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

BRIEF OF *AMICUS CURIAE* THE 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 areas across 46 states, Washington, D.C, and Puerto Rico. FAH 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. These tax-paying hospitals account for nearly 20% of U.S. hospitals and serve their communities proudly while providing high-quality health care to their patients.

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. The FAH routinely submits comments to the Centers for Medicare & Medicaid Services ("CMS") on Medicare and Medicaid payment issues and rulemakings and offers

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[1] 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. Both parties have consented to the filing of this brief.

guidance to courts regarding Medicare and Medicaid reimbursement principles.

FAH member hospitals serve some of our country's most vulnerable communities. For FAH member acute care community hospitals, uncompensated care services ("UC Services") account for 6.1% of costs and charitable services account for 4.3% of costs. Both of these figures exceed that of 340B hospitals. Many FAH member hospitals would be eligible to participate in the 340B Program based on the populations they serve if tax-paying hospitals were not statutorily excluded. *See* 42 USC § 256b(a)(4)(L)(i).

As non-340B providers, FAH members are deeply affected by the payment adjustments for 340B drugs at issue in this appeal. Because the Medicare Outpatient Prospective Payment System ("OPPS") includes a prospective budget neutrality requirement, approximately 2,208 non-340B hospitals, including FAH members, saw an increase in payments as a result of the payment adjustment for 340B drugs adopted by HHS in 2018 and continued in the years since.[2] As a result of this payment adjustment, FAH member hospitals now have additional resources to care for some of the country's most at-risk populations.

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[2] *See* Avalere Health, OPPS MEDICARE PART B PAYMENT IMPACT ANALYSIS, at 11 (Mar. 2021), https://www.fah.org/wp-content/uploads/2021/04/20210326_OPPS_Analysis_for_FAH.pdf [hereinafter Avalere Study] (last visited 25 Oct. 2021).

The FAH respectfully submits this brief as *amicus curiae* to inform the Court of the historical purposes of the OPPS and the impact of HHS's payment policy on hospitals, including 340B and non-340B hospitals and the communities they serve.

INTRODUCTION AND SUMMARY OF ARGUMENT

FAH members and other non-340B hospitals serve as essential health care institutions for some of the nation's most vulnerable communities, providing uncompensated and discounted care to patients who have few, if any, alternatives to address their health care needs. FAH member hospitals provide these underserved patient populations the full range of health care services, including emergency services, preventative care, and the treatment of life-threatening and debilitating conditions in rural and urban areas across the United States. Patients rely on FAH member hospitals because FAH member hospitals deliver high-quality care through long-standing relationships with trusted physicians and other caregivers. In addition, FAH member hospitals engage in community outreach and offer auxiliary services that deepen the ties between FAH member hospitals and the populations they serve. Much like those hospitals represented by Petitioners, FAH member hospitals are anchor-institutions in cities and towns across the country.

Prior to 2018, the Medicare Outpatient Prospective Payment System ("OPPS") intersected with Section 340B of the Public Health Services Act

("340B Program") in a manner that created inequities in Medicare payments between FAH member hospitals and some hospitals represented by Petitioners, despite providing similar services to similar populations.

The OPPS is the system through which HHS reimburses hospitals under Medicare Part B, which 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.

Separate from the Medicare program, the 340B Program permits federally funded community health care clinics and eligible hospitals to acquire certain outpatient drugs at deeply discounted rates. The 340B Program regulates a provider's cost to acquire a covered drug, *not* the amount a provider receives for dispensing that drug to a patient, nor how the provider uses the margin derived from the discounted drug.

While the 340B Program is intended to benefit providers that serve low-income populations, not all hospitals who meet the 340B Program's low-income patient thresholds are eligible for the program's benefits. FAH members and other taxpaying hospitals are statutorily precluded from participating in the 340B Program despite treating similar patient populations, providing greater levels of

uncompensated care, and offering the same services that benefit communities.

Before the Department of Health and Human Services ("HHS") adopted the payment adjustment at issue in this case, OPPS payment rates for 340B drugs far exceeded the amount that 340B hospitals actually paid to acquire those drugs under the 340B Program, creating inefficiencies and inequities in Medicare payments to hospitals. This inefficiency came at the expense of FAH members and similar non-340B hospitals. Because HHS 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 payment—despite serving similar levels of low-income patients as 340B hospitals, often in the same communities. Further, Medicare beneficiaries treated at 340B hospitals incurred excessive co-payments because Medicare payment was not aligned with the 340B hospital's costs of acquiring these drugs. These outcomes undermined Congress's intent in passing the OPPS: 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 specified covered outpatient drugs ("SCOD") for most 340B hospitals from the average sales price ("ASP") plus 6% to ASP minus 22.5%. *See* HHS, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory

Surgical Center Payment Systems and Quality Reporting Programs, Final Rule, 82 Fed. Reg. 52,356, 52,362 (Nov. 13, 2017).[3] The Secretary made this change to "better, and more appropriately, reflect the resources and acquisition costs that [340B] hospitals incur" and "allow … Medicare beneficiaries . . . to share in the savings" of the 340B Program. *Id.* at 52,495, 52,497.

The revised and now current payment policy recaptures savings that previously benefitted *only* 340B hospitals and reallocates those savings across *all* acute care hospitals paid under the OPPS, including 340B hospitals. Under this policy, HHS reduced SCOD expenditures by an estimated $1.6 billion. This allowed HHS 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 OPPS-paid acute care hospitals across the board, including FAH members and Petitioners' members. An estimated 82% of all hospitals paid under the OPPS—including 89% of rural hospitals and nearly half of 340B hospitals—have experienced a net payment *increase* as a result of the current payment policy.[4] Moreover,

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

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

the current policy increases equity in co-payments for Medicare Part B beneficiaries. 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.

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*. This case is about 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 HHS sets annually though notice and-comment rulemaking. 42 U.S.C. § 1395l(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*. § 1395l(t)(9)(B).

Congress enacted the OPPS in 1997 to incentivize the efficient delivery of outpatient services, make payments for hospital outpatient services paid under Part B of the Medicare program 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, HHS made Part B payments to hospitals retrospectively based on the cost of services actually provided. *See* HHS, Medicare Program Prospective Payment System for Hospital Outpatient Services Final Rule, 65 Fed. Reg. 18,434, 18,436 (Apr. 7, 2000). In comparison, under the OPPS, HHS sets Part B payment amounts for outpatient services prospectively at payment rates designed to approximate the costs incurred by efficient providers. Congress' intent in paying hospitals based on a prospective approximation of costs was to "offer incentives to providers to operate more efficiently" and reduce "the level of beneficiary coinsurance payments for hospital outpatient department services." 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 a general matter, payment for most services under the OPPS are bundled into unified payments that encompass most clinical services that would be provided in an outpatient visit. A different policy, however, applies with respect to many drugs used in the outpatient setting. 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. § 1395l(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. § 1395l(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]

B. The 340B Program

The 340B Program is 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 Section 340B of the Public Health Service Act, drug manufacturers participating in the Medicaid and Medicare Part B programs 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)); *see also* 42 USC § 1396r-8(a)(1); (a)(5)(A) (requiring drug manufacturers to participate in 340B Program in order to have drugs covered by Medicare Part B). At a minimum, the discount for a drug acquired under the 340B program is 23.1% off of the

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[5] Between 2006 and 2012, HHS 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. HHS, Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, Final Rule, 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, HHS switched to the calculation method set out in subclause (II) of section 1395l(t)(14)(A)(iii), and set payment at ASP plus 6%. *Id*. at 68,398.

average manufacturer price of the drug. 42 U.S.C. § 256b(a)(2)(A). In practice, many 340B providers are able to acquire 340B drugs at significantly greater discounts than the statutory ceiling price.[6]

The 340B Program is intended to benefit health care providers that serve low-income and other vulnerable populations. Federally-qualified health centers and certain other federal grantees automatically qualify as "covered entities" for participation in the 340B program. 42 U.S.C. § 256b(a)(4). In comparison, for a hospital to qualify for 340B discounts, the 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] 42 U.S.C. § 256b(a)(4)(L)(ii)&(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).

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[6] GAO, "Medicare Part B drugs: Action Needed to Reduce Incentives to Prescribe 340B Drugs at Participating Hospitals," GAO-15-442 (June 2015) ("[t]he amount of the 340B discount ranges from an estimated 20 to 50 percent off what the entity would have otherwise paid").

[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).

Not all hospitals that meet these low-income patient thresholds, however, 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 high-concentrations of low-income patients are ineligible for 340B discounts. Indeed, while many FAH member hospitals meet and exceed the applicable Medicare low-income patient thresholds, they are ineligible for 340B discounts because of their ownership structure.

Congress' primary purpose in establishing the 340B program was "to enable" certain providers "to obtain lower prices on the drugs that they provide to their patients." H.R. Rep. No. 102-384(II) (1992). Veterans Health Care Act of 1992, Pub. L. No. 102-585 § 602, 106 Stat. 4943, 4967–71 (1992). Prior to the 340B Program, Medicaid's "best price"

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[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).

requirement[10] was disincentivizing drug manufacturers from continuing their long-standing practice of offering certain providers discounted or donated "covered outpatient drugs that Medicaid patient's use[d] in any significant volume." H.R. Rep. No. 102-384(II) (1992). The 340B program exempted discounted drugs provided to eligible providers from the calculation of Medicaid's "best price" in order to preserve the discounts between drug manufacturers and these providers.

While Congress recognized that allowing 340B providers to offer expanded services would likely be a positive byproduct of the 340B program, 340B-hospitals are not *required* to pass the savings of the 340B Program on to low-income patients in the way of expanded access to particular services or in any

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[10] *See* Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, §4401, 104 Stat. 1388, 1388-143 (creating the "Medicaid Drug Rebate Program" or "MDRP"). Prior to the MDRP, drug manufacturers regularly offered discounts and drug donations to providers serving the uninsured and indigent populations. However, the MDRP subsequently required manufacturers to provide the Medicaid program their "best price" for a particular drug, and did not exempt discounts and donations to providers in the calculation of best price. 42 U.S.C. §1396r-8(c)(1)(A)(ii)(I). Under this framework, if a manufacturer offered discounts to a provider serving a low-income community or donated drugs, the manufacturer would be required to offer the drug to the Medicaid program at the same price.

other form.[11] In fact, the 340B Program "does not require or provide incentives for hospitals to repurpose financial gains [generated from the 340B program] to enhance care for underserved patients," and some studies have found that these "financial gains for hospitals have not been associated with clear evidence of expanded care or lower mortality among low-income patients."[12]

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 the ASP plus 6%, the same payment rate received by non-340B

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[11] *See* Medicare Payment Advisory Commission, REPORT TO THE CONGRESS: OVERVIEW OF THE 340B DRUG PRICING PROGRAM, at 8 (May 2015) http://www.medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0 (last visited 25 Oct. 2021). In contrast, non-hospital covered entities that qualify for the 340B Program pursuant to their status as federal grantees are required to treat revenue generated from the 340B Program as "program income," which must be used by federal grantees for a purpose that is consistent with the terms of the underlying federal grant. *See* Office of Management and Budget, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, 79 Fed. Reg. 75867 (Dec. 19, 2014).

[12] Sunita Desai and J. Michael McWilliams, *Consequences of the 340B Drug Pricing Program,* NEJM 378: 539 – 548 (Feb. 8, 2018); doi: 1056/NEJMsa1706475

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.[13]

In its Final Rule establishing OPPS rates for 2018, HHS addressed the inequity between 340B and non-340B hospitals by reducing the payment rate for drugs purchased under the 340B Program for most 340B hospitals from ASP plus 6% to ASP minus 22.5%. HHS, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, Final Rule, 82 Fed. Reg. 52,356, 52,494-52,495 (Nov. 13, 2017). The current rate—ASP minus 22.5%—was designed to reflect the "minimum" average discount received by 340B hospitals. 82 Fed. Reg. at 52,496. HHS 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. § 1395l(t)(3)(B) (setting Medicare beneficiary co-payments as a percentage of the Medicare payment

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[13] *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.

rate). As 340B hospitals typically are able to negotiate discounts that exceed ASP minus 22.5%, 340B hospitals are still able to generate positive margins from the administration of SCODs to Medicare Part B beneficiaries. Furthermore, HHS excluded Rural Sole Community Hospitals, Children's Hospitals and PPS-Exempt Cancer Hospitals from this payment adjustment. *See* 82 Fed. Reg. at 52,506. [14]

As required by statute, HHS then used the savings generated from this policy by increasing all payment rates for all non-SCOD outpatient services across the board – even benefitting most of Petitioner's members. All told, HHS 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, HHS 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 OPPS, including FAH member hospitals, other non-340B hospitals, and 340B hospitals. *See* 42 U.S.C. § 1395l(t)(9)(B); 82 Fed. Reg. at 52,624.

