21)(B) ... 22

42 U.S.C. § 1395l(t)(21)(B)(ii) ... 22, 24

Bipartisan Budget Act of 2015,
Pub. L. No. 114-74, 129 Stat. 584 ... 3, 5, 21-27

Rules

Medicare Program; Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 83 Fed. Reg. 58,818 (Nov. 21, 2018) 5, 17-20

Other Authorities

Avalere, *PAI: Physician Practice Acquisition Study: National and Regional Employment Changes* (Oct. 2016) 20

MedPAC, *Report to the Congress*: *Medicare Payment Policy* (Mar. 2017) 19

MedPAC, *Report to the Congress*: *Medicare Payment Policy* (Mar. 2018) 4, 16

MedPAC, *Report to the Congress*: *Medicare Payment Policy* (Mar. 2019) 17-20

Merriam-Webster Dictionary, https://www.merriam-webster.com/dictionary 7

Reply in Support of Pls.' Mot. for Summ. J. and Mem. in Opp'n to Def.'s Cross-Mot. to Dismiss or for Summ. J., *AHA v. Azar*, No. 1:18-cv-2841 (D.D.C.) (filed Apr. 5, 2019) (Dkt. No. 23) 10-11, 26

* Authorities upon which we chiefly rely are marked with an asterisk.

GLOSSARY

AHA:	American Hospital Association
DHPA:	Digestive Health Physicians Association
GAO:	Government Accountability Office
LUGPA:	Large Urology Group Practice Association
MedPAC:	Medicare Payment Advisory Commission
OPPS:	Outpatient Prospective Payment System

STATEMENT OF INTEREST OF *AMICI CURIAE* *

Amici curiae are three trade associations representing independent physician practices: the Digestive Health Physicians Association (DHPA), the Large Urology Group Practice Association (LUGPA), and The OrthoForum. DHPA represents more than 2,100 gastroenterologists and other physician specialists in 90 independent gastroenterology practices in 38 States across the country who provide care for over two million patients in nearly four million distinct patient encounters annually. LUGPA represents 154 independent urology groups in the United States, with approximately 2,200 physicians who, collectively, provide approximately 40% of the nation's urology services. And The OrthoForum represents approximately 100 independent orthopaedic practices with over 3,800 physicians in 39 States.

Amici's members provide many of the same services as hospital outpatient departments—just as safely and effectively—but the Medicare program has historically paid *amici*'s members a fraction of the amount paid to hospitals for identical services furnished in their off-campus outpatient departments. This payment disparity led to perverse financial incentives, causing increases in volume at outpatient departments—particularly for clinic visit services, which cover the evaluation and management of patients. The Secretary of Health and Human Services deemed these

* All parties consent to the filing of this brief. No counsel for any party in this case authored this brief in whole or in part. No person or entity—other than *amici* and their counsel—made a monetary contribution specifically for the preparation or submission of this brief.

increases in volume unnecessary because beneficiaries can safely receive the same services at physicians' freestanding medical offices but at a lower cost to the Medicare program and its beneficiaries. As a result, the Secretary promulgated the challenged rule, which effectively capped the rate paid to hospitals' off-campus outpatient departments for clinic visits at the same rate the Medicare program pays freestanding physician practices for these services. The American Hospital Association (AHA) and various hospitals sued the Secretary, contending the rule is *ultra vires*.

Amici represent the interests of nearly 8,000 physicians in the fields of gastroenterology, urology, orthopaedic surgery, pathology and radiation oncology who care for millions of Medicare beneficiaries annually in the independent practice setting. The unnecessary increases in the volume of clinic visits, which the Secretary sought to control through promulgation of the challenged rule, came directly at the expense of *amici*'s member medical practices and the patients they serve.

ARGUMENT

Historically, the Medicare program paid hospitals for services at their off-campus outpatient departments at the same rate the program paid when those services were performed in the hospitals' on-campus outpatient departments. This led to two independent problems. *First*, the policy provided hospitals with a financial incentive to open more off-campus outpatient departments by acquiring freestanding physician practices and, in so doing, shifting reimbursement for physician services from Medicare's Physician Fee Schedule to the higher-paying Outpatient Prospective

Payment System (OPPS). *Second*, hospitals had a financial incentive to have their physicians see patients for services at their off-campus outpatient departments that could be provided just as safely and effectively at a physician's office—and at a lower cost to Medicare and its beneficiaries.

In 2015, Congress stepped in to address the first problem. Through Section 603 of the Bipartisan Budget Act of 2015, Pub. L. No. 114-74, 129 Stat. 584, 598, Congress eliminated the financial incentive for hospitals to open new off-campus outpatient departments. Specifically, providers in off-campus outpatient departments acquired by hospitals after November 1, 2015—so-called non-excepted off-campus departments—would no longer be deemed to be providing "covered [outpatient department] services" and, subject to certain exceptions, would have to be paid under a fee schedule other than the OPPS. At the same time, providers in off-campus outpatient departments that existed as of November 1, 2015—so-called excepted off-campus departments—could continue to bill under the OPPS.

