UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ABBVIE INC., *Plaintiff*, v. ROBERT F. KENNEDY JR, in his official capacity as Secretary of U.S. Department of Health and Human Services, *et al.*, *Defendants*.	§	Case No. 1:26-cv-1190-RDM

PROPOSED INTERVENOR-DEFENDANTS 340B HEALTH, UMASS MEMORIAL MEDICAL CENTER, AND GENESIS HEALTHCARE SYSTEM'S
MOTION TO INTERVENE

Proposed Intervenor-Defendants 340B Health, UMass Memorial Medical Center (UMMC), and Genesis HealthCare System (Genesis) (collectively the Proposed Intervenors), by and through their counsel, respectfully submit this motion to intervene as defendants in this action pursuant to Fed. R. Civ. P. 24. In this case, Plaintiff AbbVie Inc. (AbbVie) filed suit to challenge the Health Resources Services Administration's well-established interpretation of the 340B statute. As described in more detail below, AbbVie's Complaint asks this Court to adopt a definition of "patient" that would place a significant burden the Proposed Hospital Intervenors and members of Proposed Intervenor 340B Health. If AbbVie's draconian interpretation of "patient" in the 340B statute were adopted by HRSA, it would effectively deny those 340B hospitals the full benefits of the 340B Program by improperly excluding many 340B hospital patients that currently

qualify as 340B-eligible patients. This would force most 340B hospitals to pay list price for drugs dispensed to those excluded patients, a price that significantly exceeds the 340B discounted price and depriving those 340B hospitals of the savings they generate under the 340B program. The Proposed Intervenors' interests in this case are not adequately represented by either the Federal Defendants or AbbVie. *See Fund for Animals, Inc. v. Norton*, 322 F.3d 728, 736 (D.C. Cir. 2003). Thus, the Proposed Intervenors seek to intervene to protect their interests.

Intervention by the Proposed Intervenors will not delay this case or prejudice the parties. The Federal Defendants have just filed their motion to dismiss the complaint in this action last week, which addresses jurisdictional issues and not the merits. If the Proposed Intervenors are permitted to intervene, they will not address the jurisdictional issues but only the merits and will adhere to any schedule entered in the matter regarding the merits. Accordingly, the Proposed Intervenors have the right to intervene under Federal Rule of Civil Procedure 24(a) to participate and to protect their interests in this case.

Alternatively, the Proposed Intervenors request this Court find that they meet the standard for permissive intervention under Federal Rule of Civil Procedure 24(b).

The Proposed Intervenors have conferred with counsel for AbbVie and for the Federal Defendants regarding this motion. AbbVie states it will oppose the Proposed Intervenors' motion. The Federal Defendants take no position on the Proposed Intervenors' motion.

For the reasons stated above, the Proposed Intervenors request that the Court grant their motion and (i) permit them to intervene in this action as defendants, and (ii) defer their answer/responsive pleading until such time, if any, that the Federal Defendants are required to respond. In support of this motion, the Proposed Intervenors submit a memorandum of points and

authorities, the declarations of Maureen Testoni, Meetali Desai, and Shona Carr as well as a proposed order.

Dated: June 23, 2026

Respectfully submitted,

/s/ William B. Schultz

William B. Schultz (D.C. Bar No. 218990)
Margaret M. Dotzel (D.C. Bar No. 425431)
Alyssa M. Howard (D.C. Bar No. 1708226)
ZUCKERMAN SPAEDER LLP
2100 L Street NW, Suite 400
Washington, DC 20037
Tel: (202) 778-1800
Fax: (202) 822-8106
wschultz@zuckerman.com
mdotzel@zuckerman.com
ahoward@zuckerman.com

Attorneys for Proposed Intervenors

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340B HEALTH, UMASS MEMORIAL MEDICAL CENTER, AND GENESIS HEALTHCARE SYSTEM'S
MEMORANDUM IN SUPPORT OF MOTION TO INTERVENE

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CASES

340B Health, UMass Memorial Medical Center (UMMC), and Genesis HealthCare System (Genesis) (collectively the Proposed Intervenors) 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.

The 340B Program, established by section 340B of the Public Health Service Act, 42 U.S.C. § 256b, requires, as a condition of participating in Medicaid and Medicare Part B, that pharmaceutical manufacturers sell outpatient drugs at a substantially discounted price to certain public and not-for-profit hospitals, community health centers, and other federally funded clinics that serve communities with a large numbers of low income patients (340B Providers, described in the statute as "covered entities") in order to increase the funding these entities have available to meet the needs of their patients. The purpose of the program is to assist 340B Providers to provide more services and to reach more patients. H.R. Rep. No. 102-384(II), at 12 (1992). Proposed Intervenor 340B Health is an association with over 1,600 member hospitals that are eligible to receive discounted drugs under the 340B program (340B hospitals). Proposed Intervenors UMMC and Genesis (the Proposed Hospital Intervenors) are 340B hospitals and members of 340B Health.

In a provision often referred to as the "prohibition on diversion," the 340B statute forbids 340B Providers from "resell[ing] or otherwise transfer[ring] the [340B-discounted] drug to a *person who is not a patient of the entity*." 42 U.S.C. § 256b(a)(5)(B) (emphasis added). The statute tasks the Health Resources and Services Administration (HRSA), a sub-agency of the Department of Health and Human Services (HHS), with auditing covered entities' compliance with this prohibition, § 256b(a)(5)(C); imposing sanctions for non-compliance, §§ (a)(5)(D), (d)(2)(B)(v); and resolving claims by manufacturers that a covered entity has violated the prohibition, §§

(d)(3)(A), (B). The 340B statute requires that HRSA "use its expertise" to administer it. *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 119–20 & n.6 (2011).

The 340B statute also allows drug manufacturers to initiate audits of covered entities when they suspect violations of the prohibition on diversion. 42 U.S.C. § 256b(a)(5)(C). In order to conduct an audit, a manufacturer must demonstrate "reasonable cause" (which is liberally interpreted by HRSA) that a covered entity is engaging in duplicate discounting or diversion and must submit an audit workplan to HRSA prior to the audit. *See* Manufacturer Audit Guidelines and Dispute Resolution Process 0905–ZA–19, 61 Fed. Reg. 65406–12 (Dec. 12, 1996).

Because there is no statutory definition of the term "patient of the entity," HRSA issued guidance in 1996 explaining how it interpreted that statutory term. Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55156 (Oct. 24, 1996) (the 1996 Guidelines). In the 1996 Guidelines, which remain in effect today, HRSA interpreted "patient of the entity," to refer to an individual for whom the covered entity was responsible for the medical care in question. *See id.* at 55157–58. The covered entity had to maintain records of the individual's care, and the care provider had to be employed by the covered entity or else be under a contractual or other arrangement, (such as a referral for consultation) such that responsibility for the care provided remained with the covered entity. *Id.* As the Government Defendants described the prohibition on diversion in a brief filed in the District of South Carolina in 2023,

> [u]ltimately, HRSA's commonsense understanding of the statutory language sought to account for the multitude of different contexts and covered entities included in the Program, while outlining reasonable principles that would effectuate the statutory limitation on each covered entity to only use the Program for individuals who truly were "patient[s] of the entity."

