UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, EASTERN MAINE MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER, Plaintiffs, v. ROBERT F. KENNEDY, JR., Secretary of the U.S. Department of Health and Human Services, THOMAS J. ENGELS, Administrator, Health Resources and Services Administration, THE HEALTH RESOURCES AND SERVICES ADMINISTRATION, THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and THE UNITED STATES OF AMERICA, Defendants.	Case No.:

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

REQUEST FOR IMMEDIATE RELIEF

Introduction

1. Almost thirty-five years ago, Congress created a drug pricing program that is essential to safety-net healthcare providers. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967–71 (1992), codified at § 340B, Public Health Service Act, 42 U.S.C. § 256b (1992). Now commonly known as the "340B Program," it allows these providers to purchase certain outpatient medications at reduced cost and use the savings to ensure access to care, improve patient services, and reach America's most vulnerable populations. *See* H.R. Rep. No. 102-384, pt. 2, at 12 (1992). As a unanimous Supreme Court explained a few years ago: "340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support." *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 738 (2022).

2. Since the 340B Program's enactment, drug companies have been required "to provide discounts to safety-net hospitals at the time of sale." *Am. Hosp. Ass'n v. Kennedy*, 164 F.4th 28, 31 (1st Cir. 2026) ("*AHA II*") (emphasis removed). Requiring drug companies to offer discounted medications at the time of the sale, rather than as a delayed rebate, is known as an "upfront discount." The Health Resources and Services Administration ("HRSA"), a component of the U.S. Department of Health and Human Services ("HHS"), is charged with administering the 340B Program. HRSA has long required this "upfront discount" approach because it both advances the overall purpose of the 340B statute and follows the specific statutory provision governing the mechanism for providing 340B discounts. Many covered entities that participate in the 340B Program operate on razor-thin (or negative) margins and limited cash-on-hand. They cannot afford the costs of paying upfront market prices for drugs without sacrificing the care they provide to patients.

3. For years, drug companies unsuccessfully sought to replace the upfront discount mechanism with what they call a "rebate" mechanism. Such a change would inflict *more than a billion dollars'* worth of annual costs on 340B hospitals. A rebate mechanism, for example, would impose massive administrative costs to submit, track, recover, reconcile, and dispute rebates. In addition, a rebate mechanism would inflict massive "float" costs by forcing 340B hospitals to use their limited cash-on-hand to "pay to the drug manufacturers upfront prices far exceeding the amounts that they actually owe—essentially functioning as an interest-free loan from the hospitals to the manufacturers—and then wait for a rebate." *Id*. at 32.

4. If 340B hospitals are forced to spend all this money on these administrative and "float" costs, the real-world consequences for patients and communities would be devastating: fewer free or discounted drugs for low-income patients; loss of critical medical services in underserved communities; fewer drugs readily available at rural hospitals; fewer staff available to care for patients; and more. Worse still, for some safety-net providers, these costs would prove too much to bear, forcing them to close their doors altogether. Therefore, as the First Circuit explained, "[a]lthough drug manufacturers have previously proposed a switch to a rebate model in which safety-net hospitals would pay higher upfront costs and receive reimbursements later, HHS has historically rejected such proposals as both inferior to Section 340B's current upfront-discount model and disruptive to safety-net hospitals." *Id.* at 31–32.

5. But in August 2025, with no warning to safety-net hospitals, HRSA tried to fundamentally shift the way the 340B Program has operated for thirty-plus years. HRSA announced a "340B Rebate Model Pilot Program" (hereinafter the "Rebate Program" or "Program") that would institute a rebate mechanism for ten of the costliest and most widely used drugs in the Medicare program. Given the crippling costs to caregivers in Maine and nationwide,

Plaintiffs sued on the grounds that the government did not follow basic rules of administrative law. *See* Complaint, *Am. Hosp. Ass'n v. Kennedy*, No. 2:25-cv-600 (D. Me. Dec. 1, 2025), Dkt. No. 1.

6. On December 29, 2025, Chief Judge Walker granted Plaintiffs' request for a preliminary injunction three days before the Program was set to take effect. He held that, under the Administrative Procedure Act ("APA"), Defendants "failed to follow the APA's basic blueprint in assembling the Rebate Program," displayed "casual indifference to localized impacts" of the Rebate Program, failed to consider and reasonably explain the relevant costs, and ignored thirty years of reliance interests. *Am. Hosp. Ass'n v. Kennedy*, 820 F. Supp. 3d 30, 44–45 & n.5, 47 (D. Me. 2025) ("AHA I"). Judge Walker also found that Plaintiffs had demonstrated irreparable harm because, among other things, American Hospital Association ("AHA") "members alone estimate $400 million in compliance costs, the downstream effect causing them to cut back services and suspend partnerships with drug distributors." *Id*. at 46. The First Circuit denied an emergency appeal of Chief Judge Walker's decision, describing the administrative record as "threadbare." *AHA II*, 164 F.4th at 34. Following that decision, the government agreed to vacatur and remand, which this Court granted on February 10, 2026. *See* Order, *Am. Hosp. Ass'n v. Kennedy*, No. 2:25-cv-600 (D. Me. Feb. 10, 2026), Dkt. Nos. 114, 115.

7. A mere week after remand, HRSA issued a new request for information seeking comments "to further evaluate the potential benefits and costs of a rebate model." Request for Information: 340B Rebate Model Pilot Program, 91 Fed. Reg. 7,287, 7,289 (Feb. 17, 2026) ("RFI"). In late February 2026, HRSA published another notice, an information collection request submitted to the Office of Management and Budget ("OMB"), indicating that it anticipated *expanding* its contemplated Rebate Program to 25 of the costliest and most widely used drugs, more than doubling the scope of the first program. *See* Agency Information Collection Activities:

340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-NEW, 91 Fed. Reg. 9,632, 9,632–33 (Feb. 26, 2026) ("February ICR").

8. In response, HRSA received over 2,400 comments, including 1,200 comments from 340B hospitals and other covered entities, and nearly 150 more from associations representing covered entities. These comments described in granular detail the catastrophic impact that a rebate mechanism would have on providers, patients, and communities. Commenters offered specific, facility-level data on the staggering administrative costs of a rebate mechanism, the new full-time employees ("FTEs") hospitals would need to hire, the costs of "floating" hundreds of millions of dollars to drug companies, the valuable discounts hospitals would permanently lose under a rebate mechanism, the non-economic costs on patient care, and many other overlooked costs. They also warned that the timing could hardly be worse: in 2026 and 2027, hospitals will already be absorbing billions of dollars in adverse revenue impacts from the One Big Beautiful Bill Act ("OBBBA"), Pub. L. No. 119-21, and other federal policies, making those years an especially perilous time to impose billions of dollars in new costs.

9. HRSA disregarded these warnings and data. On August 3, 2026, HRSA published a notice announcing its intent to launch its even larger "340B Rebate Model Pilot Program" that could now cover up to 25 drugs. *See* Notice Regarding 340B Rebate Model Pilot Program, 91 Fed. Reg. 48,883 (Aug. 3, 2026) ("Notice"). This new Rebate Program remains a "pilot" in name only. It applies to *every* 340B hospital and covered entity in America, regardless of geographic location, size, services offered, or any other distinguishing factor—totaling more than 15,000 covered entities and more than 49,000 sites by HRSA's own estimate. *Id.* at 48,901. Participation by covered entities is *compulsory* to obtain statutorily owed discounts. By contrast, participation is voluntary for drug companies. *Id.* at 48,900 n.32. The so-called "pilot" also has no clear end date

and, by the words it chose to describe the Program, HRSA seems to presume that it will last for more than one year: "[u]pon conclusion of the *first year* of Pilot operations, HRSA will publish an evaluation by April 30, 2028." *Id.* at 48,901 (emphasis added).

10. On October 1, 2026, HRSA announced the approval of ten drug companies' rebate plans, covering a total of 18 drugs, to begin on January 1, 2027. HRSA, 340B Rebate Model Pilot Program, https://www.hrsa.gov/opa/340b-model-pilot-program ("HRSA Rebate Program Webpage"). By almost doubling the number of drugs covered under the Rebate Program, this so-called "pilot" will increase the costs of the Program as compared to last year and further reduce access to care. In fact, the October approvals *increased* the costs that covered entities will have to bear in ways the Notice itself did not contemplate. For example, the Notice offered repeated assurances that the drug companies' plans will be consistent—that there will be no "manufacturer-specific" requirements or other variations. 91 Fed. Reg. at 48,893. But the approved plans reveal meaningful differences in what HRSA allowed each drug company to require—variations that will further increase covered entities' costs and administrative burdens.

11. HRSA's second Rebate Program violates the "APA's basic blueprint" as starkly as its first. *AHA I*, 820 F. Supp. 3d at 47. Most significantly, it contravenes the blackletter principle that an agency must accurately evaluate the costs and benefits of any regulation. "Consideration of cost reflects the understanding that reasonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions." *Michigan v. EPA*, 576 U.S. 743, 753 (2015). But even though the First Circuit recognized that a rebate mechanism would impose "significant costs" on covered entities, *AHA II*, 164 F.4th at 34, HRSA has again failed to reasonably consider "the costs and benefits associated with the regulation." *AHA I*, 820 F. Supp.

3d at 44 (quoting *Mexican Gulf Fishing Co. v. U.S. Dep't of Com.*, 60 F.4th 956, 973 (5th Cir. 2023)).

12. In particular, HRSA "unreasonably understated the costs of the Rule while unreasonably overstat[ing] the benefits," *Chamber of Com. of the U.S. v. FTC*, 820 F. Supp. 3d 473, 491 (E.D. Tex. 2026) (internal quotation marks and citation omitted), and thus failed to "identify benefits that 'bear a rational relationship to the . . . costs imposed.'" *Id.* (quoting *Chamber of Com. of the U.S. v. SEC*, 85 F.4th 760, 777 (5th Cir. 2023)). HRSA "did not even attempt to quantify the actual costs and purported benefits" of the Program, "much less perform a reasoned balancing." *Presidents' All. on Higher Educ. & Immigr. v. U.S. Dep't of Homeland Sec.*, 2026 WL 2690098, at *16 (D. Mass. Sept. 14, 2026). As a result, "the perfunctory and conclusory analysis performed by [HRSA] fails to satisfy even the bare minimum cost-benefit analysis the APA requires." *Id*. "[W]ithout a reasoned cost-benefit analysis," the Rebate Program "is arbitrary and capricious, and therefore violated the APA." *Id*.

13. HRSA's "treatment of the costs" of the Rebate Program, in particular, "was egregiously flawed and incomplete." *Id*. at *15. HRSA estimated that, under the 25-drug Rebate Program, covered entities will spend **$537,222,270 every year** just to submit claims data to drug companies. *See* Notice, 91 Fed. Reg. at 48,893 & n.20; Supporting Statement A, 340B Rebate Model Pilot Program Application, Implementation, and Evaluation Notice, OMB Control No. 0906-NEW (Aug. 4, 2026) ("Supporting Statement"). While staggering, HRSA's half-billion-dollar figure covers only a single administrative burden—submitting claims data. It excludes the massive reconciliation, start-up, information-technology, vendor, training, audit, and dispute-resolution costs that hospitals will need to shoulder—many of which are equally significant, if not greater. The administrative record shows that the full operational costs will, conservatively, exceed

$1 billion a year for 340B hospitals alone. Those hospitals are only approximately 18% of the 15,000 safety-net entities participating in the 340B Program, meaning the actual total cost is many multiples of HRSA's $500 million-plus figure.

14. HRSA's half-billion-dollar calculation rests on the inexplicable assumption that this Rebate Program will require each facility to spend only five hours of pharmacist time per week to comply. But "[f]rankly, the [HRSA] staffing plan[/labor hour] number appears as if pulled from thin air." *Am. Fed'n of Gov't Emps., AFL-CIO v. Trump*, 2026 WL 2677331, at *17 (N.D. Cal. Sept. 11, 2026). Defendants' labor-hour assumption originated back in 2025, *before* receiving a single comment, and they blindly stuck to the same approach this year. The only difference this year is that HRSA took its prior (erroneous and unsupported) labor-hour calculation and multiplied it by 2.5 to capture the 2.5 times as many drugs selected for inclusion in the new Program.

15. To arrive at the same 5-hour-per-week result as before, HRSA ignored the avalanche of comments from covered entities demonstrating that they will have to hire full-time, 40-hour-per-week employees to comply with the new Rebate Program. HRSA never revisited or explained its labor-hour figure after receiving these comments, which showed with specific, hospital-level data that HRSA's 5-hour-per-week estimate is wildly off the mark. Instead, HRSA dismissed those comments in a few conclusory sentences, asserting that it "continues to believe that the estimated burden reasonably reflects the average paperwork burden associated with the information collection," even though it conceded in the next breath that "actual burden may vary." Supporting Statement at 7. All the while, HRSA continued to hide what, if any, methodology or data lies behind its 5-hour-per-week assumption. Accordingly, HRSA failed to address the "important problem[s] the public could and did raise during the comment period," *Ohio v. EPA*, 603 U.S. 279, 298 (2024), and failed to offer the "reasoned response" the law requires. *Id.* at 293;

Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). Put simply, HRSA's approach to labor hours this time around is just as "fatal under the APA" as it was last year. *AHA I*, 820 F. Supp. 3d at 45, 47.

16. HRSA's treatment of several specific categories of additional costs starkly illustrates the deficiencies in Defendants' decision-making and explanation.

a. Many commenters informed HRSA that they would incur significant **vendor and training costs** under a rebate mechanism. HRSA brushed these costs aside by nonsensically arguing "the 340B Program has always entailed some level of compliance and operational cost." 91 Fed. Reg. at 48,894. Just because covered entities have historically incurred certain costs under the "upfront discount" mechanism does not permit HRSA to write off (and refuse to even calculate) the *added* vendor and training costs associated with its new rebate mechanism. Indeed, HRSA recognized this in its initial February 2026 RFI, asking stakeholders to "[e]stimate the *incremental* administrative and operational costs your organization would incur under a 340B Model Rebate Pilot Program." 91 Fed. Reg. at 7,289 (emphasis added). But by excluding vendor and training costs *altogether*, HRSA both underestimated costs and ignored a significant part of the problem.

b. HRSA agreed with covered entities that there would be "legitimate" **start-up costs**. 91 Fed. Reg. at 48,893. But despite abundant record evidence that these costs are substantial (including covered entities' firsthand experience with the first Rebate Program last fall), HRSA neither quantified them nor included them in its cost-benefit analysis. Instead, it dismissed start-up costs *altogether*

because, in its view, they are "transitional" and "inherent to the adoption of a new operational approach." *Id*. But labeling start-up costs as "transitional" does not analyze them, and it certainly is not a reasonable basis for excluding millions of dollars in start-up costs.

c. The administrative record also contains unrebutted evidence of certain customary discounts that 340B hospitals and other covered entities will no longer be able to obtain under a Rebate Program. In particular, covered entities repeatedly explained that they will lose millions of dollars of **prompt-pay and cost of goods sold ("COGS") discounts**. Yet HRSA did not factor these lost discounts into its cost calculations. In fact, the Notice briefly mentions COGS discounts when summarizing covered entities' comments, 91 Fed. Reg. at 48,892, but never returns to them when performing its cost-benefit analysis. They, too, were excluded *altogether*. HRSA's failure to further address and include this undisputed category of "Lost Discount Costs" was arbitrary and capricious. *See Ohio v. EPA*, 603 U.S. at 295 ("[A]wareness is not itself an explanation").

d. HRSA's analysis of the costs associated with fronting hundreds of millions of dollars to drug companies (sometimes referred to in the comments as **"float costs" or "acquisition costs"**) is equally deficient. HRSA included no such costs in its cost-benefit analysis, stating that it "believes that the Pilot is unlikely to result in unstable cash flow for covered entities." 91 Fed. Reg. at 48,894. But its entire support for this conclusion comes from two studies, both of which were self-interestedly funded by the drug industry and substantively

"unpersuasive." *Bus. Roundtable v. SEC*, 647 F.3d 1144, 1150–51 (D.C. Cir. 2011). In fact, HRSA inexplicably relied on a December 2025 study whose authors revised and *increased* their estimates of interest costs in April 2026 because some of the factual underpinnings of their previous work (on which HRSA relied) were incorrect. Moreover, these studies were concededly narrow. They did not address a host of realities that would make having to "float" hundreds of millions of dollars to drug companies even more expensive. These included risks of violating bond covenants, wholesaler escrow requirements, and the practical reality that not all claims would be rebated on time, thereby extending the "float" period beyond any programmatic guardrails. Though raised in many comments, HRSA never addressed these problems when dismissing "float costs" *altogether*.

17. HRSA also irrationally disregarded non-economic costs to patients and communities. The Notice states, without elaboration, that its Program will not "materially impair covered entities' . . . ability to furnish services to patients." 91 Fed. Reg. at 48,899. Nowhere did HRSA acknowledge, as this Court did, the "downstream effect" that requiring covered entities to spend (at least) well over $500 million on claim-submissions will force them to "cut back services." *AHA I*, 820 F. Supp. 3d at 46. Nor did HRSA grapple with the hundreds of covered-entity comments identifying in painstaking detail the specific service lines, community programs, drug price discounts, and operating hours that the Rebate Program will force them to cut. Cost "means more than dollars and cents." *Ky. Coal Ass'n, Inc. v. Tenn. Valley Auth.*, 804 F.3d 799, 802 (6th Cir. 2015). "[A]ny disadvantage could be termed a cost," including "harms that regulation

might do to human health." *Michigan*, 576 U.S. at 752. But HRSA ignored those non-economic costs *altogether*.

18. On the other side of the ledger, HRSA never quantified the benefits from its Rebate Program. It conceded that "there is no federal estimate of the financial extent of duplicate discounts in 340B." 91 Fed. Reg. at 48,887. The only figures it included in the Notice parrot the drug companies' assertions. Thus, HRSA's entire analysis of program benefits was adopted without any critical examination and without acknowledging the wealth of contrary evidence that covered entities submitted demonstrating that the drug companies vastly overstate the number of duplicate discounts that currently exist.

19. Moreover, even HRSA's parroted discussion of duplicate discounts is irrational. For example, HRSA cited assertions by "[m]anufacturer commenters" that duplicate discounts "amounted to as much as $1.5 billion annually." 91 Fed. Reg. at 48,887. But that figure encompasses *all* 340B drugs, not the 25 selected for the proposed Rebate Program, much less the 18 drugs approved to date. HRSA itself stated that the Program would cover "less than 5.5% of total 340B sales" if all 25 drugs were involved. *Id.* at 48,893. A quick back-of-the-napkin calculation (*e.g.*, 5.5% of the $1.5 billion figure equals $82.5 million) suggests the maximum benefits would be limited, but HRSA offered no estimate of the Rebate Program's actual deduplication benefit for this smaller set of drugs. Nor did it explain why it is reasonable to spend billions on administrative costs for what, at best, could amount to a fraction in savings. *See Chamber of Com. of the U.S.*, 820 F. Supp. 3d at 489 ("[T]he FTC's resource-savings argument is limited to a small subset of HSR filers, and the agency again fails to show how that limited benefit reasonably outweighs the significant costs on the thousands of other annual filers.").

20. HRSA's evaluation of the Program's benefits violates the APA many times over:

a. HRSA itself never actually calculated benefits, instead choosing to uncritically adopt data submitted by the drug companies. *E.g.*, *Cboe Futures Exch., LLC v. SEC*, 77 F.4th 971, 979 (D.C. Cir. 2023) (if an agency wants to rely on a regulated party's analysis to support its decision, "it needed to critically review and adopt [the party's] submissions or perform its own comparable analysis" (internal quotation marks omitted)).

b. HRSA never actually identified how much the Rebate Program itself can or will *incrementally* correct the duplicate discount problem it is designed to address. This is a particularly important question since the rules of the Rebate Program affirmatively prevent drug companies from denying rebates even if they suspect a duplicate discount. *E.g.*, *Chamber of Com. of the U.S.*, 85 F.4th at 779 ("[T]he rule's primary benefit—decreasing investor uncertainty about motivations underlying buybacks—is inadequately substantiated.").

c. HRSA never responded to comments explaining that the drug companies vastly overstate the duplicate discount problem and that, based on HRSA's own audit data, duplicate discounts have decreased dramatically since 2018. *See Genuine Parts Co. v. EPA*, 890 F.3d 304, 312 (D.C. Cir. 2018) (an agency "cannot ignore evidence that undercuts its judgment; and it may not minimize such evidence without adequate explanation").

d. HRSA "inconsistently and opportunistically framed the costs and benefits of the rule," *Bus. Roundtable,* 647 F.3d at 1148–49, by comparing the Program's administrative and other costs to *overall* 340B Program-wide duplicate discounts rather than the *incremental* benefits of its 25-drug Rebate Program.

E.g., Chamber of Com. of the U.S., 85 F.4th at 777 (an agency "cannot have it both ways" by embracing a premise when tallying benefits and rejecting it when tallying costs).

21. Ultimately, the Notice follows a consistent, and telling, pattern. Again and again, covered entities "offered ample basis for the truth of their positions: their extensive knowledge and experience with" hospital operations under the 340B Program. *Cath. Legal Immigr. Network, Inc. v. EOIR*, 513 F. Supp. 3d 154, 174 (D.D.C. 2021). These covered entities are "intimately familiar with their budgets and resources and therefore have a unique capacity to estimate how" the Rebate Program "would upend their normal practices and would affect the number of [patients] they can serve." *Id*. But HRSA flatly dismissed their comments and declared that it "anticipates," "expects," and "believes" the burdens will be small. 91 Fed. Reg. at 48,891, 48,893–95. By contrast, whenever drug companies and their vendors supplied assertions, HRSA uncritically adopted them as fact. That is precisely the kind of "unquestioning reliance" on a regulated party's self-serving analysis that courts forbid. *Susquehanna Int'l Grp., LLP v. SEC*, 866 F.3d 442, 447 (D.C. Cir. 2017).

22. HRSA's treatment of reliance interests fares no better under the APA. Despite having previously "agree[d]" that covered entities' reliance interests are "significant," *AHA II*, 164 F.4th at 34, HRSA has now declared them unreasonable as a "matter of law," 91 Fed. Reg. at 48,889. In its view, because the statute gives HRSA discretion to approve a rebate mechanism in certain circumstances, covered entities could not rely on thirty-three years of consistent practice and repeated agency endorsement of the upfront discount model. Under Supreme Court and First Circuit precedent, that reasoning fails as a matter of law. *E.g.*, *Dep't of Homeland Sec. v. Regents*

of the Univ. of Cal., 591 U.S. 1, 30–32 (2020); *Woonasquatucket River Watershed Council v. U.S. Dep't of Agric.*, 186 F.4th 25, 44–46 (1st Cir. 2026).

23. HRSA also failed to rationally consider obvious, less burdensome alternatives. This is particularly stunning because Defendants told the First Circuit last year that "[m]anufacturers have alternate means to deduplicate discounts," Doc. 00118385034 at 8, No. 25-2236, *Am. Hosp. Ass'n v. Kennedy* (1st Cir. 2025), and said the same to the D.C. Circuit as recently as February 2026. Doc. 2158427 at 2, No. 25-5177, *Novartis Pharms. Corp. v. Kennedy* (D.C. Cir. 2025). Yet the Notice rejects a neutral data clearinghouse in a single paragraph, 91 Fed. Reg. at 48,900, even as its sister agency, the Centers for Medicare and Medicaid Services ("CMS"), opened a similar clearinghouse on October 1, 2026, the same day HRSA announced the drug company application approvals for the Rebate Program. In addition, HRSA rejected every alternative that preserves upfront discounts based on the self-justifying logic that such alternatives "would not inform whether rebates are an efficient means" of providing 340B pricing. *Id.* at 48,890. It also ignored altogether the AHA's proposals that drug companies publish 340B and maximum fair prices prospectively, that drug companies fund the costs of any "test" they want to run, and that any pilot be deferred until after safety-net hospitals absorb the $68 billion revenue impact of the OBBBA.

24. Most fundamentally, HRSA evaluated the Rebate Program under the wrong legal standard. Congress committed the choice of pricing mechanism to Defendants with an express instruction: use "the mechanism that is the most effective and most efficient *from the standpoint of each type of 'covered entity.*'" H.R. Rep. No. 102-384, pt. 2, at 16 (1992) (emphasis added). HRSA quoted the "standpoint" standard in several legal filings over the last two years, and it applied that standard previously to another type of covered entity. *See infra* ¶¶ 51, 54–56. The D.C. Circuit repeatedly emphasized that standard just days before HRSA issued its Notice.

Novartis Pharms. Corp. v. Kennedy, 182 F.4th 1027, 1030–31 (D.C. Cir. 2026). HRSA's Notice itself even quotes this "standpoint" standard. *See* 91 Fed. Reg. at 48,884–85.

25. But HRSA never *applied* that "standpoint" standard. Instead, HRSA announced that it "must balance" covered entities' interests against "program integrity" and "competing policy concerns," *id.* at 48,887–88—a standard of the agency's own invention that elevates a "subsidiary" nonstatutory goal over the particular statutory purpose made explicit by Congress, *see PhRMA v. Frey*, 2026 WL 184504, at *9 n.10 (D. Me. Jan. 23, 2026). The reason is obvious: a payment mechanism that imposes *at least* half a billion dollars—and, more realistically, *billions* of dollars—in annual costs on safety-net providers is neither effective nor efficient from the standpoint of the covered entities. The Rebate Program was not based on the relevant factors and was "unmoored from the purposes and concerns" of the relevant law. *Judulang v. Holder*, 565 U.S. 42, 64 (2011); *Gulluni v. Levy*, 85 F.4th 76, 82 (1st Cir. 2023).

26. Thousands of 340B hospitals and other 340B providers face crushing costs and consequences should the Rebate Program go into effect as intended on January 1, 2027, jeopardizing their ability to provide care to the most vulnerable patients in their communities. Many of these safety-net hospitals provide the only healthcare services in their areas. For covered entities to continue providing their current levels of care to their patients, this Court must quickly enjoin this unlawful, unnecessary, and unexplained program that jeopardizes one of the key pillars of U.S. healthcare. The Rebate Program is arbitrary and capricious and must be set aside.

Parties

27. Plaintiff AHA is a nonprofit trade association representing hospitals, healthcare systems, networks, and other providers of care. Its principal place of business is in Chicago, Illinois. AHA represents its members, including Eastern Maine Medical Center, Nathan Littauer

Hospital & Nursing Home, Unity Medical Center, and Dallas County Medical Center, in this action. More than 2,000 of the AHA's member-hospitals participate in the 340B Program. Those members will have no choice but to participate in the Rebate Program and are therefore aggrieved by Defendants' decision to implement that Program, including the decision to implement it by the January 1, 2027 effective date. Protecting those members' interests is germane to AHA's organizational purpose of advancing the health of all individuals and communities, and the individual members' participation is not required to adjudicate the claims for relief.

28. Plaintiff Maine Hospital Association ("MHA") is a nonprofit association that represents 32 community-governed hospitals in Maine. Its principal place of business is in Augusta, Maine. MHA represents its members, including Eastern Maine Medical Center, in this action. Twenty-six of MHA's 32 member-hospitals participate in the 340B Program. Those members will have no choice but to participate in the Rebate Program and are therefore aggrieved by Defendants' decision to implement that Program, including the decision to implement it by the January 1, 2027 effective date. Protecting those members' interests is germane to MHA's organizational purpose of helping its members improve the health of their patients and the communities they serve, and the individual members' participation is not required to adjudicate the claims for relief.

29. Plaintiff Eastern Maine Medical Center ("EMMC") is a nonprofit, 411-bed tertiary medical center and the referral hospital for northern and eastern Maine. It is based in Bangor, Maine, and provides a range of services, including inpatient and outpatient infusion services, primary care, various specialty services, a Level II trauma center, a neonatal intensive care unit, and pediatric services. EMMC is a disproportionate share hospital, and it is one of nine hospitals—and one of eight 340B covered entities—in the Northern Light Health system. EMMC participates

in the 340B Program, prescribes or administers one or more drugs included in the Rebate Program, and therefore will be required to participate in the Rebate Program.

30. Plaintiff Nathan Littauer Hospital & Nursing Home is a nonprofit health system, whose mission is to provide excellent medical care in the communities it serves. It is a New York nonprofit corporation with its principal place of business in Gloversville, New York. Nathan Littauer participates in the 340B Program, prescribes one or more drugs included in the Rebate Program, and therefore will be required to participate in the Rebate Program.

31. Plaintiff Unity Medical Center is a nonprofit health system, whose mission is to provide excellent medical care in the communities it serves. It is a North Dakota nonprofit corporation with its principal place of business in Grafton, North Dakota. Unity Medical Center participates in the 340B Program, prescribes one or more drugs included in the Rebate Program, and therefore will be required to participate in the Rebate Program.

32. Plaintiff Dallas County Medical Center is a nonprofit health system, whose mission is to provide excellent medical care in the communities it serves. It is an Arkansas county-owned entity with its principal place of business in Fordyce, Arkansas. Dallas County Medical Center participates in the 340B Program, prescribes one or more drugs included in the Rebate Program, and therefore will be required to participate in the Rebate Program.

Defendants

33. Defendant Robert F. Kennedy, Jr., is the Secretary of the U.S. Department of Health and Human Services ("HHS"). He is sued in his official capacity.

34. Defendant Thomas J. Engels is the Administrator, Health Resources and Services Administration ("HRSA"), an office within HHS. He is sued in his official capacity.

35. Defendant HHS is a department of the United States government.

36. Defendant HRSA is an HHS agency that administers the 340B Program.

37. The United States of America is named in accordance with 5 U.S.C. § 702. This is an action in a court of the United States seeking relief other than money damages and stating a claim that an agency or an officer thereof acted or failed to act in an official capacity.

Jurisdiction and Venue

38. This action arises under, and asserts violations of, the APA, 5 U.S.C. §§ 551 *et seq*., and Section 340B of the Public Health Service Act, 42 U.S.C. § 256b. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1346. An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a), and this Court may grant declaratory relief, injunctive relief, and other appropriate relief pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202, and the APA, 5 U.S.C. §§ 705–706.

39. Venue lies in this District pursuant to 28 U.S.C. § 1391(e)(1) because Plaintiffs MHA and EMMC reside in the District, Plaintiffs seek relief against federal agencies and federal officials acting in their official capacities, and no real property is involved.

40. This Court may grant relief pursuant to 5 U.S.C. §§ 701–706.

41. Plaintiffs challenge a "final agency action" within the meaning of 5 U.S.C. § 704. To constitute final agency action, a decision "must [1] mark the 'consummation' of the agency's decision-making process—it must not be of a merely tentative or interlocutory nature" and "[2] be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (internal citations omitted).

42. The Rebate Program reflects the consummation of the agency's decision-making process. HRSA announced on August 3, 2026, that it will "implement a rebate approach," making that new Program "effective immediately." 91 Fed. Reg. at 48,883. On October 1, 2026, HRSA

announced the approval of ten drug company applications, corresponding to 18 drugs, to commence on January 1, 2027. *See* HRSA Rebate Program Webpage. That creates real-world consequences for Plaintiffs, their members, and other covered entities. They must either expend immense amounts of capital to comply with the Rebate Program or forgo their ability to purchase certain drugs through the 340B Program and thereby reduce access to care for their patients and communities.

43. HRSA's establishment and implementation of the 340B Rebate Model Pilot Program, as well as its approval of ten drug company applications, are final agency actions that are subject to judicial review under the APA. *See* 5 U.S.C. §§ 704, 706.

The 340B Program

44. Congress created the 340B Drug Pricing Program in 1992 to give safety-net healthcare providers a financial lifeline by allowing them to purchase certain outpatient drugs at discounted prices. When it was enacted, Congress stated that the program's overall purpose was to "enable these entities to 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 (1992); *e.g., Am. Hosp. Ass'n v. Hargan*, 289 F. Supp. 3d 45, 47 (D.D.C. 2017); *PhRMA*, 2026 WL 184504, at *9 & n.10 ("The 340B program is designed to use two other large federal spending programs to incentivize manufacturers to provide a subsidy to healthcare entities caring for underserved patients."). Examples of qualifying covered entities include federally qualified health centers, family planning clinics, state-operated AIDS drug assistance programs, and disproportionate share hospitals, *i.e.*, hospitals that serve a disproportionate share of Medicare, Medicaid, and other low-income and uninsured patients. 42 U.S.C. § 256b(a)(4).

45. Congress incentivized drug manufacturers to participate in the 340B Program by conditioning federal health-insurance coverage of their products on those manufacturers' participation. 42 U.S.C. §§ 1396r-8(a)(1), 256b(a). Specifically, if drug companies decline to provide discounted drugs to safety-net hospitals through the 340B Program, Medicaid and Medicare Part B will not cover the companies' drugs. *Id.* § 1396r-8(a)(1).

46. The 340B Program plays a critical role in ensuring the continued viability of safety-net hospitals and other covered entities. Covered entities generally pay only a fraction of the retail costs of drugs and use those savings to fund their broader caregiving operations. As of 2026, more than 2,700 hospitals participate in the 340B Program.

47. For Plaintiffs like EMMC, Nathan Littauer Hospital, Unity Medical Center, and Dallas County Medical Center, the 340B Program is necessary to their mission, if not their survival. EMMC, for example, has saved tens of millions of dollars through the 340B Program this year, but still operates on negative margins and has done so since 2019. Nathan Littauer Hospital has had negative margins for more than five consecutive years, resulting in a decrease of 58% in its days of cash-on-hand and an increase of 90% in its accounts payable over the past four years. Unity Medical Center's operating margin is just $2.2 million per year, and its 340B savings account for 73% of its 2026 operating margin. Dallas County is similarly situated; it has a margin of only 4.4% and saves more than $1 million annually through the 340B Program. Without their 340B savings, these entities could not maintain their hospital, equipment, and staffing levels, leaving their patients without access to critical services. Plaintiffs are not outliers; the savings provided by the 340B Program are critical to the operations of safety-net hospitals across the country. Hospitals and healthcare providers like these Plaintiffs are the intended beneficiaries of

the 340B Program, and Plaintiffs' experiences are perfect examples of the program functioning precisely the way Congress intended.

HRSA and the Upfront Discount Mechanism

48. HRSA is responsible for administering the 340B Program. HRSA's Administrator is charged with numerous responsibilities under the statute, including the certification of specific categories of covered entities and auditing functions to ensure covered entities have not received duplicate discounts or diverted prescriptions to non-340B patients. 42 U.S.C. § 256b(a)(4)(J)–(K), (a)(5), (7), (9).

49. To effectuate the 340B Program, HRSA's Administrator also enters into an agreement, known as a Pharmaceutical Pricing Agreement ("PPA"), "with each manufacturer of covered outpatient drugs under which the amount required to be paid . . . to the manufacturer for [such] drugs . . . purchased by a covered entity . . . does not exceed [the ceiling price]." *Id.* § 256b(a)(1). The ceiling price is calculated using a formula that considers each drug's "average" and "best" price in the Medicaid Drug Rebate Program. *Id.* § 256b(a)(1)–(2). Each PPA "require[s] that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." *Id.*; *see also* 58 Fed. Reg. 27,289, 27,291 (May 7, 1993). Manufacturers that do not comply with the PPA can be subject to monetary sanctions and even termination from the 340B Program. 42 U.S.C. § 256b(d)(1)(B)(vi).

50. Since the beginning of the 340B Program, HRSA has required drug companies to offer upfront discounts—not rebates—to covered entities. *See id.* § 256b(a)(1); 58 Fed. Reg. at 27,291–92. Covered entities often implement upfront pricing through what is known as the "product-replenishment model." Under this longstanding inventory management model, covered

entities purchase an initial package of drugs at the market price. After confirming a certain quantity of a drug has been sold to 340B-eligible patients, the provider then purchases replacement quantities at the 340B prices. *See PhRMA*, 2026 WL 184504, at *3 (explaining replenishment model). As Defendants described in an August 1, 2025 brief to the D.C. Circuit, "[u]nder this approach, providers obtain an upfront discount for purchases allowing them to get the immediate benefit that the 340B Program is meant to provide." Doc. 2128443 at 2, *Novartis Pharms. Corp. v. Kennedy*, No. 25-5177 (D.C. Cir. Aug. 1, 2025).

51. The sole, narrow exception to the "upfront discount" mechanism is for drugs sold to a certain category of covered entity: AIDS Drug Assistance Programs ("ADAPs"). Because ADAPs' drug-purchasing systems inhibited them from using the "upfront discount" mechanism, HRSA in 1998 recognized that a different payment mechanism was most effective for them. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Rebate Option, 62 Fed. Reg. 45,823, 45,824 (Aug. 29, 1997). HRSA did not extend rebates to any other type of covered entity, finding that (1) "[c]overed entities generally preferred a discount system, because they could negotiate lower prices and needed less initial outlay of drug purchasing money"; and (2) "the [upfront] discount system is functioning successfully for most covered entities[.]" *Id.* at 45,824.

