No. 20-1114

IN THE

Supreme Court of the United States

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,

Petitioners,

v.

NORRIS COCHRAN, in his official capacity as the Acting 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 *AMICI CURIAE* YALE NEW HAVEN HEALTH SYSTEM, BJC HEALTH CARE, UPMC AND VANDERBILT UNIVERSITY MEDICAL CENTER IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI

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March 12, 2021

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20002

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INTEREST OF AMICI[1]

Amici curiae are four of the nation's premier academic medical centers, Yale New Haven Health System (YNHHS), BJC Health Care (BJC), UPMC (University of Pittsburg Medical Center) and the Vanderbilt University Medical Center (VUMC).

Academic medical centers (AMCs) are the nucleus of the health system in the United States.[2] Not only do they serve as safety net hospitals for at risk populations,[3] they also train health care practitioners, discover new therapies and care for the most challenging patients.[4] Their role in training physicians is critical because America faces a shortage of up to 122,000 physicians by 2032, in both primary

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[1] No counsel for a party authored this brief in whole or in part, and no party or counsel for a party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than amici curiae, their members, or their counsel made a monetary contribution to its preparation or submission. Counsel for the amici curiae represented petitioners below in the district court and in the court of appeals, but do not represent petitioners in this case. All parties have consented in writing to the filing of this brief.

[2] Health Research Institute, *The Future of the Academic Medical Center: Strategies to Avoid a Margin Meltdown* (Feb. 2012), at 3, https://uofuhealth.utah.edu/hcr/2012/resources/the-future-of-academic-medical-centers.pdf.

[3] Howard B. Fleishon, et al., *Academic Medical Centers and Community Hospitals Integration: Trends and Strategies*, JOURNAL OF THE AMERICAN COLLEGE OF RADIOLOGY (Jan. 2017), at 45, https://www.jacr.org/article/S1546-1440(16)30586-5/pdf.

[4] *The Future of the Academic Medical Center: Strategies to Avoid a Margin Meltdown, supra* note 2.

care and in the specialty care an aging population needs.[5]

AMC's typically are affiliated with medical schools that collectively graduate nearly 17,000 physicians each year.[6] AMCs also provide communities with the kind of complex care often unavailable elsewhere. These institutions operate 71% of accredited level-one trauma centers in the United States and 98% of the nation's 41 comprehensive cancer centers. In addition, AMCs that are major teaching hospitals — which are 5% of all hospitals in the United States — provide 69% of all burn unit beds, 63% of pediatric intensive care unit beds, 19% of all alcohol unit beds, and 24% of all inpatient psychiatric beds.[7] They also provide treatment for a disproportionately high percentage of Medicare and Medicaid beneficiaries, as well as for those who are uninsured.[8] Although AMCs account for only 20% of hospital admissions, they are estimated to provide 40% of all uncompensated care.[9]

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[5] Karen Fisher, *Academic Health Centers Save Millions of Lives* (June 4, 2019), https://www.aamc.org/news-insights/academic-health-centers-save-millions-lives.

[6] *The Future of the Academic Medical Center: Strategies to Avoid a Margin Meltdown, supra* note 2.

[7] Fisher, *supra* note 5.

[8] *Id.*

[9] Fleishon, *supra* note 3, citing to *The Future of the Academic Medical Center: Strategies to Avoid a Margin Meltdown, supra* note 2.

As safety-net providers, AMC's rely on the savings from the 340B program to fund programs designed to improve the health of their communities. At no cost to taxpayers, the 340B program has been successful in providing patients with access to health care services and relief from high drug prices. Consistent with the intent of the program, safety-net hospitals invest their 340B savings in a wide variety of programs to meet the needs of their local communities and to help vulnerable patients.[10]

Amicus Yale New Haven Health System is a world-renowned heath care provider that enhances the lives of the people it serves by providing access to high value, patient-centered care in collaboration with those who share their values. YNHHS provides more than $700 million per year in IRS-defined community benefits.[11] YNHHS is committed to innovation and excellence in patient care, teaching, research and service to its communities. For over 190 years, YNHHS, which is affiliated with the Yale School of Medicine, has not only served the medical needs of the community but has also pioneered advances in

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[10] *Statement for the Record* Submitted *by the Association of American Medical Colleges (AAMC) to the Energy and Commerce Subcommittee on Health "Opportunities to Improve the 340B Drug Pricing Program" Submitted July 11, 2018,* https://www.aamc.org/media/13566/download.

[11] *2019 YNHHS Community Benefit Report,* YALE NEW HAVEN HEALTH, https://www.lmhospital.org/ynhhs/about/our-community/benefits-report-2019.aspx; *2017 YNHHS Community Benefit Report,* YALE NEW HAVEN HEALTH, https://www.lmhospital.org/ynhhs/about/our-community/benefits-report-2017.aspx.

medicine and trained thousands of doctors, nurses and other healthcare professionals. YNHHS relies on the 340B program to provide funding for a range of programs that benefit underserved populations. *See infra* at 13–14.

BJC Health Care (BJC) is one of the largest nonprofit health care integrated delivery organizations in the country with a mission of delivering services to residents primarily in the greater St. Louis, southern Illinois and mid-Missouri regions. 27% of St. Louis, Missouri residents are impoverished and 19% of St. Louis residents are uninsured. BJC's nationally recognized academic hospitals, Barnes-Jewish and St. Louis Children's hospitals, are affiliated with Washington University School of Medicine. BJC is committed to improving the health and well-being of the people and communities it serves through leadership, education, innovation and excellence in medicine. Services include inpatient and outpatient care, primary care, community health and wellness, workplace health, home health, community mental health, rehabilitation, long-term care and hospice care. BJC's Siteman Cancer Center is the only cancer program in Missouri designated by the National Cancer Institute as a Comprehensive Cancer Center. BJC provides almost $800 million per year in IRS-defined community benefits.[12] BJC relies on the 340B program to provide funding for a range of programs

[12] *2019 Community Benefit Report,* BJC HEALTHCARE, https://communitybenefit.bjc.org .

that benefit underserved populations. *See infra* at 14–16.

UPMC is a world-renowned health care provider with a mission to serve its communities by providing outstanding patient care and shaping tomorrow's health system through clinical and technological innovation, research and education.[13] UPMC, which is affiliated with the University of Pittsburgh School of Medicine, has been a leader in the response to the COVID-19 pandemic. Among other things, it has sponsored multiple trials testing clinical approaches to lessening and treating COVID-19 complications, developed a COVID test, and with its University colleagues it has been working on the development of a monoclonal antibody drug that could be used both as a curative and therapeutic treatment for COVID. UPMC provides more than $1 billion a year in IRS-defined community benefits including more care to the region's most vulnerable citizens than any other health care institution.[14] UPMC relies on the 340B program to provide funding for a range of programs that benefit underserved populations. *See infra* at 16–17.

Vanderbilt University Medical Center, which manages more than two million patient visits each year, is one of the largest academic medical centers in the Southeast and is the primary resource for

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[13] *2019-2020 Community Benefits Report*, UPMC LIFE CHANGING MEDICINE, https://www.upmc.com/about/community-commitment/benefits-report.

[14] *Id.*

specialty and primary care in hundreds of adult and pediatric specialties for patients throughout Tennessee and the Mid-South. VUMC has been and continues to be extensively involved in clinical research relating to COVID-19. VUMC participated in the clinical trial for the vaccine developed by Moderna Inc. and has been awarded a grant from the National Institutes of Health to conduct a nationwide study of convalescent plasma treatment for COVID-19. The Medical Center, which is associated with the Vanderbilt School of Medicine, is the region's locus of postgraduate medical education, with over 1,000 residents and fellows training in more than 100 specialty areas. VUMC provides over $500 million per year in IRS-defined community benefits. VUMC relies on the 340B program to provide funding for services that benefit underserved populations. *See infra* at 17–18.

INTRODUCTION

Prior to 1990, Medicaid was paying full price for prescription drugs even though other large payers obtained deep discounts.[15] In response to this disparity and to the rapidly escalating cost of prescription drugs, Congress enacted the Medicaid Rebate Program, as part of the Omnibus Reconciliation Act of 1990 (Pub. L. No. 101-508).[16]

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[15] Melvina Ford, Cong. Research Serv., *Medicaid: Reimbursement for Outpatient Prescription Drugs*, CRS-17 (Mar. 7, 1991).

