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 *AMICI CURIAE* YALE NEW HAVEN HEALTH SYSTEM, BJC HEALTH CARE, CEDARS-SINAI MEDICAL CENTER, GEISINGER, UPMC, AND VANDERBILT UNIVERSITY MEDICAL CENTER IN SUPPORT OF PETITIONERS

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September 10, 2021

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

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INTEREST OF *AMICI CURIAE*[1]

Amici curiae are six of the nation's premier academic medical centers: Yale New Haven Health System (YNHHS), BJC HealthCare (BJC), Cedars-Sinai Medical Center (CSMC), Geisinger, UPMC (University of Pittsburg Medical Center), and 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 especially critical because America faces a shortage

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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.

of up to 122,000 physicians by 2032, in both primary 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 all accredited level-one trauma centers in the United States and 98% of the nation's 41 comprehensive cancer centers. In addition, although AMCs that are major teaching hospitals comprise only 5% of all hospitals in the United States, they 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 patients, 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]

As safety-net providers, AMC's rely on the savings from the 340B program to fund programs designed to

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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.

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 non-profit health care provider that enhances the lives of the people it serves by providing access to high-value, patient-centered care. 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 medicine and trained thousands of doctors, nurses and other health care professionals. YNHHS relies on the 340B program to provide funding for a range of programs that benefit underserved populations. *See infra* at 14-15.

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[10] *Statement for the Record* Submitted *by the Association of American Medical Colleges (AAMC) to the House Congressional 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.ynhh.org/about/community/benefits-report-2019#:~:text=Community%20Benefits%20Report%20Summary&text=YNHH%20provided%20%24451.1%20million%20to,a%20loss%20of%20%24227.3%20million.

BJC HealthCare 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 and southern Illinois regions. Twenty seven percent 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 provided by BJC 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 that benefit underserved populations. *See infra* at 16-17.

Cedars-Sinai Medical Center is a California nonprofit, public benefit corporation located in Los Angeles County, California. CSMC is one of the largest nonprofit academic medical centers in the country. Since its formation in 1902, CSMC has evolved to meet the health care needs of one of the most diverse regions

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

in the nation. Clinical programs cover a complete spectrum of medical services, ranging from primary care for preventing, diagnosing, and treating common conditions to specialized treatments for rare, complex, and advanced illnesses. CSMC has a highly respected training program for residents and fellows in more than 80 specialty and subspecialty areas.[13] As a global leader in medical research, CSMC currently has more than 2100 active research projects.[14] Scientific leaps forward include using cardiac stem cells to repair damaged hearts, developing a vaccine to fight the most aggressive malignant brain tumors and developing more effective anti-cancer drugs aimed at specific molecular targets.[15] Although a portion of the costs of such research is funded by NIH grants and donor gifts, in the 2020 fiscal year, CSMC incurred over $90,000,000 for unfunded research.[16] CSMC provides approximately $670 million in community benefits annually.[17] CSMC relies on the 340B program to provide funding for services that benefit underserved populations. *See infra* at 17-19.

Geisinger is a nationally recognized provider of health care services located in central and Northeastern Pennsylvania, where it is the primary resource for

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[13] *2020 Cedars-Sinai Community Benefit Report and Plan* (Submitted to the State of California), 5, 27 at https://www.cedars-sinai.org/content/dam/cedars-sinai/community-benefits/documents/cs-community-benefit-plan-2020.pdf.

[14] *Id.*

[15] *Id.*

[16] *Id.*

[17] *Id.*

primary care and specialists, hospitals and trauma centers, medical education and research. Geisinger is committed to making better health easier for the more than one million people it serves annually. Founded more than 100 years ago, Geisinger includes nine hospital campuses, 120 clinic sites, 1,600 employed physicians and the Geisinger Commonwealth School of Medicine. Geisinger has earned a national reputation for quality, value, innovation, education, research and compassionate care. Geisinger boosts its communities by billions of dollars annually and relies on the 340B program to fund a number of initiatives that benefit the communities at large. *See infra* at 19-21.

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.[18] 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, UPMC 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 its region's most vulnerable citizens than any other health care

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[18] *2019-2020 Community Benefits Report*, UPMC LIFE CHANGING MEDICINE, https://www.upmc.com/about/community-commitment/benefits-report.

institution.[19] UPMC relies on the 340B program to provide funding for a range of programs that benefit underserved populations. *See infra* at 21-22.

Vanderbilt University Medical Center, which manages more than 2.4 million patient visits each year, is one of the largest academic medical centers in the Southeast. It is the primary resource for adult and pediatric specialty and subspeciality health care services for patients residing in Tennessee and surrounding states. 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 was 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 22-23.

