

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

ABBVIE INC.,

Plaintiff,

v.

ROBERT F. KENNEDY JR., in his official
capacity, et al.,

Defendants

and

NATIONAL ASSOCIATION OF COMMUNITY
HEALTH CENTERS, INC.; and
RYAN WHITE CLINICS FOR 340B ACCESS,

Proposed Intervenor-Defendants.

Civil Action No. 1:26-cv-1190-RDM

**JOINT MOTION OF NATIONAL ASSOCIATION OF COMMUNITY HEALTH
CENTERS, INC. AND RYAN WHITE CLINICS FOR 340B ACCESS
TO INTERVENE AS DEFENDANTS**

PLEASE TAKE NOTICE that the undersigned counsel for the National Association of Community Health Centers, Inc. (“NACHC”) and Ryan White Clinics for 340B Access (“RWC-340B”) hereby move this Court to Intervene as Defendants in this lawsuit.

In support of this Motion, NACHC and RWC-340B are submitting a Memorandum in Support of the Motion to Intervene, two declarations, one from each proposed intervenor (Exhibits A & B), and a Proposed Order. In accordance with Local Civil Rule 7(j), a Proposed Motion for Joinder in the Motion to Dismiss of Defendants (Doc. 13) is also annexed as Exhibit C.

In accordance with Local Civil Rule 7(m), NACHC and RWC-340B consulted with Counsel for Plaintiff and Defendants. Plaintiff’s counsel has advised that they will oppose the

Motion to Intervene and Defendants' counsel has advised that they will take no position on the motion.

For the reasons set forth in the Memorandum of Law in Support of the Motion to Intervene as Defendants, NACHC and RWC-340B request that the Court grant its Motion to Intervene as Defendants under Rule 24(a), or in the alternative, to allow NACHC and RWC-340B to intervene under Rule 24(b).

Dated: July 6, 2026

Respectfully submitted

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**MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF
JOINT MOTION TO INTERVENE AS DEFENDANTS
BY NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS, INC.
AND RYAN WHITE CLINICS FOR 340B ACCESS**

TABLE OF CONTENTS

TABLE OF AUTHORITIES.....	ii
INTRODUCTION AND INTERESTS OF PROPOSED INTERVENORS.....	1
BACKGROUND	9
A. The 340B Program’s Purpose and Function	9
B. 340B Program Administration and HRSA’s Diversion Prohibition Enforcement.....	11
1. HRSA’s Prior Approaches to “Duplicate Discounts” and “Diversion”	11
2. HRSA’s Origination and Location Tests Observed Through Audits.....	14
ARGUMENT.....	15
I. Proposed Intervenor’s Have a Right to Intervene Under Rule 24(a)(2).	17
A. Proposed Intervenor’s Have Standing to Intervene.....	18
B. Proposed Intervenor’s Have Numerous Protected Interests at Stake.....	21
C. Adverse Disposition of This Action Will Impair the Ability of Proposed Intervenor’s to Protect Their Interests.....	23
D. No Party Adequately Represents Proposed Intervenor’s Interests.....	26
E. Proposed Intervenor’s Motion is Timely.....	31
II. Alternatively, Proposed Intervenor’s Should be Permitted to Intervene Under Rule 24(b)	35
CONCLUSION.....	36

TABLE OF AUTHORITIES

Cases	Page(s)
<i>AbbVie, Inc. v. Murrill</i> , 166 F.4th 528 (5th Cir. 2026).....	5
<i>Am. Hosp. Ass’n v. Becerra</i> , No. 18-CV-2084 (RC), 2023 WL 143337 (D.D.C. Jan. 10, 2023).....	28
<i>Ameren Servs. Co. v. FERC</i> , 893 F.3d 786 (D.C. Cir. 2018)	34
<i>Amgen Inc. v. Kennedy</i> , No. 24-CV-3571 (JEB), 2026 WL 202157 (D.D.C. Jan. 27, 2026)	16, 33
<i>Amgen, Inc. v. Kennedy</i> , No. 24-CV-3571 (JEB), 2025 WL 2206948 (D.D.C. Aug. 4, 2025).....	5
<i>Ass’n of Washington Bus. v. United States Env’t Prot. Agency</i> , No. 23-CV-3605 (DLF), 2024 WL 3225937 (D.D.C. June 28, 2024)	35
<i>Astra USA, Inc. v. Santa Clara County</i> , 563 U.S. 110 (2011)	19
<i>Black v. LaHood</i> , No. 11-CV-1928 (JEB), 2012 WL 13054502 (D.D.C. Apr. 30, 2012).....	34
<i>Cayuga Nation v. Zinke</i> , 324 F.R.D. 277 (D.D.C. 2018).....	32, 33
<i>Crossroads Grassroots Pol’y Strategies v. FEC</i> , 788 F.3d 312 (D.C. Cir. 2015)	18, 22, 26, 29
<i>E.E.O.C. v. Nat’l Children’s Ctr., Inc.</i> , 146 F.3d 1042 (D.C. Cir. 1998)	16, 35
<i>Eli Lilly & Co. v. HHS</i> , No. 1:21-cv-00081, 2021 WL 5039566 (S.D. Ind. Oct. 29, 2021)	5
<i>Friends of the Earth, Inc. v. Laidlaw Env’t Servs. (TOC), Inc.</i> , 528 U.S. 167 (2000).....	18
<i>Fund for Animals, Inc. v. Norton</i> , 322 F.3d 728 (D.C. Cir. 2003)	<i>passim</i>
<i>Genesis Health Care, Inc. v. Becerra</i> , 701 F. Supp. 3d 312 (D.S.C. 2023).....	<i>passim</i>
<i>Genesis Health Care, Inc. v. Becerra</i> , No. 4:19-CV-01531-RBH, 2023 WL 7549156 (D.S.C. Nov. 3, 2023)	11
<i>Johnson & Johnson Health Care Sys. Inc. v. Kennedy</i> , No. 24-CV-3188 (RC), 2025 WL 1411076 (D.D.C. May 15, 2025).....	28

<i>Karsner v. Lothian</i> , 532 F.3d 876 (D.C. Cir. 2008)	16, 17, 31
<i>Lujan v. Defs. of Wildlife</i> , 504 U.S. 555 (1992).....	18
<i>Mayo v. Jarvis</i> , No. 14-CV-1751 (RC), 2015 WL 13700484 (D.D.C. Jan. 21, 2015)	22
<i>MGM Glob. Resorts Dev., LLC v. United States Dep’t of Interior</i> , No. 19-CV-2377 (RC), 2020 WL 5545496 (D.D.C. Sep. 16, 2020).....	18, 32, 33
<i>Mosaic Health, Inc. v. Sanofi-Aventis U.S., LLC</i> , 156 F.4th 68 (2d Cir. 2025)	5
<i>Nat. Res. Def. Council v. Costle</i> , 385 F.2d 904 (D.C. Cir. 1977)	25
<i>Novartis Pharms. Corp. v. Johnson</i> , 102 F.4th 452 (D.C. Cir. 2024)	5
<i>Nuesse v. Camp</i> , 385 F.2d 694 (D.C. Cir. 1967)	17, 25
<i>Pharm. Rsch. & Mfrs. of Am. v. McClain</i> , 95 F.4th 1136 (8th Cir. 2024)	5
<i>Roane v. Leonhart</i> , 741 F.3d 147 (D.C. Cir. 2014)	31, 33
<i>Sanofi Aventis U.S. LLC v. HHS</i> , 58 F.4th 696 (3d Cir. 2023)	5
<i>SEC v. Prudential Sec. Inc.</i> , 136 F.3d 153 (D.C. Cir. 1998)	17
<i>Smoke v. Norton</i> , 252 F.3d 468 (D.C. Cir. 2001)	31
<i>Susan B. Anthony List v. Driehaus</i> , 573 U.S. 149 (2014).....	20
<i>Trbovich v. United Mine Workers</i> , 404 U.S. 528 (1972).....	17, 30
<i>United States v. Am. Tel. & Tel. Co.</i> , 642 F.2d 1285 (D.C. Cir. 1980)	17
<i>Wash. All. of Tech. Workers v. U.S. Dep’t of Homeland Sec.</i> , 395 F. Supp. 3d 1 (D.D.C. 2019)	33
<i>WildEarth Guardians v. Jewell</i> , 320 F.R.D. 1 (D.D.C. 2017).....	26

WildEarth Guardians v. Salazar,
272 F.R.D. 4 (D.D.C. 2010)..... 17, 31

Wis. Cent. Ltd. v. United States,
585 U.S. 274 (2018).....11

Statutes

42 U.S.C. § 1396d.....11

42 U.S.C. § 254b..... 3, 27

Medicare Prescription Drug, Improvement, and Modernization
Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066
(codified at 42 U.S.C. § 1396r-8(a)) 9

Omnibus Budget Reconciliation Act of 1990,
Pub. L. No. 101-508, § 4401, 104 Stat. 1388
(codified at 42 U.S.C. § 1396r-8)) 9

Patient Protection and Affordable Care Act,
Pub. L. No. 111-148, § 7101, 124 Stat. 119 (2010)11

Public Health Service Act, 42 U.S.C. § 256b *passim*

Ryan White Comprehensive AIDS Resources Emergency Act,
42 U.S.C. § 300ff *et seq.*..... 2, 3, 27

Veterans Health Care Act of 1992,
Pub. L. No. 102-585, 106 Stat. 4943 (codified at 42 U.S.C. § 256b)..... 10

Regulations

340B Drug Pricing Program Omnibus Guidance,
80 Fed. Reg. 52,300 (Aug. 28, 2015) 13

42 C.F.R. § 10.20 14

42 C.F.R. § 10.23 14

42 C.F.R. Part 10..... 14

Manufacturer Audit Guidelines and Dispute Resolution Process 0905-ZA-19,
61 Fed. Reg. 65,406 (Dec. 12, 1996)..... 13

*Notice Regarding Section 602 of the Veterans Health Care Act
of 1992 Definition of “Patient”*, 72 Fed. Reg. 1543 (Jan. 12, 2007)..... 13

*Notice Regarding Section 602 of the Veterans Health Care Act
of 1992 Patient and Entity Eligibility*, 61 Fed. Reg. 55,156 (Oct. 24, 1996) 12, 27

Rule

Fed. R. Civ. P. 24..... *passim*

Other Authorities

<i>10 Things to Know About HIV Suppression</i> , Nat'l Inst. of Allergy & Infectious Diseases (Mar. 25, 2025).....	4
<i>340B Patient Definition Compliance Resources</i> , Health Res. & Servs. Admin. (Jan. 2024).....	12, 14
<i>America's Health Centers: By the Numbers</i> , NACHC (Feb. 6, 2026).....	2
<i>FY13–FY26 Audit Results</i> , Health Res. & Servs. Admin. (June 2026).....	30
H.R. Rep. No. 102-384, reprinted in 1992 WL 239341	9, 10
Health Res. & Servs. Admin., Bureau of Primary Health Care, <i>Health Center Program Compliance Manual</i> (2018).....	3
HRSA, Clarification of HRSA Audits of 340B Covered Entities, 340B Drug Program Notice 2012-1 (Mar. 5, 2012).....	13
HRSA, Clarification of HRSA Audits of 340B Covered Entities, 340B Drug Program Notice 2012-1.1 (Feb. 8, 2013)	13
<i>Medicaid Drug Rebate Program (MDRP)</i> , Ctrs. for Medicare & Medicaid Servs.	19
<i>New Data Show Over 91% Viral Suppression Rate Among Ryan White HIV/AIDS Program Clients</i> , Health Res. & Servs. Admin. (Dec. 17, 2025).....	5
Akash Pillai et al., <i>Community Health Center Patients, Financing, and Services</i> , Kaiser Fam. Found. (Feb. 4, 2026)	3
<i>Program Integrity</i> , Health Res. & Servs. Admin (June 2026).....	13
<i>Program Integrity: FY12 Audit Results</i> , Health Res. & Servs. Admin. (updated July 14, 2017).....	30
<i>Undetectable = Untransmittable (U=U)</i> , Ctrs. for Disease Control & Prevention (Aug. 19, 2024)	4
Elizabeth Watts et al., <i>340B Participation and Safety Net Engagement Among Federally Qualified Health Centers</i> , 5 JAMA Health Forum e243360 (2024).....	3

The National Association of Community Health Centers, Inc. (“NACHC”), and Ryan White Clinics for 340B Access (“RWC-340B”) (together, the “Proposed Intervenor”) hereby move this Court, pursuant to Federal Rule of Civil Procedure 24(a), or in the alternative pursuant to Federal Rule of Civil Procedure 24(b), for an Order granting their Motion to Intervene as Defendants in this lawsuit.

INTRODUCTION AND INTERESTS OF PROPOSED INTERVENORS

The prescription drug discount program established by Section 340B of the Public Health Service Act (“PHS”), 42 U.S.C. § 256b (the “340B Program”), was intended to enable statutorily-enumerated safety-net health care providers (“Covered Entities”), which serve as the core of the Nation’s public health infrastructure, to broadly purchase outpatient prescription drugs at discounted prices from pharmaceutical manufacturers. This allows Covered Entities to generate “savings” on those drugs to stretch their limited resources, lower medication costs, and reinvest into expanding patient care and other critical safety-net services in underprivileged communities. The amount of the savings they may generate is directly tied to the volume of prescription drugs they may purchase under the 340B Program for their patients and the volume of patients to whom they render services.

