

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

THE AMERICAN HOSPITAL ASSOCIATION,  
THE MAINE HOSPITAL ASSOCIATION, ST.  
MARY'S REGIONAL MEDICAL CENTER,  
NATHAN LITTAUER HOSPITAL & NURSING  
HOME, UNITY MEDICAL CENTER, and  
DALLAS COUNTY MEDICAL CENTER,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR. Secretary of the U.S.  
Department of Health and Human Services,  
THOMAS J. ENGELS, Administrator, Health  
Resources and Services Administration, THE  
HEALTH RESOURCES AND SERVICES  
ADMINISTRATION, THE UNITED STATES  
DEPARTMENT OF HEALTH AND HUMAN  
SERVICES, and THE UNITED STATES OF  
AMERICA,

Defendants.

Case No. 2:25-cv-00600-JAW

**BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.'S AND  
NOVO NORDISK INC.'S MOTION TO INTERVENE WITH  
INCORPORATED MEMORANDUM OF LAW**

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Boehringer Ingelheim Pharmaceuticals, Inc. and Novo Nordisk Inc. hereby move for leave to intervene in this action pursuant to Federal Rules of Civil Procedure 24(a) and 24(b).

### INTRODUCTION

Boehringer Ingelheim Pharmaceuticals, Inc. (“Boehringer”) and Novo Nordisk Inc. (“Novo Nordisk”) (collectively, “the Manufacturers”) move to intervene in this action to represent their distinct interests as manufacturers participating in the 340B Rebate Model Pilot Program (“pilot program”). The Manufacturers satisfy the requirements for intervention as of right pursuant to Federal Rule of Civil Procedure 24(a)(2). This motion is timely—filed only nine days after Plaintiffs filed their Complaint—and the Manufacturers will abide by any case deadlines, including the briefing schedule on Plaintiffs’ motion for immediate relief.<sup>1</sup> The Manufacturers have a clear and substantial interest in the lawfulness of the pilot program that would be impaired if Plaintiffs succeed in delaying or halting the pilot program’s implementation. The pilot program is necessary to ensure—consistent with federal statutory mandates—that manufacturers are not forced to provide steep and functionally unrecoverable duplicate discounts on their prescription drugs. Indeed, upending the pilot program at this late date will throw manufacturers’ plans for deduplication, which are overseen by two federal agencies, into disarray—and effectively require the Manufacturers to pay duplicate discounts contrary to federal law. The federal Defendants cannot adequately represent the Manufacturers’ commercial interests in ensuring that the pilot program begins as scheduled on January 1, 2026. In the alternative, the Manufacturers meet the standard for permissive intervention under Rule 24(b).<sup>2</sup>

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<sup>1</sup> The Manufacturers are also prepared to coordinate with any other Intervenor-Defendants to avoid duplicative briefing to the extent possible.

<sup>2</sup> The Manufacturers have sought the parties’ position on this motion. At the time of filing, Defendants have not yet responded. Plaintiffs stated they will oppose the motion. The Manufacturers respectfully request that any opposition to this motion be due by December 15, 2025, in line with the Court’s December 8, 2025, Minute Order.

## BACKGROUND

A pharmaceutical manufacturer participating in the 340B program must offer its products at a discount rate to statutorily defined “covered entities.” The 340B statute expressly directs that this discount rate—known as the “ceiling price”—may be effectuated by either a front-end “discount” or back-end “rebate.” 42 U.S.C. § 256b(a)(1). But the statute contains no requirement that covered entities pass through the discount to patients. 61 Fed. Reg. 43,549, 43,551 (Aug. 23, 1996) (“Section 340B does not limit the pricing behavior of covered entities.”).

Both Boehringer and Novo Nordisk manufacture innovative pharmaceutical products that are covered by the 340B program. *See* Boehringer Ingelheim, Comment Letter on 340B Rebate Model Pilot Program Notice at 1 (Sept. 8, 2025) (Ex. A); Novo Nordisk, Comment Letter on 340B Rebate Model Pilot Program Notice at 2 (Sept. 8, 2025) (Ex. B). Beginning on January 1, 2026, several of these drug products will also be subject to a new requirement in the Inflation Reduction Act (“IRA”) that directs manufacturers to provide Medicare beneficiaries access to the product at a discounted “maximum fair price” (“MFP”), as prescribed by the Centers for Medicare & Medicaid Services (“CMS”). *See* Ex. A at 1; Ex. B at 2; 42 U.S.C. § 1320f-2(a).