But even after Congress fixed the first problem, the Secretary of Health and Human Services continued to see evidence of the second—that is, an increase in the volume of services that were being performed unnecessarily by hospitals' excepted off-campus outpatient departments. In particular, there was tremendous growth in the utilization of excepted off-campus outpatient departments to handle "clinic visit services" for the evaluation and management of patients. Yet those same services could be provided just as safely and effectively by freestanding physician practices.

This second problem was costing Medicare and its beneficiaries billions of dollars in unnecessary expenses. The Medicare Payment Advisory Commission (MedPAC)—a nonpartisan legislative branch agency established to advise Congress on issues affecting Medicare—estimated that, from 2011 to 2016, clinic visits to hospital outpatient departments increased by 43.8 percent, while "the volume of office visits in freestanding [physician] offices rose by only 0.4 percent" during that same period. MedPAC, *Report to the Congress*: *Medicare Payment Policy* 73 (Mar. 2018), *available at* https://go.usa.gov/xdCzu. According to MedPAC, Medicare spent $1.8 billion more in 2016 alone than it would have if it had paid for clinic visits at hospital outpatient departments at the same rate it paid freestanding physician offices. *Id.*

The second problem also was one that the Secretary could not ignore—even if he had wanted to do so. Under the Medicare Act, Congress mandated that "the Secretary shall develop a method for controlling unnecessary increases in the volume of covered [outpatient department] services." 42 U.S.C. § 1395*l*(t)(2)(F). At the same time, Congress left to the Secretary's discretion the methods that he may employ for controlling such unnecessary increases in volume. *See id.* And to underscore the breadth of the Secretary's authority, Congress provided that courts are without jurisdiction to review those methods. *Id.* § 1395*l*(t)(12)(A).

Charged with this mandate, the Secretary finalized the challenged rule, which implemented a method for controlling the volume of unnecessary clinic visit services at off-campus outpatient departments by capping the payment for those services at a

rate equivalent to that paid under the Physician Fee Schedule. *Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs*, 83 Fed. Reg. 58,818 (Nov. 21, 2018). The Secretary opted to phase in the rule over two years. *Id.* at 59,014. In 2019 alone, however, the Secretary estimated that the method would result in roughly $300 million in savings for Medicare and an additional $80 million in savings for Medicare beneficiaries in reduced copayments. *Id.*

In response, AHA and a group of hospitals filed suit claiming that the Secretary was without authority to cap the reimbursement rate for clinic visit services as a method for controlling the unnecessary increase in the volume of those services. And the hospitals separately argued that Section 603 of the Bipartisan Budget Act of 2015 stripped the Secretary of authority to control unnecessary increases in volume at excepted off-campus outpatient departments. Neither contention has merit.

I. THE SECRETARY ACTED WITHIN HIS DISCRETION—AND CERTAINLY DID NOT COMMIT THE KIND OF EXTREME AGENCY ERROR NECESSARY TO SUSTAIN AN *ULTRA VIRES* CHALLENGE—WHEN HE ESTABLISHED A RATE CAP AS A METHOD FOR CONTROLLING UNNECESSARY INCREASES IN THE VOLUME OF CLINIC VISIT SERVICES.

The Secretary was faced with substantial evidence that hospitals were responsible for unnecessary increases in the volume of clinic visit services at their off-campus outpatient departments—increases that were costing Medicare and its beneficiaries billions of dollars. For their part, the hospitals have never seriously

disputed the factual findings that underlie the Secretary's rulemaking. Instead, the hospitals argue that the rule is *ultra vires*.

As explained below, the Secretary acted well within his authority when he promulgated the challenged rule. The hospitals have not identified a "garden-variety" error of law or fact in the Secretary's decision, let alone the kind of "'extreme' agency error" necessary to sustain their *ultra vires* challenge. *DCH Reg'l Med. Ctr. v. Azar*, 925 F.3d 503, 509 (D.C. Cir. 2019) (brackets omitted). The District Court's judgment, which had the effect of overriding a policy decision committed to the Secretary's discretion, should be reversed.

A. Congress Granted the Secretary Significant Discretion to "Develop a Method for Controlling Unnecessary Increases in the Volume of Covered [Outpatient Department] Services."

When Congress enacted the OPPS in 1997, it granted the Secretary significant discretion to control unnecessary increases in utilization by hospital outpatient departments. As a first step, Congress provided that the Secretary "shall 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 as a contingent second step, if the "volume of services . . . increased beyond" the amounts the Secretary intended after applying the "methodologies" of the first step, then the Secretary was granted the discretion to further reduce volume by updating the conversion factor, a multiplier that applies to all outpatient services. *Id.* § 1395*l*(t)(9)(C).

This case concerns the first step of the Secretary's discretion—specifically, whether capping rates is a permissible "method for controlling unnecessary increases in the volume" of clinic visit services at off-campus outpatient departments. As explained below, every principle of statutory construction shows that capping rates is a permissible method.