52. Adherence to the "upfront discount" mechanism aligns with Congress's intent for the 340B Program. As the First Circuit explained, covered entities' "financial survival relies on the upfront discounts that they have long received." *AHA II*, 164 F.4th at 34. Forcing rural hospitals and other 340B providers to spend billions of dollars to submit, reconcile, and chase rebates, and to "float" similar amounts to the drug industry each year, puts covered entities at existential risk and endangers the health of their patients and communities. Thus, an "upfront discount"

mechanism is the payment "mechanism that is the most effective and most efficient from the standpoint of each type of 'covered entity.'" H.R. Rep. No. 102-384, pt. 2, at 16 (1992). And it serves the overall purpose of the 340B Program by allowing healthcare providers to use every possible dollar saved from the 340B Program to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services," *id*. at 12.

53. HRSA has the authority to approve how drug companies must provide 340B discounts, whether through an upfront discount or a rebate mechanism. *See Novartis Pharms. Corp.*, 182 F.4th at 1029–30. But that authority is not unbounded. "Congress 'd[id] not specify whether 'covered entities' would receive [Section 340B's] favorable prices through a point-of-purchase discount, through a manufacturer rebate, or through some other mechanism' because it 'expect[ed] that the Secretary of HHS, in developing these agreements, w[ould] use the mechanism that is the most effective and most efficient from the standpoint of each type of 'covered entity.'" *Id*. at 1035 (quoting H.R. Rep. No. 102-384, pt. 2, at 16 (1992) (emphasis removed)); *see id.* at 1030 ("The primary House committee report concerning Section 340B acknowledges that optionality and states that the Committee 'expects that the Secretary of HHS, in developing these agreements, will use the mechanism that is the most effective and most efficient from the standpoint of each type of 'covered entity.'" (quoting H.R. Rep. No. 102-384, pt. 2, at 16 (1992))).

HRSA Repeatedly Rejected Drug Companies' Efforts to Move to Rebate Mechanisms

54. For years, HRSA rejected drug company efforts to impose rebate mechanisms, recognizing that they were *not* the "most effective and most efficient" mechanisms for providing discounts from the standpoint of 340B hospitals. Most recently, in 2024, Johnson & Johnson ("J&J"), Eli Lilly, Bristol Myers Squibb, Novartis, and Sanofi each announced plans to require covered entities to purchase certain drugs at the full Wholesale Acquisition Cost ("WAC")—the

highest price at which a manufacturer sells a drug, multiples of the 340B price—and then apply for a rebate after dispensing the drug to a 340B-eligible patient.

55. HRSA promptly blocked any unilateral switch to a rebate mechanism. In September 2024, HRSA warned J&J that its rebate mechanism was unlawful by forcing covered entities "to pay a higher price point up front for every purchase" and requiring them to pay prices exceeding the ceiling price in violation of "Section 340B(a)(1)." 340B_REBATES_000201 at -03, filed in *Eli Lilly & Co. v. Kennedy*, No. 24-cv-3220 (D.D.C. June 5, 2025) (the "*Eli Lilly* Case"), Dkt. 60-1. HRSA threatened to terminate J&J's participation in the 340B Program, *id.* at 340B_REBATES_000212–14, and sent materially identical letters to Eli Lilly, Bristol Myers Squibb, Novartis, and Sanofi, *see, e.g.*, *id.* at 340B_REBATES_000292.

56. The drug companies sued. *J&J Health Care Sys. Inc. v. Kennedy*, No. 24-cv-3188 (D.D.C. filed Nov. 12, 2024); *Eli Lilly & Co. v. Becerra*, No. 24-cv-3220 (D.D.C. filed Nov. 14, 2024); *Bristol Myers Squibb Co. v. Johnson*, No. 24-cv-3337 (D.D.C. filed Nov. 26, 2024); *Sanofi-Aventis U.S. LLC v. HHS*, No. 24-cv-3496 (D.D.C. filed Dec. 16, 2024); *Novartis Pharms. Corp. v. Becerra*, No. 25-cv-117 (D.D.C. filed Jan. 15, 2025). In defending those suits, HRSA and HHS repeatedly defended the "upfront discount" mechanism:

a. In their April 2025 motion for summary judgment in the *J&J* litigation, HRSA and HHS noted that HRSA "has long envisioned upfront discounts as the preferred price reduction mechanism, noting that '[c]overed entities generally preferred a discount system, because they could negotiate lower prices and needed less initial outlay of drug purchasing money.'" Dkt. 41-1 at 18, *J&J*, No. 24-cv-3188.

b. HHS and HRSA further emphasized that "[t]he Agency [HRSA] would neglect its duty if it did not consider all aspects of the problem, including . . . how the changes would affect

the operations of covered entities and the wellbeing of patients who rely on 340B drugs, before allowing manufacture[r]s to redesign the operation of the program." *Id.* at 20.

c. In an August 2025 D.C. Circuit brief, HHS and HRSA further defended upfront discounts and flagged concerns with a rebate mechanism. "Unlike discounts, rebates require covered entities to spend more money upfront and put greater financial pressure on those safety-net programs." Doc. 2128443 at 2, *Novartis Pharms. Corp. v. Kennedy*, No. 25-5177.

57. District courts agreed that HRSA could bar a unilateral rebate mechanism, crediting HRSA's explanation that covered entities would otherwise "be forced to incur higher carrying costs for these drugs, essentially floating revenue to drug manufacturers." *Johnson & Johnson Health Care Sys. Inc. v. Kennedy*, 2025 WL 1783901, at *12 (D.D.C. June 27, 2025) (internal quotation marks omitted); *see also Eli Lilly & Co. v. Kennedy*, 2025 WL 1423630, at *12 (D.D.C. May 15, 2025). On July 21, 2026—thirteen days before HRSA released the Notice central to this case—the D.C. Circuit affirmed, repeatedly emphasizing Congress's instruction that the Secretary select the mechanism "most effective and most efficient from the standpoint of each type of 'covered entity.'" *Novartis Pharms. Corp.*, 182 F.4th at 1030–31.

HRSA Unlawfully Tried to Implement a Rebate Program in 2025

58. On July 31, 2025—at the same time government attorneys representing Defendants were highlighting the risks of a rebate mechanism in federal courts—HRSA abruptly announced a "340B Rebate Model Pilot Program" by press release, followed by a corrected Federal Register notice on August 7, 2025, 90 Fed. Reg. 38,165 (the "2025 Notice").

59. The 2025 Notice offers almost no justification for switching to a rebate mechanism. It only cites "inquiries" from drug companies about deduplicating 340B discounts and the new Medicare "Maximum Fair Prices" negotiated under the Inflation Reduction Act ("IRA"), 42 U.S.C. § 1320f *et seq.* The 2025 Notice contained no estimate of the costs of compliance, no

acknowledgment of covered entities' reliance interests, no discussion of reasonable and less costly alternatives, and no acknowledgment of the financial harms HRSA itself had described to drug companies and the courts months earlier.

60. On December 1, 2025, Plaintiffs (except for EMMC) sued in this Court and moved for a temporary restraining order and preliminary injunction. Compl., *Am. Hosp. Ass'n v. Kennedy*, No. 2:25-cv-600 (D. Me. Dec. 1, 2025), Dkt. Nos. 1, 3. By then, HRSA had approved nine drug companies' applications covering ten drugs, after receiving 1,243 public comments on the 2025 Notice. 91 Fed. Reg. at 48,885.

61. On December 29, 2025, Chief Judge Walker granted a preliminary injunction and preliminarily set aside those approvals. *AHA I*, 820 F. Supp. 3d 30. The Court identified multiple independent APA violations. *First*, there was "no evidence in the administrative record that Defendants considered Plaintiffs['] significant reliance interests," a failure "alone fatal to the Rebate Program." *Id.* at 45. *Second*, Defendants had not calculated what the Rebate Program would cost before adopting it—a defect this Court also found to be "[f]atal to Defendants . . . under the APA." *Id. Third*, the Court found the record "silent on the cost of floating the full price of covered drugs" and held that Defendants were owed no deference on that question because "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." *Id.* (citing *FCC v. Nat'l Citizens Comm. for Broad.*, 436 U.S. 775, 815 (1978)).

62. Defendants appealed and sought a stay. This Court denied a stay on December 30, 2025, Dkt. No. 96; the First Circuit denied an administrative stay on December 31, 2025; and the First Circuit denied a stay pending appeal on January 7, 2026. *AHA II*, 164 F.4th at 33 n.1, 37. The First Circuit found "the administrative record does not reveal any prior consideration of the

significant costs that safety-net hospitals will incur under the Rebate Program," pointing to the federal government's concession "that it was 'currently examining' the hospitals' increased administrative costs from the Rebate Program." *Id.* at 34. The appellate court also recognized that HHS had "historically rejected such proposals as both inferior to Section 340B's current upfront-discount model and disruptive to safety-net hospitals." *Id*. at 32.

63. Defendants did not attempt to further defend the 2025 Rebate Program. On January 20, 2026, the First Circuit granted Defendants' motion to dismiss their own appeal, and on February 10, 2026, this Court vacated the Program and remanded to HHS—setting aside the "340B Program Notice: Application Process for the 340B Rebate Model Pilot Program," 90 Fed. Reg. 36,163 (Aug. 1, 2025), its Correction, 90 Fed. Reg. 38,165 (Aug. 7, 2025), and Defendants' approvals of the drug companies' applications submitted pursuant to those notices. Order, *AHA I*, No. 2:25-cv-600 (D. Me. Feb. 10, 2026), Dkt. Nos. 114, 115.

64. Ultimately, both courts faulted Defendants for the same basic failure: committing to a rebate mechanism without having calculated what it would cost the hospitals required to operate it and, therefore, not having "identif[ied] benefits that 'bear a rational relationship to the . . . costs imposed.'" *AHA I*, 820 F. Supp. 3d at 44 (quoting *Mexican Gulf Fishing Co.*, 60 F.4th at 973). As set forth below, Defendants have again made the same error, among others.

A Week After the 2025 Rebate Program Was Vacated, HRSA Hastily Started Again

65. Seven days after the vacatur, HRSA started over. On February 17, 2026, the agency published its RFI, inviting comments on a wide range of topics:

a. HRSA asked covered entities to submit estimates of the incremental "administrative and operational" costs they would bear under a rebate program, including both "one-time startup costs" and "ongoing costs." 91 Fed. Reg. at

7,289–90. It asked, for example, if (a) a rebate program "would require additional full-time employees"; (b) "any new or modified IT systems, software, or data infrastructure" would be required and at what cost; and (c) "any prompt payment incentives or discounts were currently offered by drug wholesalers for early payment and the timeframes associated with those incentives." *Id*. It also sought comments about "additional costs," including "reduction in services offered" and "impacts on access to drugs for patients." *Id*. at 7,289.

b. HRSA also showed clear awareness of potential float costs, asking commenters to "[d]escribe with specificity whether payment timing (e.g., within ten calendar days of submission of a complete claim) . . . would affect your cash flow, including any financial risks to your organization." *Id.* at 7,289–90.

66. Critically, however, nowhere does the RFI directly ask the operative question required under the 340B statute: whether a rebate mechanism is the "most effective and most efficient" *from the standpoint of the covered entity*. H.R. Rep. No. 102-384, pt. 2, at 16 (1992) (emphasis added). HRSA instead asked how to "balance" the covered entities' interests against the drug companies' interests.[1] *Id.* at 7,289.

HRSA Published an Inaccurate Cost Estimate Months Before Receiving Any Comments

67. Nearly two months before comments on the RFI were due, HRSA published an estimate of the Rebate Program's burden in the February ICR, as required by the Paperwork Reduction Act ("PRA").

[1] HRSA initially allowed thirty days for comment, setting a deadline of March 19, 2026. 91 Fed. Reg. at 7,291. On February 26, 2026, HRSA extended that deadline to April 20, 2026. Request for Information: 340B Rebate Model Pilot Program; Extension of Comment Period, 91 Fed. Reg. 9,632 (Feb. 26, 2026).

a. The ICR estimates that 14,600 covered entities making 52 claims-data submissions each year, at five hours per submission, would result in a total of 3,796,000 annual burden hours for covered entities. 91 Fed. Reg. at 9,633. As discussed *infra* ¶¶ 124–25, 145, HRSA would later confirm these hours would cost safety-net entities well over $500 million per year.

b. By contrast, HRSA estimated just 416 *total* hours for all thirteen participating drug companies—104 hours to prepare rebate model plans and 312 hours total to submit monthly reports. *Id.*

68. HRSA never explained how it arrived at its 5-hour-per-week assumption, but the provenance of the 5-hour figure is simple. For the 2025 Rebate Program, HRSA selected (without explanation) a burden estimate of two hours per week in its PRA filings. Hundreds of commenters challenged that 2-hour estimate during the multiple comment periods in 2025, and Plaintiffs showed in the prior litigation that HRSA never vetted its 2-hour estimate. Mot. for TRO at 13, No. 25-cv-600 (D. Me. Dec. 1, 2025), Dkt. No. 3; Compl. ¶¶ 63–71, No. 25-cv-600 (D. Me. Dec. 1, 2025), Dkt. No. 1; *AHA I*, 820 F. Supp. 3d at 44 ("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.'"). Nevertheless, with HRSA now having proposed to increase the number of covered drugs in the new Program by a factor of 2.5 (from 10 proposed drugs in 2025 to 25 proposed drugs in 2026), HRSA simply multiplied that prior 2-hour estimate by 2.5 to arrive at 5 hours.

69. Over the ensuing months, the administrative record amassed extensive firsthand evidence from hospitals, clinics, and other safety-net providers that would have to implement the Rebate Program. That evidence showed not only that HRSA had substantially understated the administrative burden, but also that the Program would impose overall annual administrative costs exceeding $1 billion for 340B hospitals alone and thereby threaten patient care. HRSA refused, however, to engage with that evidence, and this 5-hour-per-week contrivance remained the entirety of the cost estimate underpinning its analysis of the Rebate Program.

Commenters Detailed Enormous Costs and Harms for Safety-Net Entities

70. By the time the comment period closed on April 20, 2026, HRSA had received 2,475 comments—more than twice the number submitted the year before. *See* Notice, 91 Fed. Reg. at 48,888. Covered entities submitted detailed, empirical, firsthand evidence addressing HRSA's proposed questions and identifying additional consequences the RFI had not accounted for. Over 600 comments supplied facility-specific dollar figures, staffing plans, wholesaler contract terms, financing costs, bond covenant thresholds, other lost discounts, or additional data documenting the costs of implementing a rebate mechanism. Covered entities also detailed their experience under a separate HHS program showing that HRSA misunderstood how rebates work in practice.

71. The comments also challenged HRSA's asserted justification for imposing those costs. Covered entities submitted evidence that drug companies and their proxies had substantially overstated the prevalence of duplicate discounts, undermining the asserted benefit of a rebate mechanism. They also noted a wide range of alternative approaches to a rebate mechanism that would achieve the agency's goals at lower costs, none of which HRSA meaningfully considered.

The Staggering Administrative Costs of a Rebate Program

72. Commenters demonstrated that the administrative costs of a rebate mechanism, even one limited to the drugs selected under the Medicare Drug Price Negotiation Program ("MDPNP"), would exceed $1 billion annually just for the approximately 2,728 340B hospitals. *See generally* HRSA-2026-0001-1846 (comment letter of Plaintiff AHA) ("AHA Letter"); HRSA-2026-0001-1994 at 1 (America's Essential Hospitals providing that, "[o]verall, we estimate continuing HRSA's proposed rebate model would result in $1.5–1.6 billion in direct costs and $3.7–$4.6 billion in total costs for hospitals in 2027 alone."). This number *excludes* the costs for the roughly 12,500 covered entities that are not hospitals. Those administrative costs fall into distinct categories, each of which was documented in the record.

73. **Labor Costs**: Commenters explained that HRSA's 5-hour-per-week assumption does not accurately measure the *total* labor a rebate mechanism requires. Commenters identified two problems with this approach. *First*, HRSA had badly understated the one labor cost it attempted to measure. *Second*, overall labor costs include several additional categories: back-end reconciliation, dispute and denial management, information-technology work, cybersecurity protection, training, and so on. The comments explained that the real labor burden of a Rebate Program is many multiples of HRSA's 5-hours-per-week assumption.

74. Plaintiff AHA, for example, gathered input from its member hospitals on the additional staffing a rebate program would require. Its members reported that, on average, complying with the Program—including managing data entry, handling inputs, reconciling rebates and claims, resolving rebate disputes, and more—would conservatively require them to hire at least one new full-time employee, amounting to an additional 40 hours per week, not 5. *See* AHA Letter at 7–8. Likewise, the nonprofit Association of American Medical Colleges ("AAMC")

reported, based on its own member research, that the staff time required for submitting and reconciling claims and managing disputes and discrepancies alone "is estimated to require 25 to 40 hours per week," involving personnel not only in pharmacy but also in legal, compliance, revenue-cycle, and finance. HRSA-2026-0001-1914 at 10.

75. Covered entities of every size reported that they cannot absorb a rebate mechanism with existing staff. For example, nearly half (47%) of community health centers that responded to a National Association of Community Health Centers member assessment reported that they would need to hire an additional 0.5 to 1 full-time employee ("FTE"), more than a third (36%) would need 1 to 2 additional FTEs, and 7% would need more than two. *See, e.g.*, HRSA-2026-0001-2011 at 5 (comments of HopeHealth, citing member assessment). Likewise, a Georgia Hospital Association survey of members showed, among other things, "[i]ncremental administrative costs ranging from $100,000 to more than $530,000 annually" and an average of "[o]ne to 1.5 additional Full Time Equivalent (FTE) administrative positions[.]" HRSA-2026-0001-1894 at 2. And a Massachusetts Health & Hospital Association survey of members showed, among other things, "70% of respondents anticipate hiring more than 10 new FTEs at a cost of $1.3 million to assist with the rebate process[.]" HRSA-2026-0001-2007 at 2.

76. Small and rural hospitals reported the same need. St. Tammany Health System, a community-owned health system in Covington, Louisiana, reported "an additional 2.0 FTEs would be required." HRSA-2026-0001-0080 at 2. Graham County Hospital, a rural critical access hospital in Hill City, Kansas, reported "[a] minimum of 1.5 additional FTEs." HRSA-2026-0001-0048 at 3; *see also* HRSA-2026-0001-1564 at 2 (Knox Community Hospital, a rural community hospital in Mount Vernon, Ohio, calling HRSA's 5-hour estimate "ludicrously low"); HRSA-2026-0001-1522 at 2–3 (North Shore Health, a critical access hospital in Grand Marais, Minnesota, noting

that "[NSH] does not currently have sufficient staff to comply with a rebate-based system. Our pharmacy services are provided by two pharmacists who already operate at capacity. Even a modest increase in workload would be unsustainable. Recruiting additional qualified professionals in our rural location is extremely challenging and additional burdens could lead to staff attrition, further limiting available services.").

77. Larger systems reported larger burdens. Yale New Haven Health estimated approximately three FTEs. HRSA-2026-0001-1473 at 1–2. Vanderbilt Health projected six FTEs, or 240 hours per week, "48 times greater than HRSA's estimate." HRSA-2026-0001-1593 at 3. Equitas Health, a nonprofit community health center system based in Columbus, Ohio, projected six to seven. HRSA-2026-0001-0073 at 2. Baylor Scott & White Health, a nonprofit health system in Texas, projected "seven to eight FTEs and . . . hundreds of hours a month on program compliance and operations." HRSA-2026-0001-1485 at 1. Tarrant County Hospital District, the public safety-net hospital system in Fort Worth, Texas, calculated that it would require approximately 5,000 labor hours for tracking alone before any denials, appeals, contract complexity, or auditing. HRSA-2026-0001-1827 at 5. New York City Health + Hospitals, the nation's largest public hospital system, explained that "[t]he reality is that our organization would face in excess of 100 additional administrative hours per week, not five." HRSA-2026-0001-2021 at 4.

78. Other individual safety-net providers filled the record with similar data. The Richland Hospital, a rural critical access hospital in Wisconsin, estimated ongoing costs "of at least 40 hours and thousands of dollars per month." HRSA-2026-0001-0093 at 2. Saint Peter's University Hospital, a nonprofit teaching hospital in New Brunswick, New Jersey, estimated that fully staffing a rebate program would require twelve employees at approximately $1 million per

year. HRSA-2026-0001-0111 at 2. Ventura County Medical Center, a county-owned safety-net hospital in California, estimated $300,000–$410,000 in annual personnel costs. HRSA-2026-0001-2117 at 3. Ammonoosuc Community Health Services, a federally qualified health center serving rural northern New Hampshire, "anticipates adding 1–2 FTE that alone would put the program out of existence for all intents and purposes where the cost of administration will exceed the cost of any savings." HRSA-2026-0001-0304 at 7 (emphasis removed). Morris County Hospital, a county-owned, nonprofit, 21-bed critical access hospital in Council Grove, Kansas, informed HRSA that "alter[ing] this [upfront discount] structure with having to manually account for . . . individual rebates . . . will turn our 340B program into a workflow quagmire" and estimated that it would require 2 FTEs, at an annual cost of $104,000. HRSA-2026-0001-2455 at 2–3.

79. As these and other commenters explained, HRSA's gross undercalculation of labor costs had several sources. *First*, HRSA assumed that front-end data entry would be relatively expedited and could be collected from a single source. The reality, as commenters explained, is that the required data elements do not exist in one place and are housed across electronic health records, split-billing software, third-party administrator ("TPA") platforms, wholesaler portals, and finance systems. Significant staff hours would be consumed each week pulling data from various locations, building and verifying separate reports, and validating data integrity across systems with differing package sizes and National Drug Code ("NDC") configurations. *See, e.g.*, AHA Letter at 12–13. For example, University of California Health, the academic health system of the University of California, reported that blank payer-ID and National Provider Identifier ("NPI") fields must be manually populated and units of measure manually overridden before every submission. HRSA-2026-0001-1986 at 5; *see also* HRSA-2026-0001-2071 at 5 (Medical University of South Carolina explaining that "[r]elevant data may reside across the EHR, split-

billing platforms, revenue cycle systems, payer claims systems, wholesaler data, and TPA platforms" and that "[p]articularly for medical claims data, substantial manual work would likely be required"); HRSA-2026-0001-2013 at 6 (comment from Memorial Health System, a small rural critical access hospital in Kansas, that "the necessary data elements exist in different internal systems," that "[t]hese systems do not currently operate through a single automated data feed," and that "[o]ur hospital's systems were not designed to automatically transmit all of the required data elements directly to our third-party administrator (TPA) or other rebate-processing entities").

80. *Second*, HRSA entirely omitted the work that must occur when rebate payments come back to covered entities. Commenters explained that this back-end reconciliation, a category of labor that does not exist under an upfront discount mechanism, will likely be the single most time-consuming and costly component of the program. *See, e.g.*, AHA Letter at 14–16. For example, Legacy Health, a nonprofit healthcare provider serving Oregon and southwest Washington, noted "the increase in administrative burden . . . would be driven by the need to implement rebate reconciliation workflows and not primarily in the data submissions themselves." HRSA-2026-0001-1710 at 2–3. Likewise, Abbeville Area Medical Center, a South Carolina rural critical access hospital, explained that "[r]econciliation is the biggest concern with the increased administration cost" because "[t]here are thousands of prescriptions that are run daily and a person or TPA would need to verify the rebate had been performed." HRSA-2026-0001-1652 at 2–3. And West Virginia United Health System explained that "[t]racking rebate payments by manufacturers, matching payments back to submitted claims, reconciling, resolving good faith inquiries, reconciliation of payments, and maintaining the audit trail can easily exceed the [submission] work itself." HRSA-2026-0001-1843 at 4.[2]

[2] *See also* HRSA-2026-0001-2174 at 5–6 (University Health / Bexar County Hospital District, a public safety-net hospital system in San Antonio, estimating 1–2 additional hours per week of manual claims submission but 133

81. These commenters explained that under a rebate mechanism, hospitals must match payments received weeks or months later to individual drug purchases and claims. They also must identify claims for which rebates are missing, delayed, denied, or underpaid; investigate discrepancies between the entity's records and manufacturers' determinations; correct or resubmit claims where appropriate; and pursue unresolved amounts with manufacturers or their vendors. Hospitals also explained that rebate reconciliation creates substantial accounting and allocation burdens once a rebate payment is received. They must determine which underlying 340B transactions the payment covers, match those transactions to their own purchasing and claims records, and then allocate the payment to the appropriate internal accounts, facilities, departments, pharmacies, cost centers, or other business units. These are not merely bookkeeping formalities. They require coordination among pharmacy, finance, accounting, revenue-cycle, and information-technology personnel. In addition, because some drug companies may make lump-sum rebate payments covering many claims, hospitals will have to perform additional work simply to determine whether they were paid at all. *See* AHA Letter at 14 & n.18.

82. Hospitals' experience with analogous platforms confirmed the point. Pella Regional Health Center, a rural critical access hospital in Iowa, reported that its experience with manufacturer data-submission platforms "has been rife with costly challenges" so severe that it has assigned staff to do nothing but resolve them. HRSA-2026-0001-0296 at 3. Premier, Inc. reported that CMS's platform for the first IRA drugs "often misclassifies" claims and that its appeals process is so "complex and time intensive" that "several hospitals have been forced to

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additional hours per week for claims reconciliation, excluding dispute resolution, audit preparation, and manufacturer coordination); HRSA-2026-0001-1830 at 4 (UMC Health System, a public teaching hospital system in Lubbock, Texas, concluding that "[u]nder a rebate-based 340B model, we would face an untenable choice: either forgo rebates entirely because reconciliation is too burdensome to complete, or hire additional staff simply to access the same—or potentially less—cost savings"); HRSA-2026-0001-1600 at 1 (Family HealthCare Center, a community health center in Fargo, North Dakota, reporting that it anticipates spending approximately $300,000 for manual reconciliation alone).

redirect existing staff or hire new FTEs to manage errors and appeals." HRSA-2026-0001-0662 at 3. Others described "[m]anually opening each claim" because there is "no bulk view available," HRSA-2026-0001-1421 at 3, and the "[i]nability to correlate anonymized claims data" between platforms, HRSA-2026-0001-0663 at 1. *See also* HRSA-2026-0001-0160 at 1.

83. Some comments noted that HRSA's omission of back-end reconciliation costs seems to have been due to the agency wrongly making burden assessments by looking at a *different* data-sharing program, the 340B Enhanced Services Platform ("340B ESP"). Commenters emphasized that, unlike a rebate mechanism, 340B ESP involves no post-submission payment reconciliation whatsoever, so nothing in covered entities' current operations resembles 340B ESP's workload. *See* AHA Letter at 16; *see also* HRSA-2026-0001-0048 at 4 (Graham County Hospital explaining "[t]he data we provide today through 340B ESP and payers for billing purposes does not include the detailed financial reconciliation and rebate tracking elements required under a manufacturer rebate framework.").

84. *Third*, commenters documented that information-technology and cybersecurity labor is a distinct cost from just the pharmacists included in HRSA's analysis. *E.g.*, AHA Letter at 7 n.6; HRSA-2026-0001-1914 at 11 (comment from AAMC that "IT/data integration analysts" were among the permanent roles members have filled or expect to fill). Temple University Hospital, an academic safety-net hospital in Philadelphia, for example, explained that implementation would require a dedicated IT/accounting professional as one of two new FTEs, with each additional pair of FTEs costing $302,000 per year as drugs are added in 2027. HRSA-2026-0001-1396 at 5–6.

85. **Recurring Non-Labor Administrative Costs:** Commenters separately quantified non-labor operational costs—vendor and TPA fees, software, IT support, and financial auditing

services—"rang[ing] from $150,000 to over $750,000 per hospital" annually, "with costs increasing further if there are significant delays and denials with the rebate payments." AHA Letter at 9. Even using the bottom of that range—just $150,000 per hospital—across 2,728 340B hospitals yields more than $400 million in additional annual costs, pushing the total administrative burden on 340B hospitals alone above $1 billion each year. *Id.* at 9–11.

86. Those costs include new software and IT services—$30,000 to $50,000 per year for smaller entities and multiples of that for larger ones. Saint Peter's University Hospital estimated approximately $500,000 per year for rebate billing and tracking software alone. HRSA-2026-0001-0111 at 2. Tarrant County Hospital District estimated $100,000 to $250,000 per year in ongoing TPA fees and $40,000–$120,000 per year in IT maintenance and enhancements. HRSA-2026-0001-1827 at 3; *see also* HRSA-2026-0001-2021 at 6 (New York City Health + Hospitals commenting that "[o]ngoing expenses would include system maintenance, vendor licensing fees, data storage, interface management, cybersecurity enhancements, and continuous updates to reflect evolving program requirements," plus "recurring personnel costs for IT support and data management staff required to sustain these systems").

87. Commenters also documented new costs associated with "compliance and audit process changes to prepare for increased audits related to rebate models," "expanded audit and risk management controls," and dedicated compliance personnel. HRSA-2026-0001-1914 at 10–12 (comment of AAMC); *see also* HRSA-2026-0001-1827 at 2–3 (Tarrant County Hospital District estimates $20,000–$50,000 in one-time legal and compliance review costs, including audit preparation, plus $50,000–$120,000 per year in ongoing compliance and audit support); HRSA-2026-0001-0046 at 2–3 (Rooks County Health Center, a 22-bed critical access hospital in

Plainville, Kansas, estimates $5,000–$10,000 per year for audit preparation and support and another $5,000–$10,000 per year for ongoing legal and compliance review).

88. **Start-Up Costs:** Commenters separately identified significant one-time costs to build the infrastructure that a rebate mechanism requires. These included "claims mapping, interfaces, and secure data transmission of claims information to manufacturers"; redesigned finance and accounting systems "to allow for receivables tracking and reconciliation processes"; training; and "expanded audit and risk management controls." HRSA-2026-0001-1914 at 12. As the AHA explained, "even before the new claims and reconciliation process begins, many hundreds of staff hours must be spent across the entire hospital organization to prepare for a new discount mechanism." AHA Letter at 15. These "one-time costs are significant" and are sunk regardless of whether HRSA's "purported 'test'" succeeds. *Id.*

89. Individual covered entities quantified those costs, from tens of thousands of dollars at the smallest hospitals to millions at large systems. Bitterroot Health, a rural hospital in Hamilton, Montana, calculated $95,000 to $185,000 in one-time costs. HRSA-2026-0001-0058 at 3. Memorial Community Hospital, a critical access hospital in Blair, Nebraska, similarly expected up to $300,000 in start-up costs. HRSA-2026-0001-0105 at 1. The University of Vermont Health Network reported "an upfront cost between $3,000,000 to $4,000,000" for itself only. HRSA-2026-0001-1720 at 2; *see also* HRSA-2026-0001-1369 at 2 (Coffee Regional Medical Center, a rural nonprofit hospital in Douglas, Georgia, estimating costs "effectively doubling our current 340B administrative spend"); HRSA-2026-0001-1438 at 2 (Wabash General Hospital, a rural critical access hospital in Mount Carmel, Illinois, reporting upfront costs of $122,000 to $178,000). MultiCare Health System, a nonprofit health system based in Tacoma, Washington, reported that it had *already incurred* "approximately $60,000 in preparatory expenses for the rebate program

between Oct. 1 and Dec. 21, 2025" for the original ten drugs, plus one new FTE, such that its "total startup expenditure for the first ten rebate drugs under just the Medicare program approached $200,000." HRSA-2026-0001-2251 at 2.

Comments Detailed That the Various "Float" Costs Carried Independent and Significant Harms

90. Commenters also demonstrated, with specificity, why requiring covered entities to pay WAC while awaiting a rebate imposes severe costs, even under the nominal 10-day payment period proposed in the failed 2025 Rebate Program. 91 Fed. Reg. at 48,895.

91. Commenters gave specific calculations of how much more money safety-net hospitals and other covered entities would need to pay upfront for these drugs. Trinity Health, the Catholic Health Ministries-sponsored national system that includes 39 340B facilities, explained that its system currently spends approximately $26 million annually on the 25 drugs contemplated for the Rebate Program, but that under a Rebate Program "purchasing these same drugs in the current quantities at the much higher Wholesale Acquisition Cost (WAC) would increase the purchase price to $671M annually." HRSA-2026-0001-1627 at 3. Dallas County Hospital District, a Texas public safety-net hospital system, reported that its current acquisition cost of the 25 drugs is $9.3 million with current 340B pricing, but under the Rebate Program would cost $96 million (a $237,000-per-day carrying cost). HRSA-2026-0001-2068 at 3. The University of California health system calculated an increased outlay of $120 million for the ten drugs included in the enjoined 2025 Rebate Program, HRSA-2026-0001-1986 at 5, and the Ohio State University Wexner Medical Center calculated an increased cost of approximately $30 million for the same, HRSA-2026-0001-2057 at 11.

92. Smaller and rural facilities reported that they would face similar many-fold increases in acquisition costs. Southern Nevada Community Health Center, a federally qualified

health center in Las Vegas, Nevada, estimated it would cost $130,000 per month to purchase the ten original pilot drugs at WAC, compared to less than $1,000 per month at the 340B price. HRSA-2026-0001-1604 at 9. Glacial Ridge Health System, a critical access hospital in Glenwood, Minnesota, reported that the Rebate Program would drive the acquisition costs of 340B drugs from $431,272 to $1,776,653—an additional $1,345,381 cost that it said "is not manageable." HRSA-2026-0001-1503 at 1. Kent County Memorial Hospital, a 359-bed hospital in Warwick, Rhode Island, explained that for the 25 covered drugs it would have to advance approximately $25.7 million in additional upfront acquisition costs. HRSA-2026-0001-1624 at 4; *see also* HRSA-2026-0001-1773 at 1, 8 (Family Health Services of Darke County, a health center serving rural Ohio, noting that under the Rebate Program it would have $1 million in cash "frozen" in manufacturers' systems in 2026, rising to $1.3 million in 2027 and $2 million in 2028).

93. **The Inadequacy of a 10-Day Guardrail:** Many commenters explained why HRSA's prior proposal requiring drug companies to reimburse covered entities within 10 days of submission would not protect them from the Rebate Program's various "float" costs.

94. *First*, commenters explained that many wholesalers required payment in less than 10 days, meaning the 10-day deadline would not allow covered entities to avoid floating the WAC. The University of Arkansas for Medical Sciences explained that it "typically remits payment within 5 calendar days under current wholesaler terms." HRSA-2026-0001-0065 at 11. Clark Fork Valley Hospital, a community hospital located in Plains, Montana, commented that "pharmacy distributors already apply the most onerous payment terms on our hospital of any other vendor we deal with, at 7 days," and "they will not hesitate to cut off drug shipments if they are not paid on time." HRSA-2026-0001-1601 at 3; *see also* HRSA-2026-0001-2443 at 4 (Santa Ynez Valley Cottage Hospital, a rural critical access hospital in Solvang, California, stated that "as invoices

from wholesalers must be paid within 7 calendar days, even in a best case scenario where rebates are received within 10 days, the Hospital would still be floating the manufacturer for 3 days").[3]

95. *Second*, commenters noted that drugs may sit on shelves for long periods of time, further inhibiting immediate reimbursement. Commenters explained that "the requirement to maintain clinical safety stock for emergent cases necessitates that certain medications remain on our shelves longer than the pilot suggests," during which the hospital carries the full WAC cost of undispensed inventory. AHA Letter at 22. Hospitals therefore order drugs in advance, considering variable patient volumes and irregular utilization at rural hospitals. *See* HRSA-2026-0001-1843 at 1, 3 (West Virginia United Health System explaining that, given its service to "a large population of rural, low-income patients," medications "may sit on a shelf for weeks or months before being dispensed"). As one organization explained, "After purchasing a rebate drug, that drug would sit in the hospital's inventory until it is dispensed or administered to a patient (which could take weeks or months). Only then could the hospital prepare to submit its rebate claim to a manufacturer to be paid." HRSA-2026-0001-2437 at 7. University of Rochester Medicine, a New York academic health system, explained that "the cash flow impact is significantly exacerbated by the time between drug purchase and actual use, particularly for expensive, slow-moving inventory." HRSA-2026-0001-2287 at 5.

