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 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* 37 STATE AND REGIONAL HOSPITAL ASSOCIATIONS IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICI CURIAE*[1]

Amici curiae are 37 non-profit state and regional hospital associations.[2] They represent thousands of hospitals and health systems across the United States. *Amici* and their members are committed to improving the health of the communities they serve through the delivery of high-quality, efficient, and accessible health care. The 340B Program is essential to achieving this goal.

Congress established the 340B Program because it was "concerned that many federally funded hospital facilities serving low-income patients were incurring high prices for drugs."[3] The reimbursement rate reduction imposed by the Centers for Medicare and Medicaid Services' ("CMS") final rule undercuts Congress' intent by drastically raising drug prices for those hospitals. As a result of CMS's final rule, many of the hospitals and health systems that *amici* represent will be severely harmed. Consequently, scores of low-income, uninsured, underinsured, and rural patients will be unable to receive the same services. *Amici* have a strong interest in ensuring that their members do not face a diminution of this vital funding.

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[1] Pursuant to Supreme Court Rule 37.6, counsel for *amici curiae* state that no counsel for a party authored this brief in whole or in part, and no party or counsel for a party, or any other person other than *amici curiae* or its counsel, made a monetary contribution intended to fund the preparation or submission of this brief. All parties have consented in writing to the filing of this brief.

[2] A complete list of *amici curiae* can be found in the appendix.

[3] *Univ. Med. Ctr. of S. Nev. v. Shalala*, 173 F.3d 438, 439 (D.C. Cir. 1999).

INTRODUCTION AND SUMMARY OF ARGUMENT

This case presents weighty legal questions under the federal health care statutes and the Administrative Procedure Act. The parties are well-equipped to address those issues. *Amici* can best assist the Court in another way: by providing their perspective from the front lines of 340B care about the consequences of upholding CMS's final rule. *Amici* respectfully submit this brief to provide the Court with information about the history, importance, and impact of the 340B Program and the hospitals it supports.

Many of *amici*'s member-hospitals and member-health systems treat America's poorest patients. Often, the health care services that these members provide are uncompensated, undercompensated, or deeply discounted. Hundreds of member-hospitals therefore rely on the 340B Program, through which millions of dollars are saved each year on the purchase of outpatient drugs. And just as Congress intended, the savings from the 340B Program enable these members to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[4] Now, however, the final rule at issue in this case will stretch *amici*'s member-hospitals beyond the breaking point. If CMS's final rule is allowed to stand, 340B providers will be forced to eliminate or dramatically curtail some crucial programs that treat a wide range of medical conditions—from cancer to mental health disorders to diabetes to opioid addiction.

The numbers alone are staggering. CMS initially predicted that the new rule would cost 340B providers

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[4] H.R. Rep. No. 102-384(II), at 12 (1992).

"as much as $900 million" in reimbursements.[5] Shockingly, CMS undershot the financial cost of their proposal by nearly *80 percent*. By the time the agency issued its final rule, the estimated cost had ballooned to roughly $1.6 billion.[6] And with so many 340B facilities located in rural areas, patients in those communities will be especially harmed by CMS's final rule.[7]

But those figures, astonishing as they may be, tell only a small part of the story. The real impact of CMS's rule lies beneath those numbers, in the lived experience of patients who will no longer be able to receive vital services and the hospitals and clinics that will no longer be able to effectively treat them. In his prior capacity as California Attorney General, Respondent recognized this when he said: "[d]iscounts afforded under the 340B Drug Pricing Program are more critical now than ever. They ensure that low-income and uninsured patients have access to affordable medication as they deal with the substantial impact of the pandemic."[8] He was right. America's 340B

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[5] 82 Fed. Reg. 33,558, 33,711 (July 20, 2017).

[6] 82 Fed. Reg. 52,356, 52,623 (Nov. 13, 2017).

[7] Gov't Accountability Off., *Drug Discount Program: Characteristics of Hospitals Participating and Not Participating in the 340B Program* (Jun. 2018), https://www.gao.gov/assets/gao-18-521r.pdf.

[8] Press Release, *Attorney General Becerra Leads Bipartisan Coalition on 340B Drug Pricing Program Requirements* (Dec. 14, 2020), https://oag.ca.gov/news/press-releases/attorney-general-becerra-leads-bipartisan-coalition-340b-drug-pricing-program; *see* Letter from Attorney General Xavier Becerra, et al. to Secretary Alex Azar Re: Drug Manufacturers' Actions Violating 340B Drug Pricing Program Requirements (Dec. 14, 2020), https://portal.ct.gov/-/media/AG/Press_Releases/2019/340B-Multistate-Letter-12142020_FINAL1.pdf.

hospitals and patients cannot afford the massive cuts imposed by CMS's rule.

ARGUMENT

I. Congress Created The 340B Program To Expand Health Care Services For Patients In Underserved Communities

Medicaid has long been the "Nation's largest single purchaser of prescription drugs."[9] But for decades, "it usually pa[id] the highest prices" for those drugs, while "other large purchasers received discounts from drug manufacturers."[10]

In 1990, Congress enacted the Medicaid Rebate Program to remedy this imbalance.[11] Under this program, a drug manufacturer could not be covered by Medicaid funds for any of its outpatient drugs unless it first entered into a contract with the Secretary of Health and Human Services (or, in some instances, with a state designee).[12] The contract required the manufacturer to offer states a rebate on their purchases of certain prescription drugs, and the size of the rebate would be calculated based on the "best price" the drug manufacturer had given to any purchaser for a particular drug as of September 1, 1990.[13]

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

[10] *Id*.

