UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BRISTOL MYERS SQUIBB COMPANY *Plaintiff*, v. DOROTHY FINK, Acting Secretary of Health and Human Services, et al., *Defendants*.	§ § § § § § § § § § § §	Case No. 1:24-cv-3337-DLF

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

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340B Health, UMass Memorial Medical Center (UMass), 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. Proposed Intervenor 340B Health is an association with 1,600 member hospitals that are eligible to receive benefits under the 340B program (340B hospitals). Proposed Intervenors UMass and Genesis (the Proposed Hospital Intervenors) are 340B hospitals.

Since the beginning of the 340B Program in 1992, 340B Providers have purchased eligible 340B drugs from drug manufacturers, including Plaintiff Bristol Myers Squibb Company (BMS), at the 340B discounted price. On October 22, 2024, BMS informed the Health Resources and Services Administration (HRSA), the Department of Health and Human Services (HHS) agency tasked with implementing the 340B Program, that it would fundamentally alter the way it participates in the 340B Program by changing its pricing programs for its 340B eligible drugs to a rebate model. Instead of providing an upfront discount to 340B hospitals when they purchase 340B eligible drugs, which had been the practice of BMS and every other pharmaceutical company that participates in the 340B Program since its inception, BMS informed HRSA that it would now

require all 340B covered entities, including 340B hospitals to purchase those drugs[1] at full price, submit a claim for rebate, and then wait for BMS to provide that rebate.

BMS's proposed rebate model requires 340B hospitals to initially purchase BMS drug products at full price, resulting in higher costs for hospitals to maintain their drug inventory, before receiving any rebate. However, in order to claim the rebate, 340B hospitals would be required to collect and provide claims data to BMS, effectively imposing a new data collection and reporting requirement that appears nowhere in the 340B statute. BMS and a third-party contractor employed by BMS would then determine, based on unclear criteria, whether the 340B hospital is entitled to a rebate on each of those 340B drugs.

If that contractor determines that the 340B hospital is not entitled to a rebate, there is no clear method by which to appeal that decision. If BMS denies the rebate, the 340B hospital could seek redress through the statutorily created Administrative Dispute Resolution (ADR) Process implemented by HRSA and then appeal an unfavorable ADR decision to the federal courts. However, participation in the ADR and federal court appeals process would likely require the retention of outside counsel and hundreds of thousands of dollars in legal fees. Desai Declaration at ¶ 18. This entire process would take several months to years from the 340B hospital's submission of the original claim for rebate, and there is nothing in BMS's proposed rebate model or in the ADR process that discourages improper denials by BMS or the third-party contractor.

BMS's announcement of its intention to impose a rebate model follows on the heels of a similar announcement by Johnson & Johnson Health Care System (J&J) in August 2024 regarding

[1] While BMS states that it will initially implement the rebate model exclusively for its drug ELIQUIS, as BMS states in its Complaint, that limitation is just to "start," and Proposed Intervenors fully anticipate that BMS will expand its rebate model to all 340B eligible drugs. Complaint (Dkt No. 1) at ¶ 59.

its intention to impose a rebate model on two of its most expensive 340B drugs. Since J&J's announcement of its proposed rebate model, in addition to BMS, three other drug companies, Sanofi-Aventis U.S. LLC, Novartis Pharmaceuticals Corporation, and Eli Lilly Company, have recently announced their intentions to adopt a rebate program. More pharmaceutical companies are likely to follow, increasing the number of rebate models—and the resulting burdens—with which 340B hospitals would be forced to comply. This type of expansion is exactly what happened four and a half years ago when a single drug company announced it would restrict the number of pharmacies that covered entities could contract with to distribute one of its 340B drugs. While the restriction was initially limited in scope, that company then expanded the limitation to cover all of its drugs, and thirty-eight additional drug companies followed with similar restrictions.[2]

Plaintiff's Complaint seeks judicial approval of a rebate model that would place a significant burden on the Proposed Hospital Intervenors and members of Proposed Intervenor 340B Health and deny those 340B hospitals the substantive benefit of the 340B Program: prompt access to drugs at a discounted price. HRSA has informed BMS that the proposed rebate model is unlawful. Letter from Chantelle V. Britton, Director, Office of Pharmacy Affairs, HRSA to Linda Kamin, Executive Director, Contract Operations and Government Reporting, Bristol Myers Squibb (Nov. 4,2024) (Dkt. No 1-1). 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