1. The Secretary's Mandate Encompasses the Authority to Reduce Financial Incentives that are Driving Unnecessary Increases in Volume.

Congress did not define "method" in Subsection (t)(2)(F), but it did provide context. It commanded the Secretary 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) (emphasis added). And "method" is otherwise commonly understood to mean "a procedure or process for attaining an object." *Method*, Merriam-Webster Dictionary, https://www.merriam-webster.com/dictionary/method. Here, that object is "controlling unnecessary increases in the volume of covered" services.

Capping rates qualifies as a method for controlling unnecessary increases in volume. It is plainly a procedure or process that would no longer provide hospitals with an unfair financial incentive to increase the volume of clinic visit services that freestanding physician offices can provide just as safely and effectively.

Indeed, given that Congress sought to imbue the Secretary with the authority to control the volume of services for which the Medicare program and its beneficiaries are otherwise paying, it would be odd if Congress deprived the Secretary of a direct

economic tool to combat unnecessary increases in the volume of those services. If anything, the rate at which the federal government pays for a service is the single most effective tool to prevent unnecessary increases in volume.

Thus, capping rates is plainly a permissible method for controlling volume, but even if this were a close call, the Secretary's rule must stand—for at least two reasons. *First*, Congress provided that there "shall be no administrative or judicial review" of the "methods" that the Secretary ultimately decides to employ, 42 U.S.C. § 1395*l*(t)(12)(A), which means that, at best, the hospitals must demonstrate that the Secretary "plainly act[ed] in excess of [his] delegated powers and contrary to a specific prohibition in the statute that is clear and mandatory," *DCH*, 925 F.3d at 509 (citation omitted). Yet, because the Secretary's authority to develop methods is "open-ended," the hospitals cannot show that the Secretary's choice amounts to an "obvious violation of a clear statutory command." *Id.* at 510. *Second*, even if the ordinary rules of agency review were implicated here, Congress explicitly directed the Secretary to develop a method that Congress otherwise did not define. 42 U.S.C. § 1395*l*(t)(2)(F). Thus, this Court is to ask simply whether the rule is "reasonable." *Children's Hosp. Ass'n of Tex. v. Azar*, 933 F.3d 764, 770 (D.C. Cir. 2019) (explaining that where a delegation of discretion is "express rather than implied," the Court "skip[s] straight to asking whether the Rule is reasonable"). Either way, the hospitals' challenge fails.[1]

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[1] There is another aspect of *ultra vires* review that the hospitals cannot satisfy. As the government correctly notes, "*ultra vires* review is permitted only when 'the statutory

2. The District Court's Reliance on Implicit Limitations on the Secretary's Authority is Not Enough to Satisfy *Ultra Vires* Review, and in Any Event, the Court's Construction Violates the Text and Structure of the Medicare Act.

In asserting that the Secretary does not have the authority to cap rates as a method for controlling unnecessary increases in volume, both the District Court and the hospitals looked to other provisions of the OPPS. This was a mistake.

As an initial matter, the hospitals' structural argument—looking to other provisions of Subsection (t) to impose implicit limits on Subsection (t)(2)(F)—is too thin a reed upon which to premise an *ultra vires* challenge. The hospitals cannot prevail by showing a spirited debate on the Medicare Act; they must show an "obvious violation of a clear statutory command." *DCH*, 925 F.3d at 509. Here, the very fact that the District Court was required to divine an implicit limitation on the Secretary's authority proves that any perceived error by the Secretary was not obvious. *See, e.g.*, *Am. Hosp. Ass'n v. Azar*, 410 F. Supp. 3d 142, 159 (D.D.C. 2019) (relying on congressional silence and structural arguments to infer that "Congress did not intend [the Secretary] to use an untethered 'method' to directly alter expenditures independent of other processes"); *see also* Appellant's Br. 15-16 (noting that the District Court did not purport to show that "the [Secretary's] method was 'contrary to a specific prohibition in the statute that is clear and mandatory'").

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preclusion of review is implied rather than express.'" Appellant's Br. 15 (quoting *DCH*, 925 F.3d at 509). Here, the Medicare Act features an express provision precluding judicial review. *See* 42 U.S.C. § 1395*l*(t)(12)(A).

Yet, even if an implicit limitation is a permissible foundation on which to build an *ultra vires* challenge, the District Court's—and the hospitals'—reasoning runs contrary to the text and structure of the Medicare Act. And it makes little sense.

Critically, the District Court and the hospitals failed to give meaning to the phrase "method for controlling," which is set out in Subsection (t)(2)(F). This failure imperils the District Court's reading of the structure of the OPPS, which lies at the heart of its analysis and the hospitals' challenge. *AHA*, 410 F. Supp. 3d at 156-59.