INTRODUCTION

In 1990, Congress enacted the Medicaid Rebate Program, as part of the Omnibus Reconciliation Act of 1990 (Pub. L. No. 101-508).[20] This law requires drug companies that choose to participate in Medicaid to

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[19] *Id.*

[20] 42 U.S.C. § 1396r-8.

give states, which administer 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.[21]

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.[22] As a result, the "[p]rices paid for outpatient drugs by Federally-funded clinics and public hospitals" surged.[23]

In response, in 1992 Congress enacted section 340B of the Public Health Services Act, which extended the Medicaid discounts to 340B providers, *i.e.,* community health centers, public and nonprofit hospitals and other similar health organizations that disproportionately serve the underserved, poor and disadvantaged.[24] Under that Program, manufacturers of prescription drugs, as a condition of having their

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

[22] *Id*. at 9–10.

[23] *Id.* at 11.

[24] 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).

outpatient drugs covered through Medicaid and Medicare Part B, 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 certain hospital outpatient drugs that are reimbursed under the Outpatient Prospective Payment System (OPPS).[25]

When Congress enacted the 340B Program, the program's 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 administering section 340B, the Program furthers that objective by "lower[ing] the cost of acquiring covered outpatient drugs" from drug manufacturers, thereby generating additional

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

resources from "health insurance reimbursements."[26] This is accomplished by lowering the payment for 340B drugs to pharmaceutical companies 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 health care 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 health care services to communities with underserved populations that could not otherwise afford these services—for instance, by increasing service locations, developing

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[26] HRSA, 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) 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.

patient education programs, and providing translation and transportation services.[27]

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,[28] 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). Petitioners challenged the cuts CMS made in this regulation (and those issued in subsequent years).

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[27] 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.

[28] *Id.*

The district court agreed with Petitioners that CMS lacked the authority to make such cuts. Pet. App.76a. A divided panel of the D.C. Circuit reversed and denied rehearing. Pet. App.1a-43a, 118a. 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. National Resources Defense Council, Inc.*, 467 U.S. 837, 842 (1984), and its progeny, which, for the reasons explained in the dissenting opinion below and in Petitioners' opening brief, led to a decision that was clearly erroneous. Moreover, as set forth herein, the Rule has had a devastating impact on the nation's health care system, including academic medical centers that disproportionately serve the populations that the 340B statute was designed to support.

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 health care 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.[29]

In order to be eligible for 340B discounts, hospitals must annually certify that they serve a significantly disproportionate number of low-income patients.[30] As such, these 340B hospitals, 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*

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[29] U.S. Gov't Accountability Off., *supra* note 27.

[30] Disproportionate Share Hospitals, Eligibility at https://www.hrsa.gov/opa/eligibility-and-registration/hospitals/disproportionate-share-hospitals/index.html; Annual Recertification at https://www.hrsa.gov/opa/recertification/recertification.html.

Requirements 4-5 (Dec. 2020).[31] 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 do hospitals generally. *See, e.g.*, Allen Dobson, et al., *The Role of 340B Hospitals in Serving Medicaid and Low-income Medicare Patients* 13-16 (July 10, 2020).[32]

Every year, as part of its vital mission to promote health and wellness throughout the Greater New Haven region, Yale New Haven Health System 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 the five wide-ranging programs described below.

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

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

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

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

- Building Stronger Neighborhoods. YNHHS provided $7.1 million in financial and in-kind donations to address or support social determinants of health[33] 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.[34]

Savings from the 340B program help YNHHS fund these important programs. In addition, YNHHS hospitals absorbed $372.2 million in bad debt and Medicare shortfalls.[35]

BJC Health Care 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, education of health care professionals, community

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[33] Social determinants of health are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks. *See* HHS, Healthy People 2020 at https://health.gov/healthypeople/objectives-and-data/social-determinants-health.

[34] *2019 YNHHS Community Benefit Report*, *supra* note 11.

[35] *Id.*

health programs and safety net services.[36] 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 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 the BJC programs listed below, which are designed to help underserved and at-risk populations.

- The "No Med Left Behind" program for low-income families. 340B savings are used to provide medication access to families whose Medicaid does not cover medications or who cannot afford them. In 2020, this program served over 2,000 patients.

- 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 in savings for prescription drugs for eligible patients.

- A 14-bed behavioral health unit that BJC added to address the severe dearth of pediatric

[36] *2019 Community Benefit Report*, *supra* note 12.

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.

- 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 by non-VA providers).

