

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

THE AMERICAN HOSPITAL
ASSOCIATION, THE MAINE HOSPITAL
ASSOCIATION, EASTERN MAINE
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. 1:26-cv-00515-LEW

**ABBVIE INC.'S, PHARMACYCLICS LLC'S, BRISTOL-MYERS SQUIBB
COMPANY'S, AND BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.'S
MOTION TO INTERVENE WITH INCORPORATED MEMORANDUM OF LAW**

TABLE OF CONTENTS

TABLE OF AUTHORITIES	ii
INTRODUCTION	1
BACKGROUND	1
ARGUMENT.....	5
I. Movants Are Entitled To Intervene Under Rule 24(a).	5
II. Alternatively, Intervention Is Warranted Under Rule 24(b).	10
CONCLUSION.....	10

TABLE OF AUTHORITIES

Cases

<i>Am. Hosp. Ass’n, et al. v. Kennedy, et al.</i> , 2026 WL 2913956 (1st Cir. Sept. 25, 2026).....	6, 8
<i>Am. Hosp. Ass’n v. Kennedy</i> , 164 F.4th 28 (1st Cir. 2026).....	7, 8
<i>Am. Hosp. Ass’n v. Kennedy</i> , 2025 WL 3677386 (D. Me. Dec. 18, 2025).....	8
<i>Am. Hosp. Ass’n v. Kennedy</i> , 820 F. Supp. 3d 30 (D. Me. 2025)	4, 8
<i>Am. Hosp. Ass’n v. Kennedy</i> , No. 2:25-cv-00600 (D. Me. Feb. 10, 2026)	4
<i>Animal Prot. Inst. v. Martin</i> , 241 F.R.D. 66 (D. Me. 2007).....	8
<i>Ass’n of Conn. Lobbyists LLC v. Garfield</i> , 241 F.R.D. 100 (D. Conn. 2007).....	10
<i>B. Fernández & Hnos., Inc. v. Kellogg USA, Inc.</i> , 440 F.3d 541 (1st Cir. 2006).....	5, 6, 9
<i>Brennan v. N.Y.C. Bd. of Educ.</i> , 260 F.3d 123 (2d Cir. 2001).....	9
<i>Canadian Nat. Ry Co. v. Montreal, Me. & Atl. Ry., Inc.</i> , 2010 WL 5168003 (D. Me. Dec. 14, 2010).....	5
<i>Conservation L. Found. of New England, Inc. v. Mosbacher</i> , 966 F.2d 39 (1st Cir. 1992).....	5, 6, 8, 9
<i>Cotter v. Mass. Ass’n of Minority L. Enf’t Officers</i> , 219 F.3d 31 (1st Cir. 2000).....	6, 9
<i>Daggett v. Comm’n on Governmental Ethics & Election Pracs.</i> , 172 F.3d 104 (1st Cir. 1999).....	7, 10
<i>Geiger v. Foley Hoag LLP Ret. Plan</i> , 521 F.3d 60 (1st Cir. 2008).....	9
<i>Mass. Food Ass’n v. Mass. Alcoholic Beverages Control Comm’n</i> , 197 F.3d 560 (1st Cir. 1999).....	8
<i>Melone v. Coit</i> , 100 F.4th 21 (1st Cir. 2024).....	10

<i>NERO Int’l Holding Co. v. NEROTix Unlimited Inc.</i> , 585 F. Supp. 3d 152 (D. Mass. 2022)	5
<i>Nextel Commc’ns of Mid-Atl., Inc. v. Town of Hanson</i> , 311 F. Supp. 2d 142 (D. Mass. 2004)	9
<i>Novartis Pharms. Corp. v. Kennedy</i> , 182 F.4th 1027 (D.C. Cir. 2026)	2, 8
<i>Peaje Invs. LLC v. García-Padilla</i> , 845 F.3d 505 (1st Cir. 2017)	1
<i>Pub. Serv. Co. of N.H. v. Patch</i> , 136 F.3d 197 (1st Cir. 1998)	6
<i>T-Mobile Northeast LLC v. Town of Barnstable</i> , 969 F.3d 33 (1st Cir. 2020)	7
<i>Tirrell v. Edelblut</i> , 2025 WL 1939965 (D.N.H. July 15, 2025)	10
<i>Victim Rights Law Center v. Rosenfelt</i> , 988 F.3d 556 (1st Cir. 2021)	7

Statutes

42 U.S.C. § 256b	1, 2
42 U.S.C. § 1320f-2(a)(1)	2
42 U.S.C. § 1320f-2(a)(3)	2
42 U.S.C. § 1320f-2(a)(5)	2
42 U.S.C. § 1320f-2(d)	3
42 U.S.C. § 1320f-6(a)	2, 3
42 U.S.C. § 1320f-6(c)	2

Other Authorities

CMS, <i>CMS Announces Manufacturer Participation in Third Cycle of Medicare Drug Price Negotiation</i> (Mar. 13, 2026), https://tinyurl.com/46c52rev	4
CMS, <i>Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028</i> (Sept. 30, 2025), https://tinyurl.com/uf86dc2f	2
HRSA, 340B Rebate Model Pilot Program, https://tinyurl.com/bdhpur9n	4

Rules

Fed. R. Civ. P. 24(a)(2).....	6
Fed. R. Civ. P. 24(b)(1)(B)	10
Fed. R. Civ. P. 24(b)(3).....	10

Regulations

90 Fed. Reg. 36,163 (Aug. 1, 2025).....	3
91 Fed. Reg. 48,883 (Aug. 3, 2026).....	4, 7

INTRODUCTION

AbbVie Inc. and Pharmacyclics LLC (together, “AbbVie”), Bristol-Myers Squibb Company (“BMS”), and Boehringer Ingelheim Pharmaceuticals, Inc. (“Boehringer”) (collectively, “Movants”) seek to intervene and defend their participation in the 340B Rebate Model Pilot (“Pilot Program”). The Pilot Program is a Health Resources and Services Administration (“HRSA”) project that enables manufacturers to comply with the requirements of the 340B Drug Pricing Program and the Drug Price Negotiation Program (“DPNP”) established by the Inflation Reduction Act (“IRA”). Movants are subject to the IRA, submitted plans for the Pilot Program, and are among the ten manufacturers approved to participate.¹ Movants are entitled to intervene as of right under Federal Rule of Civil Procedure 24(a) to defend their rebate plans. Alternatively, they seek Rule 24(b) permissive intervention. Movants also request that Rule 24(c)’s responsive pleading requirement be waived or deferred until the government is ordered to answer the complaint, as no party will be prejudiced. *See Peaje Invs. LLC v. García-Padilla*, 845 F.3d 505, 515 (1st Cir. 2017).

BACKGROUND

The 340B Program. The federal 340B statute requires participating pharmaceutical manufacturers, like Movants, to offer their drugs at steep discounts to certain types of nonprofit healthcare providers called “covered entities.” 42 U.S.C. § 256b(a)(1). The net price manufacturers must offer to covered entities—known as the “ceiling price”—is set by a statutory formula. *Id.* § 256b(a)(1)-(2). The ceiling price for some drugs can be as low as one penny per unit. Scheidler Decl. ¶ 3. The text of the 340B statute explicitly allows manufacturers to provide

¹ AbbVie’s Pilot Program plan covers its drugs Imbruvica, Linzess, and Vraylar. BMS’s Pilot Program plan covers its drugs Eliquis and Pomalyst. Boehringer’s Pilot Program plan covers its drugs Jardiance, Ofev, and Tradjenta.

the 340B price through either upfront discounts or post-sale rebates. 42 U.S.C. § 256b(a)(1). Nonetheless, HRSA claims the authority to approve (or conversely to prohibit) the use of rebates. Historically, at HRSA’s direction, the 340B price has often been provided via upfront discounts. *Novartis Pharms. Corp. v. Kennedy*, 182 F.4th 1027, 1029 (D.C. Cir. 2026).

The Drug Price Negotiation Program. Some manufacturers, including Movants, are also subject to the DPNP price-control regime, which went into effect this year. Under that regime, the Secretary of Health and Human Services selects drugs and negotiates a “maximum fair price” or “MFP.” *See* 42 U.S.C. § 1320f-2(a)(1). Manufacturers of selected drugs must then make the MFP available to healthcare providers when they dispense the drugs to Medicare beneficiaries. *Id.* § 1320f-2(a)(3). Movants lack the claims data to determine MFP eligibility on the front end because pharmacies typically purchase drugs in bulk before anyone knows to whom they will be dispensed. Marsh Decl. ¶¶ 34, 52. So Movants effectuate this mandate by reimbursing dispensing entities within 14 days for the difference between the acquisition cost and the MFP, pursuant to guidance issued by the Centers for Medicare & Medicaid Services (“CMS”).² McCarthy Decl. ¶¶ 11-12. Failure to provide the MFP discount subjects manufacturers to civil monetary penalties that can reach millions of dollars per day—or penalties of up to *ten times* the overcharge per drug unit. *See* 42 U.S.C. §§ 1320f-6(a), (c), 1320f-2(a)(5); Sharp Decl. ¶ 13.

Program Overlap. A single transaction might trigger both the 340B ceiling price (under the 340B statute) and the MFP (under the IRA), as when a unit of drug eligible for IRA-discounted pricing is purchased by a 340B covered entity and dispensed to a Medicare patient. A

² CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028*, at 209-10 (Sept. 30, 2025) (“2026-28 Final Guidance”), <https://tinyurl.com/uf86dc2f> (explaining that CMS intends the deadline to “align with the timing requirements in the Part D prompt pay rules” and create “a clear standard” for monitoring MFP effectuation).

manufacturer must then provide the lower of the two prices, but the IRA expressly provides that manufacturers “shall not be required to provide” both discounts simultaneously. 42 U.S.C. § 1320f-2(d). This process—identifying which program produces the lower price, and thus which one applies to a transaction—is “deduplication.” It is purportedly the obligation of manufacturers alone.³ And it exists for a good reason: If duplicate discounts were permitted, many manufacturers would pay more in discounts than the price of their drug. *See Sharp Decl.* ¶ 10.

Accurate deduplication is complicated and time sensitive. Manufacturers typically are not asked to offer the 340B discount until long after applying the maximum fair price. But the only effective way to deduplicate consistent with the IRA’s timing provisions is by examining basic claims data—routine information identifying, among other things, the patient, provider, and prescription—before the 14-day refund deadline.⁴ *See McCarthy Decl.* ¶¶ 14, 17-18; *Marsh Decl.* ¶¶ 40-41, 51; *Scheidler Decl.* ¶¶ 16, 18. Without timely information, a manufacturer would be stuck either providing both discounts, *cf.* 42 U.S.C. § 1320f-2(d), or risking exorbitant civil monetary penalties for failing to ensure the lower of the two prices is received, *id.* § 1320f-6(a).

HRSA has twice sought to mitigate the deduplication issue with a 340B rebate program that gives manufacturers claims data. HRSA’s first attempt debuted in August 2025. 90 Fed. Reg. 36,165 (Aug. 7, 2025). That program would have allowed Movants to deduplicate the MFP and 340B discounts for their products subject to both 340B and the DPNP in 2026. *See McCarthy Decl.* ¶ 19. But largely the same plaintiffs as in this case sought and obtained a preliminary injunction preventing HRSA from implementing the program and then settled with the government

³ *Id.* at 255 (“CMS will not, at this time, assume responsibility for nonduplication of discounts between the 340B ceiling price and MFP.”); *see also id.* (“CMS is not charged with verifying or otherwise reviewing whether a particular drug claim is 340B-eligible.”).

⁴ *Id.* at 209-10.

within two months of filing suit. *Am. Hosp. Ass’n v. Kennedy*, 820 F. Supp. 3d 30 (D. Me. 2025). HRSA withdrew the program and this Court vacated the manufacturers’ rebate model approvals. *See Am. Hosp. Ass’n v. Kennedy*, No. 2:25-cv-00600 (D. Me. Feb. 10, 2026), Dkt. 115. Movants have lacked access to claims data necessary to deduplicate consistent with the IRA, including its condensed timing requirements, and have given costly duplicate discounts. McCarthy Decl. ¶¶ 19-20; Marsh Decl. ¶ 47; *see also* Scheidler Decl. ¶¶ 14, 41-42.

After a robust comment period, HRSA announced a new Pilot Program. 91 Fed. Reg. 48,883 (Aug. 3, 2026). Using a rebate mechanism and claims data, the Pilot Program allows manufacturers to determine the proper discount and ensure compliance with the IRA’s nonduplication provisions—*i.e.*, to “deduplicate” the MFP and 340B discounts. The Pilot Program will go into effect on January 1, 2027. *Id.* at 48,884. Another of AbbVie’s drugs (Botox; Botox Cosmetic), BMS’s drugs (Orencia), and Boehringer’s drugs (Tadajenta) have been selected for negotiation of an MFP for 2028. CMS, *CMS Announces Manufacturer Participation in Third Cycle of Medicare Drug Price Negotiation* (Mar. 13, 2026), <https://tinyurl.com/46c52rev>.

Movants submitted Pilot Program plans to HRSA and were approved to implement them in September 2026. *See* HRSA, 340B Rebate Model Pilot Program, <https://tinyurl.com/bdhpur9n>. Plaintiffs once again sued, claiming that the Pilot Program is arbitrary and capricious under the Administrative Procedure Act. They have asked this Court to enjoin “HRSA’s approvals of the drug companies’ plans” and enjoin HRSA “from implementing or giving effect to the Rebate Program in any way.” Dkt. 1 at 140; *see also* Dkt. 2 at 21. Such order would make it impossible for Movants to accurately deduplicate consistent with the IRA’s requirements, including its mandatory 14-day payment window. *See* Marsh Decl. ¶ 51. Movants thus seek to join this action to protect their interests.

ARGUMENT

I. Movants Are Entitled To Intervene Under Rule 24(a).

Movants qualify for intervention as of right under Rule 24(a) because they (1) timely moved to intervene, (2) have interests related to the subject of this suit, (3) face the threat that the disposition of the suit will impair their interests, and (4) are not adequately represented by an existing party. *B. Fernández & Hnos., Inc. v. Kellogg USA, Inc.*, 440 F.3d 541, 544-45 (1st Cir. 2006). Evidence of Movants' harm is critical to the Court's balancing of the equities, and that evidence can only be properly put before the Court if Movants are parties to this action. Courts in this circuit routinely grant leave to intervene under similar circumstances. *E.g., NERO Int'l Holding Co. v. NEROTix Unlimited Inc.*, 585 F. Supp. 3d 152, 156-57 (D. Mass. 2022); *Canadian Nat. Ry Co. v. Montreal, Me. & Atl. Ry., Inc.*, 2010 WL 5168003, at *5-7 (D. Me. Dec. 14, 2010).

Interest in the action. Movants have direct, concrete interests in their rebate plans, which HRSA has approved, and in avoiding tens of millions of dollars in duplicate discounts. *See Conservation L. Found. of New England, Inc. v. Mosbacher*, 966 F.2d 39, 43 (1st Cir. 1992). Movants' plans let them provide the correct price concession when the 340B Program and DPNP overlap, avoiding both civil penalties and duplicate discounts, because Movants cannot otherwise reliably obtain and validate 340B claims data, consistent with the IRA's 14-day refund deadline. *See McCarthy Decl.* ¶¶ 15, 23, 34. Without a rebate model allowing prospective nonduplication, they will pay both discounts in many cases. *Sharp Decl.* ¶ 18; *McCarthy Decl.* ¶¶ 19-20, 34; *Marsh Decl.* ¶ 51. Movants' interests in a system that allows them to avoid these losses could hardly be more direct. *See B. Fernández*, 440 F.3d at 545 ("An intervenor has a sufficient interest in the subject of the litigation where [its] contractual rights may be affected by a proposed remedy.").

Threat to the interest. Plaintiffs seek to enjoin implementation of Movants' Pilot Program plans, Dkt. 2 at 21, the only available method for Movants to accurately reconcile their IRA and

340B obligations, *see* McCarthy Decl. ¶¶ 31, 33-34; Marsh Decl. ¶¶ 47, 51. By definition, “disposing of the action may as a practical matter impair or impede” Movants’ “ability to protect [their] interest[s].” Fed. R. Civ. P. 24(a)(2). Indeed, “even a small threat” to a movant’s interests is “ample reason for finding that [its] ability to protect [its] interest ‘may’ be adversely affected.” *Cotter v. Mass. Ass’n of Minority L. Enf’t Officers*, 219 F.3d 31, 35 (1st Cir. 2000).

Adequacy of representation. Movants “need only show that representation may be inadequate,” *Mosbacher*, 966 F.2d at 44, and they do so. Movants’ ultimate objective does not “match[]” the government’s, so no presumption of adequate representation is appropriate. *B. Fernández*, 440 F.3d at 545-46. Even if such presumption applied, it would be “lighter” than in the ordinary case, where an intervenor’s purported interest is “thin and widely shared,” because Movants have “a tangible and substantial stake in the outcome of this case.” *Id.* at 546 (citation omitted). Nor should this Court adhere to its prior intervention ruling. For one thing, subsequent events—*e.g.*, the government’s disagreement about the necessity of the Pilot Program to manufacturers—confirm the “tangible basis” for Movants’ position that the government is not representing their interests. *Cf. Pub. Serv. Co. of N.H. v. Patch*, 136 F.3d 197, 207 (1st Cir. 1998). For another, the First Circuit has vacated this Court’s prior order denying intervention. *See Am. Hosp. Ass’n, et al. v. Kennedy, et al.*, 2026 WL 2913956, at *2-3 (1st Cir. Sept. 25, 2026). This Court should consider the intervention question afresh.

No presumption of adequate representation applies because Movants, unlike HRSA, are the targeted regulated parties and, unlike HRSA, seek to avoid tens of millions of dollars in duplicate discounts and civil penalties. *See, e.g.*, McCarthy Decl. ¶ 20 (BMS has already lost at least \$40 million in duplicate discounts); Scheidler Decl. ¶¶ 41-42 (AbbVie expects to lose \$35.8 million); Marsh Decl. ¶ 47 (Boehringer average losses of \$3 million each week, increasing in

2027). That distinction alone demonstrates that the presumption does not apply. A presumption exists only “where the goals of the applicants are the *same* as those of” a party, on the theory that the government “represent[s] adequately” a citizen’s undifferentiated interest in the enforcement of valid laws. *Daggett v. Comm’n on Governmental Ethics & Election Pracs.*, 172 F.3d 104, 111 (1st Cir. 1999) (emphasis added). Because Movants are among a small group of manufacturers whose Pilot Program plan approvals are at issue in this litigation, they do not stand in the shoes of “all citizens” who support HRSA’s regulatory efforts. *Cf. id.* Movants thus occupy a materially different position than the unsuccessful intervenors in cases like *Victim Rights Law Center v. Rosenfelt*, 988 F.3d 556, 561–63 (1st Cir. 2021), and *T-Mobile Northeast LLC v. Town of Barnstable*, 969 F.3d 33, 39–40 (1st Cir. 2020), who asserted only generalized interests.

Movants’ interests also differ in degree and kind from those of the government. As to kind, the government’s interest is in protecting its regulatory authority, even at Movants’ expense. For example, while manufacturers have long contended that a rebate model is the only practical way to harmonize the 340B and DPNP obligations, the government has taken the opposite position. *Am. Hosp. Ass’n v. Kennedy*, 164 F.4th 28, 37 (1st Cir. 2026) (“[T]he federal government has indicated that manufacturers have alternative methods to address the ... duplication issue.”). And here, the government merely suggests that the Pilot Program may show one way to address duplicate discounts. *See* 91 Fed. Reg. at 48,889–90, 48,899. But Movants are not participating in the Pilot Program simply to help the government test a rebate model; they *need* to participate to accurately deduplicate discounts consistent with the IRA, including its condensed timeframes. *See* Scheidler Decl. Ex. D, at 9.

As to degree, Movants will oppose Plaintiffs’ attempt to enjoin the Pilot Program by relying on evidence of their harms—evidence that only they can provide as “the real targets of the suit

and ... the subjects of the regulatory plan.” *Mosbacher*, 966 F.2d at 43. Plaintiffs seek to enjoin Movants’ rebate plans. Dkt. 1 ¶¶ 197-99. And Movants—not HRSA—bear all the relevant financial risks, whereas HRSA has no direct financial stake in the Pilot Program. HRSA cannot adequately represent Movants’ differentiated, private interests from a fundamentally different “standpoint.” *See, e.g., Animal Prot. Inst. v. Martin*, 241 F.R.D. 66, 70 (D. Me. 2007).

Experience has demonstrated that the government is not “zealously interested in upholding the validity of [its actions]”—at least with respect to Movants’ unique interests. *Cf. Mass. Food Ass’n v. Mass. Alcoholic Beverages Control Comm’n*, 197 F.3d 560, 567 (1st Cir. 1999) (declining only to create a presumption of *inadequate* representation by regulators). The Court denied drug manufacturers’ intervention motions in the first rebate program litigation, on the understanding that the government would be an adequate representative. *See Am. Hosp. Ass’n v. Kennedy*, 2025 WL 3677386, at *4–5 (D. Me. Dec. 18, 2025), *vacated and appeal dismissed as moot*, 2026 WL 2913956 (1st Cir. Sept. 25, 2026). But the government was unable to present manufacturer-specific evidence about duplicate-discount harm or operational constraints, wrongly suggested that manufacturers have other accurate mechanisms for achieving deduplication, and settled the dispute by withdrawing the first rebate program and dismissing its appeal. *See Am. Hosp. Ass’n*, 820 F. Supp. 3d at 46; *Am. Hosp. Ass’n*, 164 F.4th at 37. These decisions cost Movants tens of millions of dollars. *See McCarthy Decl.* ¶ 20; *Marsh Decl.* ¶ 47.

Moreover, because the government asserts complete authority over the use of rebates in the 340B context, including the ability to bar them, its approach conflicts with Movants’ view that rebates are necessary. *See Novartis*, 182 F.4th at 1034 (concluding HHS must “affirmatively approve rebate models”). The government is also unlikely to underscore the operational tension between the DPNP and 340B Program and explain that without the Pilot Program, manufacturers

will face serious compliance problems. *See Mosbacher*, 966 F.2d at 44 (government’s actions gave the “distinct feeling that the Secretary [was] less than wholeheartedly dedicated to opposing the [plaintiff’s] aims”). As in *Cotter*, Movants seek to develop arguments that the existing parties will not. *See* 219 F.3d at 34-36. Because Plaintiffs seek relief that would make a rebate model impossible, and the government has little incentive to contend that a rebate model is necessary, Movants are permitted to defend their own interests.

In short, Movants make the “‘minimal’ showing” of inadequacy, so they also overcome the “lighter” presumption that applies to potential intervenors with “a tangible and substantial stake in the outcome of this case.” *B. Fernández*, 440 F.3d at 545. The government does not see the Pilot Program from the “parochial” perspective of a regulated party because its “judgments are necessarily constrained by [its] view of the public welfare.” *Mosbacher*, 966 F.2d at 44. HRSA thus “might change or soften [its] position” to accommodate “broader ... institutional interests.” *Nextel Commc’ns of Mid-Atl., Inc. v. Town of Hanson*, 311 F. Supp. 2d 142, 153 (D. Mass. 2004). And it is ultimately Movants, not the government, who will suffer duplicative price concessions or civil penalties if they cannot implement their plans. Bearing none of those costs, the government is not “narrowly focused” on Movants’ interests. *Mosbacher*, 966 F.2d at 44. And given its institutional interests, the government will “behave like a stakeholder rather than an advocate.” *Brennan v. N.Y.C. Bd. of Educ.*, 260 F.3d 123, 132-33 (2d Cir. 2001). The potential for “greater adverse impact” on Movants shows that the government “may not serve as an adequate proxy.” *B. Fernández*, 440 F.3d at 547.

Timeliness. Given that Plaintiffs filed their complaint just five days ago, this motion is timely and will not delay this action or prejudice the existing parties. *See Geiger v. Foley Hoag LLP Ret. Plan*, 521 F.3d 60, 64 (1st Cir. 2008) (motion timely when “the case had not progressed

beyond the initial stages”). Movants are prepared to adhere to the schedule this Court enters.⁵

II. Alternatively, Intervention Is Warranted Under Rule 24(b).

In the alternative, the Court should grant permissive intervention. Fed. R. Civ. P. 24(b)(1)(B). In weighing permissive intervention, “the court must consider whether the intervention will unduly delay or prejudice the adjudication of the original parties’ rights.” *Id.* 24(b)(3). The Court may also consider any “rationally relevant” factor, including whether applicants may “fully develop[] the case.” *Daggett*, 172 F.3d at 113; *see also Melone v. Coit*, 100 F.4th 21, 28-29 (1st Cir. 2024). Movants’ defense of their plan approvals shares common questions of law and fact with the underlying action—indeed, unless Movants are made parties, the underlying action will resolve the legality of their plans in their absence. *See Tirrell v. Edelblut*, 2025 WL 1939965, at *3 (D.N.H. July 15, 2025) (intervenors would “assist[] in fully developing the record and in reaching a just resolution” because they were “the ones who [we]re directly affected by the challenged laws”). Movants’ “highly relevant factual perspective” as Pilot Program participants would also “significantly contribute” to this Court’s understanding of issues “critical to [their] interests,” but which HRSA “may not emphasize or vigorously defend.” *Ass’n of Conn. Lobbyists LLC v. Garfield*, 241 F.R.D. 100, 103 (D. Conn. 2007). And their motion is timely, filed within two business days of Plaintiffs’ complaint. The Court should permit intervention.

CONCLUSION

The Court should grant the motion to intervene and waive or defer Rule 24(c)’s responsive pleading requirement.

⁵ Movants will file their reply in support of intervention by Friday, November 13, so that this motion is ripe before the parties’ requested oral argument the weeks of November 16 or November 23. *See* Dkt. 14.

Dated: October 14, 2026

Respectfully submitted,

William J. Gallitto, III (Maine Bar No. 4969)
Jana L. Kenney (Maine Bar No. 6159)
BERGEN & PARKINSON, LLC
144 Main Street
Saco, ME 04043
Telephone: (207) 283-1000

Susan M. Cook*
Marlan Golden*
Claire A. Rhodes*
Carly M. Heying*
HOGAN LOVELLS CADWALADER US LLP
555 Thirteenth Street, N.W.
Washington, DC 20004-1109
Telephone: (202) 637-5600
Facsimile: (202) 637-5910
Email: susan.cook@hlc.com

*Attorneys for Proposed Intervenor-Defendant
Bristol-Myers Squibb Company*

Alfred C. Frawley IV (Maine Bar No. 004854)
MCCLOSKEY, MINA, CUNNIFF &
FRAWLEY, LLC
12 City Center
Portland, Maine 04101
Telephone: (207) 772-6805
Fax: (207) 879-9374
Email: afrawley@lawmmc.com

Kevin F. King*
Thomas Brugato*
COVINGTON & BURLING LLP
One City Center
850 10th Street N.W.
Washington, DC 20001
Telephone: (202) 662-6000
Email: kking@cov.com
tbrugato@cov.com

*Attorneys for Proposed Intervenor-Defendant
Boehringer Ingelheim Pharmaceuticals, Inc.*

/s/ Paul McDonald
Paul McDonald
Lucas Fortier
BERNSTEIN SHUR
100 Middle Street
P.O. Box 9729
Portland, ME 04104
Telephone: (207) 774-1200
Email: pmcdonald@bernsteinshur.com
lfortier@bernsteinshur.com

Matthew S. Owen*
Jessica L. Wagner*
Hank Minor*
GIBSON, DUNN & CRUTCHER LLP
1700 M Street, N.W.
Washington, DC 20036
Telephone: (202) 955-8616
Email: mowen@gibsondunn.com
jwagner@gibsondunn.com
hminor@gibsondunn.com

*Attorneys for Proposed Intervenor-Defendants
AbbVie Inc. and Pharmacyclics LLC*

**Pro hac vice certificates forthcoming*

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

THE AMERICAN HOSPITAL
ASSOCIATION, THE MAINE HOSPITAL
ASSOCIATION, EASTERN MAINE
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. 1:26-cv-00515-LEW

DECLARATION OF EDWARD SCHEIDLER

I, Edward Scheidler, hereby make this declaration in lieu of an affidavit as permitted by 28 U.S.C. § 1746. I am aware that this declaration will be filed in the United States District Court for the District of Maine, and that it is the equivalent of a statement under oath. I declare as follows in support of AbbVie Inc.'s and Pharmacyclics LLC's (collectively "AbbVie") motion to intervene as defendants and memorandum in opposition to Plaintiffs' motion for a temporary restraining order in the above-captioned action:

A. Background

1. I am over the age of 21, under no disability, and competent to testify to the matters contained in this declaration.

2. I am the Head of the 340B Center of Excellence at AbbVie. I have worked at AbbVie since 2004 and have been responsible for AbbVie's 340B Program since 2017. My responsibilities include regularly engaging with the purchasers of AbbVie's pharmaceutical products concerning AbbVie's participation in the federal 340B Program, including with respect to AbbVie's relationships with commercial pharmacies (including so-called "contract pharmacies"). I am familiar with the conditions of AbbVie's participation in federal healthcare programs, such as Medicare and Medicaid.

B. The 340B Program

3. Manufacturers participating in the federal 340B Program, like AbbVie, must offer to sell their medications at a statutorily calculated discounted price to certain nonprofit healthcare providers, known as "covered entities." *See* 42 U.S.C. § 256b. The Health Resources and Services Administration ("HRSA") administers the 340B Program. The average 340B discount across AbbVie's drug portfolio is over 60% of the drug's commercial price. For some drugs, the price is as low as one penny per unit.

4. Historically, HRSA has insisted that manufacturers provide the 340B price via upfront discounts. Although the discounts are offered upfront—that is, when purchased from a wholesaler—a drug only qualifies for the 340B discount if it is dispensed to a qualifying patient. Covered entities thus could purchase drugs at the 340B price and then maintain them as distinct inventory, dispensable only to covered entities' 340B-eligible patients. But covered entities in the 340B Program typically choose another option: virtual "replenishment" inventory models.

5. Under the replenishment model, covered entities often rely on outside pharmacies (called “contract pharmacies”) to acquire and dispense 340B-priced drugs, which are shipped directly from the wholesaler to the contract pharmacy to “replenish” the contract pharmacy’s own drug stock. These “replenishment orders” replace drugs that the contract pharmacy previously sold to 340B-eligible patients. To operate a replenishment model, 340B participants rely on a “virtual” inventory system. Under these systems, contract pharmacies do not determine prior to or at the point of sale whether the patient is eligible for 340B-discounted drugs. Instead, claims data is used by pharmacies to make patient-eligibility determinations retroactively—that is, after the drugs have already been dispensed to a patient. The pharmacy tracks these determinations and orders additional drugs at the 340B ceiling price only after it has accumulated enough dispenses. Providers and pharmacies refuse to share their claims data with manufacturers, leaving them to rely on the pharmacy’s assertion that 340B-eligible dispenses have occurred.

6. Under the replenishment model, while the 340B price is offered “prospectively,” covered entities typically base their 340B orders on dispenses that happened in the past, making the 340B price “retrospective” with respect to the dispense that triggered the discount.

7. From my experience, hospital covered entities simply put their 340B profits into their general operating budgets. Some covered entities might, at their own discretion, occasionally choose to pass portions of their 340B discounts to certain patients. But such discounts are highly unusual: I would estimate that less than 5% of 340B transactions (perhaps less than 2 or 3%) involve any sort of direct patient discount. In fact, some major contract pharmacy chains refuse to cooperate with such patient discount programs. Patients at these pharmacies cannot receive discounts for drugs purchased at those pharmacies even if the covered entity *wanted* to pass those discounts along. As a general rule, patients pay full price.

C. The Drug Price Negotiation Program

8. The Inflation Reduction Act (“IRA”) created a federal drug-discount program called the Medicare Drug Price Negotiation Program (“DPNP”). I understand that in this program, the Secretary of the Department of Health and Human Services (“HHS”) determines the price that Medicare plans will pay for certain drugs. The price set by HHS is typically called the maximum fair price (“MFP”).

9. I understand that the process CMS has mandated that manufacturers use for providing MFP refunds is incompatible with the way drugs are sold at the 340B ceiling price. *First*, there is a timing issue. Once a drug has been dispensed to a Medicare Part D enrollee, the plan sponsor has 7 days to submit that claim to CMS. Once manufacturers receive the claims data from CMS through the Medicare Transaction Facilitator (“MTF”), they have 14 days to transmit a refund to the dispensing pharmacy.¹ Manufacturers are often not asked to provide a 340B discount, however, for weeks, months, or even a year after a pharmacy dispenses a drug to a patient. That is because, as described, most 340B-eligible dispenses occur under the “replenishment model,” by which covered entities (or the pharmacy acting on their behalf) wait until an entire package of medication has been dispensed to order a new “replenishment” package at the 340B price. So MFP refunds may already have been provided on earlier dispenses by the time a covered entity places a 340B replenishment order; the physical unit dispensed to a patient generally is not separately purchased at the 340B price before the dispensing transaction. *Second*, there is a claims-data issue. Covered entities participating in the 340B Program generally refuse

¹ I understand that CMS created the MTF to facilitate the transmission of claims data from insurance plans to manufacturers. CMS, Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028 at 215-17 (Sept. 30, 2025), <https://tinyurl.com/uf86dc2f>.

to provide manufacturers with the claims data that purportedly justifies a 340B replenishment order. This decision, combined with the timing issue, means that manufacturers are unable to determine whether they have already provided the MFP on the dispense that the covered entity is relying on for 340B replenishment. **Third**, the MFP refund process involves different actors than the 340B discount model. With the MFP, manufacturers transmit refunds to dispensing entities (pharmacies), whereas I understand that with the 340B discount, covered entities place orders with drug wholesalers who later request chargebacks from manufacturers. In short, different entities seek different discounts from manufacturers at different times for the same dispensed prescription.

10. The overlap of the 340B Program and DPNP can result in negative pricing. As AbbVie has explained, “if the wholesale acquisition cost for a drug is \$1,000, the MFP is \$500, and the 340B ceiling price is \$250; a manufacturer would be forced to provide \$1,250 in discounts on a drug that cost only \$1,000.”²

11. Similar problems arise even if a covered entity does not use the replenishment model. In such a scenario, the 340B discount is due at the time of a covered entity’s purchase—committing the covered entity to dispense the drug, eventually, to a 340B-eligible patient. At the same time, the MFP refund cannot be claimed until after a drug has been dispensed to an eligible Medicare patient and approved by their plan as an eligible claim. Under the current federal framework, then, a manufacturer would provide a front-end 340B discount to the covered entity (e.g., a hospital) on a unit of drug. If that unit is ultimately dispensed to an MFP-eligible patient, the manufacturer would be required to provide a back-end refund to effectuate the MFP. Yet the dispensing entity (e.g., a pharmacy) typically will not know at the time of dispense—and indeed may never know—whether the customer is a 340B-eligible patient. A rebate model avoids this

² AbbVie Comment Letter, at 8 (Apr. 20, 2026), <https://tinyurl.com/ymf6uuck>.

problem by waiting until the dispense occurs before obligating the manufacturer to identify and provide the correct discount.

D. Pilot Program History

12. Because some drugs subject to the 340B price are also subject to the MFP, but manufacturers are not required to provide both price concessions on the same unit of drug, HRSA has twice attempted to test a rebate mechanism for delivering the 340B price.

13. First, in August 2025, HRSA promulgated a rebate model pilot program that would have applied to drugs for which MFP pricing would go into effect in 2026.³ AbbVie was approved for that limited pilot. One month before AbbVie's rebate plan was to go into effect, the American Hospital Association ("AHA") and several other plaintiffs successfully requested that AbbVie's approval be enjoined. The plaintiffs in that litigation later entered into a settlement with HHS. To effectuate the settlement, the district court vacated AbbVie's and other manufacturers' approvals to participate in that pilot program. As a result, neither AbbVie nor any other manufacturer was approved to use a 340B rebate model in 2026.

14. AbbVie had only one drug subject to the DPNP in 2026, Imbruvica (a medicine used to treat certain blood cancers), for which it was required to determine whether the MFP or 340B price applied. In 2027, AbbVie will have three drugs subject to an MFP: Imbruvica, Linzess, and Vraylar. AbbVie sells Imbruvica, Linzess, and Vraylar to covered entities nationwide, including in Maine. AbbVie expects to process rebate requests for Imbruvica, Linzess, and Vraylar from Maine-based covered entities under the Pilot Program.

15. Second, on August 3, 2026, HRSA proposed a revised Rebate Model Pilot Program for 2027 ("Pilot Program"), in which manufacturers would deliver the 340B price for drugs subject

³ 90 Fed. Reg. 38,165 (Aug. 7, 2025).

to both 340B and the DPNP using a rebate mechanism.⁴ In its Pilot Program announcement, HRSA acknowledged the elimination of duplicate claim submissions under the 340B Program and the DPNP as one reason for collecting claims data and effectuating the 340B price through a rebate mechanism.⁵

16. Collecting claims data is the most efficient and accurate method of identifying when a rebate is warranted and ensuring compliance with the IRA because it enables manufacturers to quickly identify which dispenses are both MFP-eligible and subject to 340B pricing. In my experience, duplicate discounts are inevitable unless manufacturers can use a rebate model and obtain claims data. I thus understand that one goal of the Pilot Program is to avoid duplicate discounts so that a manufacturer does not pay both the MFP and the 340B price on the same prescription.

17. Based on my experience, rebate models (like the Pilot Program), which are based on actual patient dispenses, are more likely to enhance program integrity than upfront discount models (like the prevailing replenishment model).

18. I understand that data is submitted to the MTF for claims eligible for an MFP. However, without corresponding claims data from 340B dispenses, manufacturers cannot accurately match dispenses to ensure they do not provide duplicate discounts. Moreover, it is my understanding that the primary available data field in MFP refund claims that enables manufacturers to even attempt to predict potential duplicate discounts with 340B is the NPI. But CMS specifically noted in its Final Guidance that the NPI alone provides an insufficient basis

⁴ 91 Fed. Reg. 48,883 (Aug. 3, 2026).

⁵ *Id.* at 48,887.

through which to deduplicate claims.⁶ I do not understand the physician NPI or pharmacy NPI, standing alone, to be sufficient to facilitate deduplication.

E. The Revised Pilot Program

19. The 2027 Pilot Program is a limited pilot for which only 25 specific drugs are eligible—those subject to the 340B discount as well as an MFP in 2027. It is my understanding that the selected drugs make up a very small portion of drug sales conducted under the 340B Program, estimated at less than 5.5% of total 340B sales.⁷ Three of AbbVie’s drugs are part of the Pilot Program: Imbruvica, Linzess, and Vraylar.

20. AbbVie submitted its application for HRSA’s new Pilot Program on Monday, August 24, 2026. HRSA formally approved AbbVie’s proposal for participating in the Pilot Program on Thursday, September 24, 2026. Attached hereto as Exhibit A, Exhibit B, and Exhibit C are true and correct copies of HRSA’s letters approving AbbVie for participation in the Pilot Program. AbbVie is set to start participating in the Pilot Program on January 1, 2027.