[11] *See* 42 U.S.C. § 1396r-8; *see generally Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 114–15 (2011) (explaining the Medicaid Rebate Program).

[12] 42 U.S.C. § 1396r-8; *see also* H.R. Rep. No. 102-384(II), at 9.

[13] *Id*.

Though well-intentioned, the Medicaid Rebate Program was imperfect in practice. Perhaps most problematic, many drug manufacturers simply discontinued the discounts that they had been offering non-state purchasers and raised the "best price" for the most common drugs among Medicaid patients across the board.[14] As a result, the "[p]rices paid for outpatient drugs by . . . Federally-funded clinics and public hospitals" surged.[15] In other words, the Medicaid Rebate Program inflicted collateral damage on a wide range of health care providers by inflating their costs for outpatient drugs.

Congress sought to remedy this problem in 1992 with the 340B Drug Pricing Program. Named for the section of the Public Health Service Act that established it, the 340B Program was intended to ensure that the same "Federally-funded clinics and public hospitals" that had been harmed by the Medicaid Rebate Program could acquire outpatient drugs from manufacturers at discounted prices. The 340B Program thus requires drug manufacturers to sign contracts with the Secretary of Health and Human Services in which they promise to sell drugs to certain health care providers (known as "covered entities") at or below a predetermined ceiling price in exchange for having their drugs covered under Medicaid.[16] Congress did not, however, adjust the

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[14] *Id*. at 9–10.

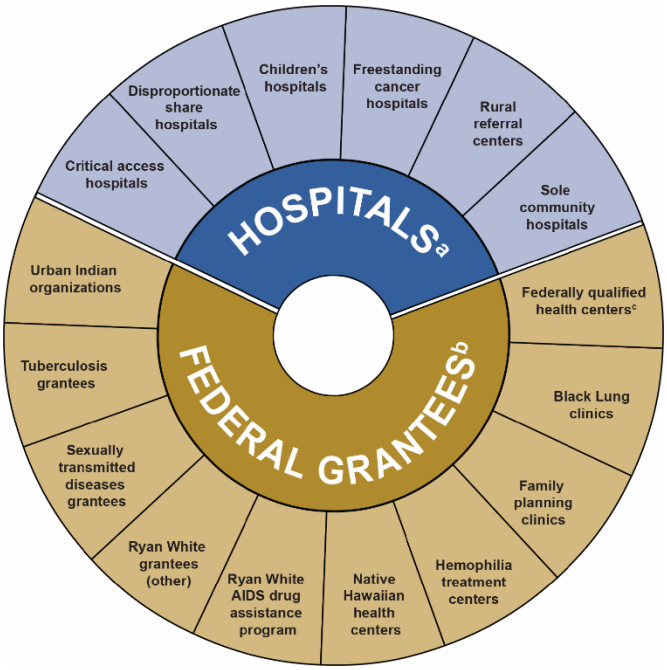
[15] *Id.* at 11.

[16] *See* 42 U.S.C. § 256b(a)(1); *Astra USA Inc.*, 563 U.S. at 113 36 ("Under § 340B, added in 1992, manufacturers participating in Medicaid must offer discounted drugs to covered entities, dominantly, local facilities that provide medical care for the poor. The 340B Program, like the Medicaid Drug Rebate Program, employs a form contract as an opt-in mechanism." (citations omitted)).

reimbursement rates that the covered entities receive from Medicare or Medicaid for the outpatient drugs the entities purchased. That was by design. As a result of these statutory decisions, covered entities can use the difference between the discounted price for outpatient drugs and the standard reimbursement to support a range of programs and services that benefit their communities. The 340B Program thus provides covered entities with valuable financial relief that comes at *no direct cost* to taxpayers or the government.

To qualify as a "covered entity," a health care provider generally must serve a high volume of patients in underserved communities. And they do so without regard to whether the patient has the ability to pay for the services received. The chart below, taken from a December 2020 Government Accountability Office report, illustrates the range of entities that currently qualify for 340B status[17]:

[17] Gov't Accountability Off., *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements* 6 (Dec. 2020), https://www.gao.gov/assets/gao-21-107.pdf; *see Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 138 F. Supp. 3d 31, 35 (D.D.C. 2015) ("Congress added a significant number of new categories to the list of covered entities" as part of the Affordable Care Act).



