No. 20-1114

IN THE

Supreme Court of the United States

AMERICAN HOSPITAL ASSOCIATION, ET AL.,

Petitioners,

v.

NORRIS COCHRAN, IN HIS OFFICIAL CAPACITY AS ACTING SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

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

BRIEF OF *AMICI CURIAE* 36 STATE AND REGIONAL HOSPITAL ASSOCIATIONS IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICI CURIAE*[1]

Amici curiae are 36 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 for 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 safety-net hospitals. As a result of CMS's unlawful final rule, many of the hospitals and health systems that *amici* represent will be severely harmed. Consequently, scores of low-income, uninsured, underinsured, and homeless patients, as well as those living in rural communities, will be unable to receive the same level of care. *Amici* have a strong interest in ensuring that their members do not face an illegal 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] *See Univ. Med. Ctr. of S. Nev. v. Shalala*, 173 F.3d 438, 439 (D.C. Cir. 1999).

INTRODUCTION AND SUMMARY OF ARGUMENT

Amici's member-hospitals and member-health systems treat millions of America's poorest patients. Often, the health care services that *amici*'s members provide to our nation's most vulnerable populations are uncompensated, undercompensated, or deeply discounted. *Amici*'s members therefore rely on the 340B Program, which saves them millions of dollars each year on the purchase of outpatient drugs.

As it is, *amici*'s member-hospitals stretch their own resources to provide care to our neediest citizens. 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 the new rule is allowed to stand, safety-net providers will be forced to eliminate or dramatically curtail 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 safety-net providers "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

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

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

rule, the estimated cost had ballooned to roughly $1.6 billion.[6]

Those numbers, 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 care and the hospitals and clinics that will no longer be able to effectively serve them. *Amici* and their members are acutely aware of these real-world effects because they provide irreplaceable care to those most in need. Given their unique position, *amici* know all too well what will happen if CMS is permitted to take a scalpel—or really, an old-fashioned amputation saw—to the 340B Program.

The size and human impact of CMS's 340B reimbursement cuts demonstrate the importance of this case to safety-net hospitals and, in turn, why it presents a critically important question that this Court should address. But this case's importance has only grown since the COVID-19 pandemic. Before COVID-19, "safety-net hospitals often ha[d] razor-thin financial margins."[7] Since COVID-19, safety-net hospitals have been thrust to the front lines of pandemic care, especially because the virus has disproportionately impacted low-income and rural communities. Tragically, however, "the safety-net providers that take all patients regardless of ability to pay have sustained enormous financial losses during the

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

[7] 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/.

COVID-19 crisis."[8] Already hanging on by the skin of their teeth, America's safety-net hospitals cannot afford the cuts imposed by CMS's unlawful rule.

Amici respectfully submit this brief to provide the Court with information about the history, importance, and impact of the 340B Program and the safety-net hospitals it supports. This background is important because the court of appeals majority "repeatedly justifie[d] its [statutory] reading by reference to the policy benefits of the agency's rate reductions."[9] But as Judge Pillard explained in dissent, "even were they relevant, the claimed policy benefits of the agency's new rate reductions are far from clear."[10] Based on their extensive experience with the 340B program, *amici* would put it more strongly than Judge Pillard did: the D.C. Circuit majority got the policy calculus completely backwards. The majority gave short shrift to Congress' intent in enacting the statutory language at issue in this case and failed to account for the devastating consequences that the challenged rule will inflict on safety-net hospitals. That misapprehension infected the majority's statutory analysis and contributed to the legal error that this Court should address.

In sum, this Court should grant certiorari not only to address the important legal question presented in the Petition for Writ of Certiorari, but also because

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[8] 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.

[9] *Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, 839 (D.C. Cir. 2020) (Pillard, J., dissenting) (citing Maj. Op. at 828, 829, 830, 831, 832–33).

[10] *Id*.

this case involves grave issues for our health care system and the millions of needy patients it serves.

ARGUMENT

I. Congress Created The 340B Program To Expand Health Care Services In Communities With Low-Income Patients

Medicaid has long been the "Nation's largest single purchaser of prescription drugs."[11] But for decades, "it usually pa[id] the highest prices" for those drugs, while "other large purchasers received discounts from drug manufacturers."[12]

In 1990, Congress enacted the Medicaid Rebate Program to remedy this imbalance.[13] 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).[14] 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.[15]

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

[12] *Id*.

[13] *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).

[14] *Id.*; *see also* H.R. Rep. No. 102-384(II), at 9.

[15] *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.[16] As a result, the "[p]rices paid for outpatient drugs by . . . Federally-funded clinics and public hospitals" surged.[17] 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. In essence, the 340B Program 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.[18] Congress did not, however, adjust the

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[16] *Id*. at 9–10.

[17] *Id.* at 11.

[18] *See* 42 U.S.C. § 256b(a)(1); *Astra USA Inc.*, 563 U.S. at 113 ("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,

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. Put another way, the 340B Program provides covered entities with valuable financial relief that comes at *no cost* to the government.

To qualify as a "covered entity," a health care provider generally must serve a high volume of the country's most vulnerable patients. Among these qualifying providers are safety-net hospitals.[19] Safety-net hospitals "play a vital role in our health care system, delivering significant care to Medicaid, uninsured, and other vulnerable patients."[20] As of 2015, safety-net hospitals treated more than 6.2 million patients annually, provided 33 percent of all inpatient days of care for Medicaid patients, and provided nearly 30 percent of all hospital uncompensated care.[21] Other "covered entities" include community health centers, Ryan White Clinics and

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employs a form contract as an opt-in mechanism." (citations omitted)).

[19] *See* 42 U.S.C. §§ 256b(a)(4)(A)–(L).

[20] Allen Dobson, Joan DaVanzo & Randy Haught, The Commonwealth Fund, *The Financial Impact of the American Health Care Act's Medicaid Provisions on Safety-Net Hospitals* 2 (June 2017), http://www.commonwealthfund.org/~/media/files/publications/fund-report/2017/jun/dobson_ahca_impact_safety_net_hosps_v2.pdf.

[21] *Id*.

Programs, Black Lung Clinics, and Hemophilia Treatment Centers.[22]

In 2010, when Congress passed the Patient Protection and Affordable Care Act, it added additional entities to the definition of "covered entities" for purposes of the 340B Program.[23] The definition now also includes: freestanding cancer hospitals; critical access hospitals[24]; sole community hospitals[25]; rural referral centers[26]; and certain children's hospitals. Together, these covered entities serve the neediest and most vulnerable members of society, and they do so without regard to whether those members have the ability to pay for the medical services they receive.

In creating the 340B Program, Congress acknowledged the critical role these institutions play in the

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[22] *See* 42 U.S.C. §§ 256b(a)(4)(A)–(L); Health Resources & Services Administration, About the Ryan White HIV/AIDS Program (Oct. 2016), https://hab.hrsa.gov/about-ryan-white-hivaids-program/about-ryan-white-hivaids-program; Health Resources & Services Administration, Black Lung Clinics Program (Apr. 2017), https://www.hrsa.gov/get-health-care/conditions/black-lung/index.html; Centers for Disease Control & Prevention, Hemophilia Treatment Centers (HTCs) (Sept. 2, 2015), https://www.cdc.gov/ncbddd/hemophilia/HTC.html.

[23] *See* 42 U.S.C. §§ 256b(a)(4)(M)–(O); *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).

[24] Rural Health Information Hub, *Critical Access Hospitals (CAHs)* (Apr. 8, 2015), https://www.ruralhealthinfo.org/topics/critical-access-hospitals.

[25] 42 C.F.R. § 412.92.

[26] Health Resources & Services Administration, *Rural Referral Centers* (Sept. 2017), https://www.hrsa.gov/opa/eligibility-and-registration/hospitals/rural-referral-centers/index.html.

lives of low-income and rural Americans. It intended to help offset the considerable costs they necessarily 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."[27] 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 widen the safety net that they offer to low-income and vulnerable populations.[28]

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

[28] *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.").

II. The 340B Program Has Successfully Allowed Covered Entities To Stretch Scarce Federal Resources And Provide More Comprehensive Services To Vulnerable Populations

In the decades since Congress enacted the 340B Program, safety-net providers like *amici*'s members have successfully implemented Congress's vision. Just as Congress hoped, the 340B Program has generated savings for health care providers that serve the country's most vulnerable populations. And those health care providers, in turn, have managed to convert their savings on outpatient drugs into a broader safety-net that "reach[es] more eligible patients and provid[es] more comprehensive services."[29]

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

- *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

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

providing specialty services, among other tangible benefits."[30]

- *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 subsidization is necessary for them to be maintained."[31]
- *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 communi-

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

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

ties as well as partially offsetting uncompensated care and Medicaid losses."[32]

- *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 use 340B funds to pay for patient-assistance programs that they otherwise could not afford.[33] The nature of these programs varies widely, in accordance with the diverse needs of the 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

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

[33] *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.

hospitals in tailoring the use of program savings to address the unique needs of our communities."[34]

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.[35] Other entities have chosen to create oncology centers, infusion clinics, women's health centers, stroke and spasticity clinics, and neonatal "programs for expectant mothers" in vulnerable communities in an effort to "increase the likelihood of healthy on-time deliveries" and diminish the probability of NICU stays.[36] Still others have used their 340B savings to offer transportation for patients who do not own a car or to fund mobile health vans and mobile "mammography coaches."

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

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[34] *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.

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

[36] 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.

survey, 71 percent of respondents reported that their 340B savings "increase their ability to provide free or discounted drugs to low income patients."[37] Forty-one percent, moreover, said that the 340B Program has an impact on the range of drugs and devices they are able to provide.[38] 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 build-up of glycogen in the body; and treatment for rabies.[39]

III. CMS's Rule Would Significantly Diminish *Amici*'s Members' Ability To Provide Comprehensive Services To Vulnerable Populations

Decades after the 340B Program was introduced, it now faces a dangerous threat in CMS's final rule. Even before this rule was finalized and COVID-19 struck, 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.[40] Budget shortfalls from COVID-19 make the situation even more dire, as states and localities are forced to further slash desperately-needed Medicaid funding. 340B hospitals simply cannot afford the

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[37] 340B Health, *340B Program Helps Hospitals Provide Services to Vulnerable Patients* 9 (May 2016), https://www.340bhealth.org/files/Savings_Survey_Report.pdf.