According to the hospitals, "the 'method' referenced in [Subsection] (t)(2)(F) is merely an *analytical mechanism*" that the Secretary may use "to '*determine*' whether there is an unnecessary increase in volume." Reply in Support of Pls.' Mot. for Summ. J. and Mem. in Opp'n to Def.'s Cross-Mot. to Dismiss or for Summ. J. at 4, *AHA v. Azar*, No. 1:18-cv-2841 (D.D.C.) (filed Apr. 5, 2019) (Dkt. No. 23) (first emphasis added) (hereinafter AHA's Dist. Ct. Reply). The real work, the hospitals claim, is done by Subsection (t)(9)(C), which would allow the Secretary to adjust—and, according to the hospitals, *only* adjust—the conversion factor. *Id.*

The District Court agreed. It believed that Congress intended that "any 'methods' developed under paragraph (t)(2)(F) be implemented through *other* provisions of the statute." *AHA*, 410 F. Supp. 3d at 159 (emphasis added).

But Subsection (t)(2)(F) does not provide a method for *determining* if there is a problem with volume; it tasks the Secretary with "develop[ing] a method for *controlling*" unnecessary increases in volume. 42 U.S.C. § 1395*l*(t)(2)(F) (emphasis

added). Two things can be ascertained from the text. First, no one would describe a "method for controlling . . . volume" as an "analytical mechanism . . . [used] to '*determine*' whether there [has been] an unnecessary increase in volume." AHA's Dist. Ct. Reply at 4. Second, Subsection (t)(2)(F) does not need to look to any other provision to empower the Secretary to "develop a method for *controlling*" unnecessary increases in volume. It reads as a self-contained grant of authority. Thus, the District Court's and the hospitals' reading of Subsection (t)(2)(F) runs contrary to the text of that provision.

The District Court's failure to give any meaning to "method for controlling" also explains why its structural reliance on Subsection (t)(9)(C) was misplaced. As noted above, Subsection (t) provides a two-step process for controlling unnecessary increases in volume. As a first step, Subsection (t)(2)(F) directs the Secretary to develop a method for controlling unnecessary increases in volume. 42 U.S.C. § 1395*l*(t)(2)(F). And as a contingent second step, "*[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*, the Secretary may appropriately adjust the update to the conversion factor otherwise applicable in a subsequent year." *Id.* § 1395*l*(t)(9)(C) (emphasis added).

The District Court concluded that the second substantive step is really the first, *AHA*, 410 F. Supp. 3d at 159, but it did so only by ignoring that the first step mandates that the Secretary "shall develop a method for *controlling*" unnecessary

increases in volume, 42 U.S.C. § 1395*l*(t)(2)(F) (emphasis added). In the process, the District Court failed to give meaning to Subsection (t)(9)(C)'s "if" clause, which plainly provides that, before the Secretary may update the conversion factor, he must have implemented "methodologies described in paragraph (2)(F)," and "determine[d]" that "the volume of services . . . increased *beyond amounts established through those methodologies*." 42 U.S.C. § 1395*l*(t)(9)(C) (emphasis added).

The District Court's overarching reading of the structure fairs no better. It purported to find limitations on the Secretary's authority under Subsection (t)(2)(F) from the "elaborate" and "detail[ed]" statutory scheme that Congress established for setting and adjusting the amount of payments under the OPPS. *AHA*, 410 F. Supp. 3d at 156-59. The District Court posited that, because "nothing in the adjustment or payment scheme permits service-specific, non-budget-neutral cuts," the "method" under Subsection (t)(2)(F) cannot include a service-specific, non-budget neutral rate cap. *Id.* at 156. This analysis, however, misunderstands the relevant processes.

The provisions the District Court highlighted involve the process for setting and adjusting payments in the ordinary course. And in each instance where Congress granted the Secretary authority in the ordinary course, it required budget neutrality.

The same cannot be said for Subsection (t)(2)(F). It lies outside the ordinary process to combat "unnecessary increases in the volume of covered [outpatient department] services." 42 U.S.C. § 1395*l*(t)(2)(F). And unlike the ordinary process, which requires budget neutrality, Congress omitted such a requirement when

empowering the Secretary to curb unnecessary increases in volume. Thus, far from showing a limitation on the Secretary's authority under Subsection (t)(2)(F), the remaining provisions show that Congress knew how to constrain the Secretary's authority but did not do so when it came to addressing unnecessary increases in volume. *See also* Appellant's Br. 19 (noting that Subsection (t)(2)(F) lies outside "the general rules that govern OPPS payments rates").

In response, the District Court claimed the most natural reading of Subsection (t)(2)(F) would allow the Secretary to "totally ignore[ ] and circumvent[ ]" the "multi-factored, complicated annual process" that he is required to use to set "relative payments for [outpatient department] services," *AHA*, 410 F. Supp. 3d at 160, analogizing the Secretary's reading to "'hid[ing] elephants in mouse holes," *id.* at 158 (quoting *Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 468 (2001)). The District Court also questioned why the Secretary would resort to his authority under Subsection (t)(9)(C) to adjust the conversion factor if he "could use paragraph (t)(2)(F) to decrease or increase payment rates for disfavored or favored services whenever [he] desired." *Id.* at 159 n.9.