In creating the 340B Program, Congress acknowledged the critical role these institutions play in the lives of low-income and rural Americans. It intended to help offset the considerable costs their providers incur by providing health care to the uninsured, underinsured, and those who live far from hospitals and clinics. Congress hoped that "[i]n giving these 'covered entities' access to price reductions" for outpatient drugs, the entities would be able to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[18] Put another way, because covered entities would be able to spend less on outpatient drugs—without any concomitant decrease in their Medicaid, health insurance, and federal grant reimbursements—they could use their 340B savings to

[18] H.R. Rep. No. 102-384(II), at 12.

widen the safety net that they offer to low-income, rural, and others within their community.[19]

II. The 340B Program Has Successfully Allowed Covered Entities To Stretch Scarce Federal Resources And Provide More Comprehensive Services To Address The Unmet Medical Needs Of Their Communities

In the decades since Congress enacted the 340B Program, providers like *amici*'s 340B-participating members have successfully implemented Congress's vision. Just as Congress hoped, the 340B savings have been used to create a broader safety-net that "reach[es] more eligible patients and provid[es] more comprehensive services."[20]

The administrative record in this case is replete with comments from *amici* hospital associations demonstrating how 340B savings benefit patients and communities:

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[19] *See also* Health Resources & Services Administration, Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Service Act 14 (July 2005), https://www.hrsa.gov/sites/default/files/opa/programrequirements/forms/hemophiliatreatmentcenter340bmanual.pdf ("The purpose of the 340B Program is to lower the cost of acquiring covered outpatient drugs for selected health care providers so that they can stretch their resources in order to serve more patients or improve services. Additional program resources are generated if drug acquisition costs are lowered but revenue from grants or health insurance reimbursements are maintained or not reduced as much as the 340B discounts or rebates.").

[20] H.R. Rep. No. 102-384(II), at 12.

- *Amicus* Greater New York Hospital Association informed CMS that its "members reinvest these savings on important safety net services such as providing free vaccines and financial assistance to uninsured patients for outpatient drugs, establishing outpatient clinics to improve access to primary and mental health care services, providing care coordination services to manage complex patients, and providing specialty services, among other tangible benefits."[21]

- *Amicus* Kentucky Hospital Association explained the 340B Program's particular importance to rural hospitals. It noted that "of the 47 impacted Kentucky hospitals, 28, or nearly two-thirds, are located in a rural area. Many rural areas in Kentucky have scarce resources due to a longstanding shortage of medical providers and fewer services. The savings hospitals realize from the 340B program are used to support the continuation and expansion of needed health care. For example, the 47 hospitals impacted by the proposed payment reduction are the main providers of essential community services, such as obstetrics, psychiatric and substance abuse treatment, and trauma care services for which financial

[21] Greater New York Hospital Association, Comment Letter on Proposed Rule Change 82 Fed. Reg. 33,558 (Sept. 11, 2017).

subsidization is necessary for them to be maintained."[22]

- *Amicus* North Carolina Hospital Association commented that "North Carolina Hospitals use 340B savings to provide local access to drugs and treatments for cancer patients, clinical pharmacy services, community outreach programs, free vaccinations, transportation to patients for follow-up appointments and many other needed services to their communities as well as partially offsetting uncompensated care and Medicaid losses."[23]
- *Amicus* Arkansas Hospital Association explained that hospitals in its state use savings from the 340B Program to "provide financial assistance to patients unable to afford their prescriptions; provide clinical pharmacy services, such as disease management programs or medication therapy management; fund other medical services, such as obstetrics, diabetes education, oncology services and other ambulatory services; establish additional outpatient clinics to improve access; create new community outreach programs; and offer free vaccinations for vulnerable populations."

These hospital associations and their member-hospitals are not unique. Hospitals across the country

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[22] Kentucky Hospital Association, Comment Letter on Proposed Rule Change 82 Fed. Reg. 33,558 (Sept. 8, 2017).

[23] North Carolina Hospital Association, Comment Letter on Proposed Rule Change 82 Fed. Reg. 33,558 (Sept. 11, 2017).

use 340B funds to pay for patient-assistance programs that they otherwise could not afford.[24] The nature of these programs varies widely, in accordance with the diverse needs of the local populations those covered entities serve. As Charlie Reuland, the Executive Vice President and Chief Operating Officer of the Johns Hopkins Hospital, told the House Committee on Energy and Commerce, "[t]he great strength of the 340B Program is the discretion it affords eligible hospitals in tailoring the use of program savings to address the unique needs of our communities."[25]

Some covered entities have used their 340B savings to provide low-income patients with comprehensive care networks of social workers, pharmacists, diabetes educators, dieticians, and home health nurses, all of whom provide follow-up care to individuals after they leave the hospital.[26] Other entities have chosen to create oncology centers, infusion clinics, and stroke clinics. Some entities have used their savings to improve women's health, creating specialized medical centers for women and girls, and neonatal "programs for expectant mothers" in communities without those services in an effort to "increase the

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[24] *E.g.*, 340B Health, *340B Program Helps Hospitals Provide Services to Vulnerable Patients* 4, 11 (May 2016), https://www.340bhealth.org/files/Savings_Survey_Report.pdf.

[25] *See* Examining How Covered Entities Utilize the 340B Drug Pricing Program Before the House of Representatives Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, 115th Cong., at p. 39 (Oct. 11, 2017), http://docs.house.gov/meetings/IF/IF02/20171011/106498/HHRG-115-IF02-Transcript-20171011.pdf.