96. *Third*, commenters explained that claims often cannot be realistically submitted for 30–45 days due to administrative burdens of submitting such claims, and the 10-day rebate clock

[3] *See also* HRSA-2026-0001-0653 at 8 (Samaritan Healthcare, a rural hospital in Moses Lake, Washington, noting that it is required to pay its wholesaler "within 7 days of receiving the invoice/product for the 25 drugs"); HRSA-2026-0001-1612 at 9 (Ohio-based Nationwide Children's Hospital, explaining it pays its "primary wholesaler based on a 7-day payment term"); HRSA-2026-0001-2102 at 3 (MetroHealth, a Cleveland-based safety-net hospital, explaining it "currently operates under net seven (7) day payment terms with its wholesale drug supplier") (emphasis removed); HRSA-2026-0001-1609 at 2–3 (Keck Medicine of University of Southern California, noting that "[o]ur organization's payment terms are currently 7 days"); HRSA-2026-0001-1886 at 9 (University of Iowa Health Care, noting its wholesaler requires payment within 7 days).

only begins when a drug company receives a completed claim submission. One survey conducted by the Greater New York Hospital Association found that "30% of the survey respondents estimate that it takes 15-30 days on average from the time they acquire a drug to when a rebate claim would be submitted," that 50% estimated "31–60 days on average," and an additional "10% estimated 61–90 days." HRSA-2026-0001-2379 at 9. Individual healthcare providers from across the nation confirmed these results. *See, e.g.*, HRSA-2026-0001-2249 at 17 (McLeod Regional Medical Center of South Carolina explaining that medical "[c]laims take a minimum of 30 days after an encounter has been closed to be submitted but can take longer."); HRSA-2026-0001-2382 at 5 (Indiana University Health, explaining that medical claims for physician-administered drugs "may not be available for weeks or longer after the drug is administered"); HRSA-2026-0001-1966 at 5 (Cambridge Public Health Commission, a Massachusetts public safety-net health system, explaining that such medical claims "can be billed out weeks or months after the drug was dispensed").

97. *Fourth*, commenters explained that some wholesalers require covered entities to fund large "prepay" or escrow accounts in response to the increase in WAC invoice amounts—an obligation that negatively affects liquidity regardless of how quickly any rebate is paid. *See, e.g.*, AHA Letter at 19. For example, University of California Health reported that its wholesaler would require an increase in its prepay deposit of approximately $30 million *per quarter*—"an immediate . . . outlay of cash that's directly tied to the rebate model." HRSA-2026-0001-1986 at 6; *see also* HRSA-2026-0001-2158 at 4 (Community Voices for 340B commented that "For those covered entities with prepay or same day wholesaler repayment terms and less than one day cash on hand, a rebate model could force them out of business").

98. *Fifth*, commenters explained that many covered entities would not have available cash-on-hand to reliably pay these new large acquisition costs under the Rebate Program. Some would need to look to lines of credit or similar loans at rates of 7% to 12%, which, of course, would not be covered by the rebate.[4] One organization representing 340B hospitals noted that a 12% interest rate would translate to "$162.8 million in interest costs for all hospitals for the 340B rebate pilot" and "will only grow as the number of drugs in the [R]ebate [Program] continues to grow." HRSA-2026-0001-1994 at 16 (comment of America's Essential Hospitals). Many commenters echoed the view expressed by Self Regional Healthcare, a nonprofit regional hospital in Greenwood, South Carolina, that borrowing to fund drug procurement "fundamentally defeats the purpose of the 340B program" by "diverting patient-care funds toward interest payments, origination fees, and debt service." HRSA-2026-0001-1495 at 6; *see also* HRSA-2026-0001-1740 at 11 (Eastern Iowa Health Center, noting that "[f]orcing CHCs into debt to maintain their drug supply creates an environment of clinical instability").

99. *Sixth*, many commenters explained that the Medicare maximum fair price ("MFP") refund process, which took effect January 1, 2026, and involves some of the same manufacturers, drugs, and vendor platforms, is experiencing significant delays. That MFP program requires

[4] *See, e.g.*, HRSA-2026-0001-2383 at 11 (Jericho Road Community Health Center, a federally qualified health center in Buffalo, New York, noting that interest rates would be approximately 7.75%); HRSA-2026-0001-1520 at 9 (Flathead Community Health Center, a federally qualified health center in Kalispell, Montana, quoted interest rates of 7.75%–11%); HRSA-2026-0001-2446 at 6 (Colorado Community Health Network, the statewide association for Federally Qualified Health Centers, noting that Small Business Administration loans carry annual interest rates upwards of 12.5% and that wholesalers charge 18% interest on late balances). One comment submitted on behalf of a health center serving homeless patients told HRSA that the Rebate Program was forcing it into "possibly having to secure a line of credit or loan to finance drug inventory, absorbing interest expenses." HRSA-2026-0001-0059. The Tennessee Primary Care Association said its members' "financial strains . . . are well known, so any creditor willing to lend to them will charge above-average rates, and many may seek to put liens on CHCs' buildings." HRSA-2026-0001-1705 at 3. Of course, this is only true for the entities that can obtain credit. Some commenters explained that credit would not be available to them. *E.g.*, HRSA-2026-0001-2052 at 2 (Jefferson Comprehensive Care System, Inc. explained that it "does not maintain unfunded liquidity at that scale, and no community bank in our service area will extend a line of credit against the promise of manufacturer reimbursement on disputed rebate claims").

repayment within 14 days. CMS, Medicare Drug Price Negotiation Program: Final Guidance § 40.4.2.1 at 206. But commenters reported that payment can take thirty to forty-five days or longer. *See* AHA Letter at 21–23 & nn.27–28. Kootenai Health, a community-owned hospital in Coeur d'Alene, Idaho, explained that it had advanced roughly $5.2 million for two to three months and collected rebates on only about 25% of eligible drugs. HRSA-2026-0001-1509 at 3. Colquitt Regional Health System, a rural nonprofit hospital in Moultrie, Georgia, reported that only 45% of its qualifying MFP dispenses were processed correctly. HRSA-2026-0001-1727 at 2. Vanderbilt Health reported a 30% claim-matching error rate, HRSA-2026-0001-1593 at 3, and Cone Health, a nonprofit health system in Greensboro, North Carolina, identified an error rate of "over 50%," HRSA-2026-0001-2336 at 5. Commenters noted that the MFP experience shows that HRSA should assume some leakage of statutorily owed discounts due to incorrect delays and denials.

100. **Costs from Loss of Liquidity:** Commenters also explained that the liquid assets that safety-net facilities would need to "float" to drug companies are not otherwise idle—they are the same cash-on-hand that funds payroll, vendor payments, capital projects, and patient care. As such, every dollar floated to a manufacturer is a dollar withdrawn from another critical need.

a. Electra Memorial Hospital, a provider in rural Texas, reported that it "currently operate[s] with only 40 days cash on hand," and that "[p]aying full price for drugs and waiting for the rebate would lower that to only 20 days, risking our ability to make payroll and meet other obligatory timelines." HRSA-2026-0001-0100 at 6. The hospital added that "[r]eplacement of radios and purchase of a ventilator for our EMS service along with purchase of new monitors for the emergency room and inpatient services have all been paused in anticipation of this drain on cash flow." *Id.*

b. Samaritan Medical Center, a nonprofit community hospital in Watertown, New York, which employs nearly 2,500 people and serves a military community of 20,000, warned that "[s]ignificant cash flow constraints could impact payroll stability and place us at risk of violating debt covenants requiring 40 days cash on hand," with "serious financial consequences, including risk to ongoing operations." HRSA-2026-0001-1614 at 4.

c. Smaller providers described the same arithmetic in starker terms. Conway Regional Health System, a nonprofit health system in Arkansas, estimated that up to $600,000 in days of cash-on-hand could be tied up, emphasizing that these estimates "represent real money that could have funded capital improvements to our facilities, maintained staffing levels in critical service lines, or expanded programs serving our most vulnerable patients. Every dollar we spend financing manufacturer drug costs under a rebate model is a dollar our community loses." HRSA-2026-0001-1615 at 2. Likewise, Central Florida Health Care, a federally qualified health center serving central Florida, calculated a "[m]onthly cash-flow deficit" of approximately $1,448,307.90, which "exceeds available reserves ***and jeopardizes the health center's ability to maintain operations***." HRSA-2026-0001-1708 at 3 (emphasis added).

101. Many commenters noted that reducing cash-on-hand would also place safety-net facilities in violation of their existing bond covenants. *See* AHA Letter at 26–27. For example, Lexington Regional Health, a rural critical access hospital in Lexington, Nebraska, reported that a revolving float of just $150,000 to $300,000 would place it "at genuine risk of a technical default on debt instruments that were issued to finance the very infrastructure we use to serve our

community." HRSA-2026-0001-1573 at 2. Boston Medical Center Health System, the largest safety-net hospital system in New England, explained that "[e]ven with perfect 10-day payment terms, we lack sufficient cash reserves to finance upfront drug purchases while awaiting rebates without depleting our days of cash-on-hand below covenant thresholds." HRSA-2026-0001-2406 at 7–8; *see also* HRSA-2026-0001-1662 at 3 (Orlando Health, a nonprofit health system in Orlando, Florida, explaining that bond covenants necessitate a minimum amount of cash-on-hand and "[r]equiring our facility to float this money . . . harms our bond rating and our ability to acquire future capital").

102. Commenters also flagged other knock-on effects of delayed payments via a rebate mechanism. For example, because states require covered entities to bill Medicaid at actual acquisition cost, hospitals must wait for the rebate before they can bill Medicaid, delaying Medicaid reimbursement on top of the rebate delay itself. HRSA-2026-0001-1914 at 12–13. California's response to the enjoined 2025 Rebate Program bore out the concern. Its Medicaid agency issued guidance requiring pharmacies to delay Medi-Cal billing until *after* manufacturer rebate reconciliation, converting a single prescription into a five-step, multi-system exercise in which the covered entity must carry the full WAC cost through dispensing, data submission, rebate receipt, retroactive Medi-Cal billing, and final reconciliation. HRSA-2026-0001-1669 at 3–4 (Elica Health Centers, a federally qualified health center in Northern California).

103. Comments about the adverse cash-flow impact for safety-net providers in Maine were especially dire. The Maine Hospital Association explained that the median days cash-on-hand for Maine hospitals is down to 9.3 days from 10.6 last year, and that "[e]ven if drug companies paid within a 10-day period as required under the prior iteration of the Rebate Program, that delayed discount will have meaningful impact on our member hospitals and the patients they

serve. . . . [T]here is a high likelihood that such a rebate model would put some hospitals at risk of violating their bond covenants." HRSA-2026-0001-1530 at 3. Other Maine commenters echoed these risks.

a. One of the Maine Hospital Association's members, MaineHealth, explained that "[c]ash on hand at MaineHealth hospitals supports payroll, pharmacy purchasing, emergency services, and compliance with bond covenants," so that "[e]ven short-term disruption in cash flow, particularly during winter months and seasonal population surges, would generate cascading operational risks." HRSA-2026-0001-1946 at 6.

b. The Maine Primary Care Association explained that "[s]imply requiring manufacturers to pay rebate claims within ten days does NOT protect CHCs from these cashflow strains. This 10-day turnaround addresses only one step in a multi-step financing process; other steps (e.g., waiting for drugs to be dispensed, meeting wholesaler payment deadlines) will still force CHCs to borrow substantial amounts of cash. . . . Also note that CHCs face substantial difficulty accessing credit from the private market at reasonable interest rates. Their financial strains (including the uncertainty around their federal grant funding and their low/negative margins) are well known, so any creditor willing to lend to them will charge above-average rates, and many may seek to put liens on CHCs' buildings." HRSA-2026-0001-1702 at 2–3.

c. One Maine community health center, Penobscot Community Health Care, explained that it was "particularly worried that the need to purchase drugs at full WAC will cause cash flow issues and potentially lead them to exceed their

> credit limits with wholesalers, halting their ability to order medications until payments are submitted." HRSA-2026-0001-1991 at 9 (emphasis removed). It further noted that "the risk of our credit limit being reached or our reserves being depleted is a direct threat to the community's safety net. If we are forced into financial limbo, the 'trickle-down' effect is immediate: longer wait times, reduced service availability, and a weakened ability to provide the steeply discounted medications that our 52 million patients across the country depend on." *Id*. at 13.

104. **Lost Prompt-Pay and Cost-of-Goods-Sold Discounts**: Commenters also identified costs that can never be recouped by rebates. As many explained, a rebate mechanism forces covered entities to forever forfeit the cost-of-goods-sold ("COGS") and prompt-pay discounts negotiated with wholesalers—generally 3% to 10% of a drug's cost—that are already built into their pharmacy budgets. *See* AHA Letter at 25. West Virginia United Health System, for example, noted that "[o]ver the course of one year, we estimate our hospital will be forced to forgo annual pre-pay discounts of $3.2 million dollars." HRSA-2026-0001-1843 at 3 (emphasis removed). Likewise, Regions Hospital, a nonprofit safety-net teaching hospital in St. Paul, Minnesota, reported it "would lose $2 million in prompt pay discounts per year" under the Rebate Program. HRSA-2026-0001-2030 at 12; *see also* HRSA-2026-0001-1839 at 2 (Bayhealth Medical Center, explaining the Rebate Program would forfeit "our prompt payment refunds"); HRSA-2026-0001-1664 at 3 (Saint Catherine Hospital, explaining that the Rebate Program could lead them to "forgo early payment discounts to preserve cash flow, but doing so would cost our organization a significant amount of money").

105. Other providers told a similar story. Fresno Community Hospital and Medical Center, a nonprofit safety-net health system in California's Central Valley, estimated that loss of these discounts alone would increase its acquisition costs for the pilot drugs by 9.5%. HRSA-2026-0001-1479 at 2. The University of Texas Medical Branch, an academic medical center in Galveston, Texas, estimated approximately $9 million annually. HRSA-2026-0001-1532 at 6. Nationwide Children's Hospital explained that these forgone discounts "would be a permanent loss not recuperated from the manufacturer 340B rebate program." HRSA-2026-0001-1612 at 8.[5] And the Maine Primary Care Association's comment letter listed the following as "Direct Financial Losses" from a rebate mechanism:

a. Loss of sub-ceiling discounts on pilot drugs (estimated at 10% - 15% of 340B price).
b. Loss of prompt payment discounts on all drug purchases (not just rebate drugs), which range from 1% to 5% of 340B purchase price.
c. Loss of other discounts, including volume discounts and Cost of Goods Sold discounts.

HRSA-2026-0001-1702 at 9. None of these losses would be recoverable through rebates.

Non-Economic Costs to Healthcare Services and Patient Care

106. Commenters explained that every dollar of administrative and float costs would have downstream effects on patient care. They catalogued the many ways in which reduced care and operations would result in patient harm. As Glacial Ridge Health System put it, the cuts resulting from Rebate Program costs "are not minor inconveniences—they are meaningful reductions in access to care." HRSA-2026-0001-1503 at 3.

107. **Reduced Drug Discounts for Low-Income Patients:** Many covered entities use 340B savings to provide drugs to patients for free or far below cost through patient assistance

[5] In addition, some states tax drug purchases at the higher WAC price. For example, Lakewood Health System, a 25-bed critical access hospital in Minnesota, explained that a 1.8% state tax would apply to the full WAC price. HRSA-2026-0001-1382 at 2.

programs and sliding-fee scales. For example, Hannibal Regional Healthcare System, a Missouri rural health system, explained the Rebate Program would reduce its 340B net benefit on the pilot drugs by an estimated 20–25%, and that money "is currently used to subsidize our sliding-fee scale for uninsured patients." HRSA-2026-0001-1554 at 2.

108. Other commenters warned that a Rebate Program would force them to curtail or terminate those vital patient-assistance programs. Graham County Hospital warned "[w]e will likely shut down our patient assistance program." HRSA-2026-0001-0048 at 4. Mosaic Health System, a nonprofit rural health system based in Missouri, likewise noted the Rebate Program would "reduce or eliminate patient assistance programs designated to the uninsured and under insured patient populations[.]" HRSA-2026-0001-1849 at 2. Other commenters flagged similar patient assistance programs imperiled by the Rebate Program. *See, e.g.*, HRSA-2026-0001-2109 at 5 (Wellstar Health System, Inc., a nonprofit health system in Georgia, noting the Rebate Program would lead to "scaling back or elimination" of medication-assistance programs); HRSA-2026-0001-0058 at 4 (Bitterroot Health Daly Hospital, noting its "SunRx cash-card program" would be imperiled). This burden reached Maine, with MaineHealth warning that "[f]or MaineHealth's hospitals . . . erosion of 340B savings would require reassessment of . . . the provision of free or discounted drugs to uninsured patients." HRSA-2026-0001-1946 at 5.

109. **Reduced Medication Inventory and Access**: Hospitals that lack the cash to acquire high-cost drugs at WAC explained that they will be forced to carry minimal inventory (or none at all). *E.g.*, AHA Letter at 30. Electra Memorial Hospital warned it would be forced "to remove high-cost drugs from our stock," likely "result[ing] in hospitalizations." HRSA-2026-0001-0100 at 7. University Medical Center El Paso warned that access to "[h]igh-cost drugs for specialty services like rheumatology, infectious disease, dermatology, and neurology could be

negatively impacted." HRSA-2026-0001-1514 at 3; *see also* HRSA-2026-0001-1445 at 3 (Cozad Community Hospital, a rural critical access hospital in Nebraska, noting that "[a] rebate model could also affect our ability to stock certain high-cost medications," and could force them to "reconsider stocking some therapies due to financial risk"). As the American Pharmacists Association explained, "some members working with high-cost specialty medications expressed concern that their organizations may reduce their specialty drug formularies or discontinue stocking certain high-cost 340B-eligible drugs due to the high carrying costs, thereby decreasing patient access to these medications." HRSA-2026-0001-1797 at 4.

110. Commenters also warned that the Rebate Program could disrupt contract pharmacy arrangements. In November and December 2025, for example, Walmart and Walgreens announced that they would not provide 340B pricing for the ten drugs in the original Rebate Program, and Walmart excluded all MFP drugs dispensed under Medicare Part D from covered entities' pharmacy services agreements, citing the "new reimbursement mechanism" and "operational constraints." AHA Letter at 32 & n.33. When those relationships lapse, patients—particularly rural patients—must travel long distances for medications they could previously fill nearby. *Id.*

111. **Reduced Patient Services:** Commenters detailed the specific services that even a limited Rebate Program would place at risk. For example, CaroMont Regional Medical Center, a nonprofit hospital in Gastonia, North Carolina, warned that the Rebate Program's costs risked forcing it to close its labor-and-delivery unit and its 63 licensed inpatient behavioral-health beds—the only such services in its county. HRSA-2026-0001-1643 at 4. Woman's Hospital, a nonprofit women's specialty hospital in Baton Rouge, Louisiana, identified mobile mammography, perinatal mental-health services, and HIV post-exposure prophylaxis as programs sustained by 340B savings. HRSA-2026-0001-1408 at 5. The Iroquois Healthcare Association explained that the costs

would "translate[] directly into program cuts, service line reductions, ***and in some cases potential facility closures***." HRSA-2026-0001-0023 at 3 (emphasis added); *see also* HRSA-2026-0001-1504 at 4 (Los Angeles County Department of Public Health, noting the Rebate Program would "reduc[e] the ability to respond to communicable disease outbreaks"); HRSA-2026-0001-1644 at 8 (Johns Hopkins Health System, warning about the erosion of $412 million in annual community benefit activity).

112. The consequences would be most acute in rural communities, where replacement services may be hours away. Heart of America Medical Center in Rugby, North Dakota, explained that patients would have to travel at least 60 miles to replace its cardiac-rehabilitation and diabetes-education programs. HRSA-2026-0001-0037 at 3. Community Care of West Virginia, a federally qualified health center serving rural West Virginia, reported that its essential services are "at risk of elimination." HRSA-2026-0001-1610 at 3. Morris County Hospital warned that losing "up to 20% more from delayed or denied rebate dispenses would likely force [it] to close some services," including "[o]bstetrics and/or pulmonary rehab." HRSA-2026-0001-1435 at 5; *see also* AHA Letter App. B (collecting comments).

113. **Disparate Localized Impact on Communities:** Many comments described how a Rebate Program would have a particularly negative impact on certain rural and underserved communities, imposing an outsized burden on specific populations. For example:

a. Many commenters flagged that rural communities served by 340B hospitals would be particularly harmed by the Rebate Program, because, for example, the unavailability of drugs at local facilities would force patients to drive great distances to the next facility that had them in stock. Lincoln County Medical Center noted that "[i]n rural communities, reductions in hospital services do not

result in inconvenience; they result in patients traveling long distances or foregoing care altogether." HRSA-2026-0001-2048 at 2; *see also* HRSA-2026-0001-2451 at 4 (comment from Shoshone Medical Center in Kellogg, Idaho, warning that the Rebate Program risks cutting staffing and services, and that "[t]he next closes[t] hospital is 38.6 miles away"). The Kansas Hospital Association added that "a rebate model could result in more rural hospital closures." HRSA-2026-0001-1424 at 2; *see also* HRSA-2026-0001-1689 at 10 (comment from Clinicas De Salud Del Pueblo warning that they will need to cut clinic hours and "for our most rural sites where we are the only provider we may need to limit days we are open or close the site entirely").

b. Many other commenters flagged that tribal communities would be acutely harmed by the Rebate Program and the costs associated with it. The Oneida Nation wrote that "Tribal healthcare facilities rely on the immediacy of 340B savings to support pharmacy operations, maintain cash flow stability, and sustain access to essential and high-cost medications for patients." HRSA-2026-0001-1698 at 2. The Pascua Yaqui Tribe noted that "[a]ny delay in realizing these savings would create cash flow gaps that could force us to reduce pharmacy hours, defer drug purchases, or draw from other program funds needed to support direct patient services." HRSA-2026-0001-1607 at 2; *see also* HRSA-2026-0001-2221 at 2 (comments of Northwest Portland Area Indian Health Board that "[t]he requirement to pay the full cost at the time of purchase will cripple the ability of IHCPs [Indian Health Care Providers] to provide healthcare services to their communities").

c. Several covered entities in Maine and their representative organizations described particular harms that would befall Maine communities under the Rebate Program. These commenters noted, for example, that many of the contract pharmacies with whom they work would likely drop out of the 340B Program for the drugs covered in the Rebate Program, as these pharmacies had announced they would in the lead-up to the first proposed Rebate Program. HealthReach Community Health Centers, operating in 12 Maine towns and serving 26,740 patients, warned that "[w]e already experienced this prospect [of lost pharmacy partners] in early 2026, when several of our contract pharmacies eliminated the 2026 MDPNP selected medications from the 340b program." HRSA-2026-0001-2187 at 1, 4. In practice, this would mean a lack of affordable medication options in different Maine communities. *See, e.g.*, HRSA-2026-0001-1702 at 3–4 (comment of Maine Primary Care Association); HRSA-2026-0001-1946 at 5 (comment of MaineHealth).

114. **Timing/Financial Environment**: Commenters separately explained why imposing these burdens in 2026 and 2027 would be especially damaging. They explained, among other things, that hospital expenses are rising roughly 5% year over year; bad debt and charity care are up 8%; drug expenses are up 7%; and the OBBBA is projected to reduce hospital revenues by $68 billion over those two years, falling most heavily on 340B hospitals. AHA Letter at 35–38; HRSA-2026-0001-1914 at 8 (citing OBBBA's "historic $1 trillion cut" from Medicaid and Marketplace spending). Individual providers described the combination of OBBBA cuts—including $137 billion in cuts to rural hospitals over ten years—and manufacturer contract-pharmacy restrictions as a "perfect storm." HRSA-2026-0001-1382 at 3 (Lakewood Health System); HRSA-2026-0001-

1534 at 2 (Astera Health); *see also* HRSA-2026-0001-1399 at 9 (Valleywise Health, a public safety-net health system in Phoenix, Arizona, noting the need for cash reserves against "OBBBA-related impacts" "is not discretionary").

115. All in all, the record before Defendants thus went well beyond generalized apprehension. Commenters supplied *specific* dollar figures, *specific* staffing plans, *specific* categories of discounts (*e.g.*, COGS and prompt-pay discounts) that they will forgo entirely, *specific* wholesaler contract terms requiring payment in less than 10 days, *specific* financing costs, *specific* liquidity challenges, *specific* bond-covenant thresholds, and four or more months of *specific*, documented operating experience under the analogous MFP rebate mechanism. They also identified the *specific* consequences those costs would have for individual facilities and their patients, and they *specifically* explained why imposing these costs in 2026 and 2027 would be particularly damaging. The Notice engages with almost none of this evidence.

Obvious and Less Burdensome Alternatives to a Rebate Program

116. Commenters proposed several alternatives to the Rebate Program that would address the underlying concerns that HRSA flagged in its RFI and elsewhere.

117. **Prospective Discounts and a Data Clearinghouse**: Commenters explained that concerns regarding duplicate discounts could be addressed by less costly and less disruptive mechanisms. The AHA, for example, proposed that drug companies could prospectively publish both the 340B price and the MFP, and covered entities could then maintain two wholesaler accounts and replenish at the lower of the two prices. AHA Letter at 47.

118. Others explained that CMS could require *prospective* effectuation of the MFP at the point of sale, so that non-340B pharmacies purchase at the MFP while covered entities continue to receive the 340B discount upfront. In the rare case where the MFP is lower than the 340B price,

the covered entity would submit limited data to the existing Medicare Transaction Facilitator ("MTF")—the federal clearinghouse CMS already operates to route claims data to manufacturers and payments back to dispensing entities—which would credit the difference. Doing so would "negate the need for retrospective 340B rebates" entirely. HRSA-2026-0001-1914 at 5–6 (comment of AAMC).

119. To the extent HRSA believed data-sharing was necessary to ensure deduplication, commenters identified an obvious alternative to handing hospitals' claims data to drug manufacturers and their agents: using a neutral clearinghouse—operated by HRSA itself or by a conflict-free, government-contracted vendor—that would verify pricing and facilitate any reconciliation without a rebate. AHA Letter at 47–48 & n.49. The National Association of Chain Drug Stores, for example, proposed "[t]he agencies should consider the development of a centralized clearinghouse run by a conflict-free vendor," noting that "CMS has already stated it plans to develop and test such a model." HRSA-2026-0001-0042 at 2. The national pharmacy chain, Walgreens, agreed, explaining "[t]his approach is not without precedent" because "CMS has already proposed testing a clearinghouse-like model that the agency is calling a '340B repository.'" HRSA-2026-0001-1548 at 3. Commenters pointed to existing federal infrastructure that could do the job—the MTF and the Medicare Part D Claims Data 340B Repository that CMS established to identify Part D prescriptions dispensed under the 340B Program. AHA Letter at 47–48 & n.49; HRSA-2026-0001-1914 at 6. Either option would avoid foisting massive costs on covered entities.

120. **Existing Accountability Mechanisms Are Sufficient:** Commenters also reminded HRSA of Defendants' own admissions that a rebate mechanism is unnecessary for deduplication. Defendants told the First Circuit on December 30, 2025, that "[m]anufacturers have alternate

means to deduplicate discounts," and said the same to the D.C. Circuit on December 31, 2025, and February 10, 2026. AHA Letter at 40. Commenters also catalogued the mechanisms that already identify and prevent duplicate discounts, such as the Medicaid Exclusion File, state billing modifiers, HRSA's annual audits, manufacturer audits on reasonable cause, and statutory sanctions and removal—tools that assign oversight to HHS rather than to drug companies conducting their own opaque enforcement. HRSA-2026-0001-1914 at 13–18 (comment of AAMC); AHA Letter at 42–46.

121. **A True "Pilot":** Finally, commenters explained that even a genuine desire to "test" a rebate mechanism does not require a mandatory, nationwide program that includes covered entities of all kinds, sizes, and locations. The AHA proposed "a volunteer-only program that would allow covered entities to opt-in," urged HRSA to solicit volunteers before declaring a voluntary design unworkable, and identified an obvious way to fill the pool—"by requiring drug companies to cover *all* costs for those volunteers. If the drug companies believe that a rebate mechanism will pass HRSA's 'test,' then they should be eager to put their money where their mouths are." AHA Letter at 47; *see also* HRSA-2026-0001-1914 at 11 (AAMC comment, to same effect). Commenters also proposed narrowing any pilot to a defined subset of drugs, limiting it by covered-entity type, and phasing it in. *See, e.g.*, HRSA-2026-0001-0721 at 3–4 (Erlanger Health System in Hamilton County, Tennessee); HRSA-2026-0001-2382 at 10 (Indiana University Health); HRSA-2026-0001-2225 at 4 (Rural Wisconsin Health Cooperative in Sauk City, Wisconsin); HRSA-2026-0001-2319 at 6 (Pillr Health, a 340B TPA).

Rejecting HRSA's Balancing Approach/Choosing the Most Effective and Most Efficient Payment Mechanism from the Standpoint of the Covered Entities

122. Finally, in response to HRSA's comment in its RFI about "balancing" interests of drug companies against those of the covered entities, many commenters explained why this

balancing approach was wrong under the statute. Commenters specifically quoted the "standpoint" standard throughout the administrative record. *See, e.g.*, HRSA-2026-0001-1628 at 2 (Sun River Health, quoting "standpoint" standard from Committee Report); HRSA-2026-0001-2011 at 17–18 (HopeHealth, to same effect); HRSA-2026-0001-2268 at 24 (Wright Centers for Community Health and Graduate Medical Education, to same effect); HRSA-2026-0001-1929 at 13 (Colorado Coalition for the Homeless, to same effect). As AHA explained, HRSA "must give primacy to covered entities on this issue" under H.R. Rep. No. 102-384, pt. 2, at 16, and its "balance-the-interests-of-two-industries" approach is "the wrong lens through which to view this question." AHA Letter at 2–3, 7 (emphasis removed); *see also* HRSA-2026-0001-1965 at 21 (similar comment from National Association of Community Health Centers).

HRSA Ignored Additional Evidence About the True Labor Costs of a Rebate Program in June 2026 ICR

123. The 2,400-plus comments submitted in response to the RFI demonstrated that HRSA's first estimate of the program's burden—3.8 million hours of labor—was nowhere near the proposed Rebate Program's real cost. Yet HRSA ignored those comments and refused to budge from the initial cost estimates that it had calculated prior to even receiving comments.

124. On June 15, 2026, HRSA submitted its ICR to the Office of Information and Regulatory Affairs ("OIRA") and published a second notice raising the covered-entity population to 15,249 and the annual burden to 3,964,740 hours. Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, 91 Fed. Reg. 35,989, 35,991 (June 15, 2026) ("June ICR"); *see* OIRA Reference No. 202606-0906-001. HRSA updated the entity count but left its 5-hour-per-week assumption in place. 91 Fed. Reg. at 35,990–91. The agency priced the program's burden on covered entities at $523,345,680 per year, disregarding the

real-world data supplied over prior months showing a much higher price tag. ICR Supporting Statement at 11; *see* Notice, 91 Fed. Reg. at 48,893 & n.20.

125. The June ICR contains one cursory sentence to justify the 5-hour-per-week figure underpinning the entirety of the $523 million cost estimate:

> To estimate burden, HRSA applied a task-based methodology that considers the discrete activities required to complete a reporting cycle, including: (1) identifying and extracting eligible claims data; (2) formatting and validating data to meet manufacturer specifications; (3) submitting the data; (4) reconciling submissions and tracking rebate status; and (5) addressing errors, denials, or follow-up requests.

91 Fed. Reg. at 35,990. There is no further explanation of this "task-based methodology," what inputs HRSA used, or why HRSA chose not to disclose any of that underlying information. HRSA also claimed that it "evaluated the range of estimates provided by commenters . . . and normalized these inputs into a per-response estimate consistent with PRA requirements," *id.*, but HRSA's 5-hour-per-week calculation had been developed long *before* the agency had received comments and was never altered in response to those comments. *See* February ICR, 91 Fed. Reg. at 9,632–33.

126. The June ICR commenced a new comment period ending July 15, 2026. HRSA received more than 175 additional comments in the ICR docket.[6] Numerous letters identified specific defects in HRSA's 5-hour-per-week assumption. 340B Health, a nonprofit organization representing more than 1,600 covered entities, noted that HRSA's estimate "rests on unfounded and heavily contradicted assumptions" and "significantly understates" actual costs. Ex. 1 at 108 (emphasis removed). Parkview Health, an Indiana nonprofit health system, noted HRSA's estimate is "unsupported and is internally inconsistent with HRSA's own definition of 'burden,'" and "omits the largest components of its own stated burden definition." Ex. 1 at 17–18. Allegheny Health Network added that HRSA's median "reflects an assumption that Covered Entities will

[6] The documents cited in Exhibit 1 are comments in response to HRSA's ICRs.

simply extract and submit data, which is a gross oversimplification" that "ignores the full lifecycle of a rebate process." Ex. 1 at 121 (emphasis removed). Boston Medical Center Health System put it simply: "HRSA is underestimating the covered entities[']' administrative burden[.]" Ex. 1 at 128. Titusville Area Hospital, a critical access hospital in Titusville, Pennsylvania, similarly reported that HRSA's five-hour-per-week estimate "is significantly understated and does not reflect the operational realities faced by covered entities." Ex. 1 at 7.

127. One threshold defect was that the estimate's methodology was opaque, making the estimate itself impossible to substantiate. As one health system in Utica, New York explained, HRSA's estimate "is not . . . accompanied by sufficient explanation to permit meaningful public review." Ex. 1 at 147 (Mohawk Valley Health System). HRSA did not identify the assumptions underlying its calculation, including "the volume of expected claims transactions," frequency of data submissions and reconciliation events, staff time required to resolve disputes or denials, or the costs of implementing and maintaining compliant systems. *Id.* Similarly, Plaintiff AHA explained that HRSA "must explain . . . exactly how it came to its 5-hour 'median' figure based on the actual numerical estimates in the record, rather than broad conclusory assertions" and cannot rely on a median without explaining "why [it] is the best measure in the first place." Ex. 1 at 29.

128. Other commenters identified a separate incorrect premise underlying the estimate: HRSA's assertion that rebate submissions would be "materially similar" to claims that covered entities already submit to Medicare, Medicaid, and commercial payers. Commenters explained that, while "[c]laims to Medicare, Medicaid, and commercial plans adjudicate electronically at the point of sale through the pharmacy switch," a rebate mechanism instead requires "retrospective file assembly, transmission through a third-party platform, and a waiting period" while the covered entity determines whether "the data matched, the platform functioned, and the manufacturer" will

pay. Ex. 1 at 136 (Holton Community Hospital, a critical access hospital in Holton, Kansas); *see also* Ex. 1 at 172 (Minneola Healthcare, a critical access hospital in Minneola, Kansas, explaining that "ordinary payer claims clear through a pharmacy switch in real time at point of sale," whereas "[a] rebate model does not operate in real time, rather requires covered entities to stitch data together from the disparate sources" that hold the required data). Parkview Health likewise explained that rebate submissions have "no analog in routine payer billing," because covered entities must "determine, claim by claim, whether a dispense is 340B-eligible . . . and then push that eligibility determination . . . into a manufacturer-controlled platform in order to recover a discount the entity is already entitled to by statute." Ex. 1 at 19. And 340B Health noted another commenter's observation that hospital systems "do not currently operate through a single automated data feed that can easily generate the information required to support rebate submissions." Ex. 1 at 113 (citation and emphasis omitted).

129. Commenters also noted that HRSA's estimate "assumes the automation works every time." Ex. 1 at 136. But, as the Kansas Hospital Association explained, "third party vendor automation does not always work," citing "340B ESP glitches, TPA glitches, and concerns regarding Beacon," and that HRSA's estimate fails to account for the "manual clean up and reconciliation" required when those systems fail. Ex. 1 at 141.

130. In general, moreover, commenters noted that HRSA could now rely on months of actual operating experience under the MFP process rather than predictions, and that experience did not support HRSA's assumptions. Mohawk Valley Health System reported, "We now have six months of experience working with Beacon [the same vendor proposed in 2025 to administer the Rebate Program] . . . and have experienced significant setbacks and struggles. . . . These denials have resulted in financial losses for our organization that we have been unable to resolve going

back to the inception of this program in January 2026." Ex. 1 at 147–48. It estimated that MFP compliance "currently requires approximately, at a minimum, 15 hours per week." *Id*. MultiCare Health System rejected HRSA's assumption that "rebate administration functions are largely automated" because, "[b]ased on MultiCare's direct experience administering manufacturer rebate programs, [this] assumption is [not] accurate," and reported that a single disputed claim requires "an average of 40 minutes" of manual investigation. Ex. 1 at 151, 153.

131. Others flagged real-world experiences that signaled massive costs for covered entities that HRSA had not considered. Boston Medical Center Health System reported that "[r]eal-world rebate administration data" from "[e]arly manufacturer rebate programs" showed that "[a]pproximately 10% of claims eligible for payment were incorrectly rejected," "[a]pproximately 30% experienced payment delays," and "[a]pproximately 40% of submitted claims required manual intervention or experienced processing issues." Ex. 1 at 129. National Jewish Health, a "small specialty hospital" in Denver, Colorado, explained that its "direct experience with existing rebate processes, including those associated with the Medicare Drug Price Negotiation Program," made clear that "[t]he incremental staffing and system costs associated with a rebate model are estimated at no less than $824,045 annually, excluding financing costs related to delayed cash flow. In many years, this would eliminate our entire operating margin." Ex. 1 at 167–68; *see also* Ex. 1 at 159 (Wayne Community Health Centers, which serves central Utah, drew on "real-world experience administering the Medicare Maximum Fair Price (MFP) rebate program over the past six months" to demonstrate that "each of these activities requires substantially more time than estimated").

