IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION; THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES; AMERICA'S ESSENTIAL HOSPITALS; EASTERN MAINE HEALTHCARE SYSTEMS; HENRY FORD HEALTH SYSTEM; and FLETCHER HOSPITAL, INC., d/b/a PARK RIDGE HEALTH,

Plaintiffs,

v.

ERIC D. HARGAN, in his official capacity as the Acting Secretary of Health and Human Services; and THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendants.

Case No. 1:17-cv-02447-RC

BRIEF OF 32 STATE AND REGIONAL HOSPITAL ASSOCIATIONS AS *AMICI CURIAE* IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION AND IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

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CORPORATE DISCLOSURE STATEMENT

Amici curiae are non-profit organizations. They have no parent corporations and do not issue stock.

INTEREST OF *AMICI CURIAE*[1]

Amici curiae are 32 non-profit state and regional hospital associations that represent thousands of hospitals and health systems.[2] *Amici* and their members are fully 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 a critical tool in helping to achieve this goal.

Many of the hospitals and health systems that *amici* represent, however, will be severely harmed by the Centers for Medicare and Medicaid Services' ("CMS") revision to the reimbursement rates for drugs purchased through the 340B Program. Indeed, the reduction in the reimbursement rate will cause these safety-net hospitals to lose hundreds of millions of dollars in funding. As a result, 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* therefore have a strong interest in ensuring that many of their member 340B hospitals do not face an unprecedented, precipitous, and—most significantly—unlawful diminution of this vital funding. They respectfully submit this brief pursuant to LCvR 7(o) to provide the Court with information directly relevant to its consideration of Plaintiffs' motion for a preliminary injunction and Defendants' motion to dismiss.

[1] In accordance with Local Civil Rule 7(o)(5) and Federal Rule of Appellate Procedure 29(a)(4)(E), *amici* certify that (1) this brief was authored entirely by counsel for *amici curiae* and not by counsel for any party, in whole or part; (2) no party or counsel for any party contributed money to fund preparing or submitting this brief; and (3) apart from *amici curiae* and their counsel, no other person contributed money to fund preparing or submitting this brief.

[2] The individual associations are described in more detail in Appendix A.

INTRODUCTION

Amici are 32 state and regional hospital associations. Their member hospitals and health systems employ thousands of medical professionals and treat millions of America's poorest patients. Often, the health care services that *amici*'s member institutions provide to our nation's most vulnerable populations are uncompensated, undercompensated, or deeply discounted. *Amici*'s member institutions therefore rely on the 340B Program, which saves them millions of dollars each year on the purchase of outpatient drugs. As it is, these 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."[3]

Now, however, CMS has issued a final rule[4] that will stretch *amici*'s members beyond the breaking point. CMS's massive cuts to the 340B Program constitute a "severe restructuring of the statutory scheme" that will have profound effects on patients and health care providers across the country.[5] As explained below, 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 to HIV/AIDS.

The numbers alone are staggering. Initially, CMS predicted that the new rule would cost safety-net providers "as much as $900 million" in reimbursements.[6] Shockingly, CMS

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

[4] *See* 82 Fed. Reg. 52,356, 52,493–52,511, 52,622–55,625 (Nov. 13, 2017).

[5] *Amgen, Inc. v. Smith*, 357 F.3d 103, 117 (D.C. Cir. 2004).

[6] 82 Fed. Reg. 33,558, 33,711 (July 20, 2017).

undershot the financial cost of their proposal by nearly 80 percent. By the time the agency issued the final rule, the estimated cost had ballooned to roughly *$1.6 billion*.[7]

But 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 subsidized 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 are on the front lines of providing irreplaceable care to those most in need. Given their unique position, *amici* respectfully submit this brief to inform the Court about what will happen if CMS is permitted to take a scalpel—or really, an old-fashioned amputation saw—to the 340B Program.

ARGUMENT

I. CONGRESS CREATED THE 340B PROGRAM TO ENABLE COVERED ENTITIES TO EXPAND HEALTH CARE SERVICES IN COMMUNITIES WITH LOW-INCOME PATIENTS.

Medicaid has long been the "Nation's largest single purchaser of prescription drugs."[8] But for decades, "it usually pa[id] the highest prices" for those drugs, while "other large purchasers received discounts from drug manufacturers."[9]

To remedy this imbalance, in 1990 Congress enacted the Medicaid Rebate Program.[10] Under this program, a drug manufacturer could not be covered by Medicaid funds for any of its

[7] 82 Fed. Reg. 52,356, 52,623 (Nov. 13, 2017).

[8] Melvina Ford, Cong. Research Serv., *Medicaid: Reimbursement for Outpatient Prescription Drugs*, CRS-17 (Mar. 7, 1991); *see also* H.R. Rep. No. 102-384(II), at 9.

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

[10] *See* 42 U.S.C. § 1396r-8.

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).[11] 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.[12]

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.[13] As a result, the "[p]rices paid for outpatient drugs by . . . Federally-funded clinics and public hospitals" ballooned.[14] 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 resolve this quandary in 1992 with the 340B Drug Pricing Program. Named for the section of the Public Health Service Act that established the program, 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

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

[12] H.R. Rep. No. 102-384(II), at 9; *see also Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 114–15 (2011) (explaining the Medicaid Rebate Program).

[13] H.R. Rep. No. 102-384(II) at 9–10.

[14] *Id.* at 11.

ceiling price in exchange for having their drugs covered under Medicaid.[15] Congress did not, however, adjust the reimbursement rates that the covered entities receive from Medicare or Medicaid for the outpatient drugs the entities purchased. Consequently, under the 340B Program, 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. These providers include:[16]

- ***Safety-Net Hospitals*:** Safety-net hospitals "play a vital role in our health care system, delivering significant care to Medicaid, uninsured, and other vulnerable patients."[17] Such hospitals often provide services that other hospitals do not, including trauma care, burn care, neonatal intensive care, and inpatient behavioral health.[18] Although they represent only about 15 percent of all U.S. acute-care hospitals, safety-net hospitals treat more than 6.2 million patients annually,

[15] *See* 42 U.S.C. § 256b(a)(1); *see also Astra USA Inc.*, 563 U.S. at 113 ("Section 340B of the Public Health Services Act imposes ceilings on prices drug manufacturers may charge for medications sold to specified health care facilities. Those facilities, here called '340B' or 'covered' entities, include public hospitals and community health centers, many of them providers of safety-net services to the poor." (citation omitted)).

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

[17] 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.

[18] *Id.*; *see also* America's Essential Hospitals, *About—Establishing the Safety Net Hospital: 1980–2005*, https://essentialhospitals.org/about-americas-essential-hospitals/history-of-public-hospitals-in-the-united-states/establishing-the-safety-net-hospital-1980-2005/ (last visited Dec. 8, 2017).

provide 33 percent of all inpatient days of care for Medicaid patients, and provided nearly 30 percent of all hospital uncompensated care in 2015.[19]

- ***Community Health Centers:*** Community health centers serve as the primary health care facility for more than 27 million people in 9,800 rural and urban communities across the country.[20] These centers "deliver care to the Nation's most vulnerable individuals and families, including people experiencing homelessness, agricultural workers, residents of public housing, and the Nation's veterans."[21] More specifically, one in six people receiving Medicaid receive treatment at a community health center, as do one in three low-income and uninsured individuals, one in three individuals living below the poverty line, and one in four rural Americans.[22] The services provided at a community health center include mental health treatment, substance use disorder treatment, and oral health treatment, and pharmacies.[23] All of these services are provided regardless of a patient's ability to pay.[24]

- ***Ryan White Clinics and Programs:*** Ryan White clinics and programs provide primary medical care and essential support services to individuals living with HIV who are uninsured or underinsured.[25] Ryan White clinics and programs exist in all 50 states and the District of Columbia, and they treat more than half a million people each year.[26] Approximately 52 percent of all people who have been

[19] 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* 4 (June 2017), http://www.commonwealthfund.org/~/media/files/publications/fund-report/2017/jun/dobson_ahca_impact_safety_net_hosps_v2.pdf.

[20] Nat'l Ass'n of Community Health Centers, *About Our Health Centers*, http:// www.nachc.org/about-our-health-centers/ (last visited Dec. 8, 2017).

[21] Health Resources & Services Administration, *What Is a Health Center?*, https://bphc.hrsa.gov/about/what-is-a-health-center/index.html (last visited Dec. 8, 2017).

[22] Nat'l Ass'n of Community Health Centers, *Community Health Center Chartbook* 9 (June 2017), http://www.nachc.org/wp-content/uploads/2017/06/Chartbook2017.pdf.

[23] *Id.* at 3.

[24] *Id.*

[25] 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.

[26] West Virginia Dep't of Health & Human Resources, *Ryan White Programs & Clinics*, https://dhhr.wv.gov/oeps/std-hiv-hep/HIV_AIDS/caresupport/Pages/RyanWhiteClinics.aspx (last visited Dec. 8, 2017).

diagnosed with HIV in the United States have received services from Ryan White clinics or programs.[27]

- ***Hemophilia Treatment Centers:*** Hemophilia is "an inherited blood disorder that can lead to chronic health problems."[28] Hemophilia treatment centers ("HTCs") are "specialized health care centers" that offer care from "professionals experienced in treating people with hemophilia."[29] According to a study conducted by the Centers for Disease Control, individuals who are treated at an HTC are 40 percent less likely to die of a hemophilia-related complication than those who do not receive care at an HTC.[30] Those treated at an HTC are also 40 percent less likely to be hospitalized for bleeding complications.[31]

- ***Black Lung Clinics*:** Black lung clinics seek out current and former coal miners and provide services to them and their families, regardless of their ability to pay.[32] These services include outreach, primary care, patient and family education and counseling, care coordination, and pulmonary rehabilitation.[33]

- ***Sexually Transmitted Disease Clinics:*** Sexually transmitted disease ("STD") clinics provide STD testing and treatment, risk reduction counseling, HIV testing, and STD and HIV prevention activities.[34] These services are provided at low or

[27] 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.

[28] Centers for Disease Control & Prevention, *Hemophilia Treatment Centers (HTCs)* (Sept. 2, 2015), https://www.cdc.gov/ncbddd/hemophilia/HTC.html.

[29] *Id.*

[30] *Id.*

[31] *Id.*

[32] Health Resources & Services Administration, *Black Lung Clinics* (Sept. 2017), https://www.hrsa.gov/opa/eligibility-and-registration/specialty-clinics/black-lung/index.html.

[33] Health Resources & Services Administration, *Black Lung Clinics Program* (Apr. 2017), https://www.hrsa.gov/get-health-care/conditions/black-lung/index.html.

[34] Karen Hoover et al., *Continuing Need for Sexually Transmitted Disease Clinics After the Affordable Care Act*, 105 Am. J. Public Health S690 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4627523/pdf/AJPH.2015.302839.pdf.

no cost to patients, many of whom are underinsured or uninsured, and they "play a critical role in addressing racial disparities in health."[35]

- ***Family Planning Clinics:*** Family planning clinics "provide critical contraceptive, sexual and reproductive health and other preventive health services to poor and low-income women."[36] Indeed, approximately 27 percent of all American women who receive contraceptive services, and approximately 44 percent of all poor women, receive those services from a family planning clinic.[37] Often, "publicly funded family planning clinics provide the only regular health care women receive."[38]

In 2010, when Congress passed the Patient Protection and Affordable Care Act ("ACA"), it added additional entities to the definition of "covered" entities for purposes of the 340B Program.[39] The definition now also includes:[40]

- Freestanding cancer hospitals;
- Critical access hospitals, a designation given to certain rural hospitals by CMS "to reduce the financial vulnerability of rural hospitals and improve access to healthcare by keeping essential services in rural communities";[41]

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[35] *Id.*; Matthew R. Golden & Peter R. Kerndt, *What Is the Role of Sexually Transmitted Disease Clinics?*, 42 Sexually Transmitted Diseases 294 (May 2015), http://journals.lww.com/stdjournal/Fulltext/2015/05000/What_Is_the_Role_of_Sexually_Transmitted_Disease.12.aspx.

[36] Mia R. Zolna & Jennifer J. Frost, Guttmacher Institute, *Publicly Funded Family Planning Clinics in 2015: Patterns and Trends in Service Delivery Practices and Protocols* 1 (Nov. 2016), https://www.guttmacher.org/sites/default/files/report_pdf/publicly-funded-family-planning-clinic-survey-2015_1.pdf.

[37] *Id.* at 4.

[38] *Id.* (citing Jennifer J. Frost, Guttmacher Institute, *U.S. Women's Use of Sexual and Reproductive Health Services: Trends, Sources of Care and Factors Associated with Use, 1995–2010* (May 2013), https://www.guttmacher.org/report/us-womens-use-sexual-and-reproductive-health-services-trends-sources-care-and-factors).

[39] *Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 138 F. Supp. 3d 31, 35 (D.D.C. 2015) (explaining that "Congress added a significant number of new categories to the list of covered entities" as part of the ACA).

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

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

- Sole community hospitals—*i.e.*, hospitals that are located more than 35 miles from other like hospitals, or are located in a rural area, and that meet other criteria related to their inaccessibility;[42]

- Rural referral centers, which are "are high-volume acute care rural hospitals that treat a large number of complicated cases";[43] 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 services they receive.

In creating the 340B Program, Congress acknowledged the critical role these entities play in the lives of low-income and rural Americans. It sought to help offset the considerable costs these entities 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" on 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."[44] 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—the entities could use their 340B savings to widen further the safety net these entities offer to low-income and vulnerable populations.[45]

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[42] 42 C.F.R. § 412.92.

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

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

[45] *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/program requirements/forms/hemophiliatreatmentcenter340bmanual.pdf ("The purpose of the 340B

Both the D.C. Circuit and this Court have acknowledged the 340B Program's purpose. The D.C. Circuit has observed that 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." [46] And this Court has explained that the "*general* stated purpose" of the 340B Program at the time of its "initial passage in 1992" was just what Congress said in the above-quoted House Report: "'to stretch scarce Federal resources as far as possible'" to ensure broad "access to drugs at a reduced cost for certain entities and in certain circumstances."[47]

II. THE 340B PROGRAM HAS EFFECTIVELY ALLOWED COVERED ENTITIES LIKE *AMICI*'S MEMBERS TO STRETCH SCARCE FEDERAL RESOURCES AND PROVIDE MORE COMPREHENSIVE SERVICES TO VULNERABLE POPULATIONS.

In the twenty-five years since Congress enacted the 340B Program, safety-net providers like *amici* have successfully implemented Congress's vision: Just as Congress had hoped, the 340B Program has generated enormous 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."[48]

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.").

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

[47] *Pharm. Research & Mfrs. of Am.*, 138 F. Supp. 3d at 34, 52 (quoting H.R. Rep. No. 102-384(II), at 12) (emphasis omitted).

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

At a recent congressional hearing, Congressman Frank Pallone declared, "It is beyond question that the resources provided through the 340B Program directly augment patient care throughout the country."[49] For support, Congressman Pallone could easily turn to powerful evidence in the administrative record that was submitted by the *amici* hospital associations and other safety-net providers. For example:

- *Amicus* North Carolina Hospital Association, explained 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."[50]

- *Amicus* California Hospital Association likewise explained that "[h]ospitals in California use the 340B savings to provide free care for uninsured patients, free vaccinations and services in mental health clinics, medication management programs and community health programs."[51]

- *Amicus* Louisiana Hospital Association commented that their members participating in the 340B Program had margins of *negative* 19.35 percent, and that the cuts would "make these hospitals' financial situations even more precarious, thus putting at risk the programs that they have developed to expand access to care for their vulnerable patient populations."[52]

- The Safety Net Hospital Alliance of Florida noted in their comments to CMS that the 340B Program "has been critical to ensuring that low-income and other disadvantaged people have access" to vital medical services, including "lifesaving cancer and transplant drugs at no cost[;] . . . clinical pharmacy programs, in which

[49] *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. 17 (Oct. 11, 2017), http://docs.house.gov/meetings/IF/IF02/20171011/106498/HHRG-115-IF02-Transcript-20171011.pdf.

[50] North Carolina Hospital Association, Comment Letter on Proposed Rule Change 82 Fed. Reg. 33,558 at 2 (Sept. 11, 2017).

[51] California Hospital Association, Comment Letter on Proposed Rule Change 82 Fed. Reg. 33,558 at 4 (Sept. 11, 2017).

[52] Louisiana Hospital Association, Comment Letter on Proposed Rule Change 82 Fed. Reg. 33,558 at 3 (Sept. 6, 2017).

pharmacists interact with patients at bedside and in the emergency department[;] and "mental health and substance abuse treatment."[53]

- The Teaching Hospitals of Texas—which includes Texas's large urban public hospitals, four University of Texas health systems, three children's hospitals, and several non-profit and rural health systems—told CMS that the 340B Program is "an important resource for [its] members," particularly at a time "when Texas [is still] recovering from the devastating impacts of Hurricane Harvey." Indeed, a small subset of its members relies on 340B subsidies to support low-income and uninsured residents through a variety of programs, including anticoagulation and drug-therapy management clinics and chemotherapy services. This one subset of hospitals stands to lose $15 million if the CMS rule goes into effect. As they explained in the Teaching Hospitals of Texas's submission to CMS, the money they receive as part of the 340B Program helps avoid "early deaths, illness and higher system costs."[54]

These hospital associations, moreover, are not unique. In a study conducted by advocacy organization 340B Health, 67 percent of the hospitals surveyed reported that their 340B savings have helped them fund patient-assistance programs that they otherwise likely could not afford.[55] The nature of these programs and facilities varies widely, in accordance with the diverse needs of the populations those covered entities serve. Indeed, 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."[56]

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[53] Safety Net Hospital Alliance of Florida, Comment Letter on Proposed Rule Change 82 Fed. Reg. 33,558 at 6–7 (Sept. 13, 2017).

[54] Teaching Hospitals of Texas, Comment Letter on Proposed Rule Change 82 Fed. Reg. 33,558 at 3, 6 (Sept. 11, 2017).

[55] 340B Health, *340B Program Helps Hospitals Provide Services to Vulnerable Patients* 4, 11 (May 2016), https://www.340bhealth.org/files/Savings_Survey_Report.pdf.

[56] *See* Examining How Covered Entities Utilize the 340B Drug Pricing Program Before the House of Representatives Subcommittee on Oversight and Investigations, Committee on

Accordingly, 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.[57] Other entities have chosen to create oncology centers, women's health centers, stroke and spasticity clinics, infusion 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.[58] Still others have used their 340B savings to offer transportation to appointments to patients who do not own a car or to fund mobile health vans or "mammography coaches," which travel around conducting free or deeply discounted health screenings in low-income communities.[59] At least one covered entity, moreover, has used its 340B savings to provide "the only cardiac catheterization lab and dedicated psychiatric emergency room" in the county in which it is located.[60]

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

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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.

[57] California Hospital Association, Comment Letter on Proposed Rule Change 82 Fed. Reg. 33,558 at 3 (Sept. 11, 2017).

[58] 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.

[59] 340B Health, *Faces of 340B: Mark Huffmyer*, http://www.340bhealth.org/340b-resources/why-340b-matters/faces-of-340b/mark-huffmyer/.

[60] 340B Health, *Faces of 340B: Tristan Greer*, http://www.340bhealth.org/340b-resources/why-340b-matters/faces-of-340b/tristan-greer/.

their ability to provide free or discounted drugs to low income patients."[61] Forty-one percent, moreover, said that the 340B Program has an impact on the range of drugs and devices they are able to provide.[62] 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.[63]

Jennifer Gallagher is just one of many patients who cites the 340B Program as having had a tangible impact on her life.[64] In 2013, Ms. Gallagher underwent an open heart surgery that requires her to be on a powerful blood thinner for the rest of her life. This expensive medication requires near-constant monitoring, and that monitoring requires countless trips to and from a health care provider.[65] Fortunately, Ms. Gallagher lives near Parkview Medical Center in Pueblo, Colorado. Thanks in large part to the 340B Program, Parkview Medical Center is able to offer Ms. Gallagher's blood thinner at a discounted price and to run an outpatient anticoagulation clinic that Ms. Gallagher depends on for care.[66] If not for those services, Ms. Gallagher would

[61] 340B Health, *340B Program Helps Hospitals Provide Services to Vulnerable Patients* 9 (May 2016), https://www.340bhealth.org/files/Savings_Survey_Report.pdf.

[62] *Id.* at 4.

[63] *Id.* at 10.

[64] 340B Health, *Faces of 340B: Jennifer Gallagher*, http://www.340bhealth.org/340b-resources/why-340b-matters/faces-of-340b/jennifer-gallagher/.

[65] *Id.*

[66] *Id.*

have to travel a considerable distance for treatment, making it difficult for her to retain a job. And she would struggle to afford the medication on which her life depends.[67]

Lamar Williams tells a similar story.[68] Mr. Williams was uninsured when he suffered a series of three heart attacks. After the third attack, Mr. Williams was enrolled in Baptist Medical Center's CareAdvisor Program in Montgomery, Alabama. That program, which is funded through the medical center's 340B savings, seeks to give uninsured outpatients a medical home base.[69] Through the program, Mr. Williams receives not only medical care, but also bus passes, medications, a nurse case manager, and a social walker—all free of charge.[70] Mr. Williams credits the program with saving his life.[71]

Finally, not long ago, one patient at Chicago's Mount Sinai Hospital—a member of *amici* Illinois Health and Hospital Association—was diagnosed with a dangerous brain parasite. If not for the 340B Program, the medication therapy needed to eliminate the parasite would have been roughly $20,000—a prohibitive expense. But thanks to Mount Sinai's 340B funds, the hospital was able to offer the medication to the patient at an affordable price. In other words, just as it was for Mr. Williams, the 340B Program was a literal life-saver for this particular individual.

Countless other patients could undoubtedly testify to the impact that the 340B Program has had on their lives. Together, these narratives provide overwhelming evidence of the success of Congress's vision in creating that program. Because covered entities like *amici*'s members

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[67] *Id.*

[68] 340B Health, *Faces of 340B: Lamar Williams*, http://www.340bhealth.org/340b-resources/why-340b-matters/faces-of-340b/lamar-williams/.

[69] *Id.*

[70] *Id.*

[71] *Id.*

have enjoyed considerable savings on outpatient drugs, they have indeed been able to "stretch scarce Federal resources as far as possible," expanding their reach to include even more patients in need of care and creating critical new programs and services for vulnerable populations.[72]

III. THE NEW RULE WOULD SIGNIFICANTLY DIMINISH *AMICI*'S ABILITY TO PROVIDE COMPREHENSIVE SERVICES TO VULNERABLE POPULATIONS.

Twenty-five years after the 340B Program was first introduced, it now faces a dangerous threat in the form of the new rule issued by CMS on November 1, 2017.[73] Under the new rule, covered entities are still entitled to purchase outpatient drugs at discounted prices. Now, however, they will receive severely diminished reimbursements for those payments. Whereas before, the covered entities' reimbursements were typically the average sales price ("ASP") of a particular drug *plus 6 percent*, under the new rule, the reimbursements will be the ASP *minus 22.5 percent.*[74] This nearly *30 percent reduction* in the reimbursement rate will have devastating consequences for safety-net providers and the millions of patients they serve.

DataGen, a third-party company that analyzes Medicare payment policy changes for 47 state hospital associations and other clients,[75] conducted a study that attempted to estimate the 340B payment reductions on a state-by-state basis. Its study concluded that health care providers

[72] H.R. Rep. No. 102-384(II), at 12; *see also* 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. 8 (Oct. 11, 2017), http://docs.house.gov/meetings/IF/IF02/20171011/106498/HHRG-115-IF02-Transcript-20171011.pdf (explaining that 340B entities "provide extraordinary amounts of uncompensated care and services to those in need").

[73] 82 Fed. Reg. 52,356 (Nov. 13, 2017).

[74] *Id.* at 52,362.

[75] DataGen, *About DataGen*, http://datagen.info/about/ (last visited Dec. 8, 2017).

in each of the *amici*'s states should expect their reimbursement for drugs acquired under the 340B Program to decrease by the following amounts:

State	**340B Reduction**
Arkansas	$14,131,200
California	$173,229,300
Colorado	$33,495,900
Georgia	$77,793,900
Illinois	$72,645,000
Kansas	$22,493,400
Louisiana	$43,099,000
Maine	$15,888,600
Massachusetts	$59,274,200
Michigan	$72,754,500
Minnesota	$29,734,500
Mississippi	$29,517,500
Missouri	$47,998,200
New Jersey	$29,518,800
New Mexico	$8,975,900
New York	$95,225,600
North Carolina	$102,145,100
Ohio	$52,668,700
Oregon	$21,341,100
Pennsylvania	$82,017,100
South Dakota	$11,969,100
Tennessee	$62,778,500
Texas	$40,856,500
Virginia	$45,869,700
West Virginia	$16,148,500
Wisconsin	$40,668,800

CMS has concededly attempted to partially offset some of these multi-million-dollar losses with separate budget-neutrality measures. But those budget-neutrality measures may only *partially* offset the financial damage for certain covered entities. The vast majority of *amici* still expect the damage inflicted by the new rule to be catastrophic. The 340B providers in the California Hospital Association, for instance, still stand to lose approximately $85 million, even if the proposed budget-neutrality measures are, in fact, implemented. The seventy-nine 340B hospitals that are part of the Georgia Hospital Association anticipate a loss of approximately $54 million. And the 340B providers in the Tennessee Hospital Association still expect they will have to overcome a difference of at least $28.5 million. In short, the number of hospitals for which the proposed budget neutrality measures will actually obviate the financial blow inflicted by the cuts to the 340B Program are the exception—not the rule.

In addition, these numbers provide only an aggregate picture. On a more granular level, particular covered entities within each state stand to suffer even more. Indeed, where budget-neutrality measures may help offset the overall impact to a state's hospitals or health systems, *individual* 340B covered entities will be forced to cope with reductions in funding that will cripple their ability to maintain their current range of health care services. Stated differently, increasing the Medicare Part B reimbursement rates for other types of services does not help all safety-net hospitals equally. The following are just a few of the many possible examples of individual hospitals that will suffer under CMS's rule:

Covered Entity	**Projected Financial Loss**
HSHS St. Vincent Hospital (Green Bay, WI)	$2,400,000
John D. Archbold Memorial Hospital (Thomasville, GA)	$2,300,000
Maimonides Medical Center (Brooklyn, NY)	$4,000,000
Midtown Medical Center (Columbus, GA)	$2,886,200

Oregon Health & Science University (Portland, OR)	$11,000,000
OSF HealthCare (Peoria, IL)	$11,000,000
Presence Health System (IL)	$7,709,482
Reading Hospital (West Reading, PA)	$18,276,068
Saint Francis Medical System (Cape Girardeau, MO)	$1,038,000
UC Health (CO)	$17,000,000

Not surprisingly, most covered entities within the *amici* hospital associations will not be able to weather these staggering financial losses without making dramatic adjustments to the range of medical services they can provide.[76] Indeed, in the 340B Health study, 40 percent of hospital respondents predicted that losing their 340B savings would force them to close one or more clinics entirely.[77] 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.[78]

Although the new CMS rule concededly does not eliminate *all* 340B funding, members of the *amici* hospital associations are nevertheless concerned that the rule's reimbursement reductions are significant enough that many of these bleak predictions will come to pass. The University of California Health system has warned that the new rule could require shuttering

[76] 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.").

[77] *Id.*

[78] *Id.*

some of the system's infusion and post-transplant centers, or some of its inner-city clinics.[79] MedStar Health, which includes seven hospitals in the District of Columbia and Maryland that participate in the 340B Program, explained that the cuts would "significantly reduce the benefits of the 340B program and harm the very hospitals that serve our most vulnerable citizens."[80] 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.[81]

These examples are part of the administrative record for the new rule. In preparing this brief, *amici* also separately asked their members to identify programs and services that will suffer as a result of CMS's new rule. Those members similarly identified particular clinics and programs that will likely struggle to stay afloat—or, worse, be forced to close—in the wake of the new rule. A few of these additional examples, drawn from hospital and health systems from every corner of the United States, are illustrative:

- A health system in New Mexico that funds more than 20 not-for-profit organizations providing a wide range of services expects to lose more than $1 million if the CMS rule is allowed to take effect. The organizations funded by this health system provide targeted medical services aimed at suicide prevention, opioid abuse, vision and dental services for low-income children, and nutritional and medical assistance for senior citizens.

- A faith-based, not-for-profit hospital in Arkansas uses its nearly $3.4 million dollars in 340B savings each year to fund, *inter alia*, an outpatient infusion center,

[79] Letter from John D. Stobo, Executive Vice President, UC Health System, to Seema Verma, Administrator, Centers for Medicare and Medicaid Services 2 (Sept. 11, 2017) (available from counsel for *amici*).

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

[81] *Id.*

which provides comprehensive cancer care, chemotherapy, and non-oncology infusion services, and to support multiple charitable care clinics serving over 6,000 patients annually. CMS's cuts will endanger this hospital's ability to provide these vital services to its low-income patients from 75 different Arkansas counties.

- One hospital in Georgia provides more than $25 million each year in free or discounted care, and is at risk of losing significant funding due to the CMS rule. In 2016, this hospital opened a retail pharmacy expressly for the purpose of serving uninsured and underinsured patients. As of August 31, 2017, this hospital had filled nearly 8,500 prescriptions at no cost to the patients. This vital service would not be possible without 340B funding.

- A Colorado critical access hospital and its four accompanying primary care clinics expect the anticipated reduction in 340B reimbursements to have a profound effect on their ability to serve aging patients in the state's more rural communities. In the hospital's own words, it relies on 340B funding to keep the doors open and fears the new rule will force a hiring freeze and will impede its ability to provide care regardless of its patients' ability to pay.

- A health system in Illinois and Wisconsin will lose roughly $4 million dollars under the new rule. The hospitals in this system serve low-income patients suffering from arthritis, cancer, cardiovascular disease, Crohn's disease, HIV, premature birth, and various other conditions and illnesses. Within this system, one hospital was able to hire a dedicated pharmacist in its Cystic Fibrosis Clinic; that position would be jeopardized as a result of the challenged rule. Another hospital in the system relies on 340B discounts to treat 120 to 140 premature infants annually who are at risk for respiratory syncytial virus (RSV). Typically, these infants receive one dose a month during a five-month period. Without 340B, each dose would cost $2,600; with 340B, the cost drops to $950. The 340B Program allows this hospital to pass on these substantial savings to patient families.

- A hospital in upstate New York will not be able to absorb the $4 million in cuts from the CMS rule without curtailing services that are needed by the community it serves. Those services include diabetes treatments, many of which are provided through a program specifically targeted at uninsured or underinsured Latina women for whom English is not their primary language. This program has been a success; the hospital has seen decreases in the number of woman at high risk from developing Type 2 diabetes.

- An Oregon health system would lose an estimated $11 million of its 340B benefits from the CMS reductions. Among the many services these cuts will impact are the health system's Hematology/Oncology infusion clinics and pharmacies, which it locates strategically throughout the community to improve access and to prevent medically-fragile patients from having to travel long distances to receive treatment. The clinics administer 9,000 doses annually to

patients suffering from cancer and other ailments. This program would be immediately at risk if the new rule goes into effect.

- The regional medical center in Tennessee has voiced concern about its clinics that serve low-income communities in rural parts of the state and its cancer center, which has traditionally devoted a significant portion of its 340B savings to helping low-income patients find funding to cover their medical bills.[82]

The list could go on and on. Covered entities in every one of the *amici* hospital associations could likely identify a specific program or clinic whose survival is threatened by the impending 340B reductions.

If *amici*'s fears are realized, and covered entities nationwide are forced to shutter facilities and slash services, the impact will be immediate and deeply felt in communities across the country. To start, a huge number of individuals have jobs that owe their existence to the 340B Program—jobs that will presumably disappear if 340B funds dry up.[83] In addition, the 340B Program reduces national health care costs by providing patients with alternatives to hospital emergency rooms, which typically have the highest costs.[84]

These repercussions should not be taken lightly, but they are far from the worst consequences of the new CMS rule: For many members of the most vulnerable patient populations, the consequences of the rule's adjustment to 340B reimbursements could, quite

[82] *See also* Letter from Edward L. Burr, Chief Administrative Officer, University Health Care System, to Keri F. Conley, Georgia Hospital Ass'n (Nov. 29, 2017) (available from counsel for *amici*) ("University has a decades-long history of providing cancer care to anyone, regardless of the ability to pay. . . . The reduction in Medicare reimbursement for 340B drugs is forcing a hard look at the viability of continuing both the medical oncology practice and the chemotherapy infusion service.").

[83] *See* Primary Care Development Corporation, Comment Letter on Proposed Rule Change 82 Fed. Reg. 33,558 at 2 (Sept. 11, 2017) ("[D]ownsizing or shuttering a hospital—often the largest employer in many communities—can devastate an area's fiscal health.").

[84] North Carolina Hospital Association, Comment Letter on Proposed Rule Change 82 Fed. Reg. 33,558 at 2 (Sept. 11, 2017) ("If 340B programs are reduced or terminated . . . patients could be forced into more costly settings, such as the emergency department, for their care.").

literally, be fatal.[85] Individuals 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,[86] and many low-income and uninsured patients will struggle to afford the services and medications that they desperately need. Equally problematically, individuals who have been immunocompromised because of illness or chemotherapy may no longer have access to the separate oncology and infusion clinics they depend on for life-saving treatment and will instead be forced to take the potentially life-threatening risk inherent in visiting a more traditional health care facility.

All in all, the patients and communities that are served by covered entities will suffer profoundly as a result of the challenged 340B provisions of the new CMS rule. While there may be a dispute over the lawfulness of CMS' slashes to that program—though there should not be, given Plaintiffs' persuasive legal arguments—there can be no disagreement about one thing: the CMS rule will have a devastating impact on those most in need of care who will be unable to receive it without the 340B Program.

CONCLUSION

In evaluating the need for a preliminary injunction, this Court must consider the extent to which an injunction is necessary to avert irreparable harm, the balance of the equities, and whether an injunction will serve the public interest.[87] It is difficult to imagine a case that more obviously satisfies those criteria. The new CMS rule will enfeeble the ability of hospitals

[85] 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.").

[86] 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.").

[87] *League of Women Voters v. Newby*, 838 F.3d 1, 6 (D.C. Cir. 2016).

throughout the United States to provide health care to low-income populations and, in turn, will jeopardize the lives and health of countless needy patients. Similarly, in evaluating Defendants' motion to dismiss, these same inevitable consequences demonstrate that the CMS rule cannot be squared with the basic purposes of the 340B Program. For these reasons, *amici* respectfully urge the Court to grant Plaintiffs' motion for a preliminary injunction and to deny Defendants' motion to dismiss.

December 8, 2017

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing complies with Local Civil Rule 7(o)(4) and does not exceed 25 pages.

December 8, 2017 */s/ Chad I. Golder*
Chad I. Golder

CERTIFICATE OF SERVICE

I hereby certify that on December 8, 2017, I caused a true and correct copy of the foregoing to be served on all counsel of record through the Court's CM/ECF system.

December 8, 2017 */s/ Chad I. Golder*
Chad I. Golder

APPENDIX

DESCRIPTION AND INTERESTS OF INDIVIDUAL *AMICI*

The Arkansas Hospital Association (ArHA) is a trade association representing over 100 hospitals and related institutions, and the more than 41,000 individuals employed by these organizations across the state of Arkansas. The ArHA is committed to improving the health of Arkansans through the delivery of high quality, efficient, and accessible health care for all. Serving a diverse population in a predominantly rural state, many Arkansas hospitals depend on the 340B Program to ensure that they can continue to provide and expand access to health care services to Arkansans, allowing them to receive the care they need close to home.

The California Hospital Association (CHA) is one of the largest hospital trade associations in the nation, serving more than 400 hospitals and health systems and 97 percent of the general acute care and psychiatric acute patient beds in California. CHA's members include all types of hospitals and health systems: nonprofit; children's hospitals; those owned by various public entities, including cities/counties, local health care districts, the University of California, and the Department of Veterans Affairs; as well as investor-owned. The vision of CHA is an "optimally healthy society," and its goal is for every Californian to have equitable access to affordable, safe, high-quality, medically necessary health care. To help achieve this goal, CHA is committed to establishing and maintaining a financial and regulatory environment within which hospitals, health care systems, and other health care providers can offer high-quality patient care. CHA promotes its objectives, in part, by participating as *amicus curiae* in important cases like this one. CHA estimates that 129 member hospitals expect to be adversely impacted by the cuts to the 340B Program. Taking into account budget-neutrality adjustments, CHA estimates that the net impact and harm to these 129 members will be nearly $85 million.

Colorado Hospital Association (CHA) represents more than 100 hospitals and health systems across the state. CHA's mission is to support its members' commitment to advance the health of their communities by delivering affordable, high-quality health care. Among other things, CHA serves its members by promoting initiatives to improve the quality, efficiency, and accessibility of health care provided by its constituent hospitals; promoting practices and legislation that best permit hospitals to improve their quality management and maintain the highest quality of service; and educating policymakers and other health care stakeholders on its member hospitals' perspectives involving important health care issues. CHA takes interest in cases that have the potential to impact the operation and financial well-being of hospitals across the state.

The Georgia Hospital Association is a non-profit trade association made up of member hospitals and individuals in administrative and decision-making positions within those institutions. Founded in 1929, the Association serves 178 hospitals in Georgia. Its purpose is to promote the health and welfare of the public through the development of better hospital care for all of Georgia's citizens. The Association represents its members in legislative matters, as well as in filing *amicus curiae* briefs on matters of great gravity and importance to both the public and to health care providers serving Georgia citizens. The Association estimates that 42 of its member hospitals will be negatively impacted by the loss of 340B savings, with a net impact of $54 million after taking into account budget-neutrality adjustments.

The Illinois Health and Hospital Association (IHA) is a statewide not-for-profit association with a membership of over 200 hospitals and nearly 50 health systems. For over 90 years, the

IHA has served as a representative and advocate for its members, addressing the social, economic, political, and legal issues affecting the delivery of high-quality health care in Illinois. As the representative of virtually every hospital in the state, the IHA has a profound interest in this case. The IHA respectfully offers this *amicus curiae* brief in hopes of providing information not addressed by the litigants that will help the Court evaluate the litigants' arguments more thoroughly. Fifty two of IHA's member hospitals will be impacted by the 340B reduction in savings, totaling $72.6 million.

The Kansas Hospital Association (KHA) is a not-for-profit voluntary state organization located in Topeka, Kansas that represents and serves 127 community hospitals, including 85 Critical Access Hospitals. Its mission is to provide education and information and be the leading advocate for its members on the state and national level. KHA estimates that five of its member hospitals will be negatively impacted by the 340B cuts, incurring losses of over $22 million.

The Louisiana Hospital Association (LHA) is a non-profit organization founded in 1926 and incorporated in 1966 for the purpose of promoting the public welfare of the State of Louisiana. The Association's membership is composed of over 150 member institutions, with more than a thousand individual members. Membership consists of hospitals of all kinds, including public, private, nonprofit, for-profit, federal, municipal, hospital service district, religious, general, specialty, acute-care, psychiatric, and rehabilitation classifications. LHA estimates that 43 member hospitals will be impacted by the 340B cuts, costing these hospitals $43 million annually.

The Maine Hospital Association (MHA) represents all 36 community-governed hospitals in Maine including 33 non-profit general acute-care hospitals, two private psychiatric hospitals, and one acute rehabilitation hospital. In addition to acute care hospital facilities, it also represents 11 home health agencies, 18 skilled nursing facilities, 19 nursing facilities, 12 residential care facilities, and more than 300 physician practices. Its acute-care hospitals are non-profit, community-governed organizations with more than 800 volunteer community leaders serving on the boards of Maine's hospitals. Maine is one of only a handful of states in which all of its acute-care hospitals are non-profit. MHA estimates that 7 of its member hospitals will be impacted by the loss of 340B savings and that these impacted hospitals will experience a net loss of approximately $8.7 million.

The Massachusetts Health and Hospital Association (MHA) is a voluntary, not-for-profit organization composed of hospitals and health systems, related providers, and other members with a common interest in promoting the good health of the people of the Commonwealth of Massachusetts. Through leadership in public advocacy, education, and information, MHA represents and advocates for the collective interests of hospitals and health care providers, and it supports their efforts to provide high-quality, cost-effective, and accessible care. Twenty-three of MHA's member hospitals are 340B hospitals. MHA estimates an impact of over $59 million on these hospitals' pharmacies.

Michigan Health & Hospital Association (MHA) is the statewide leader representing all community hospitals in Michigan. Established in 1919, the MHA represents the interests of its member hospitals and health systems in both the legislative and regulatory arenas on key issues and supports their efforts to provide quality, cost-effective and accessible care.

The Minnesota Hospital Association (MHA) is a Minnesota non-profit corporation that represents hospitals in the State of Minnesota, including 142 community-based hospitals and health systems and the physicians employed at those hospitals and health systems. MHA assists Minnesota hospitals in carrying out their responsibility to provide quality health care services to their communities; promote universal health care coverage, access, and value; and coordinate the development of innovative health care delivery systems. MHA serves it members and the State of Minnesota as a trusted leader in health care policy and as a valued source for health care information and knowledge. Of the hospitals and health systems that MHA represents, 24 will be subject to a cut pursuant to the proposed rule. MHA estimates that these 24 affected hospitals will see a reduction in payments of approximately $30 million after accounting for budget-neutrality adjustments.

The Mississippi Hospital Association (MHA) consists of hospitals, health care institutions, health care facilities, individuals, and other entities located in or doing business in the State of Mississippi. MHA anticipates that 20 of its member hospitals will be impacted by the loss of 340B savings, with a total estimated impact of more than $29 million.

The Missouri Hospital Association (MHA) members include every acute-care hospital in the state, as well as most of the federal and state hospitals and rehabilitation and psychiatric care facilities. MHA actively serves its members' needs through representation and advocacy on behalf of its members, continuing education programs on current health care topics, and education of the public and media, as well as legislative representatives, about health care issues. MHA estimates that 19 of its member hospitals will be impacted by the loss of 340B savings, and will lose millions of dollars in savings.

The New Hampshire Hospital Association (NHHA) is the leading and respected voice for hospitals and health care delivery systems in New Hampshire, working together to deliver compassionate, accessible, high-quality, and financially sustainable health care to the patients and communities served by its member hospitals. NHHA represents 31 member hospitals, including a large academic medical center, 13 critical access hospitals, two specialty rehabilitation hospitals, one state psychiatric hospital, one private behavior health hospital, and one VA Medical Center.

The New Jersey Hospital Association (NJHA) has served as New Jersey's premier health care association since its inception in 1918. NJHA currently has members across the health care continuum including hospitals, health systems, nursing homes, home health, hospice, and assisted living, all of which unite through NJHA to promote their common interests in providing quality, accessible and affordable health care in New Jersey. In furtherance of this mission, NJHA undertakes research and health care policy development initiatives, fosters public understanding of health care issues, and implements pilot programs designed to improve clinical outcomes and enhance patient safety. NJHA regularly appears before all three branches of government to provide the judiciary and elected and appointed decision makers with its expertise and viewpoint on issues and controversies involving hospitals and health systems. NJHA estimates that 22 of its member hospitals will be impacted by the loss of 340B savings.

The New Mexico Hospital Association (NMHA) is the trade association for acute-care hospitals in New Mexico. It advocates for the interests of its members at the state and federal

level in the legislative and regulatory arenas. The NMHA represents 45 not-for-profit, investor-owned, and governmental hospitals and health systems from around the state. At least 15 of those members, which serve more than 1.2 million patients, expect to be adversely impacted by the cuts to the 340B Program. These cuts will cause these members to lose more than $23 million dollars that would otherwise be spent on serving New Mexico's most needy populations.

The Healthcare Association of New York State (HANYS) is New York's statewide hospital and health system association representing over 500 not-for-profit and public hospitals and hospital based skilled nursing facilities, home health agencies, and hospices. HANYS' members range from rural Critical Access Hospitals to large, urban Academic Medical Centers and other Medicaid and safety net providers. In New York State, 78 340B hospitals will be impacted by the reduction in 340B savings, the estimated impact after budget-neutrality adjustments is a net reduction of $51 million.

The Greater New York Hospital Association (GNYHA) is a Section 501(c)(6) organization that represents the interests of nearly 150 hospitals located throughout New York State, New Jersey, Connecticut, and Rhode Island, all of which are not-for-profit, charitable organizations or publicly-sponsored institutions. GNYHA engages in advocacy, education, research, and extensive analysis of health care finance and reimbursement policy. In addition to the 78 New York State hospitals referenced by the Healthcare Association of New York State, the majority of which are also GNYHA members, approximately 14 other hospitals in its membership from the three other states will be impacted by CMS's 340B cuts.