[16] *Id.*; *see also* 42 U.S.C. § 1396r-8.

This law requires drug companies that choose to participate in Medicaid to give states and the federal government, which jointly pay for Medicaid, discounts comparable to those given to other payers. Specifically, the Medicaid Rebate Program requires manufacturers to offer states a rebate on their purchases of certain prescription drugs, and the size of the rebate is calculated based on the "best price" the drug manufacturer has given to most purchasers for a particular drug or between 13% and 23.1%, of average manufacturing price, whichever is greater.[17]

In response to the Medicaid Rebate Program, in order to avoid giving state Medicaid programs what had been their best price prior to 1990, drug manufacturers discontinued many of the discounts that they had been offering non-state purchasers which raised the "best price" for the most common drugs among Medicaid patients across the board.[18] As a result, the "[p]rices paid for outpatient drugs by Federally-funded clinics and public hospitals" surged.[19]

Stepping in once again to remedy the problem, Congress enacted section 340B of the Public Health Services Act, which extended discounts to 340B providers, *i.e.,* community health centers, public and nonprofit hospitals and other similar health

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[17] *Id.*; *see also* H.R. Rep. No. 102-384(II), at 9. This percentage has increased over the years since the program began.

[18] *Id.* at 9–10.

[19] *Id.* at 11.

organizations that disproportionately serve the underserved, poor and disadvantaged.[20] Under that Program, manufacturers of prescription drugs, as a condition of having their outpatient drugs covered through Medicaid, are required to offer 340B hospitals and clinics outpatient drugs at or below a discounted, statutorily-determined ceiling price. In general, today drug manufacturers must offer a minimum discount that is the same as the Medicaid discount. *See* 42 U.S.C. §§ 256b(a)(1), 1396r-8(c)(1)(B)(i). Drugs purchased under the 340B Program include drugs that are reimbursed under the Outpayment Prospective Payment System (OPPS).[21]

When Congress enacted the 340B Program, its stated purpose was "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384, pt. 2, at 12 (1992). As explained by the Health Resources and Services Administration (HRSA), the agency of the Department of Health and Human Services (HHS) that is responsible for

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[20] *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967–71 (1992) (creating section 340B of the Public Health Service Act). Under the statute 340B providers are called "covered entities." 42 U.S.C. § 256b(a)(4).

[21] Medicare Part B pays hospitals for covered outpatient services through the OPPS. In 2003, Congress created a separate payment methodology for separately payable prescription drugs in the Medicare Modernization Act of 2003 (MMA). *See* Pub. L. No. 108-173, 117 Stat. 2066, 2307-08. Today, the MMA's payment methodology determines how much Medicare will pay hospitals for all separately payable, prescription drugs.

administering section 340B, the Program furthers that objective by "lower[ing] the cost of acquiring covered outpatient drugs" from drug manufacturers, thereby generating additional resources from "health insurance reimbursements"."[22] This is accomplished at no cost to the federal government.

Since the 340B Program was first implemented, and consistent with the statutory design, 340B hospitals and clinics have used the savings generated by the Program to expand services and better serve disadvantaged patients. Recognizing the importance of financial flexibility to the operation of 340B providers, Congress did not specify in the statute how funds generated through the Program must be used, *see* 42 U.S.C. § 256b, although it anticipated that participation in the Program would enable 340B hospitals and clinics to provide additional healthcare services to vulnerable communities. H.R. Rep. No. 102-384, pt. 2, at 12.

A 2011 report from the U.S. Government Accountability Office ("GAO") found that this is exactly what happened. Covered entities have used the additional resources to provide critical healthcare

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[22] Health Resources and Services Administration, Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Service Act at 14 (July 2005) ("2005 HRSA Manual"), https://docplayer.net/6345832-Hemophilia-treatment-center-manual-for-participating-in-the-drug-pricing-program-established-by-section-340b-of-the-public-health-service-act.html.

services to communities with underserved populations that could not otherwise afford these services – for instance, by increasing service locations, developing patient education programs, and providing translation and transportation services.[23]

Recognizing the value of the 340B Program, in 2010 Congress amended the statute to add additional categories of "covered entities" as part of the Affordable Care Act. Originally, "covered entities" included federally-funded health centers and clinics providing services such as family planning, AIDS intervention, and hemophilia treatment, as well as public and certain not-for-profit hospitals serving a large proportion of low-income or uninsured populations. Pub. L. No. 102-585, § 602; 42 U.S.C. § 256b(a)(4)(A)–(L). The 2010 amendment expanded "covered entities" to include certain children's hospitals, free-standing cancer hospitals, critical access hospitals, and sole community hospitals. 42 U.S.C. § 256b(a)(4)(M)–(O).

Despite the success of the program in achieving Congress's goals,[24] in 2017 the Center for Medicare & Medicaid Services (CMS) issued a regulation that cut, by almost 30 percent, the Medicare Reimbursement for outpatient drugs to which 340B entities are entitled. 82 Fed. Reg. 52,356 (Nov. 13, 2017). It is this

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[23] U.S. Gov't Accountability Off., GAO-11-836, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* (Sept. 2011), at 17–18, http://www.gao.gov/assets/330/323702.pdf.

[24] *Id.*

regulation (and those issued in subsequent years) that was challenged in the cases below.

The majority opinion below acknowledged that Petitioners' argument that HHS had no authority to impose this severe reduction for outpatient drugs was "not without force." Pet. App. 24a. Nevertheless, it granted deference to HHS's construction of the statute far beyond the deference permitted by *Chevron U.S.A., Inc. v. Nat'l Research Def. Council, Inc.*, 467 U.S. 837, 842 (1984), and its progeny, which, for the reasons explained in the dissenting opinion below and in the Petition for a Writ of Certiorari, led to a decision that was clearly erroneous. The Petition also addresses an issue of exceptional importance because of the Rule's devastating impact on the nation's health care system, including academic medical centers that disproportionately serve the very populations that the 340B statute was designed to support. These two factors justify review by this Court.

ARGUMENT

I. The 340B Program has Served its Purpose of Providing Hospitals the Means to Provide Medical Care to Underserved and Disadvantaged Patients.

Congress enacted the 340B Program "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384, pt. 2, at 12. Covered entities have used the additional resources to provide critical healthcare services to communities with underserved populations that could not otherwise afford these services − for instance, by increasing service locations, developing patient education programs, and providing translation and transportation services.[25]

340B covered entities, including amici, play a uniquely important role in providing medical services to poor, underserved populations. *See, e.g.*, U.S. Gov't Accountability Off., GAO-21-107, *HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements* 4-5 (Dec. 2020).[26] The services that 340B Hospitals offer are vital, ranging from primary care, to pediatrics, trauma care, obstetrics, and psychiatric services—all of which 340B Hospitals, including amici, provide to a higher percentage of the population than hospitals generally. *See, e.g.*, Allen

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[25] U.S. Gov't Accountability Off., *supra* note 24.

[26] https://www.gao.gov/assets/720/711209.pdf.

Dobson, et al., *The Role of 340B Hospitals in Serving Medicaid and Low-income Medicare Patients* 13-16 (July 10, 2020).[27]

For example, every year, as part of its vital mission to promote health and wellness throughout the Greater New Haven region, YNHHS sponsors, develops and participates in a wide variety of community-based programs and services. During 2019**,** YNHHS provided over $741 million in financial and in-kind contributions through five wide-ranging programs:

- Guaranteeing Access to Care: YNHHS provided free or discounted healthcare services to over 83,147 eligible people at a loss of $270 million, plus under-reimbursed services for 628,333 Medicaid beneficiaries, at a loss of $308 million. YNHHS also guarantees access to care by subsidizing clinical programs at a loss of $24.3 million.

- Advancing Careers in Health Care: YNHHS provided $116 million to a variety of health education programs that train individuals to become medical professionals.

- Promoting Health & Wellness: YNHHS provided $12.6 million to local health education programs, support groups, health fairs and various community organizations.

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[27] https://www.340bhealth.org/files/340B_and_Medicaid_and_Low_Income_Medicare_Patients_Report_7.10.2020_FINAL_.pdf.

- Building Stronger Neighborhoods: YNHHS provided $7.1 million in financial and in-kind donations to address or support social determinants of health including food security, job training, affordable housing programs and/or other essential services.

- Creating Healthier Communities: YNHHS provided $2.9 million in funds and in-kind services to dozens of not-for-profit organizations.[28]

Savings from the 340B program help YNHHS fund these important programs. In addition, YNHHS hospitals provided $372.2 million in bad debt and Medicare shortfalls.[29]

Similarly, BJC provides almost $800 million per year in IRS-defined community benefits, more than any other health system in the State of Missouri. This includes charity care, reimbursable Medicaid expenses, the education of health care professionals, community health programs and safety net services.[30] Adult and Pediatric Level 1 Trauma centers, mental health care, critical access hospitals and highly specialized newborn intensive care services are all examples of safety net services that are available when the need strikes, any time, any day. These services are highly specialized, intensive and must be

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[28] *2019 YNHHS Community Benefit Report*, *supra* note 11.

[29] *Id.*

[30] *2019 Community Benefit Report*, *supra* note 13.

available around the clock, which means they are usually provided at a financial loss. Savings from the 340B program help BJC provide these services.

In addition, savings from the 340B program contribute to the funding of other BJC programs designed to help underserved and at-risk populations. These include:

- The "No Med Left Behind" program for low income families. 340B savings are used to provide medication access to families whose Medicaid did not cover medications or who could not afford them. In 2020, this program served over 2,000 patients at a cost of over $72,000;

- A social worker voucher program pursuant to which social workers provide vouchers to patients who cannot otherwise afford medications to obtain them at no cost. At 340B pricing, the program is able to provide $487,824 of prescriptions at a cost of $102,275.

- A 14-bed behavioral health unit that BJC added to address the severe dearth of pediatric behavioral health providers in the St. Louis region;

- A program for uninsured clinic patients pursuant to which BJC passes through the 340B price. The volume of prescriptions subsidized is over 31,000 annually; and

- A unique program for veterans who are only able to get medications filled at the VA. BJC provides VA patients with discharge medications at no charge to prevent delays in therapy (the VA will not accept discharge prescriptions written at BJC).

UPMC provides more than $1 billion per year in benefits to the communities it serves and delivers more care to the region's poor and underserved than any other health system in the state of Pennsylvania.[31] UPMC makes care accessible to individuals and families who are uninsured or underinsured. Thousands of patients each year qualify for financial assistance or have a Medicaid plan in which payment for services do not cover UPMC costs. The combined subsidy for these patients in 2019 was $479 million. UPMC's community benefits thus total $1.4 billion per year or almost $3.9 million per day.[32] UPMC cares for approximately 18% of the patients in Pennsylvania but provides more than 25% of the hospital charity care in the state.[33] Savings from the 340B program help UPMC fund these important programs.

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[31] *2019-2020 Community Benefits Report*, *supra* note 14.

[32] *Id.*

[33] *Care Within Reach*, UPMC LIFE CHANGING MEDICINE, https://www.upmc.com/about/community-commitment/benefits-report/our-impact/care-within-reach.

In addition, savings from the 340B program contribute to the funding of other critical programs provided by UPMC. These include:

- Access to specialized care such as behavioral health programs, treatment for opioid abuse, the SMART choices programs, and the only National Cancer Institute-designated Comprehensive Cancer Center in UPMC's region;

- Community based outreach efforts, including helping the homeless; reaching out to refugees; breast cancer awareness programs, women's health programs, and pediatric primary care; and

- New technologies and clinical advancements (*e.g.*, transplantation, cell therapies and telemedicine).

VUMC provides more than $500 million annually in IRS-defined community benefits. This includes charity care, unreimbursable Medicaid expenses, the education of health care professionals, community health programs and safety net services. In addition, VUMC hospitals provided $218 million in bad debt and Medicare shortfalls. Savings from the 340B program contribute to the funding of a number of VUMC programs designed to help underserved and at-risk populations. These programs include but are not limited to the following:

- A medication assistance program that assists patients in obtaining access to manufacturer discounts, third party foundations and other assistance programs. In its 2019 fiscal year, the cost of administering this program to VUMC was approximately $718,000, and the value of drugs provided to patients through various third-party access programs was estimated at $6 million;

- A program to support home infusion medications and related services for patients requiring such services at hospital discharge, which in fiscal year 2019 dispensed drugs costing approximately $381,000;

- The VUMC Comprehensive Care Clinic, a Ryan White grantee organization which serves persons living with HIV in Tennessee, and which in fiscal year 2019 provided drugs valued at $54,000 in excess of Ryan White Part C coverage; and

- A pharmacy program to dispense medications for patients of The Shade Tree Clinic, a health clinic run by students at Vanderbilt University School of Medicine which provides free care uninsured, underserved and homeless, and which provided drugs costing more than $70,000 during fiscal year 2019.

Amici are not unique in this respect. As has been demonstrated by petitioners and in the courts below,

340B hospitals nationwide rely on 340B funds to provide services to vulnerable patients.[34] This includes proving free or discounted drugs to low-income patients, providing access to a wider range of drugs and medical devices, and providing greater access to wider range of care.[35] This has all been accomplished at no cost to the federal government. Without the 340B Program, insurers and federal programs would be paying full price, or in the case of Medicare for outpatient drugs, the average sales price plus 6%. 42 U.S.C. § 1395l(t)(14)(A)(iii)(II). Under the 340B program, those payers pay the same, but the covered entities get the benefit of the discount and then use the additional resources as described above. This is how it has worked for all drugs since the 340B program began in 1992 and the way it has worked for Medicare outpatient drugs since Congress created a separate payment methodology for specified prescription drugs in the Medicare Modernization Act of 2003 (MMA).

Despite the success of the program, and the fact that it has accomplished its goals at no cost to the federal government, CMS has chosen to substantially cut the benefit and undercut the program created by Congress.

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[34] *See, e.g.*, 340B Health, *340B Program Helps Hospitals Provide Services to Vulnerable Patients* (May 2016), https://www.340bhealth.org/files/Savings_Survey_Report.pdf.

[35] *Id.* at 4, 11.

II. If Left Standing, CMS's Rule Will Diminish the Ability of Amici and other 340B Hospitals to Continue Programs that Benefit the Underserved.

Providing medical services to poor, underserved populations carries with it a hefty price tag. Add to this the fact that the federal government's health care programs pay less than the cost of providing care for their beneficiaries. For example, Medicare paid 87 cents for every dollar spent providing care for beneficiaries in 2019, while Medicaid paid 90 cents for every dollar spent providing care for beneficiaries (including supplemental payments).[36] Nevertheless, a 2017 survey demonstrated that in one year, 340B hospitals provided more than $64.3B in total benefits to their communities.[37] Amicus UPMC provided over $1 billion in community benefits in 2019 and Amici BJC, YNHHS and Vanderbilt each provided between five and nine hundred million dollars in community benefits in fiscal year 2019. Because of efforts such as these, many 340B hospitals "operate on razor thin

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[36] *Fact Sheet: Underpayment by Medicare and Medicaid,* AMERICAN HOSPITAL ASSOCIATION, https://www.aha.org/fact-sheets/2020-01-07-fact-sheet-underpayment-medicare-and-medicaid.

[37] *340B Hospital Community Benefit Analysis,* AMERICAN HOSPITAL ASSOCIATION, https://www.aha.org/guidesreports/2020-09-10-340b-hospital-community-benefit-analysis.

margins, with approximately one out of every four 340B hospitals having a negative operating margin."[38]

The 340B Program and in particular the availability of 340B discounts under the Medicare program are especially important today when hospitals and health systems across the country are under severe financial pressure due to the COVID-19 pandemic. Reduction in patient volume and increased expenses due to the pandemic have resulted in financial losses for many hospitals and health systems, which, according to the American Hospital Association, have already lost $323 billion as a result of the pandemic.[39]

HHS's near 30 percent reduction in the reimbursement rate, which translates to a loss of approximately $1.6 billion for 340B hospitals annually, will inevitably lead these financially strapped hospitals to cut back or eliminate essential programs that serve financially vulnerable patients.

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[38] Tom Nickels, *Report Misrepresents 340B Program to Deflect from Sky High Drug Prices*, AHA STAT: AN AMERICAN HOSPITAL ASSOCIATION BLOG (Nov. 22, 2019), https://www.aha.org/news/blog/2019-11-22-report-misrepresents-340b-program-deflect-sky-high-drug-prices#:~:text=For%20outpatient%20services%2C%20340B%20hospitals,between%2015%25%20and%2020%25. *See also* Dobson, *supra* at 13 (explaining that "[o]perating margins for 340B [disproportionate share] hospitals are significantly lower than those of non-340B hospitals").

[39] American Hospital Association, *Hospitals and Health Systems Continue to Face Unprecedented Financial Challenges due to COVD-19* (June 2020) https://www.aha.org/system/files/media/file/2020/06/aha-covid19-financial-impact-report.pdf.

When there is less money available, 340B hospitals will be forced to seriously consider reducing or eliminating programs that have adverse financial consequences.

Amici will resist these pressures, but in the end they, and other 340B hospitals will be forced to make decisions that are consistent with their ability to meet their communities most pressing needs. Already the cuts have impacted BJC's ability to pass on 340B savings to uninsured patients and YNHHS's expansion of retail pharmacy services as well as services related to home infusion, home care and integrated/affiliated health efforts. Likewise, the broad range of BJC programs described above and other programs providing increased access to underserved communities may be jeopardized or subject to significant reductions. And VUMC estimates that its 340B savings have been reduced by approximately $12.4 million due to the actions of HHS, which will impact VUMC's ability to continue to fund community benefit programs at historic levels.

As long as the severe reductions in Medicare reimbursement remain in effect, 340B hospitals, including all four amici, will have to continue to monitor their programs to determine when adjustments or cuts will have to be made. Unfortunately, the CMS rule will cause the greatest harm to the very populations that the 340B program was intended to benefit.

III. The Court Should Grant Certiorari.

This Court should grant certiorari in order to address the exceptionally important legal question presented in the Petition for a Writ of Certiorari.

The central legal question in this case is whether the court below correctly held that HHS had the authority to cut the reimbursement rate for 340B entities for outpatient drugs by basing the rate on a third party's estimate of the average acquisition cost of the drugs.

As explained in the Petition, the Medicare statute directs HHS to set the relevant reimbursement rates either under subclause (I) based on average acquisition cost (reflecting the average cost that hospitals actually incurred in purchasing the drug) *if HHS possessed specified acquisition cost survey data*; or if HHS does not have such cost survey data, under subclause (II) based on average sales price (reflecting the average price, updated quarterly, at which manufacturers sold the drug to most purchasers, not limited to hospitals). *See* 42 U.S.C. § 1395l(t)(14)(A)(iii)(I)-(II). Even though HHS concedes it did not have the survey data required by subclause I, the majority of the court below agreed with HHS that it could use its authority under subclause II to "adjust[]" reimbursements rates "as necessary for purposes of [the] paragraph" to reflect the average acquisition cost. Pet. App. 21a. In other words, the court said that the adjustment authority allowed HHS use subclause II to reach a subclause I result even

though it lacked the data that Congress required it to have.

For the reasons set forth in the Petition, the court below was wrong. As Judge Pillard concluded in her dissent, "the majority essentially reads subclause (I) out of the statute by permitting the agency to do under subclause (II) without the requisite data what subclause (I) authorizes only with that data." Pet. App. 39a.

This legal error has the potential to cause the thousands of 340B hospitals to further pare back vital services, many of which they provide a higher rate than other hospitals,[40] and which the pandemic makes all the more critical. That is why it is important for the Court to address this issue now, before amici and other 340B hospitals are forced to make even more radical cuts to or potentially discontinue programs and services that are vital to the patients in the vulnerable communities they serve.

[40] *See, e.g.*, Dobson, *supra* at 13.

CONCLUSION

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

Respectfully submitted,

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March 12, 2021