But this ignores a substantive limitation inherent in the Secretary's authority under Subsection (t)(2)(F): he is commanded to "develop a method for controlling" only upon a finding that there has been an "unnecessary increase[ ] in the volume of covered [outpatient department] services." 42 U.S.C. § 1395*l*(t)(2)(F). And the Secretary's authority to adjust the conversion factor under Subsection (t)(9)(C) is

unlocked only after the Secretary determines that the methodologies he employed under Subsection (t)(2)(F) were unsuccessful in controlling volume. *Id.* § 1395*l*(t)(9)(C). Thus, far from a tool for circumventing the ordinary process, Subsections (t)(2)(F) and (t)(9)(C) represent a response tailored for the extraordinary—combatting unnecessary increases in volume.

The District Court's constrained reading of Subsection (t)(2)(F) also makes little practical sense. According to the District Court, if the Secretary determines there has been an unnecessary increase in the volume of specific outpatient department services, then the Secretary's only recourse is to penalize all covered outpatient department services through an across-the-board cut. But there is no reason to strain linguistics to find that Congress handed the Secretary a "meat axe" when a "scalpel" would suffice. *Cf. United States v. Project on Gov't Oversight*, 616 F.3d 544, 554 (D.C. Cir. 2010); *accord* Appellant's Br. 20-21.

In the end, the Secretary's reading is far more plausible than the District Court's. But the Secretary does not have to carry that burden, given that the challenged rule must stand unless the Secretary committed an "obvious violation of a clear statutory command." *DCH*, 925 F.3d a 509.

B. The District Court Did Not Identify Any Factual Error in the Secretary's Finding that There Was an Unnecessary Increase in the Volume of Clinic Visit Services.

In the District Court, the hospitals hinted at alternative explanations for the increase in the volume of clinic visit services at outpatient departments that has

plagued the Medicare program. But they have never seriously disputed the Secretary's finding that this increase was unnecessary—and for good reason. This Court has never held that an *ultra vires* challenge is available to review a perceived error of fact, and in this instance, there is an explicit statutory provision precluding judicial review. *DCH*, 925 F.3d at 509-10 (explaining that this Court has allowed *ultra vires* review in the face of an express statutory preclusion of review only where the challenger showed an "obvious legal error" that "simultaneously made the jurisdictional bar 'inapplicable' and compelled setting aside the challenged agency action" on the merits). Perhaps for these reasons, the District Court did not purport to find any factual error underlying the Secretary's rulemaking.

Regardless, there is ample evidence that hospitals have been responsible for an unnecessary increase in the volume of clinic visit services at their off-campus outpatient departments, which has cost the Medicare program and its beneficiaries billions of dollars in unnecessary expenses. Equally relevant, there is no real dispute that freestanding physician practices are capable of providing the same services at a lower cost, which further shows the lack of necessity for the increase in the volume of clinic visit services at off-campus outpatient departments.

1. The Volume of Clinic Visit Services Provided at Off-Campus Outpatient Departments Has Increased Dramatically Over the Years, Costing the Medicare Program and Its Beneficiaries Billions of Dollars in Unnecessary Expenses.

There is ample evidence to support the Secretary's finding that there was an unnecessary increase in the volume of clinic visit services at off-campus departments. As noted above, MedPAC estimated that from 2011 through 2016 clinic visits to outpatient departments increased by 43.8 percent, while "the volume of office visits in freestanding [physician] offices rose by only 0.4 percent" during that same period. MedPAC, *Report to the Congress: Medicare Payment Policy* 73 (Mar. 2018). Because one would expect similar growth for similar services, MedPAC appropriately interpreted the disparity as evidence of a "shift of services from (lower cost) physician offices to (higher cost) [hospital outpatient departments]." *Id.* And this shift caused a significant increase in spending. According to MedPAC, Medicare spent $1.8 billion more in 2016 alone than it would have if it had paid for clinic visits at hospital outpatient departments at the same rate it paid freestanding physician offices. *Id.*

Numerous experts have linked the payment disparity to a shift in services from freestanding physician offices to hospital outpatient departments. MedPAC, for example, noted that "payment rates for evaluation and management . . . office visits are much higher in hospital outpatient departments . . . than in physicians' offices, and over the last several years, the volume of those services in [hospital outpatient departments] has increased while the volume in physicians' offices has decreased."

MedPAC, *Report to the Congress: Medicare Payment Policy* 56 (Mar. 2019), *available at* https://go.usa.gov/xdgD4.