[2] 340B Health, *Drugmakers pulling $8 Billion Out of Safety-Net Hospitals*, (July 2023) https://www.340bhealth.org/files/Contract_Pharmacy_Financial_Impact_Report_July_2023.pdf (last accessed Jan. 29, 2025); 340B Health, *UPDATED: Drugmakers Cutting 340B Discounts Reported Record Revenues in 2021*, 340B Health (Jan. 13, 2023) https://340binformed.org/2023/01/updated-drugmakers-cutting-340b-discounts-reported-record-revenues-in-2021/ (last accessed Jan. 29, 2025).

so that they can continue to provide high quality medical care to their underserved patients and communities. Intervention is particularly important here during the change of administration because during such changes, administrative agencies and the Justice Department typically re-evaluate the positions taken administratively or in litigation by the prior administration.[3]

Proposed Intervenors are also in the best position to address why BMS's assertions regarding widespread 340B program abuse and non-compliance are inaccurate, as well as complicated accounting issues that BMS raises in its Complaint, such as the central differences between BMS's rebate program and the inventory replenishment model currently used by many 340B hospitals. Proposed Intervenors have experience and data 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 time and expenses incurred if they are forced to comply with Plaintiff's proposed rebate model, 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 BMS is permitted to implement its proposed rebate model, Proposed Intervenor UMass estimates that to receive 340B rebates it would be forced to divert nearly $400,000 from its annual operating budget just to comply with BMS's rebate model requirements, which would significantly undercut its ability to support crucial community services and drug discounts to eligible patients. Desai Declaration at ¶ ¶ 16, 19.

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

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[3] Proposed Intervenors are not aware that the new Administration is contemplating a change in its ruling on the BMS petition, but they are familiar with numerous policy changes that have been made by new administrations.

BACKGROUND

On October 22, 2024, BMS informed HRSA that it planned to implement a rebate model for its 340B eligible drugs, replacing the upfront discounts that it had provided to 340B hospitals since the beginning of the 340B Program beginning in the spring of 2025. Complaint at ¶ 63. On November 12, 2024, HRSA informed BMS that BMS lacked the authority to adopt a rebate model without HRSA's prior approval. Letter from Chantelle V. Britton, Director, Office of Pharmacy Affairs, HRSA to Linda Kamin, Executive Director, Contract Operations and Government Reporting, Bristol Myers Squibb (Nov. 4,2024) (Dkt. No 1-1). HRSA further informed BMS that because the HHS had not approved BMS's proposed rebate model, implementation of that model would be inconsistent with 340B statutory requirements. *Id.*

BMS's proposed rebate model represents a significant change to the 30-year-old program and was met with understandable alarm from 340B hospitals. A program that requires 340B hospitals to pay the full price for 340B drugs and then wait to possibly be reimbursed for the discounts to which they are entitled will have significant, adverse effects on 340B hospitals. This, in turn, will harm their patients. The adverse impact of the rebate model is enhanced by BMS's failure to specify the criteria that it would use to approve rebate claims. There are no federal regulations governing how manufacturers must operate a rebate program for 340B. That absence of regulation would permit drug manufacturers, such as BMS, to apply criteria based on the manufacturer's, and not HRSA's, interpretations of 340B rules and thereby deny legitimate claims, and BMS has every incentive to find a basis for denying claims in order to increase the revenue it receives for crucial 340B drugs.

The Proposed Hospital Intervenors have reviewed BMS's proposed rebate model (to the extent it is publicly available) and have estimated the impact that rebate model will have on the

communities and patients they serve. For example, Proposed Intervenor UMass currently uses savings from the 340B Program to fund 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 ¶ ¶ 8-12. However, should UMass be forced to comply with BMS's proposed rebate model, its ability to financially support those programs will rapidly deteriorate. *Id.* at ¶ 19.

UMass calculates that it will need to reallocate over $400,000 annually that it currently uses to support these programs in order to comply with BMS's current proposed rebate model. *Id.* at ¶ 16. Those funds will be used to hire and train a new employee who will be tasked solely with collecting the data that BMS's proposed rebate model requires, submitting rebate claims, reconciling payments, disputing denied rebates, and performing monthly financial reporting. *Id.* at ¶ 17. The diverted funds will also be used to cover legal fees incurred for legal compliance consultations and challenging any disputed claims through HHS's 340B ADR Process and the federal courts. *Id.* at ¶ 18. However, UMass may very well spend more than $400,000 if BMS denies legitimate rebate claims, a likely possibility given the lack of transparency regarding the criteria BMS would use to approve or deny claims. UMass estimates that it would need to pay an additional $15,479,733 annually to purchase BMS drugs at full price upfront as opposed to paying

the 340B discount price. *Id.* at ¶ 20. As such, if BMS improperly denies a number of rebate claims, UMass will be significantly financially harmed.