132. Commenters' experience with the vendor that HRSA chose to administer the Rebate Program—Second Sight Solutions, which operates the Beacon platform and the related

340B ESP platform—was especially damning, but the Notice says nothing about it. AHA noted that "Second Sight Solutions cannot handle the work it already has, so we can easily expect more bugs, delays, and incorrect denials in the future." AHA Letter at 17. The Greater New York Hospital Association surveyed its members about the Beacon platform and reported that *82% experienced problems with the platform's system functionality*. HRSA-2026-0001-2379 at 8. Dartmouth Health reported that drug companies, "through their agent Second Sight Solutions, have automatically denied rebate claims within the Platform simply because the pharmacy is owned by . . . a 340B covered entity," "essentially holding the rebates 'hostage' and requiring the pharmacy to 'float' the full undiscounted acquisition cost of the drug." HRSA-2026-0001-2419 at 5. University of Rochester Medicine described receiving a notice from Second Sight warning that its hospital "may lose access to 340B pricing at its contract pharmacy," only to recant—an experience it reported is "not uncommon" and "will undoubtedly increase exponentially" under a Beacon-administered rebate model, "making HRSA's staffing estimates entirely unrealistic." HRSA-2026-0001-2287 at 6–7. Freeman-Oak Hill Health System described "[o]ften being 'timed out' of the platform while in the process of submissions," and noted "the hold time for 'chat help' has often exceed[ed] thirty (30) minutes"; in its view, the Beacon "platform is not capable of handling the volume of work." HRSA-2026-0001-1638 at 5. Beauregard Health System reported that Beacon demanded forms from when the hospital "first opened" in "the early 1950's" that "do not exist." HRSA-2026-0001-1572 at 5. St. Luke's Health System explained Second Sight's deficiency notices "are frequently vague and fail to identify what information is allegedly missing or why," forcing its compliance team "into frustrating cycles of guesswork, resubmission, and repeated follow-up." HRSA-2026-0001-2141 at 5.[7]

[7] Many other commenters described the same problems. *See, e.g.*, HRSA-2026-0001-2382 at 8 (Indiana University Health describing "shifting and inconsistent data submission requirements, problematic Terms and Conditions that

133. Commenters also provided HRSA with data and individualized experience showing that the agency's disregard of back-end reconciliation labor results in dramatically underestimated costs. For example, the National Association of Community Health Centers ("NACHC") conducted a time study of data submission and back-end reconciliation tasks, drawing on time studies and time estimates from 24 community health centers. Depending on certain variables, such as claim classification and claim denial rates, NACHC estimated that the two reconciliation tasks alone (reconciling submissions and tracking rebate status, and addressing errors, denials, and follow-up requests) would average roughly 13 to 38 hours per week. Ex. 1 at 194–96.

134. Others offered facility-level data that corroborated these larger estimates. Henry Ford Health, a nonprofit academic health system in Detroit, Michigan, estimated 10 to 20 hours per week of rebate reconciliation and dispute management alone. Ex. 1 at 183. Southwest Mississippi Regional Medical Center, a hospital in McComb, Mississippi, estimated 8 to 12 hours per week of finance staff time for rebate tracking, reconciliation, and variance analysis alone, within a total estimated burden of 29 to 45 hours per week. Ex. 1 at 186; *see also* Ex. 1 at 178 (American Society of Health-System Pharmacists noting that "[r]econciliation and claims denial management add hours of weekly burden per covered entity. . . . The time associated with these activities matches or exceeds HRSA's entire burden estimate"). Commenters also identified important developments that post-dated the April comments. On July 14, 2026, CMS proposed in its calendar year 2027 Physician Fee Schedule rule to require only seven data elements to identify and exclude 340B claims from Medicare Part D, compared with the eleven or more HRSA would

raised significant data privacy and security concerns, and inadequate customer service"); HRSA-2026-0001-1627 at 4 (Trinity Health reporting that Beacon's "build was continuously changing and was a 'work in progress' even as the pilot was about to begin"); HRSA-2026-0001-2386 at 9 (Baptist Health South Florida reporting that Beacon claim approvals "routinely consume the full 14-day window, or longer, despite available data, which would critically delay fund access under a rebate model"); HRSA-2026-0001-1517 at 12 (NASTAD explaining that Second Sight's 340B ESP platform "caused extreme processing delays" lasting "frequently 12 weeks or more despite promised 10-business-day turnarounds").

demand, *see* 91 Fed. Reg. at 48,903, leading a commenter to observe that "it would be highly irregular for [CMS's] sister agency to require Covered Entities to disclose more or different data to a private, for-profit data aggregator." Ex. 1 at 148 (Mohawk Valley Health System); *see also* Ex. 1 at 209 (Beth Israel Lahey Health, a Massachusetts health system, to same effect); Ex. 1 at 214 (University of Arkansas for Medical Sciences, same); Ex. 1 at 220 (Pikeville Medical Center, Inc., a hospital in eastern Kentucky, same).

HRSA Announces the Same Rebate Program as Before, Just 2.5 Times Larger and With No Clear End Date

135. Just nineteen days after the June ICR comment period closed, Defendants published the Notice without responding to any of the ICR comments. On August 3, 2026, HRSA published the Notice, announcing "the availability of a revised 340B Rebate Model Pilot Program," effective immediately. 91 Fed. Reg. at 48,883. The Rebate Program's overarching structure is identical to the program this Court enjoined in December 2025. Covered entities are required to purchase covered drugs at WAC through their existing wholesaler accounts, submit claims-level data to manufacturers through manufacturer-selected IT platforms, and await a rebate calculated as WAC minus the 340B ceiling price on the day of dispense. *Id.* at 48,902–03.

136. The meaningful differences between this Rebate Program and the one this Court enjoined all run in one direction: more cost for safety-net providers. HRSA increased the eligible drugs from 10 to 25, all of which were selected from "among the 50 qualifying single source drugs with the highest [Medicare] total expenditures" over the previous twelve months. 42 U.S.C. § 1320f-1(d)(1)(A); *see id.* § 1320f-1(a)(1)–(2), (b)(2); 91 Fed. Reg. at 48,901–02. HRSA raised the number of eligible manufacturers from 10 to 13 and made participation mandatory for every covered entity in the country (roughly 650 more than the year before) while keeping the Program voluntary for manufacturers. 91 Fed. Reg. at 48,893, 48,900 n.32. This so-called "pilot" also has

no time limit. HRSA described this version as covering its "first year," does not commit to publishing its first evaluation until sixteen months after the Program begins, *id.* at 48,901, and sets no end date. *See id*. at 48,902 (plans run "for a minimum 1-year period").

137. HRSA claimed it "carefully reviewed and evaluated all comments," "conducted a systematic assessment of stakeholder input," and "considered both the substance and the evidentiary support of the comments received." *Id.* at 48,888. But the Notice belies those claims. HRSA's treatment of the cost evidence followed a repeating pattern. It vaguely acknowledged some covered entities' estimates, declared without analysis that they "rest on assumptions that do not align with the design of the Pilot," and dismissed them on a conclusory ground. *See, e.g.*, *id.* at 48,893. Meanwhile, HRSA consistently adopted the assertions of drug companies and their technology vendors as fact, without ever critically examining their lack of firsthand experience, basis for knowledge, or self-interest. *Id.* at 48,891, 48,893. HRSA also rejected obvious, less burdensome alternatives on conclusory, speculative, circular, or other illogical grounds. And it never offered an explanation about how the Rebate Program and the accompanying hundreds of millions of dollars in costs are the "most effective and most efficient" mechanism "from the standpoint of each type of 'covered entity'"—which they could not possibly be. *See id.* at 48,885 (quoting H.R. Rep. No. 102-384, pt. 2, at 16 (1992)).

HRSA Failed to Quantify Any Specific Benefit of a Rebate Program and Provided No Actual Remedy for Suspected Medicaid Duplicate Discounts

138. Prevention of duplicate discounts is the principal justification HRSA has offered for departing from more than thirty years of precedent and imposing, at minimum, more than half a billion dollars in annual costs on covered entities. *Id.* at 48,887. Yet HRSA has never attempted to quantify the amount of duplicate discounts (despite commenters pressing it to do so) or proven that duplicate discounts are a significant problem. The Notice even concedes that "there is no

federal estimate of the financial extent of duplicate discounts in 340B," *id*., and the only figures the Notice cites are the drug industry's.

139. The Notice says that "[m]anufacturer commenters stated in 2019, when the 340B program was less than half its current size," that Medicaid/340B duplicate discounts "amounted to as much as $1.5 billion annually." *Id.* HRSA offered no independent verification of this figure and did not interrogate the veracity of the number, despite acknowledging the figure came from the very drug companies that will profit from a rebate mechanism.[8] The Notice later asserts that "industry analyses" suggest duplicate discounts "may affect up to approximately 25% of 340B drug transactions, representing tens of billions of dollars annually," *id.* at 48,898, again attributed only to unnamed "commenters." HRSA quoted this number unquestioningly, did not note its speculative nature ("may affect"), and did not interrogate its accuracy or methodology. In fact, HRSA described the number in more neutral terms about "industry analyses," cloaking the fact that this 25% number comes directly from drug company comment letters. *See, e.g.*, HRSA-2026-0001-2220 at 3 (UCB, Inc., a global biopharmaceutical company, writing that "[a]ccording to one estimate, approximately 25% of 340B sales represent a duplicate discount"). Importantly, nowhere does the Notice acknowledge that the Rebate Program covers but a fraction of 340B drug sales—HRSA estimated that all 25 eligible drugs would only be 5.5% of total 340B drugs, 91 Fed. Reg. at 48,893—and would therefore yield but a fraction of recovered duplication costs under the best of circumstances.

[8] The drug company comment letters citing this $1.5 billion figure did not hide their self-interested source: a 2021 annual report by Kalderos, one of the vendors that has promoted a rebate mechanism and stands to benefit greatly from it. HRSA-2026-0001-2226 at 5 (J&J); HRSA-2026-0001-1667 at 4 (GSK); HRSA-2026-0001-1895 at 6, 9 (PhRMA).

140. In its uncritical adoption of these numbers, HRSA studiously ignored comments showing, based on both HHS's audits and covered entities' own audit findings, that duplicate discounts occur much less frequently than drug manufacturers assert and have declined over time. For example, the AHA explained that HRSA's own audit data shows that duplicate discounts at 340B hospitals have plummeted since 2018. *See* AHA Comment Letter on Application Process for the 340B Rebate Model Pilot Program (HRSA-2025-14998), at 8–12 (Aug. 27, 2025), cited in AHA Letter at 42 n.47 and incorporated by reference, *id.* at 1 n.1. As one organization representing covered entities explained, HRSA "applies that [duplicate discount] label [to] data-entry errors, not actual findings of duplicate discounts. HRSA does not determine whether such data entry errors actually resulted in manufacturers paying a rebate on 340B Medicaid claims. In fact, HRSA's routine audits of CEs demonstrate that 340B compliance and integrity is high, including data pertaining to fee-for-service (FFS) Medicaid claims." HRSA-2026-0001-2437 at 13 (comment of 340B Health); *see also* HRSA-2026-0001-2105 at 11 (comment from Henry Ford Health that "recent HRSA audits, including those conducted at Henry Ford Health, have consistently demonstrated that diversion and duplicate discounts are not widespread areas of noncompliance, confirming that the current model already protects program integrity").

141. Likewise, HRSA ignored comments from numerous hospitals reminding the agency that it did not identify duplicate discounts during HRSA's own audits of their facilities. For example, Corewell Health, a Michigan nonprofit health system, reported that "[w]e have never had duplicate discount findings in our audits," with all entities audited, some multiple times, and duplicate discount and diversion audits conducted monthly and annually. HRSA-2026-0001-2018 at 6. Henry Ford Health reported "clean audit records across all manufacturer and HRSA audits for at least the past 10 years." HRSA-2026-0001-2105 at 10. Community Memorial Hospital, a

12-bed nonprofit rural hospital in Sumner, Iowa, reported that quarterly external audits over the prior year "have shown duplicate discount transaction rates ranging from 0% to a maximum of only 0.08%," and "our most recent HRSA audit resulted in no findings." HRSA-2026-0001-1949 at 3. Rochester Regional Health, a nonprofit health system in Rochester, New York, stated that all its 340B hospitals "have been audited by HRSA without any duplicate discount findings." HRSA-2026-0001-2399 at 4; *see also* HRSA-2026-0001-2287 at 2 (University of Rochester Medicine reporting recent audits "yielded no findings or recommendations"); HRSA-2026-0001-1755 at 9 (Sharp HealthCare, a nonprofit health system in San Diego, California, reported that reviews for potential duplicate discounts "have confirmed no duplicate discounts"); HRSA-2026-0001-1413 at 6 (Columbia Memorial Hospital, an Oregon critical access hospital, reporting "no findings in recent HRSA or external audits and no identified duplicate discounts through our internal auditing processes"). As one commenter, UnityPoint Health, a nonprofit health system serving Iowa, Illinois, and Wisconsin, explained, "[a]ssertions from manufacturers suggesting widespread duplication lack factual support and do not reflect the compliance realities of covered entities like ours." HRSA-2026-0001-2283 at 10. HRSA did not grapple with these facts or even search its own audit records to quantify the amount of duplicate discounts in the 340B Program. It instead chose to rely exclusively on unsubstantiated figures supplied by drug companies in their comment letters, citing assertions from self-interested sources as fact.

142. Critically, Defendants' Rebate Program does not even authorize a remedy for the Medicaid duplicate discounts it purports to target. According to the Notice, drug companies are not permitted to deny rebates based on "concerns with diversion or Medicaid duplicate discounts[.]" 91 Fed. Reg. at 48,903. Thus, not only did HRSA fail to *estimate* how much duplicate discounting the Rebate Program would prevent, but the Rebate Program does nothing to *stop* it.

HRSA said that "a rebate model shifts the compliance framework from a reactive enforcement posture to a prospective approach in which verification and claims-level validation occur before the discount is provided." *Id*. at 48,901. But if drug companies cannot prospectively deny claims when they identify a duplicate discount, and instead if "a manufacturer [who] has concerns regarding Medicaid duplicate discounts . . . must raise those concerns directly with HRSA/OPA or utilize the 340B statutory mechanisms, such as audits and administrative dispute resolution," *id*. at 48,903, then the rebate mechanism yields no meaningful *incremental* benefits over the current "retrospective" enforcement system for suspected Medicaid duplicate discounts. Under the very terms of the Program, drug companies must resort to that "retrospective" system regardless. HRSA certainly has not quantified any incremental benefits from its assertedly "prospective" approach, since it did not analyze or explain just how many duplicate discounts its Rebate Program will reduce under this "require-data-submission-but-wait-for-an-audit" approach.

143. Defendants therefore seek to impose, at minimum, hundreds of millions of dollars in annual costs on safety-net providers to remedy a purported harm that Defendants have never measured, through a mechanism that, by the Notice's own terms, cannot remedy it. Agency action premised on an unmeasured problem and ineffectual solution is the paradigm of arbitrary and capricious decision-making.

The Notice Disregards Covered Entities' Data-Driven Estimates of Costs

144. The Notice makes no serious attempt to account for the total costs of the Rebate Program. It never engages data-driven estimates placing administrative costs above $1 billion annually for 340B hospitals. *See* AHA Letter at 11; *supra* ¶¶ 72, 85. In many circumstances, HRSA outright ignored or eliminated entire categories of costs that numerous commenters identified. And

where it addressed firsthand evidence of costs, it dismissed those comments based on conclusory assertions, unquestioning adoption of drug companies' say-so, and manifestly illogical reasoning.

145. **Data-Submission Labor Costs:** The Notice cabins the Program's costs to $523,345,680. 91 Fed. Reg. at 48,893 & n.20. That figure is simple arithmetic: 15,249 covered entities, times 52 weekly submissions, times 5 hours, times $132 per hour, equals $523,345,680. Every input except the entity count is unchanged from the February 2026 ICR, and the 5-hour input is simply HRSA's unexplained 2025 estimate of two hours multiplied by 2.5. But scaling one arbitrary number by another does not produce a reasonable estimate. It only results in a larger arbitrary number. Nothing in the record supplies any other provenance for the number, and Defendants have never offered data supporting one.

146. At most, the Notice offers the conclusory explanation, similar to HRSA's June ICR statement, that its labor estimate "reflects a reasonable median burden across this range of entities." June ICR, 91 Fed. Reg. at 35,990. But HRSA offered no factual support to justify that proposition. Again, the only apparent basis for the 5-hour-per-week number is HRSA's earlier 2-hour-per-week estimate multiplied by 2.5. But HRSA never said that the earlier 2-hour estimate was based on any "median" calculation of record evidence. And as the AHA explained in its response to the ICR, HRSA never identified "what below-5-hours-per-week estimates it received to offset the many above-5-hours-per-week [estimates] it received from many other hospitals and other covered entities. It should not be difficult, for example, for HRSA to produce a chart showing all of the below-5-hours-per-week estimates that would allow the agency's 5-hour estimate to sit at the median." Ex. 1 at 29; *see also id*. (calling on HRSA to "explain why it used a median estimate" at all when "[r]eliance on a median can obscure substantial variation among regulated entities and can materially understate aggregate burden when compliance costs are unevenly distributed.").

147. HRSA's 5-hour-per-week estimate is even more arbitrary because the record overwhelmingly demonstrated why the labor required for data submission alone exceeds five hours per week. For example, commenters explained in detail that the required data live in separate electronic systems, package sizes and NDC configurations conflict, units of measure require manual overrides, and required payer fields are often unavailable. *See supra* ¶¶ 79–80.

148. The Notice addresses none of these specifics. It states only that the Program relies on data that covered entities "already collect, maintain, and retain in the ordinary course," 91 Fed. Reg. at 48,893, and rests that assumption on a self-interested vendor's own representations about its 340B ESP platform, *id.* at 48,891–94, a platform that handles a small fraction of claims and "routinely produces a large number of false denials that require extensive staff review." AHA Letter at 15–17. HRSA likewise never answered the ICR commenters who explained why the agency's assumption that rebate submissions are "materially similar" to claims submitted to Medicare, Medicaid, and commercial payers is wrong. As commenters explained, *see supra* ¶¶ 128–29, those Medicare, Medicaid, and commercial claims are adjudicated electronically at the point of sale, whereas a rebate mechanism requires retrospective file assembly, transmission through a third-party platform, a waiting period, and manual cleanup whenever the automation fails. HRSA has never responded to the comments identifying these fundamental differences, yet the assertion about Medicare, Medicaid, and commercial payers—which one commenter aptly called "load-bearing," Ex. 1 at 19 (Parkview Health)—is repeated multiple times in the Notice. *See, e.g.*, 91 Fed. Reg. at 48,890, 48,894, 48,897.

149. **Reconciliation Costs:** The Notice, in connection with the June ICR, admits that its cost figure covers only the "administrative costs of *reporting* claims data," *id.* at 48,893 (emphasis added), and thus excludes every recurring cost that arises after data are submitted. This exclusion

includes back-end reconciliation, which the administrative record shows will likely be the single most costly component of the Program. *See supra* ¶¶ 80–83, 133–34 (detailing the extensive new costs associated with reconciliation); AHA Letter at 16. Mountain Park Health Center, a federally qualified health center in Arizona, explained: "Reconciliation and denial management are expected to be among the most resource-intensive aspects of the pilot. Current experience with manufacturer restriction platforms and other rebate programs demonstrates that claims frequently require investigation, correction, supporting documentation, resubmission, and follow-up communication." Ex. 1 at 229 (emphasis removed). Legacy Health agreed: "In truth, the increase in administrative burden for our covered entities would be driven by the need to implement rebate reconciliation workflows and not primarily in the data submissions themselves. Rebate reconciliation is labor-intensive work that requires resources." HRSA-2026-0001-1710 at 2–3.

150. HRSA's treatment of reconciliation contradicts itself. The Notice concedes that "most covered entities currently operate under an upfront discount model that reduces the need for post-purchase reconciliation," and that a rebate mechanism will impose new "post-purchase reconciliation" burdens. 91 Fed. Reg. at 48,892. Yet, in the next breath, HRSA said that covered entities "already perform extensive administrative functions under the 340B Program," including "reconciliation activities." *Id.* at 48,892–93. Reconciliation cannot be both a new burden that the Rebate Program creates and a familiar task that covered entities already perform. Because HRSA's reasoning "is internally inconsistent, it is arbitrary and capricious." *ANR Storage Co. v. FERC*, 904 F.3d 1020, 1028 (D.C. Cir. 2018).

151. Even if HRSA could explain this internal inconsistency, its justification for excluding reconciliation costs altogether is doubly flawed. *First*, HRSA is dead wrong that covered entities "already" perform "reconciliation activities." The current "upfront discount" mechanism

does not require any back-end payment reconciliation. Because discounts are currently provided at the point of sale, there is no subsequent rebate to reconcile. HRSA's apparent belief that it does is indefensible.[9] *Second*, HRSA's statement, yet again, ignores the *incremental* effects of its Rebate Program. Simply because covered entities "already" perform some functions does not justify new and costlier requirements.

152. HRSA also insisted, without detail, that existing technology can solve new reconciliation burdens. It insisted that "covered entities . . . routinely utilize TPAs and automated systems for . . . reconciliation activities." 91 Fed. Reg. at 48,893; *see id*. at 48,894 ("[C]ommenters note that established technologies, including automated claims processing, batch data submission, and TPAs, can be leveraged to facilitate rebate submission and reconciliation with minimal manual intervention once implemented."). But consistent with its practice throughout the Notice, HRSA did not identify which commenters asserted that existing technologies can perform this new reconciliation work. Nor did HRSA weigh those mystery sources against the many comments from covered entities saying that manual reconciliation will be necessary for certain tasks. Nor did HRSA identify the specific technology that can do this. Nor did it address, assuming this technology exists, how much incremental cost this new technology would add.

153. Plaintiffs have identified two comments regarding this purported reconciliation technology, both of which are from drug companies. HRSA-2026-0001-2374 at 29 (AbbVie Inc.); HRSA-2026-0001-2226 at 19 (J&J). One cites a Beacon FAQ, stating that the Beacon platform can perform reconciliation of rebates with claims. Notably, Second Sight Solutions, the company behind Beacon, does not cite this technology in its RFI or ICR comment letters. But even if that

[9] For this reason, HRSA's initial concession about the novelty of "post-purchase reconciliation" burdens understates the point. 91 Fed. Reg. at 48,892. As numerous commenters explained, an upfront discount does not merely "reduce" the need for post-purchase reconciliation. Under that mechanism, there is nothing to reconcile at all because the discount is applied at the point of purchase rather than days, weeks, or months later. *See supra* ¶¶ 80–83.

Beacon technology were available and reliable, that does not answer how hospitals can reconcile that information across their *internal* systems when rebates come back from drug companies. Put differently, Beacon reconciliation is not the same thing as reconciliation of a covered entity's own accounting and enterprise resource planning systems. Even if Beacon provides the claim-to-rebate linkage, the covered entity will still incur massive amounts of work (1) importing that information; (2) matching it against its internal records; (3) identifying delays, exceptions, denials, and reversals; (4) assigning payments to the proper internal cost center; and so on. So, if this Beacon product is what HRSA meant by "established technologies" (again, HRSA did not say so itself), then it is no answer to the vast amount of reconciliation work (manual and otherwise) that covered entities will have to do under a rebate mechanism, none of which they had to do under an upfront discount mechanism.

154. At bottom, numerous commenters explained the Rebate Program's unprecedented reconciliation burdens, but the Notice does not respond to that on-the-ground information. It instead excludes *the entire category* of reconciliation and therefore drastically undercounts the administrative costs its Rebate Program will impose.

155. **Staffing Costs:** Hundreds of commenters explained that they would have to hire new staff to comply with the Rebate Program. HRSA's conclusory response was that "any staffing impacts will generally be modest," that "in many cases, additional staffing will be unnecessary because they may be absorbed within existing operational structures or supported through existing third-party arrangements," and that the commenters "provided only estimates of anticipated staffing impacts." 91 Fed. Reg. at 48,891, 48,893. HRSA provided no evidentiary support for the notion that these staffing costs could be replaced by third-party arrangements, whereas dozens of commenters explained that they would need to add staff ***on top of*** these existing arrangements. *See*

Env't Health Tr. v. FCC, 9 F.4th 893, 910–11 (D.C. Cir. 2021) (faulting agency for disregarding a "record contain[ing] substantial information and material from, for example, the American Academy of Pediatrics, . . . medical associations, thousands of physicians and scientists from around the world, and hundreds of people who were themselves or who had loved ones suffering from the alleged effects of RF radiation" (citations omitted)); *Coinbase, Inc. v. SEC*, 126 F.4th 175, 199 (3d Cir. 2025) (discussing and applying the *Environmental Health Trust* holding that the agency failed to address the many "studies and comments provided by the petitioners"); *District of Columbia v. U.S. Dep't of Agric.*, 496 F. Supp. 3d 213, 256 (D.D.C. 2020) ("Notwithstanding the comments alerting the agency to the adverse disparate impact of the Final Rule on minorities, women and persons with disabilities, USDA essentially kicked this problem bucket down the proverbial road . . . . That excuse rings hollow given the many comments supported by 'empirical data.'"). HRSA's conclusory, data-free response to hundreds of individualized comments about incremental staffing costs was not reasoned decision-making.

156. **Vendor, Administrator, and Audit Costs:** HRSA assigned no value at all to increased TPA and vendor fees, IT support, or financial auditing—costs the administrative record places at $150,000 to more than $750,000 per hospital annually, or more than $400 million across 340B hospitals even at the low end. AHA Letter at 9–11. Much like its response to reconciliation costs, HRSA excluded these categories entirely. HRSA's only response, that covered entities "already perform extensive administrative functions," 91 Fed. Reg. at 48,892–93, again fails to acknowledge the *incremental* cost of a new payment mechanism. *E.g.*, *Am. Equity Inv. Life Ins. Co. v. SEC*, 613 F.3d 166, 177–79 (D.C. Cir. 2010) (agency analysis arbitrary and capricious where it failed to compare impact of program against existing "baseline level," *i.e.*, conduct an incremental analysis). Indeed, HRSA even ignored the fact that its own RFI asked for stakeholders

to comment on "incremental" costs, rendering its entire approach internally inconsistent. RFI, 91 Fed. Reg. at 7,289. But when HRSA finally completed its analysis, it somehow characterized these costs as "modest" and "likely to remain low," 91 Fed. Reg. at 48,893–94, in clear contravention of the "considerable evidence in conflict," *Int'l Union, United Mine Workers v. Mine Safety & Health Admin.*, 626 F.3d 84, 94 (D.C. Cir. 2010) (quoting *AT&T Wireless Servs., Inc. v. FCC*, 270 F.3d 959, 968 (D.C. Cir. 2001)).

157. **Start-Up Costs:** HRSA likewise wrote off the entire category of one-time start-up costs. The record quantified these costs at tens of thousands of dollars for the smallest facilities and three to four million dollars for large academic systems, all incurred before a single rebate claim is submitted. HRSA's response was that such costs "will be transitional." 91 Fed. Reg. at 48,893. That says nothing. Of course, "start-up" costs are "transitional"; they are incurred so that covered entities can start their transition to a new payment mechanism. By describing them as "transitional," HRSA admitted that these costs exist, but the agency brushed them aside for a manifestly irrational reason. These "transitional" start-up costs are significant, supported by overwhelming record evidence, and should have been included in HRSA's cost calculations.

158. **"Float" Costs:** The record established that (1) covered entities must advance the full WAC, with individual facilities quantifying advances from hundreds of thousands of dollars to more than $25 million; (2) some wholesalers will require multi-million-dollar prepay escrow accounts regardless of rebate timing; (3) wholesaler payment terms are frequently 5 or 7 days, not 10; (4) the accurate measure of float costs is when the clock starts, not when the 10-day deadline kicks in; (5) some drugs will sit on shelves for long stretches of time; (6) facilities operating on limited days of cash-on-hand would breach bond and debt covenants and divert limited liquid resources away from mission-critical commitments like payroll and patient care; and (7) the

analogous MFP process, run by the same drug companies, routinely pays in thirty to forty-five days rather than the required fourteen and denies or misclassifies between 30 and 75% of claims.

159. HRSA quantified none of this. Nor did it address this record evidence in any meaningful way. It instead wrote that it "expects the cash-flow impacts on covered entities to be minimal" because the 10-day payment requirement "is intended to precede the payment deadlines associated with standard wholesaler payment terms," so that payment to wholesalers, "*in most cases*, would occur after the rebate from the manufacturer is received." *Id.* at 48,895 (emphasis added). Its entire response to the float cost evidence is that "HRSA believes that the Pilot is unlikely to result in unstable cash flow for covered entities, as certain commenters have predicted," *id.* at 48,894, without explaining which specific self-interested commenters made those predictions or analyzing the strength of those commenters' evidence. Nor did it explain why the many covered entity commenters citing these varied float costs are wrong about *their own finances*. *But see AHA I*, 820 F. Supp. 3d at 45 ("[F]inancial forecasts about what costs the 340B entities can bear for a certain period [are] not predicated on any specialized or expert knowledge of the Agency.").

160. HRSA's float analysis rests entirely on two studies funded by the drug industry: a December 2, 2025, IQVIA white paper and a 2021 study by 3 Axis Advisors. *Id.* at 48,894–95 & nn.22–23. Neither was cited in the RFI or the ICRs, nor were they exposed for public comment.

161. The IQVIA paper was funded by the National Pharmaceutical Council, an industry group whose members include manufacturers that will participate in the Rebate Program. In addition, one of the IQVIA study's co-authors sits on the board of Kalderos, a rebate program platform vendor, and documents attached to Kalderos's comment letter reveal that this co-author represented the company during negotiations with HRSA in 2019 and 2020 when Kalderos tried to persuade the agency to approve a rebate mechanism. *See* HRSA-2026-0001-2447 (Kalderos

letter used co-author's name more than 100 times). HRSA never addressed this inherent bias. *E.g.*, *Cboe Futures Exch.*, 77 F.4th at 979 ("We have previously rejected an attempt by the SEC to substitute unquestioning reliance on a regulated entity's submissions for the reasoned analysis the APA requires. Such submissions, we explained, have little supporting value because they express the self-serving views of the regulated entity. If the SEC wanted to rely on MGEX's analyses to connect the grant of exemptive relief with the goal of promoting competition, it needed to critically review and adopt MGEX's submissions or perform its own comparable analysis." (cleaned up)).

162. Substantively, the IQVIA study does not support HRSA's "float cost" predictions. The cited December 2025 IQVIA study models only *interest* costs under an assumed 30-day wholesaler payment term. It does not address more serious costs like liquidity constraints, prepay deposits, credit limits, bond covenants, denied or delayed rebates, or lost COGS, prompt-pay, and sub-ceiling discounts. IQVIA's own comment letter in response to HRSA's RFI concedes that its studies measured only "financing (interest) costs" and that actual wholesaler payment terms "are not publicly available." HRSA-2026-0001-1688 at 2–3. Despite HRSA never having cited the IQVIA study in the RFI or indicating that it would rely so heavily on it when evaluating "float" costs, America's Essential Hospitals and others offered specific, forceful critiques of the study in their comments. *See* HRSA-2026-0001-1994 at 15–16 (America's Essential Hospitals). The Notice never acknowledges or refutes the critiques.

163. Worse still, HRSA relied on the December 2025 paper while ignoring the same authors' April 17, 2026 update, published more than three months before the Notice. That revised study undermines HRSA's conclusion. Critically, the April 2026 study shortened the assumed payment term to 10.5 days because it received information from stakeholders that real-world terms varied from 7 to 14 days. This shortened payment term produced materially higher interest-cost

figures. The revised study estimated $53.7 million in annual interest costs for *just the ten 2026 drugs*. HRSA did not include that $53.7 million in its cost-benefit analysis, however. Nor did it include any interest-cost estimates for all 25 drugs in the current Rebate Program.

164. The 3 Axis study on which HRSA relied is five years old, was commissioned by a similarly biased vendor (Kalderos), and examined only covered entities that use contract pharmacies. It rests on the assumption that a month's worth of inventory arrives on day one, and half the month's claims are dispensed that same day. But these assumptions are completely untethered from reality, where, for example, hospitals take delivery on recurring wholesaler schedules, not in a single-day shipment, and hospitals dispense prescriptions continuously across the month. Even Kalderos did not cite this study in its own comment letter (likely because of these faulty assumptions). *See* HRSA-2026-0001-2447 (Kalderos). HRSA nonetheless extended 3 Axis's conclusions to *every category* of covered entity, not just contract pharmacies, when it unreasonably concluded that "float" costs would be minimal.

165. The Notice also suggests that enforcement of the Rebate Program's purported guardrails will solve for "float costs." That is wrong. Such costs exist independent of delays or denials. To be sure, delays or denials *extend* the "float" cost associated with these interest-free loans to drug companies, but the covered entities will suffer "float" costs even if every drug company were to pay rebates on time for every claim.

166. The Rebate Program's skeletal (at best) enforcement regime is flawed in other ways. For example, the Program's specified enforcement regime is entirely discretionary based on whether HRSA decides to remove a drug company from the Program. The Notice says only that HRSA "could review a sample" of transactions and "initiate removal proceedings" if 5% or more of rebates were delayed or denied without justification. 91 Fed. Reg. at 48,895. For starters, that

approach presupposes the delays and erroneous denials that commenters predicted, yet provides no remedy for the "float" cost hospitals would be forced to carry in the meantime. Put differently, HRSA admitted that it will tolerate the improper delay or denial of tens of millions of dollars in statutory discounts so long as they remain *under* 5%, and at best, HRSA merely retains the option of acting when those delays and denials *exceed* 5%. Thus, despite effectively assuming that *some* delays and denials will occur (something it must do given the track record in the MFP Program that was described in the administrative record, *see supra* ¶¶ 99, 158), HRSA nowhere discussed them in its "float cost" or cash flow analysis. Nor did it account for how any as-yet undescribed manufacturer-removal proceedings would prolong existing delays and denials, extending covered entities' cash-flow and liquidity burdens even further.

167. To make matters worse, HRSA's purported enforcement backstop is of little value because, as of now, there is none.

a. HRSA merely retains the option of entirely removing drug companies from the Program if a 5% threshold of delays and denials is exceeded. But that is all HRSA said about enforcement. It provided no standard by which it will evaluate removal, for example. It provided no information about how a removal process would work. It did not identify a removal decisionmaker or even a person who will receive complaints from covered entities in the first instance.

b. HRSA's recent updates are no more reassuring. In recently published FAQs, HRSA addresses the question "[w]hat is the process to resolve issues or denials for 340B rebates under the Pilot?" by saying, "[e]ach manufacturer has committed to addressing these issues in good faith. Covered entities should work with the manufacturer's point(s) of contact and the rebate model IT

platform vendor to resolve disputes." *See* HRSA Rebate Program Webpage. The FAQ also suggests that HRSA will publish an online form to report complaints "[i]f the issue remains unresolved after good-faith efforts," although that "link [is] forthcoming." *Id.* Again, there is no identification of how or when these disputes will be settled or who will ultimately be responsible, indicating covered entities need to be prepared to wait months or years to recover rebates.

168. Defendants are—yet again—"fly[ing] the plane before they build it," *AHA I*, 820 F. Supp. 3d at 46–47, at least with respect to how they will prevent delays, denials, or other violations of Rebate Program guardrails. Until that plane is built, however, the absence of any real enforcement will impose cash flow, liquidity, and legal costs on covered entities that HRSA did not account for. Based on the administrative record, HRSA must reasonably assume that there will be at least *some added costs* related to delays and denials, just as there are in the MFP Program. HRSA cannot erase those costs from the equation simply because it promises more information about dispute resolution 30 days after the Program begins or provides the cold comfort that it "*could* initiate removal proceedings of that manufacturer from pilot participation for non-compliance" when denials exceed 5% of the total rebates. 91 Fed. Reg. at 48,895 (emphasis added). Those inevitable delays and denials will amount to substantial expenses that appear nowhere in HRSA's "float cost" analysis. When the record demonstrates that such delays and denials are currently occurring at double-digit percentages in the MFP Program, HRSA easily could have put a conservative dollar figure on those costs for its cost-benefit analysis. It did not.