The separate discounts mandated by the IRA and 340B programs will often overlap—for example, when a Medicare patient receives treatment from a hospital that is a covered entity under the 340B program. The IRA addresses these scenarios by (1) directing manufacturers to offer only the *lower* of the MFP *or* the 340B ceiling price on a prescription, and (2) mandating that manufacturers “shall not be required to provide” both the MFP and 340B discounts. *See* 42 U.S.C. § 1320f-2(d). Manufacturers are further required to provide the MFP discount in the form of

reimbursement after the manufacturer receives notice that a patient is eligible.<sup>3</sup> Thus, if a covered entity purchases a product at the 340B price, and the product is later dispensed to an IRA-eligible patient, a duplicate discount may occur. A rebate model solves that problem by equipping manufacturers with a mechanism to prevent duplicate discounts, in accordance with the IRA, when the IRA's discount requirement takes effect in January 2026. *See* Ex. A at 1; Ex. B at 1.

On August 1, 2025, the Health Resources and Services Administration (“HRSA”) announced the 340B Rebate Model Pilot Program “primarily to address” manufacturers’ need to “de-duplicate” 340B and IRA discounts. 90 Fed. Reg. 38,165, 36,163 (Aug. 7, 2025). Accordingly, as initially created, the pilot program applies narrowly to a small group of drugs: those subject to IRA discounts beginning on January 1, 2026. *See id.* One of Boehringer’s drugs (Jardiance<sup>®</sup>) and six of Novo Nordisk’s drugs (Fiasp<sup>®</sup>; Fiasp FlexTouch<sup>®</sup>; Fiasp PenFill<sup>®</sup>; NovoLog<sup>®</sup>; NovoLog FlexPen<sup>®</sup>; and NovoLog PenFill<sup>®</sup>) fall within that category.<sup>4</sup> Under the pilot program, manufacturers will provide 340B discounts through a rebate after an initial purchase at market price, rather than through a discount at the time of purchase. *See* 90 Fed. Reg. at 36,163.

Boehringer and Novo Nordisk each applied to HRSA for authorization to operate a rebate model under the program. On October 30, 2025, HRSA approved the applications and authorized the Manufacturers to begin implementing their models on January 1, 2026. *See* Decl. of Christine Marsh, ¶¶ 33-34 (“Marsh Decl.”); Decl. of Farruq Jafery, ¶ 24 (“Jafery Decl.”). The Manufacturers also submitted an MFP effectuation plan to CMS, explaining that they would rely on the pilot to prevent duplication of IRA and 340B discounts. *See* Marsh Decl. ¶ 36; Jafery Decl. ¶ 25.

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<sup>3</sup> *See* Memorandum from CMS Deputy Admin. & Director of the Center for Medicare, *Medicare Drug Price Negotiation Program* at 127, Centers for Medicare & Medicaid Services (June 30, 2023), <https://www.cms.gov/files/document/revise-medicare-drug-price-negotiation-program-guidance-june-2023.pdf>.

<sup>4</sup> *See* CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026* (Aug. 2023), <https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf>.

On December 1, 2025, more than a month after HRSA’s approval orders, the Plaintiffs filed this action, contending that HRSA’s pilot program violates the Administrative Procedure Act (“APA”). That same day, Plaintiffs moved for a temporary restraining order (“TRO”), seeking to enjoin the pilot program before it begins. To protect their substantial interests as participants in their rebate models, the Manufacturers now move to intervene.

## ARGUMENT

### I. The Manufacturers Are Entitled to Intervene as of Right Under Rule 24(a).

The Manufacturers may intervene as of right because: (1) the motion is timely; (2) the Manufacturers have a “concrete interest” in defending the lawfulness of the pilot program; (3) there is “a realistic threat that resolution of the pending action will hinder” the Manufacturers’ ability to effectuate that interest; and (4) the federal Defendants do not adequately represent the Manufacturers’ interests. *T-Mobile Ne. LLC v. Town of Barnstable*, 969 F.3d 33, 39 (1st Cir. 2020) (citing Fed. R. Civ. P. 24(a)).

**Timeliness.** The Manufacturers’ motion to intervene—filed just nine days after Plaintiffs filed their Complaint—is timely. This case is still in “the initial stages.” *Geiger v. Foley Hoag LLP Retirement Plan*, 521 F.3d 60, 64 (1st Cir. 2008). The federal Defendants have not filed their opposition to Plaintiffs’ motion or any responsive pleading, and this Court has not ruled on any substantive motions. Courts regularly find motions to intervene timely in similar circumstances. *See, e.g., Orkin v. Albert*, 557 F. Supp. 3d 252, 260 (D. Mass. 2021); *Ne. Patients Grp. v. Maine Dep’t of Admin. & Fin. Servs.*, 2021 WL 1135019, at \*3 (D. Me. Mar. 23, 2021).