Furthermore, should BMS or one of the other companies trying to implement rebates be permitted to proceed with a proposed rebate model, it is almost certain that the entire 340B Program will shift to a rebate model. If that occurs, UMass predicts that it will have to eliminate several of the community programs it provides; even if all the drug manufacturers provide rebates on all 340B claims (a dubious position at best), the cost of providing the cash upfront would severely impact the programs UMass currently provides to vulnerable patients and underserved communities. *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, including BMS's prescription drugs, 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 ¶¶ 8-11. 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 BMS be permitted to proceed with its proposed rebate model, Genesis predicts that it will have to substantially reduce its 340B Patient Assistance Program, as it applies to BMS's drugs, because it will not be able to guarantee that BMS will actually provide a rebate, resulting in the hospital having paid the full price for the drug instead of receiving the 340B discounted price.

Providing a discount without assurance that Genesis will receive the 340B discounted price creates too large a financial risk to continue operating the 340B Patient Assistance Program at its current level. *Id.* at ¶ 14. Those cuts will have an immediate, significant impact on patients. *Id.* If patients no longer have access to the 340B Patient Assistance Program, they will likely be unable to afford the regular, out-of-pocket costs, and therefore lose access to critical drugs. *Id.* If the entire 340B Program converts to a rebate model, as is likely given that four other pharmaceutical companies already have announced their intention to impose similar rebate models, Genesis estimates that it will be required to spend an additional $5.2 million per month in upfront costs to buy 340B drugs at full price. *Id.* at ¶ 18. Even if all the rebates are issued, Genesis will still be operating at such a negative margin that it will suffer unquantifiable financial harm, leading not only to cuts to its patient assistance and community programs. *Id*.

On November 26, 2024, BMS filed suit in this Court against former Secretary Xavier Becerra, in his official capacity, and former HRSA Administrator, Carole Johnson, in her official capacity (the Government Defendants), claiming that HRSA's refusal to approve BMS's proposed rebate model violates the Administrative Procedure Act and its due process rights. The Complaint seeks a declaration that BMS's proposed rebate model is lawful and an injunction prohibiting the Government Defendants from commencing any enforcement action against BMS relating to or arising from BMS's implementation of its proposed rebate model. Complaint at 28-29.

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)) (internal citations omitted). Federal Rule of Civil Procedure 24(b) provides, "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." *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).

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 733 (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. United States Dep't of the Interior*, No. CV 19-2377 (RC), 2020 WL 5545496, at *3 (D.D.C. Sept. 16, 2020) (internal quotations omitted) (collecting cases); *see e.g., Crossroads Grassroots Pol'y Strategies v. Fed. Election Comm'n*, 788 F.3d 312, 317 (D.C. Cir. 2015) (The D.C. Circuit has "generally found a sufficient injury in fact where a party benefits from agency action, the action is then challenged in court, and an unfavorable decision would remove the party's benefit.").

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 ¶¶ 3-4. 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; 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. *American Hosp. Ass'n v. HHS,* No. 4-20-cv-08806; Testoni Declaration at ¶ 4.[4]

340B Health has standing as an association representing over 1,600 340B hospitals, all of which purchase 340B drugs and will therefore be impacted by BMS's proposed rebate model. "[A]n 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. CV 21-2317 (RC), 2021 WL 5865386, at *2 (D.D.C. Dec. 11, 2021) (alteration in the original) (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 process by which 340B hospitals access drugs at a discounted price—is plainly relevant to 340B Health's goal of supporting 340B hospitals.

[4] 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 ¶ 4. 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.* at ¶ 5. To date, 340B Health has joined twenty-four *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 current change in administration causes uncertainty regarding the legal positions that the Government Defendants may take as the litigation proceeds.

The hospital members of 340B Health, including Proposed Hospital Intervenors UMass and Genesis, also clearly have standing to sue. Should this Court set aside HRSA's denial of BMS's proposed rebate model, allowing BMS to implement its plan, these hospitals will be forced to incur significant expenses. Even assuming BMS complies with its obligations under its proposed rebate model, UMass predicts that it will need to spend over $400,000 per year to simply comply with BMS's proposed rebate model's requirements. Desai Declaration at ¶ 16. Genesis predicts that it will need to spend over $200,000 per year just to comply, in addition to legal fees. Carr Declaration at ¶ 17. Both hospitals will need to hire at least one new fulltime employee to collect the newly required data, submit rebate claims, and track and validate receipt of rebates. Desai Declaration at ¶ 17; Carr Declaration at ¶ 17. Those administrative costs alone will force UMass and Genesis to reconsider their ability to fund the critical services they currently operate, harming not only vulnerable individual patients, but also their local, underserved communities. Additionally, both expect to incur significant legal costs should they need to challenge an improper claim denial through HRSA's ADR process. Desai Declaration at ¶ 18; Carr Declaration at ¶ 17.