The Iroquois Healthcare Association (IHA) is an independent organization representing 54 hospitals and health systems, spanning over 28,000 square miles, across 32 counties of Upstate New York. IHA represents the unique needs of rural, small community safety-net providers to large, academic medical centers in Upstate New York's urban areas through advocacy, education and information, cost-savings initiatives, and innovative business solutions.

Rochester Regional Healthcare Association (RRHA) is a non-profit organization representing 17 hospitals across nine counties covering the Rochester and Finger Lakes region with a total of almost 5,000 beds. These hospitals include two teaching hospitals and serve a population of 1.3 million which makes up almost 12 percent of the state population (excluding New York City).

The Suburban Hospital Alliance of New York State is a consortium of 51 non-for-profit and public hospitals advocating for better health care policy for all those living and working in the nine counties north and east of New York City. The Suburban Alliance ensures that the specific concerns of suburban hospitals from the Hudson Valley and Long Island regions of New York are heard in Albany and Washington.

The Western New York Healthcare Association was founded in 1931 and is an industry association of health care providers in Erie, Niagara, Orleans, Genesee, Wyoming, Chautauqua, Cattaraugus, and Allegany counties, with member hospitals in rural to urban settings. The Association serves as a leading source of advocacy, policy, and health care information for its members and as an educator, communicator, and clearinghouse for health care information. While primarily focused on hospitals and affiliated nursing home providers, the Association also has non-hospital associate-level members.

The North Carolina Hospital Association (NCHA) is a statewide trade association representing 136 hospitals and health systems in North Carolina, with the mission of uniting hospitals, health systems, and care providers for healthier communities. NCHA is an advocate before the legislative bodies, the courts, and administrative agencies on issues of interest to hospitals and health systems and the patients they serve.

The Ohio Hospital Association (OHA) is a private non-profit trade association established in 1915 as the first state-level hospital association in the United States. For decades the OHA has provided a forum for hospitals to come together to pursue health care policy and quality improvement opportunities in the best interest of hospitals and their communities. The OHA is comprised of 220 hospitals and 13 health systems, all located in Ohio, and works with its member hospitals across the state to improve the quality, safety, and affordability of health care for all Ohioans. The OHA's mission is to collaborate with member hospitals and health systems to ensure a healthy Ohio.

The Oregon Association of Hospitals and Health Systems (OAHHS), founded in 1934, is a statewide, nonprofit trade association that works closely with local and national government leaders, business and citizen coalitions, and other professional health care organizations to enhance and promote community health and to continue improving Oregon's innovative health care community. Representing all 62 hospitals in Oregon, OAHHS provides leadership in health policy, advocacy, and comprehensive member services that strengthen the quality, viability, and capacity of Oregon hospitals to best serve their communities. Of the 62 hospitals in Oregon, 34 participate in the 340B Program, and have benefitted from over $300 million in savings from the program.

The Hospital and Healthsystem Association of Pennsylvania (HAP) is a statewide membership services organization that advocates for nearly 240 Pennsylvania acute and specialty care, primary care, subacute care, long-term care, home health, and hospice providers, as well as the patients and communities they serve. Thirty-four of HAP's members will be impacted by 340B cuts. HAP estimates that the direct impact will be between $80 and $100 million.

The South Dakota Association of Healthcare Organizations (SDAHO) is the professional/trade association representing and serving health care organizations across the state in advancing health communities. The association has a not-for-profit mission and is funded principally through membership dues. Membership spans various types of category, geographic location, size and complexity of services and includes 54 hospitals, 3 health care systems, 32 nursing facilities, home health agencies, assisted living centers, and hospice organizations. The two largest health systems in the state will be impacted by the loss of 340B savings with an estimated loss of nearly $12 million.

Tennessee Hospital Association (THA) was established in 1938 as a not-for-profit membership association to serve as an advocate for hospitals, health systems, and other health care organizations and the patients they serve. The Association also provides education and information for its members, and informs the public about hospitals and health care issues at the state and national levels. THA serves a region of eight counties in southern Tennessee. THA's members include three hospitals, a comprehensive cancer center, home health services, and

many primary care and specialty clinics. Two of THA's member hospitals are 340B hospitals, and THA estimates that the rule would have a negative impact of $800,000.

The Texas Hospital Association (THA) is a non-profit trade association representing Texas hospitals. THA advocates for legislative, regulatory, and judicial means to obtain accessible, cost-effective, high-quality health care. THA opposes reductions to 340B Program reimbursement that increase costs for uninsured or low-income patients and reduce hospitals' ability to provide expanded services to patients. THA estimates that 51 of its hospitals will be impacted by the loss of 340B savings with an estimated loss of over $40 million.

The Virginia Hospital & Healthcare Association (VHHA) was formed in 1926 as a non-profit trade association. The VHHA acts as representative and advocate for policy issues affecting the delivery, quality, accessibility, and cost effectiveness of health care in Virginia. The VHHA recommends goals for state health policies and promotes initiatives to help achieve those goals and works with state and federal regulatory agencies and policy-setting agencies to write new regulations, create policies, and resolve problems on behalf of its members. VHHA currently has 28 member health systems and hospitals, representing 110 community, psychiatric, rehabilitation, and specialty hospitals throughout Virginia. VHHA's member hospitals and health systems provide services across the care continuum, including, but not limited to, inpatient, outpatient, rehabilitation, psychiatric, long-term care, home care, and hospice services. VHHA estimates that roughly half of its hospitals will be impacted by the loss of 340B savings, with estimated losses of more than $45 million.

The West Virginia Hospital Association (WVHA) is a not-for-profit statewide organization representing 63 hospitals and health systems across the continuum of care. The WVHA supports its members in achieving a strong, healthy West Virginia by providing leadership in health care advocacy, education, information, and technical assistance, and by being a catalyst for effective change through collaboration, consensus building, and a focus on desired outcomes. Eleven of WVHA's hospitals will be impacted by the loss of 340B savings, with an estimated loss of more than $16 million.

The Wisconsin Hospital Association (WHA) is a statewide non-profit association with a membership of more than 130 Wisconsin hospitals and health systems. For nearly 100 years, the Wisconsin Hospital Association has advocated for the ability of its members to lead in the provision of high-quality, affordable, and accessible health care services, resulting in healthier Wisconsin communities. Wisconsin has 16 340B covered entity members. WHA estimates a financial impact of $40 million from the 340B cuts.