[38] *Id.* at 4.

[39] *Id.* at 10.

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

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:

- 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.[41] St. Vincent "delivers high quality, compassionate, personalized care to all, with special attention to those most in need."[42] Its comment letter 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."[43] 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.[44] CMS's rule would

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

[42] *Id*.

[43] *Id*.

[44] *Id*.

"result in a loss of approximately $400,000 and jeopardize program sustainability."[45]

- *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."[46] 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 able to provide patients with chemotherapy treatments and other important medical services."[47]
- Capital Health System is "a non-profit multi-hospital healthcare system providing substantial community benefit through

[45] *Id*.

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

[47] *Id*.

a spectrum of healthcare services to residents of New Jersey."[48] Its comment letter 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."[49] Capital Health "rel[ies]" on the 340B Program, which "safeguards [its] ability to continue to provide this care to our low-income communities."[50] 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."[51]

- *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 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."

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

[49] *Id*.

[50] *Id*.

[51] *Id*.

If CMS's final rule is upheld, however, this rural hospital will no longer be able to offer this service.[52]

- SCL Health is another "faith-based, non-profit health system," which has eight 340B covered entities throughout Colorado and Montana.[53] 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."[54] 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.
- 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

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

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

[54] *Id*.

> citizens."[55] 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.[56]

The list of comments could go on and on. Covered entities in every *amici* hospital associations likely could identify a specific program or clinic whose 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*.[57] Thirty-seven percent predicted that, without 340B, they would have to close one or more outpatient pharmacies, and 71 percent forecast a reduction in pharmacy services.[58] Put simply, most covered entities within the *amici* hospital associations will not be able to weather these staggering financial losses without making massive adjustments to the range of medical services they can provide.[59]

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

[56] *Id.*

[57] *Id.*

[58] *Id.*

[59] 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.").

For many members of the most vulnerable patient populations, the consequences of the rule's adjustment to 340B reimbursements could, quite literally, be fatal.[60] Patients who live in more rural parts of the country may no longer have access to medical services unless they are able to travel a considerable distance,[61] 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. 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.

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[60] 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.").

[61] 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.").

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 by 340B hospitals.[62] Neither justification withstands scrutiny, and neither justification outweighs the many harms that will result from the new rule. As such, the court of appeals majority erred in repeatedly turning to policy justifications to undergird its misguided statutory analysis.[63] That error, coupled with the devastating practical impacts of upholding the unlawful final rule discussed above, demonstrates how important it is for this Court to grant certiorari.

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.[64] But "Congress has not made any such change."[65] Instead, CMS distorted the governing statute in order to uphold the agency's unsound policy objectives.

Even if CMS were the appropriate governmental actor, its stated policy justifications lack merit and thus the majority below was wrong to rely on them. For starters, CMS's contention that Medicare recipi-

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[62] 82 Fed. Reg. 52,356, 52,498 (Nov. 13, 2017).

[63] *Azar*, 967 F.3d at 828, 829, 830, 831, 832–33.

[64] *Azar*, 967 F.3d at 840 (Pillard, J., dissenting).

[65] *Id*.

ents 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) 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.[66] Because the 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 copayment increase.[67]

Similarly, CMS's concern that "the current payment methodology may lead to unnecessary utilization and potential overutilization of separately payable drugs" is based on flawed studies and incomplete data.[68] The Department of Health & Human Services itself has

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[66] 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.

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

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

critiqued the methodology of one of the key studies relied on by CMS. It pointed out that the study failed to properly account for the differences in risk profiles for 340B versus non-340B hospitals.[69] 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.[70] The new rule does not account for this commonsense 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.[71] 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 comprehensive solution is needed than one that targets only the 340B Program and its needy patients.

More generally, concerns about overutilization do not justify the blunt instrument that CMS has chosen. Even if an overutilization problem existed, CMS has

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[69] U.S. Gov't Accountability Off., GAO-15-442, *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 ("GAO Report") 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.

[70] GAO Report at p. 37.

[71] 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.

many other regulatory remedies at its disposal. For example, MedPAC has noted that any overutilization or abuse in the 340B Program could be addressed by better clarifying the scope of the term "covered entity," greater oversight and compliance measures, and increased scrutiny on drug manufacturer pricing.[72] In short, CMS's cuts to the 340B Program cause far more harm than the asserted good CMS intends to achieve, particularly as safety-net and rural hospitals grievously suffer from the COVID-19 pandemic.

CONCLUSION

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

Respectfully submitted,

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[72] 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

Alaska State Hospital and Nursing Home Association

Arizona Hospital and Healthcare Association

Arkansas Hospital Association

California Hospital Association

Connecticut 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

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

Tennessee Hospital Association

Texas Hospital Association

Vermont Association of Hospitals and Health Systems

Washington State Hospital Association

West Virginia Hospital Association