No. 20-1114

IN THE

Supreme Court of the United States

AMERICAN HOSPITAL ASSOCIATION, et al.,
Petitioners,

v.

XAVIER BECERRA, in his official capacity as the Secretary of Health and Human Services, et al.,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

BRIEF OF *AMICUS CURIAE* FEDERATION OF AMERICAN HOSPITALS IN SUPPORT OF RESPONDENTS

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INTEREST OF THE *AMICUS CURIAE*

The Federation of American Hospitals ("FAH") is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States.[1] FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural America. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services.

Dedicated to a market-based philosophy, the FAH provides representation and advocacy on behalf of its members to Congress, the executive branch, the judiciary, 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. Uncompensated care services account for 6.1% of hospital costs for FAH

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[1] Pursuant to Rule 37.2(a), counsel for both parties received timely notice of the *amicus curiae*'s intention to file this brief and consented in writing to its filing. Pursuant to Rule 37.6, the *amicus curiae* affirms that no counsel for a party authored any part of this brief; no party or party's counsel made a monetary contribution intended to fund the preparation or submission of the brief; and no person other than the *amicus curiae*, its members, or its counsel, made a monetary contribution to the brief's preparation or submission.

member acute care community hospitals, a percentage that exceeds that of 340B hospitals. Many FAH member hospitals would be eligible to participate in the 340B Program if tax-paying hospitals were not statutorily excluded.

As non-340B providers, FAH member hospitals are deeply affected by the payment adjustments for 340B drugs at issue in this appeal. Approximately 2,208 non-340B hospitals today benefit from the payment adjustment adopted by CMS in 2018, the payment year during which CMS first made the payment adjustment for 340B drugs, because of the Medicare Outpatient Prospective Payment System's prospective budget neutrality requirement.[2] FAH member hospitals were among those 2,208 hospitals.

In the district court, FAH submitted a brief as *amicus curiae* on potential remedies, necessitated by the district court's decision to vacate the relevant portions of the Outpatient Prospective Payment System rule challenged in the litigation. FAH also submitted a brief as *amicus curiae* on appeal in the D.C. Circuit to provide the perspective of non-340B hospitals on the merits of the matter. FAH writes again as *amicus curiae*, now to this Court in support of Respondents.

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[2] *See* Avalere Health, OPPS MEDICARE PART B PAYMENT IMPACT ANALYSIS, at 11 (Mar. 2021), https://www.fah.org/fah-ee2-uploads/website/documents/US_Supreme_Court_Amicus_Brief_340B.pdf [hereinafter Avalere Study].

INTRODUCTION AND SUMMARY OF THE ARGUMENT

In cities and towns across America, FAH member hospitals are the keystone to maintaining the health of vulnerable communities. Patients rely on FAH member hospitals for emergency services, preventative care, and the treatment of life-threatening and debilitating conditions. Prior to 2018, the intersection of two separate federal programs—the Medicare Outpatient Prospective Payment System ("OPPS") and the 340B Drug Discount Program ("340B Program")—created inefficiencies and inequities in Medicare payments to hospitals. These inefficiencies and inequities increased the financial burden on FAH members and other similar non-340B hospitals despite serving similar patient populations and providing comparable or greater levels of uncompensated care compared to 340B hospitals. In a straightforward matter of statutory interpretation, the United States Court of Appeals for the District of Columbia Circuit correctly decided that the Secretary of Health and Human Services ("Secretary") acted within the authority delegated to him by Congress to adjust payment rates under the OPPS to address these inefficiencies. This Court should deny the Petition for a Writ of Certiorari.

The OPPS is the system through which CMS reimburses hospitals under Medicare Part B and provides reimbursement primarily for outpatient services. 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. CMS annually sets

payment rates under the OPPS through notice-and-comment rulemaking. For the category of "specified covered outpatient drugs" ("SCODs"), the Secretary determines payment rates based either on the average acquisition cost for the drug or on the average price for the drug "as calculated and adjusted by the Secretary as necessary" for purposes of the OPPS. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I)–(II). Any adjustments to the OPPS 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).