Br. of HHS, *Genesis Health Care Inc. v. Becerra*, No. 4:19-cv-1531-RBH (D.S.C. July 28, 2023), ECF No. 101 at 8 (internal citations omitted).

Thirty years after HRSA issued its guidance on the statutory meaning of "patient," Plaintiffs AbbVie Inc. and its subsidiaries (collectively, AbbVie) filed suit to challenge HRSA's well-established interpretation of the 340B statute. As described in more detail below, AbbVie's Complaint asks this Court to adopt a definition of "patient" that would place a significant burden on the Proposed Hospital Intervenors and members of Proposed Intervenor 340B Health. If AbbVie's harsh interpretation of "patient" in the 340B statute were adopted by HRSA, it would effectively deny those 340B hospitals the substantive benefit of the 340B Program by improperly excluding many 340B hospital patients that currently qualify as 340B-eligible patients. This would force most 340B hospitals to pay list price for drugs dispensed to those excluded patients, a price that significantly exceeds the 340B discounted price and that would deprive those 340B hospitals of the savings they generate under 340B. It would also saddle them with prohibitively expensive administrative compliance burdens. HRSA has informed AbbVie that its proposed "patient" definition, which it invented out of whole cloth, is unlawful. Compl. Exs. 2, 4, 6, 8, ECF Nos. 1-3, 1-5, 1-7, 1-9. Proposed Intervenors agree.

Intervention by Proposed Intervenors is necessary to protect their interests and to ensure that 340B hospitals have adequate access to 340B drugs at the statutorily imposed discount price so that they can continue to provide high quality medical care to their underserved patients and communities. Proposed Intervenors are also uniquely positioned to understand the real-world impact of AbbVie's narrower patient definition on patient access, hospital operations, and the delivery of care on the ground. That perspective is essential and supports intervention.

Proposed Intervenors are also well-positioned and prepared to address why AbbVie's assertions regarding widespread 340B program abuse and non-compliance as well as its characterizations of the purpose of the 340B program are inaccurate. Proposed Intervenors have

experience and information to support those arguments that the Government Defendants do not have access to.

Proposed Intervenors have standing to intervene because 340B Health's members, including the Proposed Hospital Intervenors, will be significantly harmed by the limits AbbVie proposes to place on the number of patients that would qualify for 340B discounted drugs, which would significantly increase drug costs for those patients. AbbVie's definition would exclude from 340B, the time and expenses incurred if they are forced to develop and implement a system that could comply with AbbVie's proposed "patient" definition, and because of the harm that the shortage of funds will cause their patients and the communities they serve. For example, as explained in more detail below, if HRSA enforces AbbVie's restrictive "patient" definition, Proposed Intervenor UMMC estimates that many referred patients could become ineligible for 340B pricing because the referring provider may continue to participate in the patient's care or maintain responsibility for aspects of the patient's treatment. Desai Declaration at ¶ 17. This approach does not reflect how specialty care is delivered in modern healthcare systems, where multiple providers routinely collaborate in the management of complex conditions. *Id.* at ¶¶ 17-18.

As demonstrated below, Proposed Intervenors plainly meet the standard for intervention of right. Alternatively, Proposed Intervenors meet the standard for permissive intervention.

BACKGROUND

In 2025, AbbVie sought to audit covered entities, including Barrio Comprehensive Family Health Care Center, Inc. (Barrio) and The Mount Sinai Hospital (Mount Sinai). *See* Compl. Ex. 1, Reasonable Cause Letter for Barrio Comprehensive Family Health Care Center, Inc. (CH062360), ECF No. 1-2 (June 27, 2025); Compl. Ex. 3, Letter from J. Colvin, Vice President, Legal Strategy, AbbVie, to C. Britton, Director, OPA, ECF No. 1-4 (Sept. 4, 2025); Compl. Ex. 5, Reasonable

Cause Letter for The Mount Sinai Hospital (DSH330024), ECF No. 1-6 (July 3, 2025). Arguing that HRSA's interpretation of the statutory term "patient" "is overly inclusive" and "fails to account for technological developments since 1996," AbbVie submitted proposed audit workplans to HRSA with a brand-new "non-exhaustive list of the essential elements of what it means to be a 'patient of the entity.'" Compl. ¶¶ 16–17.

In response to AbbVie's proposed audit workplans, HRSA concluded that "[t]he patient definition criteria outlined in the audit work plan and in AbbVie's accompanying correspondence goes beyond HRSA's 1996 Guidelines, which consistent with the statute contains the currently operative standard for determining whether an individual is a 340B patient." *See* Compl. Ex. 2, Letter from C. Britton, Director, OPA, to J. Colvin, Vice President, Legal Strategy, AbbVie, ECF No. 1-3 (Aug. 15, 2025), at 1. Accordingly, "[i]f AbbVie proceeds to conduct the audit using a different standard, [HRSA's Office of Pharmacy Affairs] will not be able to enforce corrective actions for any findings resulting from AbbVie's application of a patient definition that exceeds the 1996 Guidelines." *Id.*

The Proposed Hospital Intervenors have reviewed AbbVie's proposed "patient" definition as set forth in its Complaint and determined it is clearly intended to narrow the definition of "patient" in an effort to substantially reduce the quantity of drugs Proposed Hospital Intervenors could purchase under the 340B Program resulting in greater profits to AbbVie. The Proposed Hospital Intervenors have estimated the impact that interpretation of the statute will have on the communities and patients they serve. For example, savings from the 340B Program support Proposed Intervenor UMMC's funding for free care to low income patients and several community services, including a program that provides free prescription medications to uninsured patients; a program that provides mental health counseling to adolescents; the Ronald McDonald Care Mobile

Clinic, which provides free health care and dental services to medically under-served populations; the Road to Care Mobile Addiction Team, which provides health services at sites frequented by the homeless; and programs that provide post-acute medical care and social support to individuals experiencing homelessness once they are discharged from the hospital and to children who have suffered from abuse and neglect. Desai Declaration at ¶¶ 7–8, 12. However, applying AbbVie's narrow "patient" definition would substantially increase UMMC's drug costs, placing further strain on the relentless financial challenges faced by UMMC and threatening its ability to meet the needs of underserved patients in its community. *Id.* at ¶ 34.

Further, AbbVie's proposed requirement that a covered entity healthcare professional be solely responsible for diagnosing and directly managing a patient's condition could jeopardize pharmacist-led care models that are widely accepted, clinically beneficial, and increasingly utilized across healthcare systems. *Id.* at ¶ 20. These programs rely on coordinated, team-based care rather than exclusive responsibility resting with a single provider. Restricting 340B eligibility for patients participating in these programs would undermine initiatives that improve clinical outcomes, expand access to care, and reduce healthcare costs. *Id.* at ¶ 21.

Similarly, Proposed Intervenor Genesis funds several community health programs using savings earned through the 340B Program, such as its 340B Patient Assistance Program, which provides discounts on necessary medications to eligible patients in underserved communities; a shuttle service that is provided free of charge to patients who have no means of transportation to and from the hospital; an initiative that provides proactive in-home visits to high-risk, vulnerable patients; and its Meds to Bed Program, which facilitates patient access to medication following release from the hospital. Carr Declaration at ¶¶ 8–9. Genesis also funds several other programs

with 340B savings, including stroke prevention programs, smoking cessation counseling, and free mammograms to eligible community members. *Id.* at ¶ 11.