Covered Entities include community health centers (“CHCs”), which consist of federally qualified health centers (“FQHCs”) and federally qualified health center look-alikes (“FQHC-LAs”). CHCs are primary health care and other services providers that are eligible to participate in the 340B Program pursuant to 42 U.S.C. § 256b(a)(4)(A) by virtue of their receipt of federal grant funding under, and/or satisfaction of requirements of, Section 330 of the Public Health Service Act, 42 U.S.C. § 254b. Covered Entities also include Ryan White clinics (“RWCs”), which serve as the Nation’s critical source of health care and other services for low-income people who have been diagnosed with human immunodeficiency virus or acquired immunodeficiency

syndrome (“HIV/AIDS”). RWCs are eligible to participate in the 340B Program pursuant to 42 U.S.C. § 256b(a)(4)(D) and (J) by virtue of their receipt, as direct or subrecipient grantees, of grants or financial assistance under the Ryan White Comprehensive AIDS Resources Emergency (“CARE”) Act, 42 U.S.C. § 300ff *et seq.* Given their limited resources and the under-reimbursed or unreimbursed services that they provide, both CHCs and RWCs rely extensively on the 340B Program to support their statutory missions of providing affordable, comprehensive, and community-driven care to medically underserved, uninsured, and low-income patients. Decl. of Dr. Kyu Rhee (“NACHC Decl.”) ¶¶ 13–21; Decl. of Shannon Burger (“RWC-340B Decl.”) ¶¶ 13–17.

Proposed Intervenor NACHC is a national, nonprofit membership organization representing CHCs and is thus uniquely positioned to explain the crucial role the 340B Program plays in allowing NACHC’s members to serve patients and communities that otherwise face substantial barriers to accessing care. NACHC Decl. ¶¶ 4–12. Founded in 1971, NACHC’s primary objective is to further the mission and purpose of CHCs. NACHC represents approximately 1,512 CHCs that deliver care at more than 17,000 service delivery sites in every state, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the Pacific Basin. *America’s Health Centers: By the Numbers*, NACHC (Feb. 6, 2026), <https://tinyurl.com/3cbewdm3>. NACHC’s members serve as the backbone of the Nation’s primary care safety net. Together, NACHC’s member CHCs provide comprehensive primary care to approximately 32.5 million patients each year and deliver more than 139 million patient visits annually. *Id.* CHC patients are overwhelmingly poor and medically underserved: approximately 90 percent live at or below 200 percent of the federal poverty level, about half depend on Medicaid, and more than 80 percent are uninsured or rely on public insurance. Akash Pillai et al., *Community*

Health Center Patients, Financing, and Services, Kaiser Fam. Found. (Feb. 4, 2026), <https://tinyurl.com/4db55ctk>.

Critically, as CHCs, NACHC’s members are statutorily required to furnish services to people regardless of their ability to pay. 42 U.S.C. § 254b(k)(3)(G)(iii)(I) (requiring CHCs to “assure that no patient will be denied health care services due to an individual’s inability to pay for such services”); *see also* Health Res. & Servs. Admin., Bureau of Primary Health Care, *Health Center Program Compliance Manual* 32–36 (2018) (“The health center must operate in a manner such that no patient shall be denied service due to an individual's inability to pay.”), <https://tinyurl.com/2x49c3vz>. CHCs also must provide “pharmaceutical services as may be appropriate.” 42 U.S.C. § 254b(b)(i)(V). Accordingly, CHCs are fiscally responsible for the communities they serve. For their patients and communities, the savings generated by the 340B Program are not incidental—they are essential to the care CHCs are required to provide, and to the federal mission Congress charged them to accomplish. NACHC Decl. ¶¶ 13–19; Elizabeth Watts et al., *340B Participation and Safety Net Engagement Among Federally Qualified Health Centers*, 5 JAMA Health Forum e243360 (2024), <https://tinyurl.com/294tyyxy> (“Even in a year in which FQHCs received additional funding associated with the COVID-19 pandemic, 340B revenue exceeded 25% of grant funds for the top 10% of FQHCs.”).

For its part, Proposed Intervenor RWC-340B is a national association of HIV/AIDS health care clinics and service providers that receive support under the CARE Act, 42 U.S.C. § 300ff *et seq.* RWC-340B Decl. ¶ 3. RWCs are statutorily required to care for low-income and vulnerable patients living with HIV/AIDS. They serve at the frontlines of the AIDS epidemic, supporting high risk clients and communities. *Id.* ¶¶ 3, 22. RWC-340B members provide primary care, case management, and other support services for persons with low incomes who are living with

HIV/AIDS. *Id.* ¶¶ 8–12. For many of these services, RWCs receive no insurance payments and, for that reason among others, are highly dependent on the 340B Program to offset the cost of providing comprehensive care to their patients that they furnish under the CARE Act. *Id.* ¶ 14.

And that dependence is not merely financial—it is inextricably linked to the public health mission of the CARE Act itself. The 340B Program enables RWCs to acquire antiretroviral medications at substantially reduced cost and, in turn, to furnish those medications—together with the wraparound case management and adherence support their patients need—to achieve and maintain viral suppression. RWC-340B Decl. ¶¶ 7, 19. The clinical significance of that outcome is now beyond scientific dispute. As the Centers for Disease Control and Prevention has recognized, a person living with HIV “who is on treatment and maintains an undetectable viral load has zero risk of transmitting HIV to their sexual partners.” *Undetectable = Untransmittable (U=U)*, Ctrs. for Disease Control & Prevention (Aug. 19, 2024), <https://tinyurl.com/4su6bz4n>. And three large multinational studies observed no linked HIV transmissions while the partner living with HIV remained virally suppressed. *See 10 Things to Know About HIV Suppression*, Nat’l Inst. of Allergy & Infectious Diseases (Mar. 25, 2025), <https://tinyurl.com/3t8wtw6w>. In other words, a patient whom an RWC keeps virally suppressed is rendered non-infectious as a matter of settled federal public health science.

The link between the 340B Program and the Nation’s capacity to control the HIV/AIDS epidemic is therefore direct and concrete. By subsidizing the medications and support services that produce durable viral suppression, the 340B Program does not merely improve individual patient health—it prevents onward transmission of the virus and thereby advances the core objective of the CARE Act. That mechanism is borne out in the field: in 2024, 91.4% of Ryan White HIV/AIDS Program patients receiving HIV medical care achieved viral suppression, far exceeding the

national rate of roughly 65–67% among all persons diagnosed with HIV. *See New Data Show Over 91% Viral Suppression Rate Among Ryan White HIV/AIDS Program Clients*, Health Res. & Servs. Admin. (Dec. 17, 2025), <https://tinyurl.com/yc2hx48y>. HRSA has expressly recognized that these services “help clients . . . remain virally suppressed, which prevents forward HIV transmission and reduces health care costs.” *Id.* Any measure that erodes RWCs’ access to 340B savings thus threatens not only the financial viability of these frontline providers, but the demonstrated public health gains—reduced transmission and progress toward ending the epidemic—that their federally funded mission is designed to achieve. RWC-340B Decl. ¶ 22.

Over the past decade, the pharmaceutical industry, including Plaintiff AbbVie (“AbbVie”), have engaged in a sweeping and carefully orchestrated strategy to reduce the size of the 340B Program to increase their profits. *See, e.g., AbbVie, Inc. v. Murrill*, 166 F.4th 528 (5th Cir. 2026); *Mosaic Health, Inc. v. Sanofi-Aventis U.S., LLC*, 156 F.4th 68 (2d Cir. 2025). First, drug manufacturers sued the federal government over covered entities’ use of contract pharmacies to dispense 340B drugs. *See, e.g., Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452 (D.C. Cir. 2024); *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696 (3d Cir. 2023); *Eli Lilly & Co. v. HHS*, No. 1:21-cv-00081, 2021 WL 5039566 (S.D. Ind. Oct. 29, 2021). When states enacted laws protecting distribution to contract pharmacies, manufacturers and their trade association, Pharmaceutical Research and Manufacturers of America, filed multiple suits against each state. *See, e.g., Pharm. Rsch. & Mfrs. of Am. v. McClain*, 95 F.4th 1136 (8th Cir.), *cert. denied*, 145 S. Ct. 768 (2024); *AbbVie*, 166 F.4th 528. More recently, a group of drug companies sued the Department of Health and Human Services (“HHS”) seeking to disqualify most, if not all, grantee sexually transmitted disease clinics from the 340B program. *Amgen, Inc. v. Kennedy*, No. 24-CV-3571 (JEB), 2025 WL 2206948 (D.D.C. Aug. 4, 2025).

Here, AbbVie seeks to reduce the size of the 340B Program, and its discount obligations, by limiting the 340B savings that NACHC and RWC-340B members are statutorily entitled to generate to sustain their safety-net programs. Specifically, AbbVie seeks judicial approval of a new, ambiguous, and substantially narrower definition of “patient” than the 340B statute allows. Compl. ¶¶ 17, 198, 205–06 (Dkt. 1). Adoption of AbbVie’s proposed definition would significantly limit the savings Covered Entities may generate for their patients despite having established relationships with them under the plain and ordinary meaning of the term, “patient.”

The question presented in this case is therefore one of statutory interpretation: because Congress left the term “patient” undefined, its meaning is fixed by its ordinary, original public meaning at the time of enactment, not by AbbVie’s profit-driven, narrow, modern definition, and not by any definition that the federal Health Resources and Services Administration (“HRSA”), the agency that administers the 340B Program, never adopted. AbbVie seeks this Court’s approval of a “patient” definition that is flatly inconsistent with the plain, original public meaning of that term.

Specifically, AbbVie asks this Court to declare that its proposed definition “is the best reading of the term ‘patient’ as used in the 340B statute” and to direct HRSA to authorize and enforce audits applying that interpretation. Compl. Prayer for Relief ¶¶ 1–5. But AbbVie’s purported definition is inconsistent with the original public meaning of the plain text of the 340B statute and would depart from longstanding HRSA interpretive guidance. Compl. ¶¶ 17, 65–75. If adopted, AbbVie’s proposed definition would substantially upend how Proposed Intervenors’ members determine 340B patient eligibility, thereby disrupting the professional healthcare relationship between Covered Entities and their patients. NACHC Decl. ¶¶ 30–50. Covered Entities—not manufacturers—deliver care, establish and maintain patient relationships, coordinate

referrals, and provide telehealth services. By virtue of their role as health care providers, they are best positioned to determine in the first instance whether individuals who receive care from them qualify as their patients. *See* NACHC Decl. ¶¶ 20–21; RWC-340B Decl. ¶¶ 16–17.

This case arises directly from AbbVie’s efforts to audit two Covered Entities—Barrio Comprehensive Family Health Care Center, Inc. (“Barrio”), a HRSA-funded health center in Texas, and The Mount Sinai Hospital (“Mount Sinai”), a disproportionate share hospital in New York—using AbbVie’s proposed definition of “patient.” Compl. ¶¶ 13–14. On September 18, 2025, HRSA informed AbbVie that HRSA would not impose corrective action based on potential AbbVie audit findings that were inconsistent with HRSA’s longstanding guidance describing patient eligibility (the “1996 Guidelines”). *Id.* ¶¶ 13–21. AbbVie now asks this Court to set aside HRSA’s September 18, 2025, communication to AbbVie that relies on the 1996 Guidelines; declare that AbbVie’s proposed definition reflects the best meaning of “patient,” despite its inconsistency with the statute and the 1996 Guidelines; and authorize AbbVie to audit Barrio and Mount Sinai under AbbVie’s preferred definition. *Id.* ¶ 21; *id.* Prayer for Relief ¶¶ 1–5.

The relief that AbbVie seeks would have consequences far beyond the two Covered Entities identified in the Complaint. Covered Entities across the country have understandably structured 340B compliance, referral practices, telehealth policies, and patient-eligibility determinations in compliance with the plain meaning of the term “patient” in the 340B statute and HRSA’s 1996 Guidelines. NACHC Decl. ¶¶ 20–21, 32, 48; RWC-340B Decl. ¶¶ 16–17. If AbbVie were to prevail here, Covered Entities could be subject to repayment demands and corrective action disputes based on an extra-statutory standard that HRSA has not adopted and that departs from the plain meaning of the term “patient” in the 340B statute. NACHC Decl. ¶ 47. Such a result would not only destabilize the Nation’s public health infrastructure by weakening the 340B Program for

all Covered Entities, but it would also directly harm the patients and communities that depend on safety-net services from Covered Entities that are supported by 340B savings. NACHC Decl. ¶¶ 49–50; RWC-340B Decl. ¶¶ 21–22.

Intervention by Proposed Intervenors is necessary to protect the interests of their members, patients, and communities and to ensure that the Court hears from the national associations representing the Covered Entities whose operations and patient-care missions would be adversely affected by the relief that AbbVie seeks. NACHC Decl. ¶¶ 31, 49–50; RWC-340B Decl. ¶¶ 18–22. The Government Defendants represent the interests of the federal government, including HRSA; they do not represent the distinct operational, financial, and patient-care interests of Covered Entities and are not fully apprised of the resources required to furnish such services to under-resourced populations. *See* NACHC Decl. ¶¶ 7–8; RWC-340B Decl. ¶¶ 4–5. Although Proposed Intervenors support HRSA’s efforts to interpret the term “patient,” which was articulated in its 1996 Guidelines, the Government Defendants nevertheless have an incentive to reinforce HRSA’s traditional (and well-documented) desire to impose a narrower patient definition on 340B safety-net health care providers. Proposed Intervenors therefore seek intervention to defend the interests of their member Covered Entities and the underprivileged communities they serve.