Further, no party will be prejudiced if the Court allows the Manufacturers to intervene. The Manufacturers will observe all case deadlines, including the briefing schedule on Plaintiffs’ motion for a TRO. *See, e.g., S.R.C. by Cobbett-Walden v. Miller*, 2025 WL 3267608, at \*2 (D. Mass. Nov. 24, 2025) (Plaintiffs not prejudiced “because this case is only at its initial stage” where

TRO briefed). Any urgency in this case is due to Plaintiffs' delay: Plaintiffs filed their complaint four months after HRSA announced the pilot program and more than one month after HRSA approved the Manufacturers' rebate models. In contrast, as discussed below, the Manufacturers would face significant prejudice if denied the opportunity to intervene. *See, e.g., Littlefield v. U.S. Dep't of the Interior*, 318 F.R.D. 558, 560 (D. Mass. 2016) (“[G]iven the [intervenor’s] undeniable and compelling interest in the outcome of th[e] litigation, their risk of prejudice is substantial.”).

***Significantly Protectable Interest.*** The Manufacturers have a “significantly protectable interest” at stake in this litigation that is “direct, not contingent,” *Pub. Serv. Co. of N.H. v. Patch*, 136 F.3d 197, 205 (1st Cir. 1998) (quotations omitted), and “bear[s] a sufficiently close relationship to the dispute between the original litigants” over the legality of HRSA’s pilot program, *Travelers Indem. Co. v. Dingwell*, 884 F.2d 629, 638 (1st Cir. 1989) (quotations omitted). The pilot program provides a mechanism that enables the Manufacturers to apply the correct discount under *either* the 340B program *or* the IRA program, as required by statute. Without the rebate model, the Manufacturers will face either substantial economic losses due to duplicate discounts, or potential penalties due to a failure to comply with the statutes’ requirements. *See, e.g., Conservation Law Foundation v. Mosbacher*, 966 F.2d 39, 42–43 (1st Cir. 1992) (sufficient interest to support intervention where movant is “the subject[] of the regulatory plan” and will face effects to “business, both immediately and in the future”); *Pub. Serv. Co. of N.H. v. Patch*, 173 F.R.D. 17, 27 (D.N.H. 1997), *aff’d*, 136 F.3d 197 (1st Cir. 1998) (intervenors had “sufficiently close relationship” because they had “a direct interest in the substance of the” regulatory action).

***Impairment of Interest.*** Because the HRSA action challenged by Plaintiffs advances the Manufacturers’ significantly protectable interests, those interests would be impaired if Plaintiffs’ claims succeed. *See Daggett v. Comm’n on Governmental Ethics & Election Practices*, 172 F.3d

104, 110–11 (1st Cir. 1999) (requirement satisfied where disposition of the case could adversely affect the would-be intervenor’s significantly protectable interest); *see also Portland Cellular P’ship v. Inhabitants of the Town of Cape Elizabeth*, 2015 WL 12990147, at \*2 (D. Me. Feb. 3, 2015) (when intervenor’s interests are related to the dispute, “[t]he third Rule 24(a)(2) factor requires little discussion”). A ruling in Plaintiffs’ favor would invalidate or delay the pilot program, leaving the Manufacturers without a mechanism to prevent duplicate discounts—and causing Manufacturers substantial and unrecoverable economic losses.

***Inadequate Representation.*** The Manufacturers satisfy the “minimal” requirement that the representation afforded by the existing parties “may be” inadequate. *Students for Fair Admissions, Inc. v. President & Fellows of Harvard Coll.*, 807 F.3d 472, 475 (1st Cir. 2015) (quoting *Trbovich v. United Mine Workers of Am.*, 404 U.S. 528, 538 n.10 (1972)). “The essential question,” this Court has explained, “is whether the goals” of the existing governmental party “may” “differ from the goals of the Intervenors.” *Animal Protection Inst. v. Martin*, 241 F.R.D. 66, 68 (D. Me. 2007) (Woodcock, J.); *see also Mosbacher*, 966 F.2d at 44 (“[a]n intervenor need only show that representation may be inadequate, not that it is inadequate”).

