No. 25-2236

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,
Plaintiffs-Appellees,

v.

ROBERT F. KENNEDY, JR., *Secretary of the U.S. Department of Health and Human Services*, *et al.*,
Defendants-Appellants.

On Appeal from the United States District Court
for the District of Maine

MOTION FOR STAY PENDING APPEAL AND ADMINISTRATIVE STAY
[Emergency Ruling on Motion for Administrative Stay Sought by 12/31/2025]

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INTRODUCTION

In 2022, Congress authorized the Department of Health & Human Services to negotiate for the prices Medicare pays for a select set of high-expenditure drugs. The negotiated prices for the first ten drugs take effect on January 1, 2026. All manufacturers who participate in the Medicare Drug Price Negotiation Program also participate in the 340B Program, which provides drugs at reduced prices to certain safety-net healthcare providers known as "covered entities." These manufacturers must offer drugs to covered entities at the lower of the 340B ceiling price or the negotiated price, but they are not required to provide duplicate discounts. To assist manufacturers in avoiding duplicate discounts, HHS announced a limited pilot program under which it permitted manufacturers to offer 340B prices through rebates rather than upfront discounts. This program covers only the ten Negotiation Program drugs, which combined account for two percent of 340B spending.

Three days before the negotiated prices and the rebate pilot program were scheduled to take effect, the district court enjoined the pilot program. That eleventh-hour decision threatens to disrupt manufacturers' plans for implementing the Negotiation Program. Immediate relief is warranted to prevent any such disruption.

The district court was wrong on the merits. After considering covered entities' reliance interests and compliance costs, HHS reasonably determined that those concerns were outweighed by the need to study the efficacy of 340B rebates and by the desirability of offering rebates as a method for manufacturers to deduplicate 340B and Negotiation Program discounts. The district court erred in concluding otherwise by refusing to consider HHS's declaration explaining its contemporaneous thinking for these informal adjudications and by misunderstanding a statutorily authorized process by which an agency may consider paperwork burdens more fully after obtaining emergency clearance to proceed initially. Those fundamental errors of administrative law fatally undermine its injunction.

The government respectfully requests a stay pending appeal and an immediate administrative stay. To prevent disruption of industry preparations to implement the Negotiation Program on January 1, the government seeks a ruling on its request for an administrative stay by **December 31**. Plaintiffs oppose this motion.

STATEMENT

1. a. Section 340B of the Public Health Service Act, 42 U.S.C. § 256b, requires pharmaceutical manufacturers participating in Medicare Part B and Medicaid to sell drugs at reduced prices to certain safety-net healthcare providers known as "covered

entities." *See Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113-16 (2011). The statute provides that "the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary [of HHS]) to the manufacturer for covered outpatient drugs" may not exceed a ceiling price set by a statutory formula. 42 U.S.C. § 256b. Until recently, save for one limited exception, HHS has provided only for upfront discounts. The discounts provided through the 340B Program help covered entities "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384, pt. 2, at 12. In particular, it gives them extra revenue from serving insured patients because covered entities "turn a profit when insurance companies reimburse them at full price for drugs that they bought at the 340B discount." *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023). And it allows them "to give uninsured patients drugs at little or no cost." *Id.*

Most covered entities use virtual-inventory software to track dispenses and purchases of drugs at the 340B price. *Eli Lilly & Co. v. Kennedy*, No. 21-cv-2608, 2025 WL 1423630, at *2-3 (D.D.C. May 15, 2025), *appeal docketed*, No. 25-5177 (D.C. Cir. argued Nov. 17, 2025). As a result, manufacturers may not know whether drugs are eligible for 340B pricing when a covered entity first purchases the drugs.

b. Through the Negotiation Program, Congress gave HHS authority to negotiate the prices that it pays for drugs that account for a disproportionate share of Medicare's expenses. 42 U.S.C. §§ 1320f(a), 1320f-1(b), (d), (e). The Negotiation Program applies only to manufacturers that choose to participate in Medicare and Medicaid and governs only the prices that Medicare pays for certain drugs. *See id.* § 1320f-1(b), (d). If negotiations succeed, the manufacturer agrees to make the drug available to Medicare beneficiaries at the negotiated price. *Id* § 1320f-2(a). For the initial year of the Negotiation Program, HHS negotiated maximum prices to be paid for sales of ten drugs through Medicare Part D. *See generally Boehringer Ingelheim Pharms., Inc. v. HHS*, 150 F.4th 76, 81-86 (2d Cir. 2025). These prices are scheduled to take effect January 1, 2026.

The pricing provisions of the Negotiation Program and the 340B Program are not cumulative. Under a "nonduplication" provision, manufacturers must provide access to the lower of the negotiated price or the 340B ceiling price to covered entities, but they may elect not to provide both discounts. 42 U.S.C. § 1320f-2(d).

2. On August 1, 2025, HHS invited manufacturers to apply to participate in a pilot program, which would allow the 340B ceiling price to be effectuated for a select group of drugs through rebates, rather than up-front discounts. Add.47-49. HHS

indicated that it would approve applications satisfying 15 criteria, including ensuring that covered entities will be paid within 10 days of submitting rebate claims and barring manufacturers from refusing to pay rebates based on other 340B compliance concerns. Add.48-49. HHS also solicited comments, though it noted that it was "under no obligation to respond to or act on the comments." Add.47. The drugs eligible for the pilot program are the initial ten drugs selected for the Negotiation Program.

All nine eligible manufacturers responded to the call for applications, and HHS also received more than 1,100 comments. Add.28. HHS "reviewed the comments and considered suggestions and concerns" as it evaluated the applications. Add.28. It reviewed the proposed rebate plans and sought "revisions and clarifications on a number of topics having to do with claims submission, billing, rebate calculation, and inventory management." Add.28. On October 30, 2025, HHS authorized eight manufacturers to begin offering rebates on January 1, 2026; it later granted approval to a ninth manufacturer to begin offering rebates on April 1, 2026. Add.29. HHS's decision letters merely note the agency's approval of the applications and delineate the scope of the approved rebate plans. *E.g.*, Dkt. 36-2, at 14-15. The January 1, 2026, effective date applicable to most participants was chosen to "align[]" with the date that negotiated prices for those same drugs would take effect. Add.28.

HHS also obtained emergency approval under the Paperwork Reduction Act, 44 U.S.C. § 3501, *et seq.*, to roll out the pilot program while undertaking a fuller examination of the program's administrative burden. *See* Add.45-46. HHS explained that the pilot program would provide "a way to mitigate" manufacturers' deduplication concerns, noting that without timely implementation of the pilot program, "manufacturers may argue that they do not have the tools they need to effectuate nonduplication of the [negotiated price] and the 340B discount." Add.46. And it explained that it required emergency approval because it could not "reasonably comply with the normal Paperwork Reduction Act clearance procedures before" the negotiated prices take effect. Add.45.

3. Plaintiffs—the American Hospital Association, the Maine Hospital Association, and four covered entities—sued on December 1, 2025. Dkt. 1. At this preliminary stage in the case, the administrative record has not yet been assembled. Dkt. 85-1, at 2. Instead, HHS submitted a declaration from Chantelle Britton, director of the office within HHS that administers the 340B Program, Add.25-40, and a subset of correspondence between HHS and manufacturers, Dkt. 85. On December 29, the district court granted plaintiffs a preliminary injunction. *See* Add.24.

The district court primarily held that that the agency wholly failed to consider plaintiffs' reliance interests in justifying a change in position. *See* Add. 14-15. The district court reached that conclusion because it refused to consider the agency's central explanation for its decisions: a sworn declaration offered by an agency official to describe the agency's thinking in conducting these informal adjudications. Add.10-11; *see* Add.25-40. The district court stated that the Britton Declaration "largely presents post hoc rationalizations absent from the administrative record" and believed itself bound by the APA's record-review rule not to consider the declaration. *See* Add.10-11.

The district court's injunction was also based on its conclusion that HHS failed to consider plaintiffs' compliance costs because the agency was still considering those costs; the district court pointed to an ongoing study undertaken pursuant to the Paperwork Reduction Act. Add.16-17; *see* Add.41-43. And, again discounting the Britton Declaration, the district court concluded that "the administrative record is also silent on the cost of floating the full price of covered drugs until 340B entities receive their rebate." Add.17.

The district court determined that the equitable factors favor plaintiffs, Add.19-21, and universally enjoined HHS from implementing the rebate pilots, Add.22-24.

4. On December 30 district court denied the government's motion for stay pending appeal. Dkt. 92, 96; *see* Fed. R. App. P. 8(a)(1).

ARGUMENT

Defendants are likely to succeed on the merits and will face irreparable injury absent a stay, and the equities support a stay. *See Nken v. Holder*, 556 U.S. 418, 426 (2009).

I. The equities strongly favor a stay because the preliminary injunction risks imposing serious disruptions on manufacturers' implementation of the Negotiation Program.

1. HHS and manufacturers have been working to implement the Negotiation Program since 2022. When manufacturers prepared and submitted their plans to effectuate the negotiated price earlier this year, they relied, in part, on rebates to resolve 340B deduplication concerns. Three days before the negotiated prices are set to take effect, the district court threw a wrench into those plans. Manufacturers have alternate means to deduplicate discounts, but, at minimum, the injunction risks disruption to the rollout of the Negotiation Program.

The stakes of the Negotiation Program are enormous. It is estimated to save $6 billion in its first year of operations: beneficiaries would pay up to $1.5 billion less out of pocket and the Treasury would save up to an additional $4.5 billion. *See* CMS,

Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026, at 2 (Aug. 2024), https://perma.cc/R24S-WSHX. To take just one example, the list price for a 30-day supply of Enbrel (a drug used to treat autoimmune diseases), was $7,106; under the Negotiation Program, it will drop 67% to $2,355 for Part D sales. *Id.* Thus, with the Negotiation Program in effect, a senior with a standard 25% copay could see her out-of-pocket cost reduced by nearly $1,200 beginning in January.[1] *See id.* And 48,000 Part D beneficiaries use Enbrel, to say nothing of the millions of beneficiaries who use other drugs covered by the Negotiation Program. *Id.* The Negotiation Program is a cornerstone of the federal government's efforts to lower prescription drug prices and any disruption to it would be immensely harmful to beneficiaries and the fisc.

Moreover, the injunction will cause at least some operational and financial harms to the manufacturers who have spent months preparing to use rebates to deduplicate Negotiation Program and 340B discounts. *See, e.g.*, Dkt. 45-1, at 5-6 (alleging that "these preparations have required significant expenditures of time and money" and that

[1] These harms will be felt most acutely in the beginning of the year before beneficiaries reach their annual out-of-pocket caps. *See* 42 U.S.C. § 1395w-102(b)(4)(B).

manufacturers will pay significant amounts in duplicate discounts). As noted, the government disputes that manufacturers must pay duplicate discounts, but the district court did not consider these harms at all. *Cf.* Add.20-21. That "failure to identify, evaluate, and weigh" countervailing harms itself constitutes "reversible error." *See Caribbean Marine Servs. Co. v. Baldrige*, 844 F.2d 668, 677 (9th Cir. 1988).

2. In contrast, plaintiffs have not shown irreparable injury. Plaintiffs will obtain the same 340B discounts they are entitled to under the statute. They will receive rebates within 10 days of submitting claims, and they have not shown that such a minor delay will cause them significant harm, especially given the limited scope of the pilot program and the likelihood that for most purchases covered entities will receive rebates before any payment is due to the wholesaler. *See* Add.31. Nor can plaintiffs rely on compliance burdens to overcome the serious harms to the government and the public interest resulting from the injunction, especially when plaintiffs have not shown how submitting the same kinds of information they already provide to contract pharmacies, Add.35-36, could possibly create a significant burden. And to the extent that plaintiffs speculate about harm resulting from manufacturers' denial of rebate claims, they fail to recognize that HHS "severely limit[ed] the bases for the denial of claims" in response to this concern. Add.33; *see also Narragansett Indian Tribe v. Guilbert*, 934 F.2d 4, 6-7

(1st Cir. 1991) ("[S]peculative injury does not constitute a showing of irreparable harm.").

II. The government is likely to prevail on the merits.

An agency's decision must be sustained unless it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2). This is a "highly deferential" standard, and "a reviewing court may not substitute its judgment for that of the agency, even if it disagrees with the agency's conclusions." *Atieh v. Riordan*, 797 F.3d 135, 138 (1st Cir. 2015) (cleaned up). That standard is even more deferential where an agency makes predictive judgments. *FCC v. National Citizens Comm. for Broad.*, 436 U.S. 775, 813-14 (1978). "If the agency's decision is supported by any rational view of the record, a reviewing court must uphold it." *Atieh*, 797 F.3d at 138. HHS's decision to approve the rebate proposals easily satisfies this requirement.

A. HHS reasonably approved the rebate applications.

1. As HHS explained, it approved this limited rebate pilot program for two reasons.

First, for the past several years manufacturers had sought aggressively to implement rebates over the vociferous objections of covered entities. Add.26; *see Eli Lilly*, 2025 WL 1423630, at *4-*5 (describing manufacturer proposals). Indeed,

manufacturers sued HHS, arguing (unsuccessfully) that should be able to implement rebates unilaterally. *See Eli Lilly*, 2025 WL 1423630, at *9-*11 (rejecting manufacturers' argument). Given competing concerns from manufacturers and covered entities, HHS concluded that it needed more information before approving or disapproving broader rebate models. Add.48. As a result, HHS "sought to test the rebate model on a small scale to help it better understand the merits and shortcomings of a rebate model from stakeholders' perspectives while minimizing disruption to covered entities." Add.27. HHS thus designed a pilot, which broadly encompassed covered entities but included an "extremely limited" scope of drugs. Add.31. HHS decided not to restrict the pilot to a subset of covered entities in order "to collect information on the experience of a wide variety of covered entity types with the rebate model." Add.31. At the same time, it applied the pilot program to only ten drugs, which combined "account for only 2%" of 340B sales. Add.30.

This sort of limited experiment represents a responsible and appropriate way to explore new policy options. As courts have recognized in analogous contexts, experimental programs require less justification than permanent changes. *See, e.g.*, *Aguayo v. Richardson*, 473 F.2d 1090, 1103 (2d Cir. 1973) (Friendly, C.J.) ("[I]t is legitimate for an administrator to set a lower threshold for persuasion when he is asked to

approve a program that is avowedly experimental and has a fixed termination date...."). Here, HHS's decision to proceed with a limited data-gathering exercise was neither arbitrary nor capricious.

Second, HHS chose to provide the pilot program as a means to enable manufacturers to deduplicate 340B and Negotiation Program discounts through rebates. Add.47; *see* Add.28. HHS explained that "[a] 340B rebate mechanism is one way that drug manufacturers can deduplicate 340B price and [the negotiated price]" and that it is the "preferred method" of many manufacturers. Add.28. This mechanism is important to manufacturers because the use of virtual-inventory systems to effectuate 340B discounts creates operational difficulties in determining whether to provide the negotiated price. When a drug is sold through a pharmacy using a virtual-inventory system, the manufacturer may not know immediately if it will be provided to a 340B-eligible patient. *See, e.g.*, Dkt. 50-5, at 6. Manufacturers have other alternatives to deduplicate discounts,[2] but HHS acknowledges that 340B rebates are an effective means of doing so and may pose fewer logistical concerns than other options, Add.28.

