No. 19-5048, 19-5198

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

AMERICAN HOSPITAL ASSOCIATION, *et al*.,

Plaintiffs-Appellees,

v.

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

Defendants-Appellants.

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

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Brief of *Amicus Curiae* Federation of American Hospitals In Support of Defendants-Appellants

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September 10, 2019

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

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

A. Parties and Amici

All parties, intervenors, and amici appearing before the district court and in this court are listed in the Brief for Appellants.

B. Rulings Under Review

References to the rulings at issue appear in the Brief for Appellants.

C. Related Cases

This Court previously issued an opinion involving the same dispute between the same parties. *See American Hosp. Ass'n v. Azar*, 895 F.3d 822 (D.C. Cir. 2018).

Counsel is not aware of any pending related cases within the meaning of D.C. Circuit Rule 28.

/s/ Andrew M. London
Andrew M. London

CORPORATE DISCLOSURE STATEMENT

Pursuant to Local Rules 26.1 and 28(a) of this Court and Rules 26.1 and 29(a)(4)(A) of the Federal Rules of Appellate Procedure, amicus curiae Federation of American Hospitals ("FAH") is a nonprofit trade association of health systems. FAH is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. The Federation has no parent company, and no publicly held company holds more than a ten percent interest in the Federation.

/s/ Andrew M. London
Andrew M. London

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IDENTITY AND INTEREST OF *AMICUS CURIAE*[1]

The Federation of American Hospitals ("FAH") is the national representative of more than 1,000 community hospitals and health systems throughout the United States. FAH's members include investor-owned or managed teaching and non-teaching, short-stay acute, inpatient rehabilitation, long-term acute care, psychiatric and cancer hospitals in urban and rural communities across America. These hospitals provide a critical range of services, including acute, post-acute, and ambulatory services.

FAH represents and advocates on behalf of its members before the government, media, academia, accrediting organizations, and the public. FAH routinely submits comments to the Centers for Medicare & Medicaid Services ("CMS") on Medicare and Medicaid payment and rulemakings and offers guidance to courts regarding Medicare and Medicaid reimbursement principles.

FAH member hospitals serve some of our country's most vulnerable communities. Over 90% of FAH member hospitals treat greater than the level of low-income patients needed to qualify for the 340B Drug Discount Program at issue

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[1] Both Plaintiffs-Appellees and Defendants-Appellants do not object to the filing of this brief pursuant to Federal Rule of Appellate Procedure 29(a). Undersigned counsel for *amicus curiae* certify that this brief was not authored in whole or in part by counsel for any of the parties; no party or party's counsel contributed money for the brief; and no one other than *amicus* and their counsel have contributed money for this brief.

in this litigation, with an average amount that is nearly three times the qualifying level. These hospitals would be eligible to participate in the 340B Program if tax-paying hospitals were not categorically excluded.

As non-340B providers, FAH member hospitals are deeply affected by the payment adjustments for 340B drugs at issue in this appeal. Approximately 2,450 non-340B hospitals were positively impacted by the payment adjustment adopted by CMS for 2018 because of the Medicare Outpatient Prospective Payment System's prospective budget neutrality requirement. FAH member hospitals were among those 2,450 hospitals.

In the district court, FAH submitted a brief as *amicus curiae* on potential remedies necessitated by the lower court's decision to vacate the relevant portions of the outpatient prospective payment system rule challenged in the litigation. FAH writes again on appeal to provide this Court with the perspective of non-340B hospitals on the merits of this matter.

INTRODUCTION

The issue presented for resolution in this case is whether the Secretary of the Department of Health and Human Services ("HHS") may adjust the Medicare payment rate for certain separately payable drugs to address the inefficiencies and inequalities caused by the intersection of the Medicare Outpatient Prospective Payment System ("OPPS") and the 340B Drug Discount Program ("340B Program"). Under the 340B Program, eligible hospitals can acquire certain outpatient drugs at deeply discounted rates. Prior to 2018, Medicare payment rates for 340B drugs far exceeded the amount that 340B hospitals actually paid to acquire those drugs under the 340B Program, leading to over-reimbursement. Because CMS must administer prospective payments to hospitals under the OPPS in a budget-neutral manner, this overpayment came at the expense of non-340B hospitals, who received lower payment rates to account for the excess. Many non-340B hospitals bore this financial burden despite serving similar levels of low-income patients as 340B providers, often in the exact same communities.