As demonstrated below, Proposed Intervenors plainly meet the standard for intervention of right. Proposed Intervenors also satisfy the requirements for permissive intervention, which this Court should grant in the alternative.

BACKGROUND

A. The 340B Program's Purpose and Function

The 340B Program can be traced to 1990, when Congress created the Medicaid Drug Rebate Program (the “MDRP”) to lower the cost of pharmaceuticals covered by Medicaid. The MDRP requires drug companies to enter into a rebate agreement with the Secretary of the Department of Health and Human Services (“HHS”) as a precondition for coverage under Medicaid and Medicare Part B for their drugs. *See* Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, § 4401, 104 Stat. 1388, 1388-143-161 (codified at 42 U.S.C. § 1396r-8); Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified at 42 U.S.C. § 1396r-8(a)). The rebate agreement specifies that the manufacturer must pay rebates to state Medicaid programs on Medicaid claims for “covered outpatient drugs” based on the manufacturer’s “best price” for a drug, among other factors. *Id.*

After passage of the MDRP statute, manufacturers raised their “best prices” on covered outpatient drugs for preferred customers, including large governmental purchasers like the Department of Veterans Affairs, large governmental or private non-profit safety-net hospitals, and large FQHC systems. H.R. Rep. No. 102-384, pt. 2, at 9, reprinted in 1992 WL 239341, at *12. The House Report issued prior to enactment of the 340B statute referenced a study conducted by researchers at New York University, which found that, after the passage of the MDRP, manufacturers “promptly cancelled discount contracts, terminated special-price practices, and raised the prices” charged to safety net providers. *Id.* at 10. This is because higher drug prices for non-Medicaid purchasers meant a higher “best price” and correspondingly lower rebate to the Medicaid program, ultimately resulting in higher profits for manufacturers.

Congress responded to manufacturer increases in drug prices by enacting Section 340B of the Public Health Service Act. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, 106

Stat. 4943 (codified at 42 U.S.C. § 256b). Congress enacted the 340B Program with the purpose of lowering Covered Entities’ direct purchase prices for covered outpatient drugs. The savings generated by these discounted prices—pejoratively labeled by AbbVie as “spread”—were explicitly intended for 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 9 (1992), reprinted in 1992 WL 239341, at *12 (emphasis added).

Under the 340B Program, manufacturers are required to enter into a pharmaceutical pricing agreement (“PPA”) with HHS, as a condition of Medicaid and Medicare Part B coverage of their drugs. Under the PPA, manufacturers agree to provide discounts on covered outpatient drugs purchased by specified Covered Entities that serve the Nation’s most medically vulnerable patient populations. Thus, manufacturers voluntarily participate in 340B to access extremely lucrative markets for their drugs—coverage under Medicaid and Medicare Part B.

The legislative history confirms that Congress designed the 340B Program to be an access-expanding measure while declining to constrain the statutory term “patient.” Though Congress considered a more restrictive 340B Program, the legislative history demonstrates that, as the bill moved from the House of Representatives through Senate amendment to enactment, Congress repeatedly *enlarged* the roster of Covered Entities—adding family-planning projects, hemophilia treatment centers, AIDS programs, and disproportionate-share hospitals and kept the term “patient” broad.

Specifically, Congress initially defined 340B-eligible Covered Entities to include certain disproportionate share hospitals (“DSH”) that provide care to a large percentage of Medicaid and Medicare disabled beneficiaries; CHCs; state-operated AIDS drug assistance programs (“ADAPs”) and other CARE Act programs grantees; tuberculosis, black lung, family planning and

sexually transmitted disease clinics; hemophilia treatment centers; public housing primary care clinics; homeless clinics; Urban Indian clinics; and Native Hawaiian health centers. 42 U.S.C. § 256b(a)(4); 42 U.S.C. § 1396d(l)(2)(B). Congress later expanded eligibility to participate in the 340B Program to five new categories of Covered Entities: cancer hospitals, critical access hospitals, sole community hospitals, rural referral centers, and children’s hospitals. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7101, 124 Stat. 119 (2010).

Together, this history shows that, over time, Congress has expanded the 340B Program to include more categories of health care providers, increasing the number of discounts that manufacturers are required to provide. Attempts to narrow 340B’s reach run counter to that history—and, as described below, to the language Congress chose to achieve its purposes.

B. 340B Program Administration and HRSA’s Diversion Prohibition Enforcement

1. HRSA’s Prior Approaches to “Duplicate Discounts” and “Diversion”

Among other statutory compliance requirements, two are of particular focus in the 340B Program: the “duplicate discount prohibition” and the “diversion prohibition.” The Medicaid duplicate discount prohibition protects manufacturers from paying both an MDRP rebate and a 340B discount on the same drug. 42 U.S.C. § 256b(a)(5)(A). The diversion prohibition—the singular place in the statute where “patient” is mentioned—states that a Covered Entity “shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.” *Id.* § 256b(a)(5)(B).

With respect to the diversion prohibition, Congress left “patient” undefined, fixing the meaning of that term to its ordinary public meaning at the time. *See Genesis Health Care, Inc. v. Becerra*, No. 4:19-CV-01531-RBH, 2023 WL 7549156, at *12 (D.S.C. Nov. 3, 2023) (holding that because the 340B statute “does not define ‘patient,’” Congress “intended patient to have its plain and ordinary meaning”); *cf. Wis. Cent. Ltd. v. United States*, 585 U.S. 274, 284 (2018) (words take

“their ordinary ... meaning . . . at the time Congress enacted the statute”). HRSA, moreover, has finalized only one official 1996 “patient”-definition guidance in the more than three decades the 340B Program has existed. *See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility*, 61 Fed. Reg. 55,156, 55,157–58 (Oct. 24, 1996) (the “1996 Guidelines”). HRSA itself confirms that the 1996 Guidelines remain the standards that “continue to guide HRSA’s audit activities.” *340B Patient Definition Compliance Resources*, Health Res. & Servs. Admin. (Jan. 2024), <https://tinyurl.com/mry3n2p2>.

The 1996 Guidelines treat an individual as a Covered Entity’s “patient” if: (1) the entity has established a relationship with the individual and maintains records of the individual’s care (the “records maintenance test”); (2) the individual receives services from a provider employed by or under contractual or other arrangement (“e.g., referral for consultation”) with the entity (the “professional care test”); and (3) the professional health care service furnished by the covered entity to the individual is “consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity” (the “scope of the grant test”). The scope of the grant test applies only to federal grantee Covered Entities; disproportionate share hospitals are exempt from this test under the 1996 Guidelines. 61 Fed. Reg. at 55,157–58.

In 2007, HRSA published proposed guidance that would have required, as a condition of patient status, that “the covered entity *must be primarily responsible for the health care which results in the use of, or prescription for 340B drugs,*” or an “origination test,” with the prescribing provider “employed by the covered entity, or provid[ing] health care to patients of the covered entity under a valid, binding, and enforceable contract.” *Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of “Patient”*, 72 Fed. Reg. 1543, 1543–44 (Jan. 12,

2007) (emphasis added). That 2007 notice expressly contemplated replacing “all previous 340B Program guidance addressing the definition of a patient.” *Id.* at 1544. After receiving comments, HRSA decided not to finalize the 2007 proposal, and it lapsed. HRSA tried again in 2015, proposing omnibus guidance that would have imposed an origination test, requiring that the “individual receives a drug that is ordered or prescribed by the covered entity provider as a result of the service” furnished by the covered entity. *340B Drug Pricing Program Omnibus Guidance*, 80 Fed. Reg. 52,300 (Aug. 28, 2015). HRSA never finalized that proposal either.

In addition to the compliance obligations of Covered Entities, the 340B statute permits HRSA and manufacturers to audit the records of the Covered Entity that “directly pertain to the entity’s compliance” with the diversion and duplicate discount prohibitions. 42 U.S.C. § 256b(a)(5)(C). The statute limits manufacturer and HRSA audit rights to procedures established by the HHS “relating to the number, duration, and scope” of such audits. *Id.* In 1996, HRSA published manufacturer audit guidelines. It clarified those guidelines on two subsequent occasions, in March 2012 and February 2013.¹ HRSA currently maintains a web page that provides a general overview of pre-audit, onsite audit, and post-audit procedures. *Program Integrity*, Health Res. & Servs. Admin (June 2026), <https://tinyurl.com/bdf7eb7pc>. Though a manufacturer can audit Covered Entities under the 340B statute, it is ultimately the decision of HHS to determine post-audit—and after notice and hearing—whether a Covered Entity is in violation of the diversion or duplicate discount prohibitions, in which case the Covered Entity may be liable to the manufacturer for repayment. 42 U.S.C. § 256b(a)(5)(D). If the manufacturer is not satisfied with HHS’s

¹ See *Manufacturer Audit Guidelines and Dispute Resolution Process 0905-ZA-19*, 61 Fed. Reg. 65,406 (Dec. 12, 1996). See also “Clarification of HRSA Audits of 340B Covered Entities” (“Audit Policy”) (HRSA, Clarification of HRSA Audits of 340B Covered Entities, 340B Drug Program Notice 2012-1 (Mar. 5, 2012), *superseded by* HRSA, Clarification of HRSA Audits of 340B Covered Entities, 340B Drug Program Notice 2012-1.1 (Feb. 8, 2013) (“Notice 2012-1.1”).

determination, it may submit a petition through the Alternative Dispute Resolution (“ADR”) process. *Id.* § 256b(d)(3); 42 C.F.R. Part 10. A panel appointed by HHS, to which the manufacturer has the right to object based on conflicts of interest, determines whether the Covered Entity is out of compliance. 42 C.F.R. §§ 10.20(a)(2), (b), 10.23.

2. HRSA’s Origination and Location Tests Observed Through Audits

Prior to 2019 when auditing Covered Entities for prohibited “diversion” under 42 U.S.C. § 256b(a)(5)(B), HRSA treated a prescription as 340B-eligible only if that prescription “originated” from a professional health care service furnished by the Covered Entity, even though it had never adopted this “origination test” in agency guidance, or if the prescription was written from a registered 340B location, sometimes referenced as the “location test.” The location test is functionally different from the origination test because it examines whether a prescription is written at a registered 340B site to determine if that prescription is eligible to be filled with 340B drugs. In 2023, a Covered Entity successfully challenged a diversion audit finding in federal court based on HRSA’s application of the origination test. *Genesis Health Care, Inc. v. Becerra*, 701 F. Supp. 3d 312, 322 (D.S.C. 2023).

Specifically, that court, in its thorough analysis of the plain meaning of the 340B statute, stated that “[n]othing in the statute conditions an individual’s eligibility as a 340B patient on whether the health care service resulting in the prescription was initiated by the ‘covered entity.’” *Id.* at 324. HRSA considers the relief the court entered there to be limited to the plaintiff Covered Entity. *See 340B Patient Definition Compliance Resources, supra* (stating “HRSA notes that the decision in *Genesis Health Care, Inc. v. Becerra*, Civ. 4:19-cv-01531-RBH (D.S.C. November 3, 2023), is applicable solely to Genesis Health Care.”).

Given this history, Proposed Intervenor is justifiably concerned that the HRSA may at some point in this litigation revert to its prior position of trying to narrow the definition of “patient”

in a way that disserves Proposed Intervenor's interests—as well as the interests of the communities they serve.

ARGUMENT

Proposed Intervenor respectfully request the Court to grant intervention because they satisfy every requirement for intervention as of right under Rule 24(a) and, alternatively, for permissive intervention under Rule 24(b). Proposed Intervenor's motion is timely because it is filed within twenty days of the date that the Government Defendants' motion to dismiss was submitted to the court and before AbbVie filed its response, which is currently due on July 28, 2026. Proposed Intervenor seeks full intervention as defendants in this action under Rule 24, including the right to participate in the briefing on the Government Defendants' pending motion to dismiss by joining that motion and filing a reply in support of it. Proposed Intervenor does not seek to add new claims or defenses, or alter the existing briefing schedule. And they are prepared to participate on the schedule the Court has already set. Their full participation will therefore neither delay the case nor prejudice the existing parties.

The relief that AbbVie seeks implicates Proposed Intervenor's concrete, legally protected interests: The result of this litigation would directly govern how Proposed Intervenor's members determine 340B patient eligibility, structure 340B compliance, and generate savings to fund the patient care that 340B savings make possible. AbbVie's requested relief thus threatens the resources that allow Proposed Intervenor's members to serve underprivileged communities. NACHC Decl. ¶¶ 30–50.

Those interests would be impaired because a judgment adopting AbbVie's proposed patient definition would, as a practical matter, bind Covered Entities to a standard far narrower than the standard that HRSA has pronounced, Congress intended, or the plain text of Section 340B permits, exposing Covered Entities to unlawful audit findings, wrongful repayment demands, and

misappropriated safety-net “savings” by AbbVie. Moreover, no existing party adequately represents Proposed Intervenor’s interests. That is because the Government Defendants—the only parties other than AbbVie—must represent the broad institutional interests of HRSA and the United States, including preserving the agency’s own administrative authority. They are under no obligation to represent the distinct, provider-specific interests of grantee Covered Entities, whose operations are threatened by this action and that are subject to grant-specific patient eligibility requirements.