Those costs assume that BMS complies with its obligations under the rebate model. However, both UMass and Genesis are extremely concerned that BMS will improperly deny rebates. Desai Declaration at ¶ 20; Carr Declaration at ¶ 13. If BMS's rebate model is approved, in addition to the administrative costs, UMass will need to spend nearly $1.3 million more per month to purchase BMS's drugs at full price, Desai Declaration at ¶ 20, and Genesis will need to spend an additional $396,440 per month to purchase those drugs with no assurance that the additional amounts will be reimbursed through rebates. Carr Declaration at ¶ 13.

Those costs would be directly traceable to whether this Court permits BMS to go forward with its rebate model. Without a favorable decision by this Court, under HRSA's current policy,

BMS will not be permitted to impose its rebate model on 340B hospitals, and 340B hospitals will be able to continue their participation in the 340B program without incurring the additional time, expense, and uncertainty as to when or whether they will be reimbursed. Importantly, if BMS is permitted to implement its rebate model, the additional time and cost associated with its program will undeniably multiply because other drug manufacturers will be emboldened to adopt their own rebate models. In fact, four other drug manufacturers have already announced their intention to impose a similar rebate model. Just as one drug company's contract pharmacy restrictions expanded to all of that company's drugs and led thirty-eight other drug companies to impose similar restrictions four and a half years ago, BMS's proposed rebate model is likely to expand across the 340B program should this Court allow it to proceed. *See supra* n. 1.

Should the entire 340B Program begin to function as a rebate model, the costs to 340B hospitals would be massive. UMass 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 ¶ 21. Under those conditions, Genesis estimates that it will need to spend an additional $5.2 million per month to purchase 340B drugs at their full price upfront. Carr Declaration at ¶ 18. That additional cost, even if it is eventually reimbursed through a rebate, 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 ¶¶ 18-19.

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.* Courts often find that "intervention would not unduly disrupt" litigation when a motion to intervene is filed before a court issues any merits decisions. *Farmer v. United States Env't Prot. Agency*, No. 24-CV-1654 (DLF), 2024 WL 5118193, at *4 (D.D.C. Dec. 16, 2024) (granting motion to intervene filed nearly three months after the action was initiated and after motion to dismiss briefing began).

BMS filed its complaint on November 26, 2024. The Court recently issued an order granting the parties' proposed summary judgment briefing schedule and vacating the answer deadline.[5] *See* Dkt. No. 8. The Government Defendants' cross-motion for summary judgment is

[5] As the Court has vacated the deadline to answer the Complaint, Proposed Intervenors have not attached a proposed answer to this motion, which is usually required under Federal Rule of Civil Procedure 24(c). "However, 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 (quoting

due March 3, 2025, which is when Proposed Intervenors' response to Plaintiff's motion for summary judgment would be due if the Court grants intervention. As such, Proposed Intervenors have promptly moved to intervene well before any defense is required to be presented in the case and are fully prepared to comply with the current scheduling order.[6] Neither plaintiffs nor defendants will be prejudiced by intervention.

Furthermore, given that the implementation of BMS's proposed rebate model would fundamentally alter the method by which Proposed Hospital Intervenors purchase 340B eligible drugs, Proposed Intervenors' interest in the litigation is significant, and intervention is necessary to preserve their ability to challenge BMS's proposed rebate model. That significant interest would override any allegation that this Motion is delayed (though it is not). Because the Proposed 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*, 788 F.3d at 320 (quoting *Fund For Animals,*

E.E.O.C., 146 F.3d at 1045-46); *see also Washington All. of Tech. Workers v. U.S. Dep't of Homeland Sec.*, 395 F. Supp. 3d 1, 21 (D.D.C. 2019). Because the Court has excused the Government Defendants from filing an answer, Proposed Intervenors should also be excused from filing an answer as well. However, should the Court direct the Proposed Intervenors to file an answer, Proposed Intervenors are prepared to comply promptly.

[6] Should the Court prefer the Proposed Intervenors to file their motion for summary judgment and response to Plaintiff's motion for summary judgment after the Government Defendants file their motion in order to avoid duplicate arguments, the Proposed Intervenors will comply with whatever schedule the Court sets.