[2] *See* 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 § 40.4, pp. 195-232 (Oct. 2, 2024), https://perma.cc/CST8-3AU6.

This goal also dictated the scope of the pilot. An even narrower program "would have not afforded a 340B rebate option for each of the ten drugs for which manufacturers are seeking deduplication." Add.30.

2. In approving the rebate proposals, HHS considered covered entities' reliance interests and compliance burdens.

HHS acknowledged that "adopting the rebate mechanism for even this limited set of drugs will be a significant change for covered entities" from how the 340B program had previously operated. Add.32. For that reason, HHS "limited the scope" of the pilot to ten drugs. Add.27. HHS also ensured adequate "lead-time" for covered entities to adjust, Add.28-29, and took steps to minimize any cash-flow concerns for covered entities, *see* Add.32-33 (explaining decisions to opt for "shorter payment window," to approve "unit-level rebates" to ensure quicker payments, and to "severely limit[ ] the bases for the denial of claims").

Minimizing compliance burdens was a dominant theme of HHS's approval decisions. Many manufacturers sought to require covered entities to provide more data, but HHS "purposefully did not require covered entities to submit any new pharmacy and medical data elements beyond which most were already submitting … or which most had readily available through third party administrators." Add.34. Where HHS

concluded that proposed requirements "would create a significant administrative burden on covered entities," it "rejected [the] proposals." Add.34-35. HHS thus specifically rejected manufacturers' requests "to collect purchase data" in order to improve program integrity because it concluded submitting that data would cause an "undue burden" on covered entities. Add.35. Similarly, HHS opted to require manufacturers to pay rebates within ten days rather than fourteen days "in part, to address covered entity concerns regarding cash flow," and it approved manufacturers to pay "unit-level rebates" to ensure that "covered entities will not have to wait to dispense an entire package [of drugs] before being able to request a rebate." Add.32.

After considering these costs and other relevant factors, HHS reasonably decided to approve the manufacturers' rebate plans. Add.28.

B. In refusing to consider HHS's explanation for approving the rebate applications, the district court erred.

In an informal adjudication, "the APA does not specifically require the agency to explain its decision" nor provide "a written explanation on the record." *Neighborhood Ass'n of the Back Bay, Inc. v. Federal Transit Admin.*, 463 F.3d 50, 60 n.4 (1st Cir. 2006). Rather, in such circumstances, "if the agency's path may reasonably be discerned," its decision should be sustained. *FCC v. Fox Television Stations, Inc.*,

556 U.S. 502, 513-14 (2009) (cleaned up). Here, the agency's declaration explaining its decision satisfies that standard.

The district court abused its discretion in refusing to consider that declaration. *See Koon v. United States*, 518 U.S. 81, 100 (1996) ("A district court by definition abuses its discretion when it makes an error of law."). As the Supreme Court has explained, when an informal adjudication does not produce the sort of record that would permit "effective judicial review," a court appropriately should "obtain from the agency, either through affidavits or testimony, such additional explanation of the reasons for the agency decision as may prove necessary." *Camp v. Pitts*, 411 U.S. 138, 142-43 (1973); *see Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 419-20 (1971). In these circumstances, "the administrative record may be supplemented, if necessary, by affidavits, depositions, or other proof of an explanatory nature," so long as "the new material" is "explanatory of the decisionmakers' action at the time it occurred," rather than a "new rationalization[]." *Sierra Club v. Marsh*, 976 F.2d 763, 772 (1st Cir. 1992) (cleaned up). Such "illuminat[ions]" of the reasons for agency action are routinely accepted by courts. *Olivares v. TSA*, 819 F.3d 454, 464 (D.C. Cir. 2016) (accepting declaration that "furnishes an explanation of the administrative action that is necessary to facilitate effective judicial review"). Here, the HHS letters approving the rebate plans

do not explain why the agency acted; they are operational documents, simply outlining the terms of each approved rebate program. *See, e.g.*, Dkt. 36-2, at 14-15. Thus, considering the agency's declaration was appropriate as an explanation for the agency's reasoning.

The district court misunderstood the agency's declaration as an improper post-hoc rationalization. Add.10. *But see Sierra Club*, 976 F.2d at 774 (citing *Overton Park*, 401 U.S. at 420) (acknowledging that affidavits "containing post-hoc explanations" may be considered critically by courts). But here "the agency provided something more than counsel's argument. It provided the court with an explanation for the agency's action submitted by the officer who had the authority to act on the application[s]."[3] *Bagdonas v. Department of Treasury*, 93 F.3d 422, 426 (7th Cir. 1996). That type of explanation does not violate the *Chenery* principle or the record-review rule, which "forbid[ ] judges to uphold agency action on the basis of rationales offered by anyone other than the proper decisionmakers," but which do not forbid the proper decisionmaker from presenting "the considered views of the agency itself" to the court. *Alpharma, Inc. v.*

[3] While the approval letters were signed by the head of the Office of Special Health Initiatives in the Health Resources and Services Administration, Britton is the Director of the Office of Pharmacy Affairs within that HHS subagency, and her office "has delegated authority to administer the 340B Program." Add.25.

Leavitt, 460 F.3d 1, 6-7 (D.C. Cir. 2006) (citation omitted). Rather, a "court may properly uphold the [agency]'s decision on the basis of affidavits or testimony by the administrator who made the decision concerning his reasoning at the time of the decision." *Sierra Club*, 976 F.2d at 772 (citation omitted); *see also id.* at 772-73 (collecting cases).

Indeed, if the district court reconfirms its view that the record is insufficient at the summary-judgment stage, the proper remedy would be remand without vacatur to allow the agency to further explain its decision *See Central Maine Power Co. v. FERC*, 252 F.3d 34, 48 (1st Cir. 2001). In that event, the agency would produce a supplemental explanation akin to the Britton Declaration. It makes no sense to exclude the agency's explanation in an initial proceeding and then consider the same explanation following a remand. *See Alpharma*, 460 F.3d at 6-7.

The district court faulted the Britton Declaration because it included "rationalizations absent from the administrative record," Add.10; that conclusion was error. HHS still "is in the process of compiling the administrative record for this case," Dkt. 85-1, at 2, so the district court cannot know what it will eventually comprise. But more importantly, unlike the precedents on which the district court relied, the district court provided no basis to question whether the agency's views had shifted over time.

This is not a case "[w]hen an agency's initial explanation indicates the determinative reason for the final action taken," *DHS v. Regents of Univ. of Cal.*, 591 U.S. 1, 21 (2020) (cleaned up), and then the agency sought to "provide new ones." Add.10 (quoting *Regents*, 591 U.S. at 21); *see also see California v. Department of Education*, 132 F.4th 92, 99 (1st Cir. 2025); *American Textile Mfrs. Inst., Inc. v. Donovan*, 452 U.S. 490, 538 (1981). Here, the approval letters do not indicate why HHS acted. *Cf.* Dkt. 36-2, at 14-15. Instead, the agency has "provide[d] an adequate explanation for [its] action" in the form of a declaration, which is the "only way there can be effective judicial review" in a case where the informal proceedings have not generated a formal administrative record. *Overton Park*, 401 U.S. at 420. Britton's declaration "explained" how her office "took into consideration a variety of factors, including impacts on covered entities and concerns raised in comments, in making decisions on which specific aspects of the plans that it would approve." Add.28. Because the agency's position has not shifted at all, there is no conceivable basis to forbid the agency from explaining how it considered important factors in undertaking these informal adjudications.

C. HHS properly considered plaintiffs' reliance interests and compliance burdens.

HHS considered the administrative costs plaintiffs would bear in participating in the pilot program. Add.34-37. It took steps to minimize any burden by rejecting manufacturers' proposals that would have required covered entities to submit more specific and thus more burdensome information to claim rebates. Add.34-36. It noted that "most covered entities already provide the type of claims data" to their contract pharmacies that "they will need to provide under the [p]ilot" program. Add.34. And it "considered the non-monetary costs associated with moving to a rebate model." Add.36. Ultimately, HHS made the determination that the benefits of running the pilot program outweighed these costs. *See* Add.28.

Similarly, HHS considered the costs covered entities might bear in purchasing drugs at retail prices before receiving rebates, took steps to minimize those costs, and again made the determination that the benefits of implementing the pilot program outweighed these costs. *See* Add.28, 31-33.

1. The district court faulted HHS for continuing to consider administrative costs. Specifically, the district court pointed to a notice HHS issued pursuant to the Paperwork Reduction Act to collect information about the burdens of submitting

rebate claims and other associated administrative tasks. Add.16-17; *see* Add.41-43. The district court reasoned that HHS could not have properly considered compliance burdens if it was still studying them. Add.16-17. That conclusion does not follow from its premise.

The Paperwork Reduction Act generally requires federal agencies to examine the burden on the public before it conducts or sponsors any collection of information. 44 U.S.C. § 3507(a). But it also provides for emergency approval of agency plans to collect information when normal review procedures are not practical. *Id.* § 3507(j)(1); *see* 5 C.F.R. § 1320.13. HHS availed itself of that option here, obtaining approval to launch the rebate program on January 1 while undertaking a more extensive study of compliance costs. *See* Add.45-46. To hold that HHS acted unlawfully by proceeding before that more extensive study is complete, as the district court did, is inconsistent with Congress's express acknowledgement that agencies may proceed on two tracks when considering compliance burdens. *See* 44 U.S.C. § 3507(j)(1).

2. Here, HHS did what agencies must often do: it made a predictive judgment based on the best information available to it. Making a decision without "perfect empirical or statistical data … is not unusual in day-to-day agency decisionmaking." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 427 (2021). Nor is that type of decision

improper, *id.* at 427-28; to the contrary, agencies are entitled to increased deference when it comes to matters implicating predictive judgments, *see National Citizens Comm.*, 436 U.S. at 813-14. Accordingly, HHS considered how many hours would be required to collect information necessary to submit rebate claims. It estimated that each covered entity would need to expend, on average, two hours per week. Add.42. And it expressly concluded that "the benefits of the [p]ilot [program]—gathering information on the feasibility of rebates, helping to collect data for future rebate models consistent with the 340B statute and Administration priorities, improving transparency, addressing manufacturer concerns about 340B-[Negotiation Program] deduplication, and facilitating the prevention of 340B Medicaid duplicate discounts and diversion—outweighed these costs." Add.34.

Plaintiffs believe that they will need to expend more time to claim rebates, *e.g.*, Dkt. 7 at 9, but they fail to explain this conclusory assertion, *see, e.g.*, Dkt. 10-8, at 14. That failure is striking in light of the substantial overlap between the information required to obtain rebates and the information covered entities already submit to their contract pharmacies. *See* Add.34-35. Moreover, some of the bases plaintiffs assert for their inflated views of compliance costs did not materialize in the approved plans. *Compare* Dkt. 10-8, at 14 (raising concerns about different IT platforms), *with* Add.38

(all manufacturers selected same IT platform). These underbaked objections fail to show that HHS took an "[ir]rational view of the record," and thus the agency's decision must be sustained. *Atieh*, 797 F.3d at 138.

3. The district court concluded that the "administrative record is also silent on the cost of floating the full price of covered drugs until 340B entities receive their rebate," but it only reached that conclusion by discounting the Britton Declaration. Add.17. Had the district court properly looked to the agency's explanation, it would have found that HHS designed the rebate program to account for such concerns. *See* Add.31-33. For example, HHS noted competing claims about carrying costs from manufacturers and covered entities and, for that reason, "opted for [a] shorter payment window" by requiring manufacturers to pay rebates more quickly. Add.32. It approved unit-level rebates so that "for purchases from which multiple dispenses will be drawn, covered entities will not have to wait to dispense an entire package before being able to request a rebate." Add.32. And it noted the possibility that "as manufacturer commenters state, the rebate in most instances will be paid before the purchase invoice from a wholesaler … is due." Add.32. Even still, after considering these concerns, HHS "acknowledge[d] that adopting the rebate mechanism for even this limited set of drugs will be a significant change for covered entities," but it nevertheless made the policy

decision to proceed. Add.32. That level of consideration more than satisfies the agency's obligation to consider costs. *See Michigan v. EPA*, 576 U.S. 743, 759 (2015) ("It will be up to the [a]gency to decide (as always, within the limits of reasonable interpretation) how to account for cost.").

III. An administrative stay is warranted.

An administrative stay "minimize[s] harm while an appellate court deliberates" on whether to issue a stay pending appeal by preserving the status quo. *United States v. Texas*, 144 S. Ct. 797, 798 (2024) (Barrett, J., concurring). Here, the status quo was that manufacturers would begin offering rebates and using the rebate program to deduplicate 340B discounts starting January 1. *See, e.g.*, *Oregon v. Trump*, 154 F.4th 1161, 1164 (9th Cir. 2025) (looking to situation before injunctive relief granted). Disrupting the status quo could seriously complicate the years-long progress towards the rollout of negotiated prices for Medicare drugs and cause manufacturers to scramble to comply with their various pricing obligations. Immediate relief is necessary to avoid that result while this Court considers the government's stay motion.

CONCLUSION

This Court should stay the injunction pending appeal and should enter an administrative stay pending consideration of this motion.

Respectfully submitted,

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U.S. Department of Health and Human Services

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* The Assistant Attorney General is recused in this matter.

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 27(d)(2)(A) because it contains 5,141 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Word for Microsoft 365 in EB Garamond 14-point font, a proportionally spaced typeface.

/s/ Maxwell A. Baldi
MAXWELL A. BALDI

ADDENDUM

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UNITED STATES DISTRICT COURT

DISTRICT OF MAINE

AMERICAN HOSPITAL ASSOCIATION, et al.,	)	
Plaintiffs,	)	
v.	)	No. 2:25-cv-00600-LEW
ROBERT F. KENNEDY, JR., SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,	)	
Defendants.	)	

ORDER ON MOTION FOR PRELIMINARY INJUNCTION

Like the old adage, "crawl, walk, run," the Administrative Procedure Act's (APA) arbitrary and capricious standard imposes vanishingly minimal requirements that a federal agency must satisfy before launching a new program or policy. Those minimal requirements are simply that the agency action be reasonable and reasonably explained. Thus, before a new program that affects the rights and privileges of the public can be up and running, the agency must undertake the basic task of developing a contemporaneous record of the relevant factors it considered and provide a reasoned explanation for its course of action.