169. **Deadlines to Submit Rebates and New Costs:** Defendants waved away "float" costs in part by pointing to three design features of the Rebate Program: unit-level rebate processing, which lets a covered entity seek a rebate as individual units are dispensed rather than

only after a full package is replenished; a fifteen-day transition grace period at the outset of the Pilot; and a 45-day window in which to submit rebate data after dispense. None of these eliminates the costs, and some clearly impose more costs upon safety-net facilities.

a. Unit-level processing, which allows a covered entity to submit for reimbursement before a whole drug package is exhausted, imposes more administrative costs upon a covered facility by forcing it to submit more claims for reimbursement. And requiring more claims on the front-end makes it more likely that hospitals will take longer to submit them; this will further delay the 10-day clock from starting, leading to the same cash flow concerns. Moreover, unit-level processing has no effect when units purchased at WAC price languish undispensed on the shelf, because no rebate is available until dispense. Given that safety-net hospitals and other providers must retain stocks of these important drugs, *supra* ¶¶ 95, 109, the "float cost" will persist as long as the drugs remain in inventory undispensed. This fact was raised in comments but ignored.

b. The fifteen-day transition grace period, for its part, caps relief at two unreplenished packages and runs for only fifteen days. 91 Fed. Reg. at 48,902. But because drugs can sit on the shelf for months, the grace period will lapse while the hospital is still carrying the full acquisition cost of drugs it has not dispensed and on which it cannot yet seek a rebate. It is likely that many more than two packages will be impacted, causing covered entities to lose significant amounts of 340B discounts.

c. Worst of all, the Notice requires all rebate requests to be submitted within 45 days of dispense. *Id*. Although HRSA framed this as a way to limit costs, commenters made clear it would *do the opposite*—by eliminating the ability to collect discounts where unavoidable circumstances delay submissions. Commenters made clear that, for various reasons, pharmacies "often need more than 45 days to dispense an entire package of a drug." HRSA-2026-0001-1619 at 5 (CommUnityCare Health Centers, a federally qualified health center in Austin, Texas). Every drug that lingers past the forty-fifth day could be a *permanent loss* of the 340B discount.

d. The 45-day design feature also ignores how claims will be processed. Beacon—the Second Sight Solutions platform through which approved drug companies will process rebate claims—runs every submission through a battery of "back-end validations," and a claim that fails any one of them is invalidated. Beacon, *Back-end Validations* (Dec. 19, 2025), https://support.beaconchannelmanagement.com/en/articles/13186516-back-end-validations. Beacon states that the 45-day deadline "does not reset to the date of the initial claim submission." *Id*. A hospital that submits on day 40 and is told its claim is invalid therefore has only five days to diagnose the problem, correct it, and resubmit—or *permanently forfeit* the statutory discount. Meanwhile, because the drug company's 10-day payment clock restarts only upon a "completed data submission," 91 Fed. Reg. at 48,903, every invalidation resets the drug company's clock while the covered entity's clock keeps running. Beacon may also invalidate claims reflecting "aberrant quantities," meaning

quantities that exceed a number of "expected thresholds" that Beacon does not disclose, that no public standard defines, and that a covered entity has no stated means to contest. Beacon, *Back-end Validations*. Nothing in the Notice authorizes these consequences, and HRSA's burden analysis says nothing about them.

170. **Loss of Cost-of-Goods-Sold, Prompt-Pay, Sub-Ceiling, and Other Discounts:** The Notice acknowledges the "loss of wholesaler prompt-pay or cost of goods discounts" only once, in its summary of what commenters wrote. 91 Fed. Reg. at 48,892. But HRSA never returned to that category of costs, even though the record identified and quantified them, *see supra* ¶¶ 104–05, and even though it is a permanent loss that cannot be recouped. Those undisputed prompt-pay, cost of goods, and other forgone discounts translate into millions of dollars that HRSA "unreasonably understated" in its cost-benefit analysis. *Chamber of Com. of the U.S.*, 820 F. Supp. 3d at 491 (citation omitted).

171. **Costs to Patients and Communities:** The record identified concrete threats to patients, including free or discounted drugs that will no longer be provided; patients transferred or turned away; service lines closed; hospitals carrying little or no inventory of drugs because WAC price will far exceed the 340B price; national pharmacy chains withdrawing from 340B pricing for covered drugs; clinic hours shortened or days closed; and more. The Notice recites some of these consequences but illogically concludes that HRSA "does not anticipate that the Pilot will materially impair covered entities' . . . ability to furnish services to patients." 91 Fed. Reg. at 48,899. Most glaringly, HRSA acknowledged comments stating that patients may have to "go elsewhere and potentially travel far distances to obtain necessary medications—a problem that is particularly acute for rural communities," *id.* at 48,898, but it offered no response and failed to

include those non-economic harms in its cost-benefit analysis. *See Council of Parent Att'ys & Advocs., Inc. v. DeVos*, 365 F. Supp. 3d 28, 53–54 (D.D.C. 2019) (cost analysis must account for "the cost of delay on children, parents, and society"); *Md. People's Couns. v. FERC*, 761 F.2d 768, 776 (D.C. Cir. 1985) (Scalia, J.) ("Even unquantified factors, however, cannot be dismissed without further inquiry where their impact is both evident and massively significant.").

172. Astonishingly, HRSA nowhere acknowledged that the $500-plus million in data-submission costs alone will lead to patient harms because spending that money on submitting claims data makes it unavailable for free or discounted drugs and other patient care. This silence is particularly inexplicable because this Court last year emphasized the "downstream effect[s]" of having to divert hundreds of millions of dollars in administrative expenses away from patient services. *AHA I*, 820 F. Supp. 3d at 46.

173. Although Defendants need not "weigh the burdens imposed on each and every entity that makes up the Public Health Service," "the fact that the 'pilot' program impacts them all calls for something more than casual indifference to localized impacts." *Id.* at 45 n.5. In this year's Rebate Program, however, Defendants showed the same "casual indifference." The Notice analyzes the impact on no particular community, region, or facility type, despite clear evidence setting forth those localized impacts. *See supra* ¶ 113. Likewise, HRSA did not address counties risking their only labor-and-delivery unit or inpatient behavioral-health beds, *see supra* ¶ 111, rural patients facing longer travel to obtain lifesaving care, *see supra* ¶ 112, or the many healthcare providers that wrote of the particular challenges the Rebate Program will pose for their own "localized" communities, *see supra* ¶ 113.

174. **Timing/Financial Environment:** The Notice ignores the financial environment into which HRSA is launching the Program. Multiple commenters asked HRSA to consider this

important problem when deciding whether to renew its Rebate Program for 2027. HRSA did not do so. The Notice does not mention the OBBBA, Medicaid reductions, coverage losses, increases in uncompensated care, tariffs, or dwindling hospital cash-on-hand or margins. Nor did HRSA defend its decision to move forward with a Rebate Program *at this time*, in the face of these cascading challenges. On that topic, like so many others, HRSA is silent.

The Notice Rejects Every Less Burdensome Alternative on Conclusory and Circular Grounds

175. Commenters presented numerous alternatives to the Rebate Program. And Defendants themselves told two federal courts of appeals that drug companies "have other options available to them" and "alternate means to deduplicate discounts." AHA Letter at 40 (citation omitted); *see AHA II*, 164 F.4th at 37 ("[T]he federal government has indicated that manufacturers have alternative methods to address the previously described duplication issue."). Yet Defendants rejected every cheaper, less burdensome, and equally viable alternative.

176. Defendants dismissed a neutral clearinghouse as "not explicitly authorized under the 340B statute." 91 Fed. Reg. at 48,900. This was the extent of HRSA's legal analysis. It did not (1) explain its legal reasoning despite commenters' express requests to provide it or (2) explain why CMS may operate a comparable "340B repository" while HRSA supposedly cannot. *See* AHA Letter at 48 ("HHS has not, however, publicly presented its legal reasoning, and there is serious reason to question it."); *id.* at 47–49 & n.49; HRSA-2026-0001-1914 at 6, 16–17 (comment of AAMC, to same effect).

177. HRSA's only other justification for a rebate mechanism instead of a clearinghouse is based on rank speculation. It claimed that a rebate mechanism is superior to a clearinghouse because, "unlike a clearinghouse, a rebate model by its very nature incentivizes covered entity compliance as a prerequisite to receiving 340B discounts." 91 Fed. Reg. at 48,900; *see id.*

(describing a clearinghouse as "in substance, an enhanced claims modifier system operating under a different name," and rejecting it because, "[l]ike claims modifiers, a clearinghouse would depend on covered entities to accurately and completely report 340B transaction data to the intermediary, and on the intermediary to relay that information to manufacturers and payers in a timely and standardized manner"). But HRSA provided no actual evidence that covered entities will not comply with an independent clearinghouse, nor did it acknowledge that CMS has proposed to make its clearinghouse mandatory.

178. In fact, HRSA's discussion of these purported "incentives" is cut-and-pasted, with only a single word change, from a comment letter submitted by the Pharmaceutical Research and Manufacturers of America ("PhRMA"). *Compare* 91 Fed. Reg. at 48,900 ("As manufacturer commenters have observed, unlike a clearinghouse, a rebate model by its very nature incentivizes covered entity compliance as a prerequisite to receiving 340B discounts."), *with* HRSA-2026-0001-1895 at 14 (comment letter from PhRMA, writing that "[u]nlike a clearinghouse, a rebate model, by its very nature, incentivizes covered entity compliance as a precursor to receiving the 340B discount."). HRSA did not critically examine PhRMA's speculation or ask covered entities themselves whether they would participate in a clearinghouse. It simply reproduced PhRMA's statement verbatim to justify its speculation about incentives and, on that basis, dismissed a cheaper, viable clearinghouse alternative that HHS itself recently implemented (and is considering making mandatory).

179. Had HRSA critically assessed PhRMA's speculation about incentives, it would have realized that speculation was wrong. If the choice is between an independent clearinghouse and this costly Rebate Program, the incentives strongly favor participating in a clearinghouse. HRSA's speculation about "incentives" is especially problematic given the administrative record.

Numerous covered entities (and the organizations that represent them) affirmatively suggested an independent clearinghouse as an alternative to the Rebate Program. *See, e.g.*, AHA Letter at 46–49; HRSA-2026-0001-2391 at 2 (American Society of Health-System Pharmacists); HRSA-2026-0001-1965 at 32–34 (National Association of Community Health Centers); HRSA-2026-0001-2139 at 16 (UNC Health); HRSA-2026-0001-2382 at 10 (Indiana University Health); HRSA-2026-0001-2262 at 3 (Washington State Hospital Association); HRSA-2026-0001-2274 at 5 (Greater Lawrence Family Health Center); HRSA-2026-0001-1886 at 1 (University of Iowa Health Care); HRSA-2026-0001-2246 at 3 (Piggott Health System); *see also* HRSA-2026-0001-2415 at 4 (Rush University System for Health, urging that any platform used under a rebate model be "operated by a truly neutral third-party clearinghouse"). Although covered entities suggested that alternative, HRSA did not explain why it would not follow through on this. Thus, HRSA cannot reasonably dismiss an independent clearinghouse by simply reproducing verbatim PhRMA's uninformed speculation about "incentives."[10]

180. HRSA's remaining justification for rejecting alternatives is circular. HRSA rejected other alternatives because "the 340B discount is provided upfront and compliance is assessed only retrospectively," thus any alternatives that preserve the upfront mechanism "would not inform whether rebates are an efficient means of effectuating the 340B ceiling price, . . . fail[ing] to advance the central purpose of the Pilot." 91 Fed. Reg. at 48,890, 48,900–01. In other words, any alternatives to a Rebate Program are inadequate because they are not a Rebate Program. That is

[10] HRSA failed to address drug companies' incentives for participating in the Rebate Program. Because participation is voluntary for manufacturers, each one may choose which eligible drugs to include. On information and belief, multiple manufacturers withheld an eligible drug for fear of losing market share to competing products outside the Rebate Program, even though at least one drug company included a different eligible drug. If duplicate discounts were as costly as drug companies claim, manufacturers would subject all of their eligible drugs to a rebate mechanism. That they did not confirms that the duplicate discount problem is overstated and that drug companies embrace a rebate mechanism only where it serves their competitive interests.

entirely self-justifying. An agency cannot define its objective as the action itself and then reject every alternative for failing to be that action.

181. HRSA's objective must be defined independently from the Program itself. Here, HRSA identified that objective as reducing duplicate discounts. But its circular justification (testing the Program for testing's sake) does nothing to explain why the proposed alternatives would not achieve that independently defined objective. For example, HRSA's rejection of "more intensive audits and oversight" consists of the tautological assertion that such tools are "inherently reactive," *id*. at 48,899, 48,901, which is another way of saying they are not rebates.

182. Finally, HRSA's rejection of a voluntary or smaller pilot on "selection bias" grounds is speculative and conclusory. *Id.* HRSA never considered whether a representative pool would, in fact, volunteer. It never addressed whether a representative pool could be incentivized to participate, including by having drug companies pay the costs for the volunteers. And it did not explain why mere statistical tidiness justifies conscripting *all* 15,249 covered entities.

The Notice Does Not Appropriately Assess Reliance Interests

183. The Notice's treatment of reliance interests also violates controlling law. In the prior litigation, Defendants conceded that covered entities' "decades of industry reliance" on the upfront discount mechanism was "significant." *AHA I*, 820 F. Supp. 3d at 42. Both this Court and the First Circuit concluded that HRSA was required to weigh that reliance interest. *Id.* at 43; *AHA II*, 164 F.4th at 33. But now, rather than comply with this obligation, HRSA simply zeroed out the reliance interests it once deemed significant. HRSA declared that it "does not agree that exclusive reliance on an upfront discount model is reasonable," because the statute authorizes 340B pricing via rebate, and "covered entities' reliance interests . . . do not outweigh the significant benefits of proceeding with the Pilot." 91 Fed. Reg. at 48,888–89.

184. That the statute offers HHS discretion whether to approve a rebate mechanism does not erase decades of reliance. The existence of an unexercised statutory option has no bearing on the reliance that an agency's own conduct engendered. Reasonable reliance is measured by what the agency did, not by the mere existence of discretion the agency did not invoke for thirty-three years. Covered entities' reliance interests were established by unbroken agency practice, by HRSA's own 1994 and 1998 pronouncements, and by the agency's court filings defending upfront discounts as recently as 2025, *see supra* ¶¶ 50–51, 56, none of which the Notice confronts. Referring to a heretofore-unexercised statutory provision without accounting for *what caused* covered entity reliance does not reflect appropriate consideration of reliance interests. *See, e.g.*, *Regents*, 591 U.S. at 30–33.

185. The Notice's alternative finding—that reliance interests "do not outweigh the significant benefits of proceeding with the Pilot," 91 Fed. Reg. at 48,889—also lacks merit, but for a more fundamental reason. As noted above, *supra* ¶¶ 138–41, HRSA does not even know the scale of the duplicate discount problem the Rebate Program is meant to address, or whether duplicate discounting occurs at any material rate at all. HRSA blindly credited drug-industry estimates it never tested, while disregarding HHS's own audit findings to the contrary. An agency that cannot say how large a problem is cannot conclude that addressing it outweighs anything, least of all thirty-three years of reliance interests and the imposition of hundreds of millions of dollars in new costs that result from that "significant" reliance. *AHA I*, 820 F. Supp. 3d at 42.

The Notice Does Not Grapple with Important Aspects of the Problem

186. The Notice also leaves unaddressed several significant problems that commenters presented. Three examples stand out:

a. HRSA failed to address the financial environment in which it would start the new Rebate Program. Multiple commenters cited these financial headwinds, yet HRSA ignored them altogether. *See supra* ¶¶ 114, 174. At no point did it address or justify why the Rebate Program is needed *now*.

b. HRSA provided scant details concerning an operational dispute-resolution mechanism. *See supra* ¶¶ 166–68. The Notice and other disclosures identify no objective standard for when to enforce, name no ultimate decisionmaker, prescribe no procedure, and set no deadline for action or compliance, even though commenters warned that, absent HRSA's active involvement, "there is little hope that disputes will actually get resolved," and that drug companies would be affirmatively incentivized to delay and deny. AHA Letter at 51.

c. The Notice does not address the operational and structural problems commenters documented with the third-party vendor platforms that would administer the Rebate Program. Commenters report, based on firsthand experience, that they "encountered serious problems" with the Beacon platform, "including issues with terms and conditions, shifting data requirements, and inadequate customer service." HRSA-2026-0001-0023 at 4 (Iroquois Healthcare Association); *see also* HRSA-2026-0001-0044 at 4 (MyMichigan Health, a nonprofit health system with 340B hospitals, reporting similar issues); HRSA-2026-0001-1394 at 12 (Clinica Family Health & Wellness, a federally qualified health center in Colorado, stating that its "current experience in working with [Beacon] has been nothing short of flawed and frustrating"); *accord* AHA Letter at 25 (AHA, noting that Second Sight's

340B ESP platform "often experiences problems, including false denials and delays").

HRSA Rejected All Firsthand Information About Its Cost Estimate Without Explaining Its Own Calculation

187. Comments on the June ICR, the source of the $523,345,680 figure, were due July 15, 2026. While over 250 comments were submitted during that comment period, HRSA issued the 2026 Notice on August 3, 2026, without addressing those comments and without revising its estimate. 91 Fed. Reg. at 48,893–94. Instead, HRSA responded to the ICR comments on August 4, 2026, the day after the Notice was published, in a revised supporting statement for the ICR. Supporting Statement. OMB concluded its review and approved the collection without change the following day, August 5, 2026. *See* OMB, ICR History, OMB Control No. 0906-0117.

188. The Supporting Statement adheres to the 5-hour-per-week calculation of costs for covered entities first calculated in February 2026, without providing any more details or explanation as to the methodology behind that calculation and without addressing the comments noting that the assumption was unsupported and unexplained. *See* Supporting Statement at 11. The Supporting Statement changes the pharmacist wage rate ($132 to $135.50), such that HRSA's own total reached $537,222,270 to submit claims, nearly $14 million more than the $523,345,680 figure the Notice cited the day before. *Compare* Supporting Statement at 11 ($537,222,270 quoted in the Supporting Statement) *with* 91 Fed. Reg. at 48,893 & n.20 ($523,345,680 quoted in the Notice).

189. The Supporting Statement also changes its description of the 5-hour-per-week calculation from the "median" burden upon covered entities to an "average" burden, without acknowledging that important change. *Compare* Supporting Statement at 11 ("average burden") *with* June ICR, 91 Fed. Reg. at 35,990 ("median burden"). An average and a median are different things. *E.g.*, *Ferguson v. Allen*, 2020 WL 2572176, at *9 n.57 (N.D. Ala. May 21, 2020) ("The

terms 'average,' 'mean,' and 'median' can be confusing. The average and arithmetic mean are calculated by adding together all numerical values in a data set, and dividing that sum by the number of terms in the set. . . . In contrast, the median is the middle numerical value in an ordered set of data." (emphasis removed)); *see also S. Cal. Edison Co. v. FERC*, 717 F.3d 177, 182 (D.C. Cir. 2013); *Can. Ass'n of Petroleum Producers v. FERC*, 254 F.3d 289, 298–99 (D.C. Cir. 2001). But the Supporting Statement offers no explanation for those inconsistencies. Nor does it describe the more general methodology HRSA continued to use throughout this process to calculate labor costs for data submission.[11]

190. The remainder of the Supporting Statement confirms that HRSA did not meaningfully consider the comments. HRSA acknowledged that it received 180 comments in response to the February ICR and 263 in response to the June ICR. *Id.* at 6. It also acknowledged that the comments "primarily addressed the estimated paperwork burden," and that "[n]umerous commenters submitted organization-specific burden estimates that substantially exceeded HRSA's estimate." Supporting Statement at 6–7. HRSA then disregarded those estimates in a single paragraph by asserting that "many estimates assumed reporting requirements that will not be included in [the] Pilot," *id.* at 7, without (1) identifying a single example of such a misassumption, (2) acknowledging the many comments that did not make such assumptions and instead calculated burden based on the correct reporting and other programmatic requirements, or (3) providing an

[11] For example, when HRSA was relying on a median figure to determine its 5-hour-per-week labor estimate, the AHA urged HRSA to provide "what below-5-hours-per-week estimates it received to offset the many above-5-hours-per-week it received from many other hospitals and other covered entities. It should not be difficult, for example, for HRSA to produce a chart showing all of the below-5-hours-per-week estimates that would allow the agency's 5-hour estimate to sit at the median." Ex. 1 at 29. HRSA never provided that below-5-hour list. Nor did it provide any list or other data that would support its new claim that the 5-hour-per-week figure was the "average" of labor hours submitted.

additional period for commenters to correct any purported misassumptions. The Supporting Statement merely asserts in conclusory terms that

> HRSA continues to believe that the estimated burden reasonably reflects the average paperwork burden associated with the information collection, across more than 15,000 covered entities, while recognizing that actual burden may vary among respondents, and is a modest compliance cost for a program that has reached $100 billion in annual purchases in 2025. HRSA will continue to evaluate implementation experience during the Pilot to inform future burden estimates.

Id. at 7; *see* 91 Fed. Reg. at 48,893 (referring to and citing the ICR for $523,345,680 data-submission cost calculation).

191. The Supporting Statement's response on reconciliation costs, the category many commenters identified as the single largest omission from the estimate, is non-responsive. HRSA acknowledged that "[n]umerous commenters cited operational experience under existing manufacturer reporting platforms and the MDPNP as evidence that reconciliation and denial management represent a substantial portion of the overall burden." Supporting Statement at 8. But rather than estimate that burden and add it to the ICR, HRSA answered that manufacturers will be required to provide "real-time rebate status reporting" and "document the basis for rebate denials," and asserted that these features would "reduc[e] unnecessary administrative burden associated with reconciliation and dispute resolution." *Id.* HRSA still offered no recognition that it understood what work reconciliation would require, despite extensive comments explaining it to the agency. *See supra* ¶¶ 80–83, 133–34. HRSA also conflated "real-time rebate status reporting" within the third-party vendor's system with the work that covered entities will need to do on the back end to ensure rebated payments get to the right place. *See supra* ¶ 81. And HRSA did not provide any estimate of the "reduc[ed]" hours that reconciliation would entail—with or without those features. It simply left the reconciliation burden at zero.

192. The Supporting Statement likewise declines to calculate or account for start-up and training costs, even though the definition of "burden" listed in the document's definition section includes time "to train personnel." Supporting Statement at 10. HRSA never explained why it excluded them.

193. The Supporting Statement omits technology and system costs, even though its own definition of "burden" includes time "to develop, acquire, install, and utilize technology and systems." *Id.* HRSA never explained why it excluded them.

194. Thus, despite the thousands of comments submitted by hundreds of safety-net hospitals and other covered entities about the costs and impact the Rebate Program would have on rural hospitals and patient care, HRSA remained steadfastly stuck on the same labor-hour estimate that it fashioned before it received the comments. It avoided serious consideration of the mountains of firsthand cost information it received from covered entities, ignored entire categories of costs it admitted would be borne by rural and other safety-net hospitals, and offered cursory responses to points it acknowledged cast serious doubt about its own estimation of impact.

HRSA Approved Ten Drug Companies' Rebate Plans

195. On October 1, 2026, HRSA announced that it had approved rebate plans from ten drug companies—AbbVie, Amgen, Astellas, AstraZeneca, Bristol Myers Squibb, Boehringer Ingelheim, GlaxoSmithKline, Merck, Pfizer, and Teva—covering 18 drugs. These included widely prescribed anticoagulant, diabetes, oncology, respiratory, and immunology medications. *See* HRSA Rebate Program Webpage. Each approved plan takes effect January 1, 2027.

196. Neither the approvals nor the accompanying materials update the Notice's cost-benefit analysis. HRSA did not revise its 5-hour-per-week labor estimate, did not account for the reconciliation, start-up, or float costs that commenters documented, and did not quantify any

benefit. It did not acknowledge the updated IQVIA study, the financial environment facing covered entities, or the "standpoint" standard that Congress instructed HRSA to apply. HRSA simply announced that "[e]ach plan met the requirements outlined in the Federal Register Notice," without further details. *Id.* Every defect in the Notice therefore remains. And, as described below, the approved plans and HRSA's new guidance add to the Program's costs by eroding the few guardrails the Notice purported to erect.

197. The approved plans confirm the massive costs that commenters described and HRSA ignored. Every approved plan designates the same third-party platform—the "Beacon Rebate Model Platform," operated by Second Sight Solutions—as the sole channel through which covered entities must register, submit claims data, and receive rebates. HRSA, in approving ten plans that run exclusively through Beacon, did not acknowledge, let alone respond to, the many comments criticizing Second Sight Solutions' existing 340B ESP platform for false denials and manual reconciliation work. *See supra* ¶¶ 83, 129, 132, 186(c).

198. Although HRSA assured covered entities that the drug company plans would adhere to a prescribed set of common standards, 91 Fed. Reg. at 48,902, the approved plans in fact have significant differences—and thereby impose additional costs. For example, several plans adopt a "first-to-file" rule under which, if more than one covered entity submits a claim for the same dispense, only the first conforming submission is honored and all others are denied—regardless of which entity actually holds the valid 340B claim. In addition, the plans do not even agree on when the Notice's 10-day payment clock starts—some run it from submission, others only from a "complete" and "validated" submission, with no stated limit on how long "validation" may take. And some plans exclude federal holidays from the 10-day clock, even though the Notice limited the period to calendar days. Each of these variations adds confusion and creates new

administrative work, potential disputes, and potential denials—none of which HRSA considered when it issued the Notice.

199. Several plans also incorporate the drug companies' existing contract-pharmacy restrictions as conditions of payment. For example, Merck's plan limits rebate eligibility to transactions that comply with Merck's "340B Program Integrity Initiative" and declares non-compliant contract-pharmacy claims "ineligible for rebates." Bristol Myers Squibb requires that a dispensing pharmacy be "eligible under BMS's 340B program obligations and contract pharmacy policy." Amgen's Beacon validations test each pharmacy against "the manufacturer's contract pharmacy policy." Those conditions contravene the Notice's directive that plans "must ensure that 340B rebates are not denied based on eligibility or compliance concerns," *id.* at 48,903, and HRSA's own statement that rebates "may not be denied for covered-entity eligibility," HRSA Rebate Program Webpage.[12] Beacon confirms the point: it describes its back-end validations as enforcing not only "HRSA['s] 340B program requirements" but also, separately, "pharmaceutical manufacturer conditions." Beacon, *Data Validations Overview* (Dec. 19, 2025), https://support.beaconchannelmanagement.com/en/articles/13186016-data-validations-overview. The platform through which rebates will flow thus enforces exactly the compliance conditions the Notice says cannot be grounds for denial. What's more, company contract pharmacy policies differ greatly, further adding to the variation across manufacturers that the Notice promised would not exist.

[12] They also create a collision with the laws of Maine and other States—including Arkansas and North Dakota, where Plaintiffs' members operate—that prohibit drug companies from restricting 340B contract-pharmacy arrangements. Courts, including in Maine, have upheld these laws. *E.g.*, *AstraZeneca Pharms. LP v. Harris*, 2026 LX 544820, at *38 (E.D. Ark. Sept. 29, 2026); *AstraZeneca Pharms. LP v. Frey*, 2026 WL 2145194, at *1 (D. Me. July 27, 2026). But whether and how covered entities in those States will be rebated for contract-pharmacy dispenses is left entirely unaddressed. More generally, each company has a different contract pharmacy policy, so like other aspects of the approvals, this introduces significant variations across manufacturer requirements that will increase administrative complexity and costs.

200. HRSA's approval of Beacon also underscores a flaw in its Notice. In minimizing the costs of its Rebate Program, HRSA highlights a commenter who stated that covered entities "are already using its platform to collect claims data, that thousands of covered entities have registered on the platform, and that covered entities have reported fully onboarding in less than ten minutes through a self-service process." 91 Fed. Reg. at 48,892. That commenter was Kalderos, not Second Sight Solutions, which operates the chosen platform. HRSA-2026-0001-2447 at 6 ("Kalderos' Truzo platform further reduces the administrative steps required to effectively implement a 340B rebate model. The platform is designed to be fully self-service and many covered entities have reported fully onboarding in less than 10 minutes."). In reality, joining and operating under *Second Sight's Beacon platform* is costly and burdensome. To take just one example, AbbVie's plan explains that signing up for Beacon requires a covered entity to complete Beacon's Know Your Business process, provide corporate documentation such as articles of incorporation and an IRS CP 575 letter, provide bank-account information and a bank letter, and undergo a penny-test/microdeposit verification process. HRSA nowhere considers this start-up work in its cost-benefit analysis.

201. Alongside the approvals, HRSA posted a new set of "Frequently Asked Questions" on the same webpage. HRSA Rebate Program Webpage. Far from curing the defects described above, the FAQs confirm them.

a. *First*, the FAQs again recite the "pilot" label while promising only a "Final Evaluation" to be published by April 30, 2028—sixteen months after the Program takes effect. *Id.* HRSA does not say whether the Program will continue to operate between the end of its first year and publication of the Evaluation. But if it does, that additional period would add hundreds of millions of dollars

of costs on top of the billion-plus-dollar costs that will be borne by safety-net hospitals. Nor does the FAQ explain exactly what the April 30, 2028 evaluation will measure, or what, if anything, it could change. It vaguely speaks of "quantitative measures" and "qualitative feedback" but provides no meaningful indication of what constitutes a successful test.

b. *Second*, the FAQs state that "[m]anufacturers may choose to include all covered entity types as part of their rebate models or provide exceptions to certain covered entities," and that "[t]hat information will be included in the respective manufacturers' approved plan." *Id*. That statement cannot be squared with the Notice's statement that a "narrowly tailored . . . participant pool . . . would constrain the agency's ability to assess how a rebate model functions across the broader 340B environment." 91 Fed. Reg. at 48,901.[13]

c. *Third*, HRSA also now acknowledges what the Notice (but not the August Supporting Statement) ignored: that reconciliation is real work. The FAQs state that covered entities "should have access to the real-time rebate status of a claim, so they can easily reconcile claims submitted with rebates paid." HRSA Rebate Program Webpage. But access to a vendor's status screen is not reconciliation. Because claims are de-identified before they reach Beacon, a covered entity must use a vendor-assigned "unique ID" to link each Beacon record back to the identifiable record in its own systems, match the two, and

[13] The Notice also rejected the suggestion that HRSA conduct a pilot with fewer or less popular drugs, stating that "further limiting the number of drugs included in the Pilot would reduce the agency's ability to evaluate rebate administration and duplicate discount prevention in the context of the MDPNP and other overlapping pricing programs." 91 Fed. Reg. 48,901. But HRSA's October 1 approvals undermine its own rationale. HRSA ultimately approved applications for only 18 drugs (and only 10 of 13 drug companies), but it never tried to reconcile that decision with its prior reason for rejecting a less burdensome alternative.

then pursue every claim that is denied, delayed, or underpaid. Likewise, this does not capture the burdensome reconciliation work that must be done within a covered entity's internal systems to ensure that rebates get to where they belong.

Thousands of Hospitals Will Be Immediately and Irreparably Harmed by the 340B Rebate Program

202. HRSA's repeated violations of basic administrative law requirements will irreparably harm thousands of covered entities, especially the most vulnerable safety-net hospitals.

203. Beginning January 1, 2027, covered entities collectively will be required to spend at least $537,222,270 every year in new administrative costs, a figure Defendants themselves calculated, and one that by their own description covers *only* the cost of submitting claims data. Supporting Statement at 11; *see also* 91 Fed. Reg. at 48,893. Those costs are unrecoverable; covered entities cannot seek damages from the federal government to recoup them.

204. Nor are those costs a distant prospect. Months before the Program takes effect, covered entities are already spending to hire staff and build systems so that they can comply, exactly as they did before the 2025 Program was enjoined. Even the smallest safety-net hospitals must hire new employees or pull existing ones away from other work to meet the Rebate Program's administrative demands. Plaintiff Nathan Littauer Hospital will need to hire at least one additional full-time employee. Plaintiff EMMC estimates roughly 80 additional staff hours each week just to oversee and correct its third-party administrator's reports, and will need two additional analysts at approximately $123,000 a year in total compensation. Plaintiff Unity Medical Center will need the equivalent of one to two specialized full-time employees. Plaintiff Dallas County Medical Center, which administers its entire 340B program with a single employee, will, at minimum, have to divert a former pharmacy technician from community education and outreach.

205. Vendors are raising their prices, too. EMMC's third-party administrator has quoted an additional $1,000 per month for pharmacy claims submission alone. Nathan Littauer anticipates approximately $63,000 in additional annual third-party administrator, compliance-vendor, and consulting fees. After making those commitments, EMMC, Nathan Littauer, and Unity Medical Center *still* do not believe they can be ready to implement the Rebate Program by January 1, 2027.

206. The Rebate Program also forces covered entities to pay the full wholesale acquisition cost of covered drugs upfront and then wait to be repaid. For hospitals already in the red, the sums are staggering. EMMC must advance approximately $14 million a year. Even with millions of dollars in 340B savings this year, EMMC still operates on negative margins, as it has since 2019, and it has already budgeted a $6.1 million increase in bad debt and free care for 2027 as patients lose MaineCare coverage under the OBBBA. Plaintiff Unity Medical Center, a 14-bed critical access hospital with an operating margin under 3%, must float approximately *$2.5 million* to pay for the relevant 340B drugs. Dallas County Medical Center must float approximately $1.5 million, roughly ten times its annual outlay under the upfront discount model. And Plaintiff Nathan Littauer, which has run double-digit negative margins for more than five years, would have to float nearly triple its current outlay if all twenty-five drugs were approved for 2027.

207. HRSA's 10-day rebate window does not solve the problem. The clock does not start until a manufacturer receives a complete claim, and Plaintiff MHA's members estimate that the gap between dispensing a drug and receiving the rebate will run from roughly 11 days to as long as a month. Nathan Littauer's experience suggests even that estimate is optimistic: under the MTF rebate program in which it already participates, claims are supposed to be paid in 14 days but in practice take roughly 30 to 90 days, depending on the manufacturer and the drug.

208. Wholesalers will not wait that long. Payment terms among Plaintiff MHA's members range from 7 to 15 days, and certain of Dallas County Medical Center's wholesalers require payment *daily*. EMMC buys on net-15-day payment terms, which would leave it fewer than 5 days to assemble and submit a complete claim if it hoped to be repaid before its wholesaler invoice came due, a schedule it is not confident it can meet.

209. This financial squeeze also threatens bond and loan covenants at hospitals with thin reserves. The median Maine hospital has just 9.3 days of cash-on-hand. EMMC, for example, has just 52.33 days of cash-on-hand, and its parent system is bound by a bond covenant requiring at least 45 days. A $14 million annual advance puts EMMC in danger of breaching that covenant or, at minimum, being forced to draw on a line of credit, with interest, to pay its wholesaler on time. Once a covered entity exceeds its credit limit, its wholesaler stops filling orders, not just for drugs in the Rebate Program but for every 340B drug the entity buys.

210. Covered entities operating on tiny (if any) margins and limited cash-on-hand do not have these resources to spare. Every dollar spent complying with the Rebate Program is a dollar they cannot spend on patient care. To absorb these costs, covered entities across the country will have to terminate or shrink programs providing free or discounted drugs, close service lines, hire fewer clinicians, and put off replacing outdated equipment. Patients will bear the consequences.

211. The Plaintiffs and their members are already facing those choices:

a. MHA's member hospitals use their 340B savings to provide financial assistance to patients who cannot afford care, to run community health clinics in schools, nursing homes, and other easy-to-reach locations, and to offer lifesaving opioid intervention services such as naloxone, Suboxone, and methadone. They cannot sustain those services at current levels if the Rebate Program takes effect. Some

members also report that they would have to stop subsidizing physician practices or drop behavioral health, substance use treatment, or labor and delivery services altogether.

b. Dallas County Medical Center recently opened a cancer telehealth clinic that saves patients a 2-hour round trip to the nearest oncologist, and it runs an intensive outpatient psychiatric program for seniors that is the only mental health counseling available in the county. The Rebate Program puts both at risk.

c. Plaintiff Unity Medical Center may be unable to sustain its recently opened cardiac and pulmonary rehabilitation services.

d. Plaintiff Nathan Littauer Hospital has been gifted property for a new primary care clinic, but the Rebate Program puts that project in jeopardy.

e. EMMC is the primary tertiary referral hospital for northern and eastern Maine. Operating losses have already forced it to close its audiology, pain, and walk-in clinics and to cut more than 125 full-time-equivalent positions. The Rebate Program threatens further cuts.

212. Looming administrative and float costs are also forcing Plaintiffs to pause capital projects that their patients need. Dallas County Medical Center has put on hold at least $35,000 in critical boiler room maintenance, a wheelchair-accessible shower the hospital still lacks, and a telehealth clinic in a local school for children who otherwise lack access to care. Nathan Littauer Hospital has put its pharmacy build-out on hold. Unity Medical Center has paused the long-planned modernization of its inpatient pharmacy. EMMC risks losing the capital it needs to replace critical equipment, including imaging, endoscopy, and cardiac catheterization lab equipment. And MHA's members have been forced to delay or cancel planned emergency department renovations,

electronic medical record installations, and expanded emergency transportation. Each of these delays irreparably harms Plaintiffs, their patients, and their missions.

213. The burdens are severe enough that some covered entities are doubtful they can stay in the 340B Program at all. DFD Russell Medical Centers, a federally qualified health center serving rural central and western Maine, has concluded that it would have to leave the 340B Program if Defendants' rebate mechanism takes effect. The Rebate Program's staffing cost alone would exceed DFD Russell's entire remaining benefit of the 340B Program. Nathan Littauer has written into its third-party administrator contract renewal an option to reconsider its participation in the 340B Program if the Rebate Program does not make it financially whole, something it has never had to do before. And Dallas County Medical Center has concluded that the financial pressure from the Rebate Program could force it to leave the 340B Program altogether.