Given these realities, the Court should grant Proposed Intervenor’s motion to intervene. Federal Rule of Civil Procedure 24(a)(2) provides that, on timely motion, intervention is required for a proposed intervenor that “claims an interest relating to the property or transaction that is the subject of the action, and is so situated that disposing of the action may as a practical matter impair or impede the movant’s ability to protect its interest, unless existing parties adequately represent that interest.” *Karsner v. Lothian*, 532 F.3d 876, 885 (D.C. Cir. 2008) (quoting Fed. R. Civ. P. 24(a)(2)). Alternatively, Federal Rule of Civil Procedure 24(b) provides, “[o]n timely motion, the Court may permit anyone to intervene who . . . has a claim or defense that shares with the main action a common question of law or fact.” Fed. R. Civ. P. 24(b); *see also E.E.O.C. v. Nat’l Children’s Ctr., Inc.*, 146 F.3d 1042, 1045 (D.C. Cir. 1998) (setting forth standard for permissive intervention). Proposed Intervenor meets both of these alternative standards. *See, e.g., Amgen Inc. v. Kennedy*, No. 24-CV-3571 (JEB), 2026 WL 202157, at *2 (D.D.C. Jan. 27, 2026) (Boasberg, C.J.) (granting Community Care Resources of Florida’s motion to intervene despite intervenor moving for intervention 226 days after the Government defendant filed a motion to dismiss and 114 days after the court entered judgment on that motion to dismiss).

I. Proposed Intervenorors Have a Right to Intervene Under Rule 24(a)(2).

Federal Rule of Civil Procedure 24(a)(2) requires a court to grant intervention to anyone who “claims an interest relating to the property or transaction that is the subject of the action, and is so situated that disposing of the action may as a practical matter impair or impede the movant’s ability to protect its interest, unless existing parties adequately represent that interest.” Fed. R. Civ. P. 24(a)(2). In this Circuit, besides establishing standing and timeliness, a movant must satisfy three requirements: “(1) the applicant must demonstrate a legally protected interest in the action; (2) the action must threaten to impair that interest; and (3) no party to the action can be an adequate representative of the applicant’s interests.” *Karsner*, 532 F.3d at 885 (quoting *SEC v. Prudential Sec. Inc.*, 136 F.3d 153, 156 (D.C. Cir. 1998)).

Courts in this Circuit broadly construe the first two requirements, treating the inquiry as a “practical guide” aimed at “disposing of disputes with as many concerned parties as may be compatible with efficiency and due process.” *WildEarth Guardians v. Salazar*, 272 F.R.D. 4, 12–13 (D.D.C. 2010). The impairment inquiry “is not a rigid one.” *Id.* at 13. Even the prospect of an adverse *stare decisis* effect “may . . . supply the practical disadvantage that warrants intervention as of right.” *Nuesse v. Camp*, 385 F.2d 694, 702 (D.C. Cir. 1967). Regarding the third requirement, a proposed intervenor bears only a *de minimis* burden of showing that the existing parties may not adequately represent its interest; it need show only the possibility of inadequate representation. *Fund for Animals, Inc. v. Norton*, 322 F.3d 728, 735 (D.C. Cir. 2003) (citing *Trbovich v. United Mine Workers*, 404 U.S. 528, 538 (1972)). Courts grant intervention “unless it is *clear* that [a] party will provide adequate representation for the absentee.” *Id.* at 735 (emphasis added) (quoting *United States v. Am. Tel. & Tel. Co.*, 642 F.2d 1285, 1293 (D.C. Cir. 1980)). As shown below, Proposed Intervenorors satisfy all of the required elements.

A. Proposed Intervenorors Have Standing to Intervene

A party seeking to intervene as of right must establish standing under Article III, which requires (1) an injury in fact, (2) caused by the conduct complained of, (3) that is likely to be redressed by a favorable decision. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992); *Fund for Animals*, 322 F.3d at 732–33. Where, as here, proposed intervenors seek to defend agency action, they must show that they would be injured by the invalidation of that action, that the injury would be caused by that invalidation, and that the injury would be prevented if the agency action is upheld. *MGM Glob. Resorts Dev., LLC v. United States Dep’t of Interior*, No. 19-CV-2377 (RC), 2020 WL 5545496, at *3 (D.D.C. Sep. 16, 2020); *see also Crossroads Grassroots Pol’y Strategies v. FEC*, 788 F.3d 312, 316–17 (D.C. Cir. 2015) (emphasizing that the court “look[s] skeptically on government entities serving as adequate advocates for private parties”). Further, an association may assert standing on behalf of its members when its members would have standing in their own right, the interests at stake are germane to the organization’s purpose, and neither the claim nor the relief requires the participation of individual members. *Friends of the Earth, Inc. v. Laidlaw Env’t Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000). Proposed Intervenorors satisfy every requirement.

Proposed Intervenorors’ members would easily have standing to intervene in their own right because the relief AbbVie seeks would directly injure them by narrowing the class of patients to whom they may furnish 340B-priced drugs. NACHC Decl. ¶¶ 36–37; RWC-340B Decl. ¶ 18. AbbVie’s proposal would contravene the original plain meaning of “patient” and directly limit the 340B savings and the safety-net services that Proposed Intervenorors’ members render to vulnerable patient populations. NACHC Decl. ¶¶ 38–43; RWC-340B Decl. ¶¶ 19–20. And a narrowing of patient definition for 340B Program purposes would allow AbbVie to take action against Covered Entities, including Proposed Intervenorors’ members, with respect to that definition. *See* Compl. ¶¶ 17, 21, 74, 193–206. If AbbVie prevails, Proposed Intervenorors’ members would be required to

reassess longstanding compliance practices under a manufacturer-proposed standard that HRSA has not adopted. NACHC Decl. ¶¶ 34–35; *see* RWC-340B Decl. ¶¶ 16, 18. Their savings and safety-net services would be restricted. And the injuries that would flow from adoption of AbbVie’s narrow patient definition would be redressed by a judgment rejecting AbbVie’s claims.

Those injuries, moreover, may only be the first domino to fall. If AbbVie prevails here, each 340B-participating manufacturer would be able to require a separate patient definition, requiring Covered Entities to have hundreds of different policies to comply with each manufacturer’s expectations.² *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 120 (2011) (citing the congressional intent of the 340B statute’s ADR provisions as preserving HHS’s “efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis.”)

That threatened disruption is concrete and particularized. Covered Entities rely on the 340B Program to stretch limited resources, lower medication costs, and reinvest savings into patient care and community health services. NACHC Decl. ¶¶ 13, 45; RWC-340B Decl. ¶ 13. AbbVie’s proposed definition and the inevitable adoption of similar, narrow patient definitions by other manufacturers, would reduce the universe of prescriptions treated as 340B eligible, expose Covered Entities to unlawful manufacturer audit findings, repayment demands, and corrective-action disputes based on a plethora of narrow standards. NACHC Decl. ¶¶ 38, 47–48. Those consequences would directly affect Covered Entities’ financial resources, compliance obligations, and ability to serve medically underserved patients and communities. NACHC Decl. ¶¶ 43, 49; RWC-340B Decl. ¶¶ 19–21. Article III standing does not require NACHC and RWC-340B to wait

² Approximately 780 drug manufacturers participate in MDRP, each of which could implement its own patient definition under AbbVie’s proposed framework. *Medicaid Drug Rebate Program (MDRP)*, Ctrs. for Medicare & Medicaid Servs., <https://tinyurl.com/2e53rcvd> (last visited June 8, 2026).

until those harms have fully materialized; a “substantial risk” that the challenged action will cause injury is sufficient. *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014) (“An allegation of future injury may suffice [to satisfy Article III] if the threatened injury is certainly impending, or there is a substantial risk that the harm will occur.” (cleaned up)).

Proposed Intervenor’s potential injuries are also fairly traceable to the relief that AbbVie seeks. AbbVie asks this Court to declare that its proposed patient definition is the best reading of the 340B statute and that it be permitted to use that definition in future Covered Entity audits. Compl. ¶¶ 193–206; Prayer for Relief. If the Court grants that relief, the resulting change in the operative standard for evaluating 340B patient eligibility would flow directly from this litigation, not from independent third-party action untethered to the case. The harm to Proposed Intervenor’s members would be a direct consequence of a judgment displacing both the plain meaning of the statute and HRSA guidance. That harm would result from authorizing manufacturer audits under a materially narrower standard than the plain text of the statute and HRSA’s guidance.

The injury is also redressable: if the Court rejects AbbVie’s requested relief, Covered Entities would avoid the disruption, audit exposure, and compliance uncertainty that would follow from a judgment adopting AbbVie’s proposed definition. The relief Proposed Intervenor seeks—denial of AbbVie’s declaratory and injunctive claims—would prevent or substantially reduce the threatened injury to Proposed Intervenor’s members.

The remaining requirements for associational standing are likewise satisfied. The interests at stake are germane to Proposed Intervenor’s missions. NACHC exists to represent and advocate for CHCs and to support their ability to provide affordable, comprehensive, community-based care to medically underserved patients. NACHC Decl. ¶¶ 4–6. RWC-340B likewise exists to support RWCs dedicated to caring for low-income individuals living with HIV/AIDS. RWC-340B Decl.

¶¶ 3–5. This litigation directly concerns a program that funds those missions, and that funding is derived from 340B savings generated from prescriptions furnished to Covered Entities’ patients.

Further, direct participation from individual member Covered Entities is not required. Proposed Intervenor seek to object to AbbVie’s imposing its preferred patient definition on Potential Intervenor’s members and to present Covered Entities’ perspective on the appropriate patient-definition standard.³ No individual members’ participation is necessary to adjudicate whether AbbVie’s proposed definition should displace the plain meaning of the term “patient.” Accordingly, Proposed Intervenor have standing to intervene on behalf of their members whose 340B operations, compliance practices, and patient-care resources would be harmed if AbbVie succeeds in setting aside HRSA’s position and imposing its unprecedentedly narrow proposed definition of “patient.”

B. Proposed Intervenor Have Numerous Protected Interests at Stake

Given their clear standing, it is not surprising that Proposed Intervenor also have legally protected interests at stake in this litigation: The outcome of this case will directly govern how Proposed Intervenor’s members determine 340B patient eligibility for their patients, structure 340B compliance, and generate 340B savings to fund the patient care and other critical safety-net services they provide—the very interests Congress entrusted to Covered Entities under the 340B program.

Indeed, where a proposed intervenor has Article III standing, that showing also satisfies Rule 24(a)’s interest requirement. As the D.C. Circuit has explained, where a proposed intervenor

³ Proposed Intervenor are aware that 340B Health, a nonprofit hospital association, and two of its hospital members have also filed a motion to intervene in this litigation. 340B Health is an association representing hospitals that participate in the 340B Program and the other proposed intervenors are two such members. 340B Health does not represent RWCs or CHCs, which are different types of Covered Entities and, unlike hospitals in the 340B Program, are subject to the third criteria in HRSA’s patient definition.

has constitutional standing, it has “an interest relating to the property or transaction which is the subject of the action.” *Crossroads*, 788 F.3d at 320 (quoting *Fund for Animals*, 322 F.3d at 735; *see also Mayo v. Jarvis*, No. 14-CV-1751 (RC), 2015 WL 13700484, at *1 (D.D.C. Jan. 21, 2015)). Because Proposed Intervenors have demonstrated Article III standing, *see supra* § I.A., they satisfy Rule 24(a)’s interest requirement as well. *See Fund for Animals*, 322 F.3d at 735 (“Our conclusion that the NRD has constitutional standing is alone sufficient to establish that the NRD has ‘an interest relating to the property or transaction which is the subject of the action.’” (quoting Fed. R. Civ. P. 24(a)(2))); *Crossroads*, 788 F.3d at 320 (“[S]ince *Crossroads* has constitutional standing, it *a fortiori* has ‘an interest relating to the property or transaction which is the subject of the action.’”).

Proposed Intervenors’ interest is direct and substantial. Proposed Intervenors represent two categories of grantee Covered Entities that participate in the 340B Program. They rely on the plain language of the 340B statute to determine, in practice, when individuals to whom they provide care constitute their patients and are eligible to receive 340B drugs in accordance with the diversion prohibition. NACHC Decl. ¶¶ 21, 48; RWC-340B Decl. ¶¶ 16–17. The provision of those drugs to Covered Entity patients generate 340B savings that Covered Entities use to fund safety-net programs. Accordingly, Proposed Intervenors’ interest in preserving the plain meaning of the term “patient” under the statute is a protected interest of its members. Covered Entities—not AbbVie or the federal government—provide the health care services, maintain the patient relationships, coordinate referrals, conduct telehealth encounters, and administer the 340B Program compliance programs that AbbVie’s proposed definition would disrupt. NACHC Decl. ¶¶ 20–21; RWC-340B Decl. ¶ 17. Proposed Intervenors therefore have a strong interest in ensuring that the Court considers the perspective of their members, which are statutorily authorized to

ascertain their patients in the first instance, and deliver care in real-world clinical and operational settings regardless of a person's ability to pay.

AbbVie's requested relief threatens that interest. As explained previously, if AbbVie prevails, the resulting judgment would alter the standard used to evaluate Covered Entities' 340B Program compliance, and expose Covered Entities to unlawful manufacturer audit findings and corrective-action disputes under a patient definition standard that has not been adopted by Congress or through notice-and-comment procedures. Covered Entities participate in the 340B Program to reduce drug costs and allow them to generate 340B savings that they use to serve medically underserved patients and communities. *See Genesis Health Care*, 701 F. Supp. 3d at 316–21 (addressing the significance of the 340B patient-definition issue for Covered Entities); *see also* 42 U.S.C. § 256b(a)(5)(B).

Proposed Intervenor's interest is therefore not generalized or remote. It is tied directly to the central issue in this case: whether AbbVie may impose a narrower manufacturer-invented definition that would validate their audit diversion findings, potential corrective action imposed on Covered Entities under the 340B statute, and the scope of 340B savings that Proposed Intervenor's members depend on to serve the Nation's most vulnerable populations. Because the resolution of that issue would directly affect Proposed Intervenor's 340B Program compliance obligations, operations, and ability to generate savings, Proposed Intervenor easily satisfy Rule 24(a)'s interest requirement.

C. Adverse Disposition of This Action Will Impair the Ability of Proposed Intervenor to Protect Their Interests

Disposition of this action in AbbVie's favor would also impair Proposed Intervenor's ability to protect their interests because a judgment adopting AbbVie's proposed patient definition would, as a practical matter, bind Proposed Intervenor's members to a standard far narrower than

the standard HRSA adopted in its 1996 Guidelines. This would expose Covered Entities to unlawful audit findings, manufacturer repayment demands, and the loss of the 340B Program savings on which their patient care depends.

Under Rule 24(a)(2), moreover, a proposed intervenor need not show that its interests will certainly be impaired; it need only show that disposition of the action “*may* as a practical matter impair or impede” its ability to protect those interests. Fed. R. Civ. P. 24(a)(2) (emphasis added). Courts in this Circuit thus evaluate impairment pragmatically, focusing on the “practical consequences” of denying intervention. *Fund for Animals*, 322 F.3d at 735.

Those practical consequences are substantial here. AbbVie seeks a ruling that would impose an impermissibly narrow “patient” definition. If AbbVie prevails, that ruling could affect the standard used to evaluate whether AbbVie’s post-audit findings have complied with the confines of the 340B statute’s anti-diversion provision with respect to Proposed Intervenors’ members’ 340B programs and provider practices. It could also be invoked by other manufacturers seeking to challenge covered entities’ 340B practices, to impose unlawful audit findings, or to allege diversion based on that same narrowed standard or another standard unilaterally adopted by other manufacturers. NACHC Decl. ¶ 47. The resulting harm would not be abstract. Determining patient eligibility is key for Proposed Intervenors’ members ability to administer, and benefit from, their 340B programs, including their ability to extend services and drugs to low-income patients at discounted rates. NACHC Decl. ¶¶ 14, 17–20; RWC-340B Decl. ¶¶ 18–20.

Nor could those harms be easily remedied later, if at all. Covered Entities rely on 340B Program savings to stretch limited resources, lower medication costs, and reinvest in patient care and community health services. NACHC Decl. ¶¶ 13, 45; RWC-340B Decl. ¶ 13. If AbbVie’s proposed definition reduces the prescriptions considered to be 340B eligible, Covered Entities

would lose savings that support care for medically underserved communities they are required to serve under federal law or contract. Once those resources are lost and patient-care services are reduced, the harm would be difficult, if not impossible, to unwind. *See Genesis Health Care*, 701 F. Supp. 3d at 324–25. Because the disposition of this action in favor of AbbVie will practically impair Covered Entities’ 340B compliance, operations, satisfaction of community needs, and patient-care interests, Proposed Intervenor’s easily satisfy Rule 24(a)(2)’s impairment requirement.

That impairment, moreover, would include a substantial adverse precedential effect. The D.C. Circuit has long recognized that the practical effect of an adverse precedent can supply the impairment that Rule 24(a)(2) requires, holding that “stare decisis principles may in some cases supply the practical disadvantage that warrants intervention as of right.” *Nuesse*, 385 F.2d at 702); *see Fund for Animals*, 322 F.3d at 735. Here, a merits ruling construing “patient of the entity” in the manner AbbVie urges would not be limited to AbbVie’s dealings with the two providers named in the Complaint. Rather, it would become persuasive precedent that AbbVie could assert against Proposed Intervenor’s members, and any of the roughly 780 manufacturers participating in the 340B Program could invoke that precedent against Covered Entities nationwide or impose their own patient definition standards. That Covered Entities might later contest such demands in scattered, piecemeal proceedings does not cure the impairment, for “it is not enough to deny intervention under 24(a)(2) because applicants may vindicate their interests in some later, albeit more burdensome, litigation.” *Fund for Animals*, 322 F.3d at 735 (quoting *Nat. Res. Def. Council v. Costle*, 385 F.2d 904, 910 (D.C. Cir. 1977)).

For all these reasons, Proposed Intervenor’s have clearly established the requisite impairment of their interests.

D. No Party Adequately Represents Proposed Intervenor’s Interests

No existing party, moreover, adequately represents Proposed Intervenor’s interests. The burden is “minimal” to demonstrate that this criterion is met; Proposed Intervenor need only show that representation of its interests “may be inadequate.” *WildEarth Guardians v. Jewell*, 320 F.R.D. 1, 4 (D.D.C. 2017) (citing *Fund for Animals*, 322 F.3d at 735). Proposed Intervenor “should be allowed to intervene unless it is clear that the party will provide adequate representation for the absentee.” *Fund for Animals*, 322 F.3d at 735 (quoting *Am. Tel. & Tel. Co.*, 642 F.2d at 1293). And here, the Government Defendants cannot provide that adequate representation. They must defend HRSA and the United States as institutions—safeguarding the agency’s own administrative and enforcement prerogatives—rather than the distinct, provider-specific interest of the CHCs and RWCs whose 340B operations are directly at stake.

Given HRSA’s prior unlawful enforcement activities to implement its earlier origination and location tests, *see supra* § B.2, Proposed Intervenor cannot reasonably expect Government Defendants to adequately or accurately represent Proposed Intervenor’s interest in maintaining the plain meaning of the term “patient.” That meaning does not include an origination test as HRSA has previously required through its audits. *Genesis Health Care*, 701 F. Supp. 3d at 312. Government Defendants represent the interests of HHS, including HRSA, not Covered Entities. That the government and Proposed Intervenor may share the same ultimate objective here is not enough. In those circumstances, the D.C. Circuit has recognized that government representation may be inadequate because the government must represent broader public and institutional interests. *Crossroads*, 788 F.3d at 321.

That distinction is pronounced here. HRSA may elect in this case to defend its 1996 Guidelines as articulated to AbbVie in its September 18, 2025, letter as an exercise of agency authority or to preserve flexibility over future program administration. Proposed Intervenor, by

contrast, seek to protect the interests of Covered Entities that would be affected by any ruling adopting any narrow interpretation of “patient” that departs from the original plain meaning of the statute.

And, unlike Proposed Intervenor, no party or proposed party in this case represents the particular interest of grantee Covered Entities, which, unlike other Covered Entity types, are subject to the third prong of HRSA’s 1996 Guidelines—the scope of the grant test. That test permits grantee Covered Entities to establish 340B patient relationships by rendering health care services only if those services are “consistent with the service or range of services for which grant funding or Federally qualified health center look-alike status has been provided to the entity.” 61 Fed. Reg. at 55,157–58.

Proposed Intervenor are also uniquely positioned to describe the impact that AbbVie’s proposed patient definition will have on grantee Covered Entities and the patients they serve. The members of Proposed Intervenor NACHC, unlike any other covered entity category, are statutorily required to serve patients regardless of ability to pay. 42 U.S.C. § 254b(k)(3)(G)(iii)(I). And NACHC’s members are required to provide “pharmaceutical services as may be appropriate.” *Id.* § 254b(b)(1)(A)(i)(V). The members of Proposed Intervenor RWC-340B, unlike any other covered entity category, are charged with the sole mission of providing comprehensive care to individuals living with HIV/AIDs, who are often unfairly stigmatized with resultant socio-economic barriers to care. 42 U.S.C. § 300ff *et seq.* Proposed Intervenor are also equipped to address why AbbVie’s assertions regarding widespread 340B Program abuse and non-compliance are inaccurate. As such, Proposed Intervenor are uniquely able to describe the purpose and benefit of the 340B Program and articulate the real-world harm that will arise should AbbVie’s proposed “patient” definition be enforced.

The Proposed Intervenor would therefore be the only parties to represent federal grantee Covered Entities’ interests against AbbVie’s narrower proposed patient definition or against HRSA with respect to its publication and enforcement of narrower patient definition standards, including the origination test or location test. The Government Defendants therefore cannot be presumed to be willing to press the grantee-provider-specific arguments necessary to protect the interests of Covered Entities. Moreover, in prior litigation involving the 340B Program, the government has taken positions that diverged from provider interests. *See Am. Hosp. Ass’n v. Becerra*, No. 18-CV-2084 (RC), 2023 WL 143337, at *1 (D.D.C. Jan. 10, 2023) (HHS’s enforcement of payment cuts illustrating agency/provider divergence); *see also Johnson & Johnson Health Care Sys. Inc. v. Kennedy*, No. 24-CV-3188 (RC), 2025 WL 1411076, at *4 (D.D.C. May 15, 2025) (granting a hospital association and its covered entity members’ motion to intervene as defendants in 340B manufacturer challenge, acknowledging that provider interests are distinct from the government’s interests).

And the consequences of HRSA’s cramped reading of “patient” are not hypothetical; they have already forced a covered entity into federal court to vindicate the statute’s plain terms. In *Genesis Health Care, Inc. v. Becerra*, a South Carolina FQHC challenged HRSA’s insistence that, “in order for an individual to qualify as a 340B patient, [the entity] must have initiated the healthcare service resulting in the prescription, regardless if the patient had an unrelated billable FQHC encounter.” 701 F. Supp. 3d at 322. Genesis was compelled to sue to protect its ability to ascertain its patients in accordance with the plain text of Section 340B. *See id.*

The district court agreed with Genesis and rejected HRSA’s construction as unlawful, holding that HRSA’s “interpretation of the term ‘patient’ . . . [is] contrary to the plain language of the 340B statute” and that “[n]othing in the statute conditions an individual’s eligibility as a 340B

patient on whether the health care service resulting in the prescription was initiated by the ‘covered entity.’” *Id.* at 324. Indeed, the court found “no requirement that the 340B prescription be initiated from a ‘covered entity’ or contract provider,” because “[t]he plain language of the 340B statute does not require a link between a 340B prescription sold by a ‘covered entity’ to a ‘patient’ and the origination of that prescription.” *Id.* at 324–25. The court accordingly declared that “the only statutory requirement for 340B eligibility of a person is that the person be a patient of a covered entity, as clearly stated in 42 U.S.C. § 256b(a)(5)(B).” *Id.* at 331. Genesis thus stands as a judicial rejection of precisely the kind of extra-statutory eligibility test that would narrow the class of patients Congress made eligible to receive 340B drugs. Rather than taking heed to this ruling, HRSA continued to apply the origination test, further demonstrating that it will not adequately represent the interests of Proposed Intervenor

It is for reasons such as these that the D.C. Circuit has “often concluded that governmental entities do not adequately represent the interests of aspiring intervenors.” *Crossroads*, 788 F.3d at 320–21 (quoting *Fund for Animals*, 322 F.3d at 736. Accordingly, that court “look[s] skeptically on government entities serving as adequate advocates for private parties”—even where the agency and the intervenor share the same general objective. *Crossroads*, 788 F.3d at 320–21.

And here, two features of this case make the risk of inadequate representation especially acute. First, in litigating this case, the Government Defendants must weigh the federal Executive Branch’s broader litigation posture—considerations that led them to defend the September 18, 2025, letter to AbbVie on narrow administrative-authority grounds, or to preserve agency flexibility to adopt a different patient definition later, rather than to vindicate the specific provider interest in the statute’s plain meaning that Proposed Intervenor would press. The government has

no obligation to advance the provider-centered statutory and operational arguments that are Proposed Intervenors’ reason for seeking to intervene.

Second, the government’s commitment to a vigorous defense of its current position is not assured. Because the Government Defendants could narrow their defense, settle, or decline to appeal an adverse ruling without regard to the distinct consequences for Covered Entities that could stem from this case, Proposed Intervenors readily clear the “minimal” burden of showing that representation “may be” inadequate. *Trbovich*, 404 U.S. at 538 n.10.

The inadequacy of the Government’s representation is confirmed by the enforcement history that produced this dispute. Although HRSA twice declined to adopt an origination test by guidance—in its abandoned 2007 proposal and again in the withdrawn 2015 omnibus guidance—the agency’s audit program has, in practice, drifted toward origination- and location-based limits on patient eligibility that the statute does not contain. *See Program Integrity: FY12 Audit Results*, Health Res. & Servs. Admin. (updated July 14, 2017), <https://tinyurl.com/5cd8v7sn>; *see also FY13–FY26 Audit Results*, Health Res. & Servs. Admin. (June 2026), <https://tinyurl.com/bdfef7pc> (collecting HRSA covered-entity audit results for fiscal years 2012 through 2026) (citing diversion findings “for prescription[s] originating from ineligible site[s]” and “prescription[s] written at ineligible site[s]”). And it defended its application of the origination test in the *Genesis* case. *See supra* § I.D.

This case requires the Court to decide whether those origination- and location-based theories are lawful—the same theories AbbVie now seeks to entrench through its proposed patient definition. The Government Defendants cannot be expected to disclaim an enforcement posture their own agency has developed and employed in the past. Indeed, HRSA has an institutional interest in preserving the very administrative flexibility that produced these tests. Proposed

Intervenors’ members, by contrast, have every incentive to argue that the statute forecloses origination- and location-based eligibility limits altogether. That divergence is precisely why the Government’s representation “may be” inadequate and why Proposed Intervenors’ distinct, provider-side perspective is needed.

Because the Government Defendants represent the federal government’s interests, and not the distinct interests of CHCs and RWCs, Proposed Intervenors have shown at minimum that existing representation may be inadequate. That is all Rule 24(a) requires.

E. Proposed Intervenors’ Motion is Timely

Finally, Proposed Intervenors’ motion is timely because it is being filed at the outset of the litigation and before any substantive proceedings have taken place—so granting it will neither delay the case nor prejudice the existing parties. The D.C. Circuit has instructed that “[t]he timeliness of a motion to intervene is ‘to be judged in consideration of all the circumstances.’” *Roane v. Leonhart*, 741 F.3d 147, 151 (D.C. Cir. 2014) (quoting *Smoke v. Norton*, 252 F.3d 468, 471 (D.C. Cir. 2001)). To evaluate timeliness, “courts should take into account (a) the time elapsed since the inception of the action, (b) the probability of prejudice to those already party to the proceedings, (c) the purpose for which intervention is sought, and (d) the need for intervention as a means for preserving the putative intervenor’s rights.” *Salazar*, 272 F.R.D. at 12; *see also Karsner*, 532 F.3d at 885. The “most important consideration,” however, is whether any delay in seeking intervention would prejudice the existing parties. *Roane*, 741 F.3d at 151. That is because the timeliness requirement is directed primarily at preventing a proposed intervenor from “unduly disrupting litigation to the unfair detriment of the existing parties.” *Id.*

Those considerations support intervention here. AbbVie filed this action on April 8, 2026. Proposed Intervenors seek intervention while this case remains in its preliminary stages. The Government Defendants filed their response on June 16, 2026—less than three weeks before

Proposed Intervenor now seek intervention. No party has been required to present its full merits position, and the Court has not issued any substantive ruling. Intervention at this stage will not require the Court or the parties to revisit any completed proceeding, modify any merits ruling, or duplicate prior briefing. Instead, intervention will allow Proposed Intervenor to participate before the litigation has meaningfully progressed and before any party could claim prejudice from its participation. Accordingly, Proposed Intervenor's intervention motion is timely.

That the Government Defendants have already moved to dismiss does not render Proposed Intervenor's motion untimely. Courts in this District routinely find motions to intervene timely when filed shortly after—and in direct response to—a defendant's motion to dismiss. In *MGM Global Resorts Development, LLC v. U.S. Department of the Interior*, for example, the court held that a motion to intervene was timely where it was “filed on October 22, 2019, about two weeks after the Government Defendants filed their motion to dismiss,” and granted the movants leave to intervene and to file their proposed motion to dismiss. 2020 WL 5545496, at *1, *4. This Court allowed a *separate* motion to dismiss from the intervenors there because until their motion to intervene was granted, they were not yet parties, so the Rule 12 and scheduling deadlines that bind the existing parties did not run against it. Here, Proposed Intervenor is not asking to file a separate motion to dismiss, so their intervention would be less intrusive than that of the *MGM Global Resorts* intervenors.

This Court has reached the same decision in many other cases, allowing intervention despite a pending motion to dismiss. See *Cayuga Nation v. Zinke*, 324 F.R.D. 277, 282 (D.D.C. 2018) (granting intervention as timely where the movant filed “on the same day Defendants were required to respond to Plaintiffs’ Complaint” and the “Defendants filed a partial motion to dismiss on that day . . . but have yet to file an answer,” because “[t]he Court can conceive of no way in

which the timing of this motion has prejudiced any of the current parties”); *Wash. All. of Tech. Workers v. U.S. Dep’t of Homeland Sec.*, 395 F. Supp. 3d 1, 19 (D.D.C. 2019) (granting intervention and holding the motion timely—notwithstanding a pending renewed motion to dismiss—because “the Government has not yet filed an answer to the Complaint” (citing *Fund for Animals*, 322 F.3d at 735 (motion to intervene timely where filed “before the defendants filed an answer”))). The touchstone is prejudice to the existing parties, not the existing parties’ own response deadlines. *Roane*, 741 F.3d at 151 (D.C. Cir. 2014) (the timeliness requirement “is aimed primarily at preventing potential intervenors from unduly disrupting litigation, to the unfair detriment of the existing parties”); *see, e.g., Amgen*, 2026 WL 202157, at *2.

Proposed Intervenors have filed their intervention motion about three weeks after the Government Defendants’ motion to dismiss and well before AbbVie’s opposition is due. That timing is comfortably within the window that this Court and the Circuit have treated as timely. *See MGM Glob. Resorts*, 2020 WL 5545496, at *4; *Cayuga Nation*, 324 F.R.D. at 282. Proposed Intervenors moved at the threshold of the litigation, before any responsive briefing on the merits and before any party could claim prejudice from the timing. *See Roane*, 741 F.3d at 151–52 (D.C. Cir. 2014) (the timeliness requirement “is aimed primarily at preventing potential intervenors from unduly disrupting litigation, to the unfair detriment of the existing parties,” and the prejudice to existing parties is “the most important consideration”).

Nor would intervention prejudice the existing parties. Proposed Intervenors do not seek to expand the claims in this action, to inject unrelated issues, or to file a separate motion to dismiss. Instead, Proposed Intervenors seek to participate in the same dispute and motion to dismiss already before the Court. Proposed Intervenors’ participation will therefore address the same legal and factual questions already presented in AbbVie’s Complaint and the Government’s motion to

dismiss at this stage. And unlike *MGM Global Resorts*, where the D.C. District Court granted an intervention motion that was filed weeks after a defendant’s motion to dismiss and that contained a *separate motion to dismiss*, here, Proposed Intervenor’s intervention merely seeks to join a filed motion to dismiss already available for AbbVie’s review. Proposed Intervenor is prepared to file any responsive pleading or merits briefing on the schedule set by the Court and will not seek to delay the current case schedule.⁴ Under these circumstances, intervention would not impose any unfair prejudice on AbbVie or the Government Defendants.

The purpose of this proposed intervention further supports timeliness. Proposed Intervenor seeks to protect the interests of their members that would be directly affected by AbbVie’s requested relief. NACHC Decl. ¶¶ 30–50; RWC-340B Decl. ¶¶ 18–22. Intervention is also necessary to ensure that those interests are represented before the Court decides the merits, because neither AbbVie nor the Government Defendants represent the distinct operational, financial, and patient-care interests of RWCs or CHCs, federal grantee Covered Entities. *See* NACHC Decl. ¶¶ 7–8; RWC-340B Decl. ¶¶ 4–5. Accordingly, considering all the circumstances, including Proposed Intervenor’s prompt request to intervene well before AbbVie’s response to Government Defendant’s motion to dismiss is due and the absence of any prejudice to the existing parties, the Proposed Intervenor’s intervention motion is timely.

⁴ Proposed Intervenor seeks full intervention as parties under Rule 24. As full participants, they will join the Government Defendants’ pending motion to dismiss and will file a reply in support of that motion, rather than filing a separate or duplicative Rule 12 motion. A proposed pleading that adopts the existing parties’ arguments satisfies Rule 24(c). *See Black v. LaHood*, No. 11-CV-1928 (JEB), 2012 WL 13054502 (D.D.C. Apr. 30, 2012) (“That [an intervenor’s motion to dismiss] incorporates other Defendants’ arguments does not make it any less a pleading that sets out Intervenor’s defenses.”). Upon intervention, Proposed Intervenor will “become[] a full participant in the lawsuit and [be] treated just as if [they] were an original party.” *Ameren Servs. Co. v. FERC*, 893 F.3d 786, 791 (D.C. Cir. 2018) (citation omitted).

II. **Alternatively, Proposed Intervenor Should be Permitted to Intervene Under Rule 24(b)**

Even if the Court were to conclude that Proposed Intervenor do not satisfy the requirements for intervention as of right, the Court should permit Proposed Intervenor to intervene in accordance with Rule 24(b). Under Rule 24(b), on “timely motion” the Court “may permit anyone to intervene” who “has a claim or defense that shares with the main action a common question of law or fact.” Fed. R. Civ. P. 24(b)(1)(B). “Permissive intervention requires a showing of (1) ‘an independent ground for subject matter jurisdiction; (2) a timely motion; and (3) a claim or defense that has a question of law or fact in common with the main action.’” *Ass’n of Washington Bus. v. United States Env’t Prot. Agency*, No. 23-CV-3605 (DLF), 2024 WL 3225937, at *11 (D.D.C. June 28, 2024) (*quoting E.E.O.C. v. Nat’l Children’s Ctr., Inc.*, 146 F.3d 1042, 1046 (D.C. Cir. 1998)). Those requirements are satisfied here.

First, this case arises under federal law, including the federal Administrative Procedure Act and the 340B statute, alleged to provide an independent basis for subject matter jurisdiction. Compl. ¶ 22. That requirement is comfortably met. The independent-jurisdiction requirement exists because “the typical movant asks the district court to adjudicate an additional claim on the merits.” *Nat’l Children’s Ctr.*, 146 F.3d at 1046. Proposed Intervenor seek no such additional relief. They seek to intervene to advance defenses to the very claims AbbVie has already placed before the Court. Because Proposed Intervenor’s proposed defense rests on the same federal statutes and the same case or controversy already under consideration, no separate jurisdictional predicate is needed, and the requirement is satisfied.

Second, as explained above, Proposed Intervenor’s motion is timely. Proposed Intervenor seek intervention while the case remains in its preliminary stages and before the Court has issued any merits ruling. *See supra* § I.E.

Third, Proposed Intervenor's proposed defense shares common questions of law and fact with the claims already before the Court. AbbVie asks the Court to endorse AbbVie's narrower proposed definition of "patient" for purposes of the 340B statute. Proposed Intervenor's seek to ask the Court to reject AbbVie's request. Proposed Intervenor's participation therefore concerns the same legal question at the center of this case: the interpretation of the term "patient" under the 340B statute.

Nor, as explained above, would permissive intervention unduly delay or prejudice the adjudication of the existing parties' rights. Fed. R. Civ. P. 24(b)(3). No scheduling order has been entered, and the case remains in its preliminary stages. Proposed Intervenor's will comply with any schedule the Court sets, coordinate with the Defendants to avoid duplicative briefing, and focus their participation on the distinct provider-specific issues that Proposed Intervenor's are uniquely positioned to address. Proposed Intervenor's also will not seek to expand the claims, add unrelated issues, or otherwise alter the scope of the case.

In short, permitting intervention under Rule 24(b) would assist the Court without burdening the parties or delaying the proceedings. Proposed Intervenor's participation would ensure that the Court hears the unique perspective of grantee Covered Entities. Because Proposed Intervenor's requested participation will address common questions of law and fact with the issues already before the Court, and because Proposed Intervenor's will not expand the claims or delay the case, Proposed Intervenor's respectfully request this Court to grant their motion to intervene under Rule 24(b) if it does not grant intervention as of right.

CONCLUSION

The ability of Proposed Intervenor's members to carry out their statutorily authorized missions of providing low-cost healthcare to underserved populations could well turn on the outcome of this case. For that and the other reasons discussed above, Proposed Intervenor's

respectfully request that this Court grant their motion to intervene under Rule 24(a), or in the alternative, allow them to intervene under Rule 24(b).

Dated: July 6, 2026

Respectfully submitted,

/s/ Gene C. Schaerr

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EXHIBIT A

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

ABBVIE INC., a Delaware Corporation,
1 N. Waukegan Road
North Chicago, IL 60064

Plaintiff,

v.

ROBERT F. KENNEDY JR., in his official
capacity, and U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES,
200 Independence Avenue, S.W.
Washington D.C. 20201,

Civil Action No. 1:26-cv-1190-RDM

and

THOMAS J. ENGELS, in his official
capacity, and HEALTH RESOURCES AND
SERVICES ADMINISTRATION,
5600 Fishers Lane
Rockville, MD 20857

Defendants,

and

NATIONAL ASSOCIATION OF
COMMUNITY HEALTH CENTERS, INC.
7501 Wisconsin Avenue
Suite 1100W
Bethesda, MD 20814

*Proposed Intervenor-
Defendant.*

**DECLARATION OF KYU RHEE IN SUPPORT OF
NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS, INC.'S
MOTION TO INTERVENE AS A DEFENDANT**

I, Dr. Kyu Rhee, M.D., M.P.P., state as follows under penalty of perjury:

1. I am the President and Chief Executive Officer (“CEO”) of the National Association of Community Health Centers, Inc. (“NACHC”), the proposed intervenor in this action.

2. I have held the position of CEO of NACHC since 2023. Before joining NACHC, I held the position of Senior Vice President and Aetna Chief Medical Officer at CVS Health. I also served for a decade as the Chief Health Officer at IBM and, during the time of the Affordable Care Act, I held the office of Chief Public Health Officer at the Health Resources and Services Administration (“HRSA”). I have also worked at the National Institute of Health as the Director, Office of Innovation and Program Coordination.

3. The information set forth in this declaration is based upon my personal knowledge.

NACHC and the Community Health Centers It Represents

4. NACHC is the leading national advocacy organization that supports and advocates for community health centers (“CHCs”) and the patients and communities that CHCs serve. NACHC has been the voice of CHCs for 55 years.

5. NACHC is dedicated to expanding health care to low-income and medically underserved populations through support and expansion of the CHC model.

6. NACHC’s work focuses on supporting and advocating for CHCs in their provision of affordable, comprehensive, community-based primary care, particularly for medically underserved and uninsured patients and communities.

7. NACHC represents and supports over 800 CHCs and health-center organizations across the country. These 800+ CHCs are organizational members and pay dues to have NACHC represent their interests. CHCs serve as the medical home for 52 million patients, providing high-quality, affordable, comprehensive care including primary, preventative, dental, behavioral health,

pharmacy, vision, and other essential health services at over 17,000 locations nationwide, providing care for 1 in 3 rural residents and 1 in 2 people living in poverty.

8. CHCs are nonprofit, community-based, patient-governed organizations that provide affordable, comprehensive primary care in medically underserved communities and other areas with limited access to primary care providers.

9. CHCs provide care to patients regardless of income or insurance status. Many CHC patients are uninsured, underinsured, enrolled in Medicaid, or otherwise face significant barriers to accessing healthcare. As a result of its patient population, CHCs provide significant levels of unreimbursed or under-reimbursed care.

10. CHCs operate in urban, rural, and other medically underserved areas. Their patients may face barriers to care that include poverty, lack of insurance or underinsurance, transportation barriers, limited access to specialty care, chronic disease burden, behavioral health needs, and other social and economic barriers. CHCs are designed to provide community-based care to patients who otherwise may have difficulty obtaining affordable, accessible healthcare.

11. Because CHCs serve patients who often face financial and practical barriers to care, access to affordable care, including affordable medications, is central to the health-center model.

12. CHCs are eligible to participate in the 340B Drug Pricing Program, which allows safety-net providers to purchase outpatient prescription drugs at discounted prices and use the resulting savings to support patient care.

The Importance of the 340B Drug Pricing Program to CHCs

13. The 340B Drug Pricing Program is an essential source of support for CHCs, allowing them to stretch increasingly scarce federal resources and reinvest in patient care.

14. The 340B Drug Pricing Program allows CHCs to purchase outpatient drugs at significantly reduced costs. CHCs pass the savings on to their patients through reduced drug prices and invest additional savings to expand access and improve care.

15. CHC patients include people with low incomes, seniors, veterans, parents, and people with disabilities. Without the 340B Drug Pricing Program, these Americans would not have access to low-cost medications and essential health services. The high cost of medicines can easily push individuals into poverty, disease, or even death.

16. CHCs rely on the 340B Drug Pricing Program to support affordable patient care, including affordable medication access.

17. The 340B Drug Pricing Program allows eligible safety-net providers, including participating CHCs, to purchase outpatient prescription drugs at discounted prices. For CHCs, 340B discounts are an important resource because 340B discounts help reduce medication costs for patients and support services that expand access to care.

18. Depending on the needs of the communities they serve, CHCs may use savings from 340B discounted drugs to support pharmacy services, behavioral health services, dental care, specialty care, food or housing-related support, co-pay assistance, transportation assistance, outreach, or other patient-support services.

19. CHCs use 340B savings to help make medications and care more affordable and accessible for patients and communities with limited access to care.

20. CHCs have developed policies, procedures, staffing, compliance systems, and pharmacy-related operations to administer their 340B programs. As part of that administration, CHCs must determine whether individuals receiving care qualify as patients of the covered entity for purposes of 340B eligibility.

21. CHCs have made those 340B patient-eligibility determinations against the backdrop of the 340B statute and longstanding interpretations of its requirements. CHCs apply patient-eligibility standards in the clinical and operational settings where patient care is actually delivered, including in connection with in-person visits, telehealth encounters, referrals, care coordination, follow-up care, pharmacy services, and ongoing patient relationships.

CHCs Provide Necessary Care Through Referrals, Telehealth, and Care Coordination

22. CHCs often care for patients with complex medical, behavioral health, pharmacy, and social needs, serving as the medical care home for these individuals.

23. To serve patients in communities with limited access to care, CHCs frequently use coordinated models of care that may involve primary care providers, behavioral health providers, pharmacists, care coordinators, referral staff, telehealth providers, and specialists.

24. CHCs may provide care through both in-person and telehealth encounters depending on patient needs, provider availability, clinical appropriateness, and applicable legal or regulatory requirements.

25. CHCs also use telehealth to maintain access to care for patients who face transportation barriers, live in rural areas, have work or caregiving obligations, or otherwise have difficulty accessing in-person care.

26. When a patient needs services that a CHC does not provide directly, the CHC may refer the patient to an outside provider or specialist as part of the patient's broader course of care.

27. A referral does not necessarily end the CHC's involvement in the patient's care. CHCs remain involved by coordinating records, communicating with outside providers, following up with the patient, managing medications, reviewing specialist recommendations, or continuing to provide primary care or related services.

28. These referral, telehealth, and care-coordination practices allow CHCs to provide accessible, continuous, community-based care to patients who may otherwise face barriers to obtaining care.

29. CHCs evaluate whether an individual is a patient for purposes of 340B based on the specific facts and circumstances of each patient's relationship to the CHC as the individual's medical care home.

The Impact of AbbVie's Proposed Patient Definition on CHCs

30. I have reviewed AbbVie's proposed definition of "patient" to evaluate its potential impact on CHCs' current operations.

31. Based on my experience with CHCs and the 340B Drug Pricing Program, AbbVie's proposed definition would adversely affect how CHCs make and document 340B patient-eligibility determinations and maintain 340B compliance practices.

32. CHCs have built their 340B compliance practices, pharmacy operations, referral workflows, telehealth practices, and patient-eligibility determinations around the text of the 340B statute and CHCs' experience providing patient care to individuals as a medical care home.

33. AbbVie's proposed definition is significantly narrower than the longstanding statutory interpretation of patient that CHCs have relied on for over 30 years and, if adopted, would significantly reduce the number of 340B-eligible prescriptions for CHCs, in turn reducing the savings that result from access to 340B discounted drugs.

34. If AbbVie's proposed definition were adopted, CHCs would need to reassess whether prescriptions historically treated as 340B eligible would continue to qualify under AbbVie's narrower standard.

35. That reassessment would not be merely administrative. It would negatively impact qualification of prescriptions based on referrals, telehealth encounters, specialty care, integrated care teams, care coordination, follow-up care, pharmacy services, and ongoing patient relationships.

36. CHCs would continue to remain responsible for patients' whole health and wraparound services but would no longer benefit from 340B discounted drugs because AbbVie's standard would narrow the universe of 340B-eligible prescriptions.

37. CHCs would continue to provide care for all individuals regardless of insurance status and regardless of ability to pay, but CHCs would have fewer resources to support care for individuals that are unable to pay. CHCs may need to reduce services or staff as a direct result.

38. AbbVie's narrower patient definition would cause CHCs to exclude certain prescriptions from 340B treatment even where the CHC continues to provide, coordinate, or support the individual's care. As a result, CHCs would lose 340B eligibility for prescriptions for individuals who remain patients of the CHC.

39. CHCs would be required to review and revise 340B policies and procedures, compliance guidance, staff training materials, documentation practices, referral workflows, telehealth workflows, and pharmacy operations to evaluate and document patient eligibility under the narrower standard to maintain compliance.

40. This would require CHCs to devote additional staff time and resources to evaluating whether prescriptions are written during a particular encounter, for a particular condition, by a specific provider, or within a limited timeframe.

41. AbbVie's narrower patient definition would threaten patient access to critical medicines and essential health services supported by the 340B Drug Pricing Program, diverting

340B saving away from patient care and toward corporate profits, ultimately tying the hands of health center doctors and other care providers and making America sicker, not healthier.

42. CHCs may also need to make changes to health record systems, pharmacy tracking systems, third-party administrator processes, contract pharmacy arrangements, or internal audit procedures to operationalize AbbVie's narrower patient definition.

43. AbbVie's narrower patient definition would impose administrative, operational, and compliance burdens on CHCs. These burdens would consume staff time and financial resources that otherwise could be used for patient care and patient-support services.

44. In addition to those operational burdens, AbbVie's narrower patient definition would create uncertainty for CHCs in determining whether prescriptions associated with referrals, telehealth encounters, outside specialists, integrated care teams, care coordination, and ongoing patient relationships qualify for 340B pricing.

45. Reduced 340B savings as a result of AbbVie's narrower patient definition would undermine the purpose of the 340B Drug Pricing Program by limiting CHCs' ability to stretch resources, make outpatient medications more affordable, and expand health services for the patients and communities CHCs serve.

46. AbbVie's narrower patient definition would also diminish CHCs' ability to provide or sustain services supported by 340B savings, such as discounted medications, pharmacy services, behavioral health services, dental services, care coordination, enabling services, transportation assistance, outreach, and other patient-support programs.

47. AbbVie's proposed definition would also expose CHCs to costly manufacturer audits, repayment demands, and corrective-action disputes based on a patient-definition standard that neither Congress nor HRSA has adopted. AbbVie's proposed standard would treat certain

prescriptions as ineligible even where the individual continues to receive care from the CHC. Responding to those audits and disputes would require CHCs to devote staff time and resources to gathering records, reviewing claims, analyzing patient eligibility, coordinating with pharmacy vendors or third-party administrators, and consulting legal or compliance personnel. Those burdens would further divert resources from patient care and services supported by 340B savings.

48. The impact of AbbVie's proposed definition would extend well beyond the two covered entities identified in AbbVie's Complaint. If adopted, AbbVie's proposed definition would affect covered entities nationwide, including the CHCs that NACHC represents and supports, that participate in the 340B Drug Pricing Program, have structured their compliance practices around the longstanding statutory interpretation of the word patient, and rely on that interpretation to make and document 340B eligibility determinations.

49. Because CHCs care for patients and communities facing barriers to care and rely on 340B savings to support that care, adoption of AbbVie's proposed patient definition would adversely affect CHC operations, finances, and patient services by reducing the resources available to support the communities CHCs serve.

50. These consequences would directly affect the CHCs that NACHC represents and supports. Those CHCs serve patients and communities with limited access to care, rely on 340B savings to support affordable medications and health services, and have structured their 340B compliance practices around the longstanding statutory interpretation of the term patient.

Dated: Jun 27, 2026

Respectfully submitted

By: 
Dr. Kyu Hyeon, M.D., M.P.P. (Jun 27, 2026 13:54:09 GMT+9)

Dr. Kyu Rhee, M.D., M.P.P.
President and CEO, NACHC

K.R. Declaration in Support of Motion

Final Audit Report

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"K.R. Declaration in Support of Motion" History

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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

ABBVIE INC., a Delaware Corporation,
1 N. Waukegan Road
North Chicago, IL 60064

Plaintiff,

v.

ROBERT F. KENNEDY JR., in his official
capacity, and U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES,
200 Independence Avenue, S.W.
Washington D.C. 20201,

and

THOMAS J. ENGELS, in his official
capacity, and HEALTH RESOURCES AND
SERVICES ADMINISTRATION,
5600 Fishers Lane
Rockville, MD 20857

Defendants.

Civil Action No. 1:26-cv-1190-RDM

**DECLARATION OF SHANNON BURGER IN SUPPORT OF
RYAN WHITE CLINICS FOR 340B ACCESS'S
MOTION TO INTERVENE AS A DEFENDANT**

I, Shannon Burger, state as follows under penalty of perjury:

1. I am the President of Ryan White Clinics for 340B Access (“RWC-340B”), a national membership association of human immunodeficiency virus (“HIV”) and acquired immunodeficiency syndrome (“AIDS”) healthcare providers, on whose behalf I submit this declaration. I am also the Chief Executive Officer of Cempa Community Care (formerly Chattanooga C.A.R.E.S.), a Ryan White-funded clinic that serves people living with AIDS and HIV. Located in Chattanooga, Tennessee, Cempa Community Care is a covered entity that

participates in the drug discount program established at Section 340B of the Public Health Service Act, 42 U.S.C. § 256b (“340B Program”). It is also a Federally Qualified Health Center Look-Alike, designated by the Health Resources and Services Administration as an entity that meets the requirements for a grant under section 330 of the Public Health Service Act, 42 U.S.C. § 254b, but that does not receive such a grant. *See* 42 U.S.C. § 1396d(l)(2)(B). Through more than two decades of work at a Ryan White clinic, I have firsthand knowledge of how these clinics care for their patients and of the role the 340B Program plays in sustaining that care.

2. The information set forth in this declaration is based upon my personal knowledge.

RWC-340B’s Mission

3. RWC-340B is a national, not-for-profit membership association headquartered in Washington, D.C. RWC-340B’s members are HIV/AIDS healthcare clinics and service providers located throughout the United States, each of which receives funding under the Ryan White Comprehensive AIDS Resources Emergency (“CARE”) Act, whether as a direct grantee or as a subgrantee, and participates in the 340B Program as a covered entity. The CARE Act provides support for entities that primarily render services to low-income, underinsured, and/or uninsured people living with HIV/AIDS. Because they receive these grants, Ryan White providers are eligible to participate in the federal 340B Program.

4. RWC-340B’s mission is to preserve and protect the 340B Program for Ryan White clinics so that they may continue to furnish life-sustaining care and essential support services to low-income and underserved persons living with HIV and AIDS.

5. RWC-340B is dedicated to expanding healthcare to low-income and medically underserved populations through support and expansion of the Ryan White Program. Our work focuses on supporting and advocating for the interests of fellow 340B Ryan White providers.

RWC-340B was organized in 2013 by a group of providers seeking ways to preserve the benefits of the 340B Program. Since its inception, RWC-340B has expanded to include 60 organizations located in 24 states.

6. On behalf of its members, RWC-340B has participated in numerous matters concerning the 340B Program. RWC-340B was the lead plaintiff in *Ryan White Clinics for 340B Access v. Azar*, No. 1:20-cv-02906 (D.D.C.), challenging manufacturer restrictions on the use of contract pharmacies by Ryan White covered entities. RWC-340B has also appeared as *amicus curiae* in cases across the country addressing manufacturer conditions on 340B pricing and state laws protecting covered entities' access to contract pharmacies.

Ryan White Clinics

7. Data shows that Ryan White clinics are extremely successful in helping patients achieve sufficient viral suppression so that they cannot transmit HIV. In fact, in 2023, 90.6% of Ryan White HIV/AIDS Program clients receiving medical care were virally suppressed, a record high and well above the roughly 65% viral suppression rate among all people with diagnosed HIV in the United States.¹ My own clinic's experience reflects this national pattern: when patients remain connected to a Ryan White clinic's integrated team, they start and stay on treatment, and they reach and maintain an undetectable viral load. The clinics' higher rate of success is attributable in significant part to their participation in the 340B Program. RWC-340B is committed to protecting the 340B Program so that its members may continue to provide lifesaving treatments to those who need it most.

¹ Health Res. & Servs. Admin., *Ryan White HIV/AIDS Program Achieves Record-Breaking 90.6% Viral Suppression Rate among Its More than 576,000 Clients* (Dec. 2, 2024) <https://www.hrsa.gov/about/news/press-releases/ryan-white-record-breaking-viral-suppression-rate>; Ctrs. for Disease Control & Prevention, *National HIV Prevention and Care Objectives* (Feb. 7, 2025), <https://www.cdc.gov/hiv-data/nhss/national-hiv-prevention-and-care-outcomes.html>.

8. Ryan White clinics provide care to patients who are low income and living with HIV. Many Ryan White patients are uninsured, underinsured, enrolled in Medicaid, or otherwise face significant barriers to accessing healthcare. As a result of their patient population, Ryan White clinics provide significant levels of unreimbursed or under-reimbursed care.

9. Ryan White clinics build and maintain ongoing, long-term relationships with each patient. When a person living with HIV first comes to a Ryan White clinic, often newly diagnosed, uninsured, and in crisis, the clinic conducts an intake assessment, determines eligibility, and links the patient to a coordinated team that typically includes a physician or other licensed provider, a pharmacist, a medical case manager, and behavioral health and support staff. That team provides a panoply of services, including prevention services, early intervention services, and testing services. From that first contact forward, the clinic is responsible not only for prescribing and furnishing antiretroviral therapy but also for keeping the patient engaged in care over a lifetime.

10. Case management is the connective tissue of the Ryan White model and, for many patients, the single most important service the clinic provides. Congress recognized as much when it made medical case management, including treatment adherence services, one of the core medical services that Ryan White grantees must fund, and when it separately directed that case management services be available to link patients, particularly those in rural areas, to the specialized medical care they need. A medical case manager assesses each patient's needs, develops an individualized care plan, coordinates medical appointments and laboratory monitoring, provides treatment-adherence counseling, and helps the patient navigate housing, transportation, nutrition, insurance, and other barriers that would otherwise cause the patient to fall out of care.

11. For a substantial share of our member clinics' patients, including the most unstable, the most marginalized, and those at highest risk of disengaging, case management is not merely a

supplement to medical care; it is the means by which they receive care at all. Without a case manager keeping them connected, many of these patients would never make it to a clinical appointment, would never fill or take their medications, and would be lost across the continuum of care. In my experience, patients who have a case manager are far more likely to be receiving HIV care and taking antiretroviral therapy and are significantly less likely to engage in behaviors that risk transmitting the virus.

12. For many of these patients, case management is not merely the most important Ryan White service; it is the only Ryan White service they receive. Some Ryan White subrecipients that participate in the 340B Program furnish case management alone, serving their patients exclusively through case management and linking those patients to medical care, medications, and other support services delivered elsewhere. HRSA's own reporting rules expressly contemplate such case-management-only subrecipients: an organization that provides only a single core medical or support service, such as medical case management, is treated as a distinct Ryan White provider that must complete a Provider Report and submit client-level data on the patients it serves. These case-management-focused entities are part of the same integrated continuum of care, and they depend on the same 340B Program income to operate. A patient who relies on such a subrecipient for case management could lose access to that service, and thereby to the medical care it makes possible, if AbbVie's proposed patient definition is sustained and 340B savings are stripped away.

The 340B Program is Essential to RWC-340B's Mission

13. The 340B Program is essential to RWC-340B's mission of caring for low-income and vulnerable patients living with HIV/AIDS and ending the transmission of HIV. Ryan White clinics are eligible to participate in the 340B Program, which allows safety-net providers to purchase outpatient prescription drugs at discounted prices and use the resulting savings to support

patient care. The 340B Program allows our member clinics to stretch increasingly scarce federal resources and reinvest in patient care.

14. Because Ryan White clinics often receive no insurance payments for the key case management services discussed above, they depend on the 340B Program to underwrite the cost of providing this care to their patients. The 340B Program allows Ryan White clinics to maximize limited resources and support the full HIV/AIDS care continuum, from diagnosis and linkage to care through treatment adherence and viral suppression, without additional cost to taxpayers.

15. Ryan White clinics use 340B savings to reduce medication costs for eligible patients and expand access to care through additional patient services. Depending on the needs of the communities they serve, clinics may use those savings to support pharmacy services, behavioral health services, dental care, specialty care, food or housing-related support, copay assistance, transportation assistance, outreach, or other patient-support services.

16. Ryan White clinics have developed policies, procedures, staffing, compliance systems, and pharmacy-related operations to administer their 340B programs. As part of that administration, Ryan White clinics must determine whether individuals to whom they render professional healthcare services qualify as patients of the covered entity for purposes of their eligibility to receive 340B drugs.

17. Ryan White clinics have made those 340B patient-eligibility determinations against the backdrop of the 340B statute and longstanding interpretations of its requirements. Ryan White clinics apply patient-eligibility standards in the clinical and operational settings where patient care is delivered, including in connection with in-person visits, telehealth encounters, referrals, care coordination, follow-up care, pharmacy services, and ongoing patient relationships.

AbbVie's Lawsuit Threatens RWC-340B's Mission

18. I understand that AbbVie, through this litigation, seeks to narrow the definition of “patient” under the 340B statute so that far fewer of the individuals to whom Ryan White clinics dispense covered drugs would qualify as 340B-eligible patients. Under AbbVie’s proposed patient definition, drugs dispensed to many of the persons our member clinics serve today would no longer be eligible for the 340B discounted price.

19. The practical effect of AbbVie’s position would be severe. RWC-340B’s member clinics depend on the savings generated through the 340B Program to operate. Federal grant funding does not cover the full cost of caring for the patients these clinics serve; by purchasing covered drugs at the discounted 340B price and being reimbursed at a higher rate, Ryan White clinics generate program income that they reinvest into patient care. Those savings fund the very services described above, including case managers, adherence counselors, behavioral health and support staff, and wrap-around services such as housing, transportation, and nutrition assistance that are not reimbursed by Medicare, Medicaid, or private insurers but that keep patients virally suppressed.

20. If a substantial share of a Ryan White clinic’s patients are deemed ineligible under AbbVie’s proposed patient definition, that clinic must either forgo the 340B discount and pay AbbVie’s full list price for those patients’ medications or stop dispensing those drugs altogether. Either outcome strips away the program income that funds clinics’ case management and support services. Ryan White clinics would be forced to cut case managers and other staff, eliminate the support services that keep patients engaged, turn patients away, or close entirely. That harm would extend to Ryan White clinics throughout the United States, including in rural and medically underserved communities where they are often the only source of HIV care.

21. When Ryan White clinics lose the capacity to furnish care and case management, the people who lose access are among the most vulnerable in the country, including low-income, uninsured, and underinsured individuals living with HIV/AIDS who have nowhere else to turn. Interruptions in antiretroviral therapy cause patients' viral loads to rebound, which harms the individual patient and reopens the very chains of transmission that viral suppression had closed. AbbVie's proposed patient definition therefore threatens not only the financial viability of our member clinics but also the health of the patients and communities they serve.

22. In my view, AbbVie's proposed patient definition threatens the Nation's public health infrastructure. I understand that the United States has long recognized that the federal HIV safety net—anchored by the Ryan White Program and the AIDS Drug Assistance Program—is the front line of the Nation's defense against the HIV/AIDS epidemic. Ryan White clinics, funded in significant part through 340B savings, are the infrastructure through which that defense is delivered. By degrading the ability of Ryan White clinics across the country to furnish life-sustaining treatment, case management, and other safety-net services, AbbVie's proposed patient definition would weaken a system the United States has deliberately built to keep the HIV epidemic suppressed, contain transmission, and protect the public's health.

Dated: July 2, 2026

Respectfully submitted,

By: 

Shannon Burger
President
Ryan White Clinics for 340B Access

Declaration S. Burger_Clean

Final Audit Report

2026-07-06

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EXHIBIT C

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

ABBVIE INC.,

Plaintiff,

v.

ROBERT F. KENNEDY JR., in his official
capacity, et al.,

Defendants

and

NATIONAL ASSOCIATION OF COMMUNITY
HEALTH CENTERS, INC.; and
RYAN WHITE CLINICS FOR 340B ACCESS,

Proposed Intervenor-Defendants.

Civil Action No. 1:26-cv-1190-RDM

**JOINT MOTION OF NATIONAL ASSOCIATION OF COMMUNITY HEALTH
CENTERS, INC. AND RYAN WHITE CLINICS FOR 340B ACCESS
FOR JOINDER IN DEFENDANTS' MOTION TO DISMISS**

Proposed Intervenor-Defendants National Association of Community Health Centers, Inc. (“NACHC”) and Ryan White Clinics for 340B Access (“RWC-340B”) move to join in and adopt Defendants’ Motion to Dismiss (Doc. 13).¹

As mentioned in their memorandum in support of their Joint Motion to Intervene as Defendants, Proposed Intervenor-Defendants “will join the Government Defendants’ pending motion to dismiss and will file a reply in support of that motion, rather than filing a separate or duplicative Rule 12 motion.” Mem. in Support of Jt. Mot. Intervene as Defs. at 34 n.4. The

¹ Intervenor-Defendants uses the blue pagination generated by the electronic CM/ECF database, which appears in the headers of all court filings.

Intervenor-Defendants agree that AbbVie’s claims should be dismissed for the four independent reasons in the Motion to Dismiss:

“First, the Court lacks jurisdiction to hear Plaintiff’s APA claims because those claims are not ripe for review. Second, even if the claims were ripe, AbbVie’s APA claims fail because the Department’s^[2] letter permitting AbbVie to move forward with its proposed audits does not constitute final agency action. Third, AbbVie lacks Article III standing because even if a favorable ruling from this Court would redress its alleged injury—the enforcement outcome AbbVie ultimately seeks remains committed to agency discretion regardless of how the definitional questions are resolved. Fourth, and independently, the enforcement determination AbbVie seeks is committed to agency discretion by law and is therefore unreviewable under the APA. Moreover, the Department’s letter is consistent with the Department’s thirty-year-old guidance.

Doc. 13 at 5–6. For any of these reasons, the Court should dismiss the complaint in its entirety.

² “Department” is defined in the motion as “Defendants, Robert F. Kennedy, Jr., in his official capacity as Secretary of the Department of Health and Human Services, Thomas J. Engels, in his official capacity as Administrator of the Health Resources and Services Administration, the Department of Health and Human Services (“HHS”), and the Health Resources and Services Administration (“HRSA”), (collectively “Defendants” or the “Department” or the “Agency”).” Doc. 13 at 5.

Dated: July 6, 2026

Respectfully submitted

/s/ Gene C. Schaerr

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Ryan White Clinics for 340B Access*

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ABBVIE INC.,

Plaintiff,

v.

ROBERT F. KENNEDY JR., in his official
capacity, et al.,

Defendants

and

NATIONAL ASSOCIATION OF COMMUNITY
HEALTH CENTERS, INC.; and
RYAN WHITE CLINICS FOR 340B ACCESS,

Proposed Intervenor-Defendants.

Civil Action No. 1:26-cv-1190-RDM

**[PROPOSED] ORDER GRANTING JOINT MOTION OF
NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS, INC.
AND RYAN WHITE CLINICS FOR 340B ACCESS FOR
JOINDER IN DEFENDANTS' MOTION TO DISMISS**

Having considered National Association of Community Health Centers, Inc. (“NACHC”) and Ryan White Clinics for 340B Access (“RWC-340B”)’s Joint Motion for Joinder in Defendants’ Motion to Dismiss (Doc. 13), and any opposition thereto, it is hereby ORDERED that it is **GRANTED**.

SO ORDERED.

ENTERED this ____ day of _____, 2026

HON. RANDOLPH D. MOSS
United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ABBVIE INC.,

Plaintiff,

v.

ROBERT F. KENNEDY JR., in his official
capacity, et al.,

Defendants

and

NATIONAL ASSOCIATION OF COMMUNITY
HEALTH CENTERS, INC.; and
RYAN WHITE CLINICS FOR 340B ACCESS,

Proposed Intervenor-Defendants.

Civil Action No. 1:26-cv-1190-RDM

**[PROPOSED] ORDER GRANTING NATIONAL ASSOCIATION OF
COMMUNITY HEALTH CENTERS, INC. AND RYAN WHITE CLINICS
FOR 340B ACCESS' JOINT MOTION TO INTERVENE AS DEFENDANTS**

Having considered National Association of Community Health Centers, Inc. ("NACHC") and Ryan White Clinics for 340B Access ("RWC-340B")'s Joint Motion to Intervene as Defendants in this action, and any opposition thereto, it is hereby ORDERED that:

1. NACHC and RWC-340B meet the requirements to intervene under Federal Rule of Civil Procedure 24(a) or 24(b) and have established standing under Article III of the Constitution for the reasons given in the motion and supporting declaration.

2. The Motion to Intervene is therefore **GRANTED**.

SO ORDERED.

ENTERED this ____ day of _____, 2026

HON. RANDOLPH D. MOSS
United States District Judge