The First Circuit historically has recognized a rebuttable presumption of adequate representation when a potential intervenor shares an ultimate goal with an existing party or when it “seeks to appear alongside a governmental body in defense of the validity of some official action.” *T-Mobile*, 969 F.3d at 39. More recently, however, the Supreme Court has cast doubt on this presumption. *See Berger v. N.C. State Conf. of the NAACP*, 597 U.S. 179, 196–98 (2022); *see also Bost v. Ill. Bd. of Elections*, 75 F.4th 682, 688 n.3 (7th Cir. 2023) (*Berger* “called into question whether any presumption of adequate representation is appropriate”). Even if the presumption remains good law, it generally does not apply “[w]here the absentee’s interest is similar to, but not

identical with, that of one of the parties.” *Berger*, 597 U.S. at 197 (quotations omitted). Here, the federal Defendants’ interests are far from “identical” to Manufacturers’. Rather, the interests of the two groups are distinct, in at least two critical ways.

*First*, the Manufacturers have substantial commercial interests in the pilot program that the federal Defendants do not. Unlike the government, the Manufacturers would face significant economic losses from duplicate discounts or risk civil penalties for failure to provide the correct discount if they are required to provide up-front 340B discounts after the IRA’s requirements go into effect. *See* 42 U.S.C. § 1320f-2(d); *id.* § 256b(d)(1)(B)(vi). The Manufacturers thus have a particular financial interest in ensuring that their rebate models can operate on January 1, 2026. *See Animal Protection*, 241 F.R.D. at 70 (“there are private interests at stake, which the Intervenors stand to lose if [plaintiff] prevails in its action”). The Manufacturers also have expended substantial resources in modifying their 340B procedures to prepare for the program. Marsh Decl. ¶ 34; Jafery Decl. ¶ 26. Those procedures would be upended if the pilot program is enjoined.

*Second*, the federal Defendants must “bear in mind broader public-policy implications” and general concerns about the government’s regulatory authority that the Manufacturers do not. *Berger*, 597 U.S. at 196; *see Animal Protection*, 241 F.R.D. at 70 (“While the [governmental party] may take into account the Intervenors’ economic ... interests, it must also weigh countervailing factors, such as the more broadly viewed public interest”). Instead, the Manufacturers “will focus on defending [this action] vigorously on the merits without an eye to crosscutting administrative concerns.” *Berger*, 597 U.S. at 198. The Manufacturers also have a broader interest in defending their rebate models separate from the process HRSA employed in this action. Notably, Plaintiffs themselves rely on prior HRSA statements *rejecting* manufacturers’ proposals for rebate models.

*See, e.g.*, Mot. for TRO at 10; Complaint at 52. Particularly in light of HRSA’s prior statements, manufacturers have a clear interest in presenting a vigorous defense of their rebate models.

Accordingly, courts have “often concluded that governmental entities do not adequately represent the interests of aspiring intervenors” where the government must represent the public interest, not the intervenor’s unique private-sector interests. *Crossroads Grassroots Pol’y Strategies v. FEC*, 788 F.3d 312, 321 (D.C. Cir. 2015) (quoting *Fund For Animals, Inc. v. Norton*, 322 F.3d 728, 736 (D.C. Cir. 2003)); *see, e.g., Mosbacher*, 966 F.2d at 44 (government’s “judgments are necessarily constrained by [its] view of the public welfare,” while regulated parties “may see their own interest in a different . . . light”); *NYNEX Corp. v. FCC*, 153 F.R.D. 1, 3 (D. Me. 1994) (interests not adequately represented where agency “defend[s] this case from the perspective of the overall national public welfare” and favorable ruling “may” result in “new regulations” detrimental to movant’s interests).

To the extent any presumption of adequate representation applies, “the intervenor need only offer an adequate explanation as to why it is not sufficiently represented by the named party”—for example, by demonstrating “that its interests are sufficiently different in kind or degree from those of the named party.” *B. Fernandez & Hnos., Inc. v. Kellogg USA, Inc.*, 440 F.3d 541, 546 (1st Cir. 2006) (quotations omitted). The Manufacturers’ distinct financial interests described above are sufficient to overcome this presumption. *See, e.g., McDonough v. City of Portland*, 2015 WL 3755289, at \*4 (D. Me. June 16, 2015) (presumption overcome where government “must account for a spectrum of governmental interests far broader than the discrete commercial interests [a putative intervenor] seeks to protect”).