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[14] This payment adjustment policy also generally does not apply to other types of 340B-covered entities, such as Federal Qualified Health Centers ("FQHCs") and other federal grantees.

HHS has retained the ASP minus 22.5% payment policy for 340B drugs in all subsequent annual rulemakings.[15]

II. The Current Payment Policy For 340B Drugs Furthers the Goals of the OPPS

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

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.

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[15] *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).

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. In fact, non-340B hospitals provide greater or comparable levels of both charitable care services and UC Services as compared to 340B hospitals.[16] For example, an examination of recent hospital cost report data reveals that charitable services at 340B hospitals account for approximately 2.6% of 340B hospitals' total operating costs, while charitable services at non-340B hospitals account for approximately 2.7% of non-340B hospitals' total operating costs.[17] Charitable services were even higher at FAH member hospitals, accounting for 4.3% of total operating costs. UC Services account for approximately 4.1% of total operating costs in 340B

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[16] UC services are defined here consistent with the definition adopted by HHS for purposes of calculating hospitals' UC-DSH payments under the Medicare inpatient prospective payment system under 42 U.S.C. §1395ww(r)(2)(C). HHS 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* Centers for Medicare & Medicaid Services, 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).

[17] 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 June 30, 2021.

hospitals and approximately 4.2% of total operating costs in non-340B hospitals in FY 2018.[18] UC Services were also higher at FAH member hospitals, where they account for 6.1% of total operating costs.[19]

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, 13.2% of the population is uninsured, compared to 10.7% of the population nationwide.[20] 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 oncology services, dialysis, maternity care, and other critical care services to communities where they are sometimes the only service provider.

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[18] *See supra* note 17.

[19] *Id*.

[20] *How can we measure the potential of for-profit hospitals to serve as anchor institutions?*, ANCHORING HEALTH (last visited 25 Oct. 2021), https://anchoringhealth.org/national-landscape/.

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 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.[21] The financial challenges facing rural hospitals have increased due to COVID-19, which has forced some rural hospitals to reduce or suspend outpatient services.[22] When rural hospitals close, the median distance to the most common health care services increases by 20 miles.[23] 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. In fact, 89% of rural hospitals saw a net-payment increase as a result of HHS's payment adjustment for 340B drugs.

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

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[21] 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.

[22] *Id.* at 7.

[23] 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.

health care to Medicare beneficiaries, including seniors and those with disabilities. On average, Medicare outpatient payments are approximately 14% below hospital costs of care.[24] 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.

B. The Current Payment Policy Reallocates Savings to All Hospitals

The current OPPS payment policy for 340B drugs is consistent with the purposes of the OPPS. Congress' vested the Secretary with broad authority to adjust payment rates for Part B drugs under the OPPS in furtherance of Congress' purpose of improving the efficiency of Medicare payments across the Part B program. *See* 42 U.S.C. § 1395l(t)(14)(A) (stating that Medicare payment rates shall be "calculated and adjusted by the Secretary as necessary for purposes of this paragraph.").[25] Here,

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[24] American Hospital Association, FACT SHEET: SITE-NEUTRAL PAYMENT PROVISIONS (Sept. 2019), https://www.aha.org/system/files/media/file/2019/09/fact-sheet-site-neutral-0919.pdf (last visited 26 Oct. 2021).

[25] This type of Secretarial discretion is common in the Medicare program. The Secretary has similar authority to make adjustments in other areas of the Medicare program, including payment to dialysis facilities, IPPS, and the Medicare Advantage program. *See* 42 U.S.C. §§ 1395rr(b)(14)(D)(iv) (HHS can make adjustments to dialysis facility payments "as the Secretary determines appropriate"; 1395ww(d)(5)(I) (HHS

the Secretary exercised this authority after finding that the prior OPPS payment policy for 340B drugs undermined the purposes of the OPPS. Specifically, the prior payment policy undermined the efficient delivery of care, created inequitable payments across similarly situated hospitals, and resulted in copayments that were not appropriately aligned with the costs of serving beneficiaries.

The current payment policy rectifies these problems: it recaptures excess Medicare payments that benefitted *only* 340B hospitals and distributes those savings across *all* hospitals in the United States paid under the OPPS, including 340B hospitals. Under the adjustment, HHS 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 HHS to adopt a positive adjustment of 3.2% for all OPPS non-drug items and services, which is particularly important given the chronic Medicare underpayment for these items and services. *See* 42 U.S.C. §1395l(t)(9)(B); 82 Fed. Reg. at 52,624.

This positive adjustment benefits OPPS hospitals across the board and the patients they serve, including FAH members, other non-340B

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can make adjustments to inpatient hospital payments "as the Secretary deems appropriate"; 1395w-27(e)(1) (HHS can amend contracts with Medicare Advantage plans with terms and conditions "as the Secretary may find necessary and appropriate").

hospitals, and half of 340B hospitals. The positive payment adjustment has been particularly beneficial for rural communities, as HHS exempted rural sole community hospitals from the new OPPS payment rates for drugs acquired under the 340B program, but these hospitals still benefit from the positive payment adjustment on other Part B services. *See* 82 Fed. Reg. at 52,506. Avalere Health's study estimates that 82% of all hospitals paid under the OPPS—including 89% of rural hospitals, 77% of rural 340B hospitals, 49% of all 340B hospitals, and 100% of rural sole community hospitals, including 340B hospitals—would experience a net payment decrease in 2021 if HHS's current 340B payment policy for SCODs were reversed.[26] 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 significant discounted rates on covered outpatient drugs.[27] Reversing the current payment policy would eliminate the $1.6 billion in reallocated savings, penalizing non-340B hospitals

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

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

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. 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); HHS, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, Final Rule, 82 Fed. Reg. 59,216, 59,355 (Dec. 14, 2017) (citing the OIG Report). Under the current policy, beneficiary copayments more accurately reflect the costs to the hospital of acquiring a particular drug. Absent the current policy, Medicare beneficiaries would see drug copayments for SCODs, received through a 340B hospital, increase by 37% on average, or $472.8 million.[28]

The FAH does not question that 340B hospitals provide critical medical serves to vulnerable communities with acute medical needs, that they provide auxiliary and wrap-around services

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

that improve the public health, or that the COVID-19 pandemic has increased the challenges of serving distressed patient populations. But 340B hospitals are not unique in the services they provide and the challenges they face. FAH members and other non-340B hospitals are frequently anchor-institutions in vulnerable communities that have few, if any, other gateways to medical care. Yet, due to their ownership status, FAH members are ineligible for the 340B program despite serving demographically equivalent patient populations as 340B providers and providing more charity care and UC Services measured on a percentage basis. By reallocating savings among all hospitals, the current payment policy achieves a balance that is more efficient and more equitable for hospitals and the patients they serve alike.

III. The D.C. Circuit's Decision was Correctly Decided

As described more fully in Respondent's brief, this Court should affirm the decision below because 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. § 1395l(t)(14)(A). Here, the Secretary identified problems with the OPPS payment rate for certain Part B drugs that undermined Congress's purposes in creating the OPPS. Specifically, Medicare Part B payments for 340B drugs far exceeded the costs to 340B providers for acquiring those drugs, undermining the efficient delivery of care, creating inequitable payments across similarly-situated hospitals, and misaligning

beneficiary co-pays. The Secretary's adjustment corrected for these inefficiencies and thus was necessary to further the purposes of the OPPS.

IV. The Secretary's Budget Neutrality Adjustment is Not an Issue in this Case

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 case has called into question the lawfulness of the Secretary's prospective 3.2% budget neutrality adjustment. Moreover, FAH members relied on, were entitled to, and were properly paid under an OPPS payment rate designed to be budget neutral based on CMS's prospective estimates for 2018 and 2019.

In any event, 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 "may not cause the *estimated amount* of expenditures under this part for the year to increase or decrease from the *estimated amount* of expenditures under this part that would have been made") (emphasis added). The law does not permit post-hoc reconciliation or recoupment to achieve budget neutrality after payments are made to providers. *C.f. City of L.A. v. Shalala*, 192 F.3d 1005, 1016-17 (D.C. Cir. 1999) (finding 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 made to hospitals and the actual payments made to hospitals") (emphasis added).

CONCLUSION

For the foregoing reasons, the decision of the United States Court of Appeals for the D.C. Circuit should be affirmed.

Respectfully submitted,

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