[26] California Hospital Association, Comment Letter on Proposed Rule Change 82 Fed. Reg. 33,558 (Sept. 11, 2017).

likelihood of healthy on-time deliveries" and diminish the probability of NICU stays.[27] Still others have used their 340B savings to offer transportation for patients who do not own a car, or to fund remote prescription drug dispensing sites, so that patients in rural areas do not have to drive as far to obtain prescription drugs, and mobile health units, which provide services like mammographies, dental treatment, and other medical care from RVs and motorcoaches.

Savings from the 340B Program also allow health care providers like *amici*'s members to expand the range of medications and medical devices that are available to low-income patients. In the 340B Health survey, 71 percent of respondents reported that their 340B savings "increase their ability to provide free or discounted drugs to low income patients."[28] Forty-one percent, moreover, said that the 340B Program has an impact on the range of drugs and devices they are able to provide.[29] For some patients, the 340B Program is the key that has unlocked chemotherapy; IVIG infusions, which can be used to help those with certain immune deficiencies; osteoporosis prophylaxis; treatment for Pompe disease, a disorder caused by the

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[27] Examining How Covered Entities Utilize the 340B Drug Pricing Program Before the House of Representatives Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, 115th Cong., at p. 41 (Oct. 11, 2017), http://docs.house.gov/meetings/IF/IF02/20171011/106498/HHRG -115-IF02-Transcript-20171011.pdf.

[28] 340B Health, *340B Program Helps Hospitals Provide Services to Vulnerable Patients* 9 (May 2016), https://www.340bhealth.org/files/Savings_Survey_Report.pdf.

[29] *Id.* at 4.

build-up of glycogen in the body; and treatment for rabies.[30]

Rural hospitals are especially reliant on the 340B Program. A June 2018 study by the Government Accountability Office indicated that as of 2016, 62 percent of 340B hospitals were located in rural areas.[31] At the same time, rural hospitals are particularly financially strapped. Nearly half of rural hospitals currently have negative operating margins, and more than 100 rural hospitals have closed in the past decade.[32] Those financial struggles have been exacerbated by the COVID-19 pandemic.[33] CMS's cuts

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[30] *Id.* at 10.

[31] Gov't Accountability Off., *Drug Discount Program: Characteristics of Hospitals Participating and Not Participating in the 340B Program* (Jun. 2018), https://www.gao.gov/assets/gao-18-521r.pdf,

[32] The Chartis Group: Crises Collide: The COVID-19 Pandemic and the Stability of the Rural Health Safety Net (Feb. 2021), https://www.chartis.com/resources/files/Crises-Collide-Rural-Health-Safety-Net-Report-Feb-2021.pdf; *see* Government Accountability Office, Rural Hospital Closures: Affected Residents Had Reduced Access to Health Care Services (Dec. 2020), https://www.gao.gov/assets/gao-21-93.pdf (finding that "from January 2013 through February 2020, 101 rural hospitals closed").

[33] *E.g.*, Ge Bai and Gerard F. Anderson, *COVID-19 And The Financial Viability Of US Rural Hospitals*, Health Affairs (July 1, 2020), https://www.healthaffairs.org/do/10.1377/hblog20200630.208205/full/; Hoag Levins, *Already in Fiscal Crisis, Rural Hospitals Face COVID-19* (June 2020), https://ldi.upenn.edu/news/already-fiscal-crisis-ruralhospitals-face-covid-19; *see also* Frances Stead Sellers, et al., *The delta variant is putting America's hospitals back in crisis mode*, Washington Post (Aug. 18, 2021), https://www.washingtonpost.com/health/2021/08/18/covid-hospitals-delta/ ("[H]ospitals across the country are straining to respond to a deadly fourth surge of infections driven by the

to the 340B Program place rural hospitals in even greater jeopardy, which in turn will lead to a range of adverse health outcomes for the communities they serve—from fewer offerings of vital medical services to longer travel distances for basic treatments to overall poorer health outcomes for rural residents.[34] Regrettably, the final rule at issue in this case cuts most sharply at a rural safety net that was already in tatters.[35]

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delta variant . . . . The impact on hospitals is at once distressingly familiar and strikingly different from previous surges, clinicians say. In addition to handling mounting covid-19 case numbers, hospitals are playing catch-up on elective surgeries that were postponed because of the pandemic. People are out driving on the roads and playing sports, experiencing accidents and injuries, and increasing the burden on trauma departments.").

[34] Gov't Accountability Off., *Rural Hospital Closures: Affected Residents Had Reduced Access to Health Care Services* (Dec. 2020), https://www.gao.gov/assets/gao-21-93.pdf.

[35] The Rural Hospital Coalition filed an *amicus* brief opposing certiorari, arguing (at 5) that rural hospitals benefit from the "redistributed savings" that come from the final rule's reimbursement cuts. But that statement was clearly at odds with one issued *on the same day* that the Rural Hospital Coalition filed its *amicus* brief. That day, it also sent a letter to four Senators seeking special 340B treatment for rural facilities to address the "deteriorating rural health safety net." Letter from Eric Zimmerman to Sens. Smith, Rounds, Fischer, and Baldwin, Apr. 12, 2021, https://static1.squarespace.com/static/5c13fd4150a54f21cf0140ad/t/6074be0b9d423658027ae050/1618263563295/RHC+Letter+to+Senate+Rural+Working+Group+-+April+2021.pdf.