Plaintiffs’ TRO motion underscores the need for intervention. The Manufacturers have a financial interest in the uninterrupted implementation of their rebate models that Plaintiffs seek to

enjoin, and would be significantly and immediately harmed if they were precluded from using this mechanism to adjudicate 340B claims. Conversely, the federal Defendants do not suffer a similar harm if an injunction issues, since it is the Manufacturers (not the government) that are charged with implementing a mechanism that complies with the law as of January 1, 2026. Furthermore, the federal Defendants cannot provide information regarding the severe harm that would befall the Manufacturers if the program were enjoined, or the efforts the Manufacturers have undertaken prepare for the program's implementation date. Simply put, the Manufacturers, not HRSA, will suffer significant and immediate harm if the program is enjoined. And the federal Defendants' interests could deviate from those of the Manufacturers. As another court recognized, "[o]f course HRSA might treat" covered entities and manufacturers "differently," since "covered entities are the beneficiaries of the lower prices guaranteed by the 340B Program." *Johnson & Johnson Health Care Sys., Inc. v. Kennedy*, 2025 WL 1783901, at \*13 (D.D.C. June 27, 2025). The Manufacturers thus must intervene to present critical information that the federal Defendants cannot.

Notably, a group of hospitals and hospital associations moved to intervene in related litigation in which drug manufacturers challenged HRSA's denial of earlier proposals for 340B rebate models, and those motions to intervene were granted. *See, e.g.,* Order, *Johnson & Johnson v. HHS*, No. 1:24-cv-3188, ECF 50 (D.D.C. May 15, 2025) (granting intervention under Rule 24(a)); Order, *Sanofi-Aventis U.S. LLC v. HHS*, No. 1:24-cv-3496, ECF 32 (D.D.C. Mar. 4, 2025) (same). In support of these motions, the would-be intervenors argued that HRSA could not adequately represent their "financial interests," nor could HRSA "adequately describe the impact that [the] proposed rebate model w[ould] have" on their businesses. Mot. to Intervene, No. 1:24-cv-3188, ECF 14-1 at 22-23 (D.D.C. Jan. 30, 2025); *see also* Mot. to Intervene, No. 1:24-cv-3496, ECF 23-1 at 17-19 (D.D.C. Feb. 5, 2025) (similar). The same is true here.

**II. Alternatively, the Manufacturers Should Be Allowed to Intervene Under Rule 24(b).**

Federal Rule of Civil Procedure 24(b) allows a court to permit intervention where the motion is timely, the movant has a claim or defense that shares with the main action a common question of law or fact, and intervention will not unduly delay or prejudice the adjudication of the original parties' rights. These requirements are "construed liberally." *Animal Protection*, 241 F.R.D. at 68. "The fact that the applicants may be helpful in fully developing the case is a reasonable consideration in deciding on permissive intervention." *Daggett*, 172 F.3d at 113.

The Manufacturers meet these requirements. They have timely moved for leave to intervene, such that granting this motion would not prejudice the original parties or delay this case. In addition, the defenses that the Manufacturers intend to raise will involve common questions of law or fact. For example, the Manufacturers' opposition will address the standards imposed by the APA, as well as the factual record that informed HRSA's decision to implement the pilot program and approve the Manufacturers' rebate model applications. Finally, as shown above, the Manufacturers have a substantial interest in the outcome of this litigation that cannot be adequately represented by the federal Defendants, and their intervention would be helpful in fully developing the case by adding a key perspective as entities subject to the 340B rebate model pilot program.<sup>5</sup>

**CONCLUSION**

The Manufacturers have a substantial and distinct interest in the outcome of this action and have timely moved for leave to intervene. This Court should grant the motion for intervention.

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<sup>5</sup> Federal Rule of Civil Procedure 24(c) requires that a motion to intervene be accompanied by a responsive pleading. The Manufacturers request that this requirement be waived because the APA claims in this action likely will be resolved without the filing of an answer, and no party will suffer prejudice in the absence of a responsive pleading. *See Peaje Invs. LLC v. García-Padilla*, 845 F.3d 505, 515 (1st Cir. 2017) (recognizing flexibility in Rule 24(c)'s requirements, absent prejudice to any party).

Respectfully submitted,

*/s/ Alfred C. Frawley IV*

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December 10, 2025

**CERTIFICATE OF SERVICE**

I hereby certify that, on December 10, 2025, I caused the foregoing document to be filed with the Clerk of the Court of the United States District Court for the District of Maine using the Court's CM/ECF system.

*/s/ Alfred C. Frawley IV*  
Alfred C. Frawley IV

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