21. I understand that HRSA sought public comments about the Pilot Program before publishing the new Pilot Program framework. 91 Fed. Reg. 7,287 (Feb. 17, 2026). In response to that request, AbbVie submitted a comment, a true and correct copy of which is attached hereto as Exhibit D. AbbVie explained the substance of its investment of “millions of dollars and countless hours preparing for MFP effectuation.” Ex. D at 8. It explained how, under related programs, “AbbVie has millions in disputed Medicaid duplicate discount claims activity that has remained unresolved for years, largely because covered entities refuse to work with AbbVie to comply with their statutory obligations.” *Id.* at 6. And AbbVie provided specific information about how

⁶ IPAY 2026-28 Final Guidance § 40.4.5, at 254.

⁷ 91 Fed. Reg. at 48,893.

“[m]anufacturers ... would incur the bulk of the costs under a Rebate Model,” in part because of their obligation to establish and maintain a platform for the Rebate Model. *Id.* at 26.

22. Under the Pilot Program, covered entities must submit claims data in order to obtain the 340B ceiling price in the form of a rebate. For submitted claims, AbbVie will offer the 340B ceiling price through a rebate mechanism in order to prevent both duplicate price concessions between the MFP and 340B ceiling price and other issues, such as the submission of duplicate Rx claims by separate covered entities. The Pilot Program—with its claims data submission requirements and rebate model—is the only effective method for manufacturers to deduplicate the discounts required under the 340B Program and the DPNP. As HRSA has recognized, requiring an upfront discount, which necessarily results in after-the-fact dispute resolution, is “inherently reactive” and leads to “resource-intensive ‘pay-and-chase’ processes.”⁸ By contrast, a rebate model also “by its very nature incentivizes covered entity compliance” because “the covered entity must affirmatively submit validated claims data to receive the discount, which may help to align the incentive structure with program integrity objectives.”⁹ Providing claims data while discount eligibility is being adjudicated ensures that eligibility and payment align.¹⁰

23. When covered entities submit timely, complete claims, the net price paid remains the same whether they receive a discount upfront or as a rebate.

24. HRSA has specified that under the Pilot Program, covered entities will be able to make purchases through their 340B wholesaler accounts. Manufacturers are to load commercial wholesale acquisition cost (“WAC”) pricing in the 340B wholesaler account where purchases will

⁸ 91 Fed. Reg. at 48,889, 48,890.

⁹ *Id.* at 48,900.

¹⁰ *See id.* at 48,899.

be made by covered entities. Once purchased, products will be dispensed or administered to individuals, and covered entities will use claims data to determine if a particular dispense or administration was eligible for the 340B price. Then, as part of requesting a rebate to the 340B ceiling price, covered entities must submit claims data to the manufacturer. Pilot Program rebates will be calculated as WAC minus the 340B ceiling price on the date of dispense (date of service). This framework allows covered entities to use existing 340B infrastructure, which I understand will lessen any administrative burden involved in seeking 340B discounts.

25. I understand that some commenters proposed that deduplication could be facilitated via a clearinghouse, administered by HRSA or a third party, which would coordinate the spread of information about 340B transactions among covered entities, manufacturers, and others. Such an approach is impractical in this context. *First*, even if HRSA had authority to create a clearinghouse, it could not timely create a workable one.¹¹ Manufacturers have already been harmed by their effective inability to deduplicate transactions eligible for the MFP in 2026 and will soon also have to deduplicate transactions eligible for the MFP in 2027. *Second*, the commenters' version of a clearinghouse would identify duplicate discounts after they have already occurred—that is, after a pharmacy and covered entity have already benefited from a duplicate discount. As manufacturers and HRSA explained, that design does not adequately encourage compliance with claims data sharing requirements. In fact, covered entities would be incentivized not to submit claims data, so that they can keep previously paid duplicate discounts. Moreover, because such a clearinghouse would not encourage compliance, its design is likely to involve

¹¹ 91 Fed. Reg. at 48,900 (acknowledging that “clearinghouses or similar intermediaries are not explicitly authorized under the 340B statute”).

greater administrative cost than necessary, as the clearinghouse resolves duplicate discounts that could have been avoided in the first instance.

26. Manufacturers are best equipped to implement a rebate model. They have extensive operational experience with rebate programs and administer rebate programs across multiple federal and commercial markets—for example, the Medicaid Drug Rebate Program, historical Medicare Part D discount programs, and the wholesaler chargebacks that facilitate upfront 340B discounts. This existing infrastructure means that manufacturers can implement a rebate model that is predictable, scalable, and aligned with individual manufacturers' compliance requirements.

27. Moreover, as detailed below, manufacturers like AbbVie have already spent significant time and effort developing their Pilot Program plans in preparation for the 2027 DPNP, which will require them to ensure compliance with both the IRA and 340B for participating drugs.

28. The Pilot Program requires that participating manufacturers obtain claims data from covered entities to effectuate 340B rebates. In approving AbbVie's proposal for the Pilot Program, HRSA specified the data fields that AbbVie collects from covered entities in order to issue a 340B rebate. This claims data includes important information, such as date prescribed, Rx number, fill number, quantity dispensed, and the prescriber/rendering physician's National Provider Identifier, that allows manufacturers to prevent duplicate discounts. The Pilot Program does not work without claims data. Claims data is critical for AbbVie to determine the applicability of the MFP and fulfill AbbVie's duty under the IRA to provide the lower of the MFP and 340B price.

29. Without such claims data, manufacturers like AbbVie cannot accurately and exhaustively deduplicate the 340B price and MFP. One analysis concluded that, as of April 1, 2026, manufacturers have paid both discounts in at least 30% of cases where a claim was eligible

for both the MFP and 340B price, even though in such instances the claim should have received only the 340B price. Ex. D at 9.

30. Claims data also allows AbbVie to avoid duplicate claims more generally, including when multiple covered entities submit the same prescription for the same patient, a significant problem. For example, one analysis estimates that “[m]ore than 20 percent of [Medicare Part D dispenses] replenished at least once are at risk of replenishment by more than one covered entity,” and that some of those dispenses “could be replenished by more than five” covered entities.¹²

31. Claims data is ubiquitous in the healthcare industry, and covered entities routinely collect and include it on everything from hospital bills to insurance to Medicare and Medicaid claims. Claims data is often required to substantiate non-340B healthcare transactions—such as insurance payment or Medicaid reimbursement. Even though claims data is readily available to covered entities, covered entities do not generally provide claims data voluntarily or upon request, which is one reason that HRSA included a claims-data requirement as a part of the Pilot Program. That requirement aligns the 340B Program with what I understand to be ordinary practices in the healthcare industry. A similar thing is true of rebates, which are standard in the healthcare industry and are commonly used to facilitate access to reduced pricing in federal and commercial healthcare programs alike. The Pilot Program’s rebate model brings the 340B Program in line with industry norms. I am aware of and myself have had discussions with the health plan of a covered-entity hospital to discuss their formulary rebates. Many large health systems that qualify as 340B covered

¹² BRG, *340B Patient Definition and Implications for Duplicate Replenishment* (Apr. 10, 2026), <https://media.thinkbrg.com/wp-content/uploads/2026/05/06130322/Patient-Def-Dupe-Replenishment-2026-4.5.26.pdf>.

entities operate self-insured health plans and accept drug rebates as a way to effectuate their pharmacy-benefit-manager negotiated net drug prices for their employee prescriptions.

32. HRSA is preparing manufacturers, covered entities, and other stakeholders for the Pilot Program's effective date.

33. As part of the Pilot Program, HRSA requires manufacturers to pay for the costs of data collection software through which covered entities will submit claims data to manufacturers.¹³ AbbVie has worked with Berkeley Research Group ("BRG") and Second Sight Solutions ("Second Sight") to develop a platform for covered entities to submit claims data to AbbVie. Second Sight's technology platform called "Beacon" will compare 340B data submitted through the Pilot Program and MFP refund claims data received through the "Medicare Transaction Facilitator" on a daily basis to identify claims subject to both MFP and 340B pricing for AbbVie. AbbVie will use those comparisons to appropriately price and fulfill refund requests.¹⁴

34. It is my understanding that many covered entities already use "340B ESP," a Second Sight product, to submit claims data in the context of 340B replenishment orders.¹⁵ 340B ESP is similar to Second Sight's "Beacon" platform. It is my understanding that all 10 manufacturers, including AbbVie, that are participating in the Pilot Program intend to use Second Sight's "Beacon" platform to support their participation.¹⁶ In my experience, most covered entities

¹³ 91 Fed. Reg. at 48,893.

¹⁴ Beacon MFP Support Center, *Beacon MFP Frequently Asked Questions*, <https://tinyurl.com/4btsetnx>.

¹⁵ 340B ESP Help Center, *Frequently Asked Questions (FAQs)*, <https://help.340besp.com/en/articles/14482537-frequently-asked-questions-faqs>.

¹⁶ HRSA, *Approved manufacturer 340B Rebate Model plans*, <https://www.hrsa.gov/opa/340b-model-pilot-program>.

have personnel who handle claims data for eligibility determinations—or use vendors that can easily and rapidly interface with Beacon just as they do with other parties, like payers.

35. In accordance with the Pilot Program, AbbVie provides covered entities with free access to Beacon’s Pilot Program platform to support claims data submissions, as well as technical support, customer service, and educational resources at no cost to covered entities. Many covered entities work with “third-party administrators” to identify claims for discounts under the 340B Program from past dispenses, as well as discounts available through other programs. Based on my experience, these third-party administrators may be willing and able to offset covered entities’ administrative burdens by uploading necessary claims data directly to Beacon on the entities’ behalf.

36. The Pilot Program is not only small in scale—affecting perhaps 5.5% of all 340B sales—it is also structured to prevent delays and to not affect covered entities’ cash flow.¹⁷ I understand that covered entities commonly use payment windows or credit arrangements when purchasing from wholesalers, arrangements that allow covered entities to receive and dispense medications before they need to pay the wholesaler. The Pilot Program makes manufacturer rebates due within 10 days of claim submission, but covered entities typically enjoy standard wholesaler terms under which payment is due 30 days after purchase, so that covered entities can receive rebates before payment is due. HRSA has clarified that a manufacturer’s failure to pay a rebate within 10 days of submission of a complete Pilot Program claim may jeopardize a manufacturer’s participation in the Pilot Program. 91 Fed. Reg. at 48,895. Thus, even if covered entities must place orders at the WAC, they will receive rebates under the Pilot Program before they are required to remit payment for those WAC-priced orders.

¹⁷ 91 Fed. Reg. at 48,893.

37. It is my understanding that currently, under the replenishment model, a covered entity will not purchase additional drug units at the discounted 340B price until the dispenses for a drug reach a full package size. Moreover, a covered entity's payment from an external contract pharmacy usually is delayed 30 to 45 days, or more, based on the covered entity's contractual agreement with the pharmacy. As a result, it is possible that the Pilot Program will actually reduce the time that covered entities spend waiting to realize a drug discount.

38. Similarly, it is my understanding that covered entities have experience managing far greater administrative burdens and delays than those that covered entities fear will result from HRSA's Pilot Program. Many hospital pharmacies engage with outpatient Medicaid patients. For such patients, a hospital pharmacy dispenses a drug that it has already purchased, submits claim-level data, then waits for the State to adjudicate the request and pay the pharmacy. It is my understanding that this process affects all drugs dispensed to Medicaid patients, whereas only 18 drugs have currently been approved for the Pilot Program. I also understand that many covered entities use the so-called "Alternate Distribution Model" or "ADM" as a workaround to manufacturers' contract-pharmacy policies.¹⁸ The ADM requires covered entities to spend significantly, obtain a wholesaler license, and undertake the burden of redistributing drugs to contract pharmacies.

F. Duplicate Discounts and Program Costs

39. I understand that Plaintiffs' lawsuit, if successful, will prevent the revised Pilot Program from going into effect as planned on January 1, 2027. A temporary delay or permanent cancellation of the Pilot Program would adversely affect AbbVie, because—among other

¹⁸ Generally, under AbbVie's current contract-pharmacy policy, covered entities may claim the 340B price only at their in-house pharmacy or at a single, designated commercial pharmacy.

reasons—AbbVie will be forced to pay duplicate MFP and 340B discounts or risk violating federal law.

40. In 2027, AbbVie will have three drugs subject to an MFP: Imbruvica, Linzess, and Vraylar. If AbbVie cannot determine and provide the applicable price for those drugs, it will face significant risk from federal enforcement actions and steep civil penalties. Alternatively, AbbVie will be forced to provide excess price concessions, by offering 340B pricing and MFP rebates on many covered entity purchases. This risk of excess price concessions is severe: IQVIA has estimated the overlap between 340B and Medicare to be up to 40% of claims.¹⁹ A separate review concluded that manufacturers paid duplicate MFP and 340B discounts on at least “30% of total claims.”²⁰

41. For example, to consider the impact with respect to just one of AbbVie’s products, U.S. net revenue for Vraylar through Q2 2026 was approximately \$1.97 billion.²¹ Relying on these figures projected forward, adjusted for overlapping 340B and MFP eligibility, and based on the assumption that AbbVie would pay duplicate MFP and 340B discounts on at least 30% of claims without the Pilot Program, I estimate that AbbVie would lose \$265,000 each week, \$1.1 million each month, and \$13.8 million unnecessarily over the course of 2027 to improper duplicate Vraylar discounts.

¹⁹ IQVIA, *Can 340B Modifiers Avoid Duplicate Discounts in the IRA?* (Feb. 28, 2023), <https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2023/can-340b-modifiers-avoid-duplicate-discounts-in-the-ira.pdf>.

²⁰ 340B Report, *40% of Claims Miss the Mark* (Mar. 5, 2026), <https://340breport.com/40-of-claims-miss-the-mark-sponcon-rxparadigm>.

²¹ AbbVie, *AbbVie Reports First-Quarter 2026 Financial Results* at 6 (Mar. 31, 2026), <https://investors.abbvie.com/news-releases/news-release-details/abbvie-reports-first-quarter-2026-financial-results> (“First Quarter Results”); AbbVie, *AbbVie Reports Second-Quarter 2026 Financial Results* at 7 (July 31, 2026), <https://investors.abbvie.com/news-releases/news-release-details/abbvie-reports-second-quarter-2026-financial-results> (“Second Quarter Results”).

42. I understand that it has been estimated that without the Pilot Program, manufacturers would lose approximately \$5 billion in duplicate 340B and DPNP discounts in 2027 alone.²² Overall, I estimate that AbbVie would lose \$689,000 each week, \$3.0 million each month, and \$35.8 million unnecessarily over the course of 2027 to improper duplicate discounts.

43. AbbVie has also invested substantial time and money preparing for the Pilot Program, expending countless hours and millions of dollars to ensure that it is able to effectuate the MFP and accurately deduplicate 340B and MFP pricing.

44. AbbVie does not require covered entities to engage with the Pilot Program. If a covered entity does not wish to participate in the pilot, it may still send prescriptions to one of the pharmacies or specialty pharmacies capable of dispensing Imbruvica, Linzess, and Vraylar without disrupting patient care; the patient will pay the same price, but the covered entity will simply not receive the benefit of the 340B discount.

45. AbbVie's Pilot Program plan must operate uniformly across all jurisdictions.

G. Inaccurate Estimates

46. I understand that several plaintiffs contend that the Pilot Program's rebate model will require covered entities to "float" large amounts of money to manufacturers. For example, I have reviewed the declaration of Chad Golder, prepared on October 7, 2026, in support of Plaintiffs' motion for a temporary restraining order, which states that "wholesaler payment terms are frequently five or seven days." Dkt. 2-5 ¶ 20. And the declaration of Matthew Marston states that Eastern Maine Medical Center has a 15-day payment window. Dkt. 2-6 ¶ 27. I do not believe those to be accurate representations of industry-standard wholesaler practices; based on my

²² BRG, *Update on Effectuation of the Maximum Fair Price in 2026 and Outlook for 2027* at 2 (Apr. 2026), https://media.thinkbrg.com/wp-content/uploads/2026/05/06130328/Effectuation-of-the-Maximum-Fair-Price-in-2026-and-Outlook-to-2027_5.6.26.pdf.

experience, they are likely to represent unusual circumstances or unsuccessful negotiation. It is my understanding that payment to a wholesaler typically comes due in 30 days, which is more than sufficient time to compile and submit the data necessary to receive a rebate before payment to a wholesaler comes due.

47. I further understand that under virtual inventory replenishment, covered entities dispense from neutral stock and order replacement drugs only after accumulating a full package of 340B-eligible dispenses. The 340B dispenses and supporting data therefore exist before the covered entity places a replenishment order. In my experience, under the virtual inventory replenishment model, covered entities can submit claims before or around the time of the replenishment WAC purchase, allowing rebates to arrive before wholesaler invoices become due.

48. I understand that one analysis has explained that “[u]nder both pre-MFP and MFP conditions, dispensing entities experience a negative cash-flow period between day 15, when the pharmacy pays its wholesaler for the drug, and day 30, when the payer reimburses the pharmacy for the drug.”²³ Accordingly, the cash-on-hand devoted to unrebated drug purchases will merely be the rolling balance awaiting a rebate. Negative cash flow is thus far more limited than is implied by Plaintiffs’ cash-outlay estimates.

49. I have reviewed the declaration of Trapper Denton, prepared on October 8, 2026, in support of Plaintiffs’ motion for a temporary restraining order. It states that before the prior iteration of the Pilot Program was to take effect, Dallas County Medical Center’s “wholesalers were not prepared to extend the credit limits DCMC needed on its 340B accounts to operationalize even the partial rebate program,” and that “[w]hen credit limits are exceeded, wholesalers stop

²³ IQVIA, *How will a Rebate Model Impact Cash Flow for Price Negotiated Drugs in Medicare Part D?* (Dec. 9, 2025), <https://www.iqvia.com/locations/united-states/library/white-papers/how-will-a-rebate-model-impact-cash-flow>.

fulfilling drug orders . . . for every 340B product DCMC purchases.” Dkt. 2-3 ¶ 23. It also asserts “[t]he cumulative working capital DCMC would be required to float throughout 2027 to drug manufacturers is therefore approximately \$1.5 million” and that “\$1.5 million diverted to manufacturers for rebate processing is simply not possible without borrowing” or reducing services. Dkt. 2-3 ¶¶ 19-20. As explained, however, the cash-on-hand devoted to unrebated drug purchases is the rolling balance awaiting a rebate. *See supra* ¶ 45. A figure stated in annual terms is likely to overestimate an entity’s financing burden.

50. In addition, the declaration of Robert Nahoopii hypothesizes that, because drugs are purchased at the package level but rebates are issued per unit, “[a] critical access hospital that must order a non-formulary medication to meet a single patient’s need will pay WAC for the entire package, but it might only dispense one dose from the package and receive a rebate on that one dose.” Dkt. 2-8 ¶ 29. Under the current replenishment model, however, a hospital buys a package of drugs at commercial prices and receives no subsidy until a full package of eligible dispenses has accumulated. To the extent the medication was not normally dispensed by the hospital, it may never accumulate enough dispenses to obtain the 340B price. In that hypothetical case, the Pilot Program’s per-unit rebates are likely to improve a covered entity’s position.

51. The declaration of Mark Bertilrud further states that “[s]ome manufacturers reserve the right to reject a 340B rebate claim when the drug is also subject to the MFP” while “[o]thers will pay the 340B rebate in full and instead reduce the maximum fair price.” Dkt. 2-2 ¶ 25. AbbVie’s approach is consistent with its statutory obligation to offer the 340B ceiling price when it is lower than the MFP, and to provide the MFP when it is lower than the 340B ceiling price. *See* Ex. B at 4.

* * *

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 14th day of October 2026.

/s/ Edward Scheidler

Edward Scheidler

Declarant

EXHIBIT A



340B Rebate Model Pilot Plan

AbbVie Inc. manufactures IMBRUVICA® (ibrutinib). The Centers for Medicare and Medicaid Services (CMS) refers to AbbVie's wholly owned subsidiary, Pharmacyclics LLC (Pharmacyclics), as the "primary manufacturer" of IMBRUVICA for purposes of the Inflation Reduction Act's Medicare Drug Price Negotiation Program (IRA's MDPNP). Nevertheless, we refer to AbbVie and Pharmacyclics LLC herein jointly as "AbbVie." IMBRUVICA was selected by CMS under the IRA's MDPNP for Initial Price Applicability Year 2026. AbbVie hereby submits this rebate model plan for participation in the Pilot for the NDC-11s associated with IMBRUVICA listed below:

IPAY	Selected Drug Name	NDC-11s
2026	IMBRUVICA	57962-0007-12
2026	IMBRUVICA	57962-0014-28
2026	IMBRUVICA	57962-0070-28
2026	IMBRUVICA	57962-0140-09
2026	IMBRUVICA	57962-0140-12
2026	IMBRUVICA	57962-0280-28
2026	IMBRUVICA	57962-0420-28

A. General Requirements:

Our proposed plan aligns with the Notice¹ criteria, as further described herein. Beginning January 1, 2027 (Effective Date), covered entities (CEs) seeking 340B pricing on purchases of IMBRUVICA may submit data through the Beacon Rebate Model platform (Beacon). Beacon is a web-based technology platform operated by Second Sight Solutions that supports the effectuation of a 340B rebate model. AbbVie will utilize Beacon to collect 340B claims data from CEs, validate eligibility of submitted data, facilitate payment of 340B rebates to 340B covered entities, provide data and reporting, and provide real-time access to 340B rebate status to 340B covered entities and manufacturers. AbbVie will provide CEs access to Beacon at no cost. In accordance with the Pilot as proposed by HRSA that recognizes compliance risks across the full range of CE settings in which IMBRUVICA is dispensed, AbbVie's plan is applicable to all CEs. On or before October 2, 2026, AbbVie will provide CEs notice of its approved Pilot plan by providing a publicly posted notice on Second Sight Solution's website. The notice will contain relevant information about AbbVie's approved plan, including instructions for registering for Beacon. AbbVie will also provide HRSA with a copy of their final approved plan for public posting on its website. Any changes to the approved plan will be submitted to Office of Pharmacy Affairs (OPA) for review and approval prior to implementation.

CEs that elect to submit 340B claims data must first register with Beacon by navigating to <http://cm.beaconchannelmanagement.com/> and completing the registration process. Use of Beacon is governed by the Terms of Use and Privacy Policy which are available at <http://cm.beaconchannelmanagement.com/>. To comply with federal law and financial institution requirements, Second Sight requires that new users complete a Know Your Business (KYB) verification process which includes the submission of certain legal documents, such as Articles of Incorporation and IRS letter CP 575. Once a new account has been verified, additional users may be given access to the Beacon account by the initial registrant. Users must also submit bank account information for

¹ 340B Program Notice: Notice regarding 340B Rebate Model Pilot Program, 91 Fed. Reg. 48883 (Aug. 3, 2026)



ACH payments, which is verified according to financial institution requirements. Verification includes the submission of a bank letter and performance of a standard penny test.

CEs that have previously registered on Beacon during the initial iteration of the rebate pilot in 2025 will need to re-confirm documentation to ensure no information has changed. Additionally, to ensure payment can be made in a timely manner, Beacon is requiring these CEs to submit an updated bank letter and will send additional micro-deposits for verification.

Beginning on the Effective Date, all eligible orders of the NDC-11s associated with IMBRUVICA must be placed through a CE's 340B wholesale account. AbbVie will update its wholesaler pricing files to reflect Wholesale Acquisition Cost (WAC) in 340B wholesale accounts so that the 340B ceiling price is effectuated via rebate. AbbVie will make the ceiling price available via rebate only and will issue such rebates to a CE through a rebate payment to the CE via Beacon.

AbbVie will provide ongoing technical assistance, customer service, and educational resources to CEs via Beacon at no cost. Beacon's Customer Support Team is trained to engage with CEs and address questions or concerns arising from their use of Beacon for 340B rebate payments. In addition to the education and support provided through Beacon, AbbVie will offer direct educational opportunities to CEs regarding program implementation, operational requirements, and other topics relevant to participation in AbbVie's 340B rebate model. The Beacon Customer Support Team is available Monday to Friday from 9 am to 9 pm ET, via phone, web chat or email. Support topics may range from technical (e.g., How do I use Beacon?) to policy (e.g., Why was my 340B rebate determined to be ineligible?) to financial (Was my 340B rebate payment made?) in nature. Beacon will work in coordination with AbbVie to provide accurate and timely responses. Education and customer support information is provided proactively through online resources, pre-recorded training webinars and live training sessions as well as reactively through responses to inbound calls, emails, and chats. For additional information, please visit <https://cm.beaconchannelmanagement.com/pages/support-center>.

Beacon is committed to responding to CE inquiries within 24 hours of receipt of the inquiry and the Beacon Customer Support Team will work to resolve inquiries as quickly as possible. As Beacon interacts with CEs, the Beacon Customer Support Team may request additional information from the CE to properly understand and evaluate the concern. Data on CE inquiries is analyzed to identify themes and trends and may result in process or technology updates intended to address common questions raised by CEs.

During registration and throughout the Pilot, AbbVie requests that CEs engage in good faith communication with the Beacon Customer Support Team as an initial step in resolving questions or challenging denied claims, including before reporting denied rebates through HRSA's dispute process. Unresolved matters may be escalated to AbbVie's Head of 340B Center of Excellence at 340BRebateModel@abbvie.com for resolution. Engaging with the Beacon Customer Support Team directly will ensure documentation is available to inform any dispute resolution and provide a mechanism to resolve issues without unnecessarily using government resources. AbbVie and Beacon will coordinate to provide timely responses and additional information as required to assist in the resolution of denied rebate claims.

Beacon has implemented a robust data security and privacy framework to support the rebate model. In addition, Beacon provides resources on [beaconchannelmanagement.com](https://cm.beaconchannelmanagement.com) under Trust Center² and Support Center³.

² <https://cm.beaconchannelmanagement.com/pages/trust-center>

³ <https://cm.beaconchannelmanagement.com/pages/support-center>



Appendix I contains additional platform information describing Beacon's data security and privacy controls. If OPA has additional questions, AbbVie will provide more information.

B. Reporting Requirements:

CEs can submit data to Beacon either directly or through participating third-party administrators (TPAs) up to 45 calendar days from the date of dispense. Beacon's validation process will confirm that no submission exceeds 45 calendar days from the date of dispense. A CE seeking an exception to this deadline for extenuating circumstances may request an exception by contacting the Beacon Customer Support Team. AbbVie will evaluate exception requests on a case-by-case basis in accordance with AbbVie's standard business practices and may grant allowances for extenuating circumstances and other exceptions identified in the Notice, including but not limited to, operational hardships faced by certain CEs without access to a TPA such as rural hospitals, health centers, or AIDS Drug Assistance Programs (ADAPs). Exceptions for a retroactive change in a claim's 340B status will generally be considered where the request is accompanied by a documented extenuating circumstance. AbbVie also reserves the right, in its discretion, to exempt a CE from any requirement of this plan where a hardship exception is warranted.

The data collected by Beacon for IMBRUVICA dispenses will be proactively limited to HRSA-approved data fields. Regardless of data submission method, the same filtering, security, and privacy protocols apply as detailed in Appendix I. For online data submissions, client-side JavaScript functions exclude any non-IMBRUVICA records, ensuring data is filtered before its submission. Server-side validations ensure Beacon never possesses ineligible data. The TPA filtering process will use similar client-side technology provided by Beacon, ensuring filtering occurs before submission.

In Beacon, CEs will have access to real-time rebate status for submitted claims and payments made by Beacon. CEs should reverse any 340B claims submitted in error as soon as the error is discovered by submitting the same 340B rebate claim data with a negative unit amount. The reversal may generate a credit that will offset future 340B rebate payments. This process will be transparent to CEs in Beacon, and the Beacon Customer Support Team will be available to resolve any inquiries.

Through Beacon, AbbVie will provide CEs access to a quarterly pricing file containing 340B Package Pricing at the NDC-11 level. This will be available on Beacon for download on demand.

AbbVie will approve reports and will work with Beacon to send reports to HRSA/OPA consistent with the information outlined in the Notice, in the format, manner, and cadence specified by HRSA/OPA.

C. Rebates:

AbbVie and Beacon will facilitate payment of rebates to CEs on a per-unit-basis for validated claims of dispensed or administered IMBRUVICA. The rebate amount will be equal to WAC less the 340B ceiling price on the date of dispense. Rebates will be paid to CEs via Automated Clearinghouse (ACH) transfer through Beacon within 10 calendar days of receipt of a complete data submission, excluding federal holidays.

Denials will be processed in Beacon within 10 calendar days of receipt of the claim and will include documentation supporting the denial. If a claim is denied and then later resubmitted, Beacon will facilitate payment or re-denial (with documentation) within 10 calendar days of the receipt of the complete resubmission.



AbbVie encourages CEs to process any 340B-eligible accumulations or dispenses of IMBRUVICA prior to the Effective Date. AbbVie will accommodate up to 2 unreplenished accumulated packages per CE per NDC-11 for IMBRUVICA dispenses occurring during the 15 calendar days prior to the Effective Date, provided such dispenses have not otherwise been replenished through a 340B chargeback.

A 340B claim submission will be rejected if any of the required data elements in the submission are invalid or incomplete. A rebate claim submission by a CE will be deemed eligible for rebate payment when all of the following criteria and data validations set forth in Appendix II. AbbVie will notify the CE and HRSA in advance of any modifications to these criteria. A 340B rebate claim will not be rejected for diversion or Medicaid duplicate discounts.

At this time, AbbVie intends to address identified duplication between 340B and Maximum Fair Price (MFP), consistent with applicable law, CMS guidance, and AbbVie's MFP Effectuation Plan, by (i) rejecting or adjusting MFP rebate payments where the 340B ceiling price is lower than the MFP, including through the Medicare Transaction Facilitator (MTF) credit/debit ledger; or, (ii) where the MFP is lower than the 340B ceiling price, AbbVie may reject the 340B rebate claim. As documentation for each claim rejection, AbbVie will provide a rejection code identifying that the rejection is attributable to MFP/340B duplication with a brief description, which will be visible to CEs in Beacon. AbbVie may determine or modify the applicable approach, including following an initial observability period, based on available data and operational considerations.

The integrity of the data submitted to Beacon is crucial to achieving the Pilot's intended goal of minimizing duplication between 340B and MFP discounts. As such, AbbVie will regularly monitor rebate submissions to ensure that key data elements (Prescription Number, Pharmacy ID, Dispense Date, etc.) are not altered from their native values. Evidence of data integrity concerns will be promptly raised with CEs and/or HRSA.

In addition, AbbVie will continually monitor instances where non-WAC purchases were used for 340B rebate submission, deny any such rebate requests, and will immediately raise such deviations with the appropriate CE and HRSA.

Beacon allows for the resubmission of claims data, within the 45-day submission window, when a rebate claim request is deemed incomplete or fails certain validations. Good faith questions or other concerns will be addressed through the Beacon Customer Support Team and may be escalated to AbbVie's Head of 340B Center of Excellence at 340BRebateModel@abbvie.com for resolution.

D. Data Fields:

For a complete listing of fields to be requested by AbbVie and collected through Beacon, as well as associated definitions, please see Appendix II. Requested data is limited to Pharmacy and Medical claims datasets.

For details associated with the submission of insurance fields for uninsured or cash paying patients, please see Appendix II. Because BIN is a numeric field within industry systems, the value "999999" is used in place of "CASH" to indicate a cash transaction.

AbbVie does not expect CEs to provide claims data regarding wasted or undispensed units of IMBRUVICA. Undispensed or unused IMBRUVICA held by a pharmacy prior to dispensing (e.g., expired stock or returns) should be addressed under the pharmacy's applicable purchase terms with its wholesaler or AbbVie.



Finally, AbbVie will use claims data submitted to Beacon for the purposes identified in the Pilot and purposes consistent with applicable law, including to identify and address duplicate discounts and diversion, or to support good faith inquiry or audits through existing regulatory processes. A 340B rebate claim will not be rejected for diversion or Medicaid duplicate discounts.



Appendix I – Beacon Functionality Overview

(Disclaimer: Appendix I provided by Second Sight Solutions. AbbVie has made no revisions to its contents.)

Beacon Overview

Beacon is a web-based technology platform that supports the effectuation of a 340B rebate model. Beacon is used to collect 340B claims from 340B covered entities, validate eligibility of submitted data, facilitate payment of 340B rebates to 340B covered entities, and provide real-time access to 340B rebate status to 340B covered entities and pharmaceutical manufacturers. Beacon is also utilized to provide reporting to HRSA. The information provided in this document is applicable to any pharmaceutical manufacturer that selects Beacon for its 340B rebate model effectuation.

Registration

340B covered entities that elect to submit 340B claims must first register with Beacon by navigating to <http://cm.beaconchannelmanagement.com> and completing the registration process. Registration with and use of Beacon by 340B covered entities is free of charge. Use of Beacon is governed by the Terms of Use and Privacy Policy which are available at <http://cm.beaconchannelmanagement.com>. To comply with federal law and financial institution requirements, Second Sight requires that new users complete a Know Your Business (KYB) verification process which includes the submission of certain legal documents such as Articles of Incorporation and IRS letter CP 575. Once a new account has been verified, additional users may be given access to the Beacon account by the initial registrant or subsequent assigned administrators.

Users must also submit bank account information for ACH payments which is verified according to financial institution requirements. Verification includes the submission of a bank letter and performance of a standard penny test.

Data Submission

340B covered entities can submit data online through Beacon or via a direct data submission process with participating third-party administrators (TPAs). Data submissions are proactively limited to only those data elements that have been approved by HRSA and 340B covered entities cannot inadvertently submit additional data elements that fall outside the scope of the 340B rebate model pilot. Regardless of whether data is submitted online or through a TPA, the same filtering, security and privacy protocols apply.

Data Filtering

Beacon collects data for only those NDCs for which a 340B rebate model pilot has been approved. For online data submissions, client-side JavaScript functions exclude from data submissions any records that include an NDC that has not been approved for a 340B rebate model pilot by HRSA. Client-side JavaScript functions ensure that the data is filtered prior to submission to Beacon and server-side validations ensure that Beacon is never in possession of the ineligible data. For direct data submissions by a TPA, the filtering process is executed by the TPA utilizing similar client-side technology provided by Second Sight, again ensuring that data filtering occurs prior to submission to Beacon.



Data Security

Beacon is hosted on Microsoft Azure, a premier cloud computing platform known for its reliability, scalability, and security. Beacon is distributed across multiple Azure Availability Zones, each a unique physical location comprising of one or more data centers within an Azure region. By distributing applications across multiple Availability Zones, Beacon can achieve high availability and fault tolerance for its service.

At the core of the Beacon platform is a strong commitment to data security. Second Sight builds and maintains the Beacon systems in alignment with industry-recognized frameworks such as the National Institute of Standards and Technology Cybersecurity Framework (NIST CSF) and Open Web Application Security Project (OWASP) best practices. Security is embedded throughout the software development lifecycle—from design and code reviews to deployment and monitoring. Second Sight follows secure coding standards and performs regular threat modeling, vulnerability scanning, and automated testing to ensure a robust security posture.

All data in Beacon is encrypted at rest and in transit using industry-standard protocols supporting the use of Transport Layer Security (TLS) 1.2+ or higher. Beacon services enforce mandatory Multi-Factor Authentication (MFA) to ensure a high level of security for end-users, providing email, SMS, and application-based authentication methods.

Second Sight engages established third-party risk and cybersecurity firms to perform annual internal, external, and web application penetration tests, along with comprehensive security assessments across all platforms and infrastructure.

In addition, Beacon has achieved SOC 1 and SOC 2 certification, demonstrating compliance with rigorous standards for security, availability and confidentiality.

To ensure the security of the Beacon Rebate Model Platform engagement from synthetic traffic, including but not limited to AI agents, bots, or emulated users, is prohibited platform behavior. Specific monitoring devices are in place to detect and stop this behavior to protect platform security for all users.

Data Privacy

Beacon is designed to operate without the use of any protected health information (PHI) as defined by the Health Information Portability and Accountability Act (HIPAA). Second Sight has received an expert determination from Dr. Brad Malin that the data collected through Beacon meets the definition of a De-Identified Dataset under HIPAA. As described in Dr. Malin's expert determination, the de-identification process occurs prior to the submission of data to Beacon. Furthermore, Second Sight does not reidentify this data and personnel with access to identifiable data do not also have access to de-identified data. De-identified datasets can be linked to other de-identified datasets but, as discussed in Dr. Malin's expert determination, this does not constitute a reidentification of data and no PHI is exposed through this linking process. Second Sight has utilized this deidentification process with 340B claims data submitted through 340B ESP since 2020 and has successfully ensured that no HIPAA violations have occurred.



Beacon also collects personally identifiable information (PII) including user's names and email addresses. This information is stored securely, and Second Sight complies with all applicable privacy laws. Additional information on how we collect, maintain and use PII is available in our Privacy Policy.

Rebate Payments and Reconciliation Data

Following the successful validation of 340B claim submissions according to the eligibility criteria approved by HRSA, Beacon initiates the rebate payment process. Rebates are priced based on the WAC price loaded to the 340B account and 340B Ceiling price as of the claim date of dispense. Rebate payments are transmitted to the 340B covered entity via an ACH payment within the time period approved by HRSA. The transaction ID of the rebate payment is appended to the 340B rebate record maintained in Beacon giving the 340B covered entity real-time access to reconciliation data in Beacon. Rebates that are determined to be ineligible are accessible in Beacon by the 340B covered entity and include detail on the eligibility determination.

In addition to accessing information online in Beacon, 340B covered entities can also download 340B rebate data for inclusion in their proprietary systems. Because 340B claims are de-identified prior to submission to the Beacon platform, a unique ID is appended to the data submission and made available to 340B covered entities immediately following the initial 340B claims submission. This unique ID allows 340B covered entities to link de-identified data maintained in Beacon with the identifiable data maintained in 340B covered entities' proprietary systems for reconciliation purposes.

Finally, Second Sight has communicated its willingness and has already begun to integrate directly with TPAs to simplify the reconciliation process. Second Sight will not charge TPAs for this integration service though 340B covered entities will have to approve any integrations with TPAs for their specific data.



Appendix II: Data Submission Fields, Definitions and Validations

(Disclaimer: Appendix II provided by Second Sight Solutions. AbbVie has made no revisions to its contents.)

Data Submissions

Pharmacy Claims

Field	Description	Data Type	Required
Date Of Service	Date on which the pharmacy filled the prescription.	Date	Y
Date Prescribed	Date the healthcare provider wrote the prescription.	Date	Y
Rx Number	The native (unmodified) prescription number for the prescription as generated by the pharmacy.	Numeric	Y
Fill Number	Indicates the number of times the prescription has been filled as of the current fill. For example, a value of "0" indicates that the prescription has not been filled previously and the current fill is the first one. The first refill would have a value of "1".	Numeric (0-99)	Y
NDC-11	The 11-digit National Drug Code which indicates the manufacturer, product, and commercial package size.	Numeric (11 Digits)	Y
Quantity	Number of units dispensed to the patient. Appropriate Units of Measure for each product will be provided within Beacon's NDC list.	Numeric	Y
Prescriber ID	National provider identifier (NPI) of the healthcare provider that wrote the prescription.	Numeric (10 Digits)	Y
Service Provider ID	NPI of the pharmacy that filled the prescription	Numeric (10 Digits)	Y
340B ID	HRSA assigned identifier of the 340B covered entity that designated the dispense as 340B.	Alpha/Numeric	Y
BIN Number	Prescription Drug Bank Identification Number for the primary payer. Enables pharmacies to electronically transmit data to the appropriate PBM for processing and reimbursement. If a patient is uninsured or a cash payer, mark "999999" in this field.	Numeric (6 Digits)	Y
PCN Number	Processor Control Number for the primary payer. Identifier used to determine which processor will handle a prescription drug claim. If a patient is uninsured or a cash payer, mark "CASH" in this field. If there is no PCN, mark "NONE" in this field.	Alpha/Numeric	Y

Medical Claims

Field	Description	Data Type	Required
Health Plan Name	Name of the patient's primary health insurance plan. If the patient is uninsured or a cash payer, mark "CASH" in this field. If no health plan information is recorded, mark "NONE" in this field.	Alpha/Numeric	Y
Health Plan ID	The identifier code of the patient's primary health insurance plan. If the patient is uninsured or a cash payer, mark "CASH" in this field. If no health plan information is recorded, mark "NONE" in this field.	Alpha/Numeric	Y
Health Plan ID Qualifier	The qualifier for the patient's health insurance plan ID.	Alpha/Numeric	
Service Provider ID	The NPI of the healthcare entity where the patient received the medication administration. For example, this could be the NPI of a hospital outpatient surgery center or the NPI of an outpatient infusion center.	Numeric (10 Digits)	Y
NDC-11	The 11-digit National Drug Code which indicates the manufacturer, product, and commercial package size.	Numeric (11 Digits)	Y
Quantity	The quantity of medication administered to the patient. Quantity must reflect standardized billing units as defined by NCPDP for the NDC-11.	Numeric	Y
Unit of Measure	UOM must be consistent with the standardized billing unit as defined by NCPDP for the NDC-11.	Alpha/Numeric	Y
Date of Service	Date on which the medication was administered to the patient.	Date	Y
Physician ID	The NPI of the healthcare provider who rendered or supervised the care reported on the claim.	Numeric (10 Digits)	Y
Claim Number	A unique identifier for a prescription and claim processor. This value should align with the Patient Control Number or Claim Submission ID, as set within provider systems and included on EDI 837 transmissions to payers (Form 1500 Box 26 or Claim 1450 Box 3).	Alpha/Numeric	Y
Claim Line Number	Identifies an individual line number on a claim. Line numbers distinguish services that are submitted on the same claim. Wastage Claims or undispensed units submitted should include a separate claim line number from the dispensed units.	Numeric	Y
340B ID	HRSA assigned identifier of the 340B covered entity that designated the administration as 340B.	Alpha/Numeric	Y



Validations

Pharmacy Claim Validations

Validation	Description
<i>Front End Validations</i>	
Ineligible Product	NDC submitted must be subject to manufacturer policy.
Invalid [Field]	Entry must meet field requirements, e.g., NPI must be 10 digits.
Policy Exception	If an entity has a policy exception and is not eligible for rebates via Beacon, no submissions will be accepted where entity has been exempted
Registered User	Submission must be for 340B ID registered to User
<i>Back End Validations</i>	
Claim Expired	Claim submission date must be within X days after the Date of Service where X is determined by manufacturer policy.
Pharmacy Eligibility	The Service Provider ID must meet the following conditions as of the Date of Service: 1. Active and included within the NCPDP and NPDES databases, 2. A valid Covered Entity site, shipping address, or contract pharmacy according to HRSA OPA enrollment data, or 3. Eligible to dispense 340B-priced drugs according to the manufacturer's contract pharmacy policy.
CE Eligibility - Date	Covered Entity is active in HRSA OPAIS at Date of Service.
CE Eligibility - Orphan Drug	If an NDC is identified as an orphan drug, and the manufacturer does not voluntarily offer 340B pricing for certain hospital types (e.g., SCH, CAN, CAH, RRC), claims from these hospital types will not be accepted.
Aberrant Quantity	Quantity submitted must align with standard dispensing guidelines, consistent with manufacturer commercial business practices. Aberrant Ceiling: Claim quantity cannot be equal to or greater than the maximum aberrant quantity for the NDC. Aberrant Partial: Claim quantity cannot be a partial number listed for the NDC, e.g. Per NDC, the submitted quantities must be multiples of expected quantities.
NDC Expiration	Claim Date of Service must be prior to the final product expiration date for the NDC.
Prescriber ID - Provider	Prescriber ID must be in the NPI registry as a provider.
Prescriber ID - Active	Prescriber ID must be active in the NPI registry at Date of Service.
Network Eligibility	Service Provider ID must be included in the dispensed drug's Limited Distribution Network, if applicable to the NDC.
Pre-Policy Claim	Claim must have Date of Service on or after policy start, exempting specifically permitted pre-policy claims.
Duplicate - One Entity	Duplicate check is performed on distinct claim fields against past conforming claims submitted to the platform by that covered entity. Distinct claim: Date of Service, Service Provider ID, NDC, Rx Number.
Duplicate - Multiple Entities	When the same claim is submitted by multiple covered entities, the first conforming claim submitted in Beacon will be considered valid. Subsequent submissions will be considered invalid.

* AbbVie's 340B Integrity Initiative ("manufacturer's contract pharmacy policy") can be found at <https://340besp.com/resources>

abbvie

Medical Claim Validations

Validation	Description
<i>Front End Validations</i>	
Ineligible Product	NDC submitted must be subject to manufacturer policy.
Invalid [Field]	Entry must meet field requirements, e.g., NPI must be 10 digits.
Policy Exception	If an entity has a policy exception and is not eligible for rebates via Beacon, no submissions will be accepted where entity has been exempted
Registered User	Submission must be for 340B ID registered to User
<i>Back End Validations</i>	
Claim Expired	Claim submission date must be within X days after the Date of Service where X is determined by manufacturer policy.
Pharmacy Eligibility	The Service Provider ID must meet the following conditions as of the Date of Service: 1. Active and included within the NCPDP and NPDES databases, 2. A valid Covered Entity site, shipping address, or contract pharmacy according to HRSA OPA enrollment data, or 3. Eligible to dispense 340B-priced drugs according to the manufacturer's contract pharmacy policy.
Prescriber ID - Provider	Prescriber ID must be in the NPI registry as a provider.
Prescriber ID - Active	Prescriber ID must be active in the NPI registry at Date of Service.
CE Eligibility - Date	Covered Entity is active in HRSA OPAIS at Date of Service.
CE Eligibility - Orphan Drug	If an NDC is identified as an orphan drug, and the manufacturer does not voluntarily offer 340B pricing for certain hospital types (e.g., SCH, CAN, CAH, RRC), claims from these hospital types will not be accepted.
Aberrant Quantity	Quantity submitted must align with standard dispensing practices, consistent with manufacturer commercial business practices. Aberrant Ceiling: Claim quantity cannot be equal to or greater than the maximum aberrant quantity for the NDC. Aberrant Partial: Claim quantity cannot be a partial number listed for the NDC, e.g. Per NDC, the submitted quantities must be multiples of expected quantities.
NDC Expiration	Claim Date of Service must be prior to the final product expiration date for the NDC.
Pre-Policy Claim	Claim must have Date of Service on or after policy start, exempting specifically permitted pre-policy claims.
Duplicate - One Entity	Duplicate check is performed on distinct claim fields against past conforming claims submitted to the platform by that covered entity. Distinct claim: Date of Service, Service Provider ID, NDC, Claim Number.
Duplicate - Multiple Entities	When the same claim is submitted by multiple covered entities, the first conforming claim submitted in Beacon will be considered valid. Subsequent submissions will be considered invalid.

* AbbVie's 340B Integrity Initiative ("manufacturer's contract pharmacy policy") can be found at <https://340besp.com/resources>

EXHIBIT B



340B Rebate Model Pilot Plan

AbbVie Inc. manufactures LINZESS® (linaclotide). LINZESS was selected by the Centers for Medicare and Medicaid Services (CMS) under the Inflation Reduction Act's Medicare Drug Price Negotiation Program (IRA's MDPNP) for Initial Price Applicability Year 2027. AbbVie hereby submits this rebate model plan for participation in the Pilot for the NDC-11s associated with LINZESS listed below:

IPAY	Selected Drug Name	NDC-11s
2027	LINZESS	00456-1201-30
2027	LINZESS	00456-1201-04
2027	LINZESS	00456-1201-07
2027	LINZESS	00456-1202-30
2027	LINZESS	00456-1202-04
2027	LINZESS	00456-1202-07
2027	LINZESS	00456-1203-30
2027	LINZESS	00456-1203-04
2027	LINZESS	00456-1203-07

A. General Requirements:

Our proposed plan aligns with the Notice¹ criteria, as further described herein. Beginning January 1, 2027 (Effective Date), covered entities (CEs) seeking 340B pricing on purchases of LINZESS may submit data through the Beacon Rebate Model platform (Beacon). Beacon is a web-based technology platform operated by Second Sight Solutions that supports the effectuation of a 340B rebate model. AbbVie will utilize Beacon to collect 340B claims data from CEs, validate eligibility of submitted data, facilitate payment of 340B rebates to 340B covered entities, provide data and reporting, and provide real-time access to 340B rebate status to 340B covered entities and manufacturers. AbbVie will provide CEs access to Beacon at no cost. In accordance with the Pilot as proposed by HRSA that recognizes compliance risks across the full range of CE settings in which LINZESS is dispensed, AbbVie's plan is applicable to all CEs. On or before October 2, 2026, AbbVie will provide CEs notice of its approved Pilot plan by providing a publicly posted notice on Second Sight Solution's website. The notice will contain relevant information about AbbVie's approved plan, including instructions for registering for Beacon. AbbVie will also provide HRSA with a copy of their final approved plan for public posting on its website. Any changes to the approved plan will be submitted to Office of Pharmacy Affairs (OPA) for review and approval prior to implementation.

CEs that elect to submit 340B claims data must first register with Beacon by navigating to <http://cm.beaconchannelmanagement.com/> and completing the registration process. Use of Beacon is governed by the Terms of Use and Privacy Policy which are available at <http://cm.beaconchannelmanagement.com/>. To comply with federal law and financial institution requirements, Second Sight requires that new users complete a Know Your Business (KYB) verification process which includes the submission of certain legal documents, such as Articles of Incorporation and IRS letter CP 575. Once a new account has been verified, additional users may be given access to the Beacon account by the initial registrant. Users must also submit bank account information for

¹ 340B Program Notice: Notice regarding 340B Rebate Model Pilot Program, 91 Fed. Reg. 48883 (Aug. 3, 2026)



ACH payments, which is verified according to financial institution requirements. Verification includes the submission of a bank letter and performance of a standard penny test.

CEs that have previously registered on Beacon during the initial iteration of the rebate pilot in 2025 will need to re-confirm documentation to ensure no information has changed. Additionally, to ensure payment can be made in a timely manner, Beacon is requiring these CEs to submit an updated bank letter and will send additional micro-deposits for verification.

Beginning on the Effective Date, all eligible orders of the NDC-11s associated with LINZESS must be placed through a CE's 340B wholesale account. AbbVie will update its wholesaler pricing files to reflect Wholesale Acquisition Cost (WAC) in 340B wholesale accounts so that the 340B ceiling price is effectuated via rebate. AbbVie will make the ceiling price available via rebate only and will issue such rebates to a CE through a rebate payment to the CE via Beacon.

AbbVie will provide ongoing technical assistance, customer service, and educational resources to CEs via Beacon at no cost. Beacon's Customer Support Team is trained to engage with CEs and address questions or concerns arising from their use of Beacon for 340B rebate payments. In addition to the education and support provided through Beacon, AbbVie will offer direct educational opportunities to CEs regarding program implementation, operational requirements, and other topics relevant to participation in AbbVie's 340B rebate model. The Beacon Customer Support Team is available Monday to Friday from 9 am to 9 pm ET, via phone, web chat or email. Support topics may range from technical (e.g., How do I use Beacon?) to policy (e.g., Why was my 340B rebate determined to be ineligible?) to financial (Was my 340B rebate payment made?) in nature. Beacon will work in coordination with AbbVie to provide accurate and timely responses. Education and customer support information is provided proactively through online resources, pre-recorded training webinars and live training sessions as well as reactively through responses to inbound calls, emails, and chats. For additional information, please visit <https://cm.beaconchannelmanagement.com/pages/support-center>.

Beacon is committed to responding to CE inquiries within 24 hours of receipt of the inquiry and the Beacon Customer Support Team will work to resolve inquiries as quickly as possible. As Beacon interacts with CEs, the Beacon Customer Support Team may request additional information from the CE to properly understand and evaluate the concern. Data on CE inquiries is analyzed to identify themes and trends and may result in process or technology updates intended to address common questions raised by CEs.

During registration and throughout the Pilot, AbbVie requests that CEs engage in good faith communication with the Beacon Customer Support Team as an initial step in resolving questions or challenging denied claims, including before reporting denied rebates through HRSA's dispute process. Unresolved matters may be escalated to AbbVie's Head of 340B Center of Excellence at 340BRebateModel@abbvie.com for resolution. Engaging with the Beacon Customer Support Team directly will ensure documentation is available to inform any dispute resolution and provide a mechanism to resolve issues without unnecessarily using government resources. AbbVie and Beacon will coordinate to provide timely responses and additional information as required to assist in the resolution of denied rebate claims.

Beacon has implemented a robust data security and privacy framework to support the rebate model. In addition, Beacon provides resources on [beaconchannelmanagement.com](https://cm.beaconchannelmanagement.com) under Trust Center² and Support Center³.

² <https://cm.beaconchannelmanagement.com/pages/trust-center>

³ <https://cm.beaconchannelmanagement.com/pages/support-center>



Appendix I contains additional platform information describing Beacon's data security and privacy controls. If OPA has additional questions, AbbVie will provide more information.

B. Reporting Requirements:

CEs can submit data to Beacon either directly or through participating third-party administrators (TPAs) up to 45 calendar days from the date of dispense. Beacon's validation process will confirm that no submission exceeds 45 calendar days from the date of dispense. A CE seeking an exception to this deadline for extenuating circumstances may request an exception by contacting the Beacon Customer Support Team. AbbVie will evaluate exception requests on a case-by-case basis in accordance with AbbVie's standard business practices and may grant allowances for extenuating circumstances and other exceptions identified in the Notice, including but not limited to, operational hardships faced by certain CEs without access to a TPA such as rural hospitals, health centers, or AIDS Drug Assistance Programs (ADAPs). Exceptions for a retroactive change in a claim's 340B status will generally be considered where the request is accompanied by a documented extenuating circumstance. AbbVie also reserves the right, in its discretion, to exempt a CE from any requirement of this plan where a hardship exception is warranted.

The data collected by Beacon for LINZESS dispenses will be proactively limited to HRSA-approved data fields. Regardless of data submission method, the same filtering, security, and privacy protocols apply as detailed in Appendix I. For online data submissions, client-side JavaScript functions exclude any non-LINZESS records, ensuring data is filtered before its submission. Server-side validations ensure Beacon never possesses ineligible data. The TPA filtering process will use similar client-side technology provided by Beacon, ensuring filtering occurs before submission.

In Beacon, CEs will have access to real-time rebate status for submitted claims and payments made by Beacon. CEs should reverse any 340B claims submitted in error as soon as the error is discovered by submitting the same 340B rebate claim data with a negative unit amount. The reversal may generate a credit that will offset future 340B rebate payments. This process will be transparent to CEs in Beacon, and the Beacon Customer Support Team will be available to resolve any inquiries.

Through Beacon, AbbVie will provide CEs access to a quarterly pricing file containing 340B Package Pricing at the NDC-11 level. This will be available on Beacon for download on demand.

AbbVie will approve reports and will work with Beacon to send reports to HRSA/OPA consistent with the information outlined in the Notice, in the format, manner, and cadence specified by HRSA/OPA.

C. Rebates:

AbbVie and Beacon will facilitate payment of rebates to CEs on a per-unit-basis for validated claims of dispensed or administered LINZESS. The rebate amount will be equal to WAC less the 340B ceiling price on the date of dispense. Rebates will be paid to CEs via Automated Clearinghouse (ACH) transfer through Beacon within 10 calendar days of receipt of a complete data submission, excluding federal holidays.

Denials will be processed in Beacon within 10 calendar days of receipt of the claim and will include documentation supporting the denial. If a claim is denied and then later resubmitted, Beacon will facilitate payment or re-denial (with documentation) within 10 calendar days of the receipt of the complete resubmission.



AbbVie encourages CEs to process any 340B-eligible accumulations or dispenses of LINZESS prior to the Effective Date. AbbVie will accommodate up to 2 unreplenished accumulated packages per CE per NDC-11 for LINZESS dispenses occurring during the 15 calendar days prior to the Effective Date, provided such dispenses have not otherwise been replenished through a 340B chargeback.

A 340B claim submission will be rejected if any of the required data elements in the submission are invalid or incomplete. A rebate claim submission by a CE will be deemed eligible for rebate payment when all of the following criteria and data validations set forth in Appendix 2. AbbVie will notify the CE and HRSA in advance of any modifications to these criteria. A 340B rebate claim will not be rejected for diversion or Medicaid duplicate discounts.

At this time, AbbVie intends to address identified duplication between 340B and Maximum Fair Price (MFP), consistent with applicable law, CMS guidance, and AbbVie's MFP Effectuation Plan, by (i) rejecting or adjusting MFP rebate payments where the 340B ceiling price is lower than the MFP, including through the Medicare Transaction Facilitator (MTF) credit/debit ledger; or, (ii) where the MFP is lower than the 340B ceiling price, AbbVie may reject the 340B rebate claim. As documentation for each claim rejection, AbbVie will provide a rejection code identifying that the rejection is attributable to MFP/340B duplication with a brief description, which will be visible to CEs in Beacon. AbbVie may determine or modify the applicable approach, including following an initial observability period, based on available data and operational considerations.

The integrity of the data submitted to Beacon is crucial to achieving the Pilot's intended goal of minimizing duplication between 340B and MFP discounts. As such, AbbVie will regularly monitor rebate submissions to ensure that key data elements (Prescription Number, Pharmacy ID, Dispense Date, etc.) are not altered from their native values. Evidence of data integrity concerns will be promptly raised with CEs and/or HRSA.

In addition, AbbVie will continually monitor instances where non-WAC purchases were used for 340B rebate submission, deny any such rebate requests, and will immediately raise such deviations with the appropriate CE and HRSA.

Beacon allows for the resubmission of claims data, within the 45-day submission window, when a rebate claim request is deemed incomplete or fails certain validations. Good faith questions or other concerns will be addressed through the Beacon Customer Support Team and may be escalated to AbbVie's Head of 340B Center of Excellence at 340BRebateModel@abbvie.com for resolution.

D. Data Fields:

For a complete listing of fields to be requested by AbbVie and collected through Beacon, as well as associated definitions, please see Appendix II. Requested data is limited to Pharmacy and Medical claims datasets.

For details associated with the submission of insurance fields for uninsured or cash paying patients, please see Appendix II. Because BIN is a numeric field within industry systems, the value "999999" is used in place of "CASH" to indicate a cash transaction.

AbbVie does not expect CEs to provide claims data regarding wasted or undispensed units of LINZESS. Undispensed or unused LINZESS held by a pharmacy prior to dispensing (e.g., expired stock or returns) should be addressed under the pharmacy's applicable purchase terms with its wholesaler or AbbVie.



Finally, AbbVie will use claims data submitted to Beacon for the purposes identified in the Pilot and purposes consistent with applicable law, including to identify and address duplicate discounts and diversion, or to support good faith inquiry or audits through existing regulatory processes. A 340B rebate claim will not be rejected for diversion or Medicaid duplicate discounts.



Appendix I – Beacon Functionality Overview

(Disclaimer: Appendix I provided by Second Sight Solutions. AbbVie has made no revisions to its contents.)

Beacon Overview

Beacon is a web-based technology platform that supports the effectuation of a 340B rebate model. Beacon is used to collect 340B claims from 340B covered entities, validate eligibility of submitted data, facilitate payment of 340B rebates to 340B covered entities, and provide real-time access to 340B rebate status to 340B covered entities and pharmaceutical manufacturers. Beacon is also utilized to provide reporting to HRSA. The information provided in this document is applicable to any pharmaceutical manufacturer that selects Beacon for its 340B rebate model effectuation.

Registration

340B covered entities that elect to submit 340B claims must first register with Beacon by navigating to <http://cm.beaconchannelmanagement.com> and completing the registration process. Registration with and use of Beacon by 340B covered entities is free of charge. Use of Beacon is governed by the Terms of Use and Privacy Policy which are available at <http://cm.beaconchannelmanagement.com>. To comply with federal law and financial institution requirements, Second Sight requires that new users complete a Know Your Business (KYB) verification process which includes the submission of certain legal documents such as Articles of Incorporation and IRS letter CP 575. Once a new account has been verified, additional users may be given access to the Beacon account by the initial registrant or subsequent assigned administrators.

Users must also submit bank account information for ACH payments which is verified according to financial institution requirements. Verification includes the submission of a bank letter and performance of a standard penny test.

Data Submission

340B covered entities can submit data online through Beacon or via a direct data submission process with participating third-party administrators (TPAs). Data submissions are proactively limited to only those data elements that have been approved by HRSA and 340B covered entities cannot inadvertently submit additional data elements that fall outside the scope of the 340B rebate model pilot. Regardless of whether data is submitted online or through a TPA, the same filtering, security and privacy protocols apply.

Data Filtering

Beacon collects data for only those NDCs for which a 340B rebate model pilot has been approved. For online data submissions, client-side JavaScript functions exclude from data submissions any records that include an NDC that has not been approved for a 340B rebate model pilot by HRSA. Client-side JavaScript functions ensure that the data is filtered prior to submission to Beacon and server-side validations ensure that Beacon is never in possession of the ineligible data. For direct data submissions by a TPA, the filtering process is executed by the TPA utilizing similar client-side technology provided by Second Sight, again ensuring that data filtering occurs prior to submission to Beacon.



Data Security

Beacon is hosted on Microsoft Azure, a premier cloud computing platform known for its reliability, scalability, and security. Beacon is distributed across multiple Azure Availability Zones, each a unique physical location comprising of one or more data centers within an Azure region. By distributing applications across multiple Availability Zones, Beacon can achieve high availability and fault tolerance for its service.

At the core of the Beacon platform is a strong commitment to data security. Second Sight builds and maintains the Beacon systems in alignment with industry-recognized frameworks such as the National Institute of Standards and Technology Cybersecurity Framework (NIST CSF) and Open Web Application Security Project (OWASP) best practices. Security is embedded throughout the software development lifecycle—from design and code reviews to deployment and monitoring. Second Sight follows secure coding standards and performs regular threat modeling, vulnerability scanning, and automated testing to ensure a robust security posture.

All data in Beacon is encrypted at rest and in transit using industry-standard protocols supporting the use of Transport Layer Security (TLS) 1.2+ or higher. Beacon services enforce mandatory Multi-Factor Authentication (MFA) to ensure a high level of security for end-users, providing email, SMS, and application-based authentication methods.

Second Sight engages established third-party risk and cybersecurity firms to perform annual internal, external, and web application penetration tests, along with comprehensive security assessments across all platforms and infrastructure.

In addition, Beacon has achieved SOC 1 and SOC 2 certification, demonstrating compliance with rigorous standards for security, availability and confidentiality.

To ensure the security of the Beacon Rebate Model Platform engagement from synthetic traffic, including but not limited to AI agents, bots, or emulated users, is prohibited platform behavior. Specific monitoring devices are in place to detect and stop this behavior to protect platform security for all users.

Data Privacy

Beacon is designed to operate without the use of any protected health information (PHI) as defined by the Health Information Portability and Accountability Act (HIPAA). Second Sight has received an expert determination from Dr. Brad Malin that the data collected through Beacon meets the definition of a De-Identified Dataset under HIPAA. As described in Dr. Malin's expert determination, the de-identification process occurs prior to the submission of data to Beacon. Furthermore, Second Sight does not reidentify this data and personnel with access to identifiable data do not also have access to de-identified data. De-identified datasets can be linked to other de-identified datasets but, as discussed in Dr. Malin's expert determination, this does not constitute a reidentification of data and no PHI is exposed through this linking process. Second Sight has utilized this deidentification process with 340B claims data submitted through 340B ESP since 2020 and has successfully ensured that no HIPAA violations have occurred.



Beacon also collects personally identifiable information (PII) including user's names and email addresses. This information is stored securely, and Second Sight complies with all applicable privacy laws. Additional information on how we collect, maintain and use PII is available in our Privacy Policy.

Rebate Payments and Reconciliation Data

Following the successful validation of 340B claim submissions according to the eligibility criteria approved by HRSA, Beacon initiates the rebate payment process. Rebates are priced based on the WAC price loaded to the 340B account and 340B Ceiling price as of the claim date of dispense. Rebate payments are transmitted to the 340B covered entity via an ACH payment within the time period approved by HRSA. The transaction ID of the rebate payment is appended to the 340B rebate record maintained in Beacon giving the 340B covered entity real-time access to reconciliation data in Beacon. Rebates that are determined to be ineligible are accessible in Beacon by the 340B covered entity and include detail on the eligibility determination.

In addition to accessing information online in Beacon, 340B covered entities can also download 340B rebate data for inclusion in their proprietary systems. Because 340B claims are de-identified prior to submission to the Beacon platform, a unique ID is appended to the data submission and made available to 340B covered entities immediately following the initial 340B claims submission. This unique ID allows 340B covered entities to link de-identified data maintained in Beacon with the identifiable data maintained in 340B covered entities' proprietary systems for reconciliation purposes.

Finally, Second Sight has communicated its willingness and has already begun to integrate directly with TPAs to simplify the reconciliation process. Second Sight will not charge TPAs for this integration service though 340B covered entities will have to approve any integrations with TPAs for their specific data.



Appendix II: Data Submission Fields, Definitions and Validations

(Disclaimer: Appendix II provided by Second Sight Solutions. AbbVie has made no revisions to its contents.)

Data Submissions

Pharmacy Claims

Field	Description	Data Type	Required
Date Of Service	Date on which the pharmacy filled the prescription.	Date	Y
Date Prescribed	Date the healthcare provider wrote the prescription.	Date	Y
Rx Number	The native (unmodified) prescription number for the prescription as generated by the pharmacy.	Numeric	Y
Fill Number	Indicates the number of times the prescription has been filled as of the current fill. For example, a value of "0" indicates that the prescription has not been filled previously and the current fill is the first one. The first refill would have a value of "1".	Numeric (0-99)	Y
NDC-11	The 11-digit National Drug Code which indicates the manufacturer, product, and commercial package size.	Numeric (11 Digits)	Y
Quantity	Number of units dispensed to the patient. Appropriate Units of Measure for each product will be provided within Beacon's NDC list.	Numeric	Y
Prescriber ID	National provider identifier (NPI) of the healthcare provider that wrote the prescription.	Numeric (10 Digits)	Y
Service Provider ID	NPI of the pharmacy that filled the prescription	Numeric (10 Digits)	Y
340B ID	HRSA assigned identifier of the 340B covered entity that designated the dispense as 340B.	Alpha/Numeric	Y
BIN Number	Prescription Drug Bank Identification Number for the primary payer. Enables pharmacies to electronically transmit data to the appropriate PBM for processing and reimbursement. If a patient is uninsured or a cash payer, mark "999999" in this field.	Numeric (6 Digits)	Y
PCN Number	Processor Control Number for the primary payer. Identifier used to determine which processor will handle a prescription drug claim. If a patient is uninsured or a cash payer, mark "CASH" in this field. If there is no PCN, mark "NONE" in this field.	Alpha/Numeric	Y

Medical Claims

Field	Description	Data Type	Required
Health Plan Name	Name of the patient's primary health insurance plan. If the patient is uninsured or a cash payer, mark "CASH" in this field. If no health plan information is recorded, mark "NONE" in this field.	Alpha/Numeric	Y
Health Plan ID	The identifier code of the patient's primary health insurance plan. If the patient is uninsured or a cash payer, mark "CASH" in this field. If no health plan information is recorded, mark "NONE" in this field.	Alpha/Numeric	Y
Health Plan ID Qualifier	The qualifier for the patient's health insurance plan ID.	Alpha/Numeric	
Service Provider ID	The NPI of the healthcare entity where the patient received the medication administration. For example, this could be the NPI of a hospital outpatient surgery center or the NPI of an outpatient infusion center.	Numeric (10 Digits)	Y
NDC-11	The 11-digit National Drug Code which indicates the manufacturer, product, and commercial package size.	Numeric (11 Digits)	Y
Quantity	The quantity of medication administered to the patient. Quantity must reflect standardized billing units as defined by NCPDP for the NDC-11.	Numeric	Y
Unit of Measure	UOM must be consistent with the standardized billing unit as defined by NCPDP for the NDC-11.	Alpha/Numeric	Y
Date of Service	Date on which the medication was administered to the patient.	Date	Y
Physician ID (Rendering Provider ID)	The NPI of the healthcare provider who rendered or supervised the care reported on the claim.	Numeric (10 Digits)	Y
Claim Number	A unique identifier for a prescription and claim processor. This value should align with the Patient Control Number or Claim Submission ID, as set within provider systems and included on EDI 837 transmissions to payers (Form 1500 Box 26 or Claim 1450 Box 3).	Alpha/Numeric	Y
Claim Line Number	Identifies an individual line number on a claim. Line numbers distinguish services that are submitted on the same claim. Wastage Claims or undispensed units submitted should include a separate claim line number from the dispensed units.	Numeric	Y
340B ID	HRSA assigned identifier of the 340B covered entity that designated the administration as 340B.	Alpha/Numeric	Y

Validations

Pharmacy Claim Validations

Validation	Description
<i>Front End Validations</i>	
Ineligible Product	NDC submitted must be subject to manufacturer policy.
Invalid [Field]	Entry must meet field requirements, e.g., NPI must be 10 digits.
Policy Exception	If an entity has a policy exception and is not eligible for rebates via Beacon, no submissions will be accepted where entity has been exempted
Registered User	Submission must be for 340B ID registered to User
<i>Back End Validations</i>	
Claim Expired	Claim submission date must be within X days after the Date of Service where X is determined by manufacturer policy.
Pharmacy Eligibility	The Service Provider ID must meet the following conditions as of the Date of Service: 1. Active and included within the NCPDP and NPDES databases, 2. A valid Covered Entity site, shipping address, or contract pharmacy according to HRSA OPA enrollment data, or 3. Eligible to dispense 340B-priced drugs according to the manufacturer's contract pharmacy policy.
CE Eligibility - Date	Covered Entity is active in HRSA OPAIS at Date of Service.
CE Eligibility - Orphan Drug	If an NDC is identified as an orphan drug, and the manufacturer does not voluntarily offer 340B pricing for certain hospital types (e.g., SCH, CAN, CAH, RRC), claims from these hospital types will not be accepted.
Aberrant Quantity	Quantity submitted must align with standard dispensing guidelines, consistent with manufacturer commercial business practices. Aberrant Ceiling: Claim quantity cannot be equal to or greater than the maximum aberrant quantity for the NDC. Aberrant Partial: Claim quantity cannot be a partial number listed for the NDC, e.g. Per NDC, the submitted quantities must be multiples of expected quantities.
NDC Expiration	Claim Date of Service must be prior to the final product expiration date for the NDC.
Prescriber ID - Provider	Prescriber ID must be in the NPI registry as a provider.
Prescriber ID - Active	Prescriber ID must be active in the NPI registry at Date of Service.
Network Eligibility	Service Provider ID must be included in the dispensed drug's Limited Distribution Network, if applicable to the NDC.
Pre-Policy Claim	Claim must have Date of Service on or after policy start, exempting specifically permitted pre-policy claims.
Duplicate - One Entity	Duplicate check is performed on distinct claim fields against past conforming claims submitted to the platform by that covered entity. Distinct claim: Date of Service, Service Provider ID, NDC, Rx Number.
Duplicate - Multiple Entities	When the same claim is submitted by multiple covered entities, the first conforming claim submitted in Beacon will be considered valid. Subsequent submissions will be considered invalid.

*AbbVie's 340B Integrity Initiative ("manufacturer's contract pharmacy policy") can be found at <https://340besp.com/resources>.

abbvie

Medical Claim Validations

Validation	Description
<i>Front End Validations</i>	
Ineligible Product	NDC submitted must be subject to manufacturer policy.
Invalid [Field]	Entry must meet field requirements, e.g., NPI must be 10 digits.
Policy Exception	If an entity has a policy exception and is not eligible for rebates via Beacon, no submissions will be accepted where entity has been exempted.
Registered User	Submission must be for 340B ID registered to User.
<i>Back End Validations</i>	
Claim Expired	Claim submission date must be within X days after the Date of Service where X is determined by manufacturer policy.
Pharmacy Eligibility	The Service Provider ID must meet the following conditions as of the Date of Service: 1. Active and included within the NCPDP and NPPES databases, 2. A valid Covered Entity site, shipping address, or contract pharmacy according to HRSA OPA enrollment data, or 3. Eligible to dispense 340B-priced drugs according to the manufacturer's contract pharmacy policy.
Prescriber ID (Rendering Provider ID) - Provider	Prescriber ID must be in the NPI registry as a provider.
Prescriber ID (Rendering Provider ID) - Active	Prescriber ID must be active in the NPI registry at Date of Service.
CE Eligibility - Date	Covered Entity is active in HRSA OPAIS at Date of Service.
CE Eligibility - Orphan Drug	If an NDC is identified as an orphan drug, and the manufacturer does not voluntarily offer 340B pricing for certain hospital types (e.g., SCH, CAN, CAH, RRC), claims from these hospital types will not be accepted.
Aberrant Quantity	Quantity submitted must align with standard dispensing practices, consistent with manufacturer commercial business practices. Aberrant Ceiling: Claim quantity cannot be equal to or greater than the maximum aberrant quantity for the NDC. Aberrant Partial: Claim quantity cannot be a partial number listed for the NDC, e.g. Per NDC, the submitted quantities must be multiples of expected quantities.
NDC Expiration	Claim Date of Service must be prior to the final product expiration date for the NDC.
Pre-Policy Claim	Claim must have Date of Service on or after policy start, exempting specifically permitted pre-policy claims.
Duplicate - One Entity	Duplicate check is performed on distinct claim fields against past conforming claims submitted to the platform by that covered entity. Distinct claim: Date of Service, Service Provider ID, NDC, Claim Number.
Duplicate - Multiple Entities	When the same claim is submitted by multiple covered entities, the first conforming claim submitted in Beacon will be considered valid. Subsequent submissions will be considered invalid.

*AbbVie's 340B Integrity Initiative ("manufacturer's contract pharmacy policy") can be found at <https://340besp.com/resources>.

EXHIBIT C

340B Rebate Model Pilot Plan

AbbVie Inc. manufactures VRAYLAR® (cariprazine). VRAYLAR was selected by the Centers for Medicare and Medicaid Services (CMS) under the Inflation Reduction Act's Medicare Drug Price Negotiation Program (IRA's MDPNP) for Initial Price Applicability Year 2027. AbbVie hereby submits this rebate model plan for participation in the Pilot for the NDC-11s associated with VRAYLAR listed below:

IPAY	Selected Drug Name	NDC-11s
2027	VRAYLAR	61874-0115-20
2027	VRAYLAR	61874-0115-30
2027	VRAYLAR	61874-0115-07
2027	VRAYLAR	61874-0115-17
2027	VRAYLAR	61874-0130-20
2027	VRAYLAR	61874-0130-07
2027	VRAYLAR	61874-0130-30
2027	VRAYLAR	61874-0145-07
2027	VRAYLAR	61874-0145-30
2027	VRAYLAR	61874-0160-07
2027	VRAYLAR	61874-0160-30
2027	VRAYLAR	61874-0250-30
2027	VRAYLAR	61874-0275-30
2027	VRAYLAR	61874-0115-11

A. General Requirements:

Our proposed plan aligns with the Notice¹ criteria, as further described herein. Beginning January 1, 2027 (Effective Date), covered entities (CEs) seeking 340B pricing on purchases of VRAYLAR may submit data through the Beacon Rebate Model platform (Beacon). Beacon is a web-based technology platform operated by Second Sight Solutions that supports the effectuation of a 340B rebate model. AbbVie will utilize Beacon to collect 340B claims data from CEs, validate eligibility of submitted data, facilitate payment of 340B rebates to 340B covered entities, provide data and reporting, and provide real-time access to 340B rebate status to 340B covered entities and manufacturers. AbbVie will provide CEs access to Beacon at no cost. In accordance with the Pilot as proposed by HRSA that recognizes compliance risks across the full range of CE settings in which VRAYLAR is dispensed, AbbVie's plan is applicable to all CEs. On or before October 2, 2026, AbbVie will provide CEs notice of its approved Pilot plan by providing a publicly posted notice on Second Sight Solution's website. The notice will contain relevant information about AbbVie's approved plan, including instructions for registering for Beacon. AbbVie will also provide HRSA with a copy of their final approved plan for public posting on its website. Any changes to the approved plan will be submitted to Office of Pharmacy Affairs (OPA) for review and approval prior to implementation.

¹ 340B Program Notice: Notice regarding 340B Rebate Model Pilot Program, 91 Fed. Reg. 48883 (Aug. 3, 2026)

CEs that elect to submit 340B claims data must first register with Beacon by navigating to <http://cm.beaconchannelmanagement.com/> and completing the registration process. Use of Beacon is governed by the Terms of Use and Privacy Policy which are available at <http://cm.beaconchannelmanagement.com/>. To comply with federal law and financial institution requirements, Second Sight requires that new users complete a Know Your Business (KYB) verification process which includes the submission of certain legal documents, such as Articles of Incorporation and IRS letter CP 575. Once a new account has been verified, additional users may be given access to the Beacon account by the initial registrant. Users must also submit bank account information for ACH payments, which is verified according to financial institution requirements. Verification includes the submission of a bank letter and performance of a standard penny test.

CEs that have previously registered on Beacon during the initial iteration of the rebate pilot in 2025 will need to re-confirm documentation to ensure no information has changed. Additionally, to ensure payment can be made in a timely manner, Beacon is requiring these CEs to submit an updated bank letter and will send additional micro-deposits for verification.

Beginning on the Effective Date, all eligible orders of the NDC-11s associated with VRAYLAR must be placed through a CE's 340B wholesale account. AbbVie will update its wholesaler pricing files to reflect Wholesale Acquisition Cost (WAC) in 340B wholesale accounts so that the 340B ceiling price is effectuated via rebate. AbbVie will make the ceiling price available via rebate only and will issue such rebates to a CE through a rebate payment to the CE via Beacon.

AbbVie will provide ongoing technical assistance, customer service, and educational resources to CEs via Beacon at no cost. Beacon's Customer Support Team is trained to engage with CEs and address questions or concerns arising from their use of Beacon for 340B rebate payments. In addition to the education and support provided through Beacon, AbbVie will offer direct educational opportunities to CEs regarding program implementation, operational requirements, and other topics relevant to participation in AbbVie's 340B rebate model. The Beacon Customer Support Team is available Monday to Friday from 9 am to 9 pm ET, via phone, web chat or email. Support topics may range from technical (e.g., How do I use Beacon?) to policy (e.g., Why was my 340B rebate determined to be ineligible?) to financial (Was my 340B rebate payment made?) in nature. Beacon will work in coordination with AbbVie to provide accurate and timely responses. Education and customer support information is provided proactively through online resources, pre-recorded training webinars and live training sessions as well as reactively through responses to inbound calls, emails, and chats. For additional information, please visit <https://cm.beaconchannelmanagement.com/pages/support-center>.

Beacon is committed to responding to CE inquiries within 24 hours of receipt of the inquiry and the Beacon Customer Support Team will work to resolve inquiries as quickly as possible. As Beacon interacts with CEs, the Beacon Customer Support Team may request additional information from the CE to properly understand and evaluate the concern. Data on CE inquiries is analyzed to identify themes and trends and may result in process or technology updates intended to address common questions raised by CEs.

During registration and throughout the Pilot, AbbVie requests that CEs engage in good faith communication with the Beacon Customer Support Team as an initial step in resolving questions or challenging denied claims, including before reporting denied rebates through HRSA's dispute process. Unresolved matters may be escalated to AbbVie's Head of 340B Center of Excellence at 340BRebateModel@abbvie.com for resolution. Engaging with

the Beacon Customer Support Team directly will ensure documentation is available to inform any dispute resolution and provide a mechanism to resolve issues without unnecessarily using government resources. AbbVie and Beacon will coordinate to provide timely responses and additional information as required to assist in the resolution of denied rebate claims.

Beacon has implemented a robust data security and privacy framework to support the rebate model. In addition, Beacon provides resources on [beaconchannelmanagement.com](https://cm.beaconchannelmanagement.com) under Trust Center² and Support Center³. Appendix I contains additional platform information describing Beacon's data security and privacy controls. If OPA has additional questions, AbbVie will provide more information.

B. Reporting Requirements:

CEs can submit data to Beacon either directly or through participating third-party administrators (TPAs) up to 45 calendar days from the date of dispense. Beacon's validation process will confirm that no submission exceeds 45 calendar days from the date of dispense. A CE seeking an exception to this deadline for extenuating circumstances may request an exception by contacting the Beacon Customer Support Team. AbbVie will evaluate exception requests on a case-by-case basis in accordance with AbbVie's standard business practices and may grant allowances for extenuating circumstances and other exceptions identified in the Notice, including but not limited to, operational hardships faced by certain CEs without access to a TPA such as rural hospitals, health centers, or AIDS Drug Assistance Programs (ADAPs). Exceptions for a retroactive change in a claim's 340B status will generally be considered where the request is accompanied by a documented extenuating circumstance. AbbVie also reserves the right, in its discretion, to exempt a CE from any requirement of this plan where a hardship exception is warranted.

The data collected by Beacon for VRAYLAR dispenses will be proactively limited to HRSA-approved data fields. Regardless of data submission method, the same filtering, security, and privacy protocols apply as detailed in Appendix I. For online data submissions, client-side JavaScript functions exclude any non-VRAYLAR records, ensuring data is filtered before its submission. Server-side validations ensure Beacon never possesses ineligible data. The TPA filtering process will use similar client-side technology provided by Beacon, ensuring filtering occurs before submission.

In Beacon, CEs will have access to real-time rebate status for submitted claims and payments made by Beacon. CEs should reverse any 340B claims submitted in error as soon as the error is discovered by submitting the same 340B rebate claim data with a negative unit amount. The reversal may generate a credit that will offset future 340B rebate payments. This process will be transparent to CEs in Beacon, and the Beacon Customer Support Team will be available to resolve any inquiries.

Through Beacon, AbbVie will provide CEs access to a quarterly pricing file containing 340B Package Pricing at the NDC-11 level. This will be available on Beacon for download on demand.

AbbVie will approve reports and will work with Beacon to send reports to HRSA/OPA consistent with the information outlined in the Notice, in the format, manner, and cadence specified by HRSA/OPA.

² <https://cm.beaconchannelmanagement.com/pages/trust-center>

³ <https://cm.beaconchannelmanagement.com/pages/support-center>

C. Rebates:

AbbVie and Beacon will facilitate payment of rebates to CEs on a per-unit-basis for validated claims of dispensed or administered VRAYLAR. The rebate amount will be equal to WAC less the 340B ceiling price on the date of dispense. Rebates will be paid to CEs via Automated Clearinghouse (ACH) transfer through Beacon within 10 calendar days of receipt of a complete data submission, excluding federal holidays.

Denials will be processed in Beacon within 10 calendar days of receipt of the claim and will include documentation supporting the denial. If a claim is denied and then later resubmitted, Beacon will facilitate payment or re-denial (with documentation) within 10 calendar days of the receipt of the complete resubmission.

AbbVie encourages CEs to process any 340B-eligible accumulations or dispenses of VRAYLAR prior to the Effective Date. AbbVie will accommodate up to 2 unreplenished accumulated packages per CE per NDC-11 for VRAYLAR dispenses occurring during the 15 calendar days prior to the Effective Date, provided such dispenses have not otherwise been replenished through a 340B chargeback.

A 340B claim submission will be rejected if any of the required data elements in the submission are invalid or incomplete. A rebate claim submission by a CE will be deemed eligible for rebate payment when all of the following criteria and data validations set forth in Appendix II.

AbbVie will notify the CE and HRSA in advance of any modifications to these criteria. A 340B rebate claim will not be rejected for diversion or Medicaid duplicate discounts.

At this time, AbbVie intends to address identified duplication between 340B and Maximum Fair Price (MFP), consistent with applicable law, CMS guidance, and AbbVie's MFP Effectuation Plan, by (i) rejecting or adjusting either MFP rebate payments where the 340B ceiling price is lower than the MFP, including through the Medicare Transaction Facilitator (MTF) credit/debit ledger; or, (ii) where the MFP is lower than the 340B ceiling price, AbbVie may reject the 340B rebate claim. As documentation for each claim rejection, AbbVie will provide a rejection code identifying that the rejection is attributable to MFP/340B duplication with a brief description, which will be visible to CEs in Beacon. AbbVie may determine or modify the applicable approach, including following an initial observability period, based on available data and operational considerations.

The integrity of the data submitted to Beacon is crucial to achieving the Pilot's intended goal of minimizing duplication between 340B and MFP discounts. As such, AbbVie will regularly monitor rebate submissions to ensure that key data elements (Prescription Number, Pharmacy ID, Dispense Date, etc.) are not altered from their native values. Evidence of data integrity concerns will be promptly raised with CEs and/or HRSA.

In addition, AbbVie will continually monitor instances where non-WAC purchases were used for 340B rebate submission, deny any such rebate requests, and will immediately raise such deviations with the appropriate CE and HRSA.

Beacon allows for the resubmission of claims data, within the 45-day submission window, when a rebate claim request is deemed incomplete or fails certain validations. Good faith questions or other concerns will be

addressed through the Beacon Customer Support Team and may be escalated to AbbVie's Head of 340B Center of Excellence at 340BRebateModel@abbvie.com for resolution.

D. Data Fields:

For a complete listing of fields to be requested by AbbVie and collected through Beacon, as well as associated definitions, please see Appendix II. Requested data is limited to Pharmacy and Medical claims datasets.

For details associated with the submission of insurance fields for uninsured or cash paying patients, please see Appendix II. Because BIN is a numeric field within industry systems, the value "999999" is used in place of "CASH" to indicate a cash transaction.

AbbVie does not expect CEs to provide claims data regarding wasted or undispensed units of VRAYLAR. Undispensed or unused VRAYLAR held by a pharmacy prior to dispensing (e.g., expired stock or returns) should be addressed under the pharmacy's applicable purchase terms with its wholesaler or AbbVie.

Finally, AbbVie will use claims data submitted to Beacon for the purposes identified in the Pilot and purposes consistent with applicable law, including to identify and address duplicate discounts and diversion, or to support good faith inquiry or audits through existing regulatory processes. A 340B rebate claim will not be rejected for diversion or Medicaid duplicate discounts.

Appendix I – Beacon Functionality Overview

(Disclaimer: Appendix I provided by Second Sight Solutions. AbbVie has made no revisions to its contents.)

Beacon Overview

Beacon is a web-based technology platform that supports the effectuation of a 340B rebate model. Beacon is used to collect 340B claims from 340B covered entities, validate eligibility of submitted data, facilitate payment of 340B rebates to 340B covered entities, and provide real-time access to 340B rebate status to 340B covered entities and pharmaceutical manufacturers. Beacon is also utilized to provide reporting to HRSA. The information provided in this document is applicable to any pharmaceutical manufacturer that selects Beacon for its 340B rebate model effectuation.

Registration

340B covered entities that elect to submit 340B claims must first register with Beacon by navigating to <http://cm.beaconchannelmanagement.com> and completing the registration process. Registration with and use of Beacon by 340B covered entities is free of charge. Use of Beacon is governed by the Terms of Use and Privacy Policy which are available at <http://cm.beaconchannelmanagement.com>. To comply with federal law and financial institution requirements, Second Sight requires that new users complete a Know Your Business (KYB) verification process which includes the submission of certain legal documents such as Articles of Incorporation and IRS letter CP 575. Once a new account has been verified, additional users may be given access to the Beacon account by the initial registrant or subsequent assigned administrators.

Users must also submit bank account information for ACH payments which is verified according to financial institution requirements. Verification includes the submission of a bank letter and performance of a standard penny test.

Data Submission

340B covered entities can submit data online through Beacon or via a direct data submission process with participating third-party administrators (TPAs). Data submissions are proactively limited to only those data elements that have been approved by HRSA and 340B covered entities cannot inadvertently submit additional data elements that fall outside the scope of the 340B rebate model pilot. Regardless of whether data is submitted online or through a TPA, the same filtering, security and privacy protocols apply.

Data Filtering

Beacon collects data for only those NDCs for which a 340B rebate model pilot has been approved. For online data submissions, client-side JavaScript functions exclude from data submissions any records that include an NDC that has not been approved for a 340B rebate model pilot by HRSA. Client-side JavaScript functions ensure that the data is filtered prior to submission to Beacon and server-side validations ensure that Beacon is never in possession of the ineligible data. For direct data submissions by a TPA, the filtering process is executed by the TPA utilizing similar client-side technology provided by Second Sight, again ensuring that data filtering occurs prior to submission to Beacon.

Data Security

Beacon is hosted on Microsoft Azure, a premier cloud computing platform known for its reliability, scalability, and security. Beacon is distributed across multiple Azure Availability Zones, each a unique physical location comprising of one or more data centers within an Azure region. By distributing applications across multiple Availability Zones, Beacon can achieve high availability and fault tolerance for its service.

At the core of the Beacon platform is a strong commitment to data security. Second Sight builds and maintains the Beacon systems in alignment with industry-recognized frameworks such as the National Institute of Standards and Technology Cybersecurity Framework (NIST CSF) and Open Web Application Security Project (OWASP) best practices. Security is embedded throughout the software development lifecycle—from design and code reviews to deployment and monitoring. Second Sight follows secure coding standards and performs regular threat modeling, vulnerability scanning, and automated testing to ensure a robust security posture.

All data in Beacon is encrypted at rest and in transit using industry-standard protocols supporting the use of Transport Layer Security (TLS) 1.2+ or higher. Beacon services enforce mandatory Multi-Factor Authentication (MFA) to ensure a high level of security for end-users, providing email, SMS, and application-based authentication methods.

Second Sight engages established third-party risk and cybersecurity firms to perform annual internal, external, and web application penetration tests, along with comprehensive security assessments across all platforms and infrastructure.

In addition, Beacon has achieved SOC 1 and SOC 2 certification, demonstrating compliance with rigorous standards for security, availability and confidentiality.

To ensure the security of the Beacon Rebate Model Platform engagement from synthetic traffic, including but not limited to AI agents, bots, or emulated users, is prohibited platform behavior. Specific monitoring devices are in place to detect and stop this behavior to protect platform security for all users.

Data Privacy

Beacon is designed to operate without the use of any protected health information (PHI) as defined by the Health Information Portability and Accountability Act (HIPAA). Second Sight has received an expert determination from Dr. Brad Malin that the data collected through Beacon meets the definition of a De-Identified Dataset under HIPAA. As described in Dr. Malin's expert determination, the de-identification process occurs prior to the submission of data to Beacon. Furthermore, Second Sight does not reidentify this data and personnel with access to identifiable data do not also have access to de-identified data. De-identified datasets can be linked to other de-identified datasets but, as discussed in Dr. Malin's expert determination, this does not constitute a reidentification of data and no PHI is exposed through this linking process. Second Sight has utilized this deidentification process with 340B claims data submitted through 340B ESP since 2020 and has successfully ensured that no HIPAA violations have occurred.

Beacon also collects personally identifiable information (PII) including user's names and email addresses. This information is stored securely, and Second Sight complies with all applicable privacy laws. Additional information on how we collect, maintain and use PII is available in our Privacy Policy.

Rebate Payments and Reconciliation Data

Following the successful validation of 340B claim submissions according to the eligibility criteria approved by HRSA, Beacon initiates the rebate payment process. Rebates are priced based on the WAC price loaded to the 340B account and 340B Ceiling price as of the claim date of dispense. Rebate payments are transmitted to the 340B covered entity via an ACH payment within the time period approved by HRSA. The transaction ID of the rebate payment is appended to the 340B rebate record maintained in Beacon giving the 340B covered entity real-time access to reconciliation data in Beacon. Rebates that are determined to be ineligible are accessible in Beacon by the 340B covered entity and include detail on the eligibility determination.

In addition to accessing information online in Beacon, 340B covered entities can also download 340B rebate data for inclusion in their proprietary systems. Because 340B claims are de-identified prior to submission to the Beacon platform, a unique ID is appended to the data submission and made available to 340B covered entities immediately following the initial 340B claims submission. This unique ID allows 340B covered entities to link de-identified data maintained in Beacon with the identifiable data maintained in 340B covered entities' proprietary systems for reconciliation purposes.

Finally, Second Sight has communicated its willingness and has already begun to integrate directly with TPAs to simplify the reconciliation process. Second Sight will not charge TPAs for this integration service though 340B covered entities will have to approve any integrations with TPAs for their specific data.

Appendix II: Data Submission Fields, Definitions and Validations

(Disclaimer: Appendix II provided by Second Sight Solutions. AbbVie has made no revisions to its contents.)

Data Submissions

Pharmacy Claims

Field	Description	Data Type	Required
Date Of Service	Date on which the pharmacy filled the prescription.	Date	Y
Date Prescribed	Date the healthcare provider wrote the prescription.	Date	Y
Rx Number	The native (unmodified) prescription number for the prescription as generated by the pharmacy.	Numeric	Y
Fill Number	Indicates the number of times the prescription has been filled as of the current fill. For example, a value of "0" indicates that the prescription has not been filled previously and the current fill is the first one. The first refill would have a value of "1".	Numeric (0-99)	Y
NDC-11	The 11-digit National Drug Code which indicates the manufacturer, product, and commercial package size.	Numeric (11 Digits)	Y
Quantity	Number of units dispensed to the patient. Appropriate Units of Measure for each product will be provided within Beacon's NDC list.	Numeric	Y
Prescriber ID	National provider identifier (NPI) of the healthcare provider that wrote the prescription.	Numeric (10 Digits)	Y
Service Provider ID	NPI of the pharmacy that filled the prescription	Numeric (10 Digits)	Y
340B ID	HRSA assigned identifier of the 340B covered entity that designated the dispense as 340B.	Alpha/Numeric	Y
BIN Number	Prescription Drug Bank Identification Number for the primary payer. Enables pharmacies to electronically transmit data to the appropriate PBM for processing and reimbursement. If a patient is uninsured or a cash payer, mark "999999" in this field.	Numeric (6 Digits)	Y
PCN Number	Processor Control Number for the primary payer. Identifier used to determine which processor will handle a prescription drug claim. If a patient is uninsured or a cash payer, mark "CASH" in this field. If there is no PCN, mark "NONE" in this field.	Alpha/Numeric	Y

Medical Claims

Field	Description	Data Type	Required
Health Plan Name	Name of the patient's primary health insurance plan. If the patient is uninsured or a cash payer, mark "CASH" in this field. If no health plan information is recorded, mark "NONE" in this field.	Alpha/Numeric	Y
Health Plan ID	The identifier code of the patient's primary health insurance plan. If the patient is uninsured or a cash payer, mark "CASH" in this field. If no health plan information is recorded, mark "NONE" in this field.	Alpha/Numeric	Y
Health Plan ID Qualifier	The qualifier for the patient's health insurance plan ID.	Alpha/Numeric	
Service Provider ID	The NPI of the healthcare entity where the patient received the medication administration. For example, this could be the NPI of a hospital outpatient surgery center or the NPI of an outpatient infusion center.	Numeric (10 Digits)	Y
NDC-11	The 11-digit National Drug Code which indicates the manufacturer, product, and commercial package size.	Numeric (11 Digits)	Y
Quantity	The quantity of medication administered to the patient. Quantity must reflect standardized billing units as defined by NCPDP for the NDC-11.	Numeric	Y
Unit of Measure	UOM must be consistent with the standardized billing unit as defined by NCPDP for the NDC-11.	Alpha/Numeric	Y
Date of Service	Date on which the medication was administered to the patient.	Date	Y
Physician ID	The NPI of the healthcare provider who rendered or supervised the care reported on the claim.	Numeric (10 Digits)	Y
Claim Number	A unique identifier for a prescription and claim processor. This value should align with the Patient Control Number or Claim Submission ID, as set within provider systems and included on EDI 837 transmissions to payers (Form 1500 Box 26 or Claim 1450 Box 3).	Alpha/Numeric	Y
Claim Line Number	Identifies an individual line number on a claim. Line numbers distinguish services that are submitted on the same claim. Wastage Claims or undispensed units submitted should include a separate claim line number from the dispensed units.	Numeric	Y
340B ID	HRSA assigned identifier of the 340B covered entity that designated the administration as 340B.	Alpha/Numeric	Y

Validations

Pharmacy Claim Validations

Validation	Description
<i>Front End Validations</i>	
Ineligible Product	NDC submitted must be subject to manufacturer policy.
Invalid [Field]	Entry must meet field requirements, e.g., NPI must be 10 digits.
Policy Exception	If an entity has a policy exception and is not eligible for rebates via Beacon, no submissions will be accepted where entity has been exempted
Registered User	Submission must be for 340B ID registered to User
<i>Back End Validations</i>	
Claim Expired	Claim submission date must be within X days after the Date of Service where X is determined by manufacturer policy.
Pharmacy Eligibility	The Service Provider ID must meet the following conditions as of the Date of Service: 1. Active and included within the NCPDP and NPDES databases, 2. A valid Covered Entity site, shipping address, or contract pharmacy according to HRSA OPA enrollment data, or 3. Eligible to dispense 340B-priced drugs according to the manufacturer's contract pharmacy policy.
CE Eligibility - Date	Covered Entity is active in HRSA OPAIS at Date of Service.
CE Eligibility - Orphan Drug	If an NDC is identified as an orphan drug, and the manufacturer does not voluntarily offer 340B pricing for certain hospital types (e.g., SCH, CAN, CAH, RRC), claims from these hospital types will not be accepted.
Aberrant Quantity	Quantity submitted must align with standard dispensing guidelines, consistent with manufacturer commercial business practices. Aberrant Ceiling: Claim quantity cannot be equal to or greater than the maximum aberrant quantity for the NDC. Aberrant Partial: Claim quantity cannot be a partial number listed for the NDC, e.g. Per NDC, the submitted quantities must be multiples of expected quantities.
NDC Expiration	Claim Date of Service must be prior to the final product expiration date for the NDC.
Prescriber ID - Provider	Prescriber ID must be in the NPI registry as a provider.
Prescriber ID - Active	Prescriber ID must be active in the NPI registry at Date of Service.
Network Eligibility	Service Provider ID must be included in the dispensed drug's Limited Distribution Network, if applicable to the NDC.
Pre-Policy Claim	Claim must have Date of Service on or after policy start, exempting specifically permitted pre-policy claims.
Duplicate - One Entity	Duplicate check is performed on distinct claim fields against past conforming claims submitted to the platform by that covered entity. Distinct claim: Date of Service, Service Provider ID, NDC, Rx Number.
Duplicate - Multiple Entities	When the same claim is submitted by multiple covered entities, the first conforming claim submitted in Beacon will be considered valid. Subsequent submissions will be considered invalid.

AbbVie's 340B Integrity Initiative ("manufacturer's contract pharmacy policy") can be found at <https://340besp.com/resources>.

Medical Claim Validations

Validation	Description
<i>Front End Validations</i>	
Ineligible Product	NDC submitted must be subject to manufacturer policy.
Invalid [Field]	Entry must meet field requirements, e.g., NPI must be 10 digits.
Policy Exception	If an entity has a policy exception and is not eligible for rebates via Beacon, no submissions will be accepted where entity has been exempted
Registered User	Submission must be for 340B ID registered to User
<i>Back End Validations</i>	
Claim Expired	Claim submission date must be within X days after the Date of Service where X is determined by manufacturer policy.
Pharmacy Eligibility	The Service Provider ID must meet the following conditions as of the Date of Service: 1. Active and included within the NCPDP and NPDES databases, 2. A valid Covered Entity site, shipping address, or contract pharmacy according to HRSA OPA enrollment data, or 3. Eligible to dispense 340B-priced drugs according to the manufacturer's contract pharmacy policy.
Prescriber ID - Provider	Prescriber ID must be in the NPI registry as a provider.
Prescriber ID - Active	Prescriber ID must be active in the NPI registry at Date of Service.
CE Eligibility - Date	Covered Entity is active in HRSA OPAIS at Date of Service.
CE Eligibility - Orphan Drug	If an NDC is identified as an orphan drug, and the manufacturer does not voluntarily offer 340B pricing for certain hospital types (e.g., SCH, CAN, CAH, RRC), claims from these hospital types will not be accepted.
Aberrant Quantity	Quantity submitted must align with standard dispensing practices, consistent with manufacturer commercial business practices. Aberrant Ceiling: Claim quantity cannot be equal to or greater than the maximum aberrant quantity for the NDC. Aberrant Partial: Claim quantity cannot be a partial number listed for the NDC, e.g. Per NDC, the submitted quantities must be multiples of expected quantities.
NDC Expiration	Claim Date of Service must be prior to the final product expiration date for the NDC.
Pre-Policy Claim	Claim must have Date of Service on or after policy start, exempting specifically permitted pre-policy claims.
Duplicate - One Entity	Duplicate check is performed on distinct claim fields against past conforming claims submitted to the platform by that covered entity. Distinct claim: Date of Service, Service Provider ID, NDC, Claim Number.
Duplicate - Multiple Entities	When the same claim is submitted by multiple covered entities, the first conforming claim submitted in Beacon will be considered valid. Subsequent submissions will be considered invalid.

AbbVie's 340B Integrity Initiative ("manufacturer's contract pharmacy policy") can be found at <https://340besp.com/resources>.

EXHIBIT D

April 20, 2026

VIA ELECTRONIC FILING TO:
www.regulations.gov

The Honorable Thomas J. Engels
Administrator
Health Resources and Services Administration
5600 Fishers Lane, Mail Stop 14W52
Rockville, MD 20857

Re: Request for Information: 340B Rebate Model Pilot Program and Request for Public Comment; HHS Docket No. HRSA-2026-03042

Dear Administrator Engels:

AbbVie Inc. (AbbVie) is pleased to provide comments in response to the Request for Information: 340B Rebate Model Pilot Program (HHS Docket No. HRSA-2026-03042) (RFI), which the Health Resources and Services Administration (HRSA) issued on February 17, 2026.¹

AbbVie is a biopharmaceutical company committed to discovering and delivering innovative medicines and solutions that solve serious health issues today and address the medical challenges of tomorrow. We strive to have a remarkable impact on people's lives across several key therapeutic areas including immunology, oncology, and neuroscience. AbbVie focuses on these areas to accelerate the development of innovative approaches to treat disease and to respond to unmet patient needs. AbbVie has a robust pipeline of potential new medicines, with the goal of finding solutions to address complex health issues and enhance people's lives.

AbbVie provided comments in response to HRSA's initial announcement of an application process for a 340B Rebate Model Pilot Program (Pilot Program) in 2025,² and intended to participate in the Pilot Program until that program was terminated. Without the ability to offer the 340B price as a rebate, AbbVie has no effective means to deduplicate maximum fair price (MFP) and 340B claims, which poses what is anticipated to be a growing, significant harm to the Company. While AbbVie does not view the 340B statute as requiring HRSA preapproval of a manufacturer rebate model, AbbVie urges HRSA to move quickly toward approving manufacturer proposals to use a Rebate Model. A Rebate Model is the most appropriate and effective means of preventing the duplicate discounts required by both the 340B statute and Inflation Reduction Act (IRA) and curbing other widespread abuses that undermine the 340B Program's patient-focused objectives.

¹ Request for Information: 340B Rebate Model Pilot Program, 91 Fed. Reg. 7287 (Feb. 17, 2026).

² 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program; Correction, 90 Fed. Reg. 38165 (Aug. 7, 2025).

Executive Summary:

AbbVie urges HRSA to approve a Rebate Model. Doing so will achieve:

- **Greater Program Integrity:** By tying 340B pricing to specific, verified patient dispenses, the Rebate Model is the most effective and efficient way to support statutory compliance by helping to prevent diversion and allowing manufacturers to deduplicate Medicaid and MFP claims.
- **Zero Harm to Covered Entities:** The data required is industry-standard (already collected and reported for Medicare/Medicaid/commercial payers). Rebates would be paid within 10 calendar days of a clean claim submission, which is faster than the current replenishment model and provides a way for covered entities to manage without impact to their cash flows.

To be successful, the model should allow for:

1. **Expeditious Action:** HRSA must act immediately to re-approve Rebate Models with an implementation date of no later than July 1, 2026, to support the statutory requirements of the 340B program and the IRA's nonduplication requirements.
2. **More Robust Data and Compliance:** HRSA should explicitly permit manufacturers to verify 340B rebates based on appropriate claims data fields, not just for MFP deduplication, but also to prevent Medicaid duplicate discounts and documented diversion.
3. **Federal Preemption:** At least 13 states have passed laws attempting to explicitly prohibit manufacturers from requiring claims data from covered entities. HRSA must clearly articulate that the federal 340B Rebate Model preempts these state laws, as they serve as a direct obstacle to federal program enforcement.

Overview:

Section I describes the 340B Program's integrity challenges—arising from the replenishment model, duplicate discounts, and diversion—and explains why the current system is not working. **Section II** outlines how a Rebate Model would help restore program integrity and have other potential benefits, at no cost to the federal government. **Section III** explains why a Rebate Model would not burden covered entities, which already collect and report similar data elements under other healthcare programs, and could benefit from faster access to 340B pricing than that available under the prevailing replenishment model. **Section IV** urges HRSA to clarify that a federal law preempts state laws that prohibit manufacturers from collecting necessary data and interfere with the administrative dispute resolution process. **Section V** urges HRSA to act expeditiously to balance the interests of all stakeholders, and to avoid significant delays in evaluating and announcing its decision on the new Rebate Model.

I. The 340B Program Faces Significant Program Integrity Challenges and Is Rife with Abuse (Questions 5 and 7)

The 340B Program has been operating for years beyond statutory authority and serving as a profit-maximizing opportunity for covered entities, rather than as Congress intended: to help ensure that vulnerable patients have appropriate access to care and medicines.³ At the root of many of the program integrity issues discussed below are a lack of transparency and covered entities' persistent efforts to maximize their financial benefit from the 340B Program.

Covered entities utilize models that perpetuate illegal duplicate discounting and diversion. A key example is the “replenishment model,” an inventory system that many covered entities and for-profit pharmacies utilize to manage 340B drug purchases. Under a replenishment model, the 340B price is not provided at the point of sale, but rather requested after the fact through a process that shrouds program abuse. More specifically, a covered entity, through its contract pharmacy, uses a neutral inventory to dispense drugs to both 340B patients and non-340B patients alike. Drugs purchased at both the 340B price and at other prices are intermingled within this common inventory. After deciding to seek 340B pricing for an already-dispensed prescription—sometimes weeks or months later—the covered entity seeks to “replenish” its stock at the 340B ceiling price. That 340B-priced drug is then placed back in the common, neutral inventory, intermingled with and indistinguishable from drugs purchased at non-340B prices. When the pharmacy dispenses a drug to a patient, the drug comes out of that neutral inventory and neither the pharmacist, covered entity, nor patient know whether the unit dispensed is a unit for which the covered entity is permitted to receive the 340B price. Eligibility for 340B pricing is thus determined only when the replenishment order is placed, which often occurs weeks, months, or even a year after the prescription is dispensed. More recently, covered entities are adopting novel systems, such as credit-based replenishment models⁴ and “alternative distribution” models⁵ that further reduce transparency and obfuscate the “ship to, bill to” process established under HRSA’s contract pharmacy guidance.⁶ These distribution models frustrate efforts to identify duplicate discounts and present significant diversion risks.

This section describes persistent abuses of the 340B Program, including covered entities seeking statutorily-prohibited duplicate discounts and diverting 340B medicines to individuals

³ H.R. Rep. 102-384(II) at 10–12 (1992). The purpose of the federal 340B Program is to “reduce pharmaceutical costs for safety-net medical providers and the indigent populations they serve” by creating “a low-cost source of pharmaceutical medication for the indigent patients themselves.” Connor J. Baer, *Drugs for the Indigent: A Proposal to Revise the 340B Drug Pricing Program*, 57 Wm. & Mary L. Rev. 637, 638 (2015) (footnote omitted).

⁴ AmeriSource Bergen, *Looking for a Way to Remove 340B Inventory Management Burdens*, <https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/340b/isp-virtual-replenishment-program-slick.pdf> (“Leveraging a credit-based approach, 340B drugs are purchased without the need for on-site storage”).

⁵ Verity, *Alternative Distribution*, <https://verity-solutions.com/solution/alternative-distribution/> (“Our Alternative Distribution Model (ADM) restores 340B savings benefits by shipping replenished drugs directly to the covered entity, then transferring them to a contract pharmacy for dispensing.”).

⁶ 75 Fed. Reg. 10272, 10277 (March 5, 2010).

who are not their “patients.” The current system does not adequately police abuses and creates strong financial incentives for covered entities to violate statutory requirements.

A. Governmental and Manufacturer Efforts to Prevent 340B and Medicaid Duplicate Discounts Have Been Ineffective

The 340B and Medicaid statutes include a longstanding prohibition on Medicaid and 340B duplicate discounts: It is a violation of the 340B statute to cause a drug manufacturer to pay both a Medicaid rebate and provide a 340B discount on the same unit of drug.⁷ Despite this clear statutory prohibition, duplicate discounting is pervasive, in part, due to a lack of proper regulatory oversight and adequate means for manufacturers to identify and prevent duplicate discounts.

1. HRSA’s Mechanism to Prevent Illegal 340B and Medicaid Duplicate Discounts Is Insufficient

HRSA’s current approach to preventing 340B and Medicaid duplicate discounts, the Medicaid Exclusion File (MEF), has proven inadequate. Currently, when a covered entity enrolls in the 340B Program, it must inform HRSA whether it will use 340B drugs for its Medicaid fee-for-service patients (carve-in) or whether it will purchase drugs for its Medicaid fee-for-service patients through other mechanisms (carve-out).⁸ If a covered entity carves-in, the covered entity’s billing number will be reflected in the MEF, which notifies state Medicaid agencies that drugs purchased under that billing number are not eligible for a Medicaid rebate. The MEF is of limited utility because the “data on the HRSA MEF applies to Medicaid fee-for-service only, and does not apply to Medicaid managed care organizations (MCOs),”⁹ which is the “dominant delivery system for people enrolled in Medicaid.”¹⁰ With approximately 78% of Medicaid beneficiaries—more than 66 million individuals—enrolled in risk-based, comprehensive MCOs,¹¹ the MEF captures only about 22% of beneficiaries in fee-for-service or other delivery arrangements.

Another significant gap is that the MEF does not list the billing number of a covered entity’s contract pharmacy. Although HRSA guidance recommends that covered entities, contract pharmacies, and states develop arrangements to prevent duplicate discounts,¹² the Government Accountability Office (GAO) and the Health and Human Services Office of Inspector General (HHS OIG) have found that these policies often fail to prevent duplicate discounts. For example, in a 2020 report, the GAO stressed that HRSA’s failure to “ensure that covered entities are

⁷ Public Health Service Act (PHSA) § 340B(a)(5).

⁸ HRSA, Duplicate Discount Prohibition, <https://www.hrsa.gov/opa/program-requirements/medicaid-exclusion>.

⁹ HRSA, Duplicate Discount Prohibition, <https://www.hrsa.gov/opa/program-requirements/medicaid-exclusion>.

¹⁰ KFF, 10 Things to Know About Medicaid Managed Care (Feb. 27, 2025), <https://www.kff.org/medicaid/10-things-to-know-about-medicicaid-managed-care/> (“The latest national Medicaid managed care enrollment data (from 2022) show 75% of Medicaid beneficiaries were enrolled in comprehensive managed care organizations (MCOs).”).

¹¹ KFF, 10 Things to Know About Medicaid Managed Care (Feb. 27, 2025), <https://www.kff.org/medicaid/10-things-to-know-about-medicicaid-managed-care/> (“The latest national Medicaid managed care enrollment data (from 2022) show 75% of Medicaid beneficiaries were enrolled in comprehensive managed care organizations (MCOs).”).

¹² HRSA, Notice Regarding 340B Drug Pricing Program – Contract Pharmacy Services, 75 Fed. Reg. 10272, 10278 (March 5, 2010).

complying with 340B Program requirements, including the prohibition on duplicate discounts in managed care . . . not only puts drug manufacturers at risk of providing duplicate discounts, but also compromises the integrity of the 340B Program.”¹³ The HHS OIG has expressed similar concerns, emphasizing that “claim level” methods are needed to “identify 340B drug claims and correctly collect rebates for MCO drugs.”¹⁴

GAO’s and HHS OIG’s concerns are supported by a Manatt survey, which reviewed states’ differing approaches to preventing 340B and Medicaid duplicate discounts.¹⁵ According to the survey, 12 states rely solely on the MEF to identify 340B drugs that are billed to Medicaid, with certain states having *no* policies or guidance for MCOs. The survey also found that there was “significant inconsistency” in how states identify duplicate discounts at contract pharmacies. The Manatt survey is consistent with AbbVie’s experience, described further below. We have observed that states also vary in how each operationalizes carve-in and carve-out policies, further complicating efforts to identify Medicaid duplicate discounts. For example, a covered entity may be listed as carved-in on the MEF, but contract pharmacy claims may not be clearly distinguishable at the claim level. Without appropriate actions to enforce federal law requirements and clarify how states, MCOs, and contract pharmacies identify and report 340B claims, duplicate discounts will continue to go undetected at scale — imposing unlawful costs on manufacturers and undermining the integrity of both the 340B program and the Medicaid Drug Rebate Program.

2. AbbVie’s Efforts to Prevent Illegal 340B and Medicaid Duplicate Discounts

AbbVie’s own efforts to prevent illegal duplicate discounts reinforce the stark inadequacy of HRSA oversight of this issue. AbbVie’s primary method of ensuring that it is not paying both 340B discounts and Medicaid rebates on the same unit of a drug is to review purchase data from covered entities and their contract pharmacies and to identify anomalies. AbbVie has committed substantial resources to this challenge, including employing a team of ten employees and engaging two vendors. The first vendor identifies potential duplicate discounts by comparing state-level Medicaid claim data against 340B chargeback data. However, 340B chargeback data may not contain sufficient identifiers to directly match against Medicaid rebate submissions without supplemental analytics because there is no universally applied 340B indicator that is consistently transmitted at the point of sale or in-state rebate invoicing. This creates particular issues with regard to contract pharmacy arrangements, where AbbVie must perform a secondary analysis with a different vendor to identify whether a claim is expected to be 340B-eligible. To that end, AbbVie has a policy of requiring covered entities to submit claims data for any contract pharmacy locations. This commitment to data transparency aligns with the broader national push for pricing accountability in healthcare — most recently reflected in President Trump’s Executive Order,

¹³ GAO, 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement, GAO-20-212, at 27 (Jan. 2020), <https://www.gao.gov/assets/gao-20-212.pdf>.

¹⁴ OIG, State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates, OEI-05-14-00430, at 2 (June 2016), <https://oig.hhs.gov/oei/reports/oei-05-14-00430.pdf>.

¹⁵ Manatt, *State Medicaid Programs and 340B: 50-State Survey Results* (Oct. 21, 2019), <https://www.manatt.com/insights/newsletters/health-highlights/state-medicare-programs-and-340b-50-state-survey-r>.

“Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Pricing Information,”¹⁶ which underscores that opaque arrangements in the healthcare system must be met with greater transparency and accountability. Despite this significant investment in resources, AbbVie has millions in disputed Medicaid duplicate discount claims activity that has remained unresolved for years, largely because covered entities refuse to work with AbbVie to comply with their statutory obligations.

Among our biggest challenges is access to data. AbbVie’s efforts to collect the data necessary to identify and prevent duplicate discounts have faced considerable pushback from covered entities. Although covered entities are statutorily-required to maintain auditable records sufficient to demonstrate compliance with all 340B requirements¹⁷, they have refused to provide basic data that would help manufacturers, like AbbVie, identify possible program abuse. Compliant covered entities have nothing to fear from transparency. If a hospital is not engaged in diversion or other 340B abuses, it should welcome the sharing of information necessary to ensure accurate Medicaid rebate payments. Opposition to that disclosure is itself evidence of a problem, and is flatly inconsistent with both the compliance assurances these entities made as a condition of 340B participation and the transparency priorities.

As discussed further in **Section IV**, our claims data policies have also been stymied by state laws prohibiting manufacturers from requiring covered entities to provide claims data—laws that are preempted by Section 340B. As one federal judge noted, when a manufacturer can only *request* the necessary data from covered entities, a covered entity can simply decline the request and

there is not much recourse available to a manufacturer. Instead, covered entities—who may be engaging in the kind of fraud that the 340B Program’s administrative dispute resolution [(ADR)] system is meant to prevent—will essentially be the ones determining whether or not they wish to give manufacturers the very data necessary to start such an audit. The 340B Program certainly did not establish a system where the fox guards the hen house.¹⁸

Yet such a system has emerged.

¹⁶ Exec. Order No. 14221, Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Pricing Information, 90 Fed. Reg. 11005 (Feb 28, 2025), <https://www.federalregister.gov/documents/2025/02/28/2025-03440/making-america-healthy-again-by-empowering-patients-with-clear-accurate-and-actionable-healthcare>.

¹⁷ PHSA § 340B(a)(5)(C)

¹⁸ *Pharma. Rsch. & Mfrs. of Am. v. Morrissey*, 760 F. Supp. 3d 439, 453 (S.D. W. Va. 2024), *aff’d sub. nom.*, *Pharma Rsch. & Mfrs. of Am. v. McCuskey*, No. 25-1054, --- F.4th ---, 2026 WL 898259, 2026 U.S. App. LEXIS 9272 (4th Cir. Mar. 31, 2026).

AbbVie also experiences challenges accessing timely and complete Medicaid claim-level data from states, which have varying policies. In many states, AbbVie is limited in its ability to accurately match claims; certain states do not routinely provide full claim-level data, provide it in non-standardized formats, or limit key data elements (e.g., prescriber, NPI, contract pharmacy indicator, 340B indicator).

Even when AbbVie does identify duplicate 340B and Medicaid rebate claims and provides claim-level evidence, some states have taken the position that the burden of correction rests solely with the covered entity — even if the covered entity complied with the state’s policies (e.g., covered entity is properly listed in the MEF). This can create a structural impasse for manufacturers, like AbbVie, who lack contractual privity with covered entities under the Medicaid Drug Rebate Program, leading to prolonged disputes and delays in repayment. In other circumstances, covered entities refuse to work directly with AbbVie to resolve validated duplicate discounts and direct AbbVie to individual states, each of which has its own process.

Of the Medicaid duplicate discounts that AbbVie has been able to identify approximately \$250 million remain unresolved with roughly 60% pending for over two years with no sign of resolution. The current system is not working, and as explained below, a Rebate Model would provide an effective and efficient means to prevent illegal 340B/Medicaid duplicate discounts.

B. The Inflation Reduction Act Compounds 340B Nonduplication Risks and Increases Financial Exposure

The IRA provides that the manufacturer of a selected drug is only required to provide access to the lower of the MFP or the 340B price, but is *not* required to provide both.¹⁹ In guidance, CMS has asserted that responsibility rests on “manufacturers [to] ensure that the appropriate price concession is honored.”²⁰ At the same time, the IRA guidance establishes a “14-day prompt MFP payment window,” which requires Primary Manufacturers to transfer MFP refunds within 14 days of receiving limited claims data elements from the Medicare Transaction Facilitator.²¹ Significantly, these data elements do not include a mandatory 340B claim identifier or any other information that would “constitute sufficient evidence that a claim was 340B-eligible.”²²

In failing to establish a mechanism to prevent duplication of the MFP and 340B ceiling price, CMS has ignored its obligation to comply with the statutorily-required pricing and nonduplication provisions of the IRA, leaving manufacturers in the untenable position of lacking access to the data necessary to provide such access. The statute’s use of the term “shall not be required”²³ does more than delineate the responsibilities of manufacturers participating in both the Medicare Drug Price Negotiation Program (“MDPNP”) and the 340B program; it also assigns to the agency, as the administrator of the MDPNP, a duty to ensure manufacturers are not subject to

¹⁹ Social Security Act (SSA) § 1193(d).

²⁰ CMS, *Drug Price Negotiation Program: IPAY 2028 Final Guidance*, § 40.4.5, p. 253 (Sep. 30, 2025) (“IPAY 2028 Final Guidance”), <https://edit.cms.gov/files/document/ipay-2028-final-guidance.pdf>.

²¹ *Id.* § 40.4.1.

²² *Id.* at 72. *See id.*, tbl. 2 at 219.

²³ SSA § 1193(d).

duplicative discounts under the MDPNP and 340B. A recent article published on 340B Report states that of claims reviewed by a vendor, manufacturers paid duplicate MFP and 340B discounts on 30% of claims.²⁴ BRG has estimated that the cost of duplicative discounts to manufacturers of selected drugs, without mediation, in just 2026 alone, would be *over \$4 billion*.²⁵ Not only are those duplicative discounts prohibited, but they also may result in confiscatory negative pricing for manufacturers. For example, if the wholesale acquisition cost for a drug is \$1,000, the MFP is \$500, and the 340B ceiling price is \$250; a manufacturer would be forced to provide \$1,250 in discounts on a drug that cost only \$1,000.²⁶

CMS's 14-day prompt pay window means manufacturers must be able to identify in real time whether a drug is eligible for MFP or 340B pricing, or both, and then effectuate that price. Manufacturers who fail to provide access to the MFP by CMS's deadline risk massive civil monetary penalties, equal to 10 times the difference between the amount charged and the MFP for each unit of drug sold.²⁷ The widespread use of "replenishment models," however, creates significant logistical challenges. Without timely access to claims information or a requirement for covered entities to identify 340B claims in real time, manufacturers have no way to determine whether a particular prescription was subject to a lower 340B price within the 14-day payment window.

Since the IRA passed, AbbVie has invested millions of dollars and countless hours preparing for MFP effectuation. AbbVie engaged in a two-year process, forming an expansive internal team that engaged a specialized vendor, and consistently worked with CMS to build a claims evaluation procedure through which AbbVie would provide the MFP on a unit of a selected drug. AbbVie also has spent years evaluating different options for 340B deduplication, including requiring covered entities to certify claims, a rebate model, and self-identification of 340B claims by covered entities. Without the Rebate Model pilot, manufacturers must resort to estimation methodologies derived from historical 340B purchasing patterns to reasonably determine if a claim may be subject to a 340B ceiling price that is duplicative of the MFP claim. Moreover, the available data is limited – it does not and cannot account for situations where more than one covered entity is replenishing the same specific claim at the 340B ceiling price.²⁸ In fact, the primary available

²⁴ 340B Report, *40% of Claims Miss the Mark* (Mar. 5, 2026), <https://340breport.com/40-of-claims-miss-the-mark-sponcon-rxparadigm>.

²⁵ BRG, *CMS October 2024 Final Guidance for MFP Effectuation in 2026-2027: Implications for Duplication with the 340B Channel* (2024), <https://media.thinkbrg.com/wp-content/uploads/2024/10/23161214/BRG-Implications-for-Duplication-with-the-340B-Channel-2024.pdf>.

²⁶ In recent litigation, covered entities have suggested that duplicative discounts would only be at issue if manufacturers were to make an MFP available retrospectively, or through a rebate. See Compl. ¶ 88, *The Am. Hosp. Ass'n v. Kennedy*, No. 25-cv-600 (D. Me.). That is not true. Even if a manufacturer were to provide the purchase of a drug subject to an MFP prospectively that discount would still have to be validated through the MTF as going to an MFP-eligible individual and the manufacturer would still need to determine if that same claim was also the subject of a request for a 340B discount. Because the current status quo does not have a required time period in which covered entities must assert a claim is eligible for a 340B discount, there is no way to determine the duplicative discount within the 14-day period in which manufacturers must provide MFP, regardless of whether the MFP price is provided prospectively or retrospectively.

²⁷ SSA § 1197(a).

²⁸ BRG, *340B Patient Definition Implications for Duplicate Replenishment* at 2 (2026), <https://media.thinkbrg.com/wp-content/uploads/2026/04/10141302/340B-Patient-Definition-and-Implications-for-Duplicate-Replenishment.pdf> (A recent analysis of "Medicare Part D Prescription Drug Event (PDE) data for 2024

data field in MFP refund claims that will enable manufacturers to even attempt to predict potential duplicate discounts with 340B is the National Provider Identifier (“NPI”). But CMS specifically noted in its Final Guidance that NPI alone provides an insufficient basis through which to deduplicate claims.²⁹

The reality is that manufacturers are not able to identify 340B claims and are certainly paying duplicate discounts. As of April 1, 2026, BRG conservatively estimates that where a claim was eligible for both MFP and a 340B discount, manufacturers to date have paid both rebates in 40% of cases.³⁰ Without a means to identify 340B claims and 15 more drugs becoming subject to MFP next January, this issue will continue to expand. The complexity of deduplication will be further compounded beginning in 2028, when Medicare Part B claims become subject to MFP. This distinction is significant: while 80,000-plus pharmacies submit claims under Part D³¹, there are over 1.5 million healthcare providers participating in Medicare Part B³². The dramatic expansion in the number of entities to which MFP must be effectuated will substantially increase the logistical burden on manufacturers and further complicates deduplication efforts.

An appropriate 340B Rebate Model is the only reliable and effective option to address deduplication. HRSA approved AbbVie’s application under the prior Pilot Program, which would have provided an effective solution if it had gone into effect. However, MFPs became effective starting on January 1, 2026, and, without the ability to use a Rebate Model, AbbVie has been left without an effective means to deduplicate MFP and 340B claims. AbbVie faces significant harms from this inability to deduplicate 340B/MFP claims, as required under the IRA.

Moreover, the lack of a clear and transparent process for nonduplication introduces significant inefficiencies, including the increased risk of disputes over the applicable price for a particular unit. Not only do these disputes delay payments to covered entities and pharmacies, but they also financially burden manufacturers, covered entities, dispensing entities and federal oversight and dispute resolution processes. To date, HHS has failed to establish any forum or mechanism through which disputes arising from MFP determinations can be resolved. Similarly, accurate deduplication would likely decrease the number of complaints regarding MFP availability submitted to the centralized intake system established by CMS by dispensing entities, reducing the burden on CMS to track and investigate such complaints.³³ By decreasing the need for these costly and burdensome dispute and complaint procedures, accurate deduplication of MFP and 340B ceiling price through a Rebate Model would increase overall efficiency across HHS. Not to mention that the increased transparency and integrity of the 340B program would likely reduce costs to the federal government across multiple programs—including Medicare, Medicaid and the 340B program, as discussed throughout this comment.

indicates that, if all covered entities used a three-year test to define “patient,” *which many covered entities have now adopted*, 20 percent of brand drug PDEs could be replenished by more than one covered entity.” (emphasis added)).

²⁹ IPAY 2028 Final Guidance at 254 § 40.4.5.

³⁰ See *supra* note 21.

³¹ 90 Fed. Reg. 15792, 15837 (April 15, 2025) (“currently approximately 60,000-plus community pharmacies and 80,000-plus dispensing entities in total” dispense drugs to Medicare Part D beneficiaries).

³² CMS, Fast Facts at 9 (April 2025), https://data.cms.gov/sites/default/files/2025-04/CMSFastFacts2025_508.pdf (lists 1,523,718 Total Providers)

³³ Final Guidance § 90.2.2 at 290.

We support HRSA's efforts to approve the use of a rebate model and urge the agency to move quickly. In the interim, AbbVie has invested significant time and research into evaluating alternative means by which it could identify duplicate discounts. The Beacon platform has implemented a self-identification option for claims submitted as MFP-eligible. But, BRG estimates that through the first quarter of 2026, only 1.5% of claims have been self-identified as 340B, confirming that such efforts do not work.

C. Manufacturers and HRSA Lack Effective Means to Prevent Diversion to Individuals Who Are Not “Patients” of a Covered Entity

The 340B statute prohibits covered entities from selling or otherwise transferring drugs purchased under the 340B Program to a person who is not a “patient” of the covered entity (a practice known as “diversion”).³⁴ Congress included that requirement to avoid the clear constitutional problems that would arise if other entities are permitted to participate in the program or benefit from the sale of manufacturers' drugs at steeply discounted prices. Unfortunately, HRSA has not enforced Congress's commands, and as a result, manufacturers' 340B-discounted drugs are frequently sold or transferred to non-patients—both individuals who are not eligible to receive drugs at the 340B price and third-party, for-profit entities that are not entitled to participate in the 340B Program.

The problem of diversion of 340B-priced drugs to individuals who cannot reasonably be considered “patients” of the covered entity is well-documented, but HRSA has failed to adequately address it.³⁵ Drug manufacturers are unable to combat diversion effectively because, as discussed above, covered entities do not provide them with the information they need to identify diversion. Manufacturers lack direct access to claims data that may enable them to identify that a drug was dispensed to an individual who is not a patient of the covered entity, and covered entities often intentionally thwart manufacturer efforts to obtain this information to resolve suspected diversion and duplicate discounting.³⁶ For example, manufacturers can investigate suspected diversion through the exercise of their statutory right to audit covered entities, but HRSA does not always approve a manufacturer's request to audit a covered entity. And, even in instances where HRSA found a manufacturer had reasonable cause to suspect diversion and approved the audit, covered entities have sued to prevent the manufacturer from exercising its rights.³⁷ Between the lack of

³⁴ PHSA § 340B(a)(5)(B).

³⁵ See, e.g., GAO, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sep. 2011) (recommends that HRSA “finalize new, more specific guidance on the definition of a 340B patient.”); HHS OIG, *Memorandum Report, Contract Pharmacy Arrangements in the 340B Program*, OEI-05-00431 (Feb. 2014) (“Covered entities in our study reported different methods of identifying 340B-eligible prescriptions, and in some cases their determinations of 340B eligibility differ from one covered entity to another for similar types of prescriptions. This suggests a lack of clarity on how HRSA's patient definition should be applied in contract pharmacy arrangements.”).

³⁶ See *Pharma Rsch. & Mfrs. of Am. v. McCuskey*, No. 25-1054, --- F.4th ---, 2026 WL 898259, 2026 U.S. App. LEXIS 9272, at *31-32 (4th Cir. Mar. 31, 2026) (explaining that a manufacturer will be unable to identify suspected diversion if it is unable to require covered entities to provide claims data).

³⁷ See, e.g., *Or. Health & Sci. Univ. v. Engels*, No. 24-cv-2184, 2025 WL 1707630 (D.D.C. June 17, 2025).

information and covered entity efforts to thwart manufacturers' attempts at identifying program abuse, the problem of diversion of 340B-priced drugs currently has no solution.

This problem is compounded by the fact that Section 340B does not expressly define the term "patient" leaving its meaning to be understood through statutory context and the application of tools of statutory construction. In 1996, HRSA issued non-binding guidance providing that an individual is a "patient" of a covered entity only if: (1) the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; (2) the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (*e.g.*, referral for consultation) such that responsibility for the care provided remains with the covered entity; and (3) the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-Qualified Health Center (FQHC) look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this third requirement.³⁸ Under HRSA's 1996 guidance, an individual will not be considered a "patient" of the covered entity if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.³⁹

HRSA's definition of the term patient has not changed since 1996, and it sweeps in individuals who cannot reasonably be considered "patients" of a covered entity consistent with the ordinary meaning of that term. In addition to being ambiguous, HRSA's "patient" guidance has failed to keep up with technology and changes in healthcare delivery (for example, the widespread use of telemedicine). Further, under the prevailing replenishment model, 340B-priced units inevitably end up in the hands of individuals who are not patients of the covered entity—despite Congress prohibiting covered entities from "transfer[ring] the drug to a person who is not a patient of the entity."⁴⁰ A recent analysis of "Medicare Part D Prescription Drug Event (PDE) data for 2024 indicates that, if all covered entities used a three-year test to define "patient," *which many covered entities have now adopted*, 20 percent of brand drug PDEs could be replenished by more than one covered entity.⁴¹ From that statutory directive, AbbVie strongly believes that Congress did not contemplate the replenishment model when it created the 340B Program.

HRSA audit results confirm significant instances of product diversion among audited covered entities. These abuses demonstrate that covered entities are accruing deeply discounted prices on purchases that are not dispensed to eligible patients. Worse yet, as again recognized by a recent Senate Report, covered entities are not sharing the discounts with the patients they serve or even to accounting for the discounts they receive in any public or transparent way.⁴² Because their diversion goes undetected and unpunished, covered entities have little incentive to

³⁸ 61 Fed. Reg. 55156, 55157–58 (Oct. 24, 1996).

³⁹ 61 Fed. Reg. at 55157–58.

⁴⁰ PHSA § 340B(a)(5)(B).

⁴¹ BRG, *340B Patient Definition Implications for Duplicate Replenishment* at 2 (2026), <https://media.thinkbrg.com/wp-content/uploads/2026/04/10141302/340B-Patient-Definition-and-Implications-for-Duplicate-Replenishment.pdf>.

⁴² Senate HELP Committee, *Congress Must Act to Bring Needed Reforms to the 340B Drug Pricing Program* (April 24, 2025) ("HELP Report"), https://www.help.senate.gov/imo/media/doc/final_340b_majority_staff_reportpdf.pdf.

(1) enact measures to ensure their 340B-priced drugs end up only in the hands of patients, as Congress intended, and (2) to share discounts with patients.

II. A Rebate Model Would Address 340B Program Integrity Issues

HRSA must take action to address persistent abuses of the 340B Program. A critical first step would be for HRSA to allow manufacturers to use a Rebate Model. This section describes the structure of a potential Rebate Model, including its potential uses and benefits, the minimum data elements necessary to determine whether a drug is 340B-eligible, the bases for denying rebates, and evaluations to ensure that a Rebate Model is operating as intended and to its fullest potential.

A. A Rebate Model is Needed Facilitate Compliance with Statutory Prohibitions Against Duplicate Discounting and Diversion (Question 7)

A Rebate Model would provide a mechanism to enforce statutory provisions that prohibit duplicate discounts and bring much-needed transparency to the 340B Program, in line with statutory requirements and HRSA's obligation as the agency charged with administering the 340B Program, at minimal cost to the federal government and covered entities. This section describes potential uses of a Rebate Model.

A Rebate Model is needed to facilitate compliance with the 340B duplicate discount prohibitions under Medicaid and the IRA. As discussed in **Section I**, currently, manufacturers have no reliable method to identify which discount to offer on a particular unit because the current system does not require covered entities to provide manufacturers with claims data. A Rebate Model is the only solution that can provide claims data and operate within the time constraints of the MDPNP to avoid duplicative payments. Under a Rebate Model, a manufacturer can evaluate whether a specific 340B rebate request is for a unit for which another drug discount was already paid. If that is the case, and a statutory duplicate discount prohibition applies (e.g., Medicaid, MFP), the manufacturer can avoid paying duplicate discounts. This is in stark contrast to the prevailing replenishment model, under which manufacturers lack this visibility and are reliant on covered entities to indicate whether a claim has already been subject to a different federal drug program discount. As the D.C. Circuit has noted, “[t]he covered entity, the pharmacy, and the third-party administrator often divvy up the spread between the discounted price and the higher insurance reimbursement rate.”⁴³ Accordingly, “[e]ach of these actors ... has a financial incentive to catalog as many prescriptions as possible as eligible for the discount.”⁴⁴ These financial incentives, combined with delays inherent under the replenishment model, fuel program abuses.

When it approved the Pilot Program last year, HRSA declined to permit manufacturers to use the Rebate Model to deny a 340B rebate when appropriate to prevent a Medicaid duplicate discount. Instead, HRSA stated that manufacturers could raise concerns regarding Medicaid

⁴³ *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 457 (D.C. Cir. 2024).

⁴⁴ *Id.* at 457–58.

duplicate discounts “directly with OPA [(the Office of Pharmacy Affairs)] or utilize the 340B statutory mechanisms, such as audits and administrative dispute resolution (ADR)[.]”⁴⁵ While AbbVie appreciates that these mechanisms have an appropriate place in 340B Program integrity, HRSA should not push for costly audits and ADR to resolve disputes when manufacturers can use the data available under a Rebate Model to identify and remedy clear instances of program abuse and statutory violations. Moreover, in a recent report, GAO found that despite repeated recommendations, “HRSA’s audits do not fully assess compliance with the program requirement that prohibits covered entities from subjecting manufacturers to duplicate discounts, in which drugs are subject to 340B discounted prices and rebates under the Medicaid program.”⁴⁶ Relying on the audit and ADR process to address duplicate discounts is not only inefficient, but also an ineffective use of governmental and stakeholder resources.

A Rebate Model could prevent diversion of 340B drugs. A Rebate Model could prevent diversion more effectively than under the prevailing replenishment model, because instead of the pharmacy dispensing from a neutral inventory where drugs purchased at 340B prices and other prices are intermingled and indistinguishable, with a Rebate Model, the drug for which the covered entity requests a rebate is tied to a dispensed claim. This would reduce the risk of diversion, ensuring that 340B-priced drugs go to the individuals whom Congress intended. Given the evidence of increasingly brazen diversion under the 340B statute, including multiple covered entities claiming the same dispense⁴⁷ and covered entities claiming dispenses for individuals who received care from unrelated providers in other states, it is essential that HRSA take action to address rampant diversion. AbbVie believes that it would be an inefficient and ineffective use of government and stakeholder resources if instances of diversion are adjudicated solely through the ADR process making a Rebate Model a more efficient and reliable means of identifying and resolving instances of diversion.

Data from a Rebate Model could allow manufacturers (and HRSA) to identify instances when two covered entities have requested 340B pricing on the same unit of a drug. This practice patently violates the 340B statute, which describes the 340B ceiling price for a unit of drug purchased by “a covered entity,” not multiple covered entities.⁴⁸ However, without claims data from a Rebate Model, identifying this illegal and widespread practice would be impossible.

B. A Rebate Model Could Provide Additional Benefits to the Government and Stakeholders (Question 7)

In addition to the potential uses of a Rebate Model described above, below we identify other potential benefits to the federal government and 340B program stakeholders. Any costs or

⁴⁵ 90 Fed. Reg. at 38166.

⁴⁶ GAO, 340B Drug Discount Program: Agency Oversight Has Improved, but Actions Needed to Address Weaknesses, GAO-26-108784, at 27 (Oct. 2025), <https://www.gao.gov/assets/gao-26-108784.pdf>.

⁴⁷ BRG, *340B Patient Definition Implications for Duplicate Replenishment* at 2 (2026), <https://media.thinkbrg.com/wp-content/uploads/2026/04/10141302/340B-Patient-Definition-and-Implications-for-Duplicate-Replenishment.pdf> (A recent analysis of “Medicare Part D Prescription Drug Event (PDE) data for 2024 indicates that, if all covered entities used a three-year test to define “patient,” *which many covered entities have now adopted*, 20 percent of brand drug PDEs could be replenished by more than one covered entity.” (emphasis added)).

⁴⁸ PHSA § 340B(a)(1).

additional burdens under a Rebate Model—which would be minimal for the government and covered entities—are outweighed by the benefits of a Rebate Model.

Transparency Can Reduce Cost. A Rebate Model would increase transparency and the integrity of the 340B Program, ultimately reducing costs to the federal government across multiple programs—including Medicare, Medicaid and the 340B Program. Increased transparency into 340B claims can work hand-in-hand with existing statutory mechanisms to safeguard program compliance.

The 340B statute empowers manufacturers who suspect wrongdoing to conduct audits and seek resolution of disputes through a federal 340B ADR process.⁴⁹ Under current HRSA regulations, a manufacturer may audit a covered entity only when it can furnish “documentation which indicates that there is reasonable cause,” defined to mean “that a reasonable person could believe that a covered entity may have violated” the prohibitions on diversion or Medicaid duplicate discounting.⁵⁰ Thus, a manufacturer must already possess such “documentation” in order to access the audit and ADR processes. Yet covered entities routinely decline to provide manufacturers, on a voluntary basis, with access to the type of information necessary to obtain HRSA’s permission to initiate an audit. A Rebate Model would help address that informational gap, thereby facilitating the effective functioning of the audit and ADR processes.

A Rebate Model would increase program transparency, as claims data would be made available to manufacturers for review in a timely manner, reducing unnecessary disputes. The information that a manufacturer would request under a Rebate Model is comparable to the information that covered entities are already obligated to collect under the statute as a condition of receiving access to 340B pricing — including pharmacy, medical, and purchase data elements, such as the date of service, the prescriber number, and the account number. Covered entities are required to maintain this data for a set period of time—often between five to seven years.

When audits are needed, Rebate Model claims data will enable manufacturers to provide audit requests to HRSA with supporting claims documentation. A Rebate Model would facilitate more-detailed audit requests, which would allow HRSA to review audit requests with greater ease and reduce back-and-forth communications with manufacturers. Moreover, AbbVie is aware of federal budget constraints regarding 340B Program oversight; a Rebate Model will help streamline processes such that HRSA can do more on a limited budget.

Provide a Mechanism for the Government to Exclude 340B Units from Part D Inflation Rebate Calculations. A Rebate Model also could provide a mechanism for excluding 340B units from the Part D inflation rebate calculations, at no cost to the federal government. In the calendar year 2026 Physician Fee Schedule final rule, CMS states that it is “unable to *precisely* identify 340B units at the claim-level based on claims information reported to CMS by the covered entity.”⁵¹ Because of this, CMS adopted a “claims-based estimation methodology” to exclude

⁴⁹ PHSA § 340B(a)(5)(C).

⁵⁰ 61 Fed. Reg. 65,406, 65,409 (Dec. 12, 1996). <https://www.hrsa.gov/sites/default/files/hrsa/opa/dispute-resolution-process-12-12-96.pdf>.

⁵¹ 90 Fed. Reg. 49266, 49740 (Nov. 5, 2025) (emphasis added).

340B units starting on January 1, 2026.⁵² Acknowledging the limitations of an estimation methodology, CMS also established “a repository to receive *voluntary* submissions from covered entities of certain data elements from Part D 340B claims” to identify claims that should be excluded from the Part D inflation rebate calculation.⁵³ However, covered entities are unlikely to submit data to the repository voluntarily, and enforcement would require significant governmental resources. Furthermore, this data is unlikely to be available to manufacturers in a way that could enable timely 340B-MFP deduplication. But CMS need not establish complex systems to identify and exclude 340B units from the Part D inflation rebate calculation. A Rebate Model is the solution. Under a Rebate Model, the claims level data that CMS is hoping to collect under a 340B repository will already be available. AbbVie strongly recommends HRSA and CMS coordinate to structure a Rebate Model that supports Part D inflation rebate calculations.

A Rebate Model Should be Structured to Benefit Patients. Under the current system, most patients are unaware of the 340B Program⁵⁴ because the significant discounts that manufacturers provide are very rarely shared with any patient. Generally, the price an insured patient pays for a 340B drug is set by their insurance company, and the price uninsured patients pay for a 340B drug is determined by the pharmacy. If the patient is insured, covered entities and their business partners “turn a profit when insurance companies reimburse them at full price for drugs that they bought at the 340B discount.”⁵⁵ A study showed that in North Carolina, “[i]ndividual 340B hospitals collected as much as \$6,026 in average profits *per claim* by charging up to 12.7 times their 340B acquisition costs for oncology drugs.”⁵⁶ For instance, patients at one hospital paid “an average of \$5,353 for the oncology drugs that [the hospital] acquired for an average \$517 . . . [or] **paid 10.4 times the 340B acquisition costs.**”⁵⁷ While some covered entities pass a portion of 340B savings to uninsured and underinsured patients, the reality is that most do not.⁵⁸ The result is arbitrage revenue. AbbVie believes that a Rebate Model should be structured to encourage covered entities to pass on 340B savings to low-income patients. AbbVie

⁵² 90 Fed. Reg. at 49740.

⁵³ 90 Fed. Reg. at 49749.

⁵⁴ See, e.g., *AbbVie Inc. v. Drummond*, 808 F. Supp. 3d 1266, 1270 (W.D. Okla. 2025) (referring to the 340B Program as “the most important drug pricing scheme virtually no one has heard of”).

⁵⁵ *Sanofi-Aventis U.S. LLC v. Dep’t of Health & Human Servs.*, 58 F.4th 696, 699 (3d Cir. 2023).

⁵⁶ North Carolina State Health Plan, *Overcharged: State Employees, Cancer Drugs, and the 340B Drug Pricing Program*, at 2, <https://www.shpnc.gov/documents/overcharged-state-employees-cancer-drugs-and-340b-drug-price-program/download?attachment> (last visited Apr. 2, 2026).

⁵⁷ North Carolina State Health Plan, *Overcharged: State Employees, Cancer Drugs, and the 340B Drug Pricing Program*, at 2, <https://www.shpnc.gov/documents/overcharged-state-employees-cancer-drugs-and-340b-drug-price-program/download?attachment> (last visited Apr. 2, 2026) (emphasis added).

⁵⁸ GAO, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-480, at 30 (June 2018), <https://www.gao.gov/assets/gao-18-480.pdf> (“Of the 55 covered entities responding to our questionnaire, 30 reported providing low-income, uninsured patients discounts on 340B drugs dispensed at some or all of their contract pharmacies, and 25 said they did not offer discounts at their contract pharmacies. All 30 covered entities providing patients with discounts reported providing discounts on the drug price for some or all 340B drugs dispensed at contract pharmacies. Federal grantees were more likely than hospitals to provide such discounts and to provide them at all contract pharmacies.”); OIG, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, at 14 (Feb. 4, 2014), <https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf> (“Eight of thirty covered entities reported that they do not offer the 340B price to uninsured patients in any of their contract pharmacy arrangements.”).

recommends that HRSA develop a Rebate Model designed to support vulnerable patients, including through inclusion of a patient definition. A thoughtful rebate approach could bring the 340B Program back in line with the statutory text and intended purpose: to serve the most vulnerable patients.

C. Certain Minimum Data Elements Are Necessary to Ensure the Rebate Model's Benefits Are Realized (Question 5)

AbbVie believes that three categories of data elements are needed to effectuate a successful Rebate Model: pharmacy, medical, and supporting order unit data elements.

AbbVie appreciates that the prior Pilot Program included pharmacy and medical claims data elements, and we encourage HRSA to maintain these elements in a future Rebate Model.⁵⁹ Regardless of the scope of drugs included in a Rebate Model (i.e., just IRA selected drugs or a broader swatch of drugs) it is important to include both pharmacy and medical claims data elements. While the MFP is limited to Part D in initial price applicability years 2026 and 2027, selected drugs may be administered under Medicare Part B or another payer's medical benefit, and pharmacy claims fields would not provide a manufacturer with the necessary information to determine whether a 340B rebate is owed in those instances. Moreover, the inclusion of pharmacy and medical claims data elements would facilitate the expansion of a Rebate Model to additional drugs, as discussed in **Section II.E.3** of this letter.

Further, we strongly encourage HRSA to require the submissions of supporting order unit data elements from the outset of the Rebate Model. In the prior Pilot Program, HRSA did not allow manufacturers to request such data,⁶⁰ but expressed openness to “evaluat[ing] potential incorporation of certain purchase data” “[a]s the pilot progresse[d].”⁶¹ AbbVie maintains that data verifying the purchase of each individual unit is critical to a successful Rebate Model, both because proof of purchase is essential for validation of claims data and because of the importance of ensuring payment accuracy—that the amount paid in a rebate is tied appropriately to the price the covered entity paid for a drug. Consistent with how manufacturer systems operate under the chargeback model, manufacturers must know the original invoice date of the package sold to determine the appropriate credit (including insofar as Wholesale Acquisition Cost (WAC) may change from time to time or if the covered entity purchased the drug at below WAC pricing). In addition, manufacturers offer various contract prices, made available on covered entities Group Purchasing Organization (GPO) accounts, that can be used to purchase covered outpatient drugs not eligible for the ceiling price. Moreover, while supporting order unit data may be applicable to more than one claim (purchases are generally at the package level, and AbbVie understands that

⁵⁹ HRSA, 340B Rebate Model Pilot Program, <http://web.archive.org/web/20251217112038/https://www.hrsa.gov/opa/340b-model-pilot-program> (available on Dec. 17, 2025).

⁶⁰ AbbVie 340B Rebate Model Pilot Program Approval Letter, Ex. A to Decl. of E. Scheidler, *Am. Hosp. Ass'n v. Kennedy*, No. 2:25-cv-600 (D. Me. Dec. 10, 2025), ECF No. 36-2.

⁶¹ HRSA, 340B Rebate Model Pilot Program, <http://web.archive.org/web/20251217112038/https://www.hrsa.gov/opa/340b-model-pilot-program> (available on Dec. 17, 2025).

claims under the rebate model will be processed at the unit level), existing commercially-standard and readily-available information allows manufacturers to cross-reference that data and validate that a claim is attached to a verified purchase of a product under a Rebate Model. The invoice number and account number will allow manufacturers to correlate the purchases with claims data in order to ensure each claim is attached to a purchase at a non-340B price. These data elements are already standard, maintained by covered entities and their Third Party Administrators (TPA) under the replenishment model. For those covered entities that do not leverage a TPA and use a physical inventory model, wholesalers readily maintain the necessary information, on behalf of covered entities, that can be provided to manufacturers to ensure accurate rebate payments.

AbbVie also requests that HRSA add the following new data fields:

- (1) **Part B Modifier.** HRSA should leverage the existing 340B modifier that CMS requires for Medicare Part B drugs. In its Medicare Part B Inflation Rebate Program regulations, CMS requires that covered entities utilize a 340B modifier to identify Medicare Part B drugs acquired at 340B pricing.⁶² This identifier allows CMS to exclude those 340B units from manufacturer inflation rebate calculations under the IRA. This reporting mechanism operates today across covered entity types and is part of routine Part B medical claims billing. As covered entities already submit this 340B claims data under the Medicare program, it would be reasonable and impose no operational burden for covered entities to also submit this to manufacturers as part of a Rebate Model. This data would provide manufacturers with an existing field that provides pre-payment identification of 340B-discounted units for program integrity purposes.
- (2) **Part D Modifier.** Likewise, HRSA should require a 340B modifier for Part D drugs. The National Council for Prescription Drug Programs (NCPDP) standard format includes a 340B modifier,⁶³ and its use is commonly required under Part D and commercial rebate agreements.
- (3) **Any other 340B Modifier.** To the extent any additional 340B modifier is required in a federal program, HRSA should require such modifier as a required data field under the 340B Rebate Model.
- (4) **Child Site Modifier.** A “child site” is an outpatient facility, such as an infusion center, located offsite from the main covered entity hospital. Historically, HRSA required child sites to satisfy two conditions before they could receive and dispense 340B-priced drugs: (1) they had to appear on the parent hospital’s Medicare cost report, and (2) the

⁶² 42 C.F.R. § 427.303(b)(1).

⁶³ NCPDP, 340B Information Exchange Reference Guide, v. 2.0, https://www.ncpdp.org/NCPDP/media/pdf/340B_Information_Exchange_Reference_Guide.pdf?ext=.pdf (“NCPDP has developed multiple identifiers that can be used in connection with the exchange of information related to Section 340B,” including Submission Clarification Code 420-DK, which “[i]ndicates that prior to providing service, the pharmacy has determined the product being billed is purchased [under section 340B].”).

child site had to be listed in HRSA's Office of Pharmacy Affairs Information System (OPAIS) database.⁶⁴ These requirements were put in place to prevent diversion of 340B drugs, which may include when a covered entity purchases a drug at the 340B-discounted price for use at a purported child site that, in fact, does not meet the eligibility criteria under HRSA's guidance.⁶⁵ Although HRSA temporarily waived the child site registration requirement in response to the global covid pandemic,⁶⁶ covered entities have challenged the agency's decision to reinstate the child site registration policy.⁶⁷ In light of this judicial decision limiting HRSA's authority to police 340B abuse by child sites, the burden of preventing diversion of 340B drugs through child sites now will fall largely on manufacturers. A child site modifier would provide manufacturers with a means to confirm whether a drug administered at a purported child site is eligible for 340B pricing.

Although each of the three categories of necessary data elements that AbbVie is requesting serves a distinct purpose, there is significant overlap among the elements in each category (thus limiting the burden on participating covered entities), as illustrated below, in **Table 1**.

Table 1: Proposed Data Fields

2025 Pilot Program HRSA-Approved Field	Field	Description	Pharmacy Claims	Medical Claims	Supporting Order Unit Data	<u>Industry Standard[1]</u>
✓	Date of Service	Identifies date the prescription was filled at a pharmacy or professional services were rendered. Sometimes referred to as the Fill Date.	✓	✓		✓
✓	Date Prescribed	Date the prescriber wrote the prescription. Always comes on or before the Date of Service.	✓			✓
✓	Rx Number	Identifier applied to the prescription by the pharmacy.	✓			✓
✓	Fill Number	Indicates the number of times the prescription has been filled as of the current fill. (E.g., a value of 2 indicates that the prescription has been filled twice and the current fill is the second one.)	✓			✓
✓	NDC-11	11-digit National Drug Code which is a unique identifier of the drug dispensed to the patient and sold.	✓	✓	✓	✓
✓	Quantity / Quantity Dispensed	Number of units (dispensed or sold).	✓	✓	✓	✓

⁶⁴ See 59 Fed. Reg. 47884, 47886 (Sept. 19, 1994).

⁶⁵ 59 Fed. Reg. at 47886.

⁶⁶ See 88 Fed. Reg. 73859, 73859 (Oct. 27, 2023).

⁶⁷ See *Albany Med. Health Sys. v. HRSA*, No. 23-cv-03252, 2026 WL 592593, at *3–4 (D.D.C. Mar. 3, 2026).

2025 Pilot Program HRSA-Approved Field	Field	Description	Pharmacy Claims	Medical Claims	Supporting Order Unit Data	Industry Standard[1]
✓	Prescriber ID / Physician ID	National provider identifier (NPI) of the prescriber that wrote the prescription or administered the drug.	✓	✓		✓
✓	Service Provider ID / Ship-to-Pharmacy ID	ID assigned to a pharmacy or provider billing location/ Service facility location of encounter (e.g., NPI of the pharmacy that filled the prescription), also referred to as ship-to pharmacy (NPI).	✓	✓	✓	✓
✓	340B ID	HRSA-assigned identifier of the 340B covered entity that purchased the product and designated the prescription as 340B.	✓	✓	✓	
✓	BIN Number	Prescription Drug Bank Identification Number. Enables pharmacies to electronically transmit data to the appropriate PBM for processing and reimbursement.	✓			✓
✓	PCN Number	Processor Control Number. Identifier used to determine which processor will handle a prescription drug claim. Might say “CASH”.	✓			✓
✓	Group ID Number	A unique identifier assigned to a specific insurance plan that covers a group of people.	✓	✓		✓
	Account Number	Account number on the invoice used to make the purchase			✓	
	Invoice Date	Date of sales invoice			✓	
	Invoice Number	Unique identifier for the invoice			✓	
	Child Site Modifier	An indication of whether the 340B drug was dispensed by a child site of a 340B covered entity.	✓	✓		
	Medicare Part B 340B Claims Modifier	A claims-level modifier used by 340B covered entities to identify Part B drugs acquired at 340B prices.		✓		✓
	Part D 340B Modifier	A claims-level modifier used by 340B covered entities to identify Part D drugs acquired at 340B prices.	✓			✓

AbbVie believes that the requested data elements are consistent with HRSA’s expectation that under a Rebate Model, the “data submitted by covered entities to manufacturers will be comparable to data already being collected and maintained by covered entities.”⁶⁸ Thus, “the burden associated with a potential 340B Rebate Model Pilot Program data request[] may not be

⁶⁸ 91 Fed. Reg. at 9632, 9633 (Feb. 26, 2026).

significant.”⁶⁹ AbbVie further believes that the requested data elements are the minimum necessary to operate an efficient and successful Rebate Model.

D. Rebate Denials Should Be Permitted in Accordance with the 340B Statute and Based on Industry Standard Data Elements (Questions 3 and 4)

AbbVie recommends that any rebate payment deadline be triggered only upon submission of complete and validated claims data, according to the HRSA-approved criteria, as verified by the manufacturer. In AbbVie’s experience validating limited customer data submissions through 340B ESP, we have received incomplete, inaccurate, and encrypted data that required follow-ups with customers to rectify. Basing any timelines or requirements on the receipt of incomplete or inaccurate data would frustrate the intent of a Rebate Model. Further, our proposed approach would be consistent with requirements of other federal healthcare program payments to pay “clean claims,” including the 30-day window for Medicare Administrative Contractor requiring receipt of “all basic information necessary to adjudicate the claim, and all required supporting documentation,”⁷⁰ Medicare Part D claims,⁷¹ and Medicaid claims.⁷² Additionally, under the MDPNP, CMS has made clear that the 14-day payment window does not begin until after validation of claims by the Drug Data Processing System (DDPS) has been completed.⁷³ Moreover, allowing a 24 to 48 hour verification period would be reasonable and should not significantly affect the timeliness of rebate payments. Given that claim verification periods are well-established features of other federal healthcare payment ⁷⁴[REDACTED] there is no basis for subjecting 340B rebate claims to a more burdensome or truncated standard.

In the prior Pilot Program notice, HRSA limited 340B rebate denials to MFP deduplication and preventing duplicate covered entity rebate claims on the same 340B purchase.⁷⁵ AbbVie requests that HRSA also allow rebate denials to ensure compliance with other statutory requirements, including the prohibitions on Medicaid duplicate discounts and diversion.

⁶⁹ 91 Fed. Reg. at 9633.

⁷⁰ CMS, Medicare Claims Processing Manual, ch. 1 § 80.2.

⁷¹ 42 C.F.R. § 423.520(b).

⁷² 42 C.F.R. § 447.45.

⁷³ CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028* (Sept. 30, 2025) (“Once the data has been verified by the Part D plan sponsor and DDPS, and the MTF DM has verified that a claim has no DDPS edits directly related to MFP-eligibility, the MTF DM will make the claim-level data elements . . . available to the Primary Manufacturer to notify them that the selected drug was dispensed to an MFP-eligible individual. . . . The MTF DM’s transmission of the claim-level data elements to the Primary Manufacturer starts the 14-day prompt MFP payment window.” *Id.* at 225.).

⁷⁴ See, e.g., CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028*, 223, (Sep. 30, 2025), <https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf> (“After the Part D plan sponsor verifies Medicare eligibility and coverage of the selected drug, the plan pays the dispensing entity no more than the MFP plus any dispensing fees for the selected drug. . . . CMS, using DDPS, also performs verification steps to validate that the individual was an eligible Part D enrollee at the time of the claim.”).

⁷⁵ 90 Fed. Reg. at 38166.

Specifically, AbbVie requests that HRSA permit rebate denials in the following instances: (1) a 340B rebate has already been paid on a particular unit and that same unit is submitted again but by a different covered entity; (2) deduplication for MFP; (3) providing the 340B price would generate an illegal Medicaid fee-for-service or MCO duplicate discount; and (4) instances where the manufacturer has identified diversion.

E. AbbVie Supports Mandated Manufacturer Reporting to the Office of Pharmacy Affairs (Question 6)

The Pilot Program required drug manufacturers to report certain data regarding the claims they had received and rebates they had paid 21 days after the end of each monthly, reflecting data for the prior month. AbbVie supports a similar requirement with any new Rebate Model. We are confident that consistent reporting and evaluations will highlight the benefits of a Rebate Model, paving the way for its expansion to additional 340B drugs and uses.

1. Manufacturers Should Report Data Directly to HRSA, Not Apexus

AbbVie believes that if manufacturers are required to submit data for HRSA's review, those submissions must be made directly to the Office of Pharmacy Affairs (OPA). During the development of the prior Pilot Program, HRSA's Federal Register notice stated that manufacturers would provide periodic reports to OPA, detailing data on purchases provided through rebates, information related to claim delays and denials, and other information that may evaluate the effectiveness of the rebate model.⁷⁶ But, when HRSA approved AbbVie's participation in the Pilot Program, HRSA then said that AbbVie had to submit data to the 340B Prime Vendor, Apexus.⁷⁷ AbbVie has significant concerns that the draft ICR that accompanies the RFI continues to propose that manufacturers would submit data to the 340B Prime Vendor.⁷⁸

AbbVie believes such reporting to Apexus is inappropriate, creates conflicts of interest, and raises significant concerns about 340B Program integrity. Apexus is a wholly-owned subsidiary of Vizient, the largest GPO in the United States.⁷⁹ It is an "[i]ndependent[]" entity and "not . . . an agent of the Federal Government."⁸⁰ Moreover, Vizient counts many hospital covered entities as clients, stating on its website that its "clients make up 97% of academic medical centers in the U.S. [and] more than 69% of the acute care hospitals in the country."⁸¹ The conflicts of interest flowing from Apexus' relation to Vizient have been scrutinized, including in litigation asserting that "Vizient appears to be utilizing its relationship with Apexus to . . . increase its GPO business in ways its competitors cannot."⁸² Last year, the New York Times published an investigation

⁷⁶ See 90 Fed. Reg. at 38166.

⁷⁷ See AbbVie 340B Rebate Model Pilot Program Approval Letter, Ex. A to Decl. of E. Scheidler, *Am. Hosp. Ass'n v. Kennedy*, No. 2:25-cv-600 (D. Me. Dec. 10, 2025), ECF No. 36-2.

⁷⁸ 91 Fed. Reg. at 9632–33.

⁷⁹ Definitive Healthcare, *Top 10 GPOs by Staffed Beds* (Oct. 24, 2025), <https://www.definitivehc.com/blog/top-10-gpos-by-staffed-beds>; Vizient, *Frequently Asked Questions*, <https://www.vizientinc.com/frequently-asked-questions>.

⁸⁰ HRSA 340B Prime Vendor Agreement between HRSA and Apexus, at 1 (eff. Dec. 31, 2019) (Prime Vendor Agreement), available at <https://www.hrsa.gov/sites/default/files/hrsa/foia/22f269-apexus-2019-contract.pdf>.

⁸¹ Vizient, *About Us*, <https://www.vizientinc.com/about-us>.

⁸² Brief for Appellant at 14, *AIDS Healthcare Foundation v. Apexus, LLC*, (9th Cir. 2023) (No. 23-55425) (dismissed for failure to state a claim) ("Vizient leverages Apexus to gain an unfair advantage against its GPO competitors,

questioning Apexus's business practices. The article stated that "Apexus said its federal contract did not preclude it from developing other businesses, as long as they were not in conflict with the terms of the agreement."⁸³ The article also said that "[w]ith exclusive access to sales data, Apexus' 'purchasing optimization team' will analyze a hospital system's drug-buying habits and compare them with those of their competitors In some cases, Apexus will suggest that a hospital buy more 340B drugs or tweak its inventory in ways that can churn more cash."⁸⁴

More recently, Senate Republicans on the Health, Education, Labor, and Pensions Committee have renewed concerns about Apexus's role in the 340B Program.⁸⁵ Congress is investigating Apexus out of concern about the "serious lack of transparency in the 340B Program."⁸⁶ Especially in light of this ongoing investigation, it would be inappropriate to further expand Apexus's role in the 340B Program by requiring drug manufacturers with a Rebate Model to report information to Apexus. Reporting directly to OPA will be more efficient, strengthen the federal government's oversight of the 340B Program, and facilitate HRSA's oversight of the Rebate Model.

2. HRSA Should Collect Data on How the Rebate Model is Functioning And its Impact on Patients, At least on a Monthly Basis

Substantively, AbbVie supports the manufacturer reports and associated timing that HRSA adopted as part of the prior Pilot Program. This included two reports, both of which were required to be delivered to OPA within 21 days after the end of each monthly, reflecting data for the prior month:

- **Report 1:** Data extracts of all previous month's 340B Rebate claims to include the following data fields:
 - o Claim submission date
 - o 340B ID
 - o NDC-11 purchased
 - o Quantity
 - o Unit WAC price
 - o Unit 340B Ceiling Price
 - o Unit MFP price
 - o Rebate Amount

because certain 340B-eligible hospital covered entities are statutorily prohibited from using GPOs to purchase 340B drugs. Apexus, however, can do so because it is the Prime Vendor and claims it is not a GPO. And, upon information and belief, Apexus has been granted the authority to purchase non-340B drugs at sub-wholesale costs. This allows Apexus/Vizient to unfairly compete with other GPOs, because hospitals will prefer to deal with a single GPO or—in some cases—be required to by their drug wholesaler.”).

⁸³ Ellen Gabler, *How a Company Makes Millions Off a Hospital Program Meant to Help the Poor*, N.Y. Times (Jan. 15, 2025), <https://www.nytimes.com/2025/01/15/us/340b-apexus-drugs-middleman.html>.

⁸⁴ Ellen Gabler, *How a Company Makes Millions Off a Hospital Program Meant to Help the Poor*, N.Y. Times (Jan. 15, 2025), <https://www.nytimes.com/2025/01/15/us/340b-apexus-drugs-middleman.html>.

⁸⁵ Letter from Sen. B. Cassidy to C. Hatwig, President, Apexus, LLC (Feb. 1, 2026), available at https://www.help.senate.gov/imo/media/doc/26-02-01_chairman_cassidy_letter_to_apexus_finalpdf.pdf.

⁸⁶ *Id.* at 3.

- **Report 2:** Set of five data aggregations with the following information:
 - o Aggregated sales by Covered Entity as defined in Section 340B(a)(4) of the Public Health Service Act
 - o Average days from claim submission to rebate payment for all rebates paid
 - o Number of rebates paid after 10 calendar days
 - o Number of rebates denied with denial reasons
 - o Number of selected drug claims determined to be eligible for MFP instead of 340B price as a result of rebate model pilot program
 - o The number of rebates paid out in the reporting period, broken down by 340B drug for which the rebate was paid.

AbbVie believes these same reports, at the same reporting frequency, should be required for the Rebate Model.

AbbVie further recommends that manufacturers supply HRSA with any suspected diversion, duplicate discounting, or other 340B Program violations identified during the reporting period. This will enable HRSA to evaluate the need for expanded duplicate discount prevention and diversion monitoring. AbbVie also recommends that HRSA take enforcement action—including through audits—against covered entities who engage in such behavior.

Finally, AbbVie supports making public certain information from HRSA's Rebate Model evaluations. Specifically, AbbVie believes HRSA should make public the timeliness of a manufacturer's rebate payments; dispute resolution timelines; statistics regarding how many manufacturer rebate denials were due to suspected diversion, evidence of duplicate discounting, or any other reason; a breakdown of whether disputes concerned the administration of the rebate model or eligibility of claims for a 340B rebate; and information related to program integrity, such as the number of times more than one covered entity requested a rebate on the same claim. However, AbbVie requests that HRSA confirm that it will not make public any confidential or proprietary information from drug manufacturers or other 340B Program stakeholders, including but not limited to the 340B ceiling price. AbbVie would be happy to work with HRSA to identify what information falls into those categories.

3. AbbVie Supports Frequent Manufacturer Reporting to OPA Regarding the Rebate Model to Facilitate Expansion of a Rebate Model to More Drugs

AbbVie agrees with HRSA's intent to require monthly reporting from manufacturers.⁸⁷ We further encourage HRSA to regularly and frequently assess the benefits of the Rebate Model, starting as early as the end of the first quarter of its implementation, with regular reevaluations quarterly thereafter.

In the accompanying ICR, HRSA suggests that the Rebate Model may be limited to "manufacturers with MDPNP Agreements with the Centers for Medicare & Medicaid Services" for

⁸⁷ 91 Fed. Reg. at 9633.

the initial price applicability years 2026 and 2027.”⁸⁸ Given the benefits of a Rebate Model outside of the IRA—including preventing Medicaid duplicate discounts and diversion—AbbVie believes that a Rebate Model should not be limited to manufacturers with IRA selected drugs. At the very least, if the Rebate Model is initially limited to these manufacturers, it should include both drugs selected and not selected under the IRA. In particular, HRSA should consider including drugs within a class so as not to inadvertently impact prescribing choices based on 340B pricing. Further, once the data shows the Rebate Model is effective and beneficial—which we are confident that the data will demonstrate—HRSA should move quickly to expand the program to include all 340B drugs. A robust data collection with frequent evaluations would allow HRSA to build on the Rebate Model, test improvements to an existing Rebate Model in real time, and support such an expansion of a Rebate Model to additional drugs as soon as possible. More infrequent evaluations would cause all interested parties to miss out on the benefits of a potentially expanded Rebate Model, hurting 340B Program integrity.

III. The 340B Rebate Model Would Not Be Burdensome for Covered Entities

AbbVie supports a Rebate Model as an effective and efficient means to offer 340B pricing to covered entities. As explained below, we are skeptical of covered entities’ assertions that a Rebate Model would be costly, given that a Rebate Model would involve covered entities submitting claims-level data that they already collect and report under other healthcare programs. We are equally doubtful that a Rebate Model would create cash flow concerns, and believe that in reality, covered entities likely will access 340B pricing faster after dispenses to patients than under the prevailing replenishment model (which also functions as a retrospective discount). In the rare cases where a Rebate Model is not feasible for a particular covered entity, AbbVie would encourage the affected covered entity to contact our 340B Center of Excellence. AbbVie understands that sometimes there are extenuating circumstances and evaluates each request on a case-by-case basis. AbbVie plans to work with covered entities to understand their hardship request and will determine if a hardship exception is warranted in accordance with AbbVie’s standard business practices.

A. A 340B Rebate Model Would Not Impose Significant Additional Costs on Covered Entities (Questions 1 and 4)

Rebates are explicitly authorized under the 340B statute,⁸⁹ and covered entities already are required to collect and maintain claims data and establish 340B patient eligibility determinations in the normal course. Rebates have been a longstanding mechanism for manufacturers to offer the 340B ceiling price to AIDS Drug Assistance Program (ADAPs),⁹⁰ which view a Rebate Model as

⁸⁸ 91 Fed. Reg. at 9632.

⁸⁹ Under Section 340B, a pharmaceutical manufacturer must “offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.” PHSA § 340B(a)(1). To implement this provision, Section 340B directs the Secretary of Health and Human Services to “enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account *any rebate* or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs . . . does not exceed” the applicable ceiling price. *Id.* (emphasis added).

⁹⁰ 63 Fed. Reg. 35239 (June 29, 1998).

the “gold standard.”⁹¹ Rebates also are commonly used to facilitate access to reduced pricing to other federal and commercial healthcare programs, such as the Medicaid Drug Rebate Program, the IRA, and TRICARE.⁹²

AbbVie agrees with HRSA’s statement in the accompanying ICR that under a Rebate Model, the “data submitted by covered entities to manufacturers will be comparable to data already being collected and maintained by covered entities,” and therefore “the burden associated with a potential 340B Rebate Model Pilot Program data requests may not be significant.”⁹³ Covered entities already transmit similar claims data to various third-parties, such as state Medicaid agencies, health plans, and even provide limited claims data to manufacturers (e.g., on some contract pharmacy claims) to facilitate reimbursement and certain discount or rebate payment. Federal courts also have recognized that under longstanding HRSA guidance, manufacturers “may require” information from covered entities and “the burden of providing the claims data is ‘minimal.’”⁹⁴ The only change under a Rebate Model would be that covered entities would also submit this data to another entity (the 340B Rebate Model vendor). Submitting existing data to a different entity should not require additional full-time employees (FTEs) or significantly change the responsibilities of existing FTEs. Please see Appendix A for more information on industry standard data fields.

Moreover, in accordance with 340B statutory requirements, covered entities should already be reviewing 340B transactions for compliance with statutory duplicate discount prohibitions⁹⁵ and ensuring that there is no “diversion” of 340B-priced medicines to an individual who is not a “patient” of the covered entity.⁹⁶ HRSA guidance also requires covered entities to maintain auditable records⁹⁷ in anticipation of a potential audit initiated by HRSA or a manufacturer.⁹⁸ The information that a manufacturer would request under a Rebate Model is comparable to the information that HRSA would request when auditing a covered entity.⁹⁹ For example, HRSA’s sample data request list for covered entity audits includes pharmacy, medical, and purchase data elements, such as the date of service, the prescriber number, and the account number. Put simply

⁹¹ Letter from Brandon M. Macsata, CEO, ADAP Advocacy Association, to Chantelle Britton, Director, Office of Pharmacy Affairs, HRSA, Sept. 8, 2025, <https://www.regulations.gov/comment/HRSA-2025-0001-0715>.

⁹² See, e.g., 42 U.S. Code § 1396r-8 (Medicaid); CMS, *Drug Price Negotiation Program: IPAY 2028 Final Guidance* (Sep. 30, 2025) (“IPAY 2028 Final Guidance”), <https://edit.cms.gov/files/document/ipay-2028-final-guidance.pdf>; TRICARE Retail Refund Program, Manufacturer Policy and Procedures Guide (Apr. 2025) <https://health.mil/Reference-Center/Publications/2025/04/25/Manufacturer-Policy-and-Procedure-Guide>.

⁹³ 91 Fed. Reg. at 9633.

⁹⁴ *Novartis Pharms. Corp.* 102 F.4th at 463.

⁹⁵ PHSA § 340B(a)(5)(A); SSA § 1903(m)(2)(A)(xiii); SSA § 1927(j)(1); SSA § 1193(d).

⁹⁶ PHSA § 340B(a)(5)(B).

⁹⁷ Health Resources & Services Administration, Program Integrity. <https://www.hrsa.gov/opa/program-integrity> (“Covered entities participating in the 340B Drug Pricing Program must maintain accurate records to ensure compliance.”).

⁹⁸ PHSA § 340B(a)(5)(C).

⁹⁹ See 340B Prime Vendor Program, *Sample HRSA 340B Audit Data Request List (DRL) for Covered Entities*, <https://www.340bpvp.com/Documents/Public/340B%20Tools/sample-hrsa-340b-audit-data-request-for-covered-entities.pdf>.

arguments from covered entities that they will incur significant additional costs to collect and process claims data under a Rebate Model are suspect as the collection and processing of such data by covered entities and their vendors is already *required* for covered entities to ensure they are compliant with 340B program requirements.

Covered entities currently engage TPAs to assist with 340B operations and could use TPAs for Rebate Model needs as well. TPAs have broad capabilities and familiarity with Rebate Model claims submissions, so covered entities likely would not need to onboard new vendors and likely would not incur significant additional costs. Multiple TPAs and vendors have already operationalized the infrastructure necessary to support Rebate Model submissions. Covered entities have historically been able to adapt in response to changes in the 340B Program, including by setting up alternative distribution models and engaging third party administrators to assist with 340B operations. For those covered entities that do not leverage a TPA and use a physical inventory model, wholesalers readily maintain the necessary information, on behalf of covered entities, that can be provided to manufacturers to ensure accurate rebate payments.

Manufacturers also would incur the bulk of the costs under a Rebate Model, including establishing and maintaining the Rebate Model platform. For example, in the lead-up to the prior Pilot Program, AbbVie engaged Second Sight Solutions, which operates the Beacon platform, to collect the HRSA-approved data elements, apply 340B rebate eligibility criteria, provide transparent reporting, and facilitate 340B rebate payments to covered entities. If HRSA moves forward with a Rebate Model, AbbVie would incur all costs associated with operating Beacon, as well as providing initial set-up and ongoing support and resources at no cost to the covered entity. Through Beacon, AbbVie would offer ongoing technical assistance, customer service, and educational resources to covered entities at no cost, including: detailed technical assistance on the Beacon website that addresses file setup for data element submissions and data templates; training and technical support to covered entities regarding Beacon and to address any questions or concerns regarding the Beacon platform; and a variety of online resources, including pre-recorded and live training sessions, available on their website. Beacon also would provide administrative functionality that would reduce covered entity administrative costs, such as status and reconciliation reporting at no cost to covered entities. The user interface provides the covered entities (and their invited partners) access to 340B rebate model data at no cost that can be customized by the entity and allows for the viewing of multiple organizations' data, (if authorized).

Ultimately, a Rebate Model could *reduce* costs for covered entities because it would increase transparency into 340B claims and thus reduce the need for manufacturer-initiated audits. The 340B statute empowers manufacturers who suspect wrongdoing to conduct audits and seek resolution of disputes through a federal 340B ADR system.¹⁰⁰ Implementation of a Rebate Model likely would reduce the need for manufacturer audits of covered entities, as claims data would be readily available to manufacturers in close to real-time to identify and resolve disputed claims. As discussed above, when audits are needed, Rebate Model claims data will enable manufacturers to

¹⁰⁰ PHSA § 340B(a)(5)(C).

provide clearer, more robust audit requests to HRSA. Under current HRSA guidance, in order to obtain the agency’s approval to conduct an audit, manufacturers must demonstrate that there is “reasonable cause” to believe that the covered entity is engaged in wrongdoing.¹⁰¹ A Rebate Model would facilitate more detailed audit requests, which would allow HRSA to review audit requests with greater ease and reduce back-and-forth communications with manufacturers. The reduction in the number of audits, claims reversals, and other dispute-related issues could offset any administrative costs to covered entities under the Rebate Model. With respect to deduplication of MFP and 340B claims, without a rebate model, when a claim is reasonably identified as 340B by a manufacturer but has not received a 340B discount, covered entities need to wait for resolution of a good faith inquiry into a dispute over MFP payment and potentially bring the issue to HRSA for resolution—all the while waiting for reimbursement.

Regardless, any administrative costs associated with the 340B Program for covered entities—if any actually existed—would be far outweighed by the program’s benefits. While the list price value of 340B purchases in 2024 was \$148 billion, the discounted price to covered entities was significantly lower (\$81.4 billion).¹⁰² This is because manufacturers provide massive discounts to covered entities under the 340B Program. These discounted prices are significantly lower than the prices at which manufacturers sell their products to other purchasers. For the vast majority of drugs, manufacturers participating in the 340B Program must sell their products to covered entities at discounts ranging from at least 23.1% to more than 99.9% of the average market price.¹⁰³ On average, 340B covered entities receive 59% off of wholesale acquisition cost (WAC).¹⁰⁴ Many mandatory 340B ceiling prices are as little as one penny per unit of drug. Covered entities thus reap significant revenue from their participation in the program. It is more than fair for covered entities to assume minimal compliance costs associated with ensuring 340B program integrity—again, assuming there are any—in return for the ability to generate massive amounts of revenue under the program.

B. Covered Entities’ Concerns about Payment Timing and Potential Cash Flow Concerns Are Unfounded (Question 2)

1. Under the Rebate Model, Covered Entities Are Likely to Receive 340B Pricing Faster Than Under the Existing Framework

AbbVie believes that requiring rebates to be paid (or if appropriate, denied) within 10 calendar days of a manufacturer receiving complete claims data would be reasonable and would not lead to cash flow concerns for covered entities. The prior Pilot Program would have had a 10-calendar-day deadline, and the current RFI states that “[a] potential 340B Rebate Model Pilot

¹⁰¹ 61 Fed. Reg. at 65406.

¹⁰² Drug Channels Institute, *340B Hit \$81 Billion in 2024 (+23%): Why CMS and the IRA Are Poised to Cool the Program’s Runaway Growth* (Dec. 15, 2025), <https://www.drugchannels.net/2025/12/340b-hit-81-billion-in-2024-23-why-cms.html>.

¹⁰³ SSA § 1927(c); PHSA § 340B(a)(1).

¹⁰⁴ BRG, *340B Program at a Glance: 2025*, at 1 (2025), https://media.thinkbrg.com/wp-content/uploads/2025/02/19075246/340B-Program-at-a-Glance-2025_F.pdf.

Program could require that all rebates be paid to the covered entity (or denied, with documentation in support) within 10 calendar days of data submission.”¹⁰⁵

A 10-day rebate payment period would be faster than most 340B discounts are delivered today, particularly because most covered entities and the pharmacies with whom they contract use a “replenishment” model, which has inherent delays. Eligibility for 340B pricing only is determined when the replenishment order is placed, which often occurs weeks, months, or even a year after the prescription is dispensed, in part because the replenishment order is only placed after the medication is dispensed and sufficient accumulators exist to order (e.g., full package size).¹⁰⁶ This is not true under a Rebate Model. Under a Rebate Model, a covered entity would be able to submit requests for 340B pricing in near real-time, shortly after the drug is dispensed to a patient of the covered entity. Access to the 340B price would not depend on use of the entire package and could occur much faster than today (e.g., under the prior Pilot Program, no more than 10 days after submission of a claim).¹⁰⁷ Moreover, rebate payments would be sent via electronic funds transfer, directly to the covered entities registered bank account, which provides prompt payment and avoids delays (e.g., due to checks).

The transition from a wholesaler chargeback discount model to a Rebate Model framework likely should not affect covered entities’ cash flow because our understanding is that with a 10-calendar-day deadline, the rebate payment generally would be paid by the time covered entities are required to pay wholesalers.¹⁰⁸ Moreover, a 10-calendar-day deadline is far shorter than when rebate payments are due under other programs. For example, Medicaid drug rebate payments are assessed on a quarterly basis and due 37 days after receipt of the invoice,¹⁰⁹ and as discussed above, manufacturers of selected drugs have 14 days to pay MFP rebates.¹¹⁰ We understand that payment terms may vary by contract, but urge HRSA to validate timing under the chargeback discount model with wholesalers as we expect the impact to a covered entity’s cash flow is hyperbole.

A 2025 IQVIA study considered the impact of a Rebate Model on covered entities’ cash flow and concluded that “financing costs under the 340B rebate model are small and unlikely to be a barrier to its use by covered entities.”¹¹¹ The study compared interest rates under different

¹⁰⁵ 91 Fed. Reg. at 7290.

¹⁰⁶ Adam J. Fein, *Challenges for Managed Care from 340B Contract Pharmacies*, 22 J. of Managed Care & Spec. Pharm. 197 (Mar. 2016), <https://pmc.ncbi.nlm.nih.gov/articles/PMC10398234/>.

¹⁰⁷ Beacon Support Center, *Rebate Model Frequently Asked Questions*, <https://support.beaconchannelmanagement.com/en/articles/9589827-rebate-model-frequently-asked-questions> (*How long does it take for a 340B rebate payment to be processed and paid?*).

¹⁰⁸ See SmartSourceRx, *Credit and Payment Details*, <https://www.smartsourcerx.com/credit-and-payment-details>.

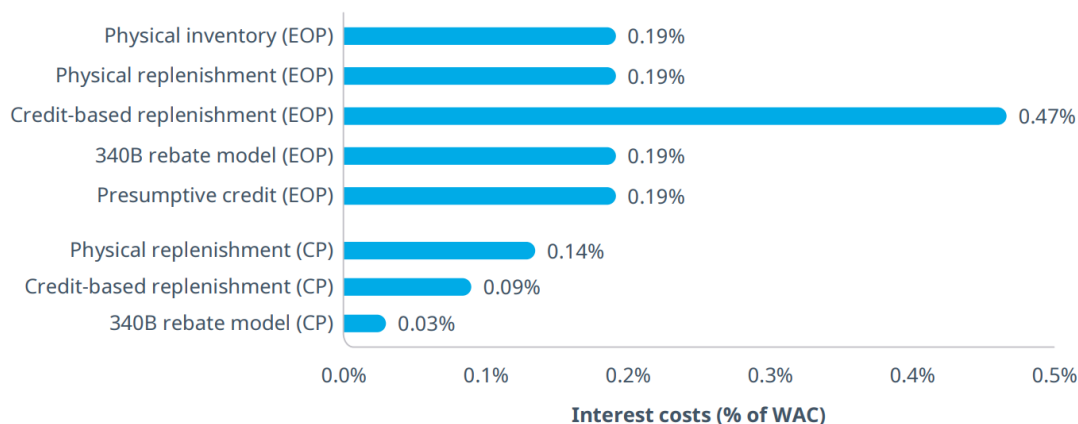
¹⁰⁹ HHS, *Medicaid Drug Rebate Program Release No. 7: 50% Rebate Cap – Technical Amendment Passed* (Apr. 29, 1993), <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-007.pdf>.

¹¹⁰ CMS, *Drug Price Negotiation Program: IPAY 2028 Final Guidance*, § 40.4.1 (Sep. 30, 2025) (“IPAY 2028 Final Guidance”), <https://edit.cms.gov/files/document/ipay-2028-final-guidance.pdf>.

¹¹¹ Chuan Sun, MS, MA, et al, IQVIA, *How Will a Rebate Model Impact Cash Flow in the 340B Drug Pricing Program?*, at 1, 13 (2025), <https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2025/iqvia-cash-flow-impact-in-340b-white-paper-2025.pdf>.

inventory models and found that rebate model interest costs (0.19%) were no larger than under physical inventory models (0.19%).¹¹² For contract pharmacies, rebate model interest costs (0.03%) were lower than physical and credit-based replenishment models.¹¹³ IQVIA found that “[e]ven under unfavorable assumptions, rebate interest costs remained under 1.2%.”¹¹⁴

Figure 4. Interest costs for the eight 340B drug inventory and rebate models



Last week, IQVIA released an updated version of their study that include all 10 drugs subject to MFP and allowed for shorter wholesaler payment terms, reconfirming the marginal nature of any potential interest costs. The study found that, “For all covered entity types, combined annual interest costs are estimated to be \$53.7 million, representing 0.40% of the \$13.4 billion in combined 340B purchases at WAC for these drugs.”¹¹⁵

2. The Beacon Rebate Model Platform Permits Covered Entities to Reconcile 340B Rebate Payments and Ensure Timely Payments

The Beacon platform, which AbbVie would use to operationalize a Rebate Model, would allow covered entities to reconcile 340B rebate payments to the submitted 340B eligible claims data, which the Beacon platform makes available for free through a downloadable data report.¹¹⁶

¹¹² Chuan Sun, MS, MA, et al, IQVIA, *How Will a Rebate Model Impact Cash Flow in the 340B Drug Pricing Program?*, at 1, 13 (2025), <https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2025/iqvia-cash-flow-impact-in-340b-white-paper-2025.pdf>.

¹¹³ Chuan Sun, MS, MA, et al, IQVIA, *How Will a Rebate Model Impact Cash Flow in the 340B Drug Pricing Program?*, at 1, 13 (2025), <https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2025/iqvia-cash-flow-impact-in-340b-white-paper-2025.pdf>.

¹¹⁴ Chuan Sun, MS, MA, et al, IQVIA, *How Will a Rebate Model Impact Cash Flow in the 340B Drug Pricing Program?*, at 1 (2025), <https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2025/iqvia-cash-flow-impact-in-340b-white-paper-2025.pdf>.

¹¹⁵ Rory Martin, Chuan Sun & William A. Sarraile, *Do 340B Rebates Create a Significant Financial Burden for 340B Providers?*, IQVIA White Paper (2026).

¹¹⁶ Beacon Support Center, *Rebate Model Frequently Asked Questions*, <https://support.beaconchannelmanagement.com/en/articles/9589827-rebate-model-frequently-asked-questions> (Can my covered entity reconcile 340B rebate payments back to claims submissions?).

Beacon also includes a functionality for covered entities to research the 340B rebate status of a particular claim and to initiate a good faith inquiry in the event that a covered entity has not received a 340B rebate that it believes is due.¹¹⁷

Moreover, there are existing pathways under the 340B statute to ensure timely payments under a Rebate Model. For instance, if a manufacturer persistently does not provide timely 340B rebates, HRSA could also consider revoking approval of its Rebate Model or consider other enforcement mechanisms. In guidance on the prior Pilot Program, HRSA stated that “[a] manufacturer that is consistently unable to timely resolve rebate reimbursement issues may have its participation in the pilot program revoked.”¹¹⁸ Further, disputes over whether a manufacturer provided the 340B price on appropriate claims could be subject to the ADR process.

IV. HRSA Must Make Clear that a Rebate Model Preempts State Laws that Restrict Claims Data Collection and Interfere with ADR.

When developing a Rebate Model, HRSA must make clear that the federal program preempts any state law that restricts the success of the Program, including by restricting a manufacturer’s ability to collect claims data. State laws purporting to restrict the use of rebate models or the collection of claims data in connection with the 340B Program unconstitutionally intrude on the objectives of the federal Rebate Model, a program that specifically contemplates that manufacturers will request—and covered entities will submit—claims data.¹¹⁹ To the extent States attempt to apply their state laws to limit or obstruct the Rebate Model, such interference undermines the federal Rebate Model and stands as a direct obstacle to a manufacturer’s ability to participate in the program.¹²⁰ At least two federal district courts and one federal Court of Appeals have found this to be true, ruling that such restrictions are unconstitutional because they “interfere[] with manufacturers’ ability to conduct audits, which are necessary to launch the HHS-administrated dispute resolution process,” and, thereby, “frustrate[] the operation of the audit mechanism and thus the enforcement of § 340B.”¹²¹

¹¹⁷ Beacon Support Center, *Rebate Model Frequently Asked Questions*, <https://support.beaconchannelmanagement.com/en/articles/9589827-rebate-model-frequently-asked-questions>.

¹¹⁸ HRSA, 340B Rebate Model Pilot Program, <http://web.archive.org/web/20251217112038/https://www.hrsa.gov/opa/340b-model-pilot-program> (available on Dec. 17, 2025).

¹¹⁹ The doctrine of federal preemption requires that “any state law, however clearly within a State’s acknowledged power, which interferes with or is contrary to federal law, must yield.” *Felder v. Casey*, 487 U.S. 131, 138 (1988); see also *McCulloch v. Maryland*, 17 U.S. 316 (1819).

¹²⁰ *Crosby v. Nat’l Foreign Trade Council*, 530 U.S. 363, 372–73 (2000) (unanimously concluding federal law preempted a Massachusetts state law “[b]ecause [although] a variety of state laws and regulations may conflict with a federal statute, whether because a private party cannot comply with both sets of provisions or because the objectives of the federal statute are frustrated, ‘field preemption may be understood as a species of conflict preemption, . . . where ‘under the circumstances of [a] particular case, [the challenged state law] stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.’”).

¹²¹ *Pharm. Rsch. & Mfrs. of Am. v. Morrissey v. McCuskey*, No. 25-1054, --- F.4th ---, 2026 WL 898259, 2026 U.S. App. LEXIS 9272, at *31-32 (4th Cir. Mar. 31, 2026); see also *Pharm. Rsch. & Mfrs. of Am. v. Morrissey*, 760 F. Supp. 3d 439, 453 (S.D. W. Va. 2024); *AbbVie v. Drummond*, 808 F. Supp. 3d 1266, 1278 (W.D. Okla. 2025).

Moreover, States are increasingly passing laws that interfere with the federal program by attempting to regulate the sale and transfer of products at the federal 340B price, changing the terms of participation in the federal program, and prohibiting manufacturers from conditioning the sale of drugs at the federal 340B price on the receipt of covered-entity claims data. To date, at least thirteen States have passed laws containing such restrictions.¹²² These state laws commonly include exceptions for where such data is required under federal law. Some States have accordingly recognized that their laws do not or cannot prohibit data collection in connection with participation in a federal Rebate Model.¹²³ However, other States have claimed that the exception for federally required data does not apply because the Rebate Model does not explicitly require drug manufacturers to request such information.¹²⁴ It is thus critical that HRSA make clear that such state-law restrictions are preempted.

The U.S. Department of Justice (DOJ) recently filed several amicus briefs on behalf of the United States, urging U.S. Courts of Appeals around the country to strike down state laws that prohibit drug manufacturers from, among other things, requiring covered entities to provide claims data as a condition of the manufacturer offering 340B prices.¹²⁵ As the brief explains, such state laws improperly interfere with the proper functioning of the federal administrative enforcement scheme.¹²⁶ Clarification about the Rebate Model's preemptive effect will prevent future erroneous interpretations of these state laws, preserving the centrality of federal enforcement and saving the judicial system the effort of having to resolve such disputes.

Congress created the 340B Program as an exclusively federal program, overseen by HRSA.¹²⁷ Such state-law data-collection restrictions also interfere with the 340B Program's ADR process in two distinct ways.

First, manufacturers cannot access the ADR process without covered-entity claims data. Such data is crucial to initiate the audit process, a necessary prerequisite to filing an ADR claim.¹²⁸ Manufacturers must establish "reasonable cause" that the covered entity is engaging in prohibited activity before HRSA will approve the audit.¹²⁹ "In practice," claims data is the *only* way that manufacturers are able to establish reasonable cause and manufacturers "likely need to 'require'

¹²² Colo. Rev. Stat. § 6-29-105 (Colorado); Me. Rev. Stat. Ann. tit. 24-A, § 7753 (Maine); N.D. Cent. Code § 43-15.3-08 (North Dakota); Neb. Rev. Stat. § 44-4620 (Nebraska); N.M. Stat. Ann. § 26-1-27 (New Mexico); Or. H.B. 2385 (Oregon); R.I. Gen. Laws §§ 5-19.3-3, -5 (Rhode Island); S.D. Codified Laws § 58-29G-3 (South Dakota); Tenn. Code Ann. § 47-18-136 (Tennessee); Utah Code Ann. § 31A-46-311; Vt. Stat. Ann. tit. 18 (Vermont), § 4682; W. Va. Code § 60A-8-6a (West Virginia).

¹²³ See, e.g., Defs. Mem. of Law at 13-14, *Pharma. Research & Mfrs. of Am. v. Arel*, No. 25-cv-600 (D. Vt. Sept. 2, 2025) (Attorney General did "not oppose entry of a preliminary injunction temporarily blocking" claims-data provision of Vermont law, in light of Pilot Program).

¹²⁴ See, e.g., Br. in Support of Mot. for Prelim. Injunction at 2, *AbbVie v. Hilgers*, No. 4:25-cv-3089 (D. Neb. Nov. 11, 2025).

¹²⁵ See, e.g., Br. of the United States as Amicus Curiae, *AbbVie v. Weiser*, No. 25-1439 (10th Cir. Feb. 25, 2026).

¹²⁶ *Id.* at 15.

¹²⁷ See PHSA § 340B(d)(1)(B)(v), (d)(3); *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110 (2011).

¹²⁸ See PHSA § 340B(d)(3)(A).

¹²⁹ 61 Fed. Reg. at 65407.

submission of claims or utilization data as a condition of delivery to contract pharmacies.”¹³⁰ As one federal judge noted, in determining that Oklahoma’s law prohibiting drug manufacturers from collecting claims data was preempted by Section 340B, “without suspicion-raising claims data, how would a manufacturer know to ever ask for an audit? The claims data . . . would be *the* way to detect possible diversion or double-dipping on discounts. The barrier to access that data created by [the Oklahoma law] thus stands in direct conflict with the 340B Program’s dispute resolution mechanism.”¹³¹ Or, as another federal judge noted in finding West Virginia’s analogous statute conflicted with Section 340B, if manufacturers cannot require the provision of claims data, “there is not much recourse available to the manufacturer. Instead, covered entities—who may be engaging in the kind of fraud that the 340B Program’s ADR system is meant to prevent—will essentially be the ones determining whether or not they wish to give manufacturers the very data necessary to start such an audit.”¹³²

Second, Congress specifically vested HHS and HRSA exclusive authority to enforce and administer the 340B Program through audits and a federal ADR program.¹³³ In 2024, HRSA recently issued a final rule setting forth additional details of the congressionally prescribed 340B ADR process.¹³⁴ The final rule established a comprehensive scheme to resolve disputes between manufacturers and covered entities arising under the 340B statute. Under the rule, a “340B ADR Panel” within HRSA is tasked with resolving not only disputes about drug prices but also claims that a manufacturer has limited the covered entity’s ability to purchase covered outpatient drugs at or below the 340B ceiling price—the exact issue States are passing laws to purportedly address.¹³⁵ By vesting enforcement authority solely in HHS, Congress withheld from States the ability to enforce the 340B Program’s requirements against manufacturers.¹³⁶ Auxiliary enforcement mechanisms beyond those contemplated in the federal statute would “undermine the agency’s efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis.”¹³⁷ As the DOJ noted in its recent amicus brief, such state laws “supplant[]” the uniform scheme Congress created “by arrogating to the State enforcement authority that properly belongs to the federal government alone. That act of self-aggrandizement conflicts with the scheme Congress designed.”¹³⁸ In sum, as the Fourth Circuit recently noted, such restrictions on the

¹³⁰ *Pharm. Rsch. & Mfrs. of Am. v. Morrissey v. McCuskey*, No. 25-1054, --- F.4th ---, 2026 WL 898259, 2026 U.S. App. LEXIS 9272, at *31 (4th Cir. Mar. 31, 2026).

¹³¹ *AbbVie v. Drummond*, 808 F. Supp. 3d 1266, 1278 (W.D. Okla. 2025).

¹³² *Pharm. Rsch. & Mfrs. of Am. v. Morrissey*, 760 F. Supp. 3d 439, 453 (S.D. W. Va. 2024).

¹³³ *Astra USA*, 563 U.S. at 120–21.

¹³⁴ See 89 Fed. Reg. 28643 (Apr. 19, 2024).

¹³⁵ See 42 C.F.R. §§ 10.3, 10.21; *accord id.* § 10.22(c)(1) (“A manufacturer is responsible for obtaining relevant information and documents from any wholesaler or other third party that facilitate the sale or distribution of its drugs to covered entities.”).

¹³⁶ See *Astra*, 563 U.S. at 120–21.

¹³⁷ *Id.*

¹³⁸ Br. of United States, *AbbVie v. Weiser*, No. 25-1439 at 15 (10th Cir. Feb. 25, 2026).

collection of claims data “interfere ... at an operational level with HHS’s enforcement authority and specific enforcement activity.”¹³⁹

AbbVie believes that some States will continue to enforce restrictions on the collection of claims data even in light of a Rebate Model. Thus, AbbVie requests HRSA issue a statement making clear that the Rebate Model preempts all state laws that attempt to impose different or additional requirements or limitations on manufacturers, such as claims data prohibitions. Such interference with an exclusively federal program violates the Supremacy Clause and will disrupt the integrity of the Rebate Model.¹⁴⁰

V. HRSA Must Act Expeditiously to Balance the Interests of All Stakeholders and Announce Its Decision on the New Rebate Model.

AbbVie appreciates HRSA’s recent efforts following litigation over the Pilot Program. AbbVie respectfully submits that re-approving a Rebate Model should not require a heavy lift. Even the district court in Maine recognized that approval of a Rebate Model would not require extensive additional explanation; HRSA simply needs to provide a well-reasoned explanation of the basis for its decision that responds to objections raised by covered entities and shows that HRSA has balanced the interests at stake. HRSA does not need more process or significant further delays; rather, HRSA needs to act expeditiously and decisively, while supporting its decision with evidence in a written record—much of which the agency already possesses. Indeed, given the ongoing nature of manufacturers’ obligations under the IRA, any significant delays will cause substantial prejudice to manufacturers and other stakeholders.

Without delay, therefore, HRSA should issue a decision that (1) re-approves manufacturers’ Rebate Models, (2) authorizes manufacturers to implement those models by a date certain (i.e., July 1, 2026), and (3) responds to all of the major objections that have been raised by covered entities, whether in comments submitted to HRSA or in litigation. In its decision moreover, HRSA should assemble and cite to specific materials, communications, or other submissions that the agency considered and upon which it relies in reaching its conclusions. The record should include all pertinent material from the initial application-and-approval process.

AbbVie appreciates the opportunity to provide comments on the Rebate Model. We strongly support the 340B Program’s original intent and we thank you for consideration of our comments in an attempt to preserve patient access to lifesaving and life-sustaining medicines. We

¹³⁹ *Pharm. Rsch. & Mfrs. of Am. v. Morrissey v. McCuskey*, No. 25-1054, --- F.4th ----, 2026 WL 898259, 2026 U.S. App. LEXIS 9272, at *32 (4th Cir. Mar. 31, 2026).

¹⁴⁰ U.S. Const. art. VI, cl. 2. State regulation of the 340B Program violates the Supremacy Clause by impermissibly changing the terms of a federal drug-pricing regime—the federal 340B Program—and significantly increasing the cost of participation in that regime.

would be pleased to discuss at your convenience. If you have questions, please contact me at hillary.cavanagh@abbvie.com.

Sincerely,

Hillary Cavanagh

Hillary Cavanagh
Vice President, US Policy and Analytics
On behalf of AbbVie Inc.

cc (via Electronic Mail): Chris Klomp
Director, Center for Medicare
Deputy Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Appendix A: Industry Standard Forms

Table 2: Standard Pharmacy Claim Forms

Form	Also Known As	Description
NCPDP D.0	National Council for Prescription Drug Programs standard	NCPDP D.0 serves as the universal format used to communicate prescription drug claim data consistently and in real-time by retail, mail-order, hospital outpatient, and specialty pharmacies whenever a prescription is dispensed (e.g. pharmacy packages patient, drug, and cost data into a standardized e-message, transmits it to the payer, and receives an instant approval/denial). Covered entities also rely on it to properly flag and bill drugs purchased under the 340B Drug Program.
CMS-1500	HCFA-1500	CMS-1500 is the standard claim form used by healthcare providers in the U.S. to bill insurance companies for medical services. It is used if providers administer drugs in an office setting or by a specialty pharmacy if a drug is billed under a medical benefit.
UB-04 / 837I	CMS-1450	UB-04 is the standard claim form used by hospitals and facility-based outpatient pharmacies when billing for services as part of a facility claim. It is used if a covered entity administers a drug as part of its services at the facility.
Prescription Drug Event	PDE	PDE is a summary record submitted to CMS for every prescription filled under a Part D plan by the Medicare Prescription Drug Plan. It is not a payment request, but a post-claim data record used to administer Part D and reconcile plan payments.

Table 3: AbbVie Rebate Model Data Fields provided for reimbursement to others

Data Field	Provided for reimbursement	NCPDP D.0	CMS-1500	UB-04	PDE
Date of Service	Yes	Field 401-D1	Box 24A	FL 45	Yes
Date Prescribed	Yes	Field 414-DE	-	-	-
Rx Number	Yes	Field 402-D2	-	-	Yes
Fill Number	Yes	Field 403-D3	-	-	Yes
NDC-11	Yes	Field 407-D7	Box 24A, shaded area	FL43*	Yes
Quantity / Quantity Dispensed	Yes	Field 442-E7	Box 24G	FL 46	Yes
Prescriber ID / Physician ID	Yes	Field 411-DB	Box 17b or Box 24J	FL 76 or FL 78–79	Yes
Service Provider ID / Ship-to-Pharmacy ID	Yes	Field 201-B1	Box 32a or Box 33a	FL 56 or FL 57	Yes
340B ID	No	-	-	-	-
BIN Number	Yes	Field 101-A1	-	-	-
PCN Number	Yes	Field 104-A4	-	-	-
Group Number	Yes	Field 301-C1	Box 11 & 9a	FL62 A-C	-
Child Site Modifier	No	-	-	-	-
Medicare Part B 340B Claims Modifier	Yes	N/A	Box 24D	FL 44	-
Part D 340B Modifier	Yes	Field 420-DK, value "20"	-	-	-

*NDC for Medicaid Drug Rebate Reporting

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

THE AMERICAN HOSPITAL
ASSOCIATION, THE MAINE HOSPITAL
ASSOCIATION, EASTERN MAINE
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. 1:26-cv-00515-LEW

DECLARATION OF JUDITH SHARP

I, Judith Sharp, hereby make this declaration in lieu of an affidavit as permitted by 28 U.S.C. § 1746. I am aware that this declaration will be filed in the United States District Court for the District of Maine, and that it is the equivalent of a statement under oath. I declare as follows in support of AbbVie Inc.'s and Pharmacyclics LLC's (collectively, "AbbVie") motion to intervene as defendants and memorandum in opposition to Plaintiffs' motion for a temporary restraining order in the above-captioned action:

A. Background

1. I am over the age of 21, under no disability, and competent to testify to the matters contained in this declaration.

2. I am Senior Director of IRA Navigation & Possibilities at AbbVie and have worked at AbbVie since 2014. My responsibilities include contributing to the development of AbbVie's plan to effectuate the "Maximum Fair Price" ("MFP") under the Inflation Reduction Act ("IRA"), including deduplication with 340B pricing. I am familiar with the conditions of AbbVie's participation in federal healthcare programs, such as Medicare and Medicaid, as well as its compliance with the IRA, which established the Medicare Drug Price Negotiation Program ("DPNP"), requiring the Secretary of the U.S. Department of Health and Human Services ("HHS") to set an MFP for selected drugs.

B. The Drug Price Negotiation Program

3. The IRA created a new price-setting program, called the DPNP. Through the DPNP, the Secretary of HHS sets the price that Medicare plans will pay for a certain number of selected drugs each year. The newly set Medicare price is the "MFP." The first set of MFPs under the DPNP just went into effect this year, on January 1, 2026.

4. A separate federal program, the 340B Program, has long required manufacturers to offer drugs to certain "covered entities" at a statutorily calculated "ceiling price." For entities entitled to purchase drugs under the 340B Program, a manufacturer must offer the lower of a selected drug's MFP and the 340B ceiling price. The IRA statute requires AbbVie to provide only the lower of the MFP and 340B ceiling price. 42 U.S.C. § 1320f-2(d). AbbVie is not required to provide both price concessions on the same unit of drug dispensed. In other words, AbbVie is not required to pay duplicate discounts. It is my understanding that the Centers for Medicare & Medicaid Services ("CMS") has declined to "assume responsibility for nonduplication of

discounts” between the 340B price and the MFP and, as such, HHS has put the responsibility for preventing duplicate discounts on manufacturers.¹

5. For the first three years of the DPNP, CMS issued Final Guidance setting forth how manufacturers are to comply with the DPNP and provide the MFP.² CMS has maintained that manufacturers “may provide access to the MFP prospectively or retrospectively.”³ That is, manufacturers may either provide access to the MFP by “(1) prospectively ensuring that the price paid by the dispensing entity when acquiring the drug is no greater than the MFP” or “(2) retrospectively providing reimbursement for the difference between the dispensing entity’s acquisition cost and the MFP.”⁴

6. To help manufacturers administer the MFP, CMS has created the Medicare Transaction Facilitator (“MTF”). The MTF facilitates the transmission of claims data from insurance plans to manufacturers. When manufacturers provide the MFP through a refund,⁵ I understand that they use claims data from the MTF to identify which medications were dispensed

¹ CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028* at 255 (Sept. 30, 2025) (“IPAY 2026-28 Final Guidance”), <https://tinyurl.com/uf86dc2f>.

² See, e.g., CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027*, § 40.4 at 195-98 (Oct. 2, 2024), <https://tinyurl.com/4n245pt3>.

³ IPAY 2026-28 Final Guidance at 212-15; see also CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027* at 187 (Oct. 2, 2024) (“IPAY 2027 Final Guidance”), <https://tinyurl.com/mrxz4hf9>; CMS, *Draft Guidance on Manufacturer Effectuation of the Maximum Fair Price in 2028 under the Medicare Drug Price Negotiation Program* (July 16, 2026) (“2028 Draft Revised Guidance”), <https://tinyurl.com/yxprj3u2>.

⁴ IPAY 2026-28 Final Guidance at 55.

⁵ Cardinal Health, *Inflation Reduction Act (IRA)*, <https://tinyurl.com/3wh2djif> (“Every manufacturer chose retrospective effectuation for IPAY2026.”).

to MFP-eligible individuals and to refund the entities that dispensed the medications (*e.g.*, pharmacies).⁶ The MTF system is composed of two key functionalities: a mandatory Data Module, which facilitates the transmission of certain data elements from Medicare Part D plan sponsors to manufacturers, and an optional Payment Module, a system through which manufacturers may transfer refund payments to dispensing entities. The MTF is a core component of implementing the DPNP, as it supports manufacturers like AbbVie in meeting their statutory obligations—including to ensure that dispensing entities are “provided access” to the MFP refund consistent with CMS guidance.⁷

7. The MTF is important because, under the IRA, a Medicare Part D plan sponsor will pay no more than the MFP (plus a dispensing fee) to a dispensing entity (*e.g.*, a pharmacy) when a Medicare Part D enrollee purchases a DPNP-selected drug. After the enrollee purchases the DPNP-selected drug, CMS requires Medicare Part D plan sponsors to provide claims data to the Drug Data Processing System (“DDPS”). Certain elements of the claims data are then transmitted to manufacturers through the MTF Data Module. Drug manufacturers are then allotted up to 14 days to process the data and provide the MTF with instructions and approvals for processing MFP refunds to the dispensing entity. Refunds are typically calculated as the difference between the dispensing entity’s acquisition cost (often using the drug’s wholesale acquisition cost (“WAC”) as a proxy) and the MFP (which is intended to be the price that the dispensing entity ultimately recovers from the enrollee’s plan).

8. It is my understanding that the MFP refund process thus far in 2026 has worked as per the timeline that CMS anticipated; AbbVie timely transmits remittance data to the MTF

⁶ IPAY 2026-28 Final Guidance at 215.

⁷ *See id.*

regarding the applicability of any refund. Plan sponsors have 7 days to submit claims data to CMS, and manufacturers have 14 days to transmit a refund after they receive the claims data from CMS through the MTF.

9. In addition, I have reviewed the declaration of Sean Fadale, prepared on October 8, 2026, in support of Plaintiffs' motion for a temporary restraining order. It states that the Pilot Program's "[t]en-[d]ay [p]romise [i]s [i]llusory," and bases that statement on Nathan Littauer Hospital's experience with the MTF, under which Nathan Littauer Hospital has received payment on claims "in approximately thirty to ninety days ... even though the payment period is supposed to be fourteen days." Dkt. 2-4 ¶ 20. I do not understand this to be an accurate representation of how the MTF functions. Plans are required to submit claims to CMS within 7 days of receipt from a dispensing entity and manufacturers are required to make prompt payment within 14 days. It is my understanding that according to data reported by the MTF to Beacon for IPAY 2026 drugs, when a pharmacy is eligible to receive an MFP refund, that refund is on average paid to the pharmacy within 21 days from the date of dispense.⁸ A minority of pharmacies have not opted into electronic funds transfer and may wait longer to receive funds because they will instead receive payment through a paper check. These timelines are contrary to the broad average of 30 to 90 days asserted in the Fadale declaration. The Fadale declaration also does not address whether the claim was initially denied within the 14-day window for manufacturers to assess whether a refund is due. It is my understanding that an MFP refund claim may be denied if a manufacturer reasonably believes the claim is subject to the 340B deduplication exception in the IRA.⁹ In the

⁸ BRG, *Update on Effectuation of the Maximum Fair Price in 2026 and Outlook for 2027* at 1 (Apr. 2026), <https://tinyurl.com/46ckpxaw> ("BRG Update").

⁹ See IPAY 2026-28 Final Guidance at 238-40.

absence of a 340B rebate model, if a covered entity believes the claim is not subject to 340B, the covered entity must then produce evidence (such as a purchase invoice or additional data) to the manufacturer to attest that the claim is not subject to 340B pricing. This is part of a dispute resolution process that, absent a rebate model, may delay the ultimate decision of whether an MFP refund is due. I also understand that dispute escalations have been minimal.

C. Program Overlap

10. Accurate deduplication is impossible without access to the data proposed to be made available through the Health Resources and Services Administration's ("HRSA") 340B Rebate Model Pilot Program ("Pilot Program"). Consider, for example, a covered entity that dispenses a drug subject to both the MFP and the 340B ceiling price. If the WAC for that drug is \$1,000, and the MFP is \$500, a Medicare Part D plan will pay the covered entity the \$500 MFP plus a dispensing fee when the covered entity dispenses the drug to a Medicare Part D enrollee. The MTF then sends elements of the claims data about that transaction to the manufacturer of the drug. Based on the data, the manufacturer must pay the covered entity (within the 14-day "prompt payment window") a "refund" that is typically the difference between the WAC and the MFP. At the same time, the 340B ceiling price for that same drug may be \$250. And because covered entities generally need not seek a 340B discount within a particular period, the manufacturer will likely have provided the MFP by the time the covered entity attempts to replenish the drug at the \$250 340B ceiling price, *i.e.*, to obtain a \$750 discount. In that way, a manufacturer would end up providing \$1,250 in discounts on a drug with a \$1,000 wholesale acquisition cost: \$500 to the covered entity as an MFP refund and \$750 as a discount on the covered entity's replenishment order. Such duplicate discounts are contrary to the IRA statute. They are the unintentional result of the temporal gap between the application of the MFP and 340B ceiling price. I understand that

this same scenario is possible with a contract pharmacy (seeking the MFP refund) and a covered entity (placing a replenishment order).

11. Duplicate discounts are inconsistent with the IRA. When a drug transaction could qualify for both the MFP and the 340B ceiling price, the IRA requires manufacturers to provide only the lower of the MFP and 340B ceiling price. In other words, AbbVie is not required to pay duplicate price concessions on the same unit of drug—although it is my understanding that HHS has thus far put the responsibility for preventing duplicate discounts on manufacturers. The only reliable way to avoid such duplication is with access to claims data, such as the date prescribed, Rx number, fill number, quantity dispensed, and National Provider Identifier (“NPI”). But covered entities do not freely provide such claims data to manufacturers. CMS has provided a pathway for pharmacies to “voluntarily and proactively indicate on a submitted claim” that the drug was purchased at the 340B price.¹⁰ And the MFP platform offers a supplemental process through which pharmacies can identify 340B claims. But to date, less than 0.5 percent of claims submitted have proactively identified that they are also associated with a 340B claim.¹¹ By comparison, analysis of Medicare Part D Prescription Drug Event data suggests that between 10 and 12 percent of claims for 2026 selected drugs are subject to 340B pricing.¹²

12. CMS is aware of the duplicate discount problem. It requires manufacturers of selected drugs to submit Maximum Fair Price Effectuation Plans (“MFP Effectuation Plans”) that detail how a manufacturer will comply with the DPNP and provide access to the MFP for selected drugs. A manufacturer’s MFP Effectuation Plan must also detail a process for deduplication of

¹⁰ BRG Update at 2.

¹¹ *Id.*

¹² *Id.*

MFP and 340B discounts.¹³ Any changes to that plan must be submitted to CMS. AbbVie submitted an MFP Effectuation Plan for the 2027 initial price applicability year, and Pharmacyclics previously submitted an MFP Effectuation Plan for the 2026 initial price applicability year. AbbVie's MFP Effectuation Plans set forth how AbbVie will comply with the IRA and identify the use of the Pilot Program for deduplication.

13. I understand that a drug manufacturer with a DPNP agreement that violates the requirements that CMS determines are "necessary" for program administration and compliance may be subject to fines of over one million dollars per day.¹⁴ A manufacturer also faces civil monetary penalties up to ten times the overcharge per drug unit if the manufacturer does not timely provide the MFP refund.¹⁵ CMS guidance has specified that a manufacturer "may meet its statutory obligation under" the IRA "to make the MFP available to dispensing entities by retrospectively transmitting payment for the difference between the dispensing entity's acquisition cost and the MFP (*i.e.*, the MFP refund amount), within the 14-day prompt MFP payment window."¹⁶

14. HRSA proposed a rebate model pilot program for use in 2026, but I understand that AbbVie's plan to participate in that program was halted before it became effective. With the 2026 pilot program enjoined (and then vacated), AbbVie concluded that it could not deduplicate 340B and MFP claims accurately for drugs subject to both programs, and, as a result, incurred sizeable losses.

¹³ IPAY 2026-28 Final Guidance at 326-32.

¹⁴ *Id.* at 339-40.

¹⁵ *See* 42 U.S.C. § 1320f-6(a).

¹⁶ IPAY 2026-28 Final Guidance at 212; *see also* 2028 Draft Revised Guidance at 11.

15. CMS permits manufacturers to offer the MFP prospectively. I understand that some covered entities have argued that drug companies can comply with the IRA and Section 340B by simply making the MFP for Medicare-negotiated drugs available prospectively. This contention is not an accurate description of manufacturers' options for two primary reasons.

16. First, prospective MFP pricing is impractical because a drug qualifies for the MFP only if it is dispensed to a Medicare Part D enrollee. When an entity purchases the drug, the manufacturer (and often the purchaser) does not yet know to whom it will be dispensed.¹⁷ Because manufacturers do not know to whom the drug will be dispensed when it is sold to a covered entity, they cannot deduplicate the MFP from the 340B price on the front end.

17. Second, prospective MFP pricing would not solve the duplicate discount problem because the MFP and 340B price may still be requested at different times, through distinct processes. Covered entities generally need not assert that a claim is eligible for a 340B discount within a particular period, so there is rarely a practical way to determine the duplicative discount within the 14-day period in which manufacturers must provide the MFP, regardless of whether the MFP price is provided prospectively or retrospectively.¹⁸ This problem is exacerbated by covered entities' use of contract pharmacies and the replenishment model described above to obtain the 340B price. Thus, without the Pilot Program, a covered entity may purchase a drug at the MFP on the front end and then, months or even a year later, attempt to replenish that same drug at the 340B ceiling price after the covered entity's contract pharmacy dispensed the drug to a patient of the

¹⁷ Additionally, providing prospective access to the MFP requires specific documentation from manufacturers that differs from the documentation necessary to facilitate retrospective access. IPAY 2026-28 Final Guidance at 238-40 (Table 5).

¹⁸ 2028 Draft Revised Guidance at 9 ("CMS requires that the Primary Manufacturer transmit payment of an amount that provides access to the MFP within 14 calendar days of when the MTF sends data to the Primary Manufacturer that verify the selected drug was either dispensed, furnished, or administered to an MFP-eligible individual.").

covered entity. To prevent such duplicate discounts, manufacturers must be able to identify whether a particular dispense was both MFP-eligible and subject to the 340B ceiling price. In other words, even if a manufacturer were to provide the MFP prospectively, that dispense would still have to be validated through the MTF as going to an MFP-eligible individual and the manufacturer would still need to determine if that same claim was also the subject of a request for a 340B discount.

18. It is my understanding that duplicate discounts will happen unless manufacturers can obtain claims data through the Pilot Program. Without the Pilot Program, manufacturers lack the claims data necessary to identify if a dispense subject to an MFP was purchased at the 340B ceiling price—or if a 340B replenishment order is based on drugs for which the MFP was already applied. This overlap exposes manufacturers to a risk of costly duplicate discounts and steep civil monetary penalties. Similarly, the Pilot Program reduces—although it does not eliminate—the timing gap between 340B discounts and the MFP. It requires covered entities to submit 340B rebate requests within 45 days of a dispense, rather than months or even a year later.

* * *

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 13th day of October 2026.

/s/ Judith Sharp
Judith Sharp
Declarant

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

THE AMERICAN HOSPITAL
ASSOCIATION, THE MAINE HOSPITAL
ASSOCIATION, EASTERN MAINE
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. 1:26-cv-515

DECLARATION OF JUSTIN MCCARTHY

I, Justin McCarthy, declare as follows:

1. I am over the age of 18. Except as expressly indicated, the facts stated below are based upon my personal knowledge, including my experience in the pharmaceutical industry, my work at Bristol-Myers Squibb Company (BMS), and my review of the business records of the company. If called to testify, I could truthfully and competently testify to these facts.

2. I am the Senior Vice President and Head of Market Access, Pricing, and Value Demonstration at BMS. In my current position, I lead our Market Access, Pricing, and Value Demonstration organization in its efforts to help ensure that patients in need of BMS's medicines

have access to them. I have over three decades of experience in the pharmaceutical industry, having served in a number of capacities related to health economics and outcomes research, real-world data and analytics, patient-centered outcomes assessment, market access, pricing, and contracting. I also have experience in public policy at the federal and state level, as well as experience serving as a pharmaceutical company's legal counsel advising on regulatory, licensing, clinical trial, and intellectual property issues.

3. BMS is a global biopharma company that is pursuing bold science to define what is possible for the future of medicine and the patients it serves. Its mission is to discover, develop, and deliver innovative medicines that help patients prevail over serious diseases. Consistent with that mission, BMS works to ensure that its products and treatments are available to as many patients as possible.

BMS'S PARTICIPATION IN THE 340B PROGRAM

4. BMS participates in the 340B Drug Pricing Program as a condition of having its drugs eligible for federal reimbursement under Medicaid and Medicare Part B. Under the 340B Program, a participating drug manufacturer must offer its covered outpatient drugs to certain hospitals and clinics—known as “covered entities”—at or below a price specified by a statutory formula. This 340B “ceiling price” results in significant price reductions on BMS's products for covered entities: The 340B price for some drugs can be as low as a penny per unit.

5. Manufacturers that participate in the 340B Program enter into an agreement with the Secretary of Health and Human Services known as a Pharmaceutical Pricing Agreement (PPA). A manufacturer's execution of the PPA indicates its commitment to participate in the 340B Program. If the Department of Health and Human Services (HHS) terminates a manufacturer's PPA, federal reimbursement under Medicaid and Medicare Part B is unavailable

for the manufacturer's drugs. BMS has participated in the 340B Program since its inception decades ago.

6. Throughout the 340B Program's history, covered entities have used various methods to purchase 340B-priced drugs. The simplest method is often called a physical inventory model. Under this model, covered entities physically segregate units purchased at the 340B price from units purchased at a commercial price on their shelves. Covered entities then determine whether a particular prescription is 340B-eligible—that is, whether it satisfies the statutory criteria to be filled with 340B-priced medicine—before the relevant drug is dispensed to a patient.

7. In the 340B Program today, covered entities typically use various virtual inventory models, most notably the “replenishment model,” instead of a physical inventory model. Under the replenishment model, a covered entity first purchases a medicine at the commercial price, places it in a single, common inventory, and dispenses it to any individual with a prescription for the medicine, without regard to whether the prescription is 340B-eligible. After the medication is dispensed—often weeks or even months later—the covered entity or a third-party administrator acting on its behalf analyzes claims data from prior dispenses to identify prescriptions it thinks were 340B-eligible. Once the covered entity identifies a certain number of units it believes were 340B-eligible, it purchases “replenishment” units at the 340B price, reasoning that it is entitled to be made whole for the 340B price on the dispensed medicine initially purchased at the commercial price. The replenishment product is placed in the common inventory, and the cycle restarts. Thus, a defining characteristic of the product-replenishment model is that covered entities do not determine whether a prescription is 340B-eligible before it is dispensed. They instead do so after the fact.

BMS'S PARTICIPATION IN THE DRUG PRICE NEGOTIATION PROGRAM

8. In 2022, Congress enacted the Medicare Drug Price Negotiation Program as part of the Inflation Reduction Act (IRA). The statute requires the Secretary of HHS to set a “Maximum Fair Price” on certain drugs that are selected each year as negotiation-eligible. HHS oversees the Drug Price Negotiation Program through its subagency, the Centers for Medicare & Medicaid Services (CMS).

9. BMS's product Eliquis[®] was selected for negotiation under the Drug Price Negotiation Program and became subject to a maximum fair price starting on January 1, 2026. The Maximum Fair Price for Eliquis is \$231.00 for a 30-day supply, a 56% discount from the list price.¹ BMS's drug Pomalyst[®] was selected for negotiation and is scheduled to have a Maximum Fair Price of \$8,650 for a 30-day supply (a 60% discount) take effect beginning in 2027.² BMS's drug Orencia[®] was selected for negotiation of a Maximum Fair Price for IPAY 2028.³

10. Once a Maximum Fair Price is in effect, manufacturers must make that price available on all sales of the selected drug to eligible Medicare beneficiaries enrolled in a prescription drug plan and to pharmacies, mail-order services, and other entities that dispense the drug to Medicare beneficiaries.

11. Under CMS guidance implementing the IRA, manufacturers like BMS may either offer dispensing entities the Maximum Fair Price for a selected drug at the time of purchase or

¹ CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026* (Aug. 15, 2024), <https://tinyurl.com/5n6kj8ec>.

² CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2027* (Nov. 2025), <https://tinyurl.com/de985fyb>.

³ CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2028* (Jan. 2026), <https://tinyurl.com/yar6ev3t>.

provide a post-purchase refund amounting to the difference between the entity's acquisition cost and the Maximum Fair Price. The latter practice is known as issuing an "MFP refund." BMS effectuates the Maximum Fair Price through refunds. For example, if the commercial price for Eliquis were \$100 and the Maximum Fair Price were \$40, BMS would initially charge its wholesaler \$100 for the drug. The wholesaler would then sell the drug to a dispensing entity, such as a pharmacy. After the pharmacy dispenses the drug to an eligible Medicare beneficiary, the customer and her Medicare plan would be charged the Maximum Fair Price (\$40), and BMS would issue a \$60 refund to the dispensing entity.

12. BMS must provide the MFP refund to the dispensing entity within 14 days after receiving claims data verifying Maximum Fair Price eligibility through a data portal set up by CMS. If BMS does not pay the MFP refund within 14 days, it risks a significant civil monetary penalty—ten times the refund amount multiplied by the number of units sold above the Maximum Fair Price. 42 U.S.C. § 1320f-6(a).

13. The IRA protects manufacturers like BMS from having to offer both a 340B discount and the Maximum Fair Price on the same unit of a drug. Manufacturers instead must provide only the lower of the Maximum Fair Price and the 340B price. 42 U.S.C. § 1320f-2(d). For example, if a unit of Eliquis had a commercial price of \$100, a 340B price of \$50, and a Maximum Fair Price of \$40, BMS would need to provide only a \$10 refund—the difference between the 340B purchase price and the MFP—on drugs purchased by a covered entity at the 340B price and dispensed to eligible Medicare beneficiaries. If the 340B price were lower than the MFP, BMS would have no legal obligation to provide an MFP refund at all.

14. For those reasons, it is essential that BMS is able to identify which units of drugs may be subject to 340B pricing—and that this identification occur in a timely manner. As noted

above, manufacturers only have 14 days after receiving claims data for a drug dispense to verify eligibility for an MFP refund under CMS rules. Without the ability to determine within that short window that a unit of drug was also 340B-eligible—*i.e.*, that it was purchased by a 340B covered entity and dispensed to an eligible patient—BMS is unable to benefit from the above statutory protections. For instance, imagine that in the above example, BMS did not know the unit of Eliquis was subject to 340B pricing until after it was forced to pay the MFP refund. It would then provide a \$60 rather than \$10 MFP refund—vastly exceeding its legal discounting obligations.

15. This presents a sequencing problem. Under the replenishment model, BMS cannot know which dispenses were considered 340B-eligible until the covered entity retroactively analyzes data—usually well after the dispense has occurred—to determine whether the previously dispensed medication qualified for the 340B price. But the 14-day MFP-refund deadline begins to run within days of the dispense, as soon as BMS receives claims data through CMS’s data portal verifying MFP eligibility. This means that in most cases, the covered entity itself may not have yet determined 340B eligibility by the time the MFP refund is due.

16. For its part, CMS has specifically disclaimed any responsibility for identifying when a unit is subject to both a 340B discount and a Maximum Fair Price, leaving manufacturers to fend for themselves. Although CMS has created a data portal to facilitate sharing claims data between dispensing entities and manufacturers to verify Maximum Fair Price transactions, no comparable mechanism exists for 340B discounts, which are currently overseen by a different subagency of HHS: the Health Resources and Services Administration (HRSA).

17. Covered entities collect claims data in the regular course of business and routinely share these data with public and private payors. Such claims data identify, for example, the date

of service, the dispensing pharmacy, the identity of the prescriber, the health insurer, and the prescription identification number assigned to each prescription.

18. BMS's current policy requires covered entities to submit claims data for 340B utilization within a 45-day post-dispense submission window, such that most data is submitted long after BMS can feasibly match it to MFP-refund claims in order to de-duplicate the discounts. BMS also exempts several states from its claims-data policy or limits the policy's scope to comply with restrictions set by state laws; in other states, noncompliance with BMS's policy is widespread. Less than half of all disproportionate share hospitals—which represent the highest 340B purchase volumes for Eliquis—are currently in compliance with BMS's policy.

19. For all these reasons, duplicate discounts not contemplated by Congress have become routine, undermining the legal protections built into the IRA. Manufacturers like BMS have been forced to pay both 340B and IRA price concessions to avoid the risk of failing to timely offer the lower of the two.

20. BMS has already lost more than \$40 million because of its inability to detect duplicate claims for 340B and Maximum Fair Price pricing since Eliquis became subject to a Maximum Fair Price in January 2026. These losses will only mount as more of BMS's products are selected for negotiation under the Drug Price Negotiation Program. That includes BMS's Pomalyst, which was subject to negotiation and scheduled for a Maximum Fair Price beginning in January 2027.

THE 340B REBATE MODEL PILOT PROGRAM

21. On July 31, 2026, HRSA, the subagency of HHS responsible for overseeing the 340B Program, announced a limited rebate model pilot program. The rebate model pilot program is very narrow in scope: It applies only to drugs subject to a Maximum Fair Price for

2026 and 2027 and only during the effective dates for the negotiated prices. HRSA had previously approved a rebate plan that BMS submitted in 2025 for Eliquis, but that approval lapsed when HRSA withdrew its first pilot program.

22. The pilot program is premised on a rebate model that will work as follows: Covered entities will purchase a unit of drug at its wholesale acquisition cost (WAC) and provide routine claims data to the manufacturer within 45 days of dispensing the unit to identify its 340B eligibility. If the unit is eligible for 340B pricing, the manufacturer will then have 10 days to give the covered entity a rebate (equal to the difference between WAC and the 340B price).

23. The rebate model embraced by the pilot program is the only feasible method for allowing manufacturers to prevent duplication of 340B discounts and MFP refunds, as required by the IRA. BMS's claims-data policy alone is not sufficient to address 340B and IRA de-duplication. Under CMS guidelines, manufacturers may not condition or withhold a Maximum Fair Price refund while receipt of 340B claims data is pending. And any data submitted under BMS's policy generally identifies only where a duplicate discount has already been given, leaving BMS to attempt to recover the discount in a post-hoc dispute with the covered entity. The rebate model solves this problem by making a 340B eligibility determination *before* the price concession is paid, and on a nationwide basis. This is the only sequence where non-duplication may be achieved prospectively so that BMS can ensure it makes the lower of the IRA and 340B prices available without having to pay both discounts.

24. The pilot program also is a necessary (but notably insufficient) step forward in terms of HRSA's broader oversight responsibilities under the 340B statute itself. That statute prohibits covered entities from selling drugs purchased at the 340B-discounted price to non-patients (diversion) and provides that covered entities may not request the 340B price on a unit

of drug that will be subject to a Medicaid rebate (another form of unlawful duplicate discounts). But without advance access to claims data, manufacturers like BMS are often unable to identify 340B transactions that violate the prohibitions against diversion and duplicate Medicaid discounts.

25. A broader 340B rebate model that extends beyond IRA-selected drugs would promote transparency and address many of these concerns. Although the pilot program is a welcome step forward in that regard, its limited scope leaves much work to be done by HRSA in fulfilling its statutory oversight obligations, particularly in the areas of improved transparency and correcting the rampant abuses in the 340B Program.

26. The burdens on covered entities imposed by the pilot program appear to be minimal, because the pilot program was designed to limit the administrative burden on covered entities. Among other things, the pilot program aligns with the 45-day submission window BMS has already built into its claims-data policy, standardizes the claims data elements that covered entities must report, and centralizes the reporting process. The pilot program also relies on routine pharmacy and medical claims data that covered entities already collect in the ordinary course of their billing and compliance activities. Additionally, manufacturers are required to bear the cost of the information technology platform used to implement the pilot program.

27. The pilot program also includes additional safeguards for covered entities. Manufacturers may deny 340B rebates only in limited circumstances to effectuate nonduplication of Maximum Fair Price and 340B discounts or when the 340B rebate has been provided to another covered entity on the same claim. In particular, HRSA prohibits manufacturers from denying 340B rebates based on eligibility or compliance concerns with diversion or Medicaid duplicate discounting. The agency has instead instructed manufacturers to

raise those concerns directly with HRSA or to use the 340B statutory auditing and alternative-dispute-resolution mechanisms. Manufacturers must also report denied claims, including the basis for denial, and they face termination from the pilot program if they do not provide acceptable justification for denials of rebate payments.

28. Manufacturers must report additional rebate data to HRSA to facilitate program oversight. HRSA plans to monitor the pilot program on an ongoing basis and to publish periodic summaries of its findings, as well as a comprehensive evaluation of the pilot program by April 30, 2028, following the first year of its operation. HRSA has explained that it will use data collected throughout the pilot program to more effectively prevent duplicate discounts and to inform future policy considerations related to 340B program integrity and compliance. The rebate model that is central to the pilot program aligns with the primary commercial model that manufacturers use with their non-340B customers, where eligibility for a reduced price is not determined until after the product is purchased. It is standard commercial practice to provide price reductions through a rebate when a given unit's eligibility for the reduced price is not known at the time of sale.

29. BMS timely applied to participate in the pilot program for its products Eliquis and Pomalyst. As detailed in its application, BMS's pilot program model incorporates safeguards designed to protect the privacy and security of protected health information in compliance with HRSA's rebate model pilot.

BMS WILL SUFFER HARM IF THE PILOT PROGRAM IS ENJOINED

30. If the pilot program does not go into effect, BMS will suffer significant and irreparable harm.

31. HRSA approved BMS's application to participate in the pilot program for its products Eliquis and Pomalyst on September 24, 2026.

32. Between the previously announced pilot program and the most recent one, BMS committed more than \$10 million and tens of thousands of hours to design, develop, test, and operationalize the infrastructure needed to implement and support its pilot program model. This work required significant planning, development, integration, and testing across internal revenue and financial systems, internal stakeholders, and external vendors. BMS also devoted significant time, money, and resources to ensure its platform will be able to process claims data and to issue rebates to covered entities within the 10-day window required by HRSA. For example, BMS has invested more than 10,000 hours in platform testing and related preparatory activities designed to support compliance with HRSA's requirements.

33. Without the ability to implement its pilot program, BMS will lack the information needed to identify in a timely manner units for which both a Maximum Fair Price rebate and a 340B price concession have been claimed, which will significantly increase the likelihood of duplicate price concessions. Such duplicate discounts are already rampant for Eliquis and will only increase as Maximum Fair Prices take effect for more of BMS's products. In addition, without the pilot program enabling BMS to review and de-duplicate claims data, BMS risks incurring significant civil monetary penalties for failure to provide the correct price required by federal law.

34. Each duplicate price concession costs BMS significant revenue that it would otherwise receive absent the unlawful duplicate price concession. BMS estimates that it has been forced to improperly pay more than \$40 million in duplicate discounts for its product

Eliquis in the first half of 2026 alone. Without a pilot program in place for 2027, BMS estimates that figure will continue to climb significantly next year.

35. This lost revenue would otherwise be used by BMS to fund mission-critical programs like research and development into new drug therapies, and to offer critical patient support, education, and access programs.

36. In short, an injunction delaying implementation of the pilot program will cause widespread disruption to BMS's efforts to comply with its statutory obligations and cause significant and irreparable harm to BMS.

I declare under penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct.

/s/ Justin McCarthy
Justin McCarthy

Executed on October 14, 2026

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

THE AMERICAN HOSPITAL
ASSOCIATION, THE MAINE HOSPITAL
ASSOCIATION, EASTERN MAINE
MEDICAL CENTER, NATHAN LITTAUER
HOSPITAL & NURSING HOME, UNITY
MEDICAL CENTER, and DALLAS
COUNTY MEDICAL CENTER,

Plaintiffs,

v.

Case No. 26-cv-00515-LEW

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.

DECLARATION OF CHRISTINE MARSH

I, Christine Marsh, declare as follows pursuant to 28 U.S.C. § 1746:

1. I am Senior Vice President, Value and Access for Boehringer Ingelheim Pharmaceuticals, Inc. (“Boehringer”), and have held that position since July 2019. I submit this declaration in opposition to Plaintiffs’ motion for a preliminary injunction.

2. As Senior Vice President, Value and Access, I am responsible for, among other things, collaborating with a broad range of Boehringer departments to ensure that Boehringer medicines are accessible to patients, including Medicare Part D and Medicaid enrollees. I have

direct oversight over the integrity and compliance of Boehringer's participation in the 340B program. Prior to my current position, I served as Senior Vice President, Market Access and Vice President, Managed Markets Sales at Boehringer, and in senior strategic leadership roles at Boehringer (where I have worked in various capacities since 1999), and Roxane Laboratories. In these roles, I have gained significant experience regarding pricing and government contracting for pharmaceutical products.

3. This declaration is based on my personal knowledge, including knowledge I have gained from others at Boehringer and company documents.

Boehringer's Jardiance®, Ofev®, and Tradjenta® Products

4. Boehringer has a long history of research and development of novel pharmaceutical products. In 2020 alone, the Boehringer family of companies (consisting of Boehringer Ingelheim Pharmaceuticals, Inc. and related entities globally) invested \$4.2 billion in pharmaceutical research and development, covering work on approximately 100 projects across all phases of the research process, many of which addressed unmet medical needs. Those investments increased to \$7.2 billion in 2025, a year in which more than 70 million people globally benefitted from therapies developed by the Boehringer family of companies.¹

5. One of the medications that has resulted from Boehringer's investments is empagliflozin—a medication used to lower blood sugar in adults with type 2 diabetes and to reduce the risk of cardiovascular death in those adults and adults with heart failure—which Boehringer manufactures and sells under the trade name Jardiance®.

¹ See Boehringer Ingelheim, *Boehringer Ingelheim delivers on late-stage pipeline with two key launches, grows sales by 7.3% in a successful 2025* (Mar. 25, 2026), <https://www.boehringer-ingelheim.com/us/media/press-releases/boehringer-ingelheim-reports-2025-growth-and-pipeline-progress>.

6. Boehringer markets Jardiance[®] in the United States under a license for the patents claiming empagliflozin and its uses. Boehringer owns title to its Jardiance[®] products (i.e., the physical, retail-packaged tablets) and exercises its rights to possess, sell, and otherwise dispose of those products, including by determining when and on what terms to make them available to others.

7. Another medication Boehringer has developed is nintedanib esylate, a groundbreaking treatment for idiopathic pulmonary fibrosis and other lung diseases. Boehringer manufactures and sells nintedanib esylate under the trade name Ofev[®].

8. Boehringer markets Ofev[®] in the United States pursuant to patents owned by Boehringer-affiliated entities. Boehringer owns title to its Ofev[®] products (i.e., the physical, retail-packaged capsules) and exercises its rights to possess, sell, and otherwise dispose of those products, including by determining when and on what terms to make them available to others.

9. Boehringer also developed linagliptin tablets, which are used to lower blood sugar in adults with type 2 diabetes. Boehringer manufactures and sells the tablets under the name Tradjenta[®].

10. Boehringer markets Tradjenta[®] in the United States pursuant to patents owned by Boehringer-affiliated entities. Boehringer owns title to its Tradjenta[®] products (i.e., the physical, retail-packaged tablets) and exercises its rights to possess, sell, and otherwise dispose of those products, including by determining when and on what terms to make them available to others.

Boehringer's Participation in Medicare, Medicaid, and 340B

11. Boehringer makes Jardiance[®], Ofev[®], Tradjenta[®], and all its other drugs—numbering more than 20—available through Medicaid and Medicare.

12. Through the Medicaid program, Boehringer provides significant rebates, often above federally mandated amounts, on its products to states that provide health coverage to low-income individuals and families.

13. Through the Medicare program, Boehringer makes its drugs available to people aged 65 and older and certain individuals with disabilities. The Medicare program is divided into multiple parts that provide various benefits to beneficiaries. As relevant to Jardiance[®], Ofev[®], and Tradjenta[®], under Medicare Part D, the Centers for Medicare and Medicaid Services (“CMS”) partially reimburses private insurance plans that provide coverage for self-administered prescription drugs to Medicare beneficiaries. *See* 42 U.S.C. § 1395w-101 *et seq.*

14. Together, Medicare and Medicaid account for nearly half of the total U.S. prescription drug market.²

15. To receive coverage for drugs under the Medicare Part B and Medicaid programs, federal law requires that manufacturers participate in the 340B Program. *See* 42 U.S.C. § 1396r-8(a)(1). Boehringer thus participates in the 340B Program, and Jardiance[®], Ofev[®], and Tradjenta[®] are drugs that are subject to the 340B Program. The 340B Program is administered by the Health Resources and Services Administration (“HRSA”).

16. Under the 340B Program, pharmaceutical manufacturers must offer drugs at a reduced price—referred to as the “340B ceiling price”—to a statutorily defined set of healthcare providers, known as “covered entities.” In turn, covered entities dispense drugs acquired at a reduced cost to patients while often billing the patients’ insurance for the full, non-discounted cost

² HHS Office of the Inspector General, *Drug Spending* (Dec. 16, 2024), <https://oig.hhs.gov/reports/featured/drug-spending/>.

of the product. Covered entities retain the difference between the reimbursement paid by the patient's insurer and the lower acquisition cost obtained through the 340B Program.

17. While the 340B statute requires that manufacturers offer discounts to covered entities, it permits manufacturers to effectuate their 340B "offers" in at least two ways: through a "discount" or a "rebate." 42 U.S.C. § 256b(a)(1).

18. The initial purpose of the 340B Program—as described in a report by the House Energy and Commerce Committee—was to enable covered entities "to stretch limited federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."³ But the 340B statute does not require covered entities to use the funds generated through the 340B Program to provide additional free or reduced-cost care to patients. In fact, there are virtually no limitations on how covered entities can use the resources obtained through the 340B Program. As a result, a 2023 study found that 69% of the disproportionate share hospitals that participate in the 340B Program provided less charity care than the national average for all hospitals.⁴

19. Since its creation, the 340B Program has evolved from a small program intended to help a limited number of safety net health providers into the second-largest prescription drug program in the country, now surpassed only by the prescription drug benefit in Medicare Part D. When the program first launched in 1992, fewer than 100 hospitals enrolled, and by 2009, the 340B Program accounted for \$4 billion in total annual sales. Since then, however, the growth has

³ House Energy and Commerce Committee. (1992). Report to Accompany H.R. 2980, The Medicaid Drug Rebate Amendments of 1992.

⁴ Alliance for Integrity & Reform, *Charity Care at 340B Hospitals is on a Downward Trend* (Oct 2023), <https://340breform.org/wp-content/uploads/2024/03/2023-Charity-Care-Report-Final-1.pdf>.

exploded. In 2025, the 340B Program accounted for a staggering \$100 billion in total sales.⁵ 2025 marks the fourth consecutive year that total 340B purchases grew by at least 20% over the previous year.⁶

20. This massive growth has been driven in part by an increase in duplicate discounts (*i.e.*, seeking both a 340B discount and another discount) and diversion of 340B drugs (*i.e.*, transferring or selling a 340B-priced drug to individuals who are not patients of the covered entity). The scope of this problem is significant: for example, HRSA issued “a total of 1,536 findings to address covered entity noncompliance ... from fiscal years 2012 through 2019.”⁷ IQVIA, an industry data provider, estimates that duplicate discounts accounted for one-quarter of total 340B drug sales in 2021, representing approximately \$20-25 billion in total.⁸ These duplicate discounts impose significant costs on pharmaceutical manufacturers. But these costs are not limited to manufacturers: a recent study found that 8% of the total increase in employer-based health insurance premiums can be attributed to increased 340B costs.⁹

⁵ *2025 340B Covered Entity Purchases*, HRSA, <https://www.hrsa.gov/opa/updates/2025-340b-covered-entity-purchases>.

⁶ William Newton, *Total 340B Purchases Reach \$100 Billion in 2025*, 340B Report (July 14, 2026), <https://340breport.com/total-340b-purchases-reach-100-billion-in-2025/>.

⁷ See U.S. Gov’t Accountability Off., *GAO-21-107, Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements* 13 (Dec. 14, 2020).

⁸ IQVIA, *Uncover the Invisible Impacts of 340B Discounts* (Dec. 20, 2021) <https://www.iqvia.com/locations/united-states/blogs/2021/12/uncover-the-invisible-impacts-of-340b-discounts>.

⁹ Neal Masia et al., *The 340B Drug Purchasing Program and Commercial Insurance Premiums* (May 2025) available at <https://www.npcnow.org/sites/default/files/2025-05/340B%20and%20Employer%20Costs%20White%20Paper.pdf>.

Boehringer's Need for the Rebate Model Pilot

21. Under the Inflation Reduction Act (“IRA”) Medicare Drug Price Negotiation Program (the “IRA Program”), CMS selects a certain number of drugs each year and imposes a “maximum fair price” (“MFP”) for each selected product.

22. Once a drug is selected for the IRA Program, the drug’s manufacturer must sign a form agreement written by CMS and submit a data package to the Agency including information about the selected drug, such as costs related to research and development, production, and commercialization. 42 U.S.C. § 1320f-3(e). On the basis of this and other information, CMS develops and transmits an initial MFP offer to the manufacturer. *Id.* § 1320f-3(b)(2)(B). By statute, CMS’s offer may not exceed a statutory ceiling.

23. On August 29, 2023, CMS selected Jardiance® for inclusion in the IRA Program, making Jardiance® subject to the CMS-dictated “maximum fair price” beginning on January 1, 2026.

24. On January 17, 2025, CMS selected Ofev® and Tradjenta® for inclusion in the IRA Program, making these drugs subject to CMS-dictated “maximum fair price[s]” beginning on January 1, 2027.

25. For Medicare Part D drugs like Jardiance®, Ofev®, and Tradjenta®, the MFP must be at least 25% to 60% below the drug’s market-based price. *Id.* § 1320f-3(c). The statute additionally directs CMS to “aim[] to achieve the lowest [MFP] for each selected drug.” *Id.* § 1320f-3(b)(1).

26. If a manufacturer fails to sign CMS’s IRA Program agreement—or an addendum to the agreement memorializing the MFP established by CMS—the manufacturer is subject to a significant excise tax on all U.S. sales of the selected drug. *See* 26 U.S.C. § 5000D. The tax is initially calculated as 186% of the drug’s sale price but increases to 1,900% after nine months. *See*

id. § 5000D(a), (b)(1), (d). A manufacturer’s only other option for avoiding the tax in this scenario is to withdraw *all* of its products (not just the selected drug) from Medicare and Medicaid entirely. *Id.* § 5000D(c). Since Medicare and Medicaid combined account for such a significant portion of the prescription drug market, total withdrawal is not economically feasible for Boehringer.

27. In August 2024, roughly one year after CMS selected Jardiance® for inclusion in the IRA Program, CMS announced that the MFP for Jardiance® would be \$197 for a 30-day supply.¹⁰ That price reflects a 66% discount off Jardiance®’s list price.¹¹

28. In November 2025, CMS announced that the MFP for Ofev® would be \$6,350 for a 30-day supply, which reflects a 50% discount off Ofev®’s list price.¹²

29. In that same announcement, CMS set the MFP for Tradjenta® at \$78 for a 30-day supply, which reflects an 84% discount off Tradjenta®’s list price.¹³

30. The MFP for Jardiance® (and all other drugs selected in August 2023 for the IRA Program’s first year) took effect on January 1, 2026. *See* 42 U.S.C. § 1320f(b). Starting on that date, Boehringer was required by statute to “provide access” to Jardiance® to Medicare beneficiaries at the MFP. 42 U.S.C. § 1320f-2(a)(1). If Boehringer fails to comply with that access requirement, it is subject to a civil monetary penalty equal to ten times the difference between the MFP and the price actually charged, multiplied by the number of units sold at the higher price. *Id.* § 1320f-6(a).

¹⁰ CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026* (Aug. 2024), <https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf>.

¹¹ *Id.*

¹² CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2027* (Nov. 2025), <https://www.cms.gov/files/document/fact-sheet-negotiated-prices-ipay-2027.pdf>.

¹³ *Id.*

31. The MFPs for Ofev[®] and Tradjenta[®] will take effect on January 1, 2027.¹⁴ Starting on that date, the same requirements and potential penalties that apply to Boehringer's sales of Jardiance[®] will also govern the sales of Ofev[®] and Tradjenta[®].

32. Each of these three drugs is subject to both the 340B Program and the IRA Program. The IRA includes a special pricing provision that governs drugs subject to both of those programs. Under this provision, the manufacturer of a drug subject to both the 340B Program and the IRA Program must provide the drug at the lower of the 340B ceiling price or the MFP but cannot be required to provide the discount under the 340B Program and the discount under the IRA Program. *See* 42 U.S.C. § 1320f-2(d). Accordingly, as CMS has explained, the IRA requires manufacturers to “ensur[e] compliance with the statutory requirement to avoid duplication of the MFP and the 340B ceiling price for a selected drug.”¹⁵

33. Moreover, the MFPs established under the IRA Program apply only to Medicare beneficiaries. Patients covered by Medicaid or private insurers, or who are uninsured, are not eligible to receive drugs at the highly discounted MFP. By contrast, covered entities can receive the 340B ceiling price for any patient regardless of the patient's health insurer. As a practical matter, that means that manufacturers must provide the lower of the MFP or 340B ceiling price only to the subset of patients of a 340B covered entity who are covered by Medicare. Manufacturers must also offer the 340B ceiling price to a covered entity for all its patients who are not Medicare beneficiaries.

¹⁴ *Id.*

¹⁵ CMS, *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026* (June 30, 2023) at 26, <https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf>.

34. Boehringer sells its drugs to wholesalers in bulk quantities. When Boehringer makes these sales, it is impossible to know which providers will dispense the drugs, which patients will receive them, and who will ultimately pay for the drug. Thus, Boehringer generally cannot know in advance which pricing rules will apply to each unit of product it sells.

35. Manufacturers generally comply with their pricing obligations under the IRA Program (and contracts in the private market) by following a two-step process. First, the manufacturer charges a uniform price—known as wholesale acquisition cost (“WAC”) or list price—when it sells its drugs to wholesalers. Second, the manufacturer pays after-the-fact rebates to pharmacies and other dispensing entities that cause the final price, net of rebates, to equal the legally required price. For example, if the WAC for a drug subject to the IRA Program were \$100, and the MFP for that drug were \$40, the manufacturer would pay a \$60 rebate to the dispensing pharmacy.¹⁶ This two-step approach allows manufacturers to provide the correct price to a wide range of dispensing entities, despite not knowing who those entities will be when the drug products first enter the stream of commerce.

36. To provide access to MFPs set under the IRA Program, CMS has developed a “Medicare Transaction Facilitator” (“MTF”) that will share data with manufacturers about claims for products subject to an MFP from dispensing entities (e.g., pharmacies). In return, the MTF can facilitate rebate payments from the manufacturers to the dispensing entities. In general, once a covered entity has dispensed a drug to a Medicare beneficiary, the MTF will send information

¹⁶ In the context of the IRA Program, CMS describes the payments from manufacturers to dispensing entities as a “refund,” but the payments are retrospective and functionally indistinguishable from a rebate. *See generally*, CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028* (Sep. 30, 2025), <https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf>.

about the claim to the manufacturer. Once the manufacturer ensures that the claim is valid, it is required to provide a rebate to the dispensing entity equal to the difference between the acquisition cost of the drug and the MFP.¹⁷ In most cases, Boehringer will provide a rebate equal to the difference between the drug's WAC and the drug's MFP. Once the manufacturer has provided this rebate to the dispensing entity, it has met its statutory obligation to provide access to the MFP.

37. A key challenge for manufacturers providing access to the MFP is that neither manufacturers nor covered entities know which patient is a Medicare beneficiary eligible for the MFP until *after* a claim has been processed. While covered entities use various distribution models to obtain drugs at the 340B ceiling price, the acquisition cost of a covered entity is typically not WAC but rather the much lower 340B ceiling price. However, when a dispensing entity submits a claim to the MTF for a rebate, there is generally no way for either the dispensing entity or the manufacturer to know that the claim involves a drug initially purchased at the 340B ceiling price. But to meet its statutory obligation to provide access to the MFP, the manufacturer must still provide a rebate to the dispensing entity equal to the difference between WAC and MFP. Since the covered entity, working through the dispensing entity, acquired the drug at a price below WAC, it would benefit from a duplicate discount in this scenario.

38. For example, if a product's WAC is \$100, its MFP is \$40, and its 340B ceiling price is \$30, the dispensing entity may submit a claim for an MFP refund and obtain \$60 from the manufacturer. But since the manufacturer sold the dispensed drug through its wholesaler to the covered entity for \$30 (the 340B ceiling price), the net result is that the manufacturer has *lost* \$30 in the transaction (i.e., the \$60 rebate paid to the dispensing entity minus the \$30 acquisition cost

¹⁷ See *id.* at 215.

of the covered entity). In other words, in this scenario, the manufacturer has received a *negative price* by paying a duplicate discount.

39. This duplicate discount would occur because determining which claims are subject to the 340B price is a process that the covered entity—which often contracts with an independent dispensing entity—determines after the drug has been dispensed. As a result, there is no way for manufacturers to prevent duplicate discounts between the 340B price and the MFP across all claims submitted to the MTF.

40. The most accurate way to avoid these duplicate discounts is to utilize the provision in the 340B statute authorizing manufacturers to offer the 340B ceiling price through a retrospective rebate (the same mechanism used to effectuate the MFP under the IRA Program). Accordingly, a rebate model is the only mechanism currently available to systematically prevent duplicate 340B and IRA discounts.

41. In the absence of a 340B rebate model, manufacturers do not have adequate data to identify those duplicate discounts. Accordingly, Boehringer has urged HRSA to authorize a 340B rebate model, which will allow covered entities to obtain the 340B ceiling price for covered drugs only if they provide manufacturers with sufficient information to identify and prevent duplicate discounts.

42. HRSA announced the first rebate model pilot program in the Federal Register on August 1, 2025, observing that manufacturers sought such a rebate model “primarily to address 340B and Maximum Fair Price (MFP) deduplication.” 90 Fed. Reg. 36,163, 36,163 (Aug. 1, 2025). Boehringer timely submitted an application to participate in the pilot program, and HRSA, which administers the 340B Program, approved Boehringer’s application on October 30, 2025.

43. Boehringer intended to implement the rebate model pilot program beginning on January 1, 2026, as authorized by HRSA. To prepare for implementation of the rebate model, Boehringer made significant organizational changes including changing IT infrastructure, contracting with additional vendors, developing new banking-payment processes, and adding additional headcount. These efforts cost Boehringer millions of dollars.

44. Boehringer also worked closely with HRSA and Beacon Channel Management to develop and implement a rebate model. In particular, Boehringer and Beacon Channel Management developed processes to simplify the data submission process for covered entities and to ensure prompt payment of any validated claims within 10 days—meaning that covered entities will promptly receive the full benefit of the 340B Program’s discounts. Boehringer also worked closely with HRSA to make targeted adjustments to business rules to address concerns from covered entities, including solutions for unreplenished dispensed product during the initial transition period. To fully plan for these anticipated changes, Boehringer also developed a robust compliance framework to ensure compliance with all current HRSA and CMS requirements relating to the 340B rebate model and MFP effectuation.

45. Boehringer informed CMS of its intent to use the rebate model pilot program to de-duplicate the MFP and 340B discounts. Boehringer also shared information with covered entities about the functioning of its proposed rebate model pilot on October 31, 2025 by physical mailing and email notification when the covered entity’s email address was available—well in advance of the January 1, 2026 effective date.

46. On December 1, 2025, several medical centers and hospital associations sued to stop the rebate model pilot program. On December 29, 2025, before the first MFPs took effect, the district court issued a preliminary injunction that blocked the rebate model from taking effect.

47. Following the district court’s December 2025 injunction, Boehringer was forced to rush to implement new, less effective 340B/MFP deduplication strategies. In other words, Boehringer has been obligated to develop an alternative process to try to identify MFP refund claims that it “reasonably believes” involved drugs purchased subject to the 340B Program.¹⁸ However, due to the structure of the 340B Program, Boehringer does not have sufficient information to identify whether many specific MFP claims overlap with 340B claims. Boehringer’s current process is therefore nowhere near as effective as a 340B Rebate Model, and Boehringer is losing an average of \$3.0 million *each week* to duplicate discounts as a result. Without access to a 340B Rebate Model, Boehringer stands to suffer even greater financial losses when the MFPs for Ofev[®] and Tradjenta[®] take effect on January 1, 2027.

48. In February 2026, HRSA issued a Request for Information (“RFI”) to gather more information about the potential use of rebates to provide the 340B price. *See* 91 Fed. Reg. 7,287 (Feb. 17, 2026).

49. Boehringer submitted a comment in response to HRSA’s RFI, explaining that, without a rebate model, it is often providing both the 340B ceiling price and an MFP refund, and may be required to sell drug products at a loss. *See* Boehringer Ingelheim Comment Letter, HRSA RFI 340B Rebate Model Pilot Program, No. HRSA-2026-0001-2323 (Apr. 20, 2026).

50. On August 3, 2026, HRSA issued a Notice Regarding 340B Rebate Model Pilot Program, 91 Fed. Reg. 48,883 (Aug. 3, 2026), announcing the availability of a rebate model qualifying manufacturers to provide the 340B price for drugs subject to IRA Program MFPs in 2027.

¹⁸ *See* CMS, IPAY 2027 Final Guidance 284, <https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf>.

51. In the absence of a rebate model, Boehringer is not aware of a mechanism capable of accurately and systematically deduplicating the discounts provided under the IRA and 340B programs.¹⁹ Thus, if Boehringer cannot proceed with the 340B Rebate Model Pilot Program, Boehringer will continue to have no viable alternative to implement the IRA's statutory prohibition on duplicate discounts. Although the Plaintiffs have proposed other approaches, those approaches would not solve the problem of duplicate discounts.

52. First, providing access to the MFP *prospectively* to every dispensing entity in the country, as the Plaintiffs have suggested, is administratively impossible and would expand the IRA Program well beyond its limits. Since only Medicare beneficiaries are eligible for the MFP, manufacturers would need to scrutinize every claim for every transaction in which their eligible products are dispensed to determine which claims do not involve Medicare beneficiaries. For those claims, manufacturers would then need to initiate after-the-fact chargebacks to recoup the difference between the MFP and WAC. This system would impose significant burdens on manufacturers, covered entities, and every other dispensing entity that does not participate in the 340B Program.

53. Second, there is no mandatory claims clearinghouse that contains the information necessary to avoid duplicate discounts between the 340B ceiling price and the MFP. While CMS did create a clearinghouse for Medicare Part D 340B claims, it did so for voluntary submissions

¹⁹ In a similar vein, a 340B rebate model could help address other 340B Program integrity issues including duplicate discounts with the Medicaid program and drug diversion. Current methods for addressing duplicate discounts between the Medicaid and 340B Program, including covered entity audits and administrative dispute resolution, are insufficient to fully address the scope of the duplicate discount problem. Despite a 340B rebate model's potential to address this concern, HRSA's notice announcing the 340B rebate model pilot expressly prohibited participating manufacturers from denying claims based on "compliance concerns with diversion or Medicaid duplicate discounts." 91 Fed. Reg. 48883, 48903 (Aug. 3, 2026). While Boehringer will comply with this requirement, we have urged HRSA to reconsider this policy.

only. 90 Fed. Reg. 49,266, 49,932 (Nov. 5, 2025). Here again, manufacturers would not have sufficient information to prevent duplicate discounts for *all* Medicare claims. Moreover, HRSA itself has determined that a claims clearinghouse would not be sufficient to fully address the nonduplication of the MFP and 340B price. In the Federal Register notice announcing the revised 340B Rebate Model, HRSA remarked that a claims clearinghouse “would preserve the current dynamic in which the discount is provided upfront and compliance verification occurs only after the fact.” 91 Fed. Reg. 48,883, 48,900 (Aug. 3, 2026). By contrast, HRSA concluded that a 340B Rebate Model “incentivizes covered entity compliance as a prerequisite to receiving 340B discounts,” directly addressing the nonduplication of the MFP and 340B price. *Id.*

54. Boehringer has suffered significant economic harm due to duplicate discounts in the absence of a rebate model and will suffer significant additional harm if the new rebate model pilot program is enjoined, as two additional drugs, Ofev[®] and Tradjenta[®], are subject to both the 340B and MFP discounts. Berkeley Research Group (“BRG”) estimated that manufacturers will lose \$4 billion in duplicate 340B and MFP discounts in 2026 alone absent the rebate pilot program.²⁰

55. Many covered entities and their contract pharmacies are not required to provide (and in fact do not provide) Boehringer the relevant claims data. Indeed, Boehringer receives claims data for only a small fraction of 340B transactions. When Boehringer does receive claims data, it can directly match and deduplicate MFP claims and 340B claims.

²⁰ BRG, *Implications for Duplication with the 340B Channel* (Oct. 2024) at 2, <https://media.thinkbrg.com/wpcontent/uploads/2024/10/23161214/BRG-Implications-for-Duplication-with-the-340B-Channel-2024.pdf>.

56. Only 1% of all MFP refund claims include 340B claims data submitted by covered entities. With respect to voluntary claims modifiers (a notation that dispensing entities can voluntarily include on a claim denoting that the product was dispensed to a 340B patient), an analysis from BRG concluded that modifiers were included in less than 0.5% of all MFP refund claims.

57. The claims data that Boehringer does receive comes from contract pharmacies and certain in-house pharmacies in states that do not prohibit claims-data collection and from the rare covered entities that voluntarily submit data to Boehringer (e.g., through voluntary claims modifiers). Although manufacturers of drugs covered by the 340B program are authorized by federal law to establish claims data requirements, *see Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452 (D.C. Cir. 2024); *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696 (3d Cir. 2023), several state laws have purported to restrict those federal rights, and many of those state laws remain in effect.

58. For claims submitted by covered entities who do not supply claims data, Boehringer employs a second approach: a “chargeback-to-sales” (“CSR”) ratio. Under this approach, Boehringer calculates a ratio equivalent to the proportion of the covered entity’s total purchases made at the 340B price over the covered entity’s total purchases for the preceding 12 months. Boehringer then pays MFP refunds to dispensing entities at least proportionate to their unique ratio. For example, if 90% of a covered entity’s drug purchases were made at the 340B price over the preceding 12-month period, Boehringer would assign a CSR ratio of 9:1. Once the dispensing entity associated with the covered entity submits MFP refund claims, Boehringer will provide the MFP refund for the first claim and not provide the MFP refund for the subsequent nine claims, repeating this process to maintain the 9:1 ratio.

59. Although these methods help address duplicate 340B/MFP discounts, they are no replacement for direct identification of specific 340B claims. In particular, Boehringer has no way of identifying whether a drug dispensed by a covered entity that does *not* share claims data was dispensed to a 340B patient. Due to these discrepancies, Boehringer is paying many duplicate discounts. According to BRG, across all drugs selected for the first year of the IRA Program, manufacturers have identified roughly 6.6% of MFP refund claims as duplicative with 340B discounts compared to roughly 10.6% of sales that are made at the 340B price for these products. And even though these imperfect screening measures result in the payment of vast duplicate discounts, covered entities have nevertheless complained about them: Boehringer has received 18,793 inquiries and 243 complaints from dispensing entities alleging that Boehringer has failed to pay the MFP refund due to the company's deduplication methodologies.

60. Because Boehringer's deduplication methodologies cannot accurately identify all duplicate discount requests, the company is effectively required to provide duplicate MFP and 340B discounts. Boehringer faces a massive, and growing, set of financial losses that is actively harming Boehringer's business.

61. Every day, thousands of Medicare beneficiaries are dispensed Jardiance[®]. Among the ten drugs selected for the IRA Program for MFPs beginning in 2026, Jardiance[®] had the second highest utilization among Medicare beneficiaries.²¹ With this utilization comes a commensurate amount of MFP refund claims, further increasing the potential for duplicate 340B and MFP discounts. As a result, since the MFP for Jardiance[®] took effect on January 1 and until a 340B

²¹ See CMS, *Fact Sheet: Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026* (Aug. 2023) (noting that 1,573,000 Medicare Part D enrollees used the drug from June 2022-May 2023).

Rebate Model is implemented, Boehringer is losing an average of \$3.0 million every week to duplicate discounts.

62. There is no reasonable method for Boehringer to retrospectively address the duplicate discounts that are currently accruing. For certain MFP refund claims, Boehringer will never receive the 340B claims data necessary to confirm whether an MFP refund should indeed have been provided. Even if the new 340B Rebate Model takes effect on January 1, 2027 as intended, covered entities will not be required to retrospectively submit 340B claims data for the vast majority of dispensing transactions that have occurred since January 1, 2026. As a result, Boehringer will have no way to retroactively remedy the duplicate discounts that the company has paid to date. Thus, as a direct result of the lack of a 340B Rebate Model for 2026, Boehringer has had to incur staggering (and growing) financial losses.

63. Because Ofev[®] and Tradjenta[®] will be subject to MFPs as of January 1, 2027, the harm to Boehringer will only continue to grow if the new 340B Rebate Model cannot take effect on January 1, 2027 as planned. That current and future harm to Boehringer is particularly acute because Boehringer will have three IRA drugs as of 2027.

The Rebate Model Pilot Will Not Harm 340B Covered Entities

64. The rebate model pilot program has been carefully designed to ensure that covered entities will not be harmed.

65. First, the pilot program is limited to a small subset of drug products, for the purpose of assessing the benefits and drawbacks of the rebate model. Out of thousands of drug products and dozens of drug manufacturers covered by the 340B Program, only the 25 products subject to IRA Program MFPs in 2027 are eligible for the rebate model pilot program. Of these 25 products, CMS has announced that four selected drugs—Entresto, Stelara, Xarelto, and the insulin aspart

products (NovoLog/Fiasp)—are exiting the IRA Program on January 1, 2027, rendering these products ineligible for the rebate model pilot program.

66. Second, I understand that the narrow set of data that is required to be submitted by covered entities is limited, industry-standard data that covered entities maintain in the ordinary course of business. HRSA approved limited data fields for covered entity submissions, including information about the distribution of the drug product (date of service, prescription number, quantity, etc.), the provider (identifying the physician and service provider), and insurance information.²² I understand that HRSA already required covered entities to maintain accurate records of this information and that HRSA or drug manufacturers could audit those records.²³ Furthermore, HRSA has required that drug manufacturers provide technical support and customer service to covered entities regarding the rebate platform, and manufacturers must bear the administrative costs of “the IT platform used for data submission.”²⁴

67. Moreover, the program provides robust protections for any claims data that is submitted. The pilot program requires that the software platform used to gather this limited data incorporate controls to ensure that the data are handled and stored appropriately.²⁵ In particular, the software platform must have “mechanisms in place to protect patient identifying information,” and must also maintain the data in a manner that complies with all applicable privacy and data security laws.²⁶ I understand that the software operator that will process rebates received an Expert Determination confirming that it is compliant with HIPAA and does not collect or maintain

²² 91 Fed. Reg. 48,903 (Aug. 3, 2026).

²³ HRSA, *Program Integrity* (Sept. 2025), <https://www.hrsa.gov/opa/program-integrity>.

²⁴ See 91 Fed. Reg. 48,902 (Aug. 3, 2026).

²⁵ See *id.*

²⁶ *Id.* at 48,897.

identifiable protected health information.²⁷ Boehringer's policy is compliant with these requirements and implements HRSA's guardrails.

68. Third, rebates must be paid promptly under the pilot: Boehringer has committed to paying rebates within 10 days of submission of a complete rebate request. Thus, covered entities that promptly submit rebate requests will not be required to "float" any funds. Under standard wholesaler payment terms, covered entities must generally pay for drug purchases within 30 days of purchase. As a result, covered entities that submit rebate claims promptly will obtain a rebate that allows them to net the 340B price on the sale well before the date on which their invoice is due to the wholesaler on the original purchase. In other words, although a covered entity will initially place an order at a standard commercial price under the 340B rebate model, the covered entity will not actually have to pay the non-340B price if it promptly submits a rebate claim, because it will receive the rebate before it needs to pay the invoice.

69. Fourth, the pilot program includes further safeguards to minimize the disruption to covered entities. For instance, manufacturers must provide 60 days' notice for covered entities before implementation of a rebate model. Boehringer issued this notice to covered entities on October 2, 2026. Furthermore, Boehringer, like other drug manufacturers, will allow covered entities to continue ordering the drugs through their existing distribution mechanisms, which will prevent delays or disruptions in the flow of drugs to covered entities and patients.²⁸

70. Fifth, HRSA has stated that it will closely monitor the pilot program to understand how a rebate model system functions in practice and to ensure that participants comply with the

²⁷ Beacon Channel Management, *Rebate Model Frequently Asked Questions*, <https://support.beaconchannelmanagement.com/en/articles/9589827-rebate-model-frequently-asked-questions>.

²⁸ See 91 Fed. Reg. 48,891 (Aug. 3, 2026).

340B Program’s requirements.²⁹ HRSA’s Office of Pharmacy Affairs (“OPA”) has selected manufacturers to participate in the pilot and will monitor its execution—for example by requiring these manufacturers, including Boehringer, to submit regular data to OPA. OPA will also solicit feedback from covered entities, provide a mechanism for stakeholders to submit comments, and facilitate the provision of “real-time reconciliation reports” for covered entities to stay apprised of the rebate status of submitted claims in real time.³⁰ OPA has reserved the right to terminate any drug manufacturer from the pilot program if it fails to meet the program’s requirements, such as by failing to provide rebates in a timely manner.³¹

71. Further, many covered entities already voluntarily use a model similar to the rebate model in the 340B context. That model is commonly referred to as a “virtual credit model.” Under this model, covered entities (or their contract pharmacies) purchase all medications at commercial prices (such as WAC) and maintain a single inventory, without differentiating between 340B and non-340B products. The covered entity dispenses medications in the ordinary course and then identifies (after the fact) transactions that it maintains are eligible for 340B pricing. The covered entity sends that data—usually through a third-party administrator—to its distributor, which attempts to match the drug transactions identified as 340B eligible with prior purchases of the same NDC and quantity. When the distributor successfully makes a match, it (i) “credit[s] the [covered entity’s] non-340B commercial account for the difference” between the commercial and 340B price, and (ii) generates “a non-inventory purchase on the 340B covered entity bill-to/ship-to

²⁹ See 91 Fed. Reg. 48,895 (Aug. 3, 2026) (“HRSA intends to use this information to monitor denial patterns and assess whether rebate determinations are applied in a consistent and appropriate manner across participating manufacturers and will remove manufacturers from the Pilot where appropriate.”).

³⁰ See *Id.* at 48,902.

³¹ *Id.* at 48,895.

account.”³² Thus, rather than replenishing their inventories by having the distributor “physically shi[p]” drugs earmarked for 340B use, covered entities and contract pharmacies buy replacement drugs at the commercial price and then obtain the 340B price through a “financial credit” applied after the fact.³³ For example, when a covered entity enrolled in a virtual credit model program purchases a drug initially for \$100 and later dispenses the drug to a 340B-eligible patient, “\$100 will be credited to” the covered entity’s “non-340B account” by the distributor “and then the entity will be invoiced for the 340B ceiling price ... in [its] 340B account.”³⁴

72. The net effect of this virtual credit model is the same as a 340B rebate model: the covered entity orders drugs at commercial prices up front, then later receives the 340B price through a rebate after a third party validates the transaction. Court records and commercial literature show that covered entities have voluntarily participated in these virtual credit model programs for nearly a decade.³⁵ Indeed, PharmaForce stated in 2024 that “a lot” of its “customers . . . are using” the virtual credit model “successfully” and that many pharmacies now “require a

³² AmerisourceBergen (now Cencora), Inventory Synchronization Program Guide, Doc. No. HS-110567, at 3, available at <https://web.archive.org/web/20240426164057/https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/pdf/hgs-230633-isp-guide-12dec23-v2.pdf>. PharmaForce, which offers a variety of 340B services for covered entities and pharmacies, has similarly identified the “adoption of credit-based replenishment models” as “a recent trend in 340B program” that “eliminates the need for physical inventory deliveries” and instead “us[es] a credit system within the pharmacy’s retail account.” PharmaForce, Credit-Based Replenishment: The Future of 340B? (accessed May 20, 2025), <https://www.thepharmaforce.com/340b-credit-based-replenishment.aspx>

³³ PharmaForce, Credit-Based Replenishment: The Future of 340B, at 5:52-6:12 (May 23, 2024), <https://www.youtube.com/watch?v=T7yz-ZgjW2w> (“PharmaForce Webinar”).

³⁴ *Id.* at 5:25-5:38.

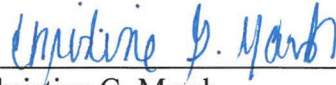
³⁵ See, e.g., Memorandum of Law in Support of Defendant’s Motion to Dismiss, *Fruth, inc. v. Cardinal Health, Inc.*, No. 3:23-cv-801, ECF No. 15, at *3 (S.D.W. Va. filed Mar. 18, 2024) (describing a similar “virtual replenishment” program operated by Cardinal Health and referring to allegation that plaintiff “began using” -it “in March 2016”); PharmaForce Webinar, *supra*, at 24:20-24:32 (referring to Cardinal Health virtual credit model program).

credit-based replenishment model.”³⁶ Likewise, Boehringer recently identified one covered entity that has shifted to making significant purchases at WAC and stated that it is doing so under a virtual credit model.

³⁶ See PharmaForce Webinar, *supra*, at 24:05-24:23.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 14 day of October, 2026.



Christine G. Marsh
Senior Vice President, Value and Access
Boehringer Ingelheim Pharmaceuticals, Inc.