Cedars-Sinai Medical Center in fiscal year 2020 discharged more than 165,000 hospital-based patients who received care through Medi-Cal (California's Medicaid insurance program) or through both Medicare and Medi-Cal.[37] Thirty nine percent of CSMC's Medicare population is insured through both Medicare and Medi-Cal based on financial indigency and these patients have elevated social needs and higher risk for readmission.[38] Additionally, as the largest Medicare provider in the state, CSMC cares for more elderly patients than any other hospital in California. These patients often have multiple, complex illnesses requiring highly specialized care. In total, 46% of CSMC patients in the 2020 fiscal year were either Medicare or Medi-Cal beneficiaries. CSMC

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[37] *Cedars-Sinai Community Benefit Report* supra note 13 at p. 3. The amount reported to the state includes the unreimbursed cost of Medicare patients.

[38] *Id.*

has cared for over 2,000 COVID-19 patients requiring hospital care.[39]

CSMC's breadth of community benefit activities reflects a longstanding commitment to helping those in greatest need.

- In fiscal year 2020, CSMC provided over $102,000,000 of unreimbursed care for the poor and the underserved, in addition to the unreimbursed cost of Medicare patients.[40] CSMC provides free care to people earning up to 400% of the federal poverty level and significantly discounted care to those earning between 400% and 600% of the federal poverty level. While more people now have insurance through the Affordable Care Act, many commercial insurance plans carry a high deductible or copay, causing financial hardship for many patients. CSMC recently expanded eligibility for free or discounted care to enable more people to receive financial assistance.

- In fiscal year 2020, CSMC provided over $350,000,000 of unreimbursed direct medical care for Medicare patients and patients in specialty government programs.[41]

- CSMC spent over $127,000,000 in fiscal year 2020 on services and programs that increase

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[39] *Id.*

[40] *Id.* at 26.

[41] *Id.*

access to medical care for individuals and families who live in the greater Los Angeles community, including those who are uninsured or underinsured, enabling people of all ages to lead healthier lives. These community benefit programs include free community education, mental health services, preventive screening, immunization programs, research focused on advancing population health and improving health care delivery, among others. [42]

- CSMC engages in over 5,000 community benefit activities each year, and in fiscal year 2020, these programs impacted over 180,000 lives. This includes over $20,000,000 in strategic, high-impact grant making to over 200 organizations to improve access to care and address social determinants of health for Los Angeles' most vulnerable populations. [43]

Geisinger, as part of its mission to improve the health of the communities it serves, provided $837.9 million in community support in fiscal year 2020, including free, uncompensated care to patients who could not afford to pay, care provided to the elderly and the poor not paid by Medicare or Medicaid, and community health, education and outreach programs.

Geisinger uses 340B savings to provide additional care to its vulnerable patient population and increase

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[42] *Id.*

[43] *Id.*

services through many programs, including those described below.

- MyCode® Community Health Initiative. With more than 200,000 patient-participants, MyCode is delivering medically relevant results to participants and their primary care doctors. More than 2,600 people have received clinical reports informing them they have a genomic variant that increases their risk of early cancers or heart disease, so their doctors can detect and treat these conditions before any clinical symptoms arise.

- Fresh Food Farmacy.® Partnering with the community, Geisinger is improving the health of adults with diabetes by providing them with free, nutritious food and comprehensive medical, dietetic, social and environmental services. Its Fresh Food Farmacy has had clinical impacts greater than those of expensive medications at a significantly lower cost.

- LIFE Geisinger. This innovative program is designed specifically for older adults to support living at home. The program helps people continue to live independently, while taking advantage of comprehensive daily living and health services. The coordination of care for patients is provided by the Geisinger team with no gap in services.

- Free2BMom. Designed to assist pregnant women and new mothers who are struggling with substance use, the program's

multidisciplinary team provides counseling, social support and medication-assisted treatment for women in recovery during pregnancy and for two years after childbirth. Free2BMom empowers each mother and her baby to thrive physically, psychologically and socially.

- Medication Therapy Disease Management Program. Geisinger's internationally recognized initiative connects pharmacists to patients who need personal guidance about medications for conditions including anticoagulation, hypertension, diabetes, cancer and chronic pain, empowering patients to meet treatment goals more easily.

UPMC provides more than $1 billion per year in benefits to the communities it serves and delivers more care to its region's poor and underserved than any other health system in the state of Pennsylvania.[44] 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.[45] UPMC cares for approximately 18%

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[44] *2019-2020 Community Benefits Report*, *supra* note 18.

[45] *Id.*

of the patients in Pennsylvania but provides more than 25% of the hospital charity care in the state.[46]

In addition, savings from the 340B program contribute to the funding of the following critical services provided by UPMC.

- Access to specialized care such as behavioral health programs, treatment for opioid abuse, the Substance Misuse and Referral to Treatment (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.

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

Vanderbilt University Medical Center provides more than $500 million annually in IRS-defined community benefits. This includes charity care, unreimbursed Medicaid expenses, 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.

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

Savings from the 340B program contribute to the funding of a number of VUMC programs designed to help underserved and at-risk populations, including those listed below.

- A medication assistance program that supports 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.

- 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, 340B hospitals

nationwide rely on 340B funds to provide services to vulnerable patients.[47] 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 a wider range of care.[48] 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. § 1395*l*(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 2003.

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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[47] *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.

[48] *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. Hospitals that provide these services must account for policies which provide 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.[49] Nevertheless, a 2017 survey demonstrated that in one year, 340B hospitals provided more than $64.3B in total benefits to their communities.[50] Amicus UPMC provided over $1 billion in community benefits in 2019 and Amici BJC, CSMC, Geisinger YNHHS, and Vanderbilt, each provided between five and nine hundred million dollars in community benefits in fiscal year 2019. The 340B Program helps to make this possible.

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

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[49] American Hospital Association, *Fact Sheet: Underpayment by Medicare and Medicaid,* https://www.aha.org/fact-sheets/2020-01-07-fact-sheet-underpayment-medicare-and-medicaid.

[50] American Hospital Association, *340B Hospital Community Benefit Analysis*, https://www.aha.org/guidesreports/2020-09-10-340b-hospital-community-benefit-analysis.

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 collectively lost $323 billion as a result of the pandemic.[51]

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

Amici will resist these pressures, but in the end they, and other 340B hospitals may have no choice. 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

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[51] 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.

$12.4 million annually due to the actions of HHS, which will impact VUMC's ability to continue to fund community benefit programs at historic levels. Geisinger estimates that it is losing $36 million annually as a result of the cuts and CSMC estimates that it is losing approximately $13.5 million annually due to the cuts, which means to date it had already lost approximately $50 million.

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

III. The Court Has Jurisdiction to Decide This Case and Should Reverse the Court Below.

This case raises two legal issues. First, is petitioners' suit challenging HHS's "adjustments" to the reimbursement rates paid to 340B providers for separately payable drugs precluded by 42 U.S.C. § 1395*l*(t)(12)? Second, did HHS have the authority to cut the reimbursement rate even though it did not have the data specifically required by the statute to make such an adjustment?

As both the district court and the court of appeals found, the reimbursement rates set by CMS under the 42 U.S.C § 1395*l*(t)(14) are subject to judicial review. Section 1395*l*(t) is very specific about which determinations are precluded. See 42 U.S.C. §§

1395*l*(t)(12), (t)(21)(E). And although Congress periodically amended the section's preclusion paragraph, 42 U.S.C. § 1395*l*(t)(12), it never added paragraph (14) to that provision—not when paragraph (14) was adopted nor anytime thereafter.

Moreover, as explained in Petitioner's opening brief, the government's efforts to rely on Congress's preclusion of other paragraphs of Section 1395*l*(t) also fails. CMS did not use the authorities in those paragraphs to set the reimbursement rate at issue and, in contrast to certain other paragraphs of subsection (t), paragraph (14) does not state that determinations made under its authority should be carried out *pursuant to* one of the paragraphs that *is* covered by a jurisdiction-stripping provision. See, *e.g.*, 42 U.S.C. § 1395*l*(t)(13)(B), (t)(18)(B). This Court applies a strong presumption in favor of judicial review of agency action, *Mach Mining, LLC* v. *Equal Employment Opportunity Commission*, 575 U.S. 480, 486 (2015), and that presumption provides added weight to the decisions by the courts below that there is no preclusion of review here.

With respect to the merits, this Court should reverse the decision below. As explained in Petitioners' opening brief, 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. *See* 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I)-(II). In the courts below, HHS conceded that it did not have the survey data required by subclause I to use acquisition costs to establish the

reimbursement rate, and the majority of the court of appeals below acknowledged the "force" of petitioners' argument that HHS's interpretation rendered subclause (I) "meaningless." Pet. App.23a-24a. Nevertheless, the majority 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 held 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 Petitioners' opening brief, the decision of the court of appeals below should be reversed. As Judge Pillard stated in her dissent below, "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 at a higher rate than other hospitals,[52] and which the pandemic makes all the more critical. Unless this Court reverses the court below, amici and other 340B hospitals may be forced to make radical cuts to or potentially discontinue programs and services that are vital to the patients in the vulnerable communities they serve.

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[52] *See, e.g.*, Dobson, *supra* at 14.

CONCLUSION

For the reasons stated, the Court should reverse the judgment of the court of appeals below.

Respectfully submitted,

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September 10, 2021