COUNT I — ADMINISTRATIVE PROCEDURE ACT
(Agency Action Not Based on Relevant Factors; Failure to Respond to Relevant and Significant Public Comments)

214. Plaintiffs repeat, re-allege, and incorporate all allegations in preceding paragraphs.

215. Defendants' establishment and January 1, 2027 implementation of the revised 340B Rebate Model Pilot Program, and their approval of drug company plans to participate in that program, are arbitrary and capricious under 5 U.S.C. § 706(2)(A).

216. Agency action must be based on "consideration of the relevant factors," *State Farm,* 463 U.S. at 43. Consistent with that principle, an agency's decision must be "connected to the purpose and concerns of relevant law." *Gulluni*, 85 F.4th at 82 (citing *Judulang*, 565 U.S. at 64).

217. Congress supplied the relevant factors here. When considering what payment mechanism to approve, Congress "expects that the Secretary of HHS, in developing these agreements, will use the mechanism that is the most effective and most efficient from the

standpoint of each type of 'covered entity.'" *Novartis Pharms. Corp.*, 182 F.4th at 1030 (quoting H.R. Rep. No. 102-384, pt. 2, at 16 (1992)).[14] The D.C. Circuit noted the "standpoint" standard days before HRSA issued the Notice. *Id.*

218. Numerous commenters cited the "standpoint" standard and explained why HRSA's balancing framework contradicts Congress's instruction for how the agency must exercise its discretion in choosing a payment mechanism. *See, e.g.*, HRSA-2026-0001-2437 at 2 (340B Health, noting that balancing the interests of covered entities and manufacturers is a "false premise" and that "Congress anticipated that the Secretary would use the rebate or discount that is the most effective and most efficient from the standpoint of each type of covered entity" (cleaned up)); HRSA-2026-0001-1991 at 21–22 (Penobscot Community Health Care, citing "standpoint" standard and noting that a rebate mechanism does "not meet the 'least burdensome' requirement"); AHA Letter at 2–3.

219. HRSA has long recognized this statutory standard. HRSA applied the "standpoint" standard during the only prior occasion when it approved a rebate mechanism, for ADAPs in 1997 and 1998. *See supra* ¶ 51. It repeatedly invoked the standard in legal briefs last year. *See supra* ¶ 56. HRSA even quoted the "standpoint" standard in the Notice. 91 Fed. Reg. at 48,884–85.

[14] The First Circuit has repeatedly relied on committee reports to set the standard Congress intended to govern an agency's exercise of delegated discretion. *E.g., Melone v. Coit*, 100 F.4th 21, 32–33 (1st Cir. 2024) (relying on "[r]elevant legislative history"—a committee report, H.R. Rep. No. 97-228, at 19 (Sept. 16, 1981)—to identify Congress's intended limitation on agency discretion and reviewing agency action against that limitation for arbitrariness); *Grinspoon v. DEA*, 828 F.2d 881, 893–94 (1st Cir. 1987) (looking to "standard contained" in committee report to determine permissible standard for agency's exercise of statutory discretion and reviewing agency's methodology against that standard for arbitrariness); *see also Union of Concerned Scientists v. Wheeler*, 954 F.3d 11, 19 (1st Cir. 2020) (citing language from a House Report as providing a "meaningful tool" for judicial review when rejecting a claim that there were no "judicially manageable standards"); *cf. Page v. Donovan*, 727 F.2d 866, 868 (9th Cir. 1984) ("Even if the statute is drawn broadly, review is not precluded if the legislative history offers standards that a reviewing court can apply.").

220. Despite reciting the "standpoint" standard, the Notice fails to apply it. Instead, the Notice adopts a decisional framework of the agency's own invention: that "HRSA must balance covered entities' longstanding reliance on the upfront discount model against the need to ensure effective program oversight, safeguard the benefits of 340B pricing, and maintain program integrity," and must "weigh competing policy concerns." *Id.* at 48,887–88.

221. Nothing in the 340B statute authorizes the Secretary to balance away the interests of covered entities. In substituting its arbitrary balancing framework for the congressional "standpoint" standard, HRSA "relied on factors which Congress has not intended it to consider," *State Farm*, 463 U.S. at 43; *see Judulang*, 565 U.S. at 55, 64, and failed to evaluate the Rebate Program under the standard Congress prescribed for choosing payment mechanisms.

222. The 2026 Notice also impermissibly inverts HRSA's prior regulatory approach. Rather than choosing a payment mechanism that is "most effective and most efficient" from the standpoint of covered entities, Defendants chose the more effective mechanism *for drug companies*. HRSA adopted its unprecedented balancing approach without displaying any awareness of that change. *See FDA v. Wages & White Lion Invs., L.L.C.*, 604 U.S. 542, 568 (2025); *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) ("An agency may not, for example, depart from a prior policy *sub silentio* or simply disregard rules that are still on the books.").

223. Separately, the Rebate Program is "unmoored" from the overall "purposes and concerns" of the 340B statute. *Judulang,* 565 U.S. at 64. The statute's undisputed purpose is to "enable [covered] entities to 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 (1992). HRSA acknowledged this purpose in the Notice, *see* 91 Fed. Reg. at 48,884–85, but

nowhere grappled with the fact that diverting at least half a billion dollars away from patient care and comprehensive services is disconnected from and damaging to that purpose.

224. Instead, HRSA merely recited the general proposition that "no statute pursues a single policy at all costs, and we are not free to rewrite this statute (or any other) as if it did." *Id.* at 48,889 (quoting *Advoc. Christ Med. Ctr. v. Kennedy*, 605 U.S. 1, 19 (2025)). But that conclusory explanation ignores two critical points.

225. *First*, many covered entities explained that the Rebate Program would put them at risk of having to close service lines (thereby providing less, rather than more, comprehensive care) or even close their doors altogether. *See supra* ¶¶ 106–13.[15] Others explained that they would need to leave the 340B Program because of its administrative and other burdens. *See supra* ¶ 213.[16] Even if a statute does not pursue its purpose at "all" costs, Congress would not have wanted to impose *these costs* given the 340B statute's undisputed overall purpose and concern. Separate and apart from Defendants' unreasonable cost-benefit analysis about the *incremental* benefits of the Rebate Program itself, *see infra* Count III, taking a half-billion dollars away from "more eligible patients and providing more comprehensive services," H.R. Rep. No. 102-384, pt. 2, at 12 (1992), unreasonably "frustrates, rather than advances, the statutory mandate," *Marasco & Nesselbush,*

[15] *See also* HRSA-2026-0001-1585 at 4 (comment from Jackson Hospital and Clinic, a nonprofit community hospital in Montgomery, Alabama, that "[c]urrently the savings from 340B is crucial for our survival"); HRSA-2026-0001-1417 at 2 (Edwards County Medical Center, a rural critical access hospital in Kinsley, Kansas, noting that "[t]he reality is" the hospital "could close its doors if 340B dollars cannot continue to help us on our bottom line"); HRSA-2026-0001-2406 at 12 (comment from Boston Medical Center Health System that "[w]e believe widespread use of rebates would put BMCHS at risk of insolvency. Essential systems like ours are operating at negative margins already; we would have no choice but to take immediate, drastic survival measures.").

[16] *See also* HRSA-2026-0001-0106 (Community Memorial Healthcare, a small critical access hospital, stating that "[t]his increase in cost surrounding our currently very compliant 340B program may put us at risk of continuing in the 340B program"); HRSA-2026-0001-1522 at 2 (comment from Cook County Hospital District that "[b]ased on the proposed rebate framework, [North Shore Health] would likely be forced to discontinue participation in the 340B program. We do not have the staffing capacity or infrastructure required to implement and sustain the additional administrative processes.").

LLP v. Collins, 6 F.4th 150, 178 (1st Cir. 2021). It is fatally unmoored from Congress's purpose in enacting the 340B statute.

226. *Second*, Defendants ignored that *this Court* has held that preventing duplicate claims and preserving program integrity are subsidiary objectives in service of the program's actual purpose, not a co-equal end that may be pursued at the expense of the covered entities or their patients. *See PhRMA*, 2026 WL 184504, at *9 n.10 ("Protecting manufacturers against duplicate claims and otherwise preventing fraud are subsidiary goals to the objective of the 340B program, which is to subsidize the cost of drugs to underserved populations."). Defendants' decision to balance *nonstatutory* objectives with the undisputed *statutory* purpose is arbitrary and capricious. *See Georgia v. Brooks-LaSure*, 2022 WL 3581859, at *17–20 (S.D. Ga. Aug. 19, 2022) (holding CMS acted arbitrarily and capriciously by relying on nonstatutory "health equity" objective and explaining that agency may not "depart from" statutory factors "to achieve some other goal"); *see also Gresham v. Azar*, 950 F.3d 93, 104 (D.C. Cir. 2020), *vacated and remanded with instructions to dismiss as moot sub nom. Becerra v. Gresham*, 142 S. Ct. 1665 (2022) (mem.) ("While . . . it is not arbitrary or capricious to prioritize one statutorily identified objective over another, it is an entirely different matter to prioritize non-statutory objectives to the exclusion of the statutory purpose."); *Nat'l Mining Ass'n v. EPA*, 59 F.3d 1351, 1364 (D.C. Cir. 1995) (finding APA violation when an agency's decision "would sacrifice a statutory objective in pursuit of ends that, at least as presented in argument to us, have not been justified . . . in terms of . . . provisions of the Act" and where agency "subordinate[d]" the statutory purpose to "other considerations not approved by Congress"); *Farmers Union Cent. Exch., Inc. v. FERC*, 734 F.2d 1486, 1500, 1501 (D.C. Cir. 1984) (agency action must remain "true to the congressional mandate" and may not

allow other policy considerations to produce an "improper departure from the basic congressional mandate").

227. For these reasons, the 340B Rebate Model Pilot Program is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, in violation of the APA.

COUNT II — ADMINISTRATIVE PROCEDURE ACT

(Rebate Program Is Arbitrary, Capricious, an Abuse of Discretion, or Otherwise Not in Accordance with Law — Failure to Adequately Consider the Costs of the Rebate Program, Including Administrative Costs and Float, Liquidity, and Financing Costs; Explanation Runs Counter to the Evidence Before the Agency)

228. Plaintiffs repeat, re-allege, and incorporate all allegations in preceding paragraphs.

229. Defendants' establishment and January 1, 2027 implementation of the revised 340B Rebate Model Pilot Program, and their approval of drug company plans to participate in that program, are arbitrary and capricious under 5 U.S.C. § 706(2)(A).

230. Under the APA, an agency must "examine the relevant data and articulate[] a satisfactory explanation for its action, including a rational connection between the facts found and the choice made." *California v. U.S. Dep't of Educ.*, 132 F.4th 92, 98 (1st Cir. 2025) (quoting *State Farm*, 463 U.S. at 43) (internal quotation marks omitted). As part of that exercise, an agency may not "unreasonably understate[] the costs of" a regulatory program. *Chamber of Com. of the U.S.*, 820 F. Supp. 3d at 491; *see also Presidents' All. on Higher Educ. & Immigr.*, 2026 WL 2690098, at *15 ("An agency acts arbitrarily and capriciously when it 'fail[s] adequately to quantify certain costs.'" (quoting *Bus. Roundtable*, 647 F.3d at 1148–49)). "Consideration of cost reflects the understanding that reasonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions," and "[n]o regulation is 'appropriate' if it does significantly more harm than good." *Michigan*, 576 U.S. at 752–53. This Court has already held these principles

applicable in this context: HRSA must "identify benefits that 'bear a rational relationship to the . . . costs imposed,'" and its failure to consider the full scope of costs before committing to a rebate mechanism is "fatal under the APA." *AHA I*, 820 F. Supp. 3d at 45.

231. Defendants have failed to satisfy these legal obligations in three ways, ignoring or unreasonably discounting (1) the full scope of administrative costs of the Rebate Program, (2) the many costs of "floating" the full list price of covered drugs while awaiting repayment of discounts owed under the 340B statute, and (3) the non-economic costs to patients and communities.

232. Defendants committed these legal errors by, among other things, (1) failing to engage the detailed evidence, based on deep institutional knowledge, that was submitted by the covered entities that will actually bear these three categories of costs, while (2) uncritically adopting the drug companies' and their vendors' mischaracterization of those costs. After all, an agency may not simply "t[ake] [a commenter's] word for it," *Susquehanna*, 866 F.3d at 445–47. If it relies on outside analysis, an agency must "critically review" that analysis or "perform its own." *In re NTE Conn., LLC*, 26 F.4th 980, 988 (D.C. Cir. 2022) (alterations removed); *Affirmed Energy, LLC v. FERC*, 166 F.4th 1070, 1083 (D.C. Cir. 2026); *Bloomberg L.P. v. SEC*, 45 F.4th 462, 473 (D.C. Cir. 2022). And it must "explain[] why" it finds the outside submission persuasive and why it credited some comments over others. *Cboe Futures Exch.*, 77 F.4th at 979 (internal quotation marks omitted); *see also AARP v. EEOC*, 267 F. Supp. 3d 14, 32 (D.D.C. 2017).

233. The administrative record contains detailed, covered entity-specific calculations from stakeholders with firsthand knowledge of hospital operations. These commenters established that administrative costs for 340B hospitals alone would exceed $1 billion annually, and that individual entities will bear costs many times the estimate presumed by HRSA. The submissions from covered entities were the product of "deep institutional knowledge and experience, not mere

conjecture." *Cath. Legal Immigr. Network*, 513 F. Supp. 3d at 174. "Grappling with relevant data requires more than a mere recitation of unfavorable evidence without further explanation." *Cigar Ass'n of Am. v. FDA*, 132 F.4th 535, 540 n.2 (D.C. Cir. 2025). Yet Defendants dismissed covered entities' cost calculations as "only estimates," while arbitrarily crediting conclusory and conjectural assertions of drug companies and their vendors. 91 Fed. Reg. at 48,891–94.

234. ***Administrative costs.*** The only covered-entity cost Defendants quantified, $537,222,270 per year, is expressly limited to "reporting claims data." Supporting Statement at 11; 91 Fed. Reg. at 48,893 & n.20. Defendants acknowledged that massive figure excludes reconciliation, rebate tracking, denial and dispute management, one-time start-up and IT integration costs, vendor and TPA fees, training costs, and every other administrative cost category the comments document. 91 Fed. Reg. at 48,893–94 & n.20; June ICR, 91 Fed. Reg. at 35,990. Commenters described these excluded categories of cost in scrupulous detail. Nevertheless, Defendants assigned no monetary value to any of these excluded categories, offering only conclusory assurances that they would be "modest." 91 Fed. Reg. at 48,893–94. Nor did Defendants revisit that figure, or any excluded category, when they approved the specific drug company plans that covered entities must implement.

235. That "fail[ure] adequately to quantify the certain costs or to explain why those costs could not be quantified" is arbitrary and capricious. *Bus. Roundtable*, 647 F.3d at 1148–49; *see also Bloomberg L.P.*, 45 F.4th at 472 ("[T]he agency did not provide a reasoned response to Bloomberg's comments that FINRA failed to quantify the direct and indirect costs of its proposed data service (or explain why certain costs could not be quantified)."); *Presidents' All. on Higher Educ. & Immigr.*, 2026 WL 2690098, at *15–16 (finding an agency acted unlawfully by excluding entire categories of costs that commenters identified). Likewise, HRSA's assertions about costs

are "conclusory or unsupported suppositions" that do not reflect reasoned decisionmaking. *NetCoalition v. SEC*, 615 F.3d 525, 539 (D.C. Cir. 2010); *see also Sorenson Commc'ns Inc. v. FCC*, 755 F.3d 702, 708 (D.C. Cir. 2014).

236. Multiple categories of administrative costs were unreasonably omitted altogether. But an agency "may not simply disregard an entire category of obvious costs." *Fla. E. Coast Ry., LLC v. Fed. R.R. Admin.*, 186 F.4th 822, 866 (11th Cir. 2026).

a. **Reconciliation Costs:** Numerous commenters explained how and why reconciliation costs would exceed submission costs. *See supra* ¶¶ 80–83, 133–34. Commenters also explained that these reconciliation requirements could not be solved by existing technology, let alone cheaply or freely, and so significantly more than five hours a week of labor would be needed to also perform this reconciliation work. The Notice excludes such costs, under the theory that covered entities "already perform extensive administrative functions under the 340B Program," including "reconciliation activities." 91 Fed. Reg. at 48,892–93. But that response irrationally fails to recognize that a rebate model introduces reconciliation requirements that *never before existed* under an upfront discount model. It also ignores the *incremental* effects of its Rebate Program, which was what commenters described to the agency. Defendants acted unreasonably by not quantifying reconciliation costs, providing a reasoned response to their existence, or otherwise appropriately considering them.

b. **Start-Up Costs:** Despite substantial record evidence of considerable start-up costs, Defendants unreasonably failed to include them in their cost-benefit

analysis for the circular reason that they are "transitional." *Id.* at 48,893–94. In fact, the Notice explains that there will be "legitimate startup activities" and that start-up costs are "inherent to the adoption of a new operational approach," *id*., but Defendants did not quantify them, provide a reasoned response to their existence, or otherwise appropriately consider them.

c. **Vendor and Training Costs:** Despite substantial record evidence of significant vendor and training costs, Defendants unreasonably failed to include them in their cost-benefit analysis because "participation in the 340B Program has always entailed some level of compliance and operational cost. Covered entities derive significant financial benefit from participation in the Program." *Id.* at 48,894. The Notice acknowledges that covered entities will be forced to bear at least some vendor and training costs, but Defendants did not quantify the increase in costs, provide a reasoned response for their exclusion, or otherwise appropriately consider them.

237. Defendants also authorized the Rebate Program after commenters showed that the 5-hour-per-week assumption that gave rise to the $537,222,270 figure was unexplained, unsupported, unreasonably low, and contrary to the overwhelming weight of evidence submitted by the very covered entities that would actually perform this labor. Defendants finalized their action without revising or justifying this labor-hour estimate, which itself was nothing more than a rote multiple of an unsubstantiated estimate that this Court found to be unsatisfactory last year. For HRSA to reach this exact same labor-hour figure again and again, it necessarily must have concluded that every single commenter that offered a higher labor-hour estimate misunderstood

the program's features or was wrong about the program's effects on its own operations. That itself is irrational.

238. When HRSA did respond, in a supporting statement submitted to OMB the day *after* the Notice was published, it dismissed the abundant countervailing evidence in conclusory terms, asserting that HRSA "continues to believe that the estimated burden reasonably reflects the average paperwork burden," "while recognizing that actual burden may vary among respondents." Supporting Statement at 7. But an agency's "statement of 'belief' is not a reasoned analysis." *Presidents' All. on Higher Educ. & Immigr.*, 2026 WL 2690098, at *19. HRSA's "own *ipse dixit* . . . is no substitute for reasoned decision-making," *Ctr. for Biological Diversity v. EPA*, 141 F.4th 153 (D.C. Cir. 2025) (Katsas, J., concurring in part and dissenting in part); *see generally Stein, Inc. v. NLRB*, 2025 WL 655081, at *3 (D.C. Cir. Feb. 28, 2025) (per curiam) ("[A]n assertion so 'conclusory' does not amount to reasoned decision making." (citing *Am. Clean Power Ass'n v. FERC*, 54 F.4th 722, 727 (D.C. Cir. 2022))). In addition, HRSA's refusal to ever explain the underlying support for its 5-hour-per-week calculation fails the APA's requirement that agency action be "reasonable and reasonably explained." *Ohio v. EPA*, 603 U.S. at 292 (quoting *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021)).

239. Moreover, because HRSA arrived at substantially the same labor-hour figure it reached before, its cost analysis warrants "a somewhat greater degree of scrutiny," given "the danger that an agency, having reached a particular result, may become so committed to that result as to resist engaging in any genuine reconsideration of the issues." *Shands Jacksonville Med. Ctr., Inc. v. Azar*, 366 F. Supp. 3d 32, 48 (D.D.C. 2018) (quoting *Greyhound Corp. v. ICC*, 668 F.2d 1354, 1358 (D.C. Cir. 1981)); *see Regents*, 591 U.S. at 21–23 (an agency's post-remand explanation "must be viewed critically"); *Wint v. Yeutter*, 902 F.2d 76, 81 (D.C. Cir. 1990)

("Because the [agency], on remand, both altered its original rationale and arrived at the same result initially vacated by the district court, close consideration of the Department's action is warranted.").

240. ***"Float," liquidity, and financing costs***. The defining feature of a rebate mechanism is that covered entities must pay drug companies sums far exceeding what they owe, "essentially functioning as an interest-free loan from the hospitals to the manufacturers," and wait for repayment. *AHA II*, 164 F.4th at 32. This Court held that the 2025 record's silence on these "float" costs established Plaintiffs' likelihood of success. *AHA I*, 820 F. Supp. 3d at 44–45. The 2026 Notice's analysis that costs will be "minimal" is an equally unreasonable explanation under the APA.

241. The Notice's conclusion that float costs will be "minimal" relies entirely on two industry-funded studies, the December 2025 IQVIA paper and the 2021 3 Axis study, neither of which was raised in the RFI or ICRs, and both of which rely on narrow, outdated data. Both studies also only address small pieces of the "float cost" problem (interest and contract pharmacies, respectively), leaving the Notice entirely barren about a range of other costs associated with the "float." *See supra* ¶¶ 93–105.

242. Reliance on "two relatively unpersuasive studies" against the weight of contrary record evidence is arbitrary and capricious. *Bus. Roundtable*, 647 F.3d at 1150–51; *Window Covering Mfrs. Ass'n v. CPSC*, 82 F.4th 1273, 1291 (D.C. Cir. 2023) (agency may not credit one interested party over hundreds of contrary commenters without explanation). And because neither study was identified in the RFI or otherwise exposed for public comment, HRSA violated the rule that "the most critical factual material that is used to support the agency's position" must "be made public in the proceeding and exposed to refutation." *Air Transp. Ass'n of Am. v. FAA*, 169 F.3d 1,

7 (D.C. Cir. 1999) (emphasis removed); *see also Chamber of Com. v. SEC*, 443 F.3d 890, 900–01 (D.C. Cir. 2006); *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 236–37 (D.C. Cir. 2008).

243. HRSA contended that its 10-day payment requirement solves for any "float cost" concerns. But the Notice ignores the abundant record evidence that contradicts this premise. Commenters identified wholesaler terms of 5 to 7 days; prepay deposits of tens of millions of dollars per quarter; days-cash-on-hand levels as low as four days; severe liquidity concerns in spite of a 10-day payment premise; diversion of limited reserves to drug companies (rather than payroll or other expenses); bond covenants this liquidity drain would breach; and drug companies' documented failure to pay MFP refunds within even a 14-day window. IQVIA's (unacknowledged) April 2026 second study itself notes that the 10-day premise is contradicted by many stakeholders. Commenters also explained that the 10-day payment requirement was less valuable given that the clock for rebating starts after a claim is submitted. An agency "cannot ignore evidence that undercuts its judgment; and it may not minimize such evidence without adequate explanation." *Genuine Parts*, 890 F.3d at 312.

244. Much like with administrative costs, at least three categories of "float" costs were unreasonably eliminated altogether:

a. **COGS, Prompt-pay, and Other Lost Discounts:** Despite substantial record evidence of these significant costs, Defendants unreasonably failed to include them in their cost-benefit analysis. Indeed, the Notice itself briefly mentions COGS discounts, but never returns to them. Thus, even though the record reflects that these lost discounts will cost covered entities millions of dollars annually, Defendants did not quantify them, provide a reasoned response to their existence, or otherwise appropriately consider them.

b. **Interest Costs:** The one type of "float cost" that the IQVIA studies acknowledged was interest costs. But despite relying on the outdated version of that study, Defendants unreasonably failed to include *any* interest costs in their cost-benefit analysis. The April 2026 follow-up IQVIA study estimates $53.7 million in such costs for only 10 drugs, but Defendants did not quantify such costs for their expanded 25-drug program, provide a reasoned response to their existence, or otherwise appropriately consider them.

c. **Delay/Denial Costs:** Defendants cannot rationally assume that there will be no rebate delays or denials that would extend the "float" timeline or leave covered entities entirely without rebates they are owed. Drug companies and their vendors, even if they were not financially interested, will never have a perfect record of providing rebates on time and as deserved. *See Dep't of Com. v. New York*, 588 U.S. 752, 785 (2019) ("[W]e are not required to exhibit a naiveté from which ordinary citizens are free." (internal quotation marks omitted)). But more than that, the administrative record is replete with real-world evidence explaining why such delays and denials will inevitably occur, particularly given the recent track record with the MFP Program. HRSA still provides no meaningful remedy to the hospitals left waiting for their rebates, suffering the liquidity and cash flow injuries that HRSA nonetheless deems "modest." An agency may not ignore "practical realities," and here, the practical reality is that there will be some number of delays and denials. *Marasco & Nesselbush,* 6 F.4th at 176–77. Defendants did not quantify

delay/denial costs, provide a reasoned response to their existence, or otherwise appropriately consider them.

245. ***Costs to patients and communities.*** Defendants failed to reasonably consider the non-monetary costs of the Program. Instead, they insisted that "[a]s a result" of various Program design features, "HRSA does not anticipate that the Pilot will materially impair covered entities' . . . ability to furnish services to patients." 91 Fed. Reg. at 48,899.

246. HRSA ignored these costs even though this Court recognized in the prior litigation that imposing $400 million in administrative costs would have "the downstream effect causing them to cut back services." *AHA I*, 820 F. Supp. 3d at 46. Here, HRSA itself conceded $537 million in data-submission costs yet nowhere considered the "downstream effect" on patient services.

247. If the prior judicial record was not enough for Defendants to take seriously patient costs, the administrative record documented these non-economic harms with remarkable specificity: inability to provide free or discounted drugs; minimal or no inventory of drugs whose WAC exceeds their 340B price fivefold; patients transferred or turned away; a county's only labor-and-delivery unit and inpatient behavioral-health beds closed; rural telehealth, cardiac rehabilitation, and diabetes education shuttered; national pharmacy chains' withdrawal from 340B pricing; and much more. *See supra* ¶¶ 106–13, 171, 211; HRSA-2026-0001-2169 at 1 (Premier Community HealthCare Group, a federally qualified health center serving Hernando and Pasco Counties, Florida, explaining that under a rebate model it "would be forced to purchase medications at the full Wholesale Acquisition Cost (WAC), which can be 4 to 5 times higher than the 340B ceiling price"); *see generally* AHA Letter at 6 n.5, 29–32, App. B; HRSA-2026-0001-1914 at 8 (comment of AAMC). HRSA neither calculated nor weighed any of these costs. Nor did it analyze the impact on any particular community, region, or facility type, demonstrating the same

"casual indifference to localized impacts" this Court found unacceptable last year. *AHA I*, 820 F. Supp. 3d at 45 n.5. That is, once more, an unreasonable underestimate of costs, a failure to consider "an important aspect of the problem," *State Farm*, 463 U.S. at 43; *Ohio v. EPA*, 603 U.S. at 293–94, and a conclusion that goes against the overwhelming weight of the record evidence.

248. For these reasons, the 340B Rebate Model Pilot Program is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, in violation of the APA.

COUNT III — ADMINISTRATIVE PROCEDURE ACT
(Rebate Program Is Arbitrary, Capricious, an Abuse of Discretion, or Otherwise Not in Accordance with Law — No Calculated Benefit Articulated; Purported Benefits Are Unsubstantiated and Bear No Rational Relationship to the Costs Imposed)

249. Plaintiffs repeat, re-allege, and incorporate all allegations in preceding paragraphs.

250. Defendants' establishment and January 1, 2027 implementation of the revised 340B Rebate Model Pilot Program, and their approval of drug company plans to participate in that program, are arbitrary and capricious under 5 U.S.C. § 706(2)(A).

251. 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.*, 60 F.4th at 965, 973 (quoting *State Farm*, 463 U.S. at 43) (emphasis added). An agency must conduct a "reasoned calculation of the costs and benefits." *Presidents' All. on Higher Educ. & Immigr.*, 2026 WL 2690098, at *16. "[A] serious flaw" in a cost-benefit analysis "can render the [resulting] rule unreasonable." *Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1040 (D.C. Cir. 2012); *see Thompson v. Clark*, 741 F.2d 401, 405 (D.C. Cir. 1984). "[V]ague and conclusory assertions" of benefit do not justify significant costs. *Chamber of Com. of the U.S.*, 820 F. Supp. 3d at 489. And "a reasoned decision would explain why any unquantified benefits cannot reasonably be quantified." *GPA Midstream Ass'n v.*

U.S. Dep't of Transp., 67 F.4th 1188, 1200 (D.C. Cir. 2023); *Tex. Indep. Ginners Ass'n v. Marshall*, 630 F.2d 398, 411 (5th Cir. 1980).

252. HRSA "unreasonably overstat[ed] the benefits" of the Rebate Program. *Chamber of Com. of the U.S.*, 820 F. Supp. 3d at 491. The only numbers in the Notice's discussion of benefits are borrowed, stale, speculative, and self-interested: drug company assertions from 2019 that Medicaid/340B duplicate discounts "amounted to as much as $1.5 billion annually," 91 Fed. Reg. at 48,887, and drug-industry comments "suggesting that duplicate discounts *may* affect up to approximately 25% of 340B drug transactions," *id.* at 48,898 (emphasis added). These figures were drawn nearly verbatim from the drug companies' comment letters, but the Notice nowhere acknowledges or grapples with that fact. Equally problematic is the fact that the drug companies themselves have been inconsistent with their numbers, sometimes reducing their claims of "billions" of dollars of deduplication costs to "potentially millions" when arguing before federal courts of appeals. *See* Doc. 2158962 at 2, *Novartis Pharms. Corp. v. Kennedy*, No. 25-5177 (D.C. Cir. Feb. 12, 2026) (describing the deduplication costs as "potentially millions").

253. HRSA has its own audit information that would illuminate the scale of any duplicate discounts but never acknowledged its possession of that information. "HRSA conducts approximately 160 audits of 340B hospitals annually—or about 6% of the 340B hospital field." AHA Comment Letter on Application Process for the 340B Rebate Model Pilot Program, at 8–12 (Aug. 27, 2025), *incorporated by reference in* AHA Letter at 42 n.47. In fact, Plaintiff EMMC received notice on September 28, 2026, that HRSA will be auditing it over the next several months. Defendants' historic audit records should have been more than enough evidence for the agency to form its own understanding of any duplicate discount problem without having to lift stale and speculative data from drug company comment letters. HRSA cited none of this audit evidence,

even as commenters urged the agency to do so and described their own experiences with clean audits. *See supra* ¶¶ 140–41 (describing comments that laid out audit results on deduplication both holistically and individually from covered entities). HRSA failed to acknowledge, let alone evaluate, contrary evidence, drawn from HHS's own audit findings, that duplicate discounts are far rarer than the industry asserts.

254. HRSA instead chose to take the drug industry's "word for it." *Susquehanna*, 866 F.3d at 447. It accepted the drug industry's figures uncritically, without demanding the industry's methodology or underlying data. This is precisely the "unquestioning reliance" on interested parties that courts find arbitrary and capricious. *Id.*; *Bus. Roundtable*, 647 F.3d at 1150–51. But "an agency cannot ignore evidence that undercuts its judgment; and it may not minimize such evidence without adequate explanation." *Genuine Parts*, 890 F.3d at 312. HRSA's "[c]onclusory explanations for matters involving a central factual dispute where there is considerable evidence in conflict do not suffice" under the APA. *Id.* (citation omitted).

255. Even on HRSA's own meager support for the frequency of duplicate discounts, the Program's benefits cannot outweigh the costs it imposes on covered entities. HRSA itself stated that "the included products represent less than 5.5% of total 340B sales with the remaining 94.5% of drug sales continuing under the upfront 340B discount model in 2027." 91 Fed. Reg. at 48,893. (That figure is even lower since only 18 drugs, not 25, have been approved to date.) But at the same time, the Notice attempts to quantify benefits based on duplicate discounts that purportedly occur across *the entire 340B Program*. This mixing of "apples and oranges" reflects precisely the kind of "[i]llogic and internal inconsistency [that is] characteristic of arbitrary and unreasonable agency action." *Chamber of Com. of the U.S. v. U.S. Dep't of Lab.*, 885 F.3d 360, 381 (5th Cir. 2018).

256. In reality, the Rebate Program will have, at most, a fractional impact on that overall figure because it includes only, at maximum, 25 drugs. Indeed, the Notice makes no assertion, nor has HRSA ever suggested, that the products responsible for this 5.5% of sales disproportionately account for a larger proportion of duplicate claims. Accordingly, even assuming that duplicate discounts "amounted to as much as $1.5 billion annually," the only specific dollar figure the Notice ever assigns to the scale of duplicated discounts, 91 Fed. Reg. at 48,887, it is clear that the benefits of the Rebate Program will be dwarfed by its costs: 5.5% of $1.5 billion would net $82.5 million in deduplication benefits annually.

257. To put it another way, if HRSA is going to rely on a figure for duplicate discounts across the entire 340B Program, it must also rely on a cost figure for the entire 340B Program. Numerous commenters explained how the costs of the program would skyrocket as more drugs are added. Given that reality, and the basic commonsense principle that costs will increase as more drugs are included, it is unreasonable to assume that adding 95% more drugs to the Program would add no costs. Yet that is what HRSA's mismatched analysis does by comparing the alleged $1.5 billion in duplicate discounts for *many thousands of drugs* in the full 340B Program to (at least) $537 million in submission costs for *just 25 drugs* in the Rebate Program. Thus, HRSA "inconsistently and opportunistically framed the costs and benefits" of the Program and violated the APA. *Bus. Roundtable*, 647 F.3d at 1148–49.

258. HRSA also did not explain how the Rebate Program itself will halt Medicaid duplicate discounts. Specifically, the Notice prohibits drug companies from denying rebates based on diversion or Medicaid duplicate discount concerns, 91 Fed. Reg. at 48,903, so the Rebate Program itself will not actually prevent a single duplicate discount or diversion. Indeed, HRSA emphasized that drug companies must use *existing* statutory audit and administrative dispute

resolution mechanisms to address duplicate discount concerns. *Id*. Accordingly, HRSA has failed to recognize that the Rebate Program itself adds few *incremental* benefits in stopping duplicate discounts because drug companies still must rely on "retrospective" statutory enforcement mechanisms that already exist.

259. In emphasizing the purported benefits of "prospective" enforcement, HRSA nowhere acknowledged its own longstanding positions that "[a] manufacturer may not condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions," Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110, 25,113–14 (May 13, 1994), and that drug companies must continue selling at the statutory price even while an authorized audit is pending, *Or. Health & Sci. Univ. v. Engels*, 2025 WL 1707630, at *3 (D.D.C. June 17, 2025) (citation omitted). An agency may not depart from its own rules *sub silentio*. *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016). Yet HRSA did so here by adopting its so-called "prospective" enforcement approach without any lawful "prospective" ability to deny duplicate discounts. Commenters correctly explained this legal barrier, but these comments went unaddressed.

260. The only asserted benefit discussed in the Notice that conceivably remains is "testing" for testing's sake, *i.e*., learning "whether rebates are an efficient means of effectuating the 340B ceiling price," 91 Fed. Reg. at 48,890. That, too, fails as a matter of law. Testing is not a benefit on its own; it is a description of the action an agency is taking. And even if it qualified as a benefit, HRSA never quantified it. HRSA's bare assertion that the testing benefits outweigh the costs, *id.* at 48,894, once again "smacks of 'clairvoyance' rather than the kind of 'exercise in logic' deserving of judicial deference." *AHA I*, 820 F. Supp. 3d at 45 (quoting *Fox*, 556 U.S. at 521).

261. For these reasons, the 340B Rebate Model Pilot Program is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, in violation of the APA.

COUNT IV — ADMINISTRATIVE PROCEDURE ACT
(Rebate Program Is Arbitrary, Capricious, an Abuse of Discretion, or Otherwise Not in Accordance with Law — Failure to Adequately Consider Obvious and Less Burdensome Alternatives)

262. Plaintiffs repeat, re-allege, and incorporate all allegations in preceding paragraphs.

263. Defendants' establishment and January 1, 2027 implementation of the revised 340B Rebate Model Pilot Program, and their approval of drug company plans to participate in that program, are arbitrary and capricious under 5 U.S.C. § 706(2)(A).