Inc., 322 F.3d at 735 (holding that the standards for constitutional standing and the second factor of the test for intervention as of right are the same)); *e.g.*, *Farmer,* 2024 WL 5118193, at *4. As previously described, *see* Sec. I.A., the imposition of a rebate model would fundamentally impact the method by which 340B hospitals purchase 340B eligible drugs and impose significant financial injury on 340B hospitals. The Proposed Intervenors clearly have an interest in the rebate model 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, even when the possibility of a future challenge to the regulation remains available. *Fund For Animals, Inc.*, 322 F.3d at 735; *Farmer*, 2024 WL 5118193, at *4. "[D]isposing of [an] action may as a practical matter impair or impede a proposed intervenor's interests when the disposition of the action would result in a substantial change in the status quo with respect to those interests." *Farmer*, 2024 WL 5118193, at *4 (quoting *District of Columbia v. Potomac Elec. Power Co.*, 826 F. Supp. 2d 227, 234 (D.D.C. 2011)) (alterations in the original).

The disposition of the present suit in Plaintiff's favor would immediately adversely affect the Proposed Intervenors. As previously described, *see* Sec. I.A., such a substantial change to the status quo would force Proposed Hospital Intervenors to invest significant time and incur substantial costs to comply with BMS's proposed rebate model, 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 should the proposed rebate model be imposed, courts in this circuit have 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. CV 20-3654 (RC), 2021 WL 12269155, at *2 (D.D.C. July 28, 2021) (collecting cases) (alteration in the original); *see e.g.*, *Waterkeeper All., Inc. v. Wheeler*, 330 F.R.D. 1, 7 (D.D.C. 2018) (collecting cases). HRSA's denial of BMS's proposed rebate model was favorable to the Proposed Intervenors, as 340B hospitals would be severely harmed if BMS were allowed to implement its proposed rebate model. *See* Sec. I.A. Plaintiff's Complaint directly attacks HRSA's denial and expressly asks this Court for a declaration that HRSA's "position regarding the 340B rebate model is unlawful." Complaint at 28. Therefore, Proposed Intervenors' interests will be impaired should this Court grant judgment in BMS's favor.

E. Inadequate Representation

The Government Defendants in this lawsuit will not adequately represent Proposed Intervenors' interests. In the D.C. Circuit, the 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 *Farmer*, No. 24-CV-1654 (DLF), 2024 WL 5118193, at *4 (D.D.C. Dec. 16, 2024) (collecting cases). 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 looks "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

(alterations 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 736). 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. HRSA denied BMS's request to implement a rebate model at the end of the Biden administration. BMS filed its Complaint just weeks after Donald Trump was elected. President Trump has repeatedly made clear that his administration will take different legal positions than the Biden administration on a variety of matters, and, while there has been no suggestion yet that the new 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 BMS's proposed rebate model violates the 340B statute.

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 a strong position to describe both that interest and the interests of their patients to the Court. *See* Sec. I.A.

And while the Proposed Intervenors fully support HRSA's decision that BMS may not proceed with its proposed rebate plan, Proposed Intervenors and HRSA apparently have a different

view of HRSA's legal authority. HRSA apparently believes that it has authority to approve a rebate model in some circumstances (which it has never defined); Proposed Intervenors intend to present the alternative argument that BMS's proposed rebate model is unlawful *per se*, and that HRSA would have no authority to approve any rebate model. *See* Letter from Intervenor 340B's Counsel to Carole Johnson, Administrator, HRSA (Aug. 22, 2024). Even though the Proposed Intervenors and the Government Defendants currently all believe BMS's proposed rebate model is unlawful, as the D.C. Circuit has repeatedly acknowledged, even "'a shared general agreement ... does not necessarily ensure agreement in all particular respects.'" *Fund for Animals*, 322 F.3d at 737 (quoting *Nat. Res. Def. Council v. Costle,* 561 F.2d 904, 912 (D.C. Cir. 1977) (alteration in the original). The Government Defendants therefore cannot adequately represent the Proposed Intervenors.

Finally, Proposed Intervenors are the only entities that can adequately describe the impact that BMS's proposed rebate model will have on 340B hospitals and the patients they serve. It is clear from the face of BMS's complaint that BMS does not understand the breadth of the benefits provided by the 340B Program, which was enacted to support 340B hospitals, which are safety nets for low income and uninsured patients, and 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 BMS's assertions regarding widespread 340B Program abuse and non-compliance are inaccurate and explain in detail how the replenishment model currently used by 340B hospitals works and why it is vastly different from BMS's proposed rebate model. 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 BMS's proposed rebate model be approved.

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*, 2022 WL 136763, at *6. 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 BMS's proposed rebate model fulfills its obligations under 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: February 5, 2025

Respectfully submitted,

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