IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ALBANY MED HEALTH SYSTEM
43 New Scotland Avenue
Albany, NY 12208

ALBANY MEDICAL CENTER HOSPITAL
43 New Scotland Avenue
Albany, NY 12208

COLUMBIA MEMORIAL HOSPITAL
71 Prospect Avenue
Hudson, NY 12534

GLENS FALLS HOSPITAL
100 Park Street
Glens Falls, NY 12801

BRONSON HEALTH CARE GROUP, INC.
301 John Street
Kalamazoo, MI 49006

BRONSON LAKEVIEW HOSPITAL
408 Hazen Street
Paw Paw, MI 49079

BRONSON METHODIST HOSPITAL
601 John Street
Kalamazoo, MI 49007

BRONSON BATTLE CREEK HOSPITAL
300 North Avenue
Battle Creek, MI 49017

CITY OF HOPE NATIONAL MEDICAL CENTER
1500 East Duarte Road
Duarte, CA 91010

FRANCISCAN ALLIANCE, INC.
1515 W Dragoon Trail
Mishawaka, IN 46544

Civ. No. 1:23-cv-3252

FRANCISCAN ALLIANCE, INC.
d.b.a. FRANCISCAN HEALTH OLYMPIA FIELDS & CHICAGO HEIGHTS
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d.b.a. FRANCISCAN HEALTH LAFAYETTE
1701 South Creasy Lane
Lafayette, IN 47905

FRANCISCAN ALLIANCE, INC.
d.b.a. FRANCISCAN HEALTH INDIANAPOLIS
8111 South Emerson Avenue
Indianapolis, IN 46237

FRANCISCAN ALLIANCE, INC.
d.b.a. FRANCISCAN HEALTH DYER
24 Joliet Street
Dyer, IN 46311

FRANCISCAN HEALTH RENSSELAER, INC.
d.b.a. FRANCISCAN HEALTH RENSSELAER
1104 East Grace Street
Rensselaer, IN 47978

HENDRICK MEDICAL CENTER
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Abilene, TX 79601

HENDRICK MEDICAL CENTER BROWNWOOD
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Brownwood, TX 76801

KECK MEDICINE OF USC
1500 San Pablo Street
Los Angeles, CA 90033

KECK MEDICAL CENTER OF USC
1510 San Pablo Street, #600
Los Angeles, CA 90033

USC ARCADIA HOSPITAL
300 W. Huntington Drive
Arcadia, CA 91007

MERCY HEALTH
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Chesterfield, MO 63017

NORTHWEST MEDICAL CENTER ASSOCIATION
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405 N College Street
Albany, MO 64402

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Maryville, MO 64468

HEARTLAND REGIONAL MEDICAL CENTER
d.b.a. MOSAIC LIFE CARE
5325 Faraon Street
St. Joseph, MO 64506

NORTHWESTERN MEMORIAL HOSPITAL
251 East Huron Street
Chicago, IL 60611

VALLEY WEST COMMUNITY HOSPITAL
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Sandwich, IL 60548

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Philadelphia, PA 19104

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PENNSYLVANIA HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM
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UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM
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THE LANCASTER GENERAL HOSPITAL
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STANFORD HEALTH CARE TRI-VALLEY
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250 W Pratt Street
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CAPITAL REGION HEALTH
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Largo, MD 20774

UNIVERSITY OF MARYLAND
SHORE REGIONAL HEALTH
219 S Washington Street
Easton, MD 21601

YALE NEW HAVEN HEALTH
SERVICES CORPORATION
789 Howard Avenue
New Haven, CT 06519

BRIDGEPORT HOSPITAL
267 Grant Street
Bridgeport, CT 06610

YALE NEW HAVEN HOSPITAL, INC.
20 York Street
New Haven, CT 06510

and

LAWRENCE + MEMORIAL HOSPITAL
365 Montauk Avenue
New London, CT 06320

Plaintiffs,

v.

HEALTH RESOURCES AND SERVICES
ADMINISTRATION
5600 Fishers Lane
Rockville, MD 20857

CAROLE JOHNSON
in her official capacity as
ADMINISTRATOR, HEALTH RESOURCES AND SER-
VICES ADMINISTRATION
5600 Fishers Lane
Rockville, MD 20857

UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES
200 Independence Avenue SW
Washington, DC 20201

and

XAVIER BECERRA,
in his official capacity as SECRETARY,
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue SW
Washington, DC 20201

Defendants.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs bring this complaint against Defendants the Health Resources and Services Administration (HRSA), Carole Johnson, in her official capacity as Administrator of HRSA, the Department of Health and Human Services (HHS), and Xavier Becerra, in his official capacity as Secretary of HHS, and allege as follows:

INTRODUCTION

1. This lawsuit seeks declaratory and injunctive relief from HRSA's recent adoption of a legislative rule that will substantially injure 340B covered-entity healthcare organizations—"dominantly, local facilities that provide medical care for the poor" (*Astra USA, Inc. v. Santa Clara County, Cal.*, 563 U.S. 110, 115 (2011))—by causing them to wait roughly 8 to 23 months before new, outpatient, offsite facilities owned and operated by the entity are eligible for discounts as part of the federal 340B program. HRSA's new rule is costing covered entities hundreds of millions of dollars—and if left unchecked, the losses will quickly be measured by the billions.

2. HRSA's rule—which is an abrupt about-face from its former policy—fails to comply with the APA's requirement of notice-and-comment rulemaking, exceeds HRSA's authority, conflicts with the statutory language, and is arbitrary and capricious several times over.

3. Every year, 340B covered-entity healthcare organizations provide collectively billions of dollars in uncompensated, undercompensated, and charitable care to their communities. Many of these organizations "serv[ing] low-income or rural communities" represent the only viable source of quality healthcare for geographically dispersed populations. *Am. Hospital Ass'n v. Becerra*, 142 S. Ct. 1896, 1899 (2022). These healthcare entities also provide valuable community

services, including healthcare education and free health screenings to build healthier communities. Such healthcare organizations play a critical role in the nation's healthcare safety net, but do so at great financial cost.

4. In 2017, 340B covered-entity hospitals provided more than $64 billion in total benefits to their communities, including uncompensated and charitable care. *340B Hospital Community Benefit Analysis*, Am. Hosp. Ass'n 2 (Sept. 2020), perma.cc/EQX8-67FY. By 2019, that figure rose to nearly $68 billion, accounting for more than 13% of the 340B hospitals' total expenses. *340B Hospital Community Benefit Analysis*, Am. Hosp. Ass'n 2 (June 2022), perma.cc/JZZ2-7DY2.

5. Congress enacted the 340B program to help these organizations "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384, pt. 2, at 12 (1992). The 340B program allows "covered entities" to purchase drugs from manufacturers at a discounted price. *Astra USA,* 563 U.S. at 115. These discounts are limited to drugs dispensed to outpatients of the covered entity.

6. In order to provide high-quality, often specialized or high acuity healthcare in the location most convenient to patients, many hospital covered entities offer care through outpatient facilities separate from their main hospital campuses, which are nonetheless part of the same hospital covered entity as defined in the 340B statute.

7. For example, some hospital covered entities operate off-campus infusion centers at which their long-term patients may receive infusion therapies, including chemotherapy. A cancer patient may be diagnosed and provided ongoing care at a covered entity's main facility, but the patient's treatment will involve frequent, time-consuming infusions of specialized drugs. To improve and expand patient access to such services, including in locations closer to patients' homes and workplaces, many hospital covered entities have established off-campus infusion centers for these patients' ongoing care needs. There are many other examples where covered entities establish off-campus facilities to provide specialized or localized care.

8. These off-campus hospital outpatient facilities are known as child sites. *See* "Child Site," *340B Glossary*, HRSA, perma.cc/8KMF-WRM2.

9. Section 340B defines several categories of "hospital[s]" eligible to participate in the program as covered entities. 42 U.S.C. § 256b(a)(4). Since at least 1994, HRSA has recognized that "hospitals offer outpatient services in off-site or satellite outpatient facilities." 59 Fed. Reg. 47,885 (Sept. 19, 1994). When a "facility is a component of a hospital" and that hospital is eligible to participate in the 340B program, the facility is eligible as well. *Id.*

10. Under the 340B statute, a covered entity may sell or transfer 340B drugs to "patient[s] of the [covered] entity." 42 U.S.C. § 256b(a)(5)(B). The key question here is whether patients seen at a child site of a covered entity are "patients of the covered entity" so that 340B drugs may be used at the child site. HRSA itself has centered this inquiry on whether the covered entity remains "responsib[le] for the care provided"—*i.e.*, when "the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care" and the patient "receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements." 61 Fed. Reg. 55,156, 55,157 (Oct. 24, 1996).

11. In 1994, HRSA took the position that patients seen at a child site of a covered entity are patients of the covered entity, and are thus eligible for 340B drugs, only if the child site appears on the most recently filed Medicare cost report for a covered entity. This creates an enormous practical problem for covered entities: Because of the periodic nature of Medicare cost reports, it will generally take about 5 to 17 months from the opening of a child site for that site to make its first appearance on a filed Medicare cost report. Additionally, HRSA only accepts registrations of new child sites on a quarterly basis, with effective dates 3 months after applications are filed, meaning that the delay can reach up to 6 months more. Thus, under HRSA's 1994 policy, child sites of 340B covered entities were ineligible to participate in the 340B program for roughly their first 8 to 23 months of operation—or potentially even longer.

12. This HRSA policy was, at that time, consciously consistent with CMS's contemporaneous approach to a similar question in the Medicare context. CMS had established criteria to determine whether the equivalent of a parent-child site relationship existed for Medicare purposes; locations that satisfied those criteria could be listed on a hospital's Medicare cost report and, after listing, receive reimbursement for their costs and expenses.

13. Over the intervening decades, however, CMS changed its approach. In 2000, responding to changes in the reimbursement mechanism for outpatient services, CMS issued a rule requiring outpatient locations to obtain permission from the agency before becoming eligible for Medicare reimbursements. But just one year later, it reversed course: CMS updated the criteria for a facility to be deemed an integral part of a covered entity (known as the "provider-based rules") and recognized that an outpatient facility is part of a hospital as soon as these criteria were satisfied. CMS concluded that there was no reason to require these entities to wait—up to 17 months—to be included on a cost report before they could be properly treated as components of the hospital for Medicare purposes. The advance application requirement simply "increase[d] paperwork burden for hospitals unnecessarily." 67 Fed. Reg. 49,982, 50,084-85 (Aug. 1, 2002).

14. Despite the fact that HRSA's approach had been left behind by the rest of the Medicare program, HRSA continued to require a child site to be listed on a Medicare cost report before HRSA would consider it part of the hospital and eligible to access and use 340B drugs.

15. In 2020, during the COVID-19 Public Health Emergency, HRSA changed course. HRSA finally announced that, "for hospitals who are unable to register their outpatient facilities because they are not yet on the most recently filed Medicare Cost Report, the patients of the new site may still be 340B eligible to the extent that they are patients of the covered entity." Ex. A. This policy—which, as shown below, is required by the text of the 340B statute—allowed child sites to be eligible for 340B drugs as soon as the relevant criteria were satisfied. It did away with the artificial waiting period required by the Medicare cost-report approach.

16. HRSA did not present this new position as a temporary policy. To the contrary, HRSA confirmed that its policy would continue independent of the Public Health Emergency.

Tom Mirga, *Exclusive: HRSA Confirms 340B Hospital Offsite Location and Telehealth Flexibilities are Permanent*, 340B Report (June 9, 2020), perma.cc/U934-U7UX.

17. Nonetheless, just before the Public Health Emergency was scheduled to end, HRSA suddenly announced—through emails and modifications to its website—a return to its earlier policy of requiring child sites to appear on Medicare cost reports before covered entities could receive 340B discounts for outpatient drugs related to encounters at those facilities.

18. On October 26, 2023, the Department of Health and Human Services (HHS) filed a Notice in the Federal Register formalizing its reimplementation of the child-site limitation, which was published in the Federal Register on October 27, 2023. Ex. B. In the Notice, HHS explained that HRSA had "determined that there is a need to verify off-site, outpatient facilities prior to their participation in the 340B program" and it would "require[] submission of the most recently filed Medicare Cost Reports." *Id.* at 2, 3 (88 Fed. Reg. at 73,859-60). HHS explained that it would not enforce this policy during a 90-day "transition period," after which compliance was strictly mandatory. *Id.* at 3 (88 Fed. Reg. at 73,861).

19. HRSA's unexpected return to its prior policy—referred to here as the "child-site limitation"—is enormously costly for covered entities who provide crucial care to underserved and vulnerable populations. As described, the gap between when a facility qualifies as part of a covered entity and when it appears on the covered entity's cost report can be up to 17 months, with another 3 to 6 months until it can be registered with and recognized by HRSA. In the interim, covered entities are forced to forgo millions of dollars in benefits specifically intended by Congress and explicitly provided for by the 340B statute.

20. HRSA's policy is at odds with the governing statute, which provides for distribution of 340B drugs to patients of a covered entity. 42 U.S.C. § 256b(a)(5)(B). HRSA agrees that patients provided care at child sites generally *do* qualify for 340B drugs, confirming that the statute must be understood to include these patients within the category of "patients of a covered entity" as eligible to receive 340B drugs. The further limitation HRSA adopted—precluding use of 340B drugs until a child site appears on a Medicare cost report—has no basis whatsoever in statutory

text. Rather, when a patient visits an outpatient facility that is an integrated component of a covered entity, subject to the same ownership and control as a covered entity, and with an integrated medical staff, there can be no question that the patient is eligible for 340B drugs.

21. HRSA's contrary decision departs from governing law and is also the antithesis of reasoned decision-making. In focusing solely on administrative convenience, HRSA failed to evaluate the enormous injury its action would inflict on covered entity hospitals, and it engaged in no cost-benefit analysis to justify its massive policy shift. It has further failed to provide any reason as to why its approach should depart from that which CMS has taken, despite its earlier conclusion that the two approaches should be harmonized. These, among several other failings, show that HRSA's recent action was arbitrary and capricious.

22. Nor did HRSA properly promulgate the child-site limitation policy. As the Notice makes plain, HRSA has created a new, substantive, binding requirement for covered entities participating in the 340B program. In general, such rules are subject to the APA's notice-and-comment rulemaking requirements; HRSA made no effort to comply here. What is more, as courts in this district have squarely held, HHS lacks authority to promulgate legislative rules concerning the 340B program *altogether*. *Pharm. Rsch. & Mfrs. of Am. v. U.S. DHHS*, 45 F. Supp. 3d 28 (D.D.C. 2014) ("*PhRMA I*"). HHS overstepped its congressionally delegated authority, and its policy announced in the Notice is unlawful for that reason, too.

23. HRSA's unlawful child-site limitation rule is costing not-for-profit hospitals millions of dollars per year. The Court must set this agency action aside.

PARTIES

24. Plaintiff Albany Med Health System is the largest and only regionally governed not-for-profit health system in northeastern New York and western New England. Albany Med is incorporated in New York and headquartered in New York.

25. Plaintiff Albany Medical Center Hospital is a 766-bed hospital offering the widest range of medical and surgical services in the Albany, New York region. Albany Medical Center Hospital is a component of Albany Med.

26. Plaintiff Columbia Memorial Hospital is a hospital and regional health system providing comprehensive primary and specialty care to patients in Columbia and Greene counties in New York. Columbia Memorial Hospital is a component of Albany Med.

27. Plaintiff Glens Falls Hospital is a hospital with a 6,000-mile service area spanning five diverse counties throughout New York. Glens Falls Hospital is a component of Albany Med.

28. Plaintiff Bronson Healthcare is a healthcare system serving patients and families throughout southwest Michigan and northern Indiana. Bronson Healthcare is incorporated in Michigan and headquartered in Michigan.

29. Plaintiff Bronson Lakeview Hospital is a not-for-profit hospital serving the people of Van Buren County since 1939. It is incorporated in Michigan and headquartered in Michigan. Bronson Lakeview Hospital is part of the Bronson Healthcare system.

30. Bronson Methodist Hospital is a regional medical center and children's hospital that serves patients in southwest Michigan. It is incorporated in Michigan and headquartered in Michigan. Bronson Methodist Hospital is part of the Bronson Healthcare system.

31. Bronson Battle Creek Hospital delivers quality care to over 200,000 people in south-central Michigan. It is incorporated in Michigan and headquartered in Michigan. Bronson Battle Creek Hospital is part of the Bronson Healthcare system.

32. Plaintiff Franciscan Alliance provides faith-based, integrated healthcare using the latest technology, innovative procedures, and compassionate staff across Indiana and in Illinois. Franciscan Alliance is incorporated in Indiana and is headquartered in Indiana.

33. Plaintiff Franciscan Alliance (d.b.a. Franciscan Health Olympia Fields & Chicago Heights) is a hospital serving patients in Illinois's far south suburban region. It is a component of Franciscan Alliance.

34. Plaintiff Franciscan Alliance (d.b.a. Franciscan Health Michigan City) is a 123-bed hospital providing robust inpatient and outpatient services in Michigan City, Indiana. Franciscan Health Michigan City is a component of Franciscan Alliance.

35. Plaintiff Franciscan Alliance (d.b.a. Franciscan Health Lafayette) is a unique, state-of-the-art hospital located in Lafayette, Indiana. Franciscan Health Lafayette is a component of Franciscan Alliance.

36. Plaintiff Franciscan Alliance (d.b.a. Franciscan Health Indianapolis) is a hospital located on the south side of Indianapolis that provides top-tier inpatient and outpatient care to its patients. Franciscan Health Indianapolis is a component of Franciscan Alliance.

37. Plaintiff Franciscan Alliance (d.b.a. Franciscan Health Dyer) is one of the largest acute-care hospitals in Northwest Indiana. It is a component of Franciscan Alliance.

38. Plaintiff Franciscan Health Rensselaer, Inc. (d.b.a. Franciscan Health Rensselaer) is a large, full-service hospital system located in Rensselaer, Indiana. Franciscan Health Rennselaer is a wholly owned component of Franciscan Alliance.

39. Plaintiff Hendrick Medical Center is a not-for-profit, faith-based healthcare organization providing a wide range of comprehensive healthcare services to the Texas Midwest. Hendrick Medical Center is incorporated in Texas and is headquartered in Texas.

40. Plaintiff Hendrick Medical Center Brownwood is a 188-bed acute care facility providing competent and compassionate care in the Central Texas area. It is incorporated in Texas and headquartered in Texas. Hendrick Medical Center Brownwood is a component of Hendrick Medical Center.

41. Plaintiff Stanford Health Care is part of the adult health care delivery system of Stanford Medicine. It is incorporated in California and headquartered in California.

42. Plaintiff Stanford Health Care Tri-Valley is a hospital providing high-quality care rooted in science and compassion to support the health and well-being of its community in the East Bay and beyond. It is incorporated in California and headquartered in California. Stanford Health Care Tri-Valley is registered with HRSA under its former name, Valley Memorial Hospital. Stanford Health Care Tri-Valley is a component of Stanford Medicine's adult health care delivery system.

43. Plaintiff Trustees of the University of Pennsylvania, on behalf of its operating division, the University of Pennsylvania Health System (UPHS), is a nationally recognized hospital system that has been providing the highest quality patient care, education, and research for more than two centuries. UPHS is incorporated in Pennsylvania and headquartered in Pennsylvania.

44. Plaintiff Hospital of the University of Pennsylvania is world-renowned for its clinical and research excellence. It is incorporated in Pennsylvania and headquartered in Pennsylvania. Hospital of the University of Pennsylvania is a component of UPHS.

45. Plaintiff The Pennsylvania Hospital of the University of Pennsylvania Health System is the nation's first hospital, founded in 1751 by Benjamin Franklin and Dr. Thomas Bond. It is incorporated in Pennsylvania and headquartered in Pennsylvania. Pennsylvania Hospital is a component of UPHS.

46. Plaintiff Presbyterian Medical Center of the University of Pennsylvania Health System (d.b.a. Penn Presbyterian Medical Center) is a regional leader in providing cutting-edge care in Pennsylvania. It is incorporated in Pennsylvania and headquartered in Pennsylvania. Penn Presbyterian Medical Center is a component of UPHS.

47. Plaintiff The Lancaster General Hospital is a 525-bed, not-for-profit hospital located in Lancaster City, Pennsylvania. It is incorporated in Pennsylvania and headquartered in Pennsylvania. Lancaster General is a component of UPHS.

48. Plaintiff Mercy Health is a non-profit Catholic organization and is the nineteenth largest healthcare system in the U.S. with hospitals, physician clinics, telehealth services, outpatient facilities, outreach ministries, and other health and human services primarily in Missouri, Oklahoma, Arkansas and Kansas. Mercy Health is incorporated and headquartered in Missouri.

49. Plaintiff Mosaic Life Care is a physician-led healthcare system serving 35 counties in northwest Missouri, northeast Kansas, southeast Nebraska, and southwest Iowa. Mosaic Life Care is incorporated in Missouri and headquartered in Missouri. Mosaic Life Care includes the Heartland Regional Medical Center (d.b.a. Mosaic Life Care) located in St. Joseph, Missouri.

Heartland Regional Medical Center is a 352-bed hospital with a Level II Trauma Center and a Level II Stroke Center.

50. Plaintiff Northwest Medical Center Association (d.b.a. Mosaic Medical Center – Albany) is a 25-bed Critical Access Hospital located in Albany, Missouri. Mosaic Medical Center – Albany is headquartered and incorporated in Missouri. It is a component of the Mosaic Life Care health system.

51. Plaintiff Mosaic Medical Center Maryville is an 81-bed hospital with a Level III Stroke Center located in Maryville, Missouri. Mosaic Medical Center Maryville is headquartered and incorporated in Missouri. It is a component of the Mosaic Life Care health system.

52. Plaintiff University of Maryland Medical System (UMMS) is a private, university-based regional health system focused on serving the health care needs of Maryland. UMMS is incorporated in Maryland and headquartered in Maryland.

53. Plaintiff University of Maryland Medical Center Downtown Campus is a 789-bed hospital located in downtown Baltimore, Maryland, striving to make a difference in West Baltimore and beyond by working with community partners to promote health and wellness for all ages. The Downtown campus is part of the University of Maryland Medical Center, which is the flagship academic medical center at the heart of UMMS. University of Maryland Medical Center Downtown Campus is a component of UMMS.

54. Plaintiff University of Maryland Medical Center Midtown Campus is a 177-bed hospital located in Midtown, Baltimore. The Midtown campus is part of the University of Maryland Medical Center, which is the flagship academic medical center at the heart of UMMS. University of Maryland Medical Center Midtown Campus is a component of UMMS.

55. Plaintiff University of Maryland Rehabilitation and Orthopaedic Institute is a leading comprehensive orthopedic rehabilitation center in Maryland. It is a component of UMMS.

56. Plaintiff University of Maryland Capital Region Health is a hospital serving patients in Prince George's County, Maryland. It is a component of UMMS.

57. Plaintiff University of Maryland Shore Regional Health is a regional, nonprofit, medical delivery care network comprising two hospitals serving patients in the Mid-Shore region of Maryland. University of Maryland Shore Regional Health is a component of UMMS.

58. Plaintiff Keck Medicine of USC is the medical enterprise of the University of Southern California, combining academic excellence, world-class research, and state-of-the-art facilities to provide highly specialized care for patients in California. Keck Medicine is incorporated in California and headquartered in California.

59. Plaintiff Keck Medical Center of USC is a component of Keck Medicine of USC, which itself comprises two 340B covered entities. USC Kenneth Norris Jr. Cancer Hospital, located in Los Angeles, is a major regional and national resource for cancer research, treatment, prevention, education, and community engagement. Keck Hospital of USC is a 401-bed acute care hospital at which internationally renowned physicians care for patients, teach, and conduct research at the Keck School of Medicine of USC, the region's first medical school. Keck Medical Center of USC is incorporated in California and headquartered in California.

60. Plaintiff USC Arcadia Hospital is a full-service hospital with 348 beds founded in one of the busiest parts of the country. USC Arcadia Hospital is incorporated in California and headquartered in California. USC Arcadia Hospital is a component of Keck Medicine.

61. Plaintiff City of Hope National Medical Center is part of a non-profit nationwide cancer treatment system with locations in California, Arizona, Illinois, and Georgia. City of Hope is one of only 56 National Cancer Institute (NCI) designated comprehensive cancer centers. City of Hope is recognized for its world-class hematology and bone marrow transplant programs, clinical trials, and advanced precision medicine and cellular therapies. City of Hope is incorporated in California and headquartered in California.

62. Plaintiff Northwestern Memorial Hospital is an academic medical center providing world-class patient care in Chicago, Illinois. It is an Illinois not-for-profit corporation doing business in Illinois.

63. Plaintiff Northwestern Medicine Valley West Community Hospital is an Illinois not-for-profit hospital doing business in Illinois.

64. Plaintiff Yale New Haven Health is Connecticut's leading healthcare system, providing comprehensive and integrated care in more than 100 medical specialties. Yale New Haven Health is incorporated in Connecticut and headquartered in Connecticut.

65. Plaintiff Bridgeport Hospital is a not-for-profit general medical and surgical hospital located in Bridgeport, Connecticut. It is incorporated and headquartered in Connecticut. Bridgeport Hospital is a member of Yale New Haven Health.

66. Plaintiff Yale New Haven Hospital, Inc. is a nationally-ranked 1,541-bed hospital located in New Haven, Connecticut. It is incorporated and headquartered in Connecticut. Yale New Haven Hospital, Inc. is a member of Yale New Haven Health.

67. Plaintiff Lawrence + Memorial Hospital is a hospital located in New London, Connecticut. It is incorporated and headquartered in Connecticut. Lawrence + Memorial Hospital is a member of Yale New Haven Health.

68. Defendant Health Resources and Services Administration (HRSA) is an agency of the United States and a division of the United States Department of Health and Human Services (HHS). HRSA is the principal agency responsible for administration of the 340B program. Its headquarters and principal place of business are in Maryland.

69. Defendant Carole Johnson is the Administrator of the Health Resources and Services Administration. The Administrator maintains an office at 5600 Fishers Lane, Rockville, Maryland 20857. She is sued in her official capacity only.

70. Defendant HHS is a cabinet-level executive department charged with enhancing the health and wellbeing of all Americans. HHS is headquartered and maintains its principal place of business in Washington, D.C.

71. Defendant Xavier Becerra is the Secretary of Health and Human Services. The Secretary maintains an office at 200 Independence Avenue SW, Washington, D.C. 20201. He is sued in his official capacity only.

JURISDICTION AND VENUE

72. Plaintiffs bring this suit under the Administrative Procedure Act, 5 U.S.C. §§ 551 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. § 2201.

73. HRSA's reversion to its earlier interpretation of the 340B statute is "final agency action for which there is no other adequate remedy." 5 U.S.C. § 704.

74. This case arises under the laws of the United States. The court's jurisdiction is thus invoked under 28 U.S.C. § 1331.

75. Venue is proper in this district under 28 U.S.C. § 1391(e) because at least one defendant resides in this district and a substantial part of the events or omissions giving rise to the claim occurred in this district.

FACTUAL ALLEGATIONS

A. The 340B Program

76. "The federal government is the largest purchaser of prescription drugs in the United States." *Prescription Drugs*, Cong. Budget Off. (accessed Aug. 21, 2023), perma.cc/MH42-SAAN. The United States pays for drugs in part through federal programs such as Medicaid and Medicare Part B. *Id.* While the United States is responsible for a significant amount of overall drug spending, manufacturer participation in Medicare and Medicaid is voluntary.

77. To obtain payment under these programs, "a manufacturer must enter a standardized agreement with" HHS in which the manufacturer "undertakes to provide rebates to States on their Medicaid drug purchases." *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 114 (2011).

78. In 1992, Congress enacted Section 340B of the Veterans Health Care Act, codified at 42 U.S.C. § 256b, which, as amended, requires manufacturers to "offer discounted drugs to covered entities" to be eligible for participation in (*i.e.,* reimbursement from) Medicaid and Medicare Part B. *Astra USA*, 563 U.S. at 115. Congress created the 340B program to provide "protection from drug price increases to specified Federally-funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans." H.R. Rep. No. 102-384, pt. 2, at 12 (1992).

79. Congress intended the 340B program to allow covered entities to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384, pt. 2, at 12 (1992); *accord* Office of the General Counsel, *Advisory Opinion 20-06: On Contract Pharmacies Under the 340B Program*, at 3 (Dec. 30, 2020), perma.cc/WU65-S48S.

80. Section 340B states that manufacturers wishing to profit from the Medicaid and Medicare Part B programs "shall enter into an agreement" with the Secretary of Health and Human Services "under which the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . purchased by a covered entity . . . does not exceed" a specified ceiling price. 42 U.S.C. § 256b(a)(1). These Pharmaceutical Pricing Agreements (PPAs) must "require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." *Id.*

81. Section 340B defines covered entities to include (among others) black lung clinics, certain children's hospitals and standalone cancer hospitals, critical access hospitals, rural referral centers, and other federally funded health centers. 42 U.S.C. § 256b(a)(4). Covered entities are "dominantly, local facilities that provide medical care for the poor." *Astra USA*, 563 U.S. at 115; *accord Am Hospital Ass'n v. Becerra*, 142 S. Ct. 1896, 1899 (2022) ("Section 340B hospitals . . . generally serve low-income or rural communities.").

82. The 340B statute's definition of "covered entity" relies heavily on Sections 1820 and 1886 of the Social Security Act, which concern the Medicare program. Disproportionate Share Hospitals (DSHs), for example, are "subsection (d) hospital[s] (as defined in section 1886(d)(1)(B) of the Social Security Act)" that "provide health care services to low income individuals" and have "a disproportionate share adjustment percentage (as determined under Section 1886(d)(5)(F) of the Social Security Act) greater than 11.75 percent." 42 U.S.C. § 256b(a)(4)(L). The definitions of "critical access hospital," "rural referral center," "cancer hospital," and "children's hospital" are lifted directly from the Social Security Act. *Id.* § 256(a)(4)(M)-(O).

B. HRSA's Shifting Approach to Child Sites

83. Since at least 1994, HRSA has recognized that some 340B "hospitals offer outpatient services in off-site or satellite outpatient facilities." *Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Outpatient Hospital Facilities*, 59 Fed. Reg. 47,884 (Sept. 19, 1994) ("1994 Policy"). These offsite facilities are known as "child sites."

84. In the 1994 Policy, HRSA explained that Section 340B "does not include any limitations on outpatient settings, and there is no requirement that [a] covered drug be used in a 'traditional' outpatient setting." *Id.* at 47,885. Because "the movement of nonprofit hospitals in recent years has been to reorganize and offer a variety of services, other than traditional inpatient hospital services, through separate divisions, lines of business, or entities," HRSA concluded that "for purposes of Section 340B drug discounts, a further interpretation of 'hospital' [was] needed" to ensure the availability of 340B pricing at child sites. *Id.*

85. Because "Congress referred to" the Social Security Act "for the definition of" covered entities, HRSA has concluded that "it is reasonable to utilize existing Medicare rules to determine eligibility for [340B] discount pricing." *Id.*[1] On a high level, the 1994 Policy allowed for 340B discount pricing at any outstanding facility that "is an integral part of a [340B] hospital." *Id.* Such facilities were required to satisfy a number of criteria furnished by the Medicare rules:

> (a) all components subject to the control and direction of one common owner (i.e., governing body) which is responsible for the operational decisions of the entire hospital enterprise; (b) one chief medical officer who reports directly to the governing body and who is responsible for all medical staff activities of all components; (c) integration of the organized medical staff (e.g., all medical staff members having privileges at all components); and (d) one chief executive officer through whom all administrative authority flows and who exercises control and surveillance over all administrative activities of all components.

Id.

[1] The 1994 Policy discussed only DSH facilities, because those were the only 340B "covered entities" at the time. Additional eligible hospital types were added pursuant to statutory changes to the 340B statute in 2010. Patient Protection and Affordable Care Act, Pub. L. No. 111-148 § 7101, 124 Stat. 119, 821 (2010).

86. HRSA, though, went beyond this functional test in its 1994 Policy: "The outpatient facility is considered an integral part of the 'hospital' and therefore eligible for section 340B drug discounts if it is a reimbursable facility included on the hospital's Medicare cost report." *Id.* at 47,886. "Only outpatient facilities which are an integral component of the [covered entity] will be included on the . . . Medicare cost report, and only those facilities will be eligible for [340B] discount pricing." *Id.* at 47,885.

87. The 1994 Policy was intended to harmonize the treatment of child sites between HRSA and the Healthcare Financing Administration (HCFA)—the predecessor agency to today's CMS. *See id.* ("We have attempted to define [covered entity] in a manner consistent with HCFA policy guidelines (Provider Certification, State Operation Manual, section 2024)."). Both in 1994 and today, Section 2024 of the Medicare State Operations Manual provided instructions for "[w]hen two or more hospitals merge" and "when a hospital establishes an additional hospital facility, geographically separate but in the same metropolitan area." CMS, *State Operations Manual* (HCFA-Pub. 7) § 2024 (Mar. 11, 2022), perma.cc/3588-LZFY ("2022 State Operations Manual"); *accord* HCFA, *State Operations Manual* (HCFA-Pub. 7) § 2024 (Jan. 1, 1991), Ex. C.

88. The current version of Section 2024 of the *State Operations Manual* does not contain its own criteria for when two facilities should be considered part of the same hospital for certification purposes. 2022 *State Operations Manual* § 2024. Instead, it adopts criteria set out in Section 2004. Section 2004 explains that, "[w]hen a location, department, remote location or satellite is established as being provider-based, it is an integral part of the provider, covered by the provider's Medicare agreement, and therefore subject to the same Medicare conditions of participation as any other part of that provider." 2022 *State Operations Manual* § 2004. Provider-based status, in turn, is defined in considerable detail by HHS regulations. 42 C.F.R. § 413.65. In essence, a "[p]rovider-based entity" is one "created by, or acquired by, a main provider for the purpose of furnishing health care services of a different type from those of the main provider under the ownership and administrative and financial control of the main provider." *Id.* § 413.65(a)(2).

89. HCFA (now CMS) has recognized that "main providers" have "owned and operated other facilities . . . that were administered financially and clinically by the main provider" since "the beginning of the Medicare program." 65 Fed. Reg. 18,443, 18,504 (Apr. 7, 2000). When it adopted the provider-based rule in 2000, HCFA provided that, to the extent overhead costs of the main provider were shared by a subsidiary facility, these costs could flow to the subordinate facility through the cost allocation process in the main provider's cost report. *Id.* In order to qualify for provider-based status, HCFA required that: (1) "a facility or organization be under the ownership and control of the main provider;" (2) "a facility or organization . . . have a reporting relationship to the main provider that is characterized by the same frequency, intensity, and level of accountability that exists in the relationship between the main provider and one if its departments;" (3) the organization and the main provider "share integrated clinical services;" (4) "the department or entity and the main provider be fully financially integrated within the main provider's financial system;" (5) "the main provider and the facility . . . be held out to the public as a single entity;" and (6) the main and provider-based facility be located on the same campus or serve the same patient population. *Id.* at 18,504-05, 18,516.

90. For a brief period, HCFA required that a facility "would have to contact HCFA and obtain an affirmative provider-based determination before billing of the facility's or organization's costs through the main provider, or inclusion of those costs on the main provider's cost report, is initiated." *Id.* at 18,504. That restriction was removed the next year, allowing outpatient hospital locations to again bill as part of a main hospital as soon as they met the provider-based requirements. 67 Fed. Reg. 49,982, 50,084-85 (Aug. 1, 2002).

91. CMS regulations defining the provider-based relationship require that a facility be open and be in operation before it can qualify as provider-based. *See generally* 42 C.F.R. § 413.65. Once a facility opens and meets the criteria to be provider-based to a hospital covered entity, the covered entity is eligible to bill Medicare for services provided at the facility as hospital services and report the corresponding costs and charges on the hospital's Medicare cost report.

92. To obtain reimbursement from Medicare, hospital covered entities must file annual cost reports. 42 C.F.R. § 413.20(b). The reporting period for each cost report is the hospital covered entity's most recent fiscal year. *Id.*

93. Hospital covered entities must submit their cost reports within five months of the end of their fiscal year. 42 C.F.R. § 413.24(f)(2)(i). A new child site opened on the first day of a hospital's fiscal year would thus not appear on a cost report for a minimum of 12 months, and most likely not for 17 months until the organization files its cost report on the due date.

94. Once a location appears on a cost report, HRSA requires covered entities to register the child site with HRSA before it is eligible to participate in and purchase discounted drugs as part of the 340B program. *Registration*, HRSA (June 2022), perma.cc/Q4PJ-J7M5. HRSA "limit[s] the registration period for . . . the addition of outpatient facilities" to four two-week periods per year. *Id.* For each period, the registration has an effective date of three months after an organization submits the registration. *Id.*

95. The result of HRSA's system is that a new child site must typically wait at least 8 months, and potentially as long as 23 months, before it can benefit from the 340B discounts to which it is statutorily entitled.

96. There is thus a significant gap between when CMS considers a facility to be provider-based, and thus to be an integral component of a hospital, and when HRSA acknowledges the existence of such a relationship, even though the child site is unquestionably a component of the hospital as soon as it meets the provider-based criteria. CMS recognizes that facilities will meet the test to qualify for reporting on a single cost report long before they appear on a cost report. CMS states that a facility "is an integral part of the provider" whenever it "is established as being provider based" (*State Operations Manual* § 2004); HRSA, by contrast, requires that the facility be provider-based *and* that it appear on a Medicare cost report in order to be considered a child site of a hospital covered entity.

97. In 1996, HRSA published another "final notice" to define the term "patient" of a covered entity under the 340B statute. 61 Fed. Reg. 55,156 (Oct. 24, 1996). HRSA considers an individual a patient of a covered entity only if:

> 1. the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and
>
> 2. the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements . . . such that responsibility for the care provided remains with the covered entity.

Id. at 55,157-58.[2]

98. HRSA intended that this definition be "flexible enough to describe accurately each covered entity's patient while at the same time not excluding eligible patients." *Id.* at 55,157; *accord* Letter from Brian J. Springer to Patricia S. Connor, Clerk of Court, ECF No. 45, *Genesis HealthCare v. Becerra*, No. 20-1701 (4th Cir. Mar. 25, 2022).

99. HRSA maintained its position on child sites up until 2020. On June 6, 2020, HRSA published "COVID-19 Resources" on its websites which included the following "frequently asked question" and response:

> **Are hospital covered entities able to register offsite, outpatient facilities before being listed as reimbursable on their Medicare Cost Report?**
>
> In order to register for the 340B Program and be listed on the 340B Office of Pharmacy Affairs Information System (340B OPAIS), HRSA must first verify that the offsite, outpatient facility is listed as reimbursable on the hospital's most recently filed Medicare cost report and has associated outpatient costs and charges as outlined in HRSA's 1994 Outpatient Hospital Facilities Guidelines.
>
> HRSA notes that for hospitals who are unable to register their outpatient facilities because they are not yet on the most recently filed Medicare Cost Report, the patients of the new site may still be 340B eligible to the extent that they are patients of the covered entity.

[2] HRSA also imposed a third requirement, that "the individual receives a health care service . . . which is consistent with the service . . . for which grant funding . . . has been provided to the entity." 61 Fed. Reg. at 55,157-55,158. This additional requirement, however, is inapplicable to "[d]isproportionate share hospitals." *Id.*

COVID-19 Resources, HRSA (July 4, 2020), https://web.archive.org/web/20200704213709/-https://www.hrsa.gov/opa/covid-19-resources (Ex. A). That is, HRSA's new policy was that "patients of the new site" would "be 340B eligible to the extent they are patients of the covered entity," even before the new site is "listed as reimbursable on the hospital's most recently filed Medicare cost report." *Id.*

100. HRSA did not indicate that this explanation of the interplay between its interpretation of "hospital" and "patients of the covered entity" was restricted to the context of the COVID-19 pandemic. Indeed, while its website noted that the agency would create certain "flexibilities" for use during the Public Health Emergency (PHE), it did not list the offsite outpatient facility policy discussed in the FAQ as one of those flexibilities. *See id.* (identifying allowances for relaxed documentation requirements during the PHE). Nor did HRSA identify this policy as a "waiver" of some preexisting policy.

101. On June 9, 2020, an independent news outlet covering the 340B program quoted a HRSA spokesperson as confirming that "[b]oth of the practices mentioned"—including the change rendering patients of a new child site 340B eligible—"are in place regardless of the COVID-19 pandemic." Tom Mirga, *Exclusive: HRSA Confirms 340B Hospital Offsite Location and Telehealth Flexibilities are Permanent*, 340B Report (June 9, 2020), perma.cc/U934-U7UX.

102. On May 18, 2020, a Vice President of Compliance at Apexus (HRSA's 340B Prime Vendor) confirmed the same understanding. In an email, William von Oehsen, the principal of Powers Pyles Sutter & Verville PC, emailed Katheryne Richardson to confirm whether the new policy was "applicable only during the COVID-19 public health emergency." Letter from William von Oehsen to Carole Johnson (May 12, 2023), perma.cc/5CPE-5JBZ. Dr. Richardson responded that the policy "is applicable regardless of COVID-19." *Id.*; *see also* Tom Mirga, *New Evidence that HRSA in 2020 Declared Permanent a 340B Policy it Abruptly Ended Last Week*, 340B Report (May 16, 2023), perma.cc/87S7-HDA2.

103. On February 9, 2023, HHS published a Fact Sheet addressing the impending termination of the COVID-19 PHE. *Fact Sheet: COVID-19 Public Health Emergency Transition*

Roadmap, HHS (Feb. 9, 2023), perma.cc/EU8V-R4RV. The announcement did not indicate any changes concerning HRSA or the 340B program.

104. On May 8, 2023, an independent news outlet covering the 340B program reported that HRSA had announced that "when the COVID-19 public health emergency ends . . . so too will a nearly three-year old policy clarification that lets hospitals under certain conditions dispense 340B drugs at offsite outpatient clinics not yet registered in the 340B program because they are not yet listed on the hospital's most recently filed Medicare cost report." Tom Mirga, *HRSA Says COVID Flexibility about Dispensing 340B Drugs in Unregistered Hospital Offsite Locations Will End Thursday*, 340B Report (May 8, 2023), perma.cc/C584-5S7S.

105. On May 9, 2023, HRSA sent an email to attorneys at McDermott Will & Emery providing information to share with clients concerning the child-site policy. Ex. D. In relevant part, the email instructed that:

> Regarding the question about sites not yet registered, during the COVID-19 PHE, HRSA understood the evolving impact of the COVID-19 pandemic and implemented additional flexibilities when possible. While HRSA allowed this flexibility during the COVID-19 PHE, HRSA is returning to pre-COVID policy regarding registration of outpatient facilities. Consistent with HRSA's longstanding 1994 Guidelines, an off-site outpatient facility is eligible to be registered in the 340B Program if the outpatient facility is listed as a reimbursable facility on a 340B hospital's most recently filed Medicare cost report and has associated outpatient costs and charges. Hospitals registering outpatient facilities will be asked to enter several figures from Worksheet A and Worksheet C from the latest filed Medicare cost report and the associated trial balance to determine eligibility. For more information on hospital off-site outpatient facility registration requirements, visit Hospital Registration Instructions (PDF). In addition, all other 340B guidance regarding the use of 340B drugs for eligible patients must be met.
>
> HRSA has reviewed this practice and to ensure compliance with program policy, we have determined that we will be returning to pre-COVID policy regarding registration of outpatient facilities. *Beginning May 11, 2023, at 11:59 PM ET, the hospital should stop purchasing and using 340B drugs for that outpatient facility that is not yet registered.* Any eligible 340B accumulations accrued during the COVID-19 PHE timeframe may be carried over with appropriate recordkeeping to the extent that the facilities were eligible. *The outpatient facility may begin purchasing and using 340B drugs once it is a reimbursable facility on the hospital's most recently filed Medicare cost report and registered on the 340B Office of Pharmacy Affairs Information System (340B OPAIS) as a child site.*

Id. (emphases added).

106. HRSA has since removed its "COVID-19 resources" page from its website. In a separate FAQ page, HRSA now states that "[u]nder the final guidelines a facility must be both reimbursable and included in the hospital's most recently filed Medicare cost report." *See FAQs*, HRSA (accessed Oct. 11, 2023) (responding to "May an outpatient facility that is reimbursed by CMS as a provider based facility, but not included on the most recently filed cost report, access 340B Drugs under the final guidance published in 1994?"), perma.cc/5VYL-SGX5.

107. Similarly, the FAQs maintained by Apexus, the 340B Prime Vendor, state that "[a] facility must be both reimbursable and included in the hospital's most recently filed Medicare cost report with associated outpatient costs and charges to access the 340B Program." *FAQs*, Apexus: 340B Prime Vendor Program (Aug. 2, 2022), perma.cc/8YHY-WCQ2.

108. On October 26, 2023, HHS filed a Notice for publication in the Federal Register enshrining its policy flip-flop. The Notice was subsequently published in the Federal Register on October 27, 2023. *Registration Requirements in the 340B Drug Pricing Program*, 88 Fed. Reg. 73,859 (Oct. 27, 2023) (Ex. B).

109. The Notice made clear that "[f]or all hospital types eligible to participate in the 340B program, HRSA requires submission of the most recently filed Medicare Cost Reports." *Id.* at 2 (88 Fed. Reg. at 73,860). The Notice explains that "HRSA requires off-site, outpatient facilities to be registered and listed in OPAIS" to be eligible to participate in the 340B program. *Id.* at 3 (88 Fed. Reg. at 73,861).

110. Acknowledging the abruptness of its departure from a policy which it had assured covered entities would continue after the end of the PHE, HRSA stated that it would "provid[e] a transition period for covered entities to come into compliance." *Id*. HRSA will first allow facilities appearing on a covered entity's most recently filed Medicare cost report to continue using 340B drugs until the next "quarterly registration period" in January 2024, at which point the facility must be registered in OPAIS or "be subject to audit and compliance action." *Id.* at 3-4 (88 Fed. Reg. at 73,861-62). Second, HRSA will allow outpatient facilities opened prior to October 26, 2023, to

continue using 340B drugs if the covered entity provides basic information about the facility to HRSA and registers the facility at the "soonest possible opportunity." *Id.* at 4 (88 Fed. Reg. at 73,862). Finally, HRSA stated that all other facilities "are out of compliance and must stop using 340B drugs at these unregistered sites as soon as practically possible, but no later than 90 days after the publication of this Federal Register Notice." *Id.*

111. The same day HHS submitted the Notice for publication in the Federal Register, HRSA publicized the Notice on its 340B website. Ex. E, *340B Drug Pricing Program: 340B Registration Requirements for Off-site, Outpatient Hospital Facilities*, HRSA (Oct. 26, 2023), perma.cc/9YT5-NN4W. HRSA explained that "[p]andemic conditions are no longer rapidly evolving in a manner that requires significant unplanned activities or changes by hospital covered entities to accommodate these exigencies." *Id.* It also cited "HRSA program integrity efforts" as confirming that the 2020 policy "has added risk and complexity to HRSA's ability to effectively oversee compliance." *Id.* As such, HRSA specified that, "in order to continue purchasing 340B drugs, covered entities' offsite, outpatient hospital facilities must (1) be listed on the hospital's most recently filed Medicare Cost Report and registered in OPAIS by the next 340B Program quarterly registration period, or (2) the covered entity must notify HRSA within 90 days of the publication of the [Notice] that they have initiated the process of listing the offsite, outpatient facility on the hospital's Medicare Cost Report and registering it in OPAIS." *Id.* HRSA confirmed that it "is providing a 90-day grace period before non-compliant entities may be subject to audit and compliance action." *Id.*

112. In addition to posting the announcement on its website, HRSA distributed an identically-worded announcement by email to various stakeholders.

113. HRSA has thus expressly reversed its prior policy that child sites could dispense 340B drugs to patients so long as they could be considered patients of the covered entity; it now requires instead that the child site appear on a Medicare cost report before it is eligible for 340B pricing.

C. HRSA's imposition of the child-site limitation is final agency action

114. "As a general matter, two conditions must be satisfied for agency action to be 'final,'" and thus subject to challenge under the APA. *Bennett v. Spear*, 520 U.S. 154, 177 (1997). "First, the action must mark the 'consummation' of the agency's decisionmaking process" instead of being "of a merely tentative or interlocutory nature." *Id.* at 177-178 (quoting *Chicago & Southern Air Lines, Inc. v. Waterman S.S. Corp.*, 333 U.S. 103, 113 (1948)). "And second, the action must be one by which 'rights or obligations have been determined' or from which 'legal consequences will flow.'" *Id.* at 178 (quoting *Port of Boston Marine Terminal Assn. v. Rederiaktiebolaget Transatlantic*, 400 U.S. 62, 71 (1970)).

115. Both of these criteria are satisfied here.

116. *First*, HRSA has conclusively determined its course of action with respect to 340B benefits at child sites that qualify as provider-based but are not yet reported on a Medicare cost report. Its statements in its May 9, 2023, email were unequivocal: "HRSA *is* returning to pre-COVID policy regarding registration of outpatient facilities" under which "an off-site outpatient facility is eligible to be registered in the 340B Program if the outpatient facility is listed as a reimbursable facility on a 340B hospital's most recently filed Medicare cost report and has associated outpatient costs and charges." Ex. D (emphasis added).

117. The October 2023 Notice removes any doubt. HHS "issue[d] this Notice to inform and remind stakeholders of the registration requirements for off-site, outpatient hospital facilities to participate in the 340B Drug Pricing Program." Ex. B at 1 (88 Fed. Reg. at 73,859). It was "issued to provide clarity to stakeholders" and allow them to "bring their operations into compliance." *Id.* at 2 (88 Fed. Reg. at 73,860). It does not seek comments or stakeholder feedback; it simply announced the agency's final position on the question.

118. *Second*, HRSA's policy determines the rights and obligations of the Plaintiff health organizations. HHS was unequivocal that it was announcing a "requirement," using that phrase liberally throughout the Notice. Ex. B at 1, 2, 3, 4 (88 Fed. Reg. at 73,859-62). The Notice states

that a "hospital *must* indicate that [an] off-site, outpatient facility" is both "reimbursable on a hospital's most recently filed Medicare Cost Report" and "also has associated outpatient costs and charges as evidenced on the hospital's most recently filed Medicare Cost Report." *Id.* at 2 (88 Fed. Reg. at 73,860). HRSA's contemporaneous announcement of the Notice, published on its website and distributed by email, confirmed that covered entities "must" comply "in order to continue purchasing 340B drugs." Ex. E.

119. HHS was unambiguous that covered entities must comply with the Notice's requirements. It created a 90-day "grace period," after which "non-compliant covered entities may be subject to audit and compliance action." Ex. B at 4 (88 Fed. Reg. at 73,862). It stated that covered entities who do not provide certain information within 90 days "will have to cease purchasing 340B drugs for use at [unregistered] facilities and will be subject to audit and compliance action." *Id*. And it specified that failure to comply with the Notice's requirements renders a hospital "out of compliance" such that the hospital "must stop using 340B drugs at [its] unregistered sites as soon as practically possible, but no later than 90 days after publication of this Federal Register Notice." *Id.*

120. Unlike previous guidelines, which HHS has clarified "create no new law and create no new rights or duties," the Notice here contains no such disclaimer. *Compare* 61 Fed. Reg. at 55,157 *with* Ex. B.

121. HHS and HRSA cannot avoid judicial review by claiming to merely be offering an interpretation of the 340B Statute. The Supreme Court has "long taken" a "'pragmatic' approach . . . to finality." *U.S. Army Corps. of Engineers v. Hawkes Co., Inc.*, 578 U.S. 590, 599 (2016) (quoting *Abbott Lab'ys v. Gardner*, 387 U.S. 136, 149 (1967)). Under this approach, even when an agency does nothing more than "give notice" of its interpretation of a statute, the notice can constitute final agency action without anything more. *Id.*; *see also, e.g.*, *Gomez v. Trump*, 485 F. Supp. 3d 145, 194 (D.D.C. 2020) ("[A]n agency's interpretation of its governing statute, with the expectation that regulated parties will conform to and rely on this interpretation, is final action fit for judicial review") (quoting *Ciba-Geigy Corp. v. EPA*, 801 F.2d 430, 438 (D.C. Cir. 1986)).

122. In addition, the D.C. Circuit has developed a "complementary" test for final agency action in the context of "pre-enforcement challenges" like this one, which the court applies in parallel with the *Bennett* analysis. *CSI Aviation Servs., Inc. v. U.S. Dep't of Transp.*, 637 F.3d 408, 411 (D.C. Cir. 2011). All three factors of this test are easily satisfied here. "First," HRSA "has issued a 'definitive' statement of the agency's legal position" which "[t]he letter [and Notice] declared in no uncertain terms." *Id.* at 412. "Not only did the statement of position admit of no ambiguity, but it gave no indication that it was subject to further agency consideration or possible modification." *Id.* (quoting *Ciba-Geigy*, 801 F.2d at 436-37). "Second, this case presents a 'purely legal' question of statutory interpretation"—whether patients treated at a provider-based, offsite outpatient facility are patients of a covered entity before the child site is listed on a Medicare cost report. *Id.* "In the absence of any disputed facts that would bear on this question, [the Court's] review of the agency's legal position would not 'benefit from a more concrete setting.'" *Id.* (quoting *Ciba-Geigy*, 801 F.2d at 435). "And third, [HRSA] has imposed an immediate and significant burden on" Plaintiffs: HRSA instructed Plaintiffs to "cease and desist" from previously permissible action, which has resulted in millions of dollars of lost savings. *Id.* This instruction "put the [Plaintiffs] to the painful choice between costly compliance and the risk of [enforcement] at an uncertain point in the future." *Id.* "At the very least, this cast a cloud of uncertainty over the viability of" many of Plaintiffs' current and future child sites. *Id.*

123. A court in this district recently explained these very principles in the context of HRSA's attempt to avoid judicial review of its interpretation of another component of the 340B statute. *See Pharm. Rsch. & Mfrs. of Am. v. U.S. DHHS*, 138 F. Supp. 3d 31 (D.D.C. 2015) ("*PhRMA II*"). There, the court considered an "interpretive rule" HRSA issued after a court vacated an identical legislative rule. The court rejected HRSA's insistence that no final agency action had occurred, noting that "pronouncements setting forth an agency's reading of a statute are not categorically insulated from review before a specific enforcement proceeding has commenced." *Id.* at 41. Instead, "where the agency issued a rule, guidance document, or letter setting forth its

view of the law" the D.C. Circuit and this Court have consistently treated the action as "final." *Id.* at 41. Just so here.

124. Plaintiffs have no adequate alternative to review under the APA. HRSA's communications and the Notice do not indicate the potential for any further agency process. And "the mere possibility that an agency might reconsider in light of 'informal discussion' and invited contentions of inaccuracy does not suffice to make an otherwise final agency action nonfinal." *Sackett v. EPA*, 566 U.S. 120, 127 (2012). HRSA's action is subject to immediate judicial review.

D. HRSA's change in position is unlawful

125. HRSA's unexplained reversion to its pre-2020 view of 340B eligibility for child sites is both contrary to law and arbitrary and capricious on multiple grounds.

126. First, HRSA failed to comply with the APA's requirements for enacting legislative rules.

127. Most concretely, HRSA has adopted a legislative rule absent the use of notice-and-comment rulemaking as required by the APA. *See* 5 U.S.C. § 553(b), (c); *Util. Solid Waste Activities Grp. v. EPA*, 236 F.3d 749, 752 (D.C. Cir. 2001). That is, HRSA purports to *require* covered entities to comply with its change in policy (*see* ¶¶ 118-122, *supra*)—but binding rules issued without notice and comment are void. *See, e.g.*, *Bloomberg L.P. v. SEC*, 45 F.4th 462, 476 (D.C. Cir. 2022) (notice and comment are required "whenever agencies promulgate a rule that intends to create new law, rights, or duties.").

128. Additionally, though the Notice creates a mandatory obligation, HRSA lacks authority to issue legislative rules implementing the 340B program. As one court in this district has held, "HHS has not been granted broad rulemaking authority to carry out all the provisions of the 340B program. Instead, Congress has limited HHS's rulemaking authority to creating a system for resolving disputes between covered entities and manufacturers—not to engaging in prophylactic non-adjudicatory rulemaking regarding the 340B program altogether." *PhRMA I*, 43 F. Supp. 3d at 42. Because the Notice "impose[s] legally binding obligations [and] prohibitions on regulated

parties" and "sets forth legally binding requirements" for regulated entities "to obtain a permit or license," the Notice is a legislative rule beyond HHS's authority to promulgate. *Nat'l Mining Ass'n v. McCarthy*, 758 F.3d 243, 251 (D.C. Cir. 2014).

129. Second, HRSA's action conflicts with the governing statute.

130. "Federal agencies are creatures of statute. They possess only those powers that Congress confers upon them. If no statute confers authority to a federal agency, it has none. If Congress has forbidden an agency from taking an action, the agency cannot so act." *Judge Rotenberg Educ. Ctr., Inc. v. FDA*, 3 F.4th 390, 399 (D.C. Cir. 2021).

131. As explained above, the 340B statute provides definitions of covered entities that are eligible to receive discounts as part of the 340B program. *See* ¶¶ 81-82, *supra*.

132. Many of those definitions are premised on the covered entity being a "hospital." *See* 42 U.S.C. § 256b(a)(4)(L)-(O). The plain meaning of "hospital" is not restricted to a single building or geographic location; rather, a hospital is "[a]n *institution or establishment* for the care of the sick or wounded, or of those who require medical treatment." *E.g.*, Hospital, *Oxford English Dictionary* (2023) (emphasis added). HRSA has therefore repeatedly recognized that child sites *are* included within the covered-entity hospitals of which they are a part. *See* ¶¶ 83-113, *supra*. This is in line with CMS's consistent interpretation of "hospital" in Section 1886(d)(1)(B) of the Social Security Act, to which the 340B statute refers for its definitions. 65 Fed. Reg. at 18,504.

133. None of this statutory text suggests that child sites somehow begin life as *not* part of their parent covered-entity hospitals, but somehow *become* part of the parent entity at the time—dictated by happenstance rather than any real-world factors—that they are listed on annual paperwork. And since that limitation does not appear in the statute, HRSA is not at liberty to read it in. *See Util. Air Reg. Grp.*, 573 U.S. 302, 328 (2014) ("[A]n agency may not rewrite clear statutory

terms to suit its own sense of how the statute should operate."); *Judge Rotenberg Educ. Ctr.*, 3 F.4th at 399 ("If no statute confers authority to a federal agency, it has none.").[3]

134. Nor does the 340B statute somehow preclude the dispensing of 340B drugs to patients seen at child sites. The only statutory requirement in this regard is that the covered entity "shall not resell or otherwise transfer the [340B] drug to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B). There is no basis to conclude that a patient seen at a child site that is an integrated part of the parent entity (*see* ¶¶ 86-91, *supra*) is not a patient of the overall covered entity—and there is certainly no basis to think that this relationship depends upon the filing of an annual reimbursement form.

135. Indeed, HRSA itself has recognized that "[a]n individual is a 'patient' of a covered entity" if (1) there is a treatment relationship "such that the covered entity maintains records of the individual's healthcare" and (2) "the individual receives health care services from a health care professional who is either [a] employed by the covered entity or [b] provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity." 61 Fed. Reg. at 55,157.[4]

136. Again, there is simply no reason why these conditions would not be satisfied by a child site of a hospital covered entity, where (1) records are maintained centrally at the parent hospital and (2) providers working at the child site are either employed by, contracted with, or provide services under other arrangements with the hospital (e.g. as members of the medical staff)—which are requirements under Medicare's provider-based rules. 42 C.F.R. § 413.65(d)(2)(i)-(vi).

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[3] To the contrary, a Committee Report accompanying the enactment of the statute makes clear that HRSA is not authorized "to limit in any way the volume of purchases that can be made [by covered entities] at the price reduction." H.R. Rep. No. 102–384(II), at 16.

[4] A third requirement is inapplicable to most 340B covered entities. 61 Fed. Reg. at 55,157-55,158; *supra* n.2.

137. That is, even during the period between the creation of an integrated child site and its appearance on a hospital covered entity's Medicare cost report—the period in which HRSA now denies covered-entity status—patients of the child site are patients of the covered entity. Those patients receive treatment at a facility owned by, operated by, and fiscally integrated into a covered entity, with an integrated medical staff and integrated medical recordkeeping. Because the child site is part of the covered entity, the covered entity is responsible for the patient's care.

138. By contrast, HRSA's position—that child sites *do* count as part of the covered entity, but *only* after they appear on the covered entity's Medicare cost report—has no plausible grounding whatsoever in any statutory text or regulation.

139. Thus, in restricting access to patients of child sites before they are listed on a cost report, HRSA has excluded some patients of the covered entity, restricting access to the program in contravention of the text of the 340B statute. By imposing additional restrictions on facilities eligible for 340B discounts beyond those contained in the 340B statute, HRSA has therefore acted beyond its authority and contrary to law. *See, e.g.*, *Util. Air Reg. Grp.*, 573 U.S. at 328; *Jama v. ICE*, 543 U.S. 335, 341 (2005) ("We do not lightly assume that Congress has omitted from its adopted text requirements that it nonetheless intends to apply.").

140. *Third*, HRSA's action is also arbitrary and capricious on multiple grounds.

141. Under the APA, an agency must base its actions "on a consideration of the relevant factors" and "examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)). In other words, "[a]n agency decision is arbitrary and capricious if it is not reasonably explained." *Antilles Consol. Educ. Ass'n v. Fed. Lab. Rels. Auth.*, 977 F.3d 10, 15 (D.C. Cir. 2020).

142. Here, HRSA "failed to provide a[] coherent explanation for its decision" and so "the agency's action [is] arbitrary and capricious for want of reasoned decisionmaking." *Fox v. Clinton*, 684 F.3d 67, 69 (D.C. Cir. 2012). In particular, agency action is "arbitrary and capricious"

for want of reasoned decisionmaking "if the agency has . . . entirely failed to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43.

143. In reverting to its earlier policy, HRSA failed to consider the substantial lost savings for covered entities that would result from its action. These lost savings are a significant aspect—if not *the most* significant aspect—of the problem HRSA was considering when it took the action in question. *See, e.g.*, *Mingo Logan Coal Co. v. EPA*, 829 F.3d 710, 733 (D.C. Cir. 2016) (Kavanaugh, J., dissenting) ("[C]ommon administrative practice and common sense require an agency to consider the costs and benefits of its proposed actions, and to reasonably decide and explain whether the benefits outweigh the costs.").

144. Indeed, rather than address the harms from delayed registration, HRSA's approach was to pretend they do not exist. The Notice states that, by "May 11, 2023, hospitals should have been able to register offsite, outpatient facilities on OPAIS"—ignoring that hospitals cannot do so until 5-17 months after a facility opens. Ex. B at 3 (88 Fed. Reg. at 73,861). And it claimed that "[t]he burden of registration and including a facility in the next filed Medicare Cost Report does not take significant resources"—but completely disregarded the delays and lost savings those two steps cause. *Id*.

145. Additionally, HRSA failed to consider that its interpretation is no longer consistent with the underlying CMS rules that are used to determine what locations and services constitute a "hospital" for purposes of the Medicare program. The 340B statute refers to the Medicare program for statutory definitions of hospitals. 42 U.S.C. § 256b(a)(4)(L)-(O). In the 1994 Policy, HRSA explained that "it is reasonable to utilize existing Medicare rules to determine eligibility for [the drug discount program]" because "Congress referred to section 1886 of the Social Security Act [], part of the Medicare statute, for the definition" of certain covered entities. 59 Fed. Reg. 47,885.

146. But HRSA has failed to recognize that the Medicare rules have since changed. Offsite, outpatient locations are now able to bill Medicare as part of a larger hospital organization as soon as they meet the criteria for eligibility, without having to wait for approval and without appearing on a Medicare cost report. 67 Fed. Reg. 49,982, 50,084-85. HRSA's reversion now puts

the agency in *conflict* with the very regulations it sought to match nearly two decades ago. HRSA has never acknowledged, much less explained, this disconnect. Indeed, it seems unaware of CMS's practices for the last two decades; the Notice incorrectly states that "[a]pproval of provider-based status requires submission of documentation demonstrating the off-campus facility's services are provided to the same patient population as the main provider." But, as discussed above, CMS abandoned any pre-approval requirement and acknowledged that facilities are provider-based as soon as the substantive criteria are satisfied. 67 Fed. Reg. at 50,084-85.

147. HRSA's only explanation for its "requirement" that covered entities forgo use of 340B drugs at child sites before they appear on a Medicare cost report is to assert that a "hospital must indicate that the off-site, outpatient facility also has associated outpatient costs and charges as evidenced on the hospital's most recently field Medicare Cost Reports." Ex. B at 2 (88 Fed. Reg. at 73,860). In essence, the Notice asserts without any justification, "HRSA is unable to verify the eligibility of 340B Program participants when off-site, outpatient facilities are permitted to participate prior to their inclusion on the most recently filed Medicare Cost Report." *Id.* at 3 (88 Fed. Reg. at 73,861). But HRSA has never articulated why a Medicare cost report—which is certainly *one* way of demonstrating associated outpatient costs—is the *only* viable evidence a covered entity can submit to justify registration of a child site. Since 2002, CMS has reimbursed for associated outpatient costs at offsite, outpatient facilities without requiring hospitals to wait until publication of a cost report. 67 Fed. Reg. at 50,084-85. Bills submitted for costs at these facilities are evidence both of the provider-based relationship and of associated outpatient costs—the two criteria HRSA looks to in determining whether a facility is a child site. Yet HRSA requires facilities to wait 5-17 months after opening to obtain a report before they can register. The interim bills submitted by covered entities to CMS provide a "reasonably obvious alternative" that is substantially less burdensome than HRSA's policy. *NRDC v. SEC*, 606 F.2d 1031, 1053 (D.C. Cir. 1979).

148. HRSA is obligated to consider alternative options that could achieve any policy objective—while minimizing the harms to the regulated public. HRSA's refusal to do so here is arbitrary and capricious. *NRDC v. SEC*, 606 F.2d 1031, 1053 (D.C. Cir. 1979).

149. In all, HRSA's failure to consider important aspects of the problem and to provide a reasoned explanation of its change in policy was arbitrary and capricious and must be set aside.

150. Furthermore, "an agency changing its course . . . [must] supply a reasoned analysis." *State Farm*, 463 U.S. at 42. The agency must "account[] for any departures" from its previous position. *Edison Elec. Inst. v. EPA*, 391 F.3d 1267, 1269 & n.3 (D.C. Cir. 2004). And, "[w]hen an agency changes course, . . . it must 'be cognizant that longstanding policies may have "engendered serious reliance interests that must be taken into account."'" *DHS v. Regents of Univ. of Cal.*, 140 S. Ct. 1891, 1913 (2020) (quoting *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221-222 (2016)). The agency must therefore "address whether there was 'legitimate reliance' on" its prior policy. *Id.* (quoting *Smiley v. Citibank (S.D.), N.A.*, 517 U.S. 735, 742 (1996)). "It would be arbitrary and capricious to ignore such matters." *Id.* (quotation marks omitted).

151. Here, HRSA plainly deviated from its previous position by flip-flopping on its interpretation of the 340B statute.

152. From 1994 until 2020, HRSA's policy was that patients seen at child sites are ineligible for 340B discounts until the child site appears on a Medicare cost report. In 2020, HRSA announced a new policy under which even before a facility appears on a Medicare cost report, the patients of the child site may still be 340B eligible to the extent that they are patients of the covered entity. HRSA consistently represented this as a new, final position not tied to the existence of the COVID-19 PHE.

153. Nonetheless, just before the PHE ended, HRSA announced that it was returning to its earlier policy of requiring facilities to appear on Medicare cost reports before covered entities could obtain 340B discounts at those facilities.

154. HRSA reversed course on child-site 340B eligibility without *any* explanation, much less the "reasoned analysis" required by the APA. *State Farm*, 463 U.S. at 42. And the agency similarly did not "assess whether there were reliance interests" generated by its previous policy—for example, the reliance interests of covered entities with child sites operating under that policy, and of the patients served by those child sites—and therefore could not "determine whether they

were significant, and weigh any such interests against competing policy concerns," as the APA and Supreme Court precedent require. *Regents*, 140 S. Ct. at 1915.

155. HRSA's failure to give a valid reason (or any explanation at all) for changing its position, and its failure to consider the potential reliance interests when reversing course, was arbitrary and capricious.

E. Finally, HRSA's unlawful action harms Plaintiffs.

156. As both CMS and HRSA have consistently recognized, the ability to provide care from off-campus locations is integral to the ability of covered entities to provide robust, quality healthcare services to underserved patient populations. Many covered entities serve geographically diverse or otherwise underserved communities. Child sites are therefore essential to covered entities' efforts to provide quality, accessible care to geographically dispersed populations and to patients for whom significant or frequent travel otherwise poses a barrier to healthcare access.

157. By denying 340B eligibility to otherwise-eligible child sites for no reason other than that, as an accident of timing, they have not yet appeared on the relevant covered entity's Medicare cost report, HRSA's action plainly harms covered entities like Plaintiffs.

158. For example, Plaintiff Albany Med Health System is a regionally governed, not-for-profit health system providing care to patients in northeastern New York and western New England. In reliance on HRSA's 2020 guidance and independent confirmation from Apexus that patients of a new outpatient site would be 340B-eligible as soon as the site was open and provider-based, Albany Med's Glens Falls Hospital opened an offsite outpatient clinic to provide oncology services to its patients on March 8, 2023. The clinic qualified as provider-based under the Medicare regulations upon opening but has not yet appeared on any covered entity's cost report. Albany Med hopes to register the clinic by next year and estimates the lost 340B savings from HRSA's return to its 1994 policy at approximately $7 million until the site is registered.