Separate from the OPPS, the 340B Program, established under section 340B of the Public Health Service Act, permits eligible hospitals to acquire certain outpatient drugs at deeply discounted rates. The 340B Program is intended to benefit providers that serve low-income populations. Yet not all hospitals who meet the 340B Program's low-income patient thresholds are eligible for the program's benefits. Indeed, many FAH members and other non-340B hospitals operate in some of the nation's poorest communities; they serve as essential health care institutions for the most vulnerable patient populations, providing uncompensated and discounted care to patients who have few, if any, alternatives to address their health care needs. But, unlike some of Petitioners' members, FAH members are unable to participate in the 340B Program despite treating the same types of patients, providing greater levels of uncompensated care, and supplying the same types of services that benefit their communities.

Prior to 2018, OPPS payment rates for 340B drugs far exceeded the amount that 340B hospitals actually paid to acquire those drugs under the 340B Program. This inefficiency came at the expense of non-340B hospitals. Because CMS must administer prospective payments to hospitals under the OPPS in a budget-neutral manner, non-340B hospitals, including FAH members, received lower payment rates to account for the excess—despite serving similar levels of low-income patients as 340B hospitals, often in the same communities. Further, Medicare beneficiaries treated at 340B hospitals paid disproportionately large copayments for covered drugs, as copayment obligations are tied to Medicare payment rates rather than to hospitals' acquisition costs. These outcomes conflicted with the OPPS's purposes to incentivize the efficient delivery of care, make Part B outpatient payments equitable for hospitals, and ensure appropriate copayments for beneficiaries.

In the 2018 annual OPPS rulemaking, the Secretary addressed these inefficiencies 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%. *See* Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 52,356, 52,362 (Nov. 13, 2017).[3] The Secretary

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[3] The 2019 annual OPPS rulemaking continued this policy and is also at issue in this case. *See* Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 83 Fed. Reg. 58,818, 58,979–80 (Nov. 21, 2018).

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." *Id.* at 52,495, 52,497.

The revised and now current payment policy recaptures savings that benefitted *only* 340B hospitals and reallocates those savings across *all* acute care hospitals, including 340B hospitals. Under this policy, CMS reduced SCOD expenditures by an estimated $1.6 billion. This allowed CMS to adopt a positive rate adjustment of 3.2% for all OPPS non-drug items and services, consistent with the OPPS budget neutrality requirement. The positive rate adjustment for non-drug items and services benefits acute care hospitals across the board, including FAH and Petitioners' members. A recent study by Avalere Health estimates that 82% of all hospitals paid under the OPPS—including 89% of rural hospitals, 77% of rural 340B hospitals, and 49% of all 340B hospitals—would experience a net payment decrease in 2021 if the current payment policy were reversed.[4] Moreover, the current policy increases equity in co-payments for Medicare Part B beneficiaries by substantially reducing the disproportionately large copayments of beneficiaries treated with SCODs at 340B hospitals. Thus, the current policy furthers the objectives of the OPPS by increasing the overall efficiency of Medicare payment rates for outpatient drugs, helping to level the playing field between 340B and non-340B hospitals, and ensuring a fairer copayment for beneficiaries receiving 340B drugs. By reallocating

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[4] Avalere Study, *supra* note 2, at 2, 10.

savings among all hospitals, the current payment policy achieves a balance that is both more efficient and more equitable.

There is no reason for this Court to review the decision of the D.C. Circuit, which correctly decided this matter. The Secretary acted appropriately and within the authority granted to him by Congress when he adjusted Part B drug payment rates to 340B hospitals. Further, this case raises no significant question of federal law; does not threaten the uniform, nationwide administration of the Medicare program; and does not arise from a split among the courts of appeals.

This Court should deny the Petition.

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 coverage primarily for outpatient and professional 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 the OPPS, which CMS sets annually though notice-and-comment rulemaking. 42 U.S.C. § 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. *See* Balanced Budget Act of 1997, Pub. L. No. 105-33 § 4523, 111 Stat. 251, 445–50 (1997). Before the enactment of the OPPS, CMS made Part B payments to hospitals retrospectively based on the cost of services actually provided. Medicare Program Prospective Payment System for Hospital Outpatient Services Final Rule, 65 Fed. Reg. 18,434, 18,436 (Apr. 7, 2000). 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 "offer incentives to providers to operate more efficiently" and reduce "the level of beneficiary coinsurance payments for hospital outpatient department service." H.R. Rep. No. 105-149, at 1323 (1997); *see also 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"); *Sw. 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").