This axiomatic principle of administrative law is no less applicable in the context of administering complex federal drug pricing laws. With the laudable goal of resolving competing congressional directives to offer price concessions to certain "covered entities"

under both the longstanding 340B Program and the nascent Inflation Reduction Act's Drug Price Negotiation Program, the Health Resources and Services Administration (HRSA) plans to launch a hastily assembled 340B Rebate Model Pilot Program (the Rebate Program) on January 1, 2026, to "deduplicate" these price concessions. Although the HRSA is empowered by statute to achieve the de-duplication objective through a rebate model, and although it applies to only a subset of drugs sold to 340B covered entities, it marks a departure from the Agency's decades-long practice of requiring upfront discounts on 340B eligible drugs, and the Agency's roll out has involved a rather threadbare administrative record that likely fails to consider and reasonably explain the impact of a rebate model on 340B hospitals, who rely on upfront price concessions to stretch few resources as far as possible to serve rural and poor communities. The APA likely requires more from Defendants. For the reasons explained below, Defendants are preliminarily enjoined from implementing the Rebate Program pending further order.

BACKGROUND

In 1990, Congress created the Medicaid drug pricing rebate program to lower the cost of pharmaceuticals reimbursed by the States under Medicaid. The program conditions Medicaid and Medicare Part B coverage for a pharmaceutical companies' (hereafter "manufacturers") products on the manufacturer's participation in rebate agreements with the Secretary of Health and Human Services (HHS). By participating, manufacturers are contractually bound to pay rebates to state Medicaid programs at the statutorily determined price for certain drugs.

In 1992, Congress separately enacted Section 340B of the Public Health Service Act to assist "covered entities" (i.e., safety-net healthcare providers serving the most vulnerable populations) with their drug-acquisition costs. Pub. L. No. 102-585 § 602 (1992). Under Section 340B, manufacturers enter into pricing agreements with the Secretary in exchange for having their drugs covered by Medicaid and Medicare Part B. 42 U.S.C. § 1396r-8(a)(1); *id.* § 256b(a). In these 340B agreements, manufacturers agree to provide upfront discounts to 340B covered entities, such as Plaintiffs. Critical to understanding this unfolding narrative is the fact that Medicaid and the 340B Program are different programs imposing different pricing constraints on participating manufacturers.

Since the inception of the 340B drug pricing program, HRSA has required drug manufacturers to provide 340B discounts at the time of sale, colloquially called "upfront discounts," *id.* § 256b(a)(1); Section 602 Guidance, 58 Fed. Reg. 27289, 27291-92 (May 7, 1993), in order to "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive resources." H.R. Rep. No. 102-384(II) at 12 (1992). As recently as last year, HRSA rejected several manufacturers' proposal to switch to a rebate model, taking the position that an upfront discount model is superior and the switch would be disruptive to the operation of the 340B program. *See* Compl. ¶¶ 43–46, 48; Ex. 1 at -66; Ex. 4 at -292; Ex. 5 at -342.

However, in the state-administered Medicaid context, a rebate model is standard. In the Inflation Reduction Act of 2022 (IRA), Congress established the Medicare Drug Price Negotiation Program, which authorizes the Secretary to negotiate a "Maximum Fair Price" (MFP) that Medicare pays for certain eligible drugs. Inflation Reduction Act of

2022, Pub. L. No. 117-169, 136 Stat. 1818; U.S.C. §§ 1320f(a), 1320f-1(b), (d), (e). State Medicaid programs generally pay more than the MFP when administering Medicaid but receive a rebate from manufacturers to ensure that they pay only the MFP on behalf of qualifying patients.

Because several drugs are subject to both the Medicaid MFP and the 340B price concession, there is the potential (commonly realized) that manufacturers are mistakenly subjected to duplicative price concessions when a MFP rebate is claimed for a drug that a covered entity purchased at the 340B price.[1] Where MFP and 340B price concessions overlap, the IRA's "nonduplication" provision requires drug manufacturers to provide the lower of the 340B ceiling price and the MFP to covered entities, but not both. 42 U.S.C. § 1320f-2(d). There does not appear to be any dispute that a well-designed program would avoid duplication, and the parties generally refer to this objective as the "de-duplication" objective.

On July 31, 2025, HRSA announced the 340B Rebate Program, which would allow certain drug manufacturers to charge their drug's wholesale price to 340B covered entities and later issue a rebate to reflect the statutorily required discount price and achieve the de-duplication objective. *See* Press Release, HRSA, HRSA Announces Application Process for the 340B Rebate Model Pilot Program and Request for Public Comment (July 31,

[1] Section 340B covered entities also serve Medicaid participants and may dispense drugs to Medicaid participants that they purchased at the 340B discount price. When a Medicaid program seeks and receives the MFP rebate on these prescriptions, manufacturers will have provided a duplicative discount. Such loses spread across the entire 340B network add up to substantial sums of money that should have been realized by the manufacturers rather than the 340B entities or state Medicaid programs.

2025), https://www.hrsa.gov/about/news/press-releases/rebate-model-pilot-program (last visited Dec. 29, 2025). The next day, August 1, 2025, HRSA published notice of the new program in the Federal Register, inviting drug manufacturers to submit applications to participate. Rebate Program Application Notice, 90 Fed. Reg. 36163 (Aug. 1, 2025). HRSA's Notice explained the purpose of the Rebate Program was to address concerns over duplicate discounting by drug manufacturers attempting to ensure that covered entities receive only the 340B upfront discount or the IRA's Medicaid MFP, but not both. Corr. Rebate Program Application Notice, 90 Fed. Reg. 38165 (August 7, 2025). Between October 30 and November 14, 2025, HRSA approved rebate applications from nine eligible drug manufacturers for ten covered drugs. Although the applications concern only ten covered drugs, the anticipated program will be implemented across the entire population of 340B covered entities, all of whom will need to free up money to pay the much higher wholesale drug prices and implement new internal processes to pursue the rebates.[2]

On December 1, 2025, the American Hospital Association (AHA) and the Maine Hospital Association (MHA), along with several of AHA's and MHA's members, (collectively, "Plaintiffs") filed their Complaint (ECF No. 1) and Motion for Temporary Restraining Order (ECF No. 3), seeking to enjoin implementation of the Rebate Program.

[2] In addition to the preceding background concerning the legislative landscape and the deduplication effort, Plaintiffs' claims rely on a collection of facts associated with the nature and quality of the administrative record and the nature and quality of the harms that will be visited upon them by the Rebate Program. I relate those particularized facts in the preliminary injunction discussion that follows.

Plaintiffs allege that Federal Defendants'[3] establishment and implementation of the 340B Rebate Program violates the Administrative Procedure Act (APA) and ask this Court to declare the program unlawful under § 706 of the APA. Compl. ¶¶ 52-62, 130-175. Because the parties have all been heard on the propriety of emergency injunctive relief, including at a December 19, 2025 hearing, I construe Plaintiffs' Motion as a request for a preliminary injunction rather than a temporary restraining order. The parties have conferred and agree to proceed on this basis. Opp'n at n.1 (ECF No. 75).

DISCUSSION

The parties' briefs raise the issues of justiciability as well as the question of whether Plaintiffs can meet all four of the preliminary injunction factors. I therefore begin this discussion with the issue of whether Plaintiffs' claims present a justiciable controversy (they do) before turning to whether preliminary injunctive relief is warranted. Because I conclude that relief is warranted on the record presently before me, I necessarily conclude with a discussion of the appropriate nature and scope of relief.

A. JUSTICIABILITY

Before reaching the merits, I first briefly address Defendants' two arguments against judicial review: HRSA's promulgation of the Rebate Program is not final agency action and the decision to effectuate 340B prices through rebates is committed to agency

[3] Robert F. Kennedy, Jr. in his official capacity as Secretary of the U.S. Department of Health and Human Services; Thomas J. Engels, in his official capacity as Administrator of Health Resources and Services Administration (HRSA); the U.S. Department of Health and Human Services (HHS); and the United States of America. *Compl.* ¶¶ 19-23.

discretion by law. I reject both arguments because they mischaracterize the nature of Plaintiffs' claims. First, Defendants pettifog on the distinction between their general authority to administer a rebate model program and the approved applications that comprise the Rebate Program itself. As Defendants concede, however, the application approvals do constitute final agency action, which by their nature are reviewable under the APA. *See* 5 U.S.C. § 704. Second, Defendants maintain that because the Public Health Service Act provides the Secretary with the discretion to effectuate the 340B ceiling prices through either rebates or discounts, without a benchmark against which to judge the Secretary's choice, Congress committed that decision to the Secretary alone and the judicial branch must avert its gaze, judicial review being unavailable. Opp'n at 11-13. According to Defendants, that unreviewable discretion extends to the Agency's decision to approve the nine drug manufacturers' applications to participate in the Rebate Program. *Id.*

Assuming without questioning the Secretary's discretion to choose between discounts and rebates to effectuate 340B price concessions, see *Webster v. Doe*, 486 U.S. 592 (1988), the Agency's approval of the drug manufacturers' individual applications is reviewable under the APA. Judicial review of the approvals, including the scope of the resulting program and the expedited pace of its implementation, is entirely consistent with the APA's strong presumption of judicial review, and the longstanding practice of narrowly reading the agency discretion exception "to those rare administrative decisions traditionally left to agency discretion." *Dept. of Homeland Security v. Regents of the Univ. of Cal.*, 591 U.S. 1, 17 (2020) (citations omitted). Accordingly, judicial review of the Agency's

approval of the nine applications to participate in the "Rebate Program," is appropriate under the APA.

B. THE PRELIMINARY INJUNCTION FACTORS

The extraordinary and drastic remedy of a preliminary injunction requires a showing of four elements: (1) substantial likelihood of success on the merits; (2) a high likelihood of irreparable harm if injunctive relief is not granted; (3) a balance of equities tips in the movant's favor; and (4) the injunctive relief is in the public interest. *See Voice of the Arab World, Inc. v. MDTV Med. News Now, Inc.*, 645 F.3d 26, 32 (1st Cir. 2011) (citing *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)). The last two factors "merge when the Government is the party opposing the preliminary injunction." *Nken v. Holder*, 556 U.S. 418, 435 (2009). The most important of the four elements is the likelihood of success on the merits—which is considered the "sine qua non" of the inquiry. *Ryan v. U.S. Immigr. & Customs Enf't*, 974 F.3d 9, 18 (1st Cir. 2020) (quoting *New Comm Wireless Servs., Inc. v. SprintCom, Inc.*, 287 F.3d 1, 9 (1st Cir. 2002)).

As explained below, the anemic administrative record alone supports a conclusion that Plaintiffs have made a strong showing of likelihood of success, at least as matters stand today. Additionally, Plaintiffs' showing of economic impact and disruption to services is substantial and, paired with such a strong showing on the merits, sufficient to demonstrate irreparable injury. With these initial factors tilting the board decisively in Plaintiffs' direction, the remaining factors easily slide in Plaintiff's favor.

1. Likelihood of Success on the Merits

The APA's arbitrary-and-capricious standard requires that agency action be both reasonable and reasonably explained. "An agency's decision is arbitrary and capricious if the agency relied on improper factors, disregarded 'an important aspect of the problem, offered an explanation that runs counter to the evidence,' or when a reasonable explanation for the agency's decision cannot be discerned." *Gulluni v. Levy*, 85 F.4th 76, 82 (1st Cir. 2023) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)); *accord Melone v. Coit*, 100 F.4th 21, 29-30 (1st Cir. 2024). Judicial review under this standard is deferential, and a court may not substitute its own policy judgment for that of the agency. *State Farm*, 463 U.S. at 43. "A court simply ensures that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision." *Federal Communications Comm'n v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021); *accord Fam. Plan. Assoc. of Me. v. U.S. Dept. of Health and Human Srvs.*, 466 F. Supp. 3d 259, 266-67, 269 (D. Me. 2020).

a. The administrative record

A significant flaw with Defendants' institution of the Rebate Program relates to the paucity of the administrative record. Defendants present for review a July 31, 2025 press release, an August 1, 2025 Federal Register Notice (correction issued August 7), the Agency website's FAQs, a letter to the Office of Management and Budget (OMB), and a few documents and correspondence related to HRSA's approval of AbbVie Inc.'s and Janssen Pharmaceuticals, Inc. and Janssen Biotech, Inc.'s applications to participate in the Rebate Program. To fill the yawning void in this administrative "record," Defendants also

offer as a load-bearing beam to carry the weight of their argument the Declaration of Chantelle Britton (ECF No. 75-1), Director of the Agency's Office of Pharmacy Affairs, which Defendants aver is permissible for the court to consider to "illuminate reasons obscured but implicit in the administrative record." Opp'n at 14 n.5 (quoting *Clifford v. Pena*, 77 F.3d 1414, 1418 (D.C. Cir. 1996)).

"It is a 'foundational principle of administrative law' that judicial review of agency action is limited to 'the grounds that the agency invoked when it took the action.'" *Regents of the Univ. of Cal.*, 591 U.S. at 20 (quoting *Michigan v. EPA*, 576 U.S. 743, 758 (2015)). And while an agency may later "elaborate" on those grounds, it "may not provide new ones." *Id.* at 21 (citing *Camp v. Pitts*, 411 U.S. 138, 143 (1973) (per curiam)). "In other words, an agency must stand by the reasons it provided at the time of its decision and cannot rely on post-hoc rationalizations developed and presented during litigation." *In re Fin. Oversight and Mgmt. Bd. for P.R.*, 37 F.4th 746, 761 (1st Cir. 2022); *see also Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 419 (1971); *State Farm*, 463 U.S. at 50.

Despite Defendants' representations to the contrary, the Britton Declaration largely presents post hoc rationalizations absent from the administrative record, precisely the non-cotemporaneous explanations excluded from consideration in APA challenges. *See Regents of the Univ. of Cal.*, 591 U.S. at 23; *Am. Textile Mfrs. Inst., Inc. v. Donovan*, 452 U.S. 490, 539 (1981) ("the post hoc rationalizations of the agency . . . cannot serve as a sufficient predicate for agency action"); *Overton Park*, 401 U.S. at 419 (rejecting "litigation affidavits" from agency officials as "merely '*post hoc*' rationalizations"); *Cal.*

v. U.S. Dept. of Educ., 132 F.4th 92, 99 (1st Cir. 2025) (rejecting litigation affidavit's "newfound claim of clarity" as post hoc rationalization). To the extent that this tatty administrative record is ambiguous, I consider the Britton Declaration for clarity, but because the record is mostly silent on salient considerations that would guide any rational policy-making process, Director Britton's representations are, for the most part, of no use. *Clifford*, 77 F.3d at 1418.

Finally, amicus AstraZeneca Pharmaceuticals LP offered documents and correspondence related to HRSA's approval of its Rebate Program application. *See* Sky Adams Decl. (ECF No. 88-1). The vast majority of these documents are AstraZeneca's own, and though I appreciate that AstraZeneca is a beneficiary of the Rebate Program, its contributions do not constitute the administrative agency record. To the extent they include HRSA's own documents, it is curious why the Agency did not incorporate them into the administrative record, let alone submit them for consideration. In any event, information presented in this filing is at best circumstantial evidence of what the Agency might have considered, not evidence that it did. Moreover, the animating principle behind the prohibition of post hoc rationalization in APA cases is that democratically unaccountable federal agencies wielding executive power to carry out congressional objectives must do their own homework, build an administrative record, and then demonstrate the application of something resembling a thought process in regard to what the record contains (more on that to follow).

b. Failure to provide a reasonable explanation or address significant reliance interests

Plaintiffs allege Defendants' failure to address significant reliance interests is fatal to the Rebate Program. Specifically, Plaintiffs' point to Defendants' failure to even state how 340B entities' more than thirty-year reliance interests in a discount model weighs against the Rebate Program's de-duplication goal. Mot. at 11. Plaintiffs further assert Defendants have failed to meet the APA's requirement of a reasoned explanation for their policy shift because they fail to offer genuine justifications for why the Rebate Program as designed was necessary to achieve its de-duplication goal, what costs and benefits might be relevant, or how patients could be affected. *Id.* at 10.

Defendants counter that they did reasonably explain the policy change and consider reliance interests. In its August 7, 2025 Federal Register Notice, HRSA explained that the purpose and nature of the Rebate Program is based on feedback from drug manufacturers and covered entities about addressing the de-duplication problem and to test the merits and shortcomings of a rebate model. Opp'n at 14-15; Corr. Rebate Program Application Notice, 90 Fed. Reg. 38165 (Aug. 7, 2025). Defendants also maintain that they did consider these reliance interests, pointing to a Federal Register Notice acknowledging the "fundamental[ ] shift" a rebate model offers, and explaining that the Agency has limited the scope of the Rebate Program to a pilot covering only 2% of total drug sales in the 340B

program.[4] Opp'n at 15; Corr. Rebate Program Application Notice, 90 Fed. Reg. 38165 (Aug. 7, 2025); Britton Decl. ¶¶ 5, 22-25.

When an agency changes position on prior policy that has engendered serious reliance interests, it is arbitrary and capricious to ignore the facts and circumstances engendered by that prior policy. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515-16 (2009); *Smiley v. Citibank (S.D.) N.A.*, 517 U.S. 735, 742 (1996). In these circumstances, "agencies are free to change their existing policies as long as they provide a reasoned explanation for the change, display awareness that they are changing position, and consider serious reliance interests." *Food and Drug Admin. v. Wages & White Lion Invs., LLC*, 604 U.S. 542, 568 (2025) (citations and quotations marks omitted). In considering reliance interests the agency must "assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns." *Regents of the Univ. of Cal.*, 591 U.S. at 33.

At the threshold, Defendants concede Plaintiffs' "decades of industry reliance" in the 340B discount model is significant. *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016). What matters then is simply whether the Agency (1) reasonably explained its change in position, (2) displayed awareness of its change, and (3) considered Plaintiffs' serious reliance interests. It is clear the Agency has displayed awareness that the Rebate

[4] Plaintiffs dispute Defendants' characterization of the Rebate Program as "limited" or a "pilot." According to Plaintiffs, at least in its current iteration, the Rebate Program is a "pilot" in name only because it applies nationwide, mandating approximately 14,600 340B entities to participate in the Rebate Program for ten of the most commonly used drugs. *See* Compl. ¶¶ 7, 56; Reply at 9.

Program constitutes a shift in policy, and Plaintiffs do not contest this factor. On the remaining two factors, I find Plaintiffs are likely to succeed on the merits of their reliance interest claim but that their reasoned explanation claim is a closer call that I need not wade into at the preliminary injunction stage because Defendants' failure to address reliance interests is fatal to a January 1, 2026 rollout of the Rebate Program.

First, there is no evidence in the administrative record that Defendants considered Plaintiffs significant reliance interests. Defendants rely on a single sentence in their August 7, 2025 Federal Register Notice acknowledging "rebate models could fundamentally shift how the 340B Program has operated for over 30 years." Opp'n at 15 (quoting Corr. Rebate Program Application Notice, Fed. Reg. 38165 (August 7, 2025)). This is problematic for several reasons. First, the sentence does not support Defendants' contention that they considered 340B entities' reliance interests. Noting a change in a program's operation is not the same as recognizing that the change will impact 340B entities in detrimental ways. Furthermore, it does not evidence that HRSA weighed any reliance interest against the competing de-duplication policy concern or the proposed de-duplication approach favored by the participating manufacturers. *Regents of the Univ. of Calif.*, 591 U.S. at 33. Indeed, the record's silence on reliance interests reverberates throughout HRSA's approval of all nine Rebate Program applications. Defendants are left only to rely on post-hoc rationalizations in the Britton Declaration, which cannot substitute for the contemporaneous record. Accordingly, without anything more from the administrative record, the Britton Declaration does not "merely illuminate" the reasons "implicit in the administrative record," but rather offers impermissible non-contemporaneous explanations

precluded from consideration. *See U.S. Dept. of Educ.*, 132 F.4th at 99 ("this newfound claim of clarity approaches the sort of 'post hoc rationalization' that we cannot allow").

Although a closer call, it stands to reason Defendants have also failed to provide a reasoned explanation for the Rebate Program, at least in regard to design components. Arbitrary and capricious review is a minimal standard, and a reviewing court is only to assess "whether the [agency's] decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Overton Park*, 401 U.S. at 416. Plaintiffs' allegations that the Rebate Program lacks "genuine justifications," Mot. at 10, seem to invite me to make a policy judgment in place of the Agency, something I cannot do. *State Farm*, 463 U.S. at 43. Defendants explain that the Rebate Program is based on resolving the deduplication problem, and it is not the provenance of the courts to second guess that determination, only to probe whether the Agency's consideration and explanation remained "within a zone of reasonableness." *Prometheus Radio Project*, 592 U.S. at 423. I agree with Defendants' explanation of my limited role regarding review of agency action, but exercising deference would be manifestly easier if there was any meaningful administrative record for me to review. It seems impossible to conclude that HRSA reasonably explained its policy change when the administrative record is entirely silent on a relevant factor—the 340B hospitals' reliance interests. And given the Agency's failure to consider significant reliance interests, I cannot say that the administrative record necessarily offers a reasonable explanation for the Defendants' establishment of the Rebate Program, though I need not wade into this at the preliminary injunction stage because Defendants' failure to address reliance interests is alone fatal to the Rebate Program.

c. Failure to consider relevant costs

Plaintiffs argue that Defendants ignored the costs associated with the Rebate Program, including administrative costs, the costs of paying full price for covered drugs and awaiting a rebate (sometimes referred to as "floating" costs), and other non-monetary costs. Pls.' Mot. at 12-15. Defendants counter they did consider these costs, citing the August 7, 2025 Federal Register Notice, their Emergency Letter to OMB, and the Britton Declaration. Opp'n at 17-18. Defendants aver the Agency's determination that the benefits of the Pilot Program outweigh those costs is entitled to substantial deference. *Id.* at 18.

A regulation is arbitrary and capricious "if the agency 'failed to consider an important aspect of the problem,'" which "includes, of course, considering the costs and benefits associated with the regulation." *Mexican Gulf Fishing Co. v. U.S. Dept. of Com.*, 60 F.4th 956, 973 (5th Cir. 2023) (quoting *State Farm*, 463 U.S. at 43). As part of its analysis, the agency must identify benefits that "bear a rational relationship to the . . . costs imposed." *Id.* "Consideration of cost reflects the understanding that reasonable regulation ordinarily requires paying attention to the advantages and the disadvantages of agency decisions." *Michigan*, 576 U.S. at 753.

Fatal to Defendants' counterargument is their own admission that the Agency is "currently examining" administrative costs. Opp'n at 17 n.7. In other words, Defendants have not yet considered an important aspect of the problem, rather they are still evaluating administrative costs. Specifically, while in its letter to OMB, the agency initially estimated $200 million in compliance costs to 340B entities, the agency is still reviewing public "comments alleging an under-estimation of administrative costs . . . and will [later] address

those concerns." Britton Decl. ¶ 35 (citing Paperwork Reduction Act Notice, 90 Fed. Reg. 44197 (Sep. 12, 2025)). This failure to consider administrative costs before approving the manufacturers' applications under the Rebate Program is fatal under the APA. *Michigan*, 576 U.S. at 759-60.

The administrative record is also silent on the cost of floating the full price of covered drugs until 340B entities receive their rebate. Defendants only response is more post hoc rationalization in the Britton Declaration that the Agency's decision to limit the scope of the Rebate Program to ten drugs and require drug manufacturers to pay rebates within ten calendar days demonstrate their consideration of the burden that will be placed on 340B entities to float upfront costs. Britton Decl. ¶¶ 5, 27-30, 34, 38, 41. Similarly, the non-monetary costs to 340B entities, including the impact these additional prices might have on their long-term viability represents another unaddressed "important aspect of the problem." *State Farm*, 463 U.S. at 43.

Defendants' call for judicial deference on this determination rings hollow. Their bald assertion that the benefits of the Rebate Program outweigh any negative impact associated with floating the full price of covered drugs, Britton Decl. ¶¶ 34, 41, smacks of "clairvoyance" rather than the kind of "exercise in logic" deserving of judicial deference. *Fox Television Stations*, 556 U.S. at 521. Particularly as here where financial forecasts about what costs the 340B entities can bear for a certain period is not predicated on any specialized or expert knowledge of the Agency. *FCC v. Nat'l Citizens Comm. for Broad.*, 436 U.S. 775, 815 (1978). Even supposing it were, Defendants make no argument that such a determination is within their expertise aside from the naked claim that we should

simply take their word for it. Furthermore, any colorable argument to that effect is belied by the absence of any evidence in the administrative record about upfront costs, particularly considering the numerous public comments estimating hundreds of millions of dollars in additional costs to 340B hospitals they might struggle to pay under a rebate model.[5] *See, e.g.*, Austin Decl. ¶¶ 13-14 (ECF No. 4); Brown Decl. ¶¶ 14, 20 (ECF No. 5); Fadale Decl. ¶¶ 14-15, 21 (ECF No. 6).

For the foregoing reasons, the administrative record's silence on Defendants' efforts to consider and reasonably explain the relevant costs associated with the Rebate Program offer independent grounds to conclude that Plaintiffs have demonstrated a likelihood of success on the merits.

d. Other relevant factors and pertinent aspects

Plaintiffs also assert that Defendants' failure to address public comments, less costly alternatives, and issues with the electronic database used to collect and store rebate claims data and the rebate dispute resolution mechanism also invalidate the Rebate Program. Defendants maintain they are not required to respond to public comments and that they did consider these aspects of the problem.

In establishing and implementing the Rebate Program, Defendants were not required to respond to public comments. *Cf.* 5 U.S.C. § 553; *Perez v. Mortgage Bankers Assoc.*, 575 U.S. 92, 96 (2015). To the extent the public comments highlighted an

[5] I do not mean to suggest that Defendants must weigh the burdens imposed on each and every entity that makes up the Public Health Service. However, the fact that the "pilot" program impacts them all calls for something more than casual indifference to localized impacts.

important aspect of the problem, they may be evidence of an agency's failure to reasonably explain its position, which I already addressed in relation to reliance interests and costs. *State Farm*, 463 U.S. at 43. Plaintiffs' arguments concerning less costly alternatives, the dispute resolution mechanism, and the rebate database all venture into the territory of asking for a policy judgment against the Agency. *Id.* In other words, digging into these arguments likely requires policy considerations about the nature and scope of the Rebate Program and the effectiveness of some of its component parts. Considering that Plaintiffs are likely to succeed on the merits without wading into these trickier issues, my analysis of the merits stops here.

2. Irreparable Harm

Plaintiffs allege irreparable harm for the costs they will incur from the Rebate Program between floating the upfront costs of covered drugs (far in excess of the costs they will ultimately be responsible for), hiring additional staff to process and track rebate claims, and cutting back or altogether abandoning certain programs and services. Mot. at 16-19. Defendants contend Plaintiffs' costs associated with the Rebate Program are not irreparable because they are speculative, mitigated by the benefits they will receive from the Rebate Program, and impermissibly rely on alleged harm to third parties. Opp'n at 19-22.

Irreparable harm is "a cognizable threat" of "a substantial injury that is not accurately measurable or adequately compensable by money damages" to the movant. *Ross-Simons of Warwick, Inc. v. Baccarat, Inc.*, 102 F.3d 12, 19 (1st Cir. 1996). Although it need not "be fatal to [the movant's] business," *id.* at 18, it "must be grounded on something more than conjecture, surmise, or a party's unsubstantiated fears of what the

future may have in store." *Charlesbank Equity Fund II v. Blinds to Go, Inc.*, 370 F.3d 151, 162 (1st Cir. 2004). "The costs of complying with challenged regulations have been recognized as irreparable given the obstacles faced when suing for monetary damages." *Cal. v. Kennedy*, No. 25-12019-NMG, 2025 WL 2807729, at *6 (D. Mass. Oct. 1, 2025) (citing *Rosario-Urdaz v. Rivera-Hernandez*, 350 F.3d 219, 222 (1st Cir. 2003)).

Plaintiffs demonstrate irreparable harm. AHA members alone estimate $400 million in compliance costs, the downstream effect causing them to cut back services and suspend partnerships with drug distributors. Mot. at 16-19; Reply at 11-12; Golder Suppl. Decl. ¶¶ 2-4; Austin Decl. ¶¶ 10-13; Brown Decl. ¶ 18; Fadale Decl. ¶ 18. These claims are not unsubstantiated fears of what the future might hold. Nor do Plaintiffs' speculative concerns about delayed receipt and inappropriate denial of rebates from drug manufacturers defeat the meritorious aspects of their irreparable harm claim. Furthermore, because Plaintiffs raise an APA challenge, they cannot recover any damages for the costs incurred from the Rebate Program should it later be invalidated—a claim on which they are likely to succeed. Accordingly, their inability to recoup those costs in this context demonstrates irreparable harm. *Kennedy*, 2025 WL 2807729, at *6.

3. Balance of Equities and Public Interest

Plaintiffs maintain that the balance of equities and public interest weigh in their favor for several reasons, including the public's interest in preserving the reach of the Public Health Service to provide critical medical services, particularly when weighed against the lack of public interest in an agency carrying out a likely unlawful action. Mot. 19-20. Defendants assert that there is strong public interest in implementing the Rebate

Program to address the de-duplication problem and assess the benefits of a rebate model. Opp'n at 22.

The balance of equities and public interest weigh in Plaintiffs' favor. Most importantly, a preliminary injunction would preserve the status quo and preserve the reach of 340B entities to continue serving the public's significant interest in receiving critical medical services. *See Starbucks Corp. v. McKinney*, 602 U.S. 339, 344 (2024); *Rio Grande Cmty. Health Ctr., Inc. v. Rullan*, 397 F.3d 56 (1st Cir. 2005). Moreover, considering that Plaintiffs are likely to succeed on the merits of their APA claims, Defendants' arguments concerning equities and public interest in the Rebate Program are necessarily diminished. To be clear, Defendants' authority to administer a rebate model program is not in question, only the quality of the Rebate Program's current rollout effort in light of the APA.

4. Summation

As complicated as certain aspects of this case might seem, it boils down to a simple principle. Defendants cannot fly the plane before they build it. The Agency's failure to abide basic requirements of the APA, Plaintiffs' irreparable injury should the program go into effect, as well as the balance of equities weighing in Plaintiffs favor, all counsel against permitting the Rebate Program to take flight on January 1, 2026.[6] That, of course, is not to say that a rebate model is impermissible. Congress clearly gave Defendants that option. The problem is that the Defendants' failed to follow the APA's basic blueprint in

[6] April 1, 2026, for the application approved for Novartis Pharmaceuticals Corporation. *See* Opp'n at 7.

assembling the Rebate Program. For these reasons, Defendants are preliminarily enjoined from implementing this iteration of the Rebate Program pending further order.

C. SCOPE OF PRELIMINARY RELIEF

1. Preliminary Injunction

Defendants' cite *Trump v. CASA, Inc.*, 606 U.S. 831 (2025), for the proposition that the breadth of this preliminary injunction is limited to the specific identified association members of AHA and MHA or that the remedy should be tailored only to address the irreparable harm shown by specific members of these associations. Opp'n at 23-25. First, *Casa* declined to "resolve[ ] the distinct question whether the [APA] authorizes federal courts to vacate federal agency action." *CASA*, 606 U.S. at 847 n.10. Second, the First Circuit has already rejected Defendants argument that the remedy here must be limited to the "members whom the organizations identified in seeking associational standing." *Doe v. Trump*, 157 F.4th 36, 80 (1st Cir. 2025).

The APA authorizes federal courts to "hold unlawful and set aside agency action," 5 U.S.C. § 706(2), including by "issu[ing] all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings," *id.* § 705. Defendants fundamentally misunderstand the nature of this 'set aside' authority, which "'empower[s] the judiciary to act directly against the challenged agency action.'" *Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 603 U.S. 799, 838 (2024) (KAVANAUGH, J., concurring) (quoting J. Mitchell, *The Writ-of-Erasure Fallacy*, 104 VA. L. REV. 933, 1012 (2018)). Moreover, courts have long understood the APA to authorize vacatur and the Supreme Court has yet

to dictate otherwise. *Id.* at 839; s*ee also Assoc. of Am. Univ. v. Dept. of Defense*, No. 25-11740-BEM, 2025 WL 2899765, at *29 (D. Mass. Oct. 10, 2025) (citing cases); *Doe v. Trump*, 796 F. Supp. 3d 599, 603 (N.D. Cal. 2025) (citing cases). As a result, the preliminary injunction in this case—based in part on a finding that the government's application approvals likely violated the APA—need not be limited to Plaintiffs. Instead, the Court has authority to preliminarily set aside those agency actions comprising the Rebate Program. *See CASA*, 606 U.S. at 873 (KAVANAUGH, J., concurring) (noting that even after *CASA*, district courts may "grant or deny the functional equivalent of a universal injunction—for example, by . . . preliminarily setting aside or declining to set aside an agency rule under the APA"); 5 U.S.C. § 705.[7]

2. Bond Requirement

In this case, a nominal bond is appropriate. Although the APA has no bond requirement, *id.* § 705, "the district courts in this circuit have generally required a bond," *Maine v. U.S. Dept. of Agric.*, 778 F. Supp. 3d 200, 237 (D. Me. 2025). Defendants face no material loss from enjoining the implementation of the Rebate Program, Plaintiffs' lawsuit concerns the public interest, and Plaintiffs are likely to succeed on the merits of their claim. *See Crowley v. Local No. 82, Furniture & Piano Moving*, 679 F.2d 978, 999-1000 (1st Cir. 1982). Accordingly, Plaintiffs must post a bond of $1,000.[8]

[7] Of course, the broad latitude the APA affords courts to fashion relief does not necessarily preclude more limited remedies, including remand for further consideration by the agency consistent with a court order. *See*, *e.g.*, *State Farm*, 463 U.S. at 59.

[8] This District and other district courts within the First Circuit have similarly required a nominal bond in this amount. *See Maine*, 778 F. Supp. 3d at 238; *Nationwide Payment Sols., LLC v. Plunkett*, 697 F. Supp.

CONCLUSION

For the foregoing reasons, Plaintiffs' Motion (ECF No. 3) is GRANTED. Defendants are enjoined from implementing the nine individual applications that comprise the 340B Model Rebate Pilot Program pending further order. Furthermore, within seven days of the date of this order, Plaintiffs are ORDERED to provide security in the amount of $1,000.

SO ORDERED.

/s/ Lance E. Walker
Chief U.S. District Judge

Dated this 29th day of December, 2025.

2d 165, 173 (D. Me. 2010); *Nw. Selecta, Inc. v. Sec'y of the Dep't Agric. of P.R.*, No. 22-1092-RAM, 2022 WL 17985926, at *7 (D.P.R. Dec. 29, 2022). I see no reason to depart from this precedent.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*, Plaintiffs, v. ROBERT F. KENNEDY, JR. SECRETARY of the U.S. Department of Health and Human Services, *et al.*, Defendants.	No. 2:25-cv-600-JAW

DECLARATION OF CHANTELLE BRITTON

I, Chantelle Britton, M.P.A., M.S., declare as follows pursuant to 28 U.S.C. § 1746:

1. I am the Director of the Office of Pharmacy Affairs (OPA). OPA is part of the Health Resources and Services Administration (HRSA), an agency within the U.S. Department of Health and Human Services (HHS). OPA has delegated authority to administer the 340B Program, which is codified in statute at 42 U.S.C. § 256b or Section 340B of the Public Health Service Act. OPA is responsible for the day-to-day administration of the 340B Program. I make this declaration based on personal knowledge and information provided to me by my staff in the course of my official duties as the Director of OPA.

2. Pursuant to 42 U.S.C. § 256b(a)(1), "[t]he Secretary [of HHS] shall 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 statutorily-defined ceiling price (emphasis added). This provision, which has been in the statute since the 340B Program's inception in 1992, has been interpreted by HHS as providing the legal authority for effectuating the 340B ceiling price by either a rebate or discount mechanism.

3. Notwithstanding that statutory authority to operationalize rebates and set conditions for rebates in the 340B Program,[1] covered entities have historically purchased covered outpatient drugs in the 340B Program at upfront discounted prices rather than through back-end rebates, with few exceptions.

4. After receiving a significant amount of feedback from (or on behalf of) manufacturers and covered entities regarding implementation of rebate models, OPA recently became interested in testing the merits and shortcomings of a rebate model, including whether it was beneficial in addressing 340B and Maximum Fair Price (MFP)[2] deduplication and the prevention of 340B Medicaid duplicate discounts and diversion. For the past several years, drug manufacturers have been aggressively pursuing the unilateral implementation of widespread 340B rebate models, insisting that a rebate model would have minimal impact on covered entities and patients and is necessary to address a wide variety of perceived program integrity concerns. Covered entities have argued just as hard in opposition to rebate models, asserting that a rebate model would adversely impact covered entities cash flow, negatively impact patients' access to drugs and services and that manufacturers' program integrity concerns are overblown. Given these hyperbolic positions, OPA felt it necessary to test rebates to see how the mechanism would impact the 340B Program and its stakeholders. The purpose of the rebate Pilot Program was also to help OPA consider any future 340B rebate models consistent with the 340B statute and the Administration's goals.

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[1] *See* 42 U.S.C. § 256b(a)(1); *see also Eli Lilly & Co. v. Kennedy*, 2025 WL 1423630 (D.D.C. May 15, 2025), *appeal filed*, No. 25-5221 (D.C. Cir. June 13, 2025); *Johnson & Johnson Healthcare Sys. Inc. v. Kennedy*, 2025 WL 1783901 (D.D.C. June 27, 2025), *appeal filed*, No. 25-5236 (D.C. Cir. June 30, 2025).

[2] Maximum Fair Price refers to the negotiated price under the Medicare Drug Price Negotiation Program (MDPNP). *See* 42 U.S.C. §§ 1320f(c)(2). Under the MDPNP "nonduplication" provision, manufacturers that agree to a Maximum Fair Price are not required to provide a covered entity access to the negotiated Maximum Fair Price under that agreement if the drug is also subject to a 340B agreement and the 340B ceiling price is lower than the Maximum Fair Price. 42 U.S.C. § 1320f-2(d). Deduplication refers to the process a manufacturer uses to assess its obligation to provide access to the Maximum Fair Price under the MDPNP nonduplication provision.

5. OPA recognized that a rebate model would be a significant shift from how the 340B program has been operating, so it sought to test the rebate model on a small scale to help it better understand the merits and shortcomings of a rebate model from stakeholders' perspectives while minimizing disruption to covered entities. It therefore limited the scope of the Pilot Program to the manufacturers with Medicare Drug Price Negotiation Program (MDPNP) Agreements with the Centers for Medicare & Medicaid Services (CMS) for the ten selected drugs for initial price applicability year 2026, in order to test the viability of rebates as an option for effectuating 340B ceiling prices.

6. Limiting the scope of the Pilot Program to the manufacturers of the ten drugs on the MDPNP Selected Drug List for 2026 was intended to allow OPA to better understand the merits and shortcomings of the rebate model from stakeholders' perspectives, including those of manufacturers seeking to address 340B and MFP deduplication.

7. On August 1, 2025, OPA published in the Federal Register a notice titled "340B Program Notice: Application Process for the 340B Rebate Model Pilot Program." 90 Fed. Reg. 36,163 (Aug. 1, 2025).

8. The notice announced the availability of a 340B Rebate Model Pilot Program as a voluntary mechanism for qualifying drug manufacturers to effectuate the 340B ceiling price through a rebate rather than upfront discount on select drugs to all covered entities, and to collect comments on the structure and application process of the Pilot. The notice also contained the criteria for manufacturers' plans to implement a rebate model and set out expectations for continued participation in the Pilot.

9. A technical correction to the notice was published on August 7, 2025, which extended the 30-day comment period by a week to September 8, 2025. 90 Fed. Reg. 38,165 (Aug. 7, 2025).

10. Applications were due on September 15, 2025, the week following the deadline for the submission of comments.

11. In response to the notice, OPA received more than 1,100 comments and applications from each of the nine manufacturers that were eligible to participate in the Pilot.

12. OPA reviewed the comments and considered suggestions and concerns raised therein when evaluating the applications.

13. Each of the nine plans for implementation of rebate models in connection with the Pilot Program submitted by the manufacturers addressed general requirements, reporting requirements, and criteria pertaining to rebates and data. OPA carefully reviewed each plan and sought revisions and clarifications on a number of topics having to do with claims submission, billing, rebate calculation, and inventory management before deciding whether to approve the plans.

14. As further explained below, OPA carefully balanced the equities and took into consideration a variety of factors, including impacts on covered entities and concerns raised in comments, in making decisions on which specific aspects of the plans that it would approve.

The January 1, 2026 Effective Date

15. The August 1, 2025 notice announced that approved manufacturer plans would take effect on January 1, 2026.

16. The January 1 effective date was chosen to align with the effective date of the first set of negotiated prices under the MDPNP, which are set to take effect on January 1, 2026. Starting January 1, manufacturers participating in MDPNP will be implementing 340B prices and Maximum Fair Price deduplication. A 340B rebate mechanism is one way that drug manufacturers can deduplicate 340B prices and Maximum Fair Price. Many drug manufacturers participating in the MDPNP stated that a 340B rebate mechanism is their preferred method to achieve deduplication.

17. At least as far back as 2024, it was widely known that OPA was considering requests from multiple drug manufacturers to implement rebate models. OPA determined that the five-month lead-time from the announcement of the Pilot to effective date was sufficient for covered entities to prepare for implementation of the Pilot, particularly given the limited scope of the Pilot.

18. OPA also required plans to allow for 60 calendar days' notice to covered entities and other impacted stakeholders before implementation of a rebate model, with instructions for registering for any IT platforms. Sixty days was more than sufficient time for covered entities to prepare for the Pilot given that the Pilot was limited in scope, the pharmacy and medical claims information being collected was limited to information that most covered entities already collect, and the Pilot was structured to use existing 340B purchasing accounts.

19. Although the notice stated that OPA's approvals of manufacturer plans would be made by October 15, 2025, the lapse in appropriations applicable to some components of HHS prevented OPA from meeting that goal. Instead, OPA announced eight manufacturers that were approved to participate in the Pilot on October 30, 2025 for a January 1, 2026 effective date. The ninth manufacturer was later approved by OPA to participate in the Pilot beginning on April 1, 2026, even though this manufacturer advised OPA that a January 1 effective date for its participation in the Pilot Program was preferred for its alignment with the effective date of the MFP for its selected drug under the MDPNP.

Alternatives to a Rebate Pilot

20. While alternatives to the Pilot were raised by commenters, OPA did not adjust the concept for its Pilot after considering these comments. Many commenters proposed alternatives that would have maintained the status quo of effectuating ceiling prices through upfront discounts or were otherwise counter to the central aim of the Pilot, which was to test whether rebates were feasible across other covered entity types besides AIDS Drug Assistance Programs. Some suggested alternatives were clearly outside the scope of OPA's legal authority or relied on questionable legal authority.

21. For example, commenters proposed OPA create a government-backed, third-party "clearinghouse" to collect data from drug manufacturers and covered entities, to deduplicate 340B prices and Maximum Fair Price under the MDPNP, and to address manufacturers' program integrity

concerns with the 340B program. Commenters asserted that examples of these "clearinghouses" already exist, such as the Medicare Transaction Facilitator, which facilitates manufacturer effectuation of Maximum Fair Price for drugs selected for negotiation under the MDPNP. OPA rejected those suggestions because those methodologies do not test the concept of a rebate, and testing the rebate methodology to effectuate the 340B ceiling price was OPA's chief aim. Moreover, there is no clear legal authority in the 340B statute for OPA to create the type of clearinghouses suggested by the commenters.

The Scope of the Pilot Program

22. OPA also rejected proposals to further limit the scope of the Pilot Program. The Pilot, which encompasses only the selected drugs of the manufacturers in the MDPNP for IPAY 2026, was narrowly tailored by design. The ten drugs that are in the Pilot Program represent ten Labeler Codes and 83 National Drug Codes (NDCs) of the 904 active Labeler Codes and 47,541 NDCs in the 340B Program. Sales in the 340B Program in 2024 totaled $81.4B. The ten drugs that are subject to the Pilot Program account for only 2% of that total. Further, of the drugs in the Pilot Program, only one, Stelara, was in the top 20 of 340B drug products purchased by covered entities in 2024.

23. Commenters suggested further restricting the number of drugs in the Pilot. OPA rejected that suggestion because reducing the number of drugs in the Pilot would interfere with one of the Pilot's goals of addressing manufacturer concerns regarding 340B-MFP deduplication. Under the MDPNP, manufacturers that agree to a Maximum Fair Price are not required to provide a covered entity access to the negotiated Maximum Fair Price under that agreement if the drug is also subject to a 340B agreement and the 340B ceiling price is lower than the Maximum Fair Price. 340B-MFP deduplication refers to the process of preventing duplicate discounts. Since the drugs with MFPs in effect under the MDPNP for CY 2026 are the only drugs eligible for the Pilot, further limiting the number of drugs would have not afforded a 340B rebate option for each of the ten drugs for which manufacturers are seeking deduplication. Reducing the number of drugs included would also interfere

with the agency's ability to collect sufficient information on which to evaluate the viability of a broader rebate model.

24. Commenters suggested that manufacturers' rebate proposals should be limited to only a subset of covered entities or to only covered entities that volunteered to participate. OPA rejected this suggestion. The 340B Program contains a wide variety of covered entity types, ranging from federally qualified health centers, certain children's hospitals and free-standing cancer hospitals, critical access hospitals, rural referral centers, black lung clinics, and other federally funded health care entities. 42 U.S.C. § 256b(a)(4). Because another important goal of the Pilot is to collect information on the experience of a wide variety of covered entity types with the rebate model, OPA decided that manufacturers should be able to structure their rebate programs for as broad a variety of covered entities as manufacturers deemed necessary to appropriately test the model.

25. The scope of the Pilot is already extremely limited because only ten drugs are included. Further limiting its scope would undermine the agency's goal of information gathering.

Drug Costs

26. Several covered entity commenters indicated that the Pilot would have a significant financial impact because it would require covered entities to "float" billions of dollars to drug manufacturers. They contended that this would occur because 340B purchases would be made at the higher wholesale acquisition cost (WAC) price and they would only be made whole later when the rebate was paid, which OPA required to be paid within ten calendar days of submission. In contrast, drug manufacturers asserted that given the short ten-day time frame for processing claims, the financial impact would be minimized as it was likely that covered entities would receive rebate payments before payment would be due by the covered entity to the wholesaler for most purchases. Several drug manufacturers also requested a longer time frame for processing claims with some wanting OPA to extend the ten days to fourteen days.

27. Given the wide variety of assertions on this topic, OPA opted for the shorter payment window, in part, to address covered entity concerns regarding cash flow and determined that it would be necessary to collect data from the Pilot to make an informed decision about any necessary future changes. OPA was of the view that the impact on covered entities would be lessened by maintaining the shorter ten-day time frame for processing claims and by the extremely limited scope of the Pilot.

28. Moreover, most drugs included in the Pilot would not "sit on the shelf for long[] periods of time before being dispensed" as Plaintiffs claim. Compl. ¶ 85. Rather, the majority of drugs included in the Pilot are dispensed as a full package size (i.e., dispensed as one prescription), which minimizes, or altogether eliminates, the necessity to wait long periods of time between ordering a package and submitting a rebate request.

29. Any financial strain on covered entities will be further mitigated by the fact that manufacturers will pay unit-level rebates rather than package-level rebates. Said another way, for purchases from which multiple dispenses will be drawn, covered entities will not have to wait to dispense an entire package before being able to request a rebate; instead, if applicable, they may do so after the first dispense from the package (e.g., a rebate may be requested for 30 tablets dispensed out of a bottle of 100 tablets).

30. OPA acknowledges that adopting the rebate mechanism for even this limited set of drugs will be a significant change for covered entities. However, covered entities derive substantial financial benefits from the 340B spread, which is additional revenue representing the difference between the cost of a drug and what a covered entity is reimbursed by a third-party payer—e.g., covered entities turn a profit when serving insured patients because insurance companies reimburse them at full price for drugs that they bought at the 340B discount. A ten-day lag before a covered entity is made whole, on balance, does not strike OPA as being as calamitous as covered entities portray, particularly if, as manufacturer commenters state, the rebate in most instances will be paid before the purchase invoice from a wholesaler for the WAC amount is due. The Pilot will allow OPA

to collect data to evaluate whether rebates are paid before a purchase invoice is due and to evaluate more generally the impact of rebates on covered entities.

31. Commenters were also concerned about delays in receiving rebates, as well as disputed claims and improperly denied claims. OPA has provided a number of guardrails to mitigate these concerns. These include, but are not limited to: 1) severely limiting the bases for the denial of claims; 2) requiring manufacturers to provide a rationale and specific documentation for any claim denials; 3) requiring manufacturers to have processes in place for the good faith resolution of disputes; and 4) requiring manufacturers to report to OPA information related to claim delays and denials.

32. In addition, OPA is planning to create a mechanism through which covered entities will be able to report to OPA when the covered entity is unable to secure a rebate and covered entities will be able to raise these types of issues through the 340B Administrative Dispute Resolution process. Given that these safeguards provide covered entities with protections that exceed the protections that covered entities maintain outside of the Pilot, OPA determined that the dispute process was sufficient and that the suggestions from commenters to address alleged unaccounted-for costs caused by perceived gaps in the dispute resolution system were unnecessary.

33. Finally, OPA recognized that covered entities could be due partial credit for 340B purchases made under the upfront discount system when covered entities transition to a rebate mechanism. Under the current upfront discount system, covered entities cannot claim the 340B price until they have dispensed a full package size. For example, if the package size for a given drug is 100 pills, if a covered entity has only dispensed 25 pills to one patient, the covered entity must wait until it dispenses the rest of the 75 pills to other patients before claiming the 340B discount. In this example, a covered entity can't claim the 340B price until it has "accumulated" the full package size by providing all 100 pills to 340B eligible patients. OPA worked with manufacturers to ensure that there was a mechanism for covered entities to obtain the 340B price for any drugs that the covered entity may not have accumulated a full package size on January 1, 2026, when they are transitioned to a rebate model.

Administrative Costs and Other Burdens

34. Commenters also raised concerns about administrative costs. As explained above, covered entities that choose to participate in the 340B program derive a significant financial benefit from it. Their participation in the 340B Program is voluntary and has always entailed certain compliance, operational, and other costs. OPA designed the Pilot Program with the aim of minimizing any additional administrative costs and burdens attributable to the Pilot and ultimately determined that the potential significant added benefits of the Pilot—gathering information on the feasibility of rebates, helping to collect data for future rebate models consistent with the 340B statute and Administration priorities, improving transparency, addressing manufacturer concerns about 340B-MFP deduplication, and facilitating the prevention of 340B Medicaid duplicate discounts and diversion—outweighed these costs.

35. OPA is currently examining the comments alleging an under-estimation of administrative costs in the context of the Paperwork Reduction Act Notice, 90 Fed. Reg. 44,197 (Sept. 12, 2025). OPA will address those concerns in the context of finalizing that notice.

36. As for the need to provide claims data to receive rebates, most covered entities already provide the type of claims data they will need to provide under the Pilot. Since at least 2021, in connection with manufacturer contract pharmacy policies, many covered entities have been submitting claims data to 340B ESP, an IT platform owned by the company Second Sight Solutions, which also operates the rebate model IT platform. OPA purposefully did not require covered entities to submit any new pharmacy and medical data elements beyond which most were already submitting either as part of the manufacturer contract pharmacy claims submission process or which most had readily available through third party administrators.

37. For example, OPA rejected proposals from manufacturers to require submission of a set of data tied to the purchase of the drug (e.g., specific invoice data, detailed wholesaler account information, and purchase account information) to avoid creating additional burdens on covered

entities as this element was not something that could be easily produced by many covered entities at this juncture. While covered entities have access to their purchase records, they do not routinely tie those records to individual dispensing records. Requiring this reconciliation would create a significant administrative burden on covered entities.

38. To elaborate, in all the plans, manufacturers sought to collect purchase data from covered entities. Manufacturers relayed that the purchase data was necessary to improve the integrity of the Pilot. They also claimed it was needed to provide visibility into 340B transactions. In particular, manufacturers thought this data would allow them to verify that the claims data submitted by covered entities showed that the drug was purchased at WAC, thus triggering the request for a rebate. In addition, manufacturers wanted to verify that there were purchases made to warrant a rebate request. OPA considered the request from manufacturers but ultimately decided against approving the collection of purchase data. It did so to avoid placing undue burden on covered entities as this information is not readily available to attach as part of the claims submission and would cause additional burden for covered entities to produce. OPA was also of the view that manufacturers could, at this juncture, use information provided by their wholesale partners to determine that there were sufficient WAC purchases to compare with rebate requests. The final approval letters to manufacturers reflected OPA's reasoned thinking on this issue and that purchase data was not necessary at this initial phase of the Pilot.

39. As another example, in all of the plans, manufacturers sought to collect medical claims data from covered entities. This was in addition to the pharmacy claims data that OPA was requiring covered entities to submit to obtain a rebate payment under the Pilot. Regarding this request, OPA considered the justification provided by the manufacturers and agreed that the data would be necessary to effectuate 340B rebates for physician-administered drugs. Medical claims data include different data than pharmacy claims data due to how the drug is received by the patient: instead of the RX number that would be supplied by a pharmacy dispense, the medical claims corresponding data field would be

the claim number. This is the type of data that is generated when a drug is administered by a physician as opposed to being dispensed at a pharmacy. In addition, OPA found that the medical claims data was analogous to pharmacy claims data used to identify 340B eligible claims and would therefore not cause additional burden for covered entities to produce as part of their claims submission when requesting a rebate.

40. Public comments submitted in response to the notice also identified the concern that the rebate model would cause difficulties with state Medicaid programs that reimburse at actual acquisition cost (AAC) and difficulties in providing sliding fees to uninsured patients. Under the upfront discount model, covered entities receive pricing files with 340B ceiling prices from wholesalers that feed the pharmacy billing systems, which allow covered entities to bill at AAC and allow for sliding fees that share savings with eligible patients. This would not exist under the rebate model because the 340B ceiling price will no longer be present in the pricing files from wholesalers for drugs in the rebate model. The WAC price, not the 340B ceiling price, will appear in the pricing files. Therefore, as OPA reviewed the plans, it became apparent that covered entities would need a separate pricing file to understand better what their ultimate rebated amount would be to help them plan. OPA requested that each manufacturer work to provide a supplemental pricing file with the 340B ceiling prices to assist covered entities with the Medicaid billing requirements and assist with providing patients with the shared savings. This file will be available for download on the rebate model's IT platform. The 340B OPAIS pricing component is also available for verification of the accuracy of the manufacturer provided files.

41. OPA considered the non-monetary costs associated with moving to a rebate model. Covered entities have asserted that a rebate model would affect patient care by limiting the availability of drugs and by reducing the benefits covered entities derive from participating in the 340B Program. Manufacturers have argued that implementation of a rebate model would not affect patient care, will not affect patient access to drugs, and will not affect covered entity participation in the 340B Program.

OPA does not believe that the rebate model will have a significantly negative impact on patient care as the rebate model is designed only to change the form of the 340B discount, not restrict the savings received by 340B covered entities for the drugs included in the Pilot. OPA does not think a ten-day lag in receiving a rebate payment will harm patients or communities that indirectly benefit from the 340B Program. These types of concerns are the reason, in part, why OPA greatly restricted the scope of the Pilot, so that it could further evaluate any unforeseen consequences of a Pilot without endangering the entire 340B Program.

Concerns about the Beacon Software Platform

42. To balance the interests of covered entities and manufacturers, OPA imposed several requirements on manufacturers participating in the Pilot regarding the IT platform a manufacturer would use to collect and store rebate claims data.

43. Manufacturers were required to, among other requirements: 1) provide covered entities and other impacted stakeholders with 60 calendar days' notice before implementation of the rebate model, with instructions for registering with any IT platform; 2) provide a technical assistance/customer service component and ensure that opportunities to engage with the manufacturer in good faith regarding questions or concerns are made available to covered entities through both the IT platform and a point of contact at the manufacturer; 3) ensure that the IT platform has assurances in place to ensure that the data is secure and protected and collection of the data is limited to the elements identified by OPA as necessary for providing 340B rebates pursuant to section 340B(a)(1) of the PHSA; 4) ensure that the IT platform has mechanisms in place to protect patient identifying information, which is required to be maintained in a manner consistent with the Health Insurance Portability and Accountability Act of 1996 and any other applicable privacy and data security laws; 5) ensure that the IT platform will have the capacity to receive data that will filter and use only the data required to effectuate the rebate (e.g., if drugs other than the selected drugs under the MDPNP included within the Pilot Program are submitted, the IT platform will be able to identify

and discard unneeded data); and 6) ensure that the IT platform will have the capability to provide real-time reconciliation reports for covered entities to be informed of the rebate status of submitted claims.

44. All manufacturers that were approved by OPA to participate in the Pilot selected Beacon Channel Management (Beacon) as their chosen IT platform. OPA did not select Beacon or in any way influence the selection of Beacon. Beacon is a private company that is an ancillary stakeholder in the 340B space, but OPA has no legal authority over Beacon. Although OPA cannot compel Beacon to act in a certain manner, it reserves the right to revoke approval of a manufacturer plan at any time if the manufacturer fails to comply with the program's criteria, including by failing to ensure its IT platform is complying with the above requirements. Also, the health care and pharmaceutical sectors are heavily regulated, and numerous federal and state laws beyond the 340B statute already exist to address unlawful conduct regarding privacy and data security.

45. There are many third-party contractors that operate in furtherance of the 340B Program. These stakeholders include wholesalers, specialty distributors, contract pharmacies, third party administrators, consultants, auditors, and pharmacy benefit managers, among others. The use of Beacon is entirely consistent with these other aspects of the 340B Program. As is the case with Beacon, OPA exercises no regulatory oversight over these stakeholders. While OPA is aware of many contracts or agreements that covered entities, for example, may enter into with these stakeholders, OPA is not involved in negotiating, setting, or even reviewing beforehand the terms and conditions of these private agreements and would only become involved to the extent there is activity that conflicts with a covered entity's (or a manufacturer's) 340B obligations. Although the Beacon IT platform is not entirely new to most covered entities because of their experience with 340B ESP (the IT platform many covered entities use in connection with manufacturer contract pharmacy policies), OPA understood that purchasing covered outpatient drugs via rebates would be a new endeavor. Consequently, OPA stipulated the requirements listed above and other guardrails to minimize the compliance costs and administrative burden for covered entities adopting the new rebate mechanism.

46. To conclude, each manufacturer seeking approval to join the Pilot made its own business decision regarding the IT platform it would use to facilitate its participation. While OPA did not select Beacon, after reviewing the manufacturer plans, it believed there were potential advantages to having all manufacturers in the Pilot using the same IT platform. In submitting and adjudicating rebate claims, covered entities would only need to acclimate to one IT service provider rather than multiple service providers with different digital platforms and rules of engagement. OPA believed a single IT platform would further minimize any perceived or actual burden on covered entities.

OPA Will Ensure Compliance and Evaluate the Pilot Program Moving Forward

47. Since announcing the approved manufacturer plans, OPA has met with various stakeholders to discuss the Pilot. Compliance and evaluation of the Pilot will be part of OPA's ongoing work. Compliance with 340B obligations by manufacturers and covered entities will be assessed through data reporting by the manufacturers and through audits for both covered entities and manufacturers. Evaluation of the Pilot will also be conducted through data and reports received from the participating manufacturers on the effectiveness of the model and covered entity and other stakeholder feedback.

48. OPA continues to encourage stakeholders to reach out with their questions and concerns, and OPA is engaging with trade organizations that represent covered entities and manufacturers regularly. OPA is collecting questions and regularly updating the OPA website that houses frequently asked questions to clarify issues that can be resolved prior to implementation.

49. OPA is also working closely with CMS to understand how the implementation of the Pilot may impact the Medicaid and Medicare programs. OPA is working with CMS to receive feedback from their stakeholders about how these stakeholders believe the Pilot is working.

50. Finally, OPA is designing a mechanism by which covered entities and manufacturer stakeholders can begin to submit their feedback once the Pilot is operational in January.

In accordance with 28 U.S.C. § 1746, I declare, under penalty of perjury, that the above information is true and correct to the best of my knowledge and belief.

Signed this 15th day of December 2025.

Chantelle V. Britton -S

Digitally signed by Chantelle V. Britton -S
Date: 2025.12.15 20:24:09 -05'00'

Chantelle Britton, M.P.A., M.S.
Director
Office of Pharmacy Affairs
Health Resources and Services Administration

If you do not wish your name and contact information be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Letise Williams, Center for Devices & Radiological Health, Food and Drug Administration, 10903 New Hampshire Avenue, Building 66, Room 5407, Silver Spring, MD 20993, *Letise.Williams@fda.hhs.gov,* 301–796–8398, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform.

On November 6, 2025, the Committee will discuss and make recommendations on the topic of ''Generative Artificial Intelligence-Enabled Digital Mental Health Medical Devices.'' Many of these medical devices pose novel risks and, as mental health devices continue to evolve in complexity, regulatory approaches ideally will also evolve to accommodate these novel challenges and opportunities to provide a reasonable assurance of their safety and effectiveness while promoting innovation to support public health. There is an increasing demand for mental health services in the US and insufficient access to mental health care providers. These new devices may be one way to help address this gap in care for people, potentially improving outcomes and access. The committee will discuss the benefits, risks to health, and risk mitigations that might be considered for these new digital mental health devices, including premarket evidence and postmarket monitoring considerations.

FDA intends to make background material and the link to the live webcast available to the public no later than (2) business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background materials and the link to the online teleconference and/or video conference meeting will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

The meeting will include slide presentations with audio and video components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before October 17, 2025, will be provided to the Committee. Oral presentations from the public will be scheduled between approximately between 10:30 a.m. and 12:30 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 9, 2025. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 10, 2025.

For press inquiries, please contact the HHS Press Room at *www.hhs.gov/press-room/index.html* or 202–690–6343. FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact CDR Daniel Bailey, M.S., M.B.A, M.DIV, at *Daniel.bailey@fda.hhs.gov* or 301–529–54505 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–17651 Filed 9–11–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906–0111—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection

projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than November 12, 2025.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14NWH04, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906–0111—Extension.

Abstract: HRSA's Office of Pharmacy Affairs (OPA) is introducing a 340B Rebate Model Pilot Program as a voluntary mechanism for qualifying drug manufacturers to effectuate the 340B ceiling price on select drugs to covered entities, as outlined in a **Federal Register** *Notice* (90 FR 38165; herein referred to as the ''Notice'') issued on August 7, 2025. This information collection request includes the collection of 340B Rebate Model Pilot Program plans from drug manufacturers, the collection of reports from drug manufacturers for OPA's evaluation of the pilot program and for overall 340B Program surveillance, and the collection of data submitted by covered entities to manufacturers to request a rebate.

Need and Proposed Use of the Information: The scope of the 340B Rebate Model Pilot Program will be limited to manufacturers with Medicare Drug Price Negotiation Program Agreements with the Centers for Medicare & Medicaid Services' for the initial price applicability year 2026.[1] Once selected plans are approved in accordance with the Notice, manufacturers may then begin to effectuate the 340B rebate starting January 1, 2026. This information collection request includes the collection of 340B Rebate Model Pilot Program plans from drug manufacturers, the collection of sales data from drug manufacturers for OPA's evaluation of the pilot program and for overall 340B Program surveillance, and the collection of data submitted by covered entities to manufacturers to request a rebate.

Collection of Drug Manufacturer Applications: OPA will evaluate and approve plans for participation in the 340B Rebate Pilot Program based on the elements required in the Notice (90 FR 38166–67).

Collection of Reporting Data from Manufacturers: Manufacturers will be required to submit data to the 340B Prime Vendor on a monthly basis to ensure program integrity and to provide transparency in the 340B Program. Monthly submissions will provide better data for tracking 340B data and reduce lag time in assessing Program metrics. The data submitted is also being collected to support the assessment of the 340B Rebate Model Pilot Program.

Collection of Data Submitted by Covered Entities to Manufacturers: Covered entities are required to provide specific data to participating manufacturers in order for the manufacturers to provide rebates to effectuate the 340B discount on the entities' covered outpatient drug purchases. Specific requirements that detail the type of and frequency of such submittals can be found in the Notice (FR 38166). The data collected will be kept private to the extent permitted by the law.

HRSA received an emergency clearance from OMB on August 26, 2025. The emergency clearance will ensure that the agency will collect drug manufacturer applications by September 15, 2025. This 60-day **Federal Register** *Notice* will allow HRSA to fully consider all public comments on its burden statement. HRSA has taken all practicable steps to consult with the public to minimize burden (including a 30-day comment period in the Notice).

Likely Respondents: Pharmaceutical manufacturers and 340B covered entities.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Name	Number of respondents *	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
340B Program Rebate Model Pilot Program Plan Submission	9	1	9	8	72
Monthly purchase reports	9	12	108	2	216
Covered Entities reporting claims data to third party platform	14,600	52	759,200	2	1,518,400
Total	14,609		759,317		1,518,688

* The same nine manufacturers will submit Plans and Monthly Purchase Reports (first two rows, above), while the 14,600 Covered Entities will submit Claims Data (third row, above). Therefore, the total number of respondents is 14,609.

[1] The Fact Sheet for Negotiated Prices for Applicability Year 2026 includes the list of Primary Manufacturers with selected drugs, available at *https://www.cms.gov/files/document/fact-sheetnegotiated-prices-initial-price-applicability-year2026.pdf.*

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2025–17641 Filed 9–11–25; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Nurse Faculty Loan Program Forms OMB No. 0915–0314—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than November 12, 2025.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14NWH04, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Nurse Faculty Loan Program Forms OMB No. 0915–0314—Revision.

Abstract: This clearance request seeks approval for the Nurse Faculty Loan Program (NFLP) Forms. The forms included are the NFLP—Program Specific Data Form, NFLP—Annual Performance Report (APR) Financial Data Form, and the NFLP Due Diligence Form. They are currently approved under OMB Approval No. 0915–0314, with the expiration date of August 31, 2026. For greater clarity and consistency, the only change to this information collection request is to change the title from the ''Nurse Faculty Loan Program—Program Specific Data Form, Annual Performance Report Financial Data Form, and NFLP Due Diligence Form'' to the ''Nurse Faculty Loan Program Forms.''

Need and Proposed Use of the Information: Section 846A of the Public Health Service Act provides the Secretary of HHS with the authority to provide grants to accredited schools of nursing for the establishment and operation of student loan funds to increase the number of qualified nurse faculty. HRSA makes awards to accredited schools of nursing and the schools provide loans to students enrolled in advanced education nursing degree programs who are committed to becoming nurse faculty. Following graduation from the NFLP grant recipient school, NFLP borrowers may receive up to 85 percent of loan cancellation over a 4-year period in exchange for service as full-time faculty at a school of nursing. The NFLP grant recipient school collects any portion of the loan that is not cancelled and any loans that go into repayment and deposits these monies into the NFLP loan fund to make additional NFLP loans.

The NFLP—Program Specific Data Form is a required electronic attachment within the NFLP application materials. The data provided in the form is an essential component of the formula-based criteria used to determine the amount awarded to the applicant schools. The form collects application-related data from applicants such as the amount requested, number of students to be funded, tuition information, and projected unused loan fund balance. This data collection assists HRSA in streamlining the application submission process, enabling an efficient award determination process, and facilitating reporting on the use of funds and analysis of program outcomes. There are no changes to this form.

The NFLP—APR Financial Data Form is an online form that collects outcome and financial data to capture the NFLP loan fund account activity related to financial receivables, disbursements, and borrower account data related to employment status, loan cancellation, loan repayment and collections. NFLP grant recipient schools will provide HHS with current and cumulative information on (1) NFLP loan funds received, (2) number and amount of NFLP loans made, (3) number and amount of loans cancelled, (4) number and amount of loans in repayment, (5) loan default rate percent, (6) number of NFLP graduates employed as nurse faculty, and (7) other related loan fund costs and activities. The NFLP—APR Financial Data Form is used to monitor grantee performance by collecting information related to the NFLP loan fund operations and financial activities for a specified reporting period (July 1 through June 30 of the academic year). NFLP grant recipient schools are required to complete and submit the NFLP—APR Financial Data Form annually. The data provided in the form is essential for HRSA to effectively monitor the school's use of NFLP funds in accordance with the statute and program guidelines. There are no changes to this form.

The NFLP Due Diligence Form is a required form that is completed and submitted electronically by NFLP grant recipient schools. This form indicates that due diligence has been exercised in the cancellation of any remaining loan funds for NFLP borrowers due to permanent/total disability, death, and uncollectible/bad debt write-offs. The data collected on the due diligence form will include the student borrower's unique ID number, reason for cancellation, the amount of principal loaned, the total amount of principal loan funds and corresponding interest canceled, and the outstanding amount of principal/interest that would be canceled because of death or permanent disability or written-off as uncollectible/bad debt. The NFLP Due Diligence Form is essential for monitoring performance measure outcomes and to verify and validate accuracy of information submitted on the NFLP Annual Performance Reports. There have been no changes to this form.

Likely Respondents: NFLP grant recipient schools and applicants to the NFLP program.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose

EXHIBIT 29

DATE: August 25, 2025

TO: Jeffrey Clark, Acting Administrator of the Office of Information and Regulatory Affairs

FROM: Thomas J. Engels, Administrator, Health Resources and Services Administration

SUBJECT: Request for Emergency Approval – Assessment of Administrative Burden 340B Rebate Model Pilot Program Application, Implementation, and Evaluation

ACTION REQUESTED

The Health Resources and Services Administration (HRSA) is requesting Paperwork Reduction Act (44 U.S.C. § 3501 et seq.) emergency approval (as detailed under 5 C.F.R § 1320.13) for the 340B Rebate Model Pilot Program Application, Implementation, and Evaluation. This 340B Rebate Model Pilot Program is described in the Federal Register Notice published 8/1/2025 at 90 FR 36163. Because this 340B rebate pilot program has impacts on the Centers for Medicare & Medicaid Services' implementation of manufacturer effectuation of the Maximum Fair Price (MFP) requirements under the Medicare Drug Price Negotiation Program (MDPNP), HRSA needs emergency approval for this information collection request (ICR) because HRSA cannot reasonably comply with the normal Paperwork Reduction Act clearance procedures before the manufacturer's statutory obligation in accordance with section 1193(d)(1) of the Social Security Act take effect on January 1, 2026. HRSA requests that the Office of Management and Budget approve this emergency ICR within 7 calendar days of receipt of this memo.

DISCUSSION

HRSA's Office of Pharmacy Affairs (OPA) is introducing this 340B Rebate Model Pilot Program to test the rebate model on selected drugs with an agreed-upon MFP for price applicability year 2026 starting on January 1, 2026. This approach will test the rebate model in a methodical and thoughtful manner. This information collection request includes the collection of 340B Rebate Model Pilot Program plans, the collection of periodic sales data from drug manufacturers for OPA's evaluation of the pilot program and for overall 340B Program surveillance, and the collection of data submitted by covered entities to manufacturers to request a rebate.

Sections 11001 and 11002 of the Inflation Reduction Act of 2022 (IRA; P.L. 117-169) established the MDPNP to negotiate prices for selected drugs (referred to as the MFP in statute) and the requirements for this program are described in sections 1191 through 1198 of the Social Security Act (the Act).[1] One such requirement at section 1193(d)(1) of the Act is for nonduplication, confirming that manufacturers do not have to provide both a MFP and the 340B ceiling price to a covered entity for a selected drug dispensed to an individual with Medicare.

The first call to submit rebate model plans for OPA review is for the manufacturers with MDPNP Agreements with CMS for initial price applicability year 2026. Manufacturers are

[1] For more information on the IRA provisions, please see CMS' website at: https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/guidance-and-policy-documents.

required, in accordance with Program Guidance released by CMS, to include their process for nonduplication of the MFP and 340B ceiling price in their MFP effectuation plans.[2]

Manufacturers have expressed interest in implementing rebate models under 340B as a way to deduplicate 340B discounts and MFP. HRSA issued the rebate model pilot program as a way to mitigate some of those concerns if and when a manufacturer's rebate model is approved. Manufacturer plans for participation in the 340B Rebate Model Pilot Program must be submitted no later than September 15, 2025. Approval of the plans will be made prior to October 15, 2025, for manufacturers to implement for a January 1, 2026, effective MFP date. HRSA is seeking emergency clearance because HRSA will need to begin application information collection by September 2025. Other aspects of this information collection will not begin until January 2026. If HRSA does not receive emergency approval, then manufacturers may argue that they do not have the tools they need to effectuate nonduplication of the MFP and the 340B discount. HRSA has taken all practicable steps to consult with the public to minimize burden (including a 30-day comment period on the "340B Program Notice: Application Process for the 340B Rebate Model Pilot Program" (90 FR 36163).

HRSA is submitting this ICR to the Office of Management and Budget for a 5-month emergency approval. Once this clearance is granted, HRSA will create a regular ICR for this collection.

[2] See: 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 (October 2, 2024).

and associated materials (see **ADDRESSES**).

CMS–10680—Electronic Visit Verification Compliance Survey

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collections

1. *Title of Information Collection:* Electronic Visit Verification Compliance Survey; *Type of Information Collection Request:* Extension without change of a currently approved collection; *Use:* The web-based survey will allow states to self-report their progress in implementing electronic visit verification (EVV) for personal care services (PCS) and home health care services (HHCS), as required by section 1903(l) of the Social Security Act. CMS will use the survey data to assess states' compliance with section 1903(l) of the Act and levy Federal Medical Assistance Percentage (FMAP) reductions where necessary as required by 1903(l) of the Act.

The survey will be disseminated to all 51 state Medicaid agencies (including the District of Columbia) and the Medicaid agencies of five US territories. States will be required to complete the survey in order to demonstrate that they are complaint with Section 1903(l) of the Act by reporting on their EVV implementation status for PCS provided under sections 1905(a)(24), 1915(c), 1915(i), 1915(j), 1915(k), and Section 1115 of the Act; and HHCS provided under 1905(a)(7) of the Act or under a demonstration project or waiver (*e.g.,* 1915(c) or 1115 of the Act).

The survey will be a live form, meaning states will have the ability to update their 1903(l) compliance status on a continuous basis. As FMAP reductions are assigned quarterly per 1903(l) of the Act, states who are not in compliance will be asked to review their survey information on a quarterly basis to ensure it is up-to-date and to update their survey responses as needed until they come into compliance. *Form Number:* CMS–10680 (OMB control number: 0938–1360); *Frequency:* On occasion; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Number of Responses:* 336; *Total Annual Hours:* 504. (For questions regarding this collection contact Ryan Shannahan at 410–786–0295.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2025–14524 Filed 7–31–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

340B Program Notice: Application Process for the 340B Rebate Model Pilot Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Announcement of Application Process for the 340B Rebate Model Pilot Program and Request for Public Comment.

SUMMARY: The U.S. Department of Health and Human Services (HHS) Health Resources and Service Administration (HRSA), Office of Pharmacy Affairs (OPA), which administers the 340B Drug Pricing Program (340B Program), is issuing this Notice to announce the availability of a 340B Rebate Model Pilot Program as a voluntary mechanism for qualifying drug manufacturers to effectuate the 340B ceiling price on select drugs to all covered entities, and to collect comments on the structure and application process of the 340B Rebate Model Pilot Program, as outlined in this Notice. OPA will consider comments received but is under no obligation to respond to or act on the comments. This Notice is effective immediately as published, unless revised by a future notice. OPA reserves the right to issue revisions or addenda to this Notice at a later date (including, but not limited to, revisions or addenda informed by public comment).

DATES: Submit comments no later than September 2, 2025.

ADDRESSES: Electronic comments should be submitted *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions on the website for submitting comments. Include the HHS Docket No. HRSA–2025–_____ in your comments. All comments received will be posted without change to *https://www.regulations.gov.* Please do not include any personally identifiable or confidential business information you do not want publicly disclosed.

FOR FURTHER INFORMATION CONTACT: Chantelle Britton, Director, Office of Pharmacy Affairs, HRSA, 5600 Fishers Lane, Mail Stop 14W52, Rockville, MD 20857; email: *340Bpricing@hrsa.gov;* telephone 301–594–4353.

SUPPLEMENTARY INFORMATION: OPA has received inquiries from manufacturers related to different proposed rebate models for the 340B Program, primarily to address 340B and Maximum Fair Price (MFP) deduplication,[1] but also to facilitate other aims such as the prevention of 340B Medicaid duplicate discounts and diversion.

A ''rebate'' for purposes of this pilot program, means a reimbursement made from the manufacturer to the covered entity in the amount of the standard acquisition cost (*i.e.,* wholesale acquisition cost) of a covered outpatient drug less the statutory 340B ceiling price as defined at section 340B(a)(1) of the Public Health Service Act (PHSA).

Whereas the 340B Program has traditionally operated as an upfront discount program (*i.e.,* a covered entity purchases a covered outpatient drug at the discounted 340B price), under a rebate model, a covered entity would pay for the drug at a higher price upfront and then later receive a post-purchase rebate that reflects the difference between the higher initial price and the 340B price. Section 340B(a)(1) of the PHSA states, ''[t]he Secretary shall enter into an agreement with each manufacturer of covered

[1] As stated in Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2026, ''in accordance with section 1193(d)(1) of the Social Security Act, the Primary Manufacturer of a selected drug is not required to provide access to the Maximum Fair Price (MFP) for a selected drug to MFP-eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at a covered entity described in section 340B(a)(4) of the (Public Health Service (PHS)) Act if the selected drug is subject to an agreement described in section 340B(a)(1) of the PHSA and the 340B ceiling price (defined in section 340B(a)(1) of the PHS Act is lower than the MFP for such selected drug. Under section 1193(d)(2) of the Social Security Act, the Primary Manufacturer is required to provide access to the MFP to 340B covered entities in a deduplicated amount to the 340B ceiling price if the MFP for the selected drug is lower than the 340B ceiling price for the selected drug.''

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 . . . purchased by a covered entity . . . does not exceed [designated prices].'' As the Department has previously informed stakeholders, implementing a rebate model without Secretarial approval would violate section 340B(a)(1) of the PHSA.

Due to the significant amount of feedback received from (or on behalf of) manufacturers and covered entities regarding implementation of rebate models, and in light of the fact that rebate models could fundamentally shift how the 340B Program has operated for over 30 years, OPA is inviting certain drug manufacturers, that meet the criteria described below, to apply for participation in a voluntary 340B Rebate Model Pilot Program for a minimum of 1 year. OPA is introducing this pilot program to test the rebate model on a select group of drugs (as described below) in a methodical and thoughtful approach to ensure a fair and transparent 340B rebate model process for all stakeholders involved. OPA is also implementing this pilot to better understand the merits and shortcomings of the rebate model from stakeholders' perspectives, and to inform OPA consideration of any future 340B rebate models consistent with the 340B statute and the Administration's goals.

The scope of this voluntary 340B Rebate Model Pilot Program will be limited to the NDC–11s included on the CMS Medicare Drug Price Negotiation Selected Drug List,[2] regardless of payer.

The first call to submit plans for OPA review is for the manufacturers with Medicare Drug Price Negotiation Program (MDPNP) Agreements with CMS for initial price applicability year 2026.[3] Manufacturer plans for participation in the 340B Rebate Model Pilot Program should be submitted to *340BPricing@hrsa.gov* no later than September 15, 2025. Approvals will be made by October 15, 2025, for a January 1, 2026, effective date. Manufacturers may not implement plans without first receiving approval in accordance with section 340B(a)(1) of the PHSA. OPA may announce a call for plans from manufacturers with MDPNP Agreements for other applicability years, at a later time.

After assessment of the pilot, which will include OPA's evaluation of data and reports received from the participating manufacturers on the effectiveness of the model and covered entity and other stakeholder feedback, OPA may consider expanding the rebate pilot to other drugs purchased under the 340B Program. Additional information about manufacturer reporting and stakeholder feedback opportunities will be provided in the future.

Manufacturer plans for the 340B Rebate Model Pilot Program should include the criteria outlined below. Manufacturer plans that exceed or go beyond these criteria should include detailed justification and will be subject to additional review by OPA prior to implementation. OPA will review submitted plans and notify manufacturers if they are approved to participate in the 340B Rebate Model Pilot Program. Submitted plans should not exceed 1,000 words and should address all of the criteria below. OPA reserves the right to revoke approval of a manufacturer plan at any time if a manufacturer is not in compliance with the criteria outlined in the ''Rebate Model Pilot Program Criteria'' below.

OPA is seeking public comment on all aspects of this Notice and the 340B Rebate Model Pilot Program. Specifically, commenters are encouraged to include supporting data and sources underpinning any factual claims. Commenters should also consider the following questions when providing comment on this Notice and the Pilot Program:

- Are there any additional flexibilities to maximize efficiency and efficacy for participating manufacturers that should be considered in the pilot design?
- Are there any additional safeguards to mitigate adverse, unintended impacts for covered entities that should be considered in the pilot design?
- Are there any additional data or reporting elements that should be required to improve implementation and evaluation of the pilot?
- Are there any potential implementation issues not yet sufficiently accounted for in the pilot design (*e.g.,* logistical or administrative burdens)?

Rebate Model Pilot Program Criteria

General Requirements

1. Plan should include assurances that all costs for data submission through an Information Technology (IT) platform be borne by the manufacturer and no additional administrative costs of running the rebate model shall be passed onto the covered entities.

2. Plan should allow for 60 calendar days' notice to covered entities and other impacted stakeholders before implementation of a rebate model, with instructions for registering for any IT platforms.

3. Plan should allow for covered entities to order the selected drugs under existing distribution mechanisms (*e.g.,* 340B wholesaler accounts with pre-rebate prices loaded) to ensure purchases flow through existing infrastructure.

4. Plan should provide a technical assistance/customer service component and ensure that opportunities to engage with the manufacturer in good faith regarding questions or concerns are made available to covered entities through both the IT platform and a point of contact at the manufacturer.

5. Plan should ensure that the IT platform has assurances in place to ensure that the data is secure and protected and collection of the data is limited to the elements listed below that are necessary for providing 340B rebates pursuant to section 340B(a)(1) of the PHSA.

6. Plan should ensure that the IT platform has mechanisms in place to protect patient identifying information, which is required to be maintained in a manner consistent with the Health Insurance Portability and Accountability Act of 1996 and any other applicable privacy and data security laws.

Reporting Requirements

7. Plan should ensure that covered entities are allowed to submit and report data (as detailed below) for up to 45 calendar days from date of dispense, with allowances for extenuating circumstances and other exceptions, including adjustments when a 340B status change occurs on a claim.

8. Plan should ensure that the IT platform will have the capacity to receive data that will filter and use only the data required to effectuate the rebate (*e.g.,* if drugs other than selected drugs under the MDPNP are submitted, the platform will be able to identify and discard unneeded data).

9. Plan should ensure that the IT platform will have the capability to provide real-time reconciliation reports for covered entities to be informed of the rebate status of submitted claims.

10. A manufacturer should agree to provide OPA with periodic reports consistent with the information outlined in this Notice, in a format and manner

[2] Medicare Drug Price Negotiation Selected Drug List, available at *https://www.cms.gov/files/zip/medicare-drug-price-negotiation-selected-drug-list.zip*.

[3] The Fact Sheet for Negotiated Prices for Applicability Year 2026 includes the list of Primary Manufacturers with selected drugs, available at *https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf*.

specified by OPA (instructions forthcoming). Such reports should detail 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.

Rebates

11. Plan should specify if rebates are paid at the package level, or at the unit level.

12. Plan should ensure that all rebates are paid to the covered entity (or denied, with documentation in support) within 10 calendar days of data submission.

13. Plan should ensure that 340B rebates are not denied based on compliance concerns with diversion or Medicaid duplicate discounts, pursuant to sections 340B(a)(5)(A) and (B) of the Public Health Service Act and should provide for rationale and specific documentation for reasons claims are denied (*e.g.,* deduplication for MFP or 340B rebate provided to another covered entity on the same claim). If a manufacturer has concerns regarding diversion or Medicaid duplicate discounts, the manufacturer should raise those concerns directly with OPA or utilize the 340B statutory mechanisms, such as audits and administrative dispute resolution (ADR), for addressing such issues. Covered entities are also afforded opportunities to raise concerns with OPA if there are issues with rebate delays and denials, or any other administrative or logistical issues emerging through implementation of the rebate model.

14. Plan should ensure that 340B rebates are only paid on sales of drugs selected under the MDPNP, regardless of payer.

Data

15. All data requested as part of the Plan should be limited to only the following readily available pharmacy claim fields:

a. Date of Service
b. Date Prescribed
c. RX number
d. Fill Number
e. 11 Digit National Drug Code (NDC)
f. Quantity Dispensed
g. Prescriber ID
h. Service Provider ID
i. 340B ID
j. Rx Bank Identification Number (BIN)
k. Rx Processor Control Number (PCN)

Thomas J. Engels,

Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–0361.

Proposed Project: 988 Suicide and Crisis Lifeline and Crisis Services Program Evaluation—New Package

The Substance Abuse and Mental Health Services Administration (SAMHSA) 988 & Behavioral Health Crisis Coordinating Office (BHCCO) is requesting clearance for the new data collection associated with the evaluation of the SAMHSA 988 Suicide and Crisis Lifeline and Crisis Services Program Evaluation (988 Suicide and Crisis Lifeline Evaluation). The collection of this information is critical to successfully oversee the operational response and quality of service through the 988 Suicide and Crisis Lifeline to ensure connections to care for individuals in suicidal crisis or emotional distress contacting in for 988 phone, chat, and text support for connecting local, state/territory, and national outcomes and monitoring contractual obligations for current and future 988 grant programs.

In 2020, Congress designated the three-digit number 9–8–8 for the Suicide and Crisis Lifeline, and the Suicide and Crisis Lifeline transitioned to the 3-digit number in July 2022. As a part of the federal government's commitment to addressing the mental health and opioid crises in America, unprecedented federal resources have been invested to expand crisis centers in support of 988. Since its launch in July 2022, the 988 Suicide & Crisis Lifeline has answered over 10 million contacts (SAMHSA, 2024). Progress recognized in 2023 continues in all areas including crisis line features, crisis center supports, and funding. In FY2024, nearly $500 million was allocated for new funding opportunities to support the 988 Lifeline Administrator and other grantees at the state, territorial, Tribal, and center levels, as part of the commitment to strengthen crisis care nationally. In Section 1103(a)(2)(B) of the Consolidated Appropriations Act, 2023 (Pub. L. 117–328), Congress called for enhanced program evaluation, including performance measures to assess program response and improve readiness and performance of the service, including review of each contact to ensure timely connection of service and quality provision in line with evidence-based care. To meet the standards and requirements set forth in the statute, ongoing communication of key outcomes within this OMB request must be received and reviewed to ensure connection and quality of care through the 988 Suicide and Crisis Lifeline.

The information collected will be used by SAMHSA to conduct an evaluation of the 988 Suicide and Crisis Lifeline and Crisis Services, to ensure individuals in suicidal, mental health, and/or substance use crisis can contact 988 Suicide and Crisis Lifeline and are connected to crisis centers providing evidence-based care and receiving critical resource referral and linkage, including opportunities for mobile crisis support, crisis receiving and stabilizing facilities, peer respite centers, and withdrawal management services. The purpose of the 988 Lifeline and Crisis Services Program Evaluation is to assess the implementation and expansion of the 988 Lifeline in the U.S. The evaluation will provide SAMHSA, grantees, and other interested parties with the information needed to strengthen the Behavioral Health Crisis Services Continuum (BHCSC) for all people in crisis. The evaluation utilizes multiple studies to conduct the evaluation of the 988 Lifeline and Crisis Services across a 5-year period. The 988 Lifeline and Crisis Services Program Evaluation includes three levels: system-level, client-level, and impact. Embedded within each of the three evaluation levels are inquiries into differences in utilization of 988 Lifeline and BHCSC services and outcomes.

The System-level Evaluation examines the characteristics, collaborations, and structures of the crisis services infrastructure within states, territories, and Tribal jurisdictions that support improved client outcomes. The Systems-level Evaluation includes two studies: the System Composition and Collaboration Study and the System-Level Service Utilization Study. The System Composition and Collaboration Study examines the structure of the 988 Lifeline and the BHCSC at the national, state, territory, and Tribal levels, and the extent to which crisis service agencies work together. The System-level Service Utilization Study