159. At the end of the PHE, Albany Med's Glens Falls Hospital was also in the process of opening an additional off-site clinic later in the year to provide oncology and infusion services

to its patients. The clinic would also meet the provider-based requirements upon opening, but under HRSA's current policy there would be significant delay before it could realize 340B savings. Albany Med estimates that HRSA's child-site limitation will result in approximately $6 million in lost 340B savings from its prior planned opening until registration. Albany Med is currently reevaluating its plan to open the clinic given HRSA's child-site limitation.

160. Similarly, Plaintiff Hendrick Medical Center is a faith-based, community-focused, not-for-profit healthcare institution providing a wide range of comprehensive healthcare services to the Texas Midwest. One of Hendrick Medical Center's newest child sites contains a radiology department. The child site was opened in August 2022, but was not listed on a Medicare cost report until January 30, 2023, and was registered with HRSA at the earliest opportunity, resulting in a HRSA OPAIS Participating Start Date of July 1, 2023. During the PHE, Hendrick Medical Center was able to obtain 340B savings pursuant to HRSA's policy at this child site even though it did not appear on a cost report. After the PHE ended, Hendrick followed HRSA's updated guidance and did not obtain discounts on otherwise eligible prescriptions, resulting in thousands of dollars of lost savings in less than two months.

161. Hendrick Medical Center also recently opened a cardiology clinic which satisfied the criteria to be provider-based on August 28, 2023. Hendrick estimates that a delay in 340B eligibility at this clinic until it appears on a cost report would result in $3 million of lost savings per year.

162. Plaintiff Stanford provides quality healthcare to patients across Northern California, including some of the state's most vulnerable populations. Its healthcare system comprises two large 340B covered entities: Stanford Health Care and Stanford Health Care Tri-Valley (also called Valley Memorial Hospital). Stanford plans to open outpatient, provider-based clinics at its Tri-Valley location, including infusion clinics. It had originally planned to open the first of these clinics in fall of 2023. Stanford estimates that if it were forced to forgo 340B discounts on drugs at each infusion center, it would lose at least $5 million in 340B savings in the period between when the clinics qualify as provider-based and when they appear on the Medicare cost reports.

163. Plaintiff UPHS traces its history back to the founding of the nation's first hospital (Pennsylvania Hospital) in 1751 and the nation's first medical school in 1765. UPHS has pioneered medical frontiers with a staff composed of innovators who have dedicated their lives to advancing medicine through excellence in education, research, and patient care.

164. UPHS's healthcare system comprises four 340B covered entities. Between these entities, UPHS has a variety of hospital-based clinics registered as child sites with HRSA and appearing on a 340B covered entity's Medicare cost report.

165. During the PHE, UPHS opened the Radnor Infusion Center as a child site of one of its covered entities. Due to HRSA's position at the time, UPHS was able to immediately realize savings at the Radnor Infusion Center, amounting to approximately $35 million in savings in 2022. If UPHS were to open the same center today under HRSA's current guidance, it would forgo millions of dollars in 340B savings while it waited for the facility to appear on a Medicare cost report.

166. By contrast, UPHS recently opened the PAH Neurology practice. Because of HRSA's newest guidance, UPHS has forgone 340B discounts for patients seen at that facility until it appears on a Medicare cost report. These lost savings amount to approximately $2.4 million per year.

167. Plaintiff Keck Medicine recently opened an infusion center, which meets the qualifications to be a provider-based outpatient, offsite facility of one of its covered entities. Because of HRSA's child-site limitation, Keck Medicine will not be able to register this center with HRSA until April of 2024, and is thus currently unable to obtain 340B benefits for the drugs currently being dispensed at that location. Keck Medicine estimates that HRSA's child-site limitation will result in $1.7 million in lost 340B savings at this facility alone.

168. Keck Medicine also plans to open several new child sites in the next several years at which patients can receive life-saving infusion therapies. If HRSA's child-site limitation remains in place, Keck Medicine estimates that its lost 340B savings at these new facilities will exceed $10 million in total.

169. Yale New Haven Health has new outpatient locations that will not be eligible for 340B discounts under HRSA's child-site limitation for up to 18 months after opening. As a result of HRSA's policy, Yale New Haven Health could experience a delay in the opening of these new locations until the end of the fiscal year to minimize the delays in eligibility. The child-site limitation will thus delay additional and enhanced services for the patients in Yale New Haven Health's community.

170. Plaintiff City of Hope National Medical Center is in the process of opening two off-site provider-based locations in Southern California. City of Hope estimates that if it were forced to forgo 340B discounts on drugs in these new locations, it would lose approximately $10 million in 340B savings during the period between when these locations open and when they can be registered in OPAIS after appearing on the Medicare cost report.

171. These and other monetary harms to Plaintiffs flow directly from HRSA's challenged action, entitling them to bring suit to set that action aside. *See, e.g.*, *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2204 (2021) ("If a defendant has caused . . . monetary injury to the plaintiff, the plaintiff has suffered a concrete injury in fact under Article III.").

CLAIMS FOR RELIEF

Count I
Improperly adopted legislative rule

172. The APA requires administrative agencies to publish within the Federal Register a "[g]eneral notice of proposed rulemaking" for substantive rules, and to "give interested persons an opportunity to participate in the rule making[.]" 5 U.S.C. § 553(b), (c); *see also Util. Solid Waste Activities Grp. v. EPA*, 236 F.3d 749, 752 (D.C. Cir. 2001) ("[T]here must be publication of a notice of proposed rulemaking; opportunity for public comment on the proposal; and publication of a final rule accompanied by a statement of the rule's basis and purpose.").

173. A new legal standard is considered substantive if it "adopts a new position inconsistent with existing regulations," *Mendoza v. Perez*, 754 F.3d 1002, 1021 (D.C. Cir. 2014), or

"'affect[s] individual rights and obligations,'" *Comm. for Fairness v. Kemp*, 791 F. Supp. 888, 893 (D.C. Cir. 1992) (quoting *Chrysler Corp. v. Brown*, 441 U.S. 281, 302 (1979)).

174. HRSA's initial announcement of the child-site limitation makes clear that HRSA is treating its policy as binding. It stated that "an off-site outpatient facility *is* eligible to be registered in the 340B Program if the outpatient facility is listed as a reimbursable facility on a 340B hospital's most recently filed Medicare cost report and has associated outpatient costs and charges." Ex. D. This action commands that hospitals "should stop purchasing and using 340B drugs for" unregistered child sites. *Id.* Such child sites "may begin purchasing and using 340B drugs once" they appear on the hospital's most recent Medicare cost report and are registered with HRSA. *Id.*

175. The Notice is similarly clear that it is imposing mandatory obligations. It repeatedly describes the "requirements" for registration of an offsite, outpatient facility. It restricts what evidence can be submitted to the agency to demonstrate eligibility and provides a deadline for compliance. It states that failure to follow the Notice's requirements results in facilities being "out of compliance" such that they "must" cease purchasing 340B drugs. And it threatens enforcement action after the end of a short grace period. *See generally* Ex. B.

176. Through these statements, HRSA announced its intent to "speak[] with the force of law." *Nat'l Council for Adoption v. Blinken*, 4 F.4th 106, 114 (D.C. Cir. 2021) (quoting *NRDC v. Wheeler*, 955 F.3d 68, 83 (D.C. Cir. 2020)).

177. HRSA's readoption of the child-site limitation lacked the notice and comment required by the APA. It was therefore "without observance of procedure required by law." 5 U.S.C. § 706(2)(D). It must be set aside.

178. In the alternative, HRSA's adoption of a substantive rule exceeds its statutory authority and is therefore "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 705(2)(C); *see Pharm. Rsch. & Mfrs. of Am. v. U.S. DHHS*, 45 F. Supp. 3d 28, 41 (D.D.C. 2014).

Count II
Agency Action Contrary to Law

179. Plaintiffs incorporate and re-allege the foregoing paragraphs as though fully set forth herein.

180. The APA requires a reviewing court to "hold unlawful and set aside agency action" that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," or is "otherwise not in accordance with law." 5 U.S.C. § 706.

181. HRSA's actions violate these APA requirements. By imposing additional restrictions on facilities and patients eligible for 340B discounts beyond those contained in the 340B statute, HRSA has acted beyond its authority and contrary to law. *See, e.g.*, *Decker v. Nw. Envtl. Def. Ctr.*, 568 U.S. 597, 609 (2013) ("It is a basic tenet that 'regulations, in order to be valid, must be consistent with the statute under which they are promulgated.'"); *Judge Rotenberg Educ. Ctr., Inc. v. FDA*, 3 F.4th 390, 399 (D.C. Cir. 2021) ("Federal agencies . . . possess only those powers that Congress confers upon them . . . If no statute confers authority to a federal agency, it has none.").

182. HRSA's action must therefore be set aside. 5 U.S.C. § 706(2).

Count III
Arbitrary and Capricious Agency Action

183. Plaintiffs incorporate and re-allege the foregoing paragraphs as though fully set forth herein.

184. The APA compels courts to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

185. HRSA's action violates these APA requirements. It fails to "articulate . . . a 'rational connection between the facts found and the choice made';" it "fail[s] to consider . . . important aspect[s] of the problem;" and it "offer[s] an explanation for its decision that runs counter to the evidence before the agency." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). It also demonstrates a failure by the agency to "be cognizant

that longstanding policies may have 'engendered serious reliance interests that must be taken into account,'" and thus to "address whether there was 'legitimate reliance' on" its prior policy. *DHS v. Regents of Univ. of Cal.*, 140 S. Ct. 1891, 1913 (2020) (first quoting *Encino Motorcars*, 579 U.S. 211, 221-222 (2016); then quoting *Smiley v. Citibank (S.D.), N.A.*, 517 U.S. 735, 742 (1996)).

186. HRSA's action must therefore be set aside. 5 U.S.C. § 706(2).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment in their favor and that the Court:

(a.) Set aside and vacate HRSA's child-site limitation;

(b.) Declare that patients seen at child sites are patients of a covered entity for purposes of the 340B program as soon as the child sites qualify as part of the covered entity;

(c.) Award Plaintiffs attorney's fees and costs; and

(d.) Award Plaintiffs such other and further relief as the Court may deem just and proper.

Dated: October 31, 2023

Respectfully submitted,

/s/ *Paul W. Hughes*

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**pro hac vice motion forthcoming*