Indeed, it is hard to ignore the financial incentives created by these payment disparities. In 2019, the unadjusted Medicare payment under the OPPS for a clinic visit was roughly $116, with an average copayment of $23 from the beneficiary. 83 Fed. Reg. at 59,009. In contrast, the Medicare Physician Fee Schedule paid physicians in independent practice just $46 for the same service, and the average beneficiary copayment was around $9. *Id.*

Not surprisingly, clinic visits were the predominant service at hospitals' off-campus outpatient departments. "In 2017, outpatient clinic visits were by far the most frequently provided service in off-campus [outpatient departments], constituting 46 percent of total Medicare service volume and 18 percent of total Medicare revenue in that setting." MedPAC, *Report to the Congress: Medicare Payment Policy* 76 (Mar. 2019). "In contrast, outpatient clinic visits were only 14 percent of total Medicare volume and 4 percent of total Medicare revenue in on-campus [outpatient departments]." *Id.*

Nor is this increase in volume explained by complexity. As MedPAC recently noted, "the services provided in off-campus [outpatient departments] are less complex than the services provided in on-campus outpatient settings." *Id.* In 2017, "the average relative weight of a service (a measure of resources needed to furnish a service) provided in an off-campus [outpatient department] was 2.18, compared with 5.00 (2.3 times higher) for the average relative weight of a service provided in an on-

campus hospital outpatient department." *Id.* "The higher the relative weight, the more complex the service." *Id.*

This is consistent with the Secretary's conclusion that patient acuity was not the main driver of the shift from freestanding physician offices to hospital outpatient departments, but rather the disparate financial incentives. 83 Fed. Reg. at 59,007. In this regard, the Secretary noted that a study by the Government Accountability Office (GAO) found that there was a relationship between the shift of services away from freestanding physician offices to hospital outpatient departments in those counties with high levels of vertical integration, which involves hospital acquisition of physician practices. *Id.* at 59,011. In fact, GAO "found that, in 2013, the number of [evaluation and management] office visits performed in [hospital outpatient departments] per 100 beneficiaries was 26 for the counties with low levels of vertical consolidation, whereas the number was substantially higher—82 services per 100 beneficiaries—in counties with the highest levels of vertical consolidation." *Id.* Notably, GAO found that "[b]eneficiaries from counties with higher levels of vertical consolidation were not sicker, on average, than beneficiaries from counties with lower levels of consolidation." *Id.* at 59,012. From all of this, the Secretary appropriately concluded that "areas with higher [evaluation and management] office visit utilization in [hospital outpatient departments] are not composed of sicker-than-average beneficiaries." *Id.*

Thus, the Secretary's finding—of an unnecessary increase in volume of clinic visit services at off-campus outpatient departments—is supported by substantial evidence. And in any event, it does not amount to the kind of "'extreme' agency action" necessary to sustain an *ultra vires* challenge. *DCH*, 925 F.3d at 509.

2. Independent Physician Practices Are Equipped to Provide the Same Covered Services to Patients at a Lower Cost, Which Further Shows the Increase in Volume at Off-Campus Outpatient Departments Was Unnecessary.

There is undisputed evidence that independent physician practices provide clinic visit services to patients just as safely and effectively as at the hospitals' off-campus facilities—but at a fraction of the cost. Indeed, the challenging hospitals have never contended otherwise.

As the Secretary recognized and MedPAC documented, the increase in volume was due in part because "many off-campus departments converted from physicians' offices to hospital outpatient departments without a change in either the physical location or a change in the acuity of the patients seen." 83 Fed. Reg. at 59,008; *accord* MedPAC, *Report to the Congress: Medicare Payment Policy* 70 (Mar. 2017), *available at* https://go.usa.gov/xdCzG. This alone is powerful evidence that independent physician practices can provide the same services at issue here.

The Secretary also appropriately reasoned that a shift in volume toward hospitals' off-campus facilities is "unnecessary if the beneficiary can safely receive the same services in a lower cost setting but instead receives care in a higher cost setting."

83 Fed. Reg. at 59,006. Indeed, to the "extent that similar services can be safely provided in more than one setting," the Secretary reasonably concluded that it was not "prudent for the Medicare program to pay more for these services in one setting than another." *Id.* at 59,008.

For these reasons, the Secretary set his sights on clinic visit services, which cover patient evaluation and management. As MedPAC noted, these services are "comparable across" the "outpatient and physician office" settings. MedPAC, *Report to the Congress: Medicare Payment Policy* 61 (Mar. 2019). Thus, the Secretary reasonably found that patients can "safely" receive clinic visit services in physician offices, and that the volume of outpatient services was unnecessary. 83 Fed. Reg. at 59,009.