III. CMS's Rule Would Significantly Diminish *Amici*'s Members' Ability To Provide Comprehensive Services To The Communities They Serve

Decades after the 340B Program was introduced, it faces a dangerous threat in CMS's final rule. Even before this rule was finalized, 340B hospitals could barely make ends meet. Data indicates that 25.8% of 340B hospitals affected by the new rule already had negative operating margins.[36] And that was before the COVID-19 pandemic.[37] 340B hospitals simply cannot afford the nearly 30 percent reduction in the reimbursement rate that CMS has imposed in the challenged final rule.

Comments in the administrative record from state hospital associations and individual hospitals explained how these cuts would adversely impact hospitals and their patients:

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[36] *See* AHA Data, *Data Collection Methods*, http://www.ahadata.com/data-collection-methods/.

[37] Already operating with "razor-thin financial margins," many 340B hospitals found themselves on the front lines of pandemic care, especially because the virus has disproportionately impacted low-income and rural communities. Peter P. Reese, et al., *Preparing For The Next COVID-19 Crisis: A Strategy To Save Safety-Net Hospitals* (June 22, 2020), https://www.healthaffairs.org/do/10.1377/hblog20200617.787349/full/. Tragically, "the safety-net providers that take all patients regardless of ability to pay have sustained enormous financial losses during the COVID-19 crisis." Michael Ollove, *Virus Imperils Health Care Safety Net* (Sept. 1, 2020), https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2020/09/01/virus-imperils-health-care-safety-net. Already hanging on by the skin of their teeth, CMS's cuts make a grim post-COVID financial future even worse for 340B safety-net providers.

- MedStar Health, which includes seven 340B hospitals in the District of Columbia and Maryland, cautioned that the cuts would "significantly reduce the benefits of the 340B program and harm the very hospitals that serve our most vulnerable citizens."[38] In particular, MedStar noted that the cuts would affect in-home services to more than 3,000 of Washington, D.C.'s most vulnerable elderly patients, an after-hours clinic that provides free health care at a Southeast D.C. homeless shelter, a no-charge clinic for uninsured patients in Baltimore, and other facilities.[39]

- St. Vincent Hospital, a faith-based health care organization in Indianapolis "is one of Indiana's largest employers with 20 hospitals," 10 of which are eligible under the 340B Program.[40] St. Vincent "delivers high quality, compassionate, personalized care to all, with special attention to those most in need."[41] It informed CMS that the proposed cuts in the 340B Program would "substantially limit the ability of 340B-covered entities . . . to provide care and more comprehensive health care services to low-income patients and ultimately put key services at risk."[42]

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[38] MedStar Health, Comment Letter on Proposed Rule Change 82 Fed. Reg. 33,558 at 1 (Sept. 5, 2017).

[39] *Id.*

[40] St. Vincent, Comment Letter on Proposed Rule Change 82 Fed. Reg. 33,558 at 3 (Sept. 11, 2017).

[41] *Id*.

[42] *Id*.

For example, St. Vincent explained that its Joshua Max Primary Care Pharmacy "provides its patients the prescription medications they need regardless of their ability to pay," including by allowing patients to pay no more than $1 for most prescriptions.[43] CMS's rule would "result in a loss of approximately $400,000 and jeopardize program sustainability."[44]

- *Amicus* Texas Hospital Association provided CMS with the example of the Childress Regional Medical Center (CRMC), "a rural health care facility located in an isolated town in the southeast corner of the Texas panhandle."[45] CRMC is the primary health care provider for 30,000 residents in a five-county area. It provides services ranging from hospice care to a rural health clinic to a dialysis center. Thanks to 340B savings, it also was able to start a chemotherapy treatment program and monthly cancer clinic; this was particularly important to the community because the nearest cancer center was more than 100 miles away. Despite all its hard work, however, CRMC's overall profit margin is just 0.6 percent ($248,000 on $40 million in gross revenue). As the Texas Hospital Association explained, "[w]ithout the discounts provided by the 340B Program, CRMC would be in the red and would not be

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[43] *Id*.

[44] *Id*.

[45] Texas Hospital Association, Comment Letter on Proposed Rule Change 82 Fed. Reg. 33,558 (Sept. 5, 2017).

able to provide patients with chemotherapy treatments and other important medical services."[46]

- Capital Health System is "a non-profit multi-hospital healthcare system providing substantial community benefit through a spectrum of healthcare services to residents of New Jersey."[47] It explained to CMS that many other safety-net hospitals have fled the area, but "Capital Health has developed its most resource intensive and complex programs at Regional Medical Center to better serve the Greater Trenton Region."[48] Capital Health "rel[ies]" on the 340B Program, which "safeguards [its] ability to continue to provide this care to our low-income communities."[49] CMS's cuts, however, "will severely and negatively impact [Capital Health's] ability to continue to offer critical services to vulnerable populations, impacting the overall health of our surrounding communities."[50]

- *Amicus* California Hospital Association commented that "340B hospitals in California will scale back or eliminate programs and service lines supported by 340B savings, programs that support our state's safety net." It noted, for example, that "a rural 340B

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[46] *Id.*

[47] Capital Health System, Comment Letter on Proposed Rule Change 82 Fed. Reg. 33,558 (Sept. 8, 2017).