Should this Court adopt AbbVie's artificially narrow interpretation of the term "patient," Genesis predicts that it will have to substantially reduce its 340B Patient Assistance Program. If AbbVie were to narrow its 340B patient definition such that its prescriptions no longer qualify for 340B pricing, Genesis's eligible patients would experience a direct loss of access to reduced copay assistance tied to those medications. As a result, patients—particularly those who are uninsured or underinsured—would face higher out-of-pocket costs for AbbVie therapies, which are often high-cost specialty or chronic disease medications. This increase in financial burden could lead to decreased medication adherence, delays in therapy initiation, or treatment discontinuation. Ultimately, limiting access to 340B-supported affordability programs would undermine Genesis's ability to support vulnerable populations, potentially worsening health outcomes and increasing downstream utilization of more costly healthcare services. Carr Declaration at ¶ 14.

Enforcement of AbbVie's "patient" definition will have a similar impact on Genesis' Meds to Bed program. The Meds to Bed program already operates at a loss; the program requires one fulltime pharmacist, four fulltime pharmacy technicians, and one fulltime pharmacy courier to effectively operate the program, at an estimated annual salary and benefit cost of $433,000. Those six individuals focus solely on providing outpatient pharmacy services to patients being discharged from the hospital. The program is funded through the 340B savings generated by the Genesis Outpatient Pharmacy and exists as a benefit to its patients and to aid in the reduction of readmissions. If Genesis' 340B savings are substantially reduced, then it may no longer be able to afford to operate the program. *Id.* at ¶ 15.

If AbbVie's "patient" definition were enforced, Genesis would suffer large financial harm, resulting in unquantifiable consequences to patients, programs, and the overall care for the community Genesis serves. Not only does Genesis predict that it will have to limit or potentially close its 340B Patient Assistance and Meds to Bed programs, but Genesis also predicts that it will have to evaluate its ability to financially support other community benefits, which would have a significant impact on the community's most vulnerable patients and drastically reduce healthcare access for surrounding communities. Genesis' ability to borrow funds to support these programs will also be impaired by the significant negative margin created by the considerable administrative burdens that would be required to comply. *Id.* at ¶ 17.

On April 8, 2026, AbbVie filed suit in this Court against Secretary Robert F. Kennedy, Jr., in his official capacity, HHS, HRSA Administrator Thomas J. Engels, in his official capacity, and HRSA (the Government Defendants), claiming that HRSA's refusal to enforce its forthcoming audits of Barrio and Mount Sinai violates the 340B statute and the Administrative Procedure Act. The Complaint seeks a declaration that HRSA's interpretation of "patient" set forth in its 1996 Guidelines does not accord with the 340B statute and an order setting aside HRSA's decision not to enforce AbbVie's audits for Barrio and Mount Sinai. Compl. ¶ 21.

ARGUMENT

Federal Rule of Civil Procedure 24(a)(2) provides that, on timely motion, the Court must permit "anyone" to intervene 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." *Karsner v. Lothian*, 532 F.3d 876, 885 (D.C. Cir. 2008) (quoting Fed. R. Civ. P. 24 (a)(2)). Federal Rule of Civil Procedure 24(b)(1)(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." *See also E.E.O.C. v. Nat'l Children's Ctr., Inc.*, 146 F.3d 1042, 1045 (D.C. Cir. 1998) (quoting Fed. R. Civ. P. 24(b)). Proposed Intervenors meet both standards.

I. PROPOSED INTERVENORS HAVE A RIGHT TO INTERVENE UNDER RULE 24(A).

To intervene as of right in the D.C. Circuit, four prerequisites must be met: "(1) the application to intervene must be timely; (2) the applicant must demonstrate a legally protected interest in the action; (3) the action must threaten to impair that interest; and (4) no party to the action can be an adequate representative of the applicant's interests." *Karsner*, 532 F.3d at 885 (internal citations omitted); *see Roane v. Leonhart*, 741 F.3d 147, 151 (D.C. Cir. 2014) ("A district court must grant a timely motion to intervene that seeks to protect an interest that might be impaired by the action and that is not adequately represented by the parties.").

In addition to satisfying those four factors, "a party seeking to intervene as of right must demonstrate that it has standing under Article III of the Constitution." *Fund For Animals, Inc. v. Norton*, 322 F.3d 728, 731–32 (D.C. Cir. 2003) (collecting cases), *abrogated on other grounds*, *Inst. Shareholder Servs., Inc. v. S.E.C.*, 142 F.4th 757 (D.C. Cir. 2025).

A. Standing

"To establish standing under Article III, a prospective intervenor—like any party—must show: (1) injury-in-fact, (2) causation, and (3) redressability." *Id.* at 732–33 (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992)). When, as here, a "party seeks to intervene as a defendant to uphold an action taken by the government," the proposed intervenor "must establish that it will be 'injured in fact by the setting aside of the government's action it seeks to defend, that this injury would have been caused by that invalidation, and the injury would be prevented if the government action is upheld.'" *MGM Glob. Resorts Dev., LLC v. U.S. Dep't of*

the Interior, No. 19-cv-2377 (RC), 2020 WL 5545496, at *3 (D.D.C. Sept. 16, 2020) (internal citations omitted).

Proposed Intervenors easily satisfy the standing requirements. Proposed Intervenor 340B Health is the leading 340B advocate for 340B hospitals on federal legislative and regulatory issues related to 340B drug pricing. Testoni Declaration at ¶ 3. 340B Health is uniquely positioned to participate in this lawsuit, both because it represents 1,600 340B hospital members across the country, and because it has been at the forefront of all efforts to ensure that 340B hospitals can continue to access the benefits of the 340B drug discount program, including by participating in related lawsuits. *Id.* at ¶ 4. For example, 340B Health was party to the lawsuit filed in this district seeking to require HHS to issue regulations implementing the Congressionally established civil money penalties. *American Hosp. Ass'n v. HHS*, No. 1:18-cv-2112 (D.D.C. Sept. 11, 2018); Testoni Declaration at ¶ 4. 340B Health was also party to a lawsuit filed in the Northern District of California seeking to require HHS to prohibit drug companies from refusing to sell drugs at 340B prices to hospitals that contracted with community pharmacies to distribute their drugs. *Am. Hosp. Ass'n v. HHS*, No. 4:20-cv-8806 (N.D. Cal. Dec. 11, 2020); Testoni Declaration at ¶ 4.[1]

[1] After HHS adopted the position advocated by 340B Health in the community pharmacy lawsuit that drug companies were required to sell drugs at 340B prices to hospitals that contracted with community pharmacies, 340B Health continued to advocate for 340B hospitals. 340B Health participated as one of several *amici* supporting HHS in six lawsuits filed by drug companies in an attempt to restrict the covered entities use of community pharmacies to dispense drugs to 340B patients. Testoni Declaration at ¶ 5. And 340B Health is currently participating as an *amicus* supporting State Attorneys General in cases challenging state laws designed to ensure that 340B hospitals may use community pharmacies to dispense drugs to 340B patients. *Id.* To date, 340B Health has joined 80 *amicus* briefs in those cases. *Id.* However, as discussed below, 340B Health has determined that participation as an intervenor in the present case is necessary because the *amicus* briefs recently filed by the Government Defendants in the community pharmacy litigation causes uncertainty regarding the legal positions that the Government Defendants may take in other 340B litigation, including this case.

340B Health has standing as an association representing over 1,600 340B hospitals, all of which purchase 340B drugs and would therefore be impacted if HRSA were forced to adopt AbbVie's narrow definition of "patient." "An association has standing to bring suit on behalf of its members when its members would otherwise have standing to sue in their own right, the interests at stake are germane to the organization's purpose, and neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Friends of Earth v. Haaland*, No. 21-cv-2317 (RC), 2021 WL 5865386, at *2 (D.D.C. Dec. 11, 2021) (quoting *Friends of the Earth, Inc. v. Laidlaw Env't Servs. Inc*., 528 U.S. 167, 181 (2000)). 340B Health's mission is to support 340B hospitals in their mission to serve low income, underserved, and rural patients. Testoni Declaration at ¶ 3. The interest at stake in this litigation—the ability of 340B hospitals to access drugs at a discounted price consistent with the statute—is plainly relevant to 340B Health's goal of supporting 340B hospitals.

The hospital members of 340B Health, including Proposed Hospital Intervenors UMMC and Genesis, also clearly have standing to sue. Should this Court require HRSA to adopt AbbVie's narrow definition of "patient," Proposed Hospital Intervenors would lose access to the 340B statutory discount for many of the eligible patients they treat. For example, UMMC frequently provides medications to patients following discharge from inpatient admissions. These medications are often critical to ensuring continuity of care, preventing complications, reducing readmissions, and supporting successful recovery. Desai Declaration at ¶ 22. But AbbVie's proposed definition appears to require that a covered outpatient drug be prescribed as a direct result of a qualifying outpatient encounter. This framework could exclude many discharge prescriptions because they originate from an inpatient episode of care rather than a qualifying outpatient visit, even though the patient remains under the care and responsibility of the covered entity. Limiting

access to 340B pricing for discharge medications would adversely affect transitions of care and increase barriers to medication access following hospitalization. This impact would be particularly significant for uninsured and underinsured patients. UMMC currently utilizes 340B savings to support patient assistance programs that provide free medications or substantial discounts to financially vulnerable patients. Reduced access to 340B pricing could significantly impair our ability to continue offering these affordability programs and could result in patients delaying, foregoing, or discontinuing medically necessary therapy. *Id.* at ¶ 24.

Further, Genesis would be forced to incur significant expenses to comply. Genesis predicts that it will need to spend over $80,000 per year just to comply, in addition to legal fees. Carr Declaration at ¶ 13. Genesis will also need to hire new fulltime employees to ensure compliance with the new "patient" definition. *Id.* at ¶ 13. Those administrative costs alone will force Genesis to cut the critical services they currently provide, harming not only vulnerable individual patients, but also their local, underserved communities. Additionally, Genesis expects to incur significant legal costs should it need to challenge a manufacturer overcharge or improper manufacturer audit finding through HRSA's ADR process. *Id.* at ¶ 13.

Those costs would be directly traceable to whether this Court adopts AbbVie's "patient" definition. Without a favorable decision by this Court, affirming HRSA's current, long-standing interpretation of "patient of the entity," 340B hospitals will be unable to continue their participation in the 340B program without incurring the additional time, expense, and uncertainty that would result from HRSA adopting AbbVie's proposed "patient" definition. Importantly, if HRSA were forced to narrow its interpretation of "patient," the additional time and cost associated with implementing the 340B program will undeniably multiply.

If HRSA adopted AbbVie's narrow definition of "patient," the costs to 340B hospitals would be massive. UMMC predicts that it likely will be unable to continue funding some or all of its community programs and may even be unable to stay afloat depending on reimbursement by governmental payers, which represent almost 70% of its patients**.** Desai Declaration at ¶ 4. Under those conditions, Genesis estimates that it will have to evaluate its ability to financially support other community benefits, which would have a significant impact on the community's most vulnerable patients and drastically reduce healthcare access for surrounding communities. Genesis' ability to borrow funds to support these programs will also be impaired by the significant negative margin created by the considerable administrative burdens that would be required to comply. Carr Declaration at ¶ 17. That additional cost will create such a negative margin that Genesis predicts that it will have to cut its 340B Patient Assistance and Meds to Bed Programs, significantly impacting some of the most underserved individuals, and likely leaving many of those individuals without access to critical medications. *Id.* at ¶¶ 15, 17.

As such, Proposed Intervenors plainly have standing to sue.

B. Timeliness

"The timeliness of a motion to intervene is 'to be judged in consideration of all the circumstances.'" *Roane*, 741 F.3d at 151 (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." *WildEarth Guardians v. Salazar*, 272 F.R.D. 4, 12 (D.D.C. 2010); *see Karsner*, 532 F.3d at 885. However, the "most important consideration in deciding whether a motion for intervention is untimely is whether the delay in moving for intervention will prejudice the existing parties to the case." *Roane*, 741 F.3d at 151. That

consideration is paramount because "the requirement of timeliness is aimed primarily at preventing potential intervenors from unduly disrupting litigation, to the unfair detriment of the existing parties." *Id.*

AbbVie filed its Complaint on April 8, 2026, and the Government Defendants moved to dismiss just last week on June 16, 2026. Proposed Intervenors needed to wait to file the instant intervention motion until the Government Defendants filed their responsive pleading to the Complaint to see what position the Government Defendants would take in this case. As such, Proposed Intervenors have promptly moved to intervene just after the Government Defendants filed their responsive pleading. Proposed Intervenors do not intend to address the jurisdictional issues raised in the Government's recent motion to dismiss but intend to address the merits of this action once the merits are raised by either party. Proposed Intervenors will comply with any scheduling order the Court establishes for briefing the merits. Neither AbbVie nor Defendants will be prejudiced by intervention.[2]

Furthermore, given that the enforcement of AbbVie's "patient" definition would fundamentally alter the Proposed Hospital Intervenors' processes for complying with the 340B statute, Proposed Intervenors' interest in the litigation is significant, and intervention is necessary to preserve their ability to challenge AbbVie's "patient" definition. That significant interest would override any allegation that this Motion is delayed (though it is not). Because the Proposed

[2] Proposed Intervenors have not attached a proposed answer to this motion since the action could be resolved on the Government's motion to dismiss. Although Proposed Intervenors understand that an Answer is ordinarily required under Federal Rule of Civil Procedure 24(c), "courts in this Circuit have not applied this rule particularly rigidly," and the D.C. Circuit has expressly "noted its 'willingness to adopt flexible interpretations of Rule 24 in special circumstances.'" *MGM Glob. Resorts Dev., LLC*, 2020 WL 5545496, at *6. Intervenors propose that they not be required to file an answer until they file a pleading on the merits, but they will of course file one expeditiously if required by the Court.

Intervenors have promptly moved to intervene and their intervention will not unduly disrupt the litigation or prejudice existing parties, the Motion to Intervene is timely.

C. Interest

The Proposed Intervenors must also have a "legally protected" interest in the action. *Karsner*, 532 F.3d at 885. As the Proposed Intervenors have already demonstrated standing, they "'*a fortiori*' ha[ve] 'an interest relating to the property or transaction which is the subject of this action.'" *Crossroads Grassroots Pol'y Strategies v. Fed. Election Comm'n*, 788 F.3d 312, 320 (D.C. Cir. 2015), *abrogated on other grounds*, *Inst. Shareholder Servs., Inc. v. S.E.C.*, 142 F.4th 757 (D.C. Cir. 2025) (internal citation omitted); *see e.g.*, *Mayo v. Jarvis,* No. 14-cv-1751 (RC), 2015 WL 13700484, at *1 (D.D.C. Jan. 21, 2015) (collecting cases). As previously described, *see* Sec. I.A., the enforcement of AbbVie's narrow interpretation of the statutory term "patient" would impose substantial financial injury on 340B hospitals, including by narrowing the pool of eligible patients (thereby decreasing revenue from 340B discounts) and significantly impacting the 340B hospitals' costs to comply with the 340B statute. The Proposed Intervenors clearly have an interest in HRSA's interpretation of "patient" that is the subject of this litigation.

D. Interest Impaired

To determine whether a proposed intervenor's interests will be impaired, courts in the D.C. Circuit consider the "practical consequences" of denying intervention and therefore denying proposed intervenors the ability to protect their interest. *Fund For Animals, Inc.*, 322 F.3d at 735. The disposition of the present suit in AbbVie's favor would immediately adversely affect the Proposed Intervenors. As previously described, *see* Sec. I.A., such an abrupt change to the status quo would force Proposed Hospital Intervenors to invest significant time and incur substantial costs to comply with the new definition of "patient," thereby reducing the hospitals' funds to support patient care and services and causing harm to patients.

In addition to the costs that would be incurred by Proposed Hospital Intervenors if AbbVie's definition of "patient" were enforced, this Court has consistently found that where, as here, "an agency's 'decision below was favorable to [the proposed intervenor], and the present action is a direct attack on that action' . . . the action threatens to impair the intervenor's protected interests." *S. Utah Wilderness All. v. Haaland*, No. 20-cv-3654 (RC), 2021 WL 12269155, at *2 (D.D.C. July 28, 2021) (collecting cases) (alteration in the original). The 340B hospitals would be severely harmed if HRSA were compelled to enforce AbbVie's narrow definition of "patient" in future audits by other manufacturers. *See* Sec. I.A. AbbVie's Complaint directly attacks HRSA's refusal to enforce its audit results and expressly asks this Court to declare that "the interpretation in HRSA's 1996 Guidelines does not accord with the 340B statute" and "to set aside HRSA's decisions not to enforce AbbVie's audits for Barrio and Mount Sinai." Compl. ¶ 21. Therefore, Proposed Intervenors' interests will be impaired should this Court grant judgment in AbbVie's favor.

E. Inadequate Representation

The Government Defendants are not an adequate representative of Proposed Intervenors' interests. Courts in this circuit hold that this burden of showing inadequate representation is "minimal," and that a party seeking intervention of right must only make a showing that the representation "may be" inadequate. *WildEarth Guardians v. Jewell*, 320 F.R.D. 1, 4 (D.D.C. 2017) (Contreras, J.) (citing *Fund For Animals, Inc.*, 322 F.3d at 735). Generally, a movant "should be allowed to intervene unless it is clear that the party will provide adequate representation for the absentee." *Fund For Animals, Inc.*, 322 F.3d at 735.

At the outset, the D.C. Circuit "look[s] skeptically on government entities serving as adequate advocates for private parties," and has "stressed that even when the interest of a federal agency and potential intervenor can be expected to coincide, that does not necessarily mean [ ]

adequacy of representation is ensured." *Crossroads Grassroots Pol'y Strategies*, 788 F.3d at 321 (alteration in the original). As such, a government entity may not adequately represent a proposed intervenor, even when the federal agency and the proposed intervenor "undisputedly" agree that the federal agency's actions are lawful. *Id.* (citing *Fund For Animals, Inc.*, 322 F.3d at 726). Government representation is frequently considered inadequate because the government's obligation is to represent the interests of its citizens, as opposed to the interest of private parties, which may represent "a more narrow 'parochial' financial interest not shared" by those citizens. *Fund for Animals*, 322 F.3d at 736–37 (quoting *Dimond v. D.C.*, 792 F.2d 179, 192-933 (D.C. Cir. 1986)). The D.C. Circuit has therefore "often concluded that governmental entities do not adequately represent the interests of aspiring intervenors." *Fund for Animals*, 322 F.3d at 736.

The D.C. Circuit's concerns about the federal government adequately representing the interests of private parties are particularly salient here. While the Government Defendants defended HRSA's interpretation of "patient" set forth in the 1996 Guidelines under the Biden Administration, *see Genesis Healthcare Inc. v. Becerra*, No. 4:19-cv-1531-RBH (D.S.C.), President Trump has repeatedly made clear that his administration will take different legal positions than the Biden Administration on a variety of matters. While there has been no suggestion yet that the current administration will take a different position on this matter, there is also no assurance that it will continue to defend the instant suit nor maintain the position that the 1996 Guidelines represent the best reading of "patient" under the 340B statute. Further, as evidence of the Trump Administration's tendency to take different legal positions from its predecessor, the Government Defendants have recently began filing *amicus* briefs in litigation relating to state laws regulating delivery of 340B drugs to community pharmacies with which 340B hospitals have

contracts. This position represents a rejection of the Government's prior support for contract pharmacies.

Additionally, while both the Government and the Proposed Intervenors have a strong interest in the medical care of hospital patients, the Proposed Intervenors also represent the financial interests of 340B hospitals and are in the best position to describe both that interest and the interests of their patients to the Court. *See* Sec. I.A.

Finally, Proposed Intervenors are the only entities that can adequately describe the impact that AbbVie's proposed "patient" definition will have on 340B hospitals and the patients they serve. It is clear from the face of AbbVie's Complaint that AbbVie does not understand the breadth of the benefits provided by the 340B Program, which was enacted to not only support 340B hospitals, which are safety nets for low income and uninsured patients, but also to help 340B hospitals fund and provide crucial community services. As described above, the Proposed Hospital Intervenors have used savings from the 340B Program to provide tremendous benefits to the patients and communities they serve. Proposed Intervenors are also best equipped to address why AbbVie's assertions regarding widespread 340B Program abuse and non-compliance are inaccurate. As such, Proposed Intervenors 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.

In sum, the Proposed Intervenors meet the standard for intervention of right.

II. ALTERNATIVELY, PROPOSED INTERVENORS SHOULD BE PERMITTED TO INTERVENE UNDER RULE 24(B).

Proposed Intervenors also satisfy the requirements of Federal Rule of Civil Procedure 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.*, 146 F.3d at 1046).

Proposed Intervenors easily meet these requirements. First, this is a federal-question case, which provides the Court with an independent basis for subject matter jurisdiction. *Ass'n of Washington Bus.*, 2024 WL 3225937 at 11; *Friends of Earth v. Haaland*, No. 21-cv-2317 (RC), 2022 WL 136763, at *6 (D.D.C. Jan. 15, 2022). Second, for the reasons described above, *see* Sec. I.B., this motion is timely and thus will not delay the proceedings or prejudice the parties. Third, the Proposed Intervenors ask the Court to resolve the same question that is currently in front of it—whether the definition of "patient" set forth in HRSA's 1996 Guidelines is the best reading of that term in the 340B statute.

Accordingly, if the Court denies intervention under Rule 24(a), Proposed Intervenors should be permitted to intervene under Rule 24(b).

CONCLUSION

For the foregoing reasons, Proposed Intervenors request that the Court grant their motion to intervene of right under Rule 24(a), or, in the alternative, allow Proposed Intervenors to intervene under Rule 24(b).

Dated: June 23, 2026

Respectfully submitted,

/s/ William B. Schultz

William B. Schultz (D.C. Bar No. 218990)
Margaret M. Dotzel (D.C. Bar No. 425431)
Alyssa M. Howard (D.C. Bar No. 1708226)
ZUCKERMAN SPAEDER LLP
2100 L Street NW, Suite 400
Washington, DC 20037
Tel: (202) 778-1800
Fax: (202) 822-8106
wschultz@zuckerman.com
mdotzel@zuckerman.com
ahoward@zuckerman.com

Attorneys for Proposed Intervenors

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ABBVIE INC., *Plaintiff*, v. ROBERT F. KENNEDY JR, in his official capacity as Secretary of U.S. Department of Health and Human Services, *et al.*, *Defendants*.	§	Case No. 1:26-cv-1190-RDM

DECLARATION OF MAUREEN TESTONI IN SUPPORT OF 340B HEALTH, UMASS MEMORIAL MEDICAL CENTER, AND GENESIS HEALTHCARE SYSTEM'S MOTION TO INTERVENE

I, Maureen Testoni, state as follows under the penalty of perjury:

1. I am the President and Chief Executive Officer of 340B Health, a Proposed Intervenor in this action.

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

3. 340B Health is a national, not-for-profit, membership organization headquartered in Washington, D.C. that represents over 1,600 hospital members across the country. 340B Health's mission is to be the leading 340B advocate and resource supporting hospitals in their mission to serve low income, underserved, and rural patients.

4. 340B Health has been a plaintiff in several lawsuits related to the 340B Program, including a suit in the District Court for the District of Columbia that sought to require the Department of Health and Human Services (HHS) to issue regulations implementing Congressionally established civil money penalties. *Am. Hosp. Ass'n v. HHS*, No. 1:18-cv-2112. 340B Health was also a plaintiff in a suit in in the Northern District of California seeking to require HHS to prohibit drug companies from refusing to sell drugs at 340B prices to hospitals that contracted with community pharmacies to distribute their drugs. *Am. Hosp. Ass'n v. HHS,* No. 4-20-cv-00805. 340B Health also intervened as a defendant in four cases now pending in the D.C. Circuit involving drug company challenges to defendants' denial of proposals to implement rebates models. *See Novartis Pharms. Corp. v. Kennedy*, No. 25-2553 (D.C. Cir.).

5. 340B Health has also filed *amicus* briefs in numerous cases across the country relating to the 340B Program. 340B Health participated as one of several *amici* supporting the HHS in six lawsuits filed by drug companies in an attempt to restrict the covered entities use of community pharmacies to dispense drugs to 340B patients. 340B Health is currently participating as an *amicus* supporting State Attorneys General in cases challenging state laws designed to ensure that 340B hospitals may use community pharmacies to dispense drugs to 340B patients. To date, 340B health has joined over 80 *amicus* briefs in those cases.

On this 22 th day of June, 2026, I declare under penalty of perjury that the foregoing is true and correct.

Maureen Testoni
President and Chief Executive Officer
340B Health

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ABBVIE INC., *Plaintiff*, v. ROBERT F. KENNEDY JR, in his official capacity as Secretary of U.S. Department of Health and Human Services, *et al.*, *Defendants*.	§	Case No. 1:26-cv-1190-RDM

DECLARATION OF MEETALI DESAI IN SUPPORT OF 340B HEALTH, UMASS MEMORIAL MEDICAL CENTER, AND GENESIS HEALTHCARE SYSTEM'S MOTION TO INTERVENE

I, Meetali Desai, state as follows under the penalty of perjury:

1. I am the Director of Pharmacy Business Services at UMass Memorial Medical Center (UMMC), a Proposed Intervenor in this action.

2. I have been the Director of Pharmacy Business Services for four years. Before that, I was the Manager of 340B and Pharmacy Business Office.

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

UMass and the Community Services It Provides

4. UMMC is among the nation's most distinguished academic health care systems and strives to improve the health of diverse communities throughout Central New England through

clinical care, service, teaching, and research. UMMC is a wholly controlled subsidiary of UMass Memorial Health, which is a non-profit health system designed to fulfill important public health missions, including providing health services to indigent patients in Central Massachusetts and providing highly specialized clinical care. Pursuant to this mandate, UMMC provides more care to indigent and underserved patients than any other provider in Central Massachusetts, accounting for over 70% of the region's Medicaid inpatient care.

5. UMMC is a "covered entity," as defined in section 340B of the Public Health Service Act, 42 U.S.C. § 256b(a)(4)(L), by virtue of its qualification as a "disproportionate share" hospital that treats a large percentage of indigent patients.

6. UMMC is a member of 340B Health, which is also a Proposed Intervenor in this case.

7. UMMC relies heavily on savings gained through the 340B Program to meet the healthcare needs of underserved patients in its community. For example, and as further described below, UMMC relies on those savings to provide services that support vulnerable populations, such as financial assistance for medications, community benefit programs, the Ronald McDonald Care Mobile Clinic, mobile addiction programs, and medical respite beds. Through these services, in FY'23 alone, UMass has served over 14,631 individuals and provided 669 prescriptions at no cost to qualifying patients.

8. Through a program that provides financial assistance for medications, UMMC offers free prescription medications to uninsured patients and dedicates resources to connect underinsured individuals with financial support options, such as copay assistance programs, grants, and charitable foundations.

9. 340B also supports UMass' Child Protection Program, which is the only comprehensive program in the region that addresses clinical issues associated with child abuse, neglect, and placement in substitute care.

10. In addition, UMMC offers community benefit programs, which target ethnically diverse, low-income patients who are medically underserved. Those programs focus on addressing social determinants of health, reducing racial and ethnic health disparities and substance abuse, and improving mental health, violence prevention programs, access-to-care services, and pediatric asthma interventions. For example, UMMC provides medical services at Hector Reyes House, a residential substance abuse treatment program for Latino men. In addition to offering on-site medical care and cognitive behavioral therapy, which reduces relapses and improves transitions to independent living, the program offers job training and workforce skill development. UMMC also participates in a city-wide task force that addresses high rates of pediatric asthma and related emergency department visits through evidence-based intervention programs. In those programs, culturally competent community health workers provide home visits to ensure that medication is correctly administered and to address home triggers.

11. Additionally, UMMC's Ronald McDonald Care Mobile Clinic provides free health care and dental services to medically underserved populations in ten low-income neighborhoods. The Clinic provides more than 4,500 annual visits and partners with twenty-eight local public schools.

12. UMMC also provides mobile addiction services through its Road to Care Mobile Addiction Team, which provides health services to individuals with behavioral health and substance use disorders at sites frequented by the homeless population. Those services include health screenings, primary care, substance use disorder treatment, screenings for sexually

transmitted infections, referrals to social support services, and laboratory and medication services. The program aims to reduce morbidity and mortality and break down healthcare barriers, such as a lack of transportation and trust in the healthcare system. In 2023, the program had 3,699 clinical encounters and served nearly 869 patients, a 76% increase from the previous year, reflecting the increase in demand for the program.

13. In partnership with South Middlesex Opportunity Council, UMMC provides post-acute medical care and social support to individuals experiencing homelessness who have been discharged from the hospital and still require medical attention.

14. UMMC also operates the St. Paul Consortium Mental and Behavioral Health Equity Initiative, which provides mental health counseling and clinical observation to adolescents. In 2023, the initiative reached more than 800 students in four schools from PreK to 12th grade, and there are currently more than fifty students receiving ongoing counseling.

The Impact of AbbVie's Narrow Definition of "Patient" on Genesis

15. I have had the opportunity to review the definition of "patient" advocated by AbbVie Inc. (AbbVie) in its complaint and to evaluate its potential impact on Genesis' current operations. AbbVie's proposed "patient" definition threatens to reduce the amount Genesis saves through the 340B Program and, as a result, Genesis' ability to provide critical services to the most vulnerable patients.

16. UMMC serves as a regional referral center for patients throughout Central Massachusetts. Many patients are referred to UMMC by community physicians and other healthcare providers for specialty services, including oncology, rheumatology, infectious disease, neurology, cardiology, infusion therapy, and specialty pharmacy services.

17. Under AbbVie's proposed patient definition, many referred patients could become ineligible for 340B pricing because the referring provider may continue to participate in the patient's care or maintain responsibility for aspects of the patient's treatment. This approach does not reflect how specialty care is delivered in modern healthcare systems, where multiple providers routinely collaborate in the management of complex conditions.

18. Although a referring provider may remain involved in a patient's overall care, UMMC specialists assume significant responsibility for evaluating, treating, monitoring, and managing the conditions for which patients are referred. Excluding these patients from 340B eligibility would disregard the substantial clinical services provided by the covered entity and could reduce access to critical specialty medications for vulnerable patients.

Impact on Pharmacist-Led Medication Management Programs

19. UMMC operates clinical pharmacy and medication management programs that support patients with complex and chronic conditions. Clinical pharmacists routinely work under collaborative care models with physicians and advanced practice providers to optimize medication therapy, improve adherence, monitor treatment response, manage side effects, and prevent avoidable hospitalizations.

20. AbbVie's proposed requirement that a covered entity healthcare professional be solely responsible for diagnosing and directly managing a patient's condition could jeopardize pharmacist-led care models that are widely accepted, clinically beneficial, and increasingly utilized across healthcare systems. These programs rely on coordinated, team-based care rather than exclusive responsibility resting with a single provider.

21. Restricting 340B eligibility for patients participating in these programs would undermine initiatives that improve clinical outcomes, expand access to care, and reduce healthcare costs.

Impact on Patients Receiving Medications Following Hospital Discharge

22. UMMC frequently provides medications to patients following discharge from inpatient admissions. These medications are often critical to ensuring continuity of care, preventing complications, reducing readmissions, and supporting successful recovery.

23. AbbVie's proposed definition appears to require that a covered outpatient drug be prescribed as a direct result of a qualifying outpatient encounter. This framework could exclude many discharge prescriptions because they originate from an inpatient episode of care rather than a qualifying outpatient visit, even though the patient remains under the care and responsibility of the covered entity.

24. Limiting access to 340B pricing for discharge medications would adversely affect transitions of care and increase barriers to medication access following hospitalization. This impact would be particularly significant for uninsured and underinsured patients. UMMC currently utilizes 340B savings to support patient assistance programs that provide free medications or substantial discounts to financially vulnerable patients. Reduced access to 340B pricing could significantly impair our ability to continue offering these affordability programs and could result in patients delaying, foregoing, or discontinuing medically necessary therapy.

Impact on Infusion Services

25. Many patients receive infusion therapies at UMMC based on referrals from physicians who are not directly employed by the hospital, but who are credentialed and privileged to practice at the covered entity and continue to participate in the patient's ongoing care.

26. Under AbbVie's proposed definition, patients could lose eligibility for 340B pricing if the diagnosing or treating provider is not directly employed by or contracted with the covered entity, despite the fact that the covered entity is responsible for administering the medication, monitoring treatment response, managing adverse effects, maintaining the necessary clinical infrastructure, and coordinating ongoing care.

27. This restriction would significantly affect patients receiving complex therapies through infusion centers and would fail to recognize the covered entity's substantial role in delivering and managing these treatments.

Impact on Patients Treated by Privileged But Non-Employed Providers

28. UMMC relies on a broad network of credentialed and privileged physicians and healthcare professionals who provide services within the hospital, including clinics, and participate in patient care.

29. AbbVie's proposed definition appears to exclude situations in which healthcare professionals maintain hospital privileges but are not directly employed by or contracted with the hospital. Such a restriction would disregard longstanding care delivery models relied upon by academic medical centers and health systems throughout the country.

30. Patients receiving treatment from privileged providers practicing within UMMC facilities could lose eligibility for 340B pricing despite receiving care within the hospital's integrated clinical environment and despite the hospital's responsibility for supporting and delivering those services.

Impact of the Proposed 12-Month Requirement

31. AbbVie's proposed requirement that a drug be prescribed within 12 months of a qualifying encounter does not reflect the realities of caring for patients with chronic and complex diseases.

32. Many patients remain clinically stable on long-term therapies and may not require frequent in-person visits while still receiving ongoing monitoring, medication refills, laboratory review, care coordination, and clinical oversight. Their treatment remains actively managed by healthcare professionals affiliated with the covered entity.

33. The proposed time limitation would arbitrarily exclude patients who remain under active clinical management and continue to receive medically necessary therapies solely because they have achieved clinical stability and require less frequent face-to-face visits.

Financial and Patient Care Impact

34. If AbbVie's proposed definition were adopted, a substantial number of patients currently served through legitimate hospital-based care models could become ineligible for 340B pricing. The resulting loss of 340B savings would significantly reduce UMMC's ability to sustain the community benefit programs and would impair our ability to expand access to care and medications for vulnerable patients.

35. AbbVie's proposed definition reflects a fragmented and outdated view of healthcare delivery that does not align with the coordinated, multidisciplinary, and team-based care models utilized by modern health systems. The adverse effects of this proposal would be felt not only by covered entities but, more importantly, by the patients who depend on these services for access to medically necessary care and medications.

On this 22nd day of June, 2026, I declare under penalty of perjury that the foregoing is true and correct.

Meetali Desai
Director, Pharmacy Business Services
UMass Memorial Medical Center

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ABBVIE INC., *Plaintiff*, v. ROBERT F. KENNEDY, JR., Secretary of Health and Human Services, *et al.*, *Defendants.*	§	Case No. 1:26-cv-1190-RDM

DECLARATION OF SHONA CARR IN SUPPORT OF 340B HEALTH, UMASS MEMORIAL MEDICAL CENTER, AND GENESIS HEALTHCARE SYSTEM'S MOTION TO INTERVENE

I, Shona Carr, state as follows under the penalty of perjury:

1. I am the Director of 340B & Ambulatory Pharmacies at Genesis HealthCare System (Genesis), a Proposed Intervenor in this action.

2. I have been the Director of 340B & Ambulatory Pharmacies for six years. Before that I was the 340B Pharmacy Manager.

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

Genesis and the Population It Serves

4. Genesis is an integrated healthcare delivery system based in Zanesville, Ohio. Its flagship organization, Genesis Hospital, is a not-for-profit hospital that provides care to all members of the community, regardless of their ability to pay. Genesis serves six counties in Ohio

with a total population of 235,000 in its primary service area (PSA). That population is materially disadvantaged compared to the state as a whole in nearly every indicator of community health: the median household income in the PSA is $59,600, while the median household income in Ohio is $72,200; about 15.25% of the population in the PSA lives below the poverty line, while about 12.7% of the population of Ohio lives below the poverty line; and about 30.6% of the population in the PSA rely on Medicaid for health insurance, which is well above the percentage of the population in Ohio that rely on Medicaid for health insurance. Additionally, smoking, obesity, diabetes, heart disease, stroke, cancer, and substance abuse rates in the PSA are all above the median of those rates in Ohio. Each year, Genesis uses its savings to provide millions of dollars in free care for people who cannot afford health services, and over 200,000 community members have benefitted from those programs.

5. Genesis is a "covered entity," as defined in section 340B of the Public Health Service Act, 42 U.S.C. § 256b(a)(4)(A), by virtue of its qualification as a "disproportionate share" hospital that treats a large percentage of indigent patients.

6. Genesis is a member of 340B Health, also a Proposed Intervenor in this case.

7. Genesis relies on savings gained through the 340B Program to help support comprehensive services for the medically underserved community.

8. For example, Genesis relies on those savings to fund its 340B Patient Assistance Program, which provides medications, including AbbVie's drugs—Creon, Humira, Mavyret, Restasis, Rinvoq, and Synthroid—at a discount to eligible patients in underserved communities, allowing them to access essential drugs at a lower cost. In 2025, that program filled 33,991 prescriptions for 3,062 patients and saved those patients a total of $2.26 million in out-of-pocket costs.

9. Genesis also uses 340B savings to fund its Meds to Bed Program, which ensures that patients have access to necessary medications once they are discharged from the hospital. In 2025, that program filled 16,393 prescriptions for 5,586 patients and saved those patients a total of $25,140 in out-of-pocket costs.

10. Genesis additionally offers a shuttle service that is provided free of charge to discharged patients who need a ride home and have no other means of transportation. This service covers six counties and has provided transportation to about 1,200 patients in the past two years.

11. Genesis has recently implemented an initiative focused on providing proactive in-home visits for high-risk patients with chronic conditions. This Paramedicine Program is designed to benefit the community by bringing a healthcare specialist to the patient's residence to provide a variety of services, such as drawing lab work, conducting a health assessment, initiating a physician tele visit, and ensuring medication compliancy. This referral service is free to the community, helps fill the gaps identified in the existing healthcare model, and improves patients' quality of life. Genesis additionally funds several other programs, in part with their 340B savings, including smoking cessation counseling, stroke prevention programs, and free mammograms to eligible community members.

The Impact of AbbVie's Narrow Definition of "Patient" on Genesis

12. I have had the opportunity to review the definition of "patient" advocated by AbbVie Inc. (AbbVie) in its complaint and to evaluate its potential impact on Genesis' current operations. AbbVie's proposed "patient" definition threatens to reduce the amount Genesis saves through the 340B Program and, as a result, Genesis' ability to provide critical services to the most vulnerable patients.

13. If AbbVie were to impose a 340B patient definition that differs from the standard used by HRSA and other manufacturers, Genesis would face substantial administrative burdens. Ultimately, adhering to this new 340B "patient" definition would divert resources away from patient care and complicate Genesis's ability to operate a consistent, efficient, and compliant 340B program. Genesis will be forced to divert funds used to provide care to the underserved to maintain compliance with AbbVie's proposed "patient" definition. Genesis estimates that it will need to spend an additional $80,000 annually to hire and train a new full-time employee, who will be tasked solely ensuring compliance with AbbVie's patient definition. There will also be additional, significant legal fees that Genesis may have to pay if it is forced to use HRSA's Alternative Dispute Resolution Process to dispute improper claim denials as a result of AbbVie's unreasonably narrow definition of "patient."

14. More specifically, should AbbVie be allowed to enforce its "patient" definition, Genesis will be forced to re-evaluate its 340B Patient Assistance Program. If AbbVie were to narrow its 340B patient definition such that its prescriptions no longer qualify for 340B pricing, Genesis's eligible patients would experience a direct loss of access to reduced copay assistance tied to those medications. As a result, patients—particularly those who are uninsured or underinsured—would face higher out-of-pocket costs for AbbVie therapies, which are often high-cost specialty or chronic disease medications. This increase in financial burden could lead to decreased medication adherence, delays in therapy initiation, or treatment discontinuation. Ultimately, limiting access to 340B-supported affordability programs would undermine Genesis's ability to support vulnerable populations, potentially worsening health outcomes and increasing downstream utilization of more costly healthcare services.

15. Enforcement of AbbVie's "patient" definition will have a similar impact on Genesis' Meds to Bed program. The Meds to Bed program already operates at a loss; the program requires one fulltime pharmacist, four fulltime pharmacy technicians, and one fulltime pharmacy courier to effectively operate the program, at an estimated annual salary and benefit cost of $433,000. Those six individuals focus solely on providing outpatient pharmacy services to patients being discharged from the hospital. The program is funded through the 340B savings generated by the Genesis Outpatient Pharmacy and exists as a benefit to our patients and to aid in the reduction of readmissions. If Genesis' 340B savings are substantially reduced, then it may no longer be able to afford to operate the program.

16. The increased administrative costs of complying with AbbVie's "patient" definition would force Genesis to evaluate the ability to continue these free community programs that its patients and community rely on, potentially leaving patients without transportation to or from the hospital and cutting the service that provides free mammograms.

17. If AbbVie's "patient" definition were enforced, Genesis would suffer large financial harm, resulting in unquantifiable consequences to patients, programs, and the overall care for the community Genesis serves. Not only does Genesis predict that it will have to limit or potentially close its 340B Patient Assistance and Meds to Bed programs, but Genesis also predicts that it will have to evaluate its ability to financially support other community benefits, which would have a significant impact on the community's most vulnerable patients and drastically reduce healthcare access for surrounding communities. Genesis' ability to borrow funds to support these programs will also be impaired by the significant negative margin created by the considerable administrative burdens that would be required to comply.

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On this 22 nd day of June, 2026, I declare under penalty of perjury that the foregoing is true and correct.

Shona Carr
Director, 340B & Ambulatory Pharmacies
Genesis HealthCare System