In this regard, the Secretary acted with considerable restraint. There are numerous other services that can be performed safely in physician offices, and yet, Medicare pays much higher rates to hospital outpatient departments for these services. For example, the Secretary had before him evidence that, for "certain cardiology, orthopedic, and gastroenterology services, employed physicians were seven times more likely to perform services in a [hospital outpatient department] setting than independent physicians, resulting in additional costs of $2.7 billion to Medicare and $411 million in patient copayments over a 3-year period." *Id.* at 59,010 (citing Avalere, *PAI: Physician Practice Acquisition Study: National and Regional Employment Changes* (Oct. 2016)). As another example, there is usually no difference in terms of access or technology related to diagnostic imaging services at hospitals and physicians'

offices, and yet, the payment differential in 2016 alone was $2.165 billion for diagnostic imaging for the 371 CPT/HCPCS codes in the range 700xxx-76xxx. And the wide payment disparities help explain the shift in utilization. In 2016, for example, Medicare reimbursed a freestanding gastroenterology practice $136.41 for a one-hour intravenous infusion of Remicade, which is used to treat ulcerative colitis and Crohn's disease, but a hospital outpatient department received $416.68 for the same treatment—or 305 percent more. As another example under the 2017 payment rates, Medicare reimbursed a freestanding urology practice $321.22 for a cystometrogram with voiding pressure, which is used to evaluate bladder function, but a hospital outpatient department received $549.21 for the same service—or 171 percent more.

The point here is simply that the challenged rule was narrowly tailored to address what the Secretary perceived to be a substantial problem—explosive growth in the volume of clinic visits at off-campus outpatient departments. There is ample evidence that the identical services are performed just as safely and effectively in independent physician practices, and as a result, the Secretary reasonably determined that the increase in volume was unnecessary at off-campus outpatient departments.

II. NOTHING IN THE BIPARTISAN BUDGET ACT OF 2015 ALTERED THE SECRETARY'S EXISTING AUTHORITY TO CONTROL UNNECESSARY INCREASES IN VOLUME AT OFF-CAMPUS OUTPATIENT DEPARTMENTS.

In the proceedings below, the hospitals invoked Section 603 of the Bipartisan Budget Act of 2015 as a separate constraint on the Secretary's authority. They argued

that Section 603 had the effect of stripping the Secretary's distinct authority to control unnecessary increases in the volume of covered outpatient department services at off-campus outpatient departments. The District Court declined to address this argument, *AHA*, 410 F. Supp. 3d at 160 n.11, but the hospitals may present it as an alternative basis for affirmance. Any such argument should fail.

At the outset, the hospitals' Section 603 argument is simply a variant of their mistaken structural argument; it involves looking to Section 603 as an implicit limitation on the Secretary's authority to develop methods for controlling unnecessary increases in volume under Subsection (t)(2)(F). And as above, this cannot serve as the basis for their *ultra vires* challenge, because an implicit limitation on authority cannot produce an "obvious violation of a clear statutory command." *DCH*, 925 F.3d at 509.

Regardless, the hospitals are mistaken. Congress enacted Section 603 to end the proliferation of hospital off-campus outpatient departments by providing that departments that were not billing under the OPPS prior to November 2, 2015, are no longer permitted to bill for "covered [outpatient department] services" under the OPPS. 42 U.S.C. § 1395*l*(t)(1)(B)(v), (t)(21)(B). For those off-campus departments excepted from this provision—that is, for departments that are still entitled to bill for "covered [outpatient department] services," *id.* § 1395*l*(t)(21)(B)(ii)—nothing in Section 603 limits the Secretary's separate authority to "develop a method for controlling unnecessary increases in the volume of covered [outpatient department] services," *id.* § 1395*l*(t)(2)(F); *see also* Appellant's Br. 7.

A. Section 603 of the Bipartisan Budget Act Was Aimed at Eliminating the Proliferation of New Off-Campus Outpatient Departments, Not Controlling Unnecessary Increases in the Volume of Services at Existing Outpatient Departments.

As discussed above, the Medicare program's policy of paying hospitals to operate off-campus departments at the same rate the program paid on-campus outpatient departments gave rise to two problems. *First*, the policy provided hospitals with a financial incentive to open more off-campus departments by acquiring freestanding physician practices, thereby permitting the acquired practice to bill as an off-campus outpatient department without providing any difference in service and driving up the cost of the service for the Medicare program and for its beneficiaries in the form of higher co-pays. *Second*, hospitals had a financial incentive to increase the volume of services at their existing off-campus outpatient departments.

Through the passage of Section 603 of the Bipartisan Budget Act of 2015, Congress took aim at the first problem, but not the second. Specifically, Congress amended 42 U.S.C. § 1395*l*(t) to redefine "covered [outpatient department] services" under Subsection (t)(1)(B). Under the new definition, which is subject to certain exemptions for items and services furnished by a dedicated emergency department, *see* 42 U.S.C. § 1395*l*(t)(21)(A), "covered [outpatient department] services" do "not include applicable items and services . . . that are furnished on or after January 1, 2017, by an off-campus outpatient department of a provider," *id.* § 1395*l*(t)(1)(B)(v). But the amendment also included an exception: The new limitation does not apply to

off-campus outpatient departments that were billing under the OPPS prior to November 2, 2015. *See id.* § 1395*l*(t)(21)(B)(ii).