In the 2018 annual OPPS Rulemaking, the Secretary addressed this inefficiency by reducing the Medicare payment rate for separately payable drugs for most 340B hospitals from the average sales price ("ASP") plus 6% to ASP minus 22.5%. The Secretary made this change to "better, and more appropriately, reflect the resources and acquisition costs that [340B] hospitals incur" and "allow the

Medicare Program and Medicare beneficiaries…to share in the savings." *See* Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. at 52,356, 52,495-97 (November 13, 2017). This policy change furthered the objectives of the OPPS by increasing the overall efficiency of Medicare payment rates for outpatient drugs, ensuring a fairer copayment for beneficiaries receiving 340B drugs, and helping to level the playing field between 340B and non-340B hospitals. The district court's decision should accordingly be reversed.

SUMMARY OF ARGUMENT

Prior to the payment adjustment in the 2018 rulemaking, the Medicare payment rate for 340B drugs increased the financial burdens on non-340B hospitals, including FAH member hospitals. The Medicare payment rate for 340B drugs caused a mismatch between 340B hospitals' acquisition costs and payment rates. The gains realized by 340B hospitals came at the expense of non-340B hospitals, who, as a result of the OPPS prospective budget neutrality requirement, received lower overall payments under the OPPS despite often serving similar low-income populations as 340B hospitals. This mismatch conflicted with the purposes of the OPPS, which are to incentivize the efficient delivery of care, make Part B outpatient payments equitable for hospitals, and ensure appropriate copayments for beneficiaries.

Congress has authorized the Secretary to adjust payment rates for Part B drugs to further the purposes of the OPPS. *See* 42 U.S.C. § 1395*l*(t)(14)(A) (stating that the Medicare payment amounts shall be "calculated and adjusted by the Secretary as necessary for purposes of this paragraph").[2] The Secretary acted appropriately and within this authority when he adjusted Part B drug payment rates to 340B hospitals. For these reasons, the district court's order should be reversed.

ARGUMENT

I. OVERVIEW OF THE OPPS AND THE 340B PROGRAM

A. The Medicare Outpatient Prospective Payment System

Medicare is a federal health insurance program for the elderly and disabled administered by HHS through CMS. 42 U.S.C. § 1395 *et seq.* At issue here is a reimbursement methodology under Medicare Part B, a voluntary program for Medicare beneficiaries that provides supplemental coverage primarily for outpatient services, such as those provided in a hospital outpatient department or in a physician's office. Under Part B, hospitals payment rates for their outpatient services for the upcoming year are based on a prospective payment system, or OPPS, which CMS sets annually though notice-and-comment rulemaking. 42 U.S.C. §

[2] While FAH recognizes that the Secretary's adjustment authority has its limits, the adjustment in this case fits squarely within those boundaries. FAH otherwise takes no position on the contours of the Secretary's adjustment authority under 42 U.S.C. § 1395*l*(t)(14)(A) or under any other similar provision of the Act.

1395*l*(t). Any adjustments to the OPPS—including payment classifications, relative payment weights, and other components—must be "budget-neutral," meaning the "adjustments for a year may not cause the estimated amount of expenditures . . . for the year to increase or decrease from the estimated amount of expenditures . . . that would have been made if the adjustments had not been made." *Id.* § 1395*l*(t)(9)(B).

Congress enacted the OPPS in 1997 to incentivize the efficient delivery of outpatient services, make Part B outpatient payments more equitable for hospitals, and ensure appropriate copayments for beneficiaries.[3] Before the OPPS, CMS made Part B payments to hospitals retrospectively based on the cost of services actually provided. 65 Fed. Reg. at 18,436. By switching to the OPPS, which pays hospitals for outpatient services prospectively at payment rates designed to approximate the costs incurred by efficient providers, Congress sought to incentivize more efficient care delivery.

As part of the OPPS, the Secretary sets payment rates for "specified covered outpatient drugs" ("SCODs"), a category of separately payable drugs that are not

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[3] Balanced Budget Act of 1997, Pub. L. No. 105-33 § 4523, 111 Stat. 251 (1997); Medicare Program Prospective Payment System for Hospital Outpatient Services Final Rule, 65 Fed. Reg. 18,434, 18,436 (Apr. 7, 2000); *Paladin Cmty. Mental Health Ctr. v. Sebelius*, 684 F.3d 527, 528-29 (5th Cir. 2012) (Congress established the OPPS to "encourage more efficient delivery of care"); *Southwest Ambulatory Behavioral Servs. v. Burwell*, 2016 U.S. Dist. LEXIS 43936, *3 (W.D. La. Mar. 30, 2016) (Congress enacted the OPPS to "increase efficiency in the delivery of outpatient services").

bundled with other outpatient services but have their own payment classification group. 42 U.S.C. § 1395*l*(t)(14). Congress directed the Secretary to calculate SCODs payment rates as either:

> (I) [T]he average acquisition cost for the drug . . . as determined by the Secretary taking into account the hospital acquisition cost survey data; *or*
>
> (II) If hospital acquisition cost data are not available, the average price for the drug in the year established under . . . section 1395w-3a . . . *as calculated and adjusted by the Secretary*.

Id. § 1395*l*(t)(14)(A)(iii)(I)-(II) (emphasis added). The cross-referenced statute in subclause (II), Section 1395w-3a, generally sets the starting payment rate as ASP plus 6%. *See id.* § 1395w-3a(b).[4]

B. The 340B Program

This case involves the interaction between OPPS and the 340B Program, a separate, non-Medicare program that allows a limited class of hospitals and other health care providers to obtain prescription drugs from manufacturers at significantly reduced prices. Under the 340B Program, participating drug manufacturers must

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[4] Between 2006 and 2012, CMS set SCODs rates using the method outlined in subclause (I), as the ASP plus a fixed, add-on percentage intended to reflect hospitals' acquisition costs for drugs and biologicals. 77 Fed. Reg. 68,210, 68,383-85 (Nov. 15, 2012). This methodology yielded a payment rate of between ASP plus 4% and ASP plus 6% in different years. *Id.* at 68,386. In 2013, citing "continuing uncertainty" about acquisition costs, CMS switched to the calculation method set out in subclause (II) of § 1395*l*(t)(14)(A)(iii), and set payment at ASP plus 6%. *Id.* at 68,398.

agree to offer covered outpatient drugs to covered entities at or below a "maximum" or "ceiling" price, which is calculated pursuant to a statutory formula. 42 U.S.C. § 256b(a)(1)-(2). Congress's stated rationale behind the 340B Program is to maximize scarce federal resources, reach more eligible patients, and provide more comprehensive services.[5]

The 340B Program is intended to benefit providers that serve low-income populations. To qualify for 340B discounts, a hospital[6] must be receiving a Medicare Disproportionate Share Hospital ("DSH") payment adjustment of at least 11.75%, or—in the case of rural referral centers or sole community hospitals—8%.[7] Pediatric and cancer hospitals, which do not receive DSH payments, qualify for 340B discounts if their applicable low-income patient percentage rates would have reached the 11.75% threshold.

However, not all hospitals who meet these low-income patient thresholds are eligible for the 340B Program.[8] To qualify, hospitals must be (1) owned or operated

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[5] Veterans Health Care Act of 1992, Pub. L. No. 102-585 § 602, 106 Stat. 4943, 4967-71 (1992).
[6] With the exception of critical access hospitals ("CAHs").
[7] Medicare DSH payment adjustments are determined by a statutory formula that approximates the percentage of low-income patients treated by a hospital.
[8] Only six categories of hospitals qualify for 340B discounts: disproportionate share hospitals, children's hospitals and cancer hospitals exempt from the Medicare prospective payment system, sole community hospitals, rural referral centers, and CAHs. 42 U.S.C. §256b(a)(4).

by state or local government, (2) a public or private non-profit corporation which is formally granted governmental powers by state or local government, or (3) a private non-profit organization that has a contract with a state or local government to provide care to low-income individuals who do not qualify for Medicaid or Medicare. 42 U.S.C. §256b(a)(4)(L)(i). These criteria means that many hospitals which provide care to low-income patients are ineligible for 340B discounts. Indeed, while the vast majority (92.5%) of FAH member hospitals meet the applicable Medicare DSH payment adjustment, they are ineligible for 340B discounts because of their ownership structure.

C. OPPS Payment Policy for 340B Drugs

The 340B Program only addresses a hospital's drug acquisition costs, not its payment rates for those drugs. As stated above, for Medicare, payments for SCODs are separately set by the OPPS. As a result, from 2013 to 2018, 340B hospitals received payment for covered Part B drugs at ASP plus 6%, the same payment rate received by non-340B hospitals. Because 340B hospitals acquire covered drugs at prices far below the ASP, however, there was a significant mismatch between the amount 340B hospitals paid to acquire the drugs and the rate Medicare paid them for providing the drugs to beneficiaries. For example, in 2013, 340B hospitals paid an estimated 33.6% below the ASP to acquire Part B drugs. *See* Medicare Payment

Advisory Commission Report to the Congress: Medicare Payment Policy, p. 79 (March 2016).[9]

In its final rule establishing OPPS rates for 2018, CMS addressed the inequity between 340B and non-340B hospitals by reducing the payment rate for drugs purchased under the 340B Program from ASP plus 6% to ASP minus 22.5%. 82 Fed. Reg. 52,356, 52,356 (Nov. 13, 2017). The OPPS 2019 Final Rule later retained the same reduced rate for 340B drugs. 83 Fed. Reg. 58,818, 58,979-80 (Nov. 21, 2018). The new rate—ASP minus 22.5%—was designed to reflect the "minimum" average discount received by 340B hospitals, allowing 340B hospitals to retain some profit margin on the administration of SCODs. 82 Fed. Reg. at 52,496.

CMS intended the new rate to "better, and more appropriately, reflect the resources and acquisition costs that [340B] hospitals incur," while also ensuring that beneficiaries "share in the savings on drugs acquired through the 340B Program." 82 Fed. Reg. at 52,362, 52,495-97; *see* 42 U.S.C § 1395*l*(t)(3)(B) (setting Medicare beneficiary co-payments as a percentage of the Medicare payment rate).[10]

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[9] A*vailable at* http://www.medpac.gov/docs/default-source/reports/march-2016-report-to-the-congress-medicare-payment-policy.pdf.

[10] The adjustment did not impact all 340B hospitals—CMS exempted "[r]ural sole community hospitals (SCHs), children's hospitals, and [prospective payment system]-exempt cancer hospitals," as well as critical access hospitals, which are paid through a separate scheme under the OPPS. *Id.* at 52,362.

All told, CMS estimated that the new adjusted rate would save Medicare $1.6 billion on OPPS drug expenditures in 2018. *Id.* at 52,509. Per the OPPS prospective budget neutrality requirement, CMS redistributed these savings to all hospitals paid under the OPPS, including FAH member hospitals, other non-340B hospitals, and 340B hospitals.

II. THE NEW PAYMENT POLICY FOR 340B DRUGS FURTHERS THE GOALS OF THE OPPS

A. The Prior 340B Payment Policy was Inefficient and Inequitable

The inefficiencies created by the prior Medicare payment rate for 340B drugs harmed non-340B hospitals, including FAH member hospitals, as well as Medicare beneficiaries who needed SCODs. Because of the OPPS prospective budget neutrality requirement, the gains realized by 340B hospitals as a result of the mismatch between acquisition costs and payment rates came at the expense of non-340B hospitals, who received lower OPPS payments to account for the comparatively inflated payments to 340B hospitals. This inefficiency exacerbated existing challenges faced by non-340B hospitals. For example, for non-340B hospitals, Medicare Part B payment rates are often insufficient to cover hospitals' operating costs. As FAH member hospitals experienced first-hand, the pre-2018 OPPS payment rates to non-340B hospitals significantly increased the financial burden of providing outpatient services.

Non-340B hospitals bore this financial burden despite serving similar levels of low-income patients as 340B providers, often in the exact same communities. For example, 340B and non-340B hospitals provide comparable levels of both charitable care services, specifically, and uncompensated care services ("UC Services"),[11] more broadly. An examination of recent hospital cost report data reveals that charitable services at 340B hospitals accounted for approximately 2.8% of a hospital's total costs, while charitable services at non-340B hospitals that would otherwise qualify for the 340B Program accounted for approximately 2.7% of a hospital's total costs.[12] UC Services accounted for approximately 4.3% of costs in 340B hospitals and approximately 4.2% of costs in non-340B hospitals that would otherwise qualify for the 340B Program. Moreover, FAH members that would otherwise qualify for the 340B Program had even higher UC Service costs (6.0%)

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[11] Uncompensated care services are defined here consistent with the definition adopted by CMS for purposes of calculating hospitals' UC-DSH payments under the Medicare inpatient prospective payment system under 42 U.S.C. §1395ww(r)(2)(C). CMS defines uncompensated care as charity care plus bad debt. *See* 42 C.F.R. §412.106(g)(1)(iii)(C)(5) (defining term); s*ee also* Medicare Provider Reimbursement Manual § 4012 (defining uncompensated care as charity care, non-Medicare bad debt, and non-reimbursable Medicare bad debt) *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929.html.

[12] This cost information was developed from individual providers' latest cost reports that covered the period between July 30, 2017 and March 31 2019, as contained in the provider's June 30, 2019 CMS Healthcare Provider Cost Reporting Information System ("HCRIS") file.

than 340B hospitals (4.3%). Unsurprisingly given these figures, over 80% of non-340B hospitals treat a sufficient percentage of low-income patients to qualify for the 340B Program. The percentage is even higher—92.5%—amongst FAH member hospitals. Thus, the prior 340B payment policy was not only inefficient, but also inequitable. The policy favored 340B hospitals at the expense of non-340B hospitals despite both groups of hospitals providing similar levels of charitable and uncompensated care.

Additionally, the prior payment policy was inequitable to Medicare beneficiaries. Under Medicare Part B, beneficiaries' 20% coinsurance obligation is tied to Medicare's payment rates rather than to hospitals' acquisition costs. 42 U.S.C § 1395*l*(t)(3)(B). Because Medicare payment rates far exceeded 340B hospitals' acquisition costs, beneficiaries were making disproportionately large coinsurance payments compared to 340B hospitals' costs of acquiring the drugs. *See* Office of Inspector General, OEI-12-14-00030, *Part B Payments for 340B-Purchased Drugs*, at 9 (November 2015); 2018 OPPS Final Rule, 82 Fed. Reg. 59,216, 59,355 (Dec. 14, 2017) (citing the OIG Report).

B. The Secretary Had Authority to Correct These Inefficiencies and Inequities

Congress enacted the OPPS to incentivize the efficient delivery of outpatient services and to make Part B outpatient payments equitable to hospitals. To ensure

that these objectives could be maintained over time, Congress vested the Secretary with authority to adjust payment rates for Part B drugs under the OPPS. *See* 42 U.S.C. § 1395*l*(t)(14)(A) (stating that the Medicare payment amounts shall be "calculated and adjusted by the Secretary as necessary for purposes of this paragraph"); H.R. Rep. No. 105-149, at 1323 (1997) ("The Committee has given the Secretary discretion in determining the adjustment factors that will be applied to the OPD prospective rates.").[13] Here, the Secretary identified problems with the OPPS payment rate for Part B drugs that went to the very heart of the OPPS program's goals, namely that the 340B payment policy was incentivizing the inefficient delivery of care, creating inequitable payments across similarly-situated hospitals, and misalignment of beneficiaries' copayments.

The district court erred by concluding that the Secretary lacked authority to correct these inefficiencies and inequities. The Secretary's adjustment allowed CMS to reduce projected 2018 OPPS expenditures by $1.6 billion, and, consistent with the OPPS' prospective budget neutrality requirement, the reduction allowed CMS to adopt a positive adjustment of 3.2% for all OPPS non-drug items and services. *See*

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[13] As previously stated in footnote 2, FAH recognizes that the Secretary's adjustment authority has its limits, but the adjustment in this case fits squarely within those boundaries. FAH otherwise takes no position on the contours of the Secretary's adjustment authority under 42 U.S.C. § 1395*l*(t)(14)(A) or under any other similar provision of the Act.

42 U.S.C. §1395*l*(t)(9)(B); 82 Fed. Reg. at 52,624. This positive adjustment benefits hospitals across the board. FAH estimates that 80% of all hospitals paid under the OPPS—including 89% of rural hospitals, 74% of government hospitals, and 43% of 340B hospitals—will experience a net payment increase in 2019 under CMS's 340B payment policy. *See* Federation of American Hospitals, *Comment Letter to CMS regarding CY 2019 OPPS Proposed Rule*, at 15 (Sept. 24, 2018).[14] The result of the Secretary's adjustment was thus a more efficient payment system and a more equitable system for non-340B hospitals and beneficiaries.

III. THE SECRETARY'S BUDGET NEUTRALITY ADJUSTMENT IS NOT AT ISSUE IN THIS APPEAL

As mentioned above, the OPPS' prospective budget neutrality requirement allowed the Secretary to adopt a positive payment adjustment of 3.2% for all OPPS non-drug items and services as a result of the change in payment policy for 340B drugs. Neither party to this appeal has called into question the lawfulness of the Secretary's prospective 3.2% budget neutrality adjustment.

In the district court, FAH submitted a brief as *amicus curiae* on potential remedies necessitated by the lower court's decision to vacate the relevant portions of the OPPS rule challenged in the litigation. *See* Dkt. 38. The district court noted

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[14] *Available at* https://www.fah.org/fah-ee2-uploads/website/documents/FAH_CY2019_OPPS_Proposed_Rule_Comment_Letter.pdf.

that FAH's brief was "helpful" in reaching its decision to remand this case to the agency for further proceedings regarding remedy. Dkt. 50 at p. 19, n. 18. As FAH noted in that brief, the Medicare Act only requires the Secretary to make adjustments to achieve a *prospective* estimate of budget neutrality. See 42 U.S.C. §1395*l*(t)(9)(B) (stating that adjustments to the OPPS "many 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") (emphases added). The law does not permit post-hoc reconciliation or recoupment to achieve budget neutrality after payments are made to providers. *C.f. Cty. of L.A. v. Shalala*, 192 F.3d 1005, 1016-17 (D.C. Cir. 1999) (finding that it was reasonable for the Secretary to interpret the Medicare Act's outlier-payment provision to mean that "there is no necessary connection between the amount of *estimated* outlier payments and the *actual* payments made to hospitals" (emphases added)).

CONCLUSION

The new Medicare OPPS payment policy for 340B drugs reduces inefficiencies in payment for these drugs and benefits CMS, beneficiaries, and non-340B hospitals by equitably distributing payment for hospital outpatient services. This new policy furthers the objectives of the OPPS, and the Secretary was authorized to make adjustment to further these purposes. For these reasons, the district court's decision should be reversed.

Respectfully submitted,

THE FEDERATION OF AMERICAN HOSPITALS ASSOCIATION

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CERTIFICATE OF SERVICE

I, Andrew M. London, hereby certify that on this 10th day of September, 2019, I electronically filed the foregoing document using the CM/ECF system, which will send notification of such filings to all counsel of record.

/s/ Andrew M. London
Andrew M. London

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 29(a)(5) because it contains 3,568 words.

This brief also complies with the typeface requirements of Fed. R. App. P. 32(a)(5)(A) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman font size 14.

Dated: September 10, 2019

/s/ Andrew M. London
Andrew M. London