[48] *Id.*

[49] *Id.*

[50] *Id.*

hospital in Northern California offers a Community Care Network to help vulnerable patients after they leave the hospital . . . . The program is free of charge and has helped keep patients healthy and out of the hospital." If CMS's final rule is upheld, however, this rural hospital will no longer be able to offer this service.[51]

- SCL Health is a "faith-based, nonprofit health system," which has eight 340B covered entities throughout Colorado and Montana.[52] In 2015 alone, SCL provided $34 million in financial aid and charity care to low income patients, as well as $119.4 million in uncompensated care. It explained that the "340B Program is instrumental in helping SCL Health fulfill its mission of treating those in need," and CMS's rule "will have a devastating impact on [its] abilities to treat low income patients."[53] SCL warned that it would have to cut its charitable aid by at least 25% and reduce services like its "Meds to Beds" program, which improves medication adherence, and its distribution of pediatric care products to hundreds of families across Colorado.

The list of comments could go on and on. Covered entities in every *amicus* hospital association likely could identify a specific program or clinic whose

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[51] California Hospital Association, Comment Letter on Proposed Rule Change 82 Fed. Reg. 33,558 (Sept. 5, 2017).

[52] SCL Health, Comment Letter on Proposed Rule Change 82 Fed. Reg. 33,558 (Sept. 8, 2017).

[53] *Id*.

survival is threatened by CMS's 340B reductions. Indeed, in the 340B Health study discussed above, 40 percent of hospital respondents predicted that losing their 340B savings would force them to close one or more clinics *entirely*.[54] Thirty-seven percent predicted that, without 340B, they would have to close one or more outpatient pharmacies, and 71 percent forecasted a reduction in pharmacy services.[55] Most covered entities within the *amici* hospital associations will not be able to weather these staggering financial losses without making considerable reductions to the range of medical services they provide.[56]

Instead of expanding services as Congress intended, for many patients, the consequences of the rule's adjustment to 340B reimbursements could be life-threatening.[57] Patients who live in more rural parts of

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[54] *Id.*

[55] *Id.*

[56] 340B Health, *340B Program Helps Hospitals Provide Services to Vulnerable Patients* 5 (May 2016), https://www.340bhealth.org/files/Savings_Survey_Report.pdf ("340B savings impact the bottom line for our organization . . . The loss of 340B savings would put the hospital in the red. All services would be affected.").

[57] *See* 340B Health, *Faces of 340B*: *Alton Condra*, http://www.340bhealth.org/340b-resources/why-340b-matters/faces-of-340b/alton-condra/ ("Anything that would tamper with the 340B program, pull it back, or change it would be messing with people['s] lives."); *see also* Editorial, *Protect 340B: Legislation needed for lowering drug pricing*, The Parkersberg News and Sentinel (July 14, 2021), https://www.newsandsentinel.com/opinion/editorials/2021/07/protect-340b-legislation-needed-for-lowering-drug-pricing/ ("Most patients are likely unaware of the ins and outs of the 340B drug pricing program, which requires pharmaceutical companies to provide drugs at a discount for certain hospitals and clinics serving the neediest of patients. But in

the country may no longer have access to medical services unless they are able to travel a considerable distance,[58] and many low-income and uninsured patients will struggle to afford the services and medications that they desperately need. Equally problematic, individuals who have been immunocompromised because of illness or chemotherapy may no longer have access to the separate oncology and infusion clinics that they depend on for life-saving treatment; they instead will be forced to take the potentially life-threatening risk inherent in traveling to a different health care facility.

All in all, the patients and communities that 340B hospitals and health systems serve will suffer profoundly under the challenged CMS rule. In turn, CMS's final rule will have a devastating impact on those most in need of care, many of whom will be unable to receive it without the 340B Program.

IV. CMS's Justifications For Its Cuts To The 340B Program Lack Merit

CMS justifies its drastic reimbursement reductions by contending that the rule will reduce Medicare beneficiaries' copayments when seeking care from 340B hospitals, and by suggesting that the rule is necessary to avoid the overutilization of costly drugs

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areas such as rural Appalachia, that kind of program can mean the difference between life and death for some.").

[58] 340B Health, *340B Program Helps Hospitals Provide Services to Vulnerable Patients* 17 (May 2016), https://www.340bhealth.org/files/Savings_Survey_Report.pdf ("Without this additional revenue [from 340B], our entire facility would be in jeopardy, and our next closest hospital is 60 miles away.").

by 340B hospitals.[59] Neither justification withstands scrutiny, and neither justification outweighs the many harms that will result from the new rule. As such, the court of appeals erred in repeatedly turning to policy justifications to undergird its statutory analysis.[60]

As an initial matter, even if CMS had meritorious policy justifications for its unlawful final rule—which it does not—it was *Congress'* job to implement them. As the dissenting judge below explained, Congress can easily alter the 340B Program if it wishes to achieve the same ends that CMS did in its final rule.[61] But "Congress has not made any such change."[62]

Even if CMS were the appropriate governmental actor, its stated policy justifications lack merit. For starters, CMS's contention that Medicare recipients will benefit from reduced drug copayments is misleading. While it is true that lowering the reimbursement rate for Part B drugs will impact the associated copayments for those drugs, the majority of Medicare beneficiaries will *not* receive a direct benefit. A Medicare Payment Advisory Commission (MedPAC)

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[59] 82 Fed. Reg. 52,356, 52,362 (Nov. 13, 2017) (stating that the cuts to 340B reimbursements would "better, and more appropriately, reflect the resources and acquisition costs that these hospitals incur," and "lower drug costs for Medicare beneficiaries for drugs acquired by hospitals under the 340B Program").

[60] *See Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, 828, 829, 830, 831, 832-33 (D.C. Cir. 2020); *id.* at 839 (Pillard, J., dissenting) ("[T]he majority repeatedly justifies its reading by reference to the policy benefits of the agency's rate reductions and the reasonableness of the agency's alternative data and resulting estimates . . . . It bears noting that, even were they relevant, the claimed policy benefits of the agency's new rate reductions are far from clear.").

[61] *Id.* at 840.

[62] *Id*.

analysis demonstrated that 86 percent of all Medicare beneficiaries have supplemental coverage that covers their copayments, and 30 percent of those individuals have their copayments paid for by a public program like Medicaid.[63] Because the vast majority of Medicare beneficiaries who seek treatment from 340B hospitals do not actually pay their own copayments, CMS's 340B payment reduction proposal will not benefit the majority of Medicare beneficiaries. Moreover, because the redistributions that result from budget neutrality would increase reimbursement for other services, Medicare beneficiaries may actually see *increases* in out of pocket costs for other non-drug OPPS services. One analysis of the new rule found that only 3 percent of beneficiaries being treated at 340B hospitals would see their copayments reduced overall, whereas 97 percent would see their copayments increase.[64] Accordingly, CMS was wrong to conclude that its rule would "lower drug costs for Medicare beneficiaries for drugs acquired by hospitals under the 340B Program."[65]

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[63] MedPAC, A Databook Book, Health Care Spending and the Medicare Program, June 2016, Section 3, p. 27, http://www.medpac.gov/docs/default-source/data-book/june-2016-data-book-health-care-spending-and-the-medicare-program.pdf. MedPAC is an independent Congressional agency that was created to advise Congress on issues affecting the Medicare program. *See* MedPAC, About MedPAC, http://www.medpac.gov/-about-medpac-; *see id*. ("MedPAC meets publicly to discuss policy issues and formulate its recommendations to the Congress . . . . Two reports—issued in March and June each year—are the primary outlet for Commission recommendations.").

[64] American Hospital Association, Comment Letter on Proposed Rule Change 82 Fed. Reg. 33,558 at 12 (Sept. 11, 2017).

[65] 82 Fed. Reg. 52,356, 52,362 (Nov. 13, 2017).

Similarly, CMS's concern that "the current payment methodology may lead to unnecessary utilization and potential overutilization of separately payable drugs" has been refuted by more recent analysis.[66] Contrary to CMS's view in the final rule, MedPac found that the "340B Drug Pricing Program *doesn't* create strong incentives for participating hospitals to use more expensive drugs."[67] In reaching this conclusion, MedPac analyzed drug spending on five types of cancers[68]; it did so because "drugs used exclusively or

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[66] *See* Kim Neuman, Nancy Ray, Shinobu Suzuki, *MedPac PowerPoint Presentation: Does the 340b program create incentives for participating hospitals to use more expensive drugs?* (Jan. 17, 2020), http://medpac.gov/docs/default-source/default-document-library/consolidation_340b_public_jan_2020.pdf?sfvrsn=0; MedPac, *Report to Congress, Medicare Payment Policy* (March 2020), http://www.medpac.gov/docs/default-source/reports/mar20_entirereport_sec.pdf?sfvrsn=0.

[67] Michael Brady, MedPAC: 340B hospitals don't use more expensive drugs, *Modern Healthcare* (Jan. 17, 2020), https://www.modernhealthcare.com/safety-net-hospitals/medpac-340b-hospitals-dont-use-more-expensive-drugs (emphasis added); *see* Revenue Cycle Advisor, *MedPAC: 340B drug discount program doesn't incentivize higher spending* (Jan. 22, 2020), https://revenuecycleadvisor.com/news-analysis/medpac-340b-drug-discount-program-doesn%E2%80%99t-incentivize-higher-spending ("The 340B drug discount program does not appear to incentivize hospitals to use more expensive drugs, according a Medicare Payment Advisory Commission (MedPAC) report presented at its January 17 meeting . . . . The report concluded that the effects on cancer drug spending are likely specific to the type of cancer and can't be generalized to other types of cancer or conditions. Overall, the higher drug spending in some cases is not likely to have an impact on patients' out of pocket costs, depending on the patient's condition and supplemental coverage.").