The passage of Section 603 had the effect of creating two types of off-campus outpatient departments: excepted and non-excepted off-campus departments. Excepted off-campus departments could continue to provide "covered [outpatient department] services" at their off-campus departments and bill under the OPPS. Non-excepted off-campus departments could no longer do so and were subject to reimbursement at a rate equivalent to the Physician Fee Schedule.

Properly understood, the challenged rule does not make an end-run around Section 603. That Section pays a non-excepted off-campus department at a rate equivalent to what would be paid under the Physician Fee Schedule for *all services* furnished at the non-excepted off-campus department. In contrast, through the challenged rule, the Secretary established a rate cap for excepted off-campus departments that applies *only to clinic visit services*—a single type of service provided at excepted off-campus departments. And the Secretary imposed this rate cap only after finding that there was an unnecessary increase in the volume of this specific service.

B. It Cannot be that the Secretary is Now Powerless to Prevent Unnecessary Increases in the Volume of Services at Certain Off-Campus Outpatient Departments.

Nothing in Section 603 displaces the Secretary's existing authority to "develop a method for controlling unnecessary increases in the volume of covered [outpatient department] services" under Subsection (t)(2)(F). As explained above, Section 603

had the effect of stripping certain off-campus departments of their ability to bill for "covered [outpatient department] services." But in the case of excepted off-campus departments (those that can still bill for "covered [outpatient department] services"), every other provision of paragraph (t) remains in force. Thus, for excepted off-campus departments, the Secretary retains the authority to set annual rates and make adjustments for "covered [outpatient department] services," 42 U.S.C. § 1395*l*(t), and he retains the authority to "develop a method for controlling unnecessary increases in the volume of covered [outpatient department] services," *id.* § 1395*l*(t)(2)(F).

The challenging hospitals' contrary interpretation calls into question the entire process for adjusting rates under the OPPS, because, like the "method for controlling unnecessary increases in . . . volume," the entirety of the OPPS is tied to "covered [outpatient department] services." *See generally id.* § 1395*l*(t) (containing forty-seven references to "covered [outpatient department] services"). In other words, if, as the hospitals contend, Section 603 stripped the Secretary of authority to control unnecessary increases in the volume of "covered [outpatient department] services" at excepted off-campus departments, then it likewise stripped the Secretary of any ability to regulate and set the annual rate of payment for all "covered [outpatient department] services" at excepted off-campus departments.

In reality, Section 603 does just the opposite, but only for *non*-excepted off-campus departments: It carves out these *non*-excepted off-campus departments from the OPPS by precluding them from billing for certain "covered [outpatient

department] services." The Secretary otherwise retains full control over excepted off-campus departments, which continue to bill for "covered [outpatient department] services" subject to regulation (and control) under the OPPS.

The hospitals' contrary interpretation also makes little practical sense. It would be strange if, in deciding to allow excepted off-campus departments to continue to provide "covered [outpatient department] services," Congress intended to strip the Secretary (albeit implicitly) of his pre-existing authority to control unnecessary increases in the volume of those covered outpatient department services. This, in turn, would mean that the Secretary would lack any authority to control runaway increases in the volume of unnecessary services at excepted off-campus departments, including the ability to invoke his fallback authority under Subsection (t)(9)(C) to "adjust the update to the conversion factor," *id.* § 1395*l*(t)(9)(C), which is tied to "covered [outpatient department] services," *id.* § 1395*l*(t)(3)(C)(ii). Thus, the Secretary would be deprived of the ability to exercise authority that the challenging hospitals otherwise concede he possesses under Subsection (t)(9)(C). *See, e.g.*, AHA's Dist. Ct. Reply at 4 (acknowledging that the Secretary has authority to adjust the conversion factor under 42 U.S.C. § 1395*l*(t)(9)(C) based on an unnecessary increase in volume).

Finally, the hospitals' argument is premised on reading Section 603 as an implicit limitation on the Secretary's pre-existing authority under Subsection (t)(2)(F). But that is not sufficient to show an "obvious violation of a clear statutory

command." *DCH*, 925 F.3d at 509. Simply put, the hospitals cannot rely on Section 603 to sustain their *ultra vires* challenge.

CONCLUSION

The Secretary acted within his discretion—and he certainly did not commit an "obvious violation of a clear statutory command, *id.*"—when he imposed a rate cap as a "method for controlling unnecessary increases in the volume" of clinic visit services, a subset of "covered [outpatient department] services." And because there is an express statutory bar on review of that "method" under 42 U.S.C. § 1395*l*(t)(12)(A), the judgment of the District Court should be vacated and the case remanded for the entry of an order dismissing the case for lack of jurisdiction.

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Respectfully Submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g)(1) and D.C. Circuit Rule 32(e)(2)(C), I hereby certify that that the foregoing Brief of *Amici Curiae* is proportionately spaced; uses a Roman-style, serif typeface (Garamond) of 14-point; and contains **6,485 words**, exclusive of the material not counted under Federal Rule of Appellate Procedure 32(f).

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing Brief of *Amici Curiae* 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 on January 30, 2020.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

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