264. An agency acts arbitrarily when it "fail[s] to consider 'significant and viable and obvious alternatives.'" *Dist. Hosp. Partners v. Burwell*, 786 F.3d 46, 59 (D.C. Cir. 2015) (quoting *Nat'l Shooting Sports Found., Inc. v. Jones*, 716 F.3d 200, 215 (D.C. Cir. 2013)); *Massachusetts v. HHS*, 513 F. Supp. 3d 215, 225 (D. Mass. 2021) (agency must consider "significant and viable and obvious alternatives" (internal quotation marks and citations omitted)); *Massachusetts v. Dep't of Educ.*, 828 F. Supp. 3d 198, 216 (D. Mass. 2026) (agency "must consider and explain its rejection of . . . significant and viable and obvious alternatives" (internal quotation marks and citations omitted)); *Stauffer v. IRS*, 285 F. Supp. 3d 474, 484 (D. Mass. 2017) (agency "must have a reasoned explanation for rejecting the 'reasonably obvious alternatives' available to it").

265. Although the 2026 Notice, unlike its predecessor, purports to address alternatives, its rejection of those alternatives is conclusory, circular, conjectural, and contradicted by Defendants' own concurrent conduct with the CMS clearinghouse. This amounts to a failure to engage in any meaningful consideration of those alternatives. *See Int'l Union, United Mine*

Workers, 626 F.3d at 94; *Lilliputian Sys., Inc. v. Pipeline & Hazardous Materials Safety Admin.*, 741 F.3d 1309, 1313–14 (D.C. Cir. 2014).

266. *First*, two of the alternatives that the AHA and other commenters pressed most directly are absent from the Notice: (1) the proposal that drug companies prospectively publish both the 340B price and the maximum fair price, allowing covered entities to purchase at the lower of the two and to submit limited claims data to the existing MTF for verification and reconciliation, obviating the need for any rebate; and (2) the proposal that the drug companies be required to fund participating covered entities' costs (the Notice shifted only some IT platform costs to manufacturers and never addressed the balance). Each of these alternatives would have preserved covered entities' decades of settled reliance on upfront discounts while fully serving the agency's deduplication objective. The Notice nowhere evaluates them.

267. *Second*, HRSA's rejection of four "alternatives considered" is unsupported and unreasonable. The Notice acknowledges four general categories of alternatives, requests for (1) enhanced use of claims modifiers; (2) a centralized clearinghouse; (3) more intensive audits and oversight; and (4) narrower pilot structures. HRSA then rejected all four with inadequate, illogical, or illusory analysis. 91 Fed. Reg. at 48,899.

a. **Narrower Pilot Structures.** The Notice rejects all proposals to narrow the Pilot, including fewer drugs, voluntary participation on behalf of the entities, entity-type limits, or exclusion of physician-administered drugs and contract pharmacies. HRSA did so because, in its view, a "narrowly tailored or self-selected participant pool" "could introduce substantial selection bias and reduce the reliability and generalizability of Pilot findings," and that the duplicate discount risk "attaches to particular drugs . . . rather than to particular categories

of covered entities." *Id.* at 48,901. HRSA never asked whether a representative pool would volunteer, as the AHA urged; it just speculated about the possible pool. Nor did it consider whether it could evaluate a rebate mechanism notwithstanding an imperfectly representative pool, which is exactly what pilot programs do all the time. And, in general, its rationale subordinates the concrete, documented harms of a mandatory nationwide program to the statistical purity of an "evaluation" whose objectives, metrics, and success criteria the Notice never defines. HRSA's explanation is even more unreasonable given that, in approving specific rebate plans submitted by the ten drug companies, it empowered the drug companies to exempt covered entities due to various hardships. This inconsistent treatment underscores HRSA's arbitrariness.

b. **The neutral clearinghouse.** HRSA rejected a clearinghouse as "not explicitly authorized under the 340B statute," *id.* at 48,900, without explaining or justifying that legal conclusion, despite commenters' express requests for HRSA to do so. *See supra* ¶¶ 119, 176. HRSA's legal conclusion, moreover, cannot be squared with HHS's own Medicare Part D Claims Data 340B Repository, which CMS opened to covered entities in October 2026 and has proposed to make mandatory for 2028. An agency's decision based on the "conclusory assertion that its hands were tied" is arbitrary. *Cigar Ass'n of Am. v. FDA*, 480 F. Supp. 3d 256, 279 (D.D.C. 2020). Likewise, HRSA's reliance on covered entities' purported "incentives" to comply with a rebate mechanism

is speculative, illogical, and contrary to the administrative record. *See supra* ¶¶ 177–79 & n.9.

c. **More intensive audits and oversight.** The third alternative that HRSA listed received no individualized engagement. Despite identifying "more intensive audits and oversight activities" as a distinct alternative proposal, 91 Fed. Reg. at 48,899, the Notice never returns to it. Its only response is the generic assertion that "[r]etrospective reviews, audits, and dispute resolution processes are inherently reactive, identifying potential duplicate discounts only after they have occurred." *Id.* at 48,901. That is not consideration; it is a description or, at best, a circular argument that because audits and oversight are not a rebate mechanism, they are not a valid alternative to one.

d. **Claims modifiers.** The Notice rejects "enhanced use of claims modifiers" because oversight reports have criticized the Medicaid Exclusion File, which "relies on claims modifiers as its central mechanism," and because modifiers "can be applied inconsistently, may be incomplete or unavailable at the time of adjudication, and depend on voluntary compliance." *Id.* at 48,899–900. But that answers a proposal no one made. Commenters did not defend the *existing* Medicaid Exclusion File; they proposed enhancing the modifier system by standardizing identifiers, extending them to Medicaid managed care, and pairing them with the data-sharing arrangements the Notice itself acknowledges commenters proposed, *id.* at 48,890, but never separately addresses.

268. *Third*, the Notice dismisses *any* alternative that preserves upfront discounts on grounds that such an alternative "would not inform whether rebates are an efficient means of

effectuating the 340B ceiling price . . . and therefore would fail to advance the central purpose of the Pilot." *Id.* at 48,890. But that rationale is, again, circular: the alternatives to a rebate mechanism are inadequate because they are not a rebate mechanism. An agency cannot define its objective as the action itself and then reject every alternative for failing to be that action. *See Am. Pub. Health Ass'n v. Nat'l Insts. of Health*, 145 F.4th 39, 54 (1st Cir. 2025) (describing "circular reasoning" as a "hallmark[] of arbitrary and capricious decision-making"); *Firearms Regul. Accountability Coal., Inc. v. Garland,* 112 F.4th 507, 523–24 (8th Cir. 2024) (finding agency action to be arbitrary and capricious where it "relie[d] on circular reasoning").

269. For these reasons, the 340B Rebate Model Pilot Program is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, in violation of the APA.

COUNT V — ADMINISTRATIVE PROCEDURE ACT
(Rebate Program Is Arbitrary, Capricious, an Abuse of Discretion, or Otherwise Not in Accordance with Law — Failure to Consider Serious Reliance Interests)

270. Plaintiffs repeat, re-allege, and incorporate all allegations in preceding paragraphs.

271. Defendants' establishment and January 1, 2027 implementation of the revised 340B Rebate Model Pilot Program, and their approval of drug company plans to participate in that program, are arbitrary and capricious under 5 U.S.C. § 706(2)(A).

272. An agency must "assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns." *Regents*, 591 U.S. at 33; *see Doe v. Noem*, 152 F.4th 272, 290 (1st Cir. 2025). And where its prior policy "has engendered serious reliance interests," it must provide "a more detailed justification." *Fox*, 556 U.S. at 515; *Encino Motorcars*, 579 U.S. at 222, 224 ("conclusory statements do not suffice" in light of "decades of industry reliance"). "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." *AHA I*, 820 F. Supp. 3d at 42 (citing *Fox,* 556 U.S. at 515–16, and *Smiley v. Citibank (S.D.), N.A.*, 517 U.S. 735, 742 (1996)); *see AHA II*, 164 F.4th at 33 (reliance interests are "a critical factor in the analysis of an arbitrary-and-capricious claim").

273. Defendants' treatment of reliance interests fails these requirements. Having conceded in the prior litigation that covered entities' three decades of reliance on upfront discounts is significant—a concession credited by this Court and the First Circuit—Defendants have now declared that "exclusive reliance on an upfront discount model" was never reasonable "as a matter of law" because the statute authorizes rebates for some covered entities and because a separate federal program uses rebates. 91 Fed. Reg. at 48,888–89. In HRSA's view, covered entities *never* should have relied on HHS's consistent thirty-plus-year practice because the agency always had the discretion to change course.

274. That is not weighing reliance; it is defining it away. Courts have rejected similar efforts. *See Regents*, 591 U.S. at 31–32 (rejecting the argument that an agency "does not need to" consider reliance interests where a policy "conferred no substantive rights," provided benefits only in two-year increments, and was revocable at the agency's discretion); *Texas v. Biden*, 20 F.4th 928, 989–91 (5th Cir. 2021) (observing that in *Regents* the Supreme Court acknowledged that DACA was a discretionary program but DHS had still unlawfully failed to consider reliance interests), *rev'd and remanded on other grounds*, *Biden v. Texas*, 597 U.S. 785 (2022); *Centro Legal de la Raza v. EOIR*, 524 F. Supp. 3d 919, 971 (N.D. Cal. 2021) ("The government's contention that the agency was free to dismiss any reliance interests because there is no right to discretionary *sua sponte* reopening is akin to the government's losing argument in *Regents* . . . ."); *Am. Fed'n of Gov't Emps. v. U.S. Fed. Lab. Rels. Auth.*, 2026 WL 1870987, at *11 (D.

Mass. June 29, 2026) ("In both *Centro Legal* and *Regents*, the courts concluded that the fact that reliance interests in a prior rule did not stem from a vested right granted by said rule did not absolve the agency of the need to consider reliance interests."). Indeed, the First Circuit recently applied *Regents* in rejecting the government's argument that it need not weigh reliance interests where the underlying grants "allow for termination in certain circumstances." *Woonasquatucket River*, 186 F.4th at 46–47 (agencies "acted arbitrarily and capriciously by failing to consider reliance interests"). Just because a framework allows for the "foreseeable" changes in circumstances does not make reliance on thirty years of prior practice and policy any less reasonable.

275. Here, the covered entities' reliance rests on decades of unbroken agency practice, HRSA's published guidance confining rebates to ADAPs, and the agency's own representations (in *Federal Register* notices, letters to manufacturers, and federal court filings as recently as 2025) that upfront discounts are the preferred and superior payment mechanism. The Notice confronts none of this history and relies principally on the fact that the decision to authorize an upfront discount mechanism was discretionary. But "particular[ly] because of decades of industry reliance on the Department's prior policy," *Encino Motorcars*, 579 U.S. at 222, HRSA was required to offer more than its blithe explanation ("you should know we can change our minds at any time") for dismissing covered entities' reliance interests.

276. HRSA's reliance analysis also erects a straw man, writing: "But even if one assumed for the sake of discussion that covered entities' reliance interests in this context are reasonable as a matter of law, such a conclusion does not thereby transform such reliance interests into a categorical prohibition against the Secretary exercising his express statutory discretion to provide for 340B pricing via 'rebate or discount.'" 91 Fed. Reg. at 48,889. No stakeholder makes those arguments. Rather, the reliance interest was generated by HRSA's consistent adherence to,

and affirmative endorsement of, the upfront-discount mechanism. The more that happened, the more reasonably covered entities could expect HRSA not to abandon that approach and structure their operations and investments around it. Put differently, despite HRSA always having had the *discretion* to switch to a rebate mechanism, covered entities had ample basis, based on HRSA's own words and deeds, to "buil[d] up decades of reliance" on the upfront discount mechanism. *Wages & White Lion Invs.*, 604 U.S. at 585. HRSA discussed none of those words or deeds, and it thus failed to provide the "more detailed justification" required here. *Fox*, 556 U.S. at 515.

277. Further, contrary to HRSA's contention, 91 Fed. Reg. at 48,888, the use of rebates in other federal programs does not diminish covered entities' reliance on thirty-three years of the upfront discount mechanism in *this* federal program. Medicare Part D, which the Notice highlights as relying extensively on rebates, is a separate program for a non-identical set of purchasers and drugs. And Medicare Part D is fundamentally different from 340B in mechanics and purpose. The use of a rebate program in this altogether different context does not diminish the reliance interests of covered entities in this context.

278. HRSA's fallback argument also fails. In a single paragraph of analysis, the agency insisted that any reliance interests are "on balance" outweighed by "the significant benefits of proceeding with the Pilot as described in this Notice." *Id.* at 48,889. But HRSA has not reasonably calculated those benefits, making it impossible for those purported "benefits" to reasonably outweigh any reliance interests. *See supra* ¶¶ 138–43, 252–57. HRSA's conclusory statement that it "has taken into consideration covered entities' reliance interests" and found that they do not outweigh the benefits of the Program, 91 Fed. Reg. at 48,889, also does not adequately assess reliance interests. *See AHA I*, 820 F. Supp. 3d at 42 ("It is arbitrary and capricious to ignore the facts and circumstances engendered by that prior policy."). On *both* sides of the balance, HRSA

did not conduct a rational weighing of the reliance interests and purported benefits. And at a minimum, this again is not the "more detailed justification" required under these circumstances. *Fox*, 556 U.S. at 515.

279. For these reasons, the 340B Rebate Model Pilot Program is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, in violation of the APA.

COUNT VI — ADMINISTRATIVE PROCEDURE ACT
(Rebate Program Is Arbitrary, Capricious, an Abuse of Discretion, or Otherwise Not in Accordance with Law — Failure to Consider Important Aspects of the Problem)

280. Plaintiffs repeat, re-allege, and incorporate all allegations in preceding paragraphs.

281. Defendants' establishment and January 1, 2027 implementation of the revised 340B Rebate Model Pilot Program, and their approval of drug company plans to participate in that program, are arbitrary and capricious under 5 U.S.C. § 706(2)(A).

282. Defendants failed to consider other important aspects of the problem squarely presented in the comments. *State Farm*, 463 U.S. at 43; *Ohio v. EPA*, 603 U.S. at 293–94.

283. The starkest failure is HRSA's silence about the financial environment confronting safety-net hospitals, including the OBBBA's "historic $1 trillion cut" from Medicaid and Marketplace spending. The AHA and others expressly told Defendants that this is an important aspect of the problem they were obligated to confront. They explained that these pressures "will hit many of America's 340B hospitals the hardest because they treat large Medicaid populations while operating . . . on the thinnest of margins," and that HRSA "must provide a reasoned explanation for imposing the costs of the Rebate Program *on top of* the costs of the OBBBA and other developments." AHA Letter at 37–38 (emphasis in original); *see also* HRSA-2026-0001-1783 at 2–3; HRSA-2026-0001-1994 at 5. The Notice offers no explanation at all.

284. While Defendants failed to consider myriad other important aspects of the problem, two additional failures loom particularly large:

a. **Vendor Problems**: Defendants failed to confront the documented failures of the drug-company-selected vendor platforms on which the entire Pilot depends. Covered entities raised concrete, quantified evidence from their 2026 experience under the Medicare Drug Price Negotiation Program: misclassified claims, false denials, and payment delays running months past the applicable window, described *supra* ¶¶ 99, 130–32, 158. Instead of engaging with the evidence of significant issues that plagued the 2026 MFP platforms, HRSA parroted statements from Second Sight Solutions' comment letter, uncritically crediting the vendor's self-interested assertions. 91 Fed. Reg. at 48,891–94.

b. **Dispute Resolution:** The administrative record showed that a workable, impartial process for resolving rebate delays and denials is an essential prerequisite to any rebate mechanism. Without HRSA's active role, "there is little hope that disputes will actually get resolved," and drug companies will be affirmatively incentivized to delay and deny. AHA Letter at 51. The AHA asked for a designated point of contact, a specified procedure, decisions within thirty days, and a denial form requiring a narrative explanation, primary-source support, and an attestation. *Id.* at 51–52 & nn.50–52; *see also* HRSA-2026-0001-1914 at 13–16 (comment of AAMC). The Notice and follow-up FAQs identify no decisionmaker, prescribe no procedure, set no deadline, and provide no remedy; the Notice defers reporting "tools" until after the Pilot begins, offers only a discretionary "could review a sample" construct, and otherwise relegates

covered entities to an administrative dispute resolution process whose backlog means disputes would outlast the one-year "pilot" itself. 91 Fed. Reg. at 48,895–96, 48,903.

285. As to each of these problems, the Notice either says nothing or offers a response that runs counter to the evidence before the agency. *State Farm*, 463 U.S. at 43.

286. For these reasons, the 340B Rebate Model Pilot Program is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, in violation of the APA.

COUNT VII — ADMINISTRATIVE PROCEDURE ACT
(Rebate Program Is Arbitrary, Capricious, an Abuse of Discretion, or Otherwise Not in Accordance with Law — Predetermined Result)

287. Plaintiffs repeat, re-allege, and incorporate all allegations in preceding paragraphs.

288. Defendants' establishment and January 1, 2027 implementation of the revised 340B Rebate Model Pilot Program, and their approval of drug company plans to participate in that program, are arbitrary and capricious under 5 U.S.C. § 706(2)(A).

289. An agency acts unlawfully when it is "unwilling or unable to rationally consider counterarguments" because it has committed to a predetermined result. *New York v. U.S. Dep't of Com.*, 351 F. Supp. 3d 502, 663 (S.D.N.Y. 2019), *aff'd in part, rev'd in part on other grounds sub nom. Dep't of Com. v. New York*, 588 U.S. 752 (2019); *see Kravitz v. U.S. Dep't of Com.*, 366 F. Supp. 3d 681, 750 (D. Md. 2019); *Davis v. Mineta*, 302 F.3d 1104, 1112–13 (10th Cir. 2002).

290. Courts closely scrutinize an agency that, after judicial rejection of its position, arrives at the same result. In those circumstances, the agency's action "must be more than a barren exercise of supplying reasons to support a pre-ordained result," *Food Mktg. Inst. v. ICC*, 587 F.2d 1285, 1290 (D.C. Cir. 1978); *see Greyhound Corp.*, 668 F.2d at 1358; *Wint*, 902 F.2d at 81; *Regents*, 591 U.S. at 21 (an agency's post-remand explanation "must be viewed critically to ensure

that the action is not upheld by the court on the basis of impermissible post hoc rationalization" (cleaned up)).

291. *First*, Defendants' conduct following the dismissal of the prior action proves their commitment to a predetermined outcome. Despite receiving more than 4,000 total comments across the 2025 Notice, the 2025 ICR, the 2026 RFI, the February 2026 ICR, and the June 2026 ICR, HRSA has not deviated in any meaningful way from its predetermined conclusion to forge ahead with a rebate mechanism. After issuing an RFI just days after its original Rebate Program was vacated, the agency adopted the same rebate mechanism architecture, the same mandatory nationwide scope, the same erroneous 10-day payment premise, and the same reliance on manufacturer-selected platforms, while *expanding* the program from ten drugs to 18 (with more to possibly come) and avoiding any firm end date for its purported "pilot."

292. *Second*, at every disputed factual juncture, the agency credited the drug companies' and their vendors' conclusory assertions over the detailed, firsthand evidence of the entities the statute protects. Indeed, "after this Court enjoined [HRSA's] original [Rebate Program] . . . , the agency 'cherry-picked' materials to support the same predetermined policy choice." *Kingdom v. Trump*, 2026 WL 1746251, at *12 (D.D.C. June 17, 2026) (quoting *Afr. Communities Together v. Noem*, 820 F. Supp. 3d 48, 67 (D. Mass. 2026), *rev'd and remanded on other grounds sub nom. Afr. Communities Together v. Mullin,* 183 F.4th 77 (1st Cir. 2026)). HRSA *always* took the word of those who supported its predetermined result, even though covered entities are best situated to assess what the on-the-ground costs of this proposed program will be and regardless of how flimsy the contrary evidence (*e.g.*, the IQVIA study, 2019 estimates of duplicate discounts, etc.) was. In fact, although courts and Plaintiffs use "word" in the metaphorical sense when they say HRSA took the drug industry's "word" for it, *see Susquehanna*, 866 F.3d at 447, here, it is literally true.

In many instances, HRSA used *exactly the same text* as drug companies or their trade association without ever attributing that language or critically assessing it in the face of contrary evidence. *See supra* ¶ 178.

293. *Third*, HHS officials engaged in *ex parte* communications with drug companies prior to the 2025 Rebate Program and, on information and belief, thereafter. The drug companies attached documentation to their litigation filings in the prior litigation citing some of these communications. *See, e.g.*, *Am. Hosp. Ass'n v. Kennedy*, No. 2:25-cv-600 (D. Me.), Dkt. Nos. 85, 85-2, 85-3, 88, 88-1. Plaintiffs do not know the substance or extent of these private conversations, but their closed-door nature raises serious concerns about HRSA's willingness "to rationally consider counterarguments" from covered entities. *New York v. U.S. Dep't of Com.*, 351 F. Supp. 3d at 663.

294. *Fourth,* many stakeholders asked HRSA to provide a further opportunity for comment on the specifics of any new program because the RFI proposed no concrete design on which meaningful comment was possible. *See* AHA Letter at 53; HRSA-2026-0001-1914 at 4 (without the parameters of a potential rebate mechanism, "it is impossible to accurately provide the information HRSA is looking for"). HRSA never responded to that request in the Notice, and in fact wrongly faulted covered entities for not considering certain programmatic design features when submitting their cost estimates. HRSA instead announced a completed program, effective immediately upon publication, with manufacturer plan approvals to quickly follow within seven weeks. It appears that HRSA did this because it wanted to initiate its Rebate Program by January 1, 2027, but its agreement with Plaintiffs required the agency to provide 90 days of lead time before implementation. Joint Motion for Vacatur and Remand at 4, *Am. Hosp. Ass'n v. Kennedy*, No. 2:25-cv-600 (D. Me. Feb. 5, 2026), Dkt. No. 114. Thus, not only was HRSA committed to moving

forward with its predetermined Rebate Program, but it was also committed to doing so by a predetermined date, regardless of (1) whether its ICR/cost analysis was complete; (2) whether it was ready to announce a dispute-resolution process (*see supra* ¶¶ 166–68, 186(b)); and (3) whether an additional round of comments would have informed its decision about key design elements of the Program.

295. For these reasons, the 340B Rebate Model Pilot Program is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, in violation of the APA.

Prayer for Relief

Wherefore, Plaintiffs respectfully request that this Court declare that HRSA's approvals of drug company plans under the 340B Rebate Model Pilot Program are unlawful; "set aside" the 340B Rebate Model Pilot Program and the approvals under 5 U.S.C. § 706(2)(A); and award any other relief the Court deems necessary and just, including as appropriate using its equitable powers to enter orders providing:

A. The Rebate Program and HRSA's approvals of the drug companies' plans are permanently enjoined as unlawful and invalid;

B. Defendants are enjoined from implementing or giving effect to the Rebate Program in any way, including by approving drug company plans; and

C. Defendants are directed to rescind any and all statements, guidance, or direction already issued relating to announcing, implementing, or enforcing the Program, including Frequently Asked Questions, as they pertain to the Rebate Program.

Dated: October 9, 2026

Respectfully submitted,

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**Pro hac vice application forthcoming.*

EXHIBIT 1

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Titusville Area Hospital

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The Honorable Thomas J. Engels
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane Rockville, MD 20852

April 2, 2026

Re: Request for Information: 340B Rebate Model Pilot Program, HHS Docket No. HRSA-2026-03042

Dear Administrator Engels:

On behalf of Titusville Area Hospital [TAH], we are grateful for the opportunity to comment on the Department of Health and Human Services' (HHS) "Request for Information: 340B Rebate Model Pilot Program." Among other things, this RFI asks "whether HRSA should implement a rebate model under the 340B program" instead of the upfront discount model that has worked successfully for decades. The answer is "no."

As explained below, *any* rebate mechanism will impose enormous costs and burdens on TAH that far outweigh any benefits that might come from it. HRSA's own calculations of costs are extraordinary. More fundamentally, HRSA's desire to test a rebate model is seemingly based on the incorrect premise that it must balance the interests of 340B hospitals and drug companies when choosing a discount mechanism. In reality, HRSA must give primacy to the needs of covered entities so that they can "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Preserving the upfront discount mechanism, which TAH has relied on for years, is the best way to fulfill that purpose of the 340B program.

The RFI poses 30 questions and encourages commenters to include supporting facts, research, and evidence in their responses. Titusville Area Hospital has done its best to provide detailed answers in the limited time available to us. For purposes of estimating costs, we have assumed that any future Rebate Program will include the 10 drugs that HRSA previously approved for its original Program and those that have been approved under the Medicare Drug Price Negotiation Program (MDPNP) for 2027, per HRSA's February 25, 2026 Information Collection Request. With the addition of the 2027 drugs, our cost estimates have increased over the estimates we had calculated for the 2026 drugs alone. After all, more drugs and more drug companies mean *more* claims to submit, *more* rebates to track and reconcile, *more* money that we will need to float to drug companies

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while we await our statutory discount, *more* likely disputes over delays and denials, and therefore *less* money that TAH can spend on patient care and comprehensive health care services.

Administrative Costs Under A Potential 340B Rebate Program. Any rebate program would require Titusville Area Hospital to spend significant sums on new administrative costs. When we chose to participate in the 340B program, Titusville Area Hospital understood that we would incur some reasonable administrative costs. We designed our hiring, operations, and program administration around an upfront discount model. A shift to a new kind of discount mechanism demands new resources, imposing considerable additional costs and burdens on our institution that go far above and beyond what we had expected and planned for as a 340B hospital—and far above and beyond what we are experiencing now.

It is important to note that the manufacturer contract pharmacy policies – on which the Health Resources and Services Administration (HRSA) has not yet issued formal guidance or an opinion - have already created a ***significant*** administrative burden within TAH. The responsibilities of our 340B auditors have shifted substantially from traditional auditing and compliance activities to extensive data management. This now includes compiling data within our third-party administrators (TPAs), exporting data into Excel, manipulating the data to meet required reporting templates, and uploading claims data into multiple data warehouses.

In addition, the entire team is responsible for monitoring pricing accuracy at both designated and non-designated contract pharmacies. One full-time employee maintains a comprehensive eligibility file used to assess program compliance, while a 340B analyst was hired primarily to evaluate contract pharmacy data and make recommendations regarding which contract pharmacy should be designated for each manufacturer.

The proposed 340B Rebate Model Program would impose further operational and administrative burdens on an already strained staff. Titusville Area Hospital has estimated the following incremental administrative and operational costs in relation to the proposed 340B Rebate Model Program:

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Incremental Costs:

- Additional staff expense year one: $15,457
- Additional staff expense year two: $30,252
- Additional staff expense year three: $34,615
- **Cumulative three-year total of additional staff expense**: $80,325
- Software to track and monitor both 340B and MFP rebates: $30,000/year
- Software to monitor drug pricing and payments: $150,000/year

The incremental staffing expenses listed above were estimated at **10 minutes per claim**- consistent with the time required for processing rebates under the MFP rebate model – and were based upon historical volumes. These costs encompass claim submissions, claims processing and reconciliation, denial management, and analysis of contract pharmacy service agreements and their financial feasibility.

Beyond the incremental costs associated with this proposed program, Titusville Area Hospital has already incurred one-time startup costs in preparation for a potential 340B Rebate Model. These startup costs include staff education and training through webinars and consultant-led sessions, and the use of internal IT resources to modify our 340B TPA interfaces to incorporate new data fields that were not previously required.

The added costs of purchasing drugs initially at WAC versus 340B is estimated below in additional to the one-time start up expenses.

One-time Startup Costs:

- Information systems interface modification: $245
- Staff education and training: $5,756

Variance in Upfront Drug Expense [WAC vs 340B]:

- Year one variance in initial drug spend: $2,311,394
- Year two variance in initial drug spend: $4,721,710
- Year three variance in initial drug spend: $5,186,806
- **Cumulative three-year total variance in drug spend:** $12,219,909

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Additionally, there are cost of good impacts that will occur with each drug removed from the 340B contract model and placed onto the IRA rebate model on wholesale purchase agreements between covered entities and wholesalers. Commonly, one such modifier that affects overall cost of good discounts offered by the drug wholesalers to the covered entities in their contracts is the percentage of purchases made on contract. Our wholesaler agreement considered purchasing on the Apexus 340B contracts as meeting this requirement of purchasing an item on contract. When the drugs are removed from the Apexus 340B contract, and there is no longer a contract on that drug purchase, this decreases the spend on contracted items per our agreement. This ultimately results in an impact on the overall cost of any goods purchased through the wholesaler, regardless of an item's individual contracted status.

Staffing Impacts Under a Potential 340B Rebate Program. Titusville Area Hospital currently does not have sufficient staffing resources to comply with the operational requirements of a 340B Rebate Model Program. As noted above, the estimated time required to process a single rebate model claim is approximately **10 minutes per claim.** Based on Titusville Area Hospital's historical claim volumes for the 2026 and 2027 IRA drugs, as well as the proposed 2028 IRA drugs, the administrative workload associated with tracking and processing rebate model claims will increase significantly.

By 2028 (Year Three), the total estimated time required to manage Rebate Model claims is **960 hours annually**, which represents the need for an additional ½ of a full time equivalent employee.

These projections demonstrate that the Health Resources and Services Administration estimate of five hours per week to administer the Rebate Model is significantly understated and does not reflect the operational realities faced by covered entities such as Titusville Area Hospital.

Systems and Infrastructure for Implementation of a Potential 340B Rebate Program. TAH has designed its technological systems and operational infrastructure in reliance on an upfront discount model. Any shift to a rebate mechanism will force us to incur significant costs to change those systems.

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Titusville Area Hospital's existing data interfaces with our third-party administrators did not previously include certain medical claims data elements that will be required under the proposed 340B Rebate Model Program. As a result, our data feed must be modified to incorporate additional fields, including the CPT code for the drug and the quantity billed on each claim. These new data elements will also require ongoing auditing to ensure that the appropriate billing units are captured accurately and consistently.

In addition, our TPAs have invested significant time developing reports that align with the required template specifications allowing TAH to extract the data and subsequently upload it into Beacon.

Historically, TAH's clean sites were not interfaced with our TPAs. Therefore, an additional informatics build could be required to ensure that complete in-house medical claims data would flow appropriately into the TPA system. As a result of this enhancement, our TPA may charge TAH an additional $3,600 per year to maintain this functionality.

Furthermore, if denial management associated with the rebate process becomes increasingly burdensome, TAH may need to engage external vendors that specialize in rebate model and Medicare drug price negotiation support under the Inflation Reduction Act. An initial quote for these services was $30,000 annually.

HRSA should also consider a dispute resolution process for denied 340B rebates. This could be similar to the administrative dispute resolution process between payers and hospitals for out of network claims.

Data Collection by Covered Entities. During the prior iteration of the Rebate Program, both HRSA and the drug companies stated that a rebate mechanism would not impose new data-related burdens on 340B hospitals like ours. For example, both insisted that hospitals already provide the required information through 340B ESP. That is incorrect.

Presently, data is transmitted from TAH's electronic medical records system to our third-party administrators. 340B eligibility is determined based on TAH's internal policies and procedures, which align with the 340B Program requirements outlined in the Federal

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Register and guidance provided by HRSA. TAH's auditors routinely download 340B-eligible claims from our TPAs to conduct monthly compliance audits. During these reviews, auditors verify that the provider, service location, financial class, and drug meet eligibility requirements in accordance with the established policies and program guidelines. These claim downloads are maintained in Excel files and stored in a shared folder for documentation and reference.

In addition, 340B staff routinely monitor the integrity of the IT interface, 340B accumulations, wholesale acquisition pricing, invoices, and contract pharmacy eligibility in accordance with manufacturer restrictions. A 340B auditor also compiles and downloads 340B-eligible claims on a weekly basis for submission to the 340B ESP program.

The proposed 340B Rebate Model Program would introduce an additional layer of data collection and oversight for Titusville Area Hospital. The Rebate Model requires submission of in-house claims data that historically has not been requested or provided. As a small rural hospital with a robust oncology clinic, our covered entity realizes a significant portion of its 340B savings through in-house dispensing rather than through contract pharmacies. As the rebate model expands under the IRA drug Model to include additional drugs, the volume of data requiring monitoring, reconciliation, and auditing will increase accordingly.

Also, while drug manufacturers have indicated that access to in-house medical claims data will help identify potential duplicate discounts, this information would primarily allow manufacturers to enforce compliance with their own policies. Additionally, because drug manufacturers are not covered entities under HIPAA, it is unclear whether a Business Associate Agreement (BAA) would be required between the 340B hospitals and manufacturers. Important questions remain regarding how manufacturers will use patients' data, whether they will be prohibited from sharing this information with third parties, and what responsibilities they will bear in the event of a data breach. Specifically, clarification is needed regarding whether manufacturers would be responsible for notifying affected patients and providing credit monitoring or other remediation services if a breach were to occur.

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Finally, manufacturers should be required to report on the number of duplicate discounts identified and explain how any associated savings was utilized. They should also be required to report the number of 340B rebate claims that are denied, along with the reason for those denials.

Payment Timing and Potential Cash Flow Impacts. Unlike the existing upfront discount mechanism, any rebate mechanism will force TAH to effectively provide drug companies interest-free loans as we await the discounts that we are owed under the 340B statute. Even if drug companies paid within a 10-day period as required under the prior iteration of the Rebate Program, that delayed discount will have meaningful impact on our institution and the patients we serve.

TAH is currently operating under limited financial resources, and this unexpected increase in supply costs would further strain our health system's cash flow. Specifically, purchasing the IRA high-cost medications selected for the Rebate Model Pilot Program at wholesale acquisition cost (WAC) could increase our small critical access hospital's annual drug spend by more than $5 million by 2028. This projected variance to our cash flow is estimated to reduce our Health System's days cash on hand by approximately 3.27 days by 2028. Such a reduction could place our organization at risk of violating strict bond covenants.

This diversion of already limited financial resources would further reduce the funds our covered entity relies upon to care for our low-income rural population which directly conflicts with the intent of the 340B Program. It is also important to consider that presently Medicare- and in some cases commercial payers- currently reimburse drugs at 101% of the cost for critical access hospitals. Under the IRA model, the reimbursement for the selected drugs will now be lower due to the smaller purchase price. Our contract pharmacies' reimbursement will also decrease from 106% of ASP to 106% of the low negotiated price. As a result, TAH anticipates a significant reduction in pharmacy reimbursement, creating an additional negative impact on our cash flow.

Decrease in Reimbursement:

- Year one decrease in reimbursement: $(1,124,978)
- Year two decrease in reimbursement: $(2,884,963)

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- Year three decrease in reimbursement: $(3,322,308)
- **Cumulative three-year decrease in reimbursement:** $(7,332,248)

Also, under the proposed model, TAH would be required to purchase the selected drugs at WAC. HRSA's assumption that covered entities will receive 340B rebates within 10 days appears to underestimate the operational realities hospitals face. Under our current replenishment model, drugs would remain in TAH's inventory at WAC pricing until a qualifying 340B dispensation occurs, which may take **weeks or even months**.

Given these circumstances, additional transparency is needed regarding the average time manufacturers take to issue 340B rebates. HRSA should consider whether manufacturers should be subject to penalties for untimely rebate payments outside of the proposed 10-day window, such as requiring manufacturers to pay daily interest to covered entities for delayed rebates. Manufacturers should also be required to report on the average length of time they are issuing rebates in an effort of transparency.

The combined potential reduction in reimbursement and increase in staffing and supply costs under the 340B Rebate Model Program could be detrimental to TAH.

Adverse Impacts of These Additional Costs and Burdens. All of these many different costs and burdens add up. Unfortunately, that means that TAH will no longer be able to use our 340B savings as effectively and comprehensively as we did under an upfront discount model. As a result, our patients and community will suffer in concrete ways.

Titusville Area Hospital utilizes its 340B savings to stretch scarce Federal resources, consistent with the intent of the program for safety-net hospitals such as ours. These savings help subsidize essential patient programs including rural health clinics, mental health clinics, dental clinics, and charity care. As 340B savings decline, costs increase, and reimbursement continues to decrease, TAH will need to carefully evaluate whether it can sustain these services for our low-income rural patient population.

Given these concerns, has HRSA considered excluding critical access hospitals, rural referral centers and critical access hospitals from participation in the 340B Rebate Model? Small rural covered entities such as TAH already face persistent staffing shortages and have been significantly impacted by the declining Medicaid enrollment. Across the

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country, many rural hospitals are being absorbed by larger health systems that subsequently reduce or eliminate essential services.

In addition, critical access hospitals have experienced substantial reductions in 340B savings due to increasingly restrictive manufacturer contract pharmacy policies. TAH alone has lost approximately $5.2 million annually as a result of these policies. Further reductions in 340B savings through the proposed rebate model could place additional strain on safety net hospitals that are already operating under significant financial pressure.

Reliance Interests. The RFI expressly invites comment on "reliance interests in continuing to obtain the 340B ceiling prices through upfront discounts and whether such reliance interests are reasonable in light of the Secretary's express statutory authority to provide for discounts via 'rebate or discount.'" Respectfully, that framing rests on a flawed premise. The mere existence of statutory authority does not imply that the agency will—or reasonably may—exercise it in a particular manner. That is especially so here, where the 340B Program has, since its inception, consistently provided discounts through upfront pricing rather than post-sale rebates. Titusville Area Hospital reasonably relied on this history when designing its internal operations, staffing, third-party contractual relationships, and financial planning for the use of 340B savings—all based on an upfront-discount model. A fundamental switch now would disrupt these settled reliance interests engendered by the agency's prior policy. Absent any identified problems with the upfront discount model, and given the massive costs that this disruption will impose on 340B hospitals like ours, there is no reason to switch to a rebate mechanism, even in so-called "pilot" form.