[68] Kim Neuman, Nancy Ray, Shinobu Suzuki, *MedPac PowerPoint Presentation: Does the 340b program create incentives for participating hospitals to use more expensive drugs?* (Jan. 17,

largely for cancer treatment account for nearly three-quarters of Part B drug spending in the hospital outpatient setting."[69] Although MedPac found that spending on cancer treatment was somewhat higher for two of the five cancers, it ultimately concluded that this spending was "much smaller than the effects of the general trend in oncology spending" and, more importantly, was attributable to the type of patients 340B hospitals treat, as well as "the type of cancer that people are treated for rather than 340B's financial incentives."[70] As one observer put it, MedPac's findings "throw cold water on big pharma's perennial complaint that the [340B] program, established in 1992 to lower drug prices for safety net hospitals, is a major driver of healthcare spending."[71] More to the point here, MedPac's work also throws cold water on CMS's justification for its final rule.

Even if MedPac's recent analysis were somehow incorrect, CMS's reasoning was faulty in another critical way. Respondent itself has recognized CMS's concerns about overutilization were based on flawed

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2020), http://medpac.gov/docs/default-source/default-document-library/consolidation_340b_public_jan_2020.pdf?sfvrsn=0.

[69] MedPac, *Report to Congress, Medicare Payment Policy* xxvi (March 2020), http://www.medpac.gov/docs/default-source/reports/mar20_entirereport_sec.pdf?sfvrsn=0.

[70] *Id*; Michael Brady, MedPAC: 340B hospitals don't use more expensive drugs, *Modern Healthcare* (Jan. 17, 2020), https://www.modernhealthcare.com/safety-net-hospitals/medpac-340b-hospitals-dont-use-more-expensive-drugs.

[71] Rebecca Pifer, MedPAC finds 340B effect on pricing 'modest,' going against pharma critique, *Healthcare Dive* (Jan. 17, 2020), https://www.healthcaredive.com/news/medpac-finds-340b-effect-on-pricing-modest-going-against-pharma-critique/570683/.

studies and incomplete data.[72] For example, HHS critiqued the methodology of one of the key studies relied on by CMS, pointing out that the study failed to properly account for the differences in risk profiles for 340B versus non-340B hospitals.[73] Given the patient population that the 340B program serves, it is unsurprising that the higher expenditures for 340B hospitals are more likely a direct consequence of generally sicker beneficiaries at 340B hospitals.[74] The final rule does not account for this reality when imposing its indiscriminate cuts.

In addition, it is far more likely that higher overall drug prices, and not differential utilization by 340B and non-340B hospitals, is the primary driver of increased Medicare Part B drug expenditures. That conclusion is consistent with CMS's own projections.[75] CMS forecasts average annual increases of 6.4 percent from 2017-2025, particularly as a result of high-cost specialty drugs. These trends suggest that a more

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[72] CMS OPPS Proposed Rule, Federal Register, Vol. 82, No. 138, July 20, 2017, p. 33633.

[73] Gov't Accountability Off., *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals* (June 2015), https://www.gao/gov/assets/680/670676.pdf at p. 37; *see also* 340B Health, *340B Analysis of GAO Findings Related to Medicare Part B Spending*, https://www.340bhealth.org/files/340B_Health_Analysis_of_GAO_Report_Part_B_07.24.17.pdf.

[74] Gov't Accountability Off., *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals* (June 2015), https://www.gao/gov/assets/680/670676.pdf.

[75] See Centers for Medicare & Medicaid Services, *National Health Expenditure Projections 2015-2025*, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2015.pdf.

comprehensive solution to drug price increases is needed than one that targets only the 340B Program and its needy patients. Likewise, concerns about overutilization do not justify the blunt instrument that CMS has chosen. Even if an overutilization problem existed, CMS has many other regulatory remedies at its disposal.[76]

Put simply, CMS's cuts to the 340B Program cause far more harm than the policy ends that CMS intended to achieve. As this Court evaluates the important legal questions at issue in this case, *amici* respectfully submit that it should not lose sight of the needless damage that the final rule inflicts on America's 340B hospitals and the underserved communities they treat.

CONCLUSION

This Court should reverse the decision below.

Respectfully submitted,

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[76] *See generally* MedPac, *Report to Congress, Overview of the 340B Drug Pricing Program* (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.

APPENDIX

APPENDIX

List of *Amici Curiae*

Alaska State Hospital and Nursing Home Association

Arkansas Hospital Association

California Hospital Association

Connecticut Hospital Association

District of Columbia Hospital Association

Florida Hospital Association

Georgia Hospital Association

Greater New York Hospital Association

Healthcare Association of New York State

Idaho Hospital Association

Illinois Hospital Association

Iowa Hospital Association

Louisiana Hospital Association

Kansas Hospital Association

Kentucky Hospital Association

Maine Hospital Association

Massachusetts Health & Hospital Association

Michigan Health & Hospital Association

Minnesota Hospital Association

Mississippi Hospital Association

Missouri Hospital Association

Montana Hospital Association

Nebraska Hospital Association

New Hampshire Hospital Association

New Jersey Hospital Association

New Mexico Hospital Association

North Carolina Healthcare Association

North Dakota Hospital Association

Ohio Hospital Association

Oklahoma Hospital Association

Oregon Association of Hospitals and Health Systems

The Hospital and Healthsystem Association of Pennsylvania

South Dakota Association of Healthcare Organizations

Texas Hospital Association

Vermont Association of Hospitals and Health Systems

Washington State Hospital Association

West Virginia Hospital Association