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 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 as necessary* for purposes of this paragraph.

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).[5]

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[5] 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. Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 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 section 1395*l*(t)(14)(A)(iii), and set payment at ASP plus 6%. *Id.* at 68,398.

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, named for its section in the Public Health Service Act, participating drug manufacturers must 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. Public Health Service Act § 340B(a)(1)–(2) (codified at 42 U.S.C. § 256b(a)(1)–(2)). At a minimum, the discount for a drug acquired under the 340B program is generally 23.1% off of the average manufacturer price of the drug. 42 U.S.C. § 256b(a)(2)(A).[6] Congress's stated rationale behind the 340B Program is to maximize scarce federal resources, reach more eligible patients, and provide more comprehensive services. Veterans Health Care Act of 1992, Pub. L. No. 102-585 § 602, 106 Stat. 4943, 4967–71 (1992).

The 340B Program is intended to benefit providers that serve low-income populations. To qualify for

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[6] 340B hospitals can, and often do, negotiate steeper discounts that make their acquisition cost for the drug even lower than the ceiling price guaranteed by the 340B Program. *See Overview of the 340B Drug Pricing Program*, 340B HEALTH (last visited Mar. 7, 2021), https://www.340bhealth.org/members/340b-program/overview/ (discussing 340B Prime Vendor Program, through which covered entities may "negotiate sub-ceiling prices" for covered drugs).

340B discounts, a hospital[7] 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%.[8] *See* 42 U.S.C. § 256b(a)(4)(L)(ii); *id.* § 256b(a)(4)(O). 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. *See id.* § 256b(a)(4)(M).

However, not all hospitals who meet these low-income patient thresholds are eligible for the 340B Program.[9] To qualify, a hospital must be (1) owned or operated 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. *Id.* § 256b(a)(4)(L)(i). Given these criteria, tax-paying hospitals that provide care to low-income patients are ineligible for 340B discounts. Indeed, while many FAH member hospitals

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[7] With the exception of critical access hospitals ("CAHs"). *See* 42 U.S.C. § 256b(a)(4)(N).

[8] Medicare DSH payment adjustments are determined by a statutory formula that takes into account the percentage of low-income patients treated by a hospital. 42 U.S.C. 1395ww(d)(5)(F).

[9] 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).

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.[10]

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%. Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 52,356, 52,356

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[10] *See* Medicare Payment Advisory Commission, REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY, at 79 (Mar. 15 2016), http://www.medpac.gov/docs/default-source/reports/march-2016-report-to-the-congress-medicare-payment-policy.pdf.

(Nov. 13, 2017). The OPPS Final Rule for 2019, 2020, and 2021 later retained the same reduced rate for 340B drugs.[11] The current 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 this 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." *Id.* at 52,495, 52,497; *see* 42 U.S.C. § 1395*l*(t)(3)(B) (setting Medicare beneficiary co-payments as a percentage of the Medicare payment rate).[12]

All told, CMS estimated that the adjusted rate would save Medicare $1.6 billion on OPPS drug expenditures in 2018. 82 Fed. Reg. at 52,509. Per the OPPS prospective budget neutrality requirement, CMS adopted a positive adjustment of 3.2% for all OPPS non-drug items and services, redistributing the $1.6 billion savings to *all* hospitals paid under the

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[11] *See* 83 Fed. Reg. 58,818, 58,979–80 (Nov. 21, 2018); 84 Fed. Reg. 61,142, 61,324 (Nov. 12, 2019); 85 Fed. Reg. 85,866, 86,054 (Dec. 29, 2020).

[12] The OPPS 340B drug payment adjustment did not impact all 340B hospitals. As previously mentioned, critical access hospitals retain the 340B discount because they are not paid under the OPPS. Further, CMS exempted "[r]ural sole community hospitals (SCHs), children's hospitals, and [prospective payment system]-exempt cancer hospitals," which continue to be paid for SCODs at ASP plus 6%. 82 Fed. Reg. at 52,362.

OPPS, including FAH member hospitals, other non-340B hospitals, and 340B hospitals. *See* 42 U.S.C. §1395*l*(t)(9)(B); 82 Fed. Reg. at 52,624.

II. The Current Payment Policy for 340B Drugs Furthers Congress's Goals in Enacting the OPPS.

A. The Prior Payment Policy Was Inefficient and Inequitable to Medicare Providers and Beneficiaries.

Congress enacted the OPPS to incentivize efficient delivery of outpatient services, make Part B outpatient payments equitable for hospitals, and provide appropriate copayments for beneficiaries. *See* H.R. Rep. No. 105-149, at 1323 (1997). The prior Medicare payment policy for SCODs created inefficiencies and increased beneficiary out-of-pocket expenses for SCODs, undermining Congress's intent in passing the OPPS. As described above, not all hospitals treating uninsured and otherwise vulnerable patient populations are eligible to purchase drugs through the 340B program. 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.

Non-340B hospitals bore the financial burden of the prior payment policy despite serving similar levels of uninsured or otherwise vulnerable patients as 340B hospitals, often in the same or demographically

similar communities. The State and Regional Hospital Association *amici* note that "safety net hospitals . . . provide nearly 30% of all uncompensated care." State and Regional Hospital Association Brief at 7. But despite the State and Regional Hospital Association *amici*'s suggestion, "safety-net hospital" is neither a statutorily defined term nor commonly limited to 340B hospitals.[13] Instead, health care policy experts frequently adopt the Institute of Medicine's definition of "safety-net providers" as "those providers that organize and deliver a significant level of health care and other health-related services to uninsured, Medicaid, and other vulnerable patients."[14] As such, safety-net hospitals include both 340B and non-340B hospitals. Non-340B hospitals in fact provide greater or comparable levels of both charitable care services and uncompensated care services ("UC Services") as

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[13] The State and Regional Hospital Association *amici* provide a citation to a section of the U.S. Code, which defines a "covered entity" for purposes of the 340B program. The term "safety net hospital" does not appear in that definition.

[14] Institute of Medicine Committee on the Changing Market, Managed Care, and the Future Viability of Safety Net Providers, AMERICA'S HEALTH CARE SAFETY NET: INTACT BUT ENDANGERED (Marion Ein Lewin & Stuart Altman eds., 2000); *see* Peter Cunningham & Laurie Felland, ENVIRONMENTAL SCAN TO IDENTIFY THE MAJOR RESEARCH QUESTIONS AND METRICS FOR MONITORING THE EFFECTS OF THE AFFORDABLE CARE ACT ON SAFETY NET HOSPITALS, at 5 (June 2013), https://aspe.hhs.gov/system/files/pdf/33811/rpt_ACA_and_Safety_Net_%20EnvScan.pdf; Janet Pagon Sutton et al., CHARACTERISTICS OF SAFETY-NET HOSPITALS (2014), https://www.ncbi.nlm.nih.gov/books/NBK401306/.

compared to 340B hospitals.[15] For example, an examination of recent hospital cost report data reveals that charitable services at 340B hospitals accounted for approximately 2.8% of 340B hospitals' total operating costs, while charitable services at non-340B hospitals accounted for approximately 2.9% of non-340B hospitals' total operating costs.[16] UC Services accounted for approximately 4.2% of total operating costs in 340B hospitals and approximately 4.4% of total operating costs in non-340B hospitals in FY 2018.[17] UC Services are even higher at FAH member

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[15] 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); *see also* Medicare Provider Reimbursement Manual § 4012, *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929.html (defining uncompensated care as charity care, non-Medicare bad debt, and non-reimbursable Medicare bad debt).

[16] The cost information was developed from cost report periods beginning in Federal Fiscal Year 2018 (October 1, 2017 to September 30, 2018) as contained in CMS Healthcare Provider Cost Reporting Information System ("HCRIS") file dated December 31, 2020.

[17] Avalere Study, *supra* note 2, at 11. The data underlying the Avalere Study is derived directly from information reported by hospitals to CMS that is used for calculating payments under Medicare's disproportionate share payment regime. Acute care hospitals that treat a statistically "disproportionate share" of low-income individuals are entitled to additional payments under Medicare's inpatient payment system. 42 U.S.C. 1395ww(d)(5)(F)(i)(I). Those payments are higher for hospitals that provide a higher relative amount of uncompensated care. *See id*. at § 1395ww(r)(2)(C)(i) (specifying DSH adjustment factor

hospitals, where they account for 6.1% of total operating costs.[18]

In addition, tax-paying hospitals are more likely than other types of hospitals to be located in areas with significant economic and health needs. In areas served by tax-paying hospitals, 13.1% of the population is uninsured, compared to 10.7% of the population nationwide.[19] In fact, many FAH member hospitals would qualify for the 340B program if they were not statutorily precluded from qualifying due to their tax-paying status. The pre-2018 policy favored 340B hospitals at the expense of non-340B hospitals despite both groups of hospitals serving similar patient populations.

The inefficiencies of the pre-2018 payment policies had tangible impacts on non-340B hospitals and the communities they serve. FAH members and other non-340B hospitals provide essential benefits to their communities and can be the only service provider in vulnerable areas. Non-340B hospitals provide oncology services, dialysis, maternity care, and other critical care services.

Non-340B hospitals are a particularly essential part of the health care infrastructure in rural communities, where patients often have fewer alternative options for care. The financial health of

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for acute care hospitals with a higher volume of uncompensated care relative to all acute care hospitals).

[18] See *supra* note 16.

[19] *How can we measure the potential of for-profit hospitals to serve as anchor institutions?*, ANCHORING HEALTH (last visited 10 Mar. 2021), https://anchoringhealth.org/national-landscape/.

rural hospitals is particularly perilous. Forty-six percent of rural hospitals have a negative operating margin, and over 100 rural hospitals have closed since 2010.[20] The financial challenges facing rural hospitals have increased due to COVID-19, which has forced some rural hospitals to reduce or suspend outpatient services.[21] When rural hospitals close, the median distance to the most common health care services increases by 20 miles.[22] FAH members and other non-340B hospitals provide critical services to rural areas notwithstanding the fact that they do not have access to the 340B Program.

The pre-2018 payment policy exacerbated the challenges of providing these life-saving services in communities with high-rates of uncompensated care. Medicare Part B payments are often insufficient to cover the significant costs of providing high-quality health care to uninsured and other vulnerable populations. The pre-2018 OPPS payment rates to non-340B hospitals significantly increased the financial burden of providing outpatient services, by requiring non-340B hospitals to effectively subsidize the provision of identical services to 340B hospitals serving comparable patient populations.

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[20] The Chartis Group, CRISES COLLIDE: THE COVID-19 PANDEMIC AND THE STABILITY OF THE RURAL HEALTH SAFETY NET, at 2 (Feb. 2021), https://www.chartis.com/resources/files/Crises-Collide-Rural-Health-Safety-Net-Report-Feb-2021.pdf.

[21] *Id.* at 7.

[22] United States Government Accountability Office, RURAL HOSPITAL CLOSURES: AFFECTED RESIDENTS HAD REDUCED ACCESS TO HEALTH CARE SERVICES, at 14 (Dec. 2020), https://www.gao.gov/assets/gao-21-93.pdf.

The prior payment policy also resulted in a significant, negative impact on 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 Current Payment Policy Reallocates Savings to All Hospitals.

To ensure that Congress's objectives for the OPPS could be sustained, 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 Medicare payment rates shall be "calculated and adjusted by the Secretary as necessary for purposes of this paragraph."). Here, the Secretary exercised this authority after finding that the 340B payment policy in fact incentivized inefficient delivery of care, created inequitable payments across similarly situated hospitals, and resulted in disproportionately large copayments for certain beneficiaries—problems that conflicted with the OPPS's core goals.

The current payment policy rectifies these problems: it recaptures savings that benefitted *only* 340B hospitals and distributes those savings across *all* hospitals in the United States, including 340B

hospitals. Under the adjustment, CMS reduced SCOD expenditures by an estimated $1.6 billion. 82 Fed. Reg. at 52,509. And, consistent with the OPPS budget neutrality requirement, the downward adjustment in SCOD payments to 340B hospitals allowed CMS to adopt a positive adjustment of 3.2% for all OPPS non-drug items and services, which is particularly important given the deep and chronic Medicare underpayment for these items and services. *See* 42 U.S.C. §1395*l*(t)(9)(B); 82 Fed. Reg. at 52,624.[23]

This positive adjustment benefits hospitals across the board, including FAH members and those members of Petitioners who do not qualify for the 340B program. Avalere Health's study estimates that 82% of all hospitals paid under the OPPS—including 89% of rural hospitals, 77% of rural 340B hospitals, and 49% of all 340B hospitals—would experience a net payment decrease in 2021 if CMS's current 340B payment policy for separately payable drugs were reversed.[24] Accordingly, the financial burden on non-340B hospitals of providing critical services to low-income populations has eased since 2018 when the current payment policy took effect, while 340B hospitals continue to receive the 340B Program's discounted rates on covered outpatient drugs.[25]

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[23] *See* Medicare Payment Advisory Commission, REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY, at 71 (Mar. 13, 2020), http://www.medpac.gov/docs/default-source/reports/mar20_entirereport_rev_sec.pdf?sfvrsn=0 (projecting a negative 8% aggregate margin between Medicare payments and providers' costs for 2020).

[24] Avalere Study, *supra* note 2, at 2, 10.

[25] Even after the adjustments of the 2018 OPPS rulemaking, the SCOD reimbursement rate for 340B hospitals still exceeds 340B

Reversing the current payment policy would eliminate the $1.6 billion in reallocated savings, penalizing non-340B hospitals and restoring the excess payments for 340B hospitals caused by the prior payment policy's inefficiencies.

Further, the current policy increases equity in co-payments for Medicare Part B beneficiaries. Because beneficiaries' copayment obligation is tied to Medicare payment rates rather than hospitals' acquisition costs, the Secretary's payment rate adjustment reduces the disproportionately large copayments of beneficiaries treated with SCODs at 340B hospitals. *See* 42 U.S.C. § 1395*l*(t)(3)(B). Reversing the policy in 2021 would increase beneficiaries' drug copayments by 37% on average, or $472.8 million at 340B hospitals.[26] The current policy thus better aligns the OPPS payment rate and beneficiary copayment for Part B drugs with the OPPS's purpose of ensuring the efficient delivery of care to Medicare beneficiaries.

FAH does not question the importance of the 340B Program in serving the needs of hospitals, especially those in financial distress, many of which have been devastated by the COVID-19 pandemic; in serving the needs of the community, including uninsured patients and immigrants of all legal statuses; or in maintaining

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hospitals' acquisition costs for such drugs. As discussed above, the aggregate discount on Part B drugs received by covered entities in 2013 was 33.6% of ASP. Medicare Payment Advisory Commission, REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY, at 79 (Mar. 15, 2016), http://www.medpac.gov/docs/default-source/reports/march-2016-report-to-the-congress-medicare-payment-policy.pdf.

[26] Avalere Study, *supra* note 2, at 2, 6, 10.

critical hospital services, such as dialysis and chemotherapy. But *all* hospitals provide these services, yet not all hospitals are eligible to participate in the 340B Program. By reallocating savings among all hospitals, the current payment policy achieves a balance that is more efficient and more equitable for hospitals and beneficiaries alike.

III. There Is No Reason for This Court to Review the D.C. Circuit's Decision.

The D.C. Circuit correctly decided a straightforward case of statutory interpretation. The OPPS statute plainly authorizes the Secretary to adjust Medicare payment rates as necessary to serve the OPPS's purposes. *See* 42 U.S.C. § 1395*l*(t)(14)(A). Because the Secretary's payment rate adjustment is entirely consistent with the statute's grant of discretionary authority, this Court need not engage in a searching examination of the principles established in *Chevron* as requested by Petitioners. *See Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842 (1984). Moreover, this case raises no significant question of federal law that compels review. Given the OPPS budget neutrality requirement, the current payment policy does not affect federal spending on the Medicare program; it simply partially redistributes funds among Medicare providers. *See* 42 U.S.C. §1395*l*(t)(9)(B). The D.C. Circuit's decision also does not threaten the uniform, nationwide administration of the Medicare program. Finally, there is no split among the courts of appeals that requires review. The D.C. Circuit's decision should stand.

CONCLUSION

This Court should deny the Petition for a Writ of Certiorari.

Respectfully submitted,

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