Titusville Area Hospital utilizes historical purchase and savings data in conjunction with the preparation of our health system's annual operating budget. Because the impact of the proposed 340B Rebate Model Program is largely unknown (how many drugs will be denied the 340B rebate, what will be the length of time TAH is floating the discount to the largely profitable drug manufacturers, etc.) it will now be virtually impossible to prepare a reliable and accurate operating budget.

Problems with the Beacon IT Platform. Under HRSA's original Rebate Program, the approved drug companies were planning to use Second Sight Solutions' Beacon IT

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platform to operate the Program. In the few weeks we had to prepare for the start of that Program, we encountered serious problems with Beacon.

The first issue with Beacon is their terms of use. Second Sight Solutions receives the irrevocable license to use, disclose, and sub-license data submitted by covered entities. Second Sight also disclaims liability for, and is not responsible for, any damages or data losses arising from the use of the platform, including for HIPAA breaches. It should be considered if a BAA is required between the covered entities and drug manufacturers as the manufacturers are not covered under HIPAA and have not previously been provided this detailed patient information.

The second set of issues are in relation to tracking claims to understand the reason for the denial. For example, the Rx number is not ingested by Beacon from the MTF because they do not want PHI in their system. This makes it difficult to analyze payments and requires staff to look further into the MTF report, our TPA, and also our entity-owned contract pharmacy's software program, Pioneer. In addition, Beacon will assign "340B" as a reason to deny payment for an MFP rebate. TAH has found that these were dispensed at contract pharmacies that were not designated by TAH for that specific drug manufacturer and thus would not have received 340B pricing. Lastly, the ICN (internal control number) is the identifier that the MTF and Beacon are using to track claims. If a claim is changed (the dispense quantity, NDC, etc.) a **new** ICN will generate. Although you can follow the chain of ICNs within the Beacon platform, that chain is not visible when the data is downloaded.

Efforts to Avoid 340B/MDPNP Duplicate Discounts. HRSA has already made clear that drug companies have other available options to address the need to deduplicate 340B and MDPNP pricing. Given the tremendous costs that a rebate mechanism will impose on TAH, HRSA should rely on those other options. Any other decision would impermissibly privilege the interests of drug companies over those of covered entities, their patients, and the communities they serve.

Likewise, we support the AHA's position that there are viable, lawful, and less burdensome alternatives that could achieve the same potential benefits as a rebate mechanism. In particular, we urge HRSA to adopt a third-party clearinghouse, rather than a rebate mechanism, to advance 340B/MDPNP deduplication, program integrity, and any

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other potential benefits. At a minimum, HRSA must provide a reasoned explanation for why the third-party clearinghouse is neither viable nor less costly than a rebate mechanism.

Titusville Area Hospital and our entity-owned contract pharmacies have not had any notifications from drug manufacturers regarding 340B/MDPNP deduplication issues to date. Under our current deduplication process, TAH carves in Medicaid on the in-house book of business, regularly update OPAIS with Medicaid billing NPIs, and our state relies on the MEF. For our contract pharmacy side, Medicaid is carved out from 340B eligibility based upon the payers' BIN and PCN data.

Summary. Titusville Area Hospital is a small critical access hospital that relies on 340B savings to subsidize programs such as mental health counseling, rural health clinics, dental clinics, and charity care. TAH also provides more than $1.6 million annually in charity care to our low-income patient population. If our supply and staffing costs increase as anticipated due to the proposed rebate model, TAH may be forced to cut back on some these essential services. To more easily visualize the overall financial impact the proposed 340B Rebate Model could have on Titusville Area Hospital, the below illustration summarizes what our comments hoped to convey.

	2026	2027	2028	Cumulative Total
Additional Drug Spend	$ 2,311,394	$ 4,721,710	$ 5,186,806	$ 12,219,910
Incremental Staffing Costs	15,457	30,252	34,615	$ 80,324
Decline in Reimbursement	1,124,978	2,884,963	3,322,308	$ 7,332,249
IT Infrastructure	33,600	33,600	33,600	$ 100,800
Staff Education / Webinars	5,756	-	-	$ 5,756
Additional FTE(s)	-	-	35,000	$ 35,000
Overall Impact:	**$ 3,491,185**	**$ 7,670,525**	**$ 8,612,329**	**$ 19,774,039**
% Increase over current 340B expenses:	*174%*	*263%*	*283%*	
Decrease to days cash on hand	*1.32*	*2.91*	*3.27*	

For all of these reasons, Titusville Area Hospital respectfully submits that the costs of *any* Rebate Program will outweigh any expected benefits. HRSA therefore should abandon the concept altogether and embrace a neutral, third-party clearinghouse.

If, however, HRSA chooses to move forward with this ill-conceived effort, it must allow TAH and other covered entities to comment on the specifics of its new program. While we have endeavored to provide the most detailed information possible, we are doing

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so without precise knowledge of which drugs will be included in a Rebate Program and many other critical details (*e.g.*, data required, possible grounds for denial of rebates, dispute resolution processes, other guardrails). A failure to permit additional comments on the specific features of the program will be, in effect, a wholesale failure to consider important aspects of the problem.

We appreciate your consideration of these comments and look forward to working with HRSA on this important issue, which has profound implications for the millions of patients who rely on the 340B Program. Please contact me if you have questions.

Sincerely,

Holli Wolfe
Vice President Operations
Titusville Area Hospital
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Parkview Health

PARKVIEW HEALTH

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Re: Comments on the Information Collection Request, "340B Rebate Model Pilot Program Application, Implementation, and Evaluation," OMB Control No. 0906-NEW; 91 Fed. Reg. 35,989 (June 15, 2026)

Parkview Health is a not-for-profit health system serving Indiana and northwest Ohio, and a disproportionate-share hospital (DSH) covered entity under Section 340B of the Public Health Service Act.

We appreciate the opportunity to comment on the Information Collection Request (ICR) referenced above, which the Health Resources and Services Administration (HRSA) has submitted to the Office of Management and Budget (OMB) for review under the Paperwork Reduction Act (PRA).[1]

Our comments are directed to the matters OMB must evaluate under the PRA: whether the collection is necessary and will have practical utility, whether HRSA's burden estimate is accurate, whether the quality and clarity of the information can be enhanced, and how the burden on respondents can be minimized.[2] We confine our comments to these matters in light of HRSA's statement that concerns not directly related to the burden of this collection will be addressed in a separate Federal Register notice. As explained below, the estimate of covered-entity burden is unsupported and is internally inconsistent with HRSA's own definition of "burden." We respectfully urge OMB to decline to approve this collection as submitted and to return it to HRSA for a corrected burden analysis.

Parkview previously submitted comments addressing the substantive and legal deficiencies of a 340B rebate model.[3] We incorporate those comments by reference and expressly reserve all substantive, statutory, and constitutional objections to a rebate mechanism. The exclusion of those

[1] Agency Information Collection Activities: Proposed Collection; Public Comment Request; 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Control No. 0906-NEW, 91 Fed. Reg. 35,989 (June 15, 2026), federalregister.gov/d/2026-11989. Comments are due July 15, 2026.

[2] 44 U.S.C. § 3506(c)(2)(A); 5 C.F.R. § 1320.8(d)(1) (specifying the matters on which an agency must solicit and consider public comment, including whether the collection is necessary and has practical utility, the accuracy of the burden estimate, enhancement of quality and clarity, and minimization of burden, including through automated collection techniques).

[3] Parkview Health, April 20, 2026, Comment on HRSA's Request for Information: 340B Rebate Model Pilot Program, Comment mo7-t7ne-csej, https://www.regulations.gov/comment/HRSA-2026-0001-2338.

arguments from this letter reflects only HRSA's scoping of the present notice and is not a waiver of any position.

I. The burden estimate is internally inconsistent with HRSA's own definition of burden.

HRSA's own Burden Statement in the ICR defines the burden of the collection to include not only the time to transmit data, but also the time to develop, acquire, install, and utilize technology and systems for collecting, validating, verifying, processing, and maintaining the information, and the time to train personnel to respond.[4] Yet in defending its five-hour estimate, HRSA disregards precisely those activities. HRSA acknowledges that commenters described claims identification, extraction, formatting, validation, submission, reconciliation, denial management, and ongoing auditing, and that these may require additional staffing, system modifications, and cross-departmental coordination.[5] It then sets those inputs aside on the ground that they reflect "overall operational impacts rather than the incremental time required to complete individual reporting responses."[6] That distinction cannot be reconciled with HRSA's own definition. The activities HRSA excludes–system development, validation, processing, and training–are the very activities its Burden Statement says to count. An estimate that omits the largest components of its own stated burden definition is not an accurate estimate within the meaning of the PRA and its implementing regulations[7]; it is a partial transmission-time estimate mislabeled as the entire burden estimate.

II. A flat five-hour weekly estimate cannot be accurate because the required work scales with claim volume.

Even setting that inconsistency aside, a flat figure of five hours per week cannot accurately describe the burden, because the work HRSA itself lists scales with the number of claims, not with the number of weeks. Identifying eligible claims, applying 340B eligibility logic to each, validating each against manufacturer specifications, reconciling each rebate, and managing denials are per-claim activities. A covered entity dispensing a handful of qualifying units per week and one dispensing thousands cannot plausibly incur the same weekly burden. HRSA's estimate is invariant to volume, which is the single most important driver of the actual workload. For a high-volume DSH hospital, the understatement is severe.

HRSA compounds the error by speculating that larger or more complex entities "may have a more sophisticated operations infrastructure that will lower the burden."[8] Sophistication is not spare capacity. Existing pharmacy and revenue-cycle systems are configured to bill payers for payment;

[4]91 Fed. Reg. at 35,991 (Burden Statement); accord HRSA, Supporting Statement A at 11, "Estimates of Annualized Hour Burden" (same definition, expressly including time to "develop, acquire, install, and utilize technology and systems… [and] to train personnel").

[5]Id. at 35,990.

[6]Id. (declining to credit higher commenter estimates as reflecting "overall operational impacts rather than the incremental time required to complete individual reporting responses"); accord Supporting Statement A at 9 ("HRSA determined that these estimates reflect total operational workload rather than the incremental time required to complete individual reporting responses").

[7]44 U.S.C. § 3506(c)(2)(A); 5 C.F.R. § 1320.8(d)(1).

[8]91 Fed. Reg. at 35,990.

they are not configured to determine 340B rebate eligibility on a per-claim basis and transmit that determination to a manufacturer's adjudication platform. Building and validating that additional capacity is net-new effort that the estimate ignores.

III. The estimate rests on a false equivalence between rebate-claim submission and obligations covered entities already perform.

HRSA's low estimate also depends on the premise that the required data is "comparable to data already being collected and maintained by covered entities through existing third-party vendor relationships" and "materially similar" to obligations under Medicare, Medicaid, and commercial payers.[9] That premise is incorrect, and because it is load-bearing, it undermines the entire estimate. Payer claims are submitted to obtain payment for a service and are adjudicated under established, standardized transaction rules. This collection requires something fundamentally different: a covered entity must determine, claim by claim, whether a dispense is 340B-eligible–applying the orphan-drug exclusion, the GPO prohibition, contract-pharmacy and child-site rules, and Medicaid duplicate-discount logic–and then push that eligibility determination, in each manufacturer's required format, into a manufacturer-controlled platform in order to recover a discount the entity is already entitled to by statute. Under the prior pilot, that platform was a single manufacturer-selected vendor responsible for validating eligibility and issuing payment.[10] Integrating with such a platform, conforming to its specifications, and contesting its eligibility denials has no analog in routine payer billing. HRSA's own Supporting Statement concedes the point in part, acknowledging that certain payer fields such as BIN and PCN are not routinely requested for these 340B transactions and that medical-claims data is generated from different sources than retail pharmacy claims–data that, by HRSA's own account, is not already in hand. Characterizing the requirement as "materially similar" to existing obligations is incorrect and further erodes the accuracy of HRSA's estimate of the burden.

IV. HRSA's own figures contradict its characterization of the collection as a minimal burden.

HRSA's own calculation of effort refutes its characterization of the collection as limited or minimal. The eleven participating manufacturers–the parties that benefit from substituting rebates for upfront discounts–bear 352 total annual hours between plan submissions and monthly reports. Covered entities bear 3,964,740 annual hours. More than 99.9 percent of the total burden of this

[9] Id. at 35,990–91 (data described as "comparable to data already being collected and maintained by covered entities through existing third-party vendor relationships" and "materially similar" to Medicare, Medicaid, and commercial-payer obligations). HRSA's Supporting Statement nonetheless concedes that "some payer information fields (ex. BIN/PCN) are fields not routinely requested for these 340B transactions" and that medical-claims data "is generated from different sources than from retail pharmacy claims." Supporting Statement A at 5, "Efforts to Identify Duplication and Use of Similar Information."

[10] Under the original pilot, the participating manufacturers selected Second Sight Solutions' Beacon platform to validate 340B rebate-claim eligibility and issue rebate payments. See National Ass'n of Community Health Centers, 340B Rebate Model Pilot Program.

collection falls on the covered entities that neither sought nor benefit from the change.[11] A collection so lopsided warrants exacting scrutiny of whether its practical utility justifies its cost.

Respondent and form	Total annual burden hours	Share of total
Manufacturers (pilot-plan submissions + monthly purchase reports)	352	< 0.01%
Covered entities (claims-data reporting to platform)	3,964,740	99.99%
Total	**3,965,092**	**100%**

Source: 91 Fed. Reg. at 35,991, Table 1.

That scrutiny is dispositive here, because HRSA has already quantified the cost in its own Supporting Statement, and the figure is enormous. In its "Estimated Annualized Burden Costs to Respondents," HRSA values covered-entity burden at a $132.00 per-hour pharmacist wage–May 2024 Bureau of Labor Statistics data, doubled for overhead and benefits–and states a covered-entity cost of $523,345,680 per year, over half a billion dollars of effort per year, with the participating manufacturer cost of only $39,248.[12] This is not an outside extrapolation; it is HRSA's own estimate, and it rests on the five-hour figure shown above to be understated. HRSA's accompanying footnote concedes that the collection produces "large aggregate cost figures," and defends them only on the grounds that the Pilot covers roughly five percent of 340B sales and that the program's benefits are "expected to outweigh the compliance costs." An agency that estimates more than half a billion dollars in annual covered entity cost has not described a minimal burden; it has described a substantial one and asks, without any justification or reasoned articulation, that covered entities bear it in order to access 340B discounts to which they are legally entitled.

The understatement compounds that cost. HRSA itself characterizes the five-hour figure as only a "median" across covered entities of varying size and volume, and acknowledges that burden is proportional to the number of dispenses relative to the size of the entity–expressly recognizing that smaller entities will report less.[13] The corollary HRSA does not address is that high-volume DSH

[11] 91 Fed. Reg. at 35,991 (Table 1). Manufacturer burden = 88 hours (plan submissions) + 264 hours (monthly purchase reports) = 352 hours; covered-entity burden = 3,964,740 hours; total = 3,965,092 hours.

[12] HRSA, Supporting Statement A, at 12, 340B Rebate Model Pilot Program ICR, OMB Control No. 0906-NEW (ICR Ref. No. 202606-0906-001), "Estimated Annualized Burden Costs to Respondents." HRSA applies a $132.00 hourly pharmacist wage (May 2024 BLS data, "doubled to account for overhead costs and benefits") to 3,964,740 covered-entity hours for a covered-entity cost of $523,345,680, within a total respondent cost of $523,384,928. The Supporting Statement is available through HRSA's OMB submission at reginfo.gov. Accounting additionally for vendor, IT, and audit costs, AHA estimated total annual cost to 340B hospitals exceeding $1 billion. See AHA, Comment Letter (Apr. 20, 2026).

[13] HRSA, Supporting Statement A, at 9 (describing the five-hour figure as "a reasonable median burden across this range" and stating that the burden "will be proportional to the number of dispenses relative to the size of the covered entity"). On the field estimates, see AHA, Comment Letter (Apr. 20, 2026) (citing a NACHC assessment in which

hospitals occupy the upper tail that a median omits. Independent field evidence confirms the gap: covered entities have estimated that compliance will require between roughly one-half and more than two full-time equivalents per entity, whereas five hours per week is approximately one-eighth of a single FTE. The gap between HRSA's median estimate and operational reality is not marginal; it is a multiple.

V. HRSA did not consider readily available, less-burdensome alternatives, as the PRA requires.

The PRA requires HRSA to minimize the burden of the collection, including through the use of automated collection techniques and other forms of information technology. HRSA has not done so. Commenters identified a centralized clearinghouse as a means of achieving HRSA's stated integrity objectives–preventing duplicate discounts and diversion–through a single submission rail rather than entity-by-entity, manufacturer-by-manufacturer transmissions. HRSA declined, stating in its Supporting Statement that clearinghouses are "not specifically authorized under the 340B statute" and "would not allow for pre-payment adjudication of 340B claims transactions."[14] Neither rationale addresses burden, and the second rationale cannot be reconciled with the fact that the rebate model itself is post-payment by design. The PRA requires HRSA to weigh a less-burdensome alternative on its burden merits; HRSA rejected this one without analyzing the burden difference at all. The architecture HRSA chose instead multiplies burden as the program grows: the present collection already spans eleven manufacturers, more than the nine in the original pilot, and HRSA contemplates further expansion.[15] HRSA also assumes that automation will reduce burden, yet the cost of building, integrating, and validating that automation is itself burden under HRSA's own definition and is nowhere accounted for in the estimate.[16] An agency cannot both claim the benefit of assumed automation and decline to count its cost.

VI. Undefined data terms undermine practical utility and impose unaccounted burden.

Finally, the collection's practical utility and the quality of the information cannot be assessed as required, because material terms governing the covered-entity data submission remain undefined and, where defined under the prior pilot, were inadequate. The collection requires transmission of claims-level–and thereby patient-level–information into a manufacturer-controlled platform. Under the prior pilot, the contractual protections governing that data were presented as non-negotiable and contained far too limited data privacy and security assurances, including only a $100 cap on the vendor's liability for misuse or breach, which requires covered entities to accept,

47% of responding health centers estimated needing 0.5–1 FTE, 36% estimated 1–2 FTEs, and 7% estimated more than 2 FTEs). Five hours per week is approximately 0.125 FTE.

[14]HRSA, Supporting Statement A, at 7-8 (declining to establish a federal clearinghouse on the grounds that clearinghouses are "not specifically authorized under the 340B statute" and "would not allow for pre-payment adjudication of 340B claims transactions"); see also 91 Fed. Reg. at 35,989 (acknowledging clearinghouse and other alternative-design comments).

[15]The original pilot covered ten drugs from nine manufacturers. Implementation was paused on December 29, 2025 by an order of the U.S. District Court for the District of Maine. See Request for Information: 340B Rebate Model Pilot Program, 91 Fed. Reg. 7,287 (Feb. 17, 2026), federalregister.gov/d/2026-03042.

[16] 91 Fed. Reg. at 35991.

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without any opportunity to negotiate, substantial risk that they would be saddled with the full burden of a data breach, a risk that should be factored into OMB's consideration. The security and privacy infrastructure a covered entity must build to transmit such data safely is, again, burden under HRSA's own definition and is unaccounted for. More fundamentally, OMB cannot find that this collection has demonstrated practical utility, or that its quality and clarity are adequate, when the data specifications, frequency, and protective terms are to be set only later, in a notice HRSA has not yet issued. The PRA contemplates that practical utility be demonstrable at the time of approval, not deferred to a future and as-yet-unwritten notice.

Recommended action.

For the reasons above, Parkview respectfully urges OMB not to approve this collection as submitted. At a minimum, OMB should return the ICR to HRSA and direct it to: (1) re-estimate covered-entity burden using a volume-based, per-response methodology that counts the system-development, validation, reconciliation, denial-management, training, and data-security activities encompassed by HRSA's own definition of burden; (2) substantiate, with record evidence, its assertion that the required data is already collected and transmissible without material new effort; (3) analyze at least one less-burdensome alternative, including a centralized clearinghouse; and (4) reconcile its burden estimate with the administrative cost implied by its own per-hour valuation. A burden estimate that omits the largest components of the agency's own burden definition, that does not vary with the volume that drives the work, and that the agency's own cost figures contradict, does not meet the PRA's requirement of an accurate estimate or a demonstrated practical utility.

Thank you for the opportunity to comment. We are available to provide additional detail, at the Desk Officer's request.

Respectfully submitted,



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Parkview Health

July 15, 2026

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July 15, 2026

The Honorable Thomas J. Engels
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Re: Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation (OMB Number 0906-NEW)

Dear Administrator Engels:

On behalf of our more than 2,000 member hospitals and health systems that participate in the 340B Drug Pricing Program, the American Hospital Association (AHA) appreciates the opportunity to respond to this Information Collection Request (ICR) about the Health Resources and Services Administration's (HRSA) proposed 340B Rebate Model Program. The AHA previously submitted comments in response to HRSA's Feb. 26, 2026, ICR. We resubmit those comments here. *See* Attachment A.

The facts have not changed since our initial submission. The proposed Rebate Program will inflict *more than a billion dollars* in annual costs on 340B hospitals alone. A meaningful percentage of those costs — far more than 5 hours of labor per week — will be spent on consolidating and submitting the information that 340B hospitals will be required to provide to drug companies and their chosen third-party vendor.

What appears to have changed, however, is the scope of this ICR. The current ICR notice makes clear that, under the Paperwork Reduction Act (PRA) of 1995, the agency is evaluating only a portion of the Rebate Program's overall costs. HRSA notes that it previously considered burdens associated with "reconciling submissions and tracking rebate status" and "addressing errors, denials, or follow-up requests," but those two categories of costs are now considered outside the scope of the ICR. Instead, the current ICR draws a distinction between "overall operational impacts" and "the incremental time required to complete individual reporting responses under the PRA framework." Consequently, the ICR will exclude a broad range of costs, including "float costs," non-economic costs, the massive costs at the back-end of the rebate process to track and reconcile rebates, and costs associated with disputing errors, denials or

follow-up requests. While the agency may believe that approach best adheres to the purposes of the Paperwork Reduction Act of 1995, *see* 44 U.S.C. § 3501; *Dole v. United Steelworkers of Am.*, 494 U.S. 26, 36–37 (1990), it is of limited value in assessing the overall costs and benefits of the proposed Rebate Program itself, *e.g., Michigan v. EPA*, 576 U.S. 743, 752 (2015).

Even so, it is still important that the agency's Paperwork Reduction Act estimates be accurate. But rather than crediting the empirical calculations of the 340B covered entities that will actually bear the costs of collecting and submitting the required information, HRSA appears to have discounted them. In holding firm to its 5 hours-per-week estimate, the agency seems to have accepted the drug industry's erroneous and conclusory premise that the required "data elements are commonly available and already generated, maintained, and transmitted by covered entities or their vendors." In fact, HRSA's Supporting Statement concludes (at 9) that the "implementation costs" for 340B hospitals "are likely to remain low" because "the data that would be submitted to drug manufacturers reflects information that covered entities already routinely generate, maintain, and transmit to third parties for billing and reimbursement purposes."

The drug industry's premise is wrong. HRSA's uncritical acceptance of that premise leads to a burden estimate that does not reflect the realities covered entities will face. HRSA's ensuing conclusion about "low" implementation costs, therefore, misses the mark.

First, HRSA's analysis does not fully account for what 340B hospitals have told the agency about how their information systems work in the real world. Under the proposed Rebate Program, the agency would require hospitals to submit data fields from two general categories: "Pharmacy Claims Data Fields" and "Medical Claims Data Fields." Our members inform us that these two sets of fields are commonly housed on different electronic systems within their hospitals. HRSA seems to recognize this. The Supporting Statement (at 5) explains that "some payer information fields (ex. BIN/PCN) are fields not routinely requested for these [contract pharmacy] transactions. Additionally, medical claims data is generated from different sources than from retail pharmacy claims." Similarly, the information that hospitals submit to Medicare, Medicaid, and commercial insurers for *billing purposes* is kept on still other electronic systems, and hospitals do not submit all of the required information (*e.g.*, wholesaler invoice number and product sterilization number) to insurers.

Put simply, the data fields that the Rebate Program will require do not exist in one place, and the idea that all hospitals can seamlessly integrate data between disparate systems is unfounded and unreasonable. As one 340B hospital explained in an earlier comment letter that is part of the ICR record, a Rebate Program "would require us to extract and reconcile data from multiple internal and external systems and manually assemble submission files in ways that are not part of our current 340B processes." And

because they are not part of those existing processes, HRSA has vastly undercounted the cost and labor required to assemble it for submission to the drug companies.

So while it may be true that hospitals "generate, maintain, and transmit" certain aspects of this information for certain purposes, that premise overlooks the reality that combining this disparate information and submitting it to drug companies for the purpose of obtaining 340B discounts will require time, work and money. It is not enough for HRSA (at 5) to rely on the drug industry's position that a Rebate Program would not "require covered entities to collect or maintain any new or additional information beyond what is already captured in the ordinary course of billing and claims processing for Medicare, Medicaid and commercial payers." The initial "collect[ing] or maintain[ing]" of data is not the most burdensome part of the submission process; the added costs and labor hours stem from the combining of the data from different sources and then ensuring that it is accurate and capable of being submitted without rejection.

Perhaps the following analogy will make all of this more understandable. At the Department of Health and Human Services (HHS), information is stored across a number of different electronic systems, including different subagencies (*e.g.*, Office of the Secretary, Centers for Medicare & Medicaid Services, Centers for Disease Control and Prevention, etc.) and sometimes different components within those subagencies. Nevertheless, that information is "commonly available"; HHS has "already generated [and] maintained" it. But when a Freedom of Information Act (FOIA) request comes in, HHS must expend time, labor, and money to 1) combine that information from across the different systems, 2) review that information to make sure it is accurate and capable of release, and then 3) transmit it to the FOIA requester. *See, e.g.*, Fourth Decl. of William H. Holzerland, *Citizens for Responsibility and Ethics in Washington v. United States Centers for Disease Control and Prevention*, Case No. 25-1020, Dkt. 43-3 ¶ 14 (D.D.C. Sep. 4, 2025) ("The time needed [to process FOIA requests] depends on factors such as … the need to search in multiple offices or systems…."). That process can be quite expensive and burdensome. So too for hospitals under a Rebate Program.

Ultimately, HRSA cannot dismiss or lose sight of the fact that 340B hospitals have built, tested and refined their information systems based on 30 years of operating under an upfront discount model. They never had to do Rebate Program submissions before. So the fact that this information exists *somewhere* on a hospital's many networks does not mean that it is costless to retrieve it from different places, combine it in the way that the drug companies require, and submit it for discounts they previously would have received at the time of sale. The cost- and hours-estimates that the AHA and its hospital members submitted in the first round of comments reflected this decades-old reliance. HRSA should not discard these estimates while uncritically accepting comments from those who do not operate hospital information systems day-to-day.

Second, HRSA's assumption that hospitals "already routinely generate, maintain, and transmit to third parties for billing and reimbursement purposes" ignores critical real-

world timing differences between billing and the proposed Rebate Program. According to the Supporting Statement, hospitals will be required to submit information within 45 days of dispense. But hospitals have much longer — often 90 or 120 days — to submit claims for billing purposes.

This time difference is significant. For starters, the accelerated Rebate Program timeline means that hospitals will need to devote additional labor and money to meet a 340B submission deadline they otherwise do not have to meet for "billing and reimbursement purposes." Needless to say, it is easier to collect and submit information when you have more time to do so. Thus, it is wrong to argue that "the data sharing requirements contemplated with rebates are materially similar to existing obligations imposed by Medicare, Medicaid, and commercial payers." In reality, the timing is materially *dissimilar*.

In addition, the 45-day timeline means that some information will not even be available for submission by the Rebate Program deadline. Consider the example of a baby who came to a 340B hospital's emergency department and was subsequently admitted for care in a Neonatal Intensive Care Unit. Sadly, babies often require NICU care for far longer than 45 days. In the real world of hospital operations, the data required under a Rebate Program would not even be available for submission until *after* the baby has been discharged. The same is true for countless other patients who require care for close to or longer than 45 days. Again, this is how hospital information systems have been structured and have operated for decades, *i.e.*, without the need to submit information before discharge simply to receive a 340B discount that is owed by statute. Under the Rebate Program, however, hospitals will lose out on 340B discounts or have to expend massive time and resources altering their internal systems to meet the data submission requirements of a one-year, so-called "pilot program." Nothing in the statute allows an arbitrarily chosen 45-day deadline to determine whether a covered entity will receive a discount owed by law.

Third, HRSA repeatedly emphasizes that the Rebate Program will involve a "limited set of drugs." But that is no answer. Although data will need to be submitted for "only" up to 25 drugs, a hospital's internal information systems cannot be easily altered just for those drugs. Our members tell us that they will need to make wholesale changes to their systems to accommodate a Rebate Program. Just as HHS cannot easily alter its internal information systems solely to capture only those documents that are or might be subject to a FOIA request, hospitals cannot easily alter their systems only for information about drugs required under a Rebate Program.

Fourth, HRSA notes that some commenters asserted that "particularly after initial implementation, ongoing reporting activities may be automated or integrated into existing workflows, thereby reducing incremental burdens on covered entities." This statement is merely speculative and has no actual evidence to support it. Moreover, automation is not costless even when it is feasible. Hospitals — particularly those in

rural and other underserved areas — do not have the resources to invest in this effort, nor should they have to make those investments just so that they can obtain discounts owed by statute. HRSA makes no suggestion that automation can occur within the timeframe that the pilot program envisions. If HRSA is serious that this is a one-year, so-called "pilot," then the alleged automation efficiencies cannot be implemented in that time frame. Our members inform us that any automation changes will take years. Thus, the full cost of implementing the Rebate Program's information submission requirements, much of which will require manual labor by additional full-time employees, will be borne during the purported one-year "pilot" period.

Fifth, HRSA's 5 hours-per-week estimate does not account for the problems associated with the drug companies' preferred third-party vendor. Both the AHA and its members have explained the many technical difficulties they have had with these vendors. In fact, hospitals are *already* experiencing those problems in connection with the Medicare Drug Price Negotiation Program; members have informed the AHA (and HRSA in their comment letters) that the third-party vendors create additional burdens through improper delays and denials based on incorrect assertions of submission errors. Even with what the Supporting Statement calls a "technical assistance/customer service component," resolving these difficulties takes time and money. These vendor-associated challenges require hours of additional labor — most often manual labor to follow up on mistakes and to ensure that data submitted will actually be accepted. A 5-hour-per-week estimate does not capture the added costs that the third-party vendor will create, and HRSA's analysis should fully account for this important aspect of the problem in its ICR Notice and Supporting Statement.

Sixth, the agency's cost analysis is based solely on hourly burden. It does not include one-time monetary costs to set up a new data collection system or ongoing non-labor fees to keep those systems running. In addition, as one ICR commenter explained, HRSA cannot rely on "solely the time required to submit data"; it must also consider costs related to "cybersecurity, data governance, [and] staff training." These omissions demonstrate either the narrowness of the Paperwork Reduction Act analysis or a significant error in how the agency is conducting the burden analysis here. Either way, the failure to consider non-hourly burdens leads to a significant undercounting of the costs that a Rebate Program will inflict on 340B covered entities. HRSA's approach also contradicts the ICR notice itself. The notice's Burden Statement defines burden to include "the time needed to" "develop, acquire, install, and utilize technology and systems" and "to train personnel." That is precisely what the excluded estimates measure. HRSA cannot define these costs into the ICR's burden statement and then define them out of its burden estimate.

Seventh, OMB and the public are being asked to evaluate a collection whose requirements do not yet exist. The ICR notice states that "[s]pecific requirements detailing the type and frequency of such submittals will be defined in a Federal Register notice" at some future date. Neither OMB nor commenters can meaningfully assess the burden

imposed by data elements, formats, and submission deadlines that HRSA has not yet defined. Indeed, HRSA's burden table already assumes that covered entities will submit claims data 52 times per year, even though the notice says the frequency of submissions "will be defined" later.

Finally, the AHA has serious concerns about how HRSA calculated the 5-hour-per-week estimate. The agency notes in the Supporting Statement that it chose its 5-hour-per-week estimate as a "reasonable median burden" since the "actual burden may be lower for some entities and higher for others." Having reviewed the comment submissions in the record, however, the AHA does not believe that this math is accurate. Going forward, HRSA must explain in greater detail: 1) exactly how it came to its 5-hour "median" figure based on the *actual numerical estimates* in the record, rather than broad conclusory assertions about what burdens "may be" lower and higher; 2) specifically, what below-5-hours-per-week estimates it received to offset the many above-5-hours-per-week it received from many other hospitals and other covered entities. It should not be difficult, for example, for HRSA to produce a chart showing all of the below-5-hours-per-week estimates that would allow the agency's 5-hour estimate to sit at the median.

More fundamentally, HRSA must explain why it used a median estimate rather than one that better captures what labor covered entities will have to devote to the Rebate Program. Reliance on a median can obscure substantial variation among regulated entities and can materially understate aggregate burden when compliance costs are unevenly distributed, or the population of covered entities that experience the burdens is not evenly distributed. Because the median reflects only the midpoint observation, it fails to capture the burden imposed on entities facing significantly above-median costs and therefore may not provide a reliable estimate of the rule's overall impact. Ultimately, if HRSA does not provide meaningful responses about (1) the numbers it actually used, (2) the math it performed to reach a 5-hour-per-week "median" estimate, and (3) why a median is the best measure in the first place, the agency will be ignoring both record evidence and important aspects of the problem.

All in all, HRSA's 5-hour estimate understates the work required to submit the information that will be required under the Rebate Program. As demonstrated above, the agency relies on a series of flawed premises to reach that incorrect estimate. Once those premises are corrected, HRSA cannot discount the higher estimates that hospitals and other covered entities submitted in the earlier round of comments. Those estimates — which were far more detailed than the conclusory statements submitted by drug companies and their trade associations — accurately reflect the real world of hospital operations. Hospitals, not drug companies, best understand what will be required to complete the limited tasks considered under this ICR. Their estimates of costs under the Paperwork Reduction Act should be privileged. And when the *overall* costs of the Rebate Program —*i.e.*, not just the narrow category that is being

considered in this ICR — are taken into consideration, they vastly outweigh any purported benefits.

The AHA appreciates your careful consideration of these issues. We are eager to meet to address any questions that you might have about the Rebate Program's tremendous costs and burdens on 340B covered entities.

Sincerely,

/s/

Chad Golder
General Counsel and Secretary

Attachment: Appendix A

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April 27, 2026

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Re: 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-NEW

To Whom It May Concern:

On behalf of our more than 2,000 member hospitals and health systems that participate in the 340B Drug Pricing Program, the American Hospital Association (AHA) appreciates the opportunity to respond to this Information Collection Request (ICR) about the Health Resources and Services Administration's (HRSA) potential 340B Rebate Model Program.

Last week, the AHA submitted lengthy comments in response to the Request for Information about the proposed Rebate Model Program itself. Our letter contains detailed information that also is responsive to this ICR, and so we attach those.

To avoid repetition, we simply reiterate that the estimated burden is wildly off-the-mark. As we explain in our letter, our members inform us—and as they have informed HRSA—that they will need to devote far more than five hours per week on any Rebate Model Program. We also explain that massive amounts of manual labor will be required to comply with any rebate mechanism because automated collection techniques or other forms of information technology cannot minimize the information collection burden. Finally, our comments explain that the burden will involve far more than labor hours; it also includes payment to outside vendors, the costs of "floating" millions of dollars to drug companies as zero-interest loans, and non-economic costs to patients and communities.

In short, the record already demonstrates that costs of a Rebate Program far outweigh any purported benefits. *E.g.*, *Michigan v. EPA*, 576 U.S. 743, 752 (2015). When the agencies satisfy their Paperwork Reduction Act requirements and conduct an accurate burden analysis, that will become even clearer.

We appreciate your careful consideration of these issues. Please contact me if you have any questions.

Sincerely,

/s/

Chad Golder
General Counsel & Secretary

American Hospital Association™
Advancing Health in America

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April 20, 2026

The Honorable Thomas J. Engels
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20852

Re: Request for Information: 340B Rebate Model Pilot Program (HRSA–2026–03042)

Dear Administrator Engels:

On behalf of our more than 2,000 member hospitals and health systems that participate in the 340B Drug Pricing Program, the American Hospital Association (AHA) appreciates the opportunity to respond to the Health Resources and Services Administration's (HRSA) Request for Information regarding a potential 340B Rebate Model Pilot Program.

This RFI asks, among other things, "whether HRSA should implement a rebate model under the 340B program." Request for Information: 340B Rebate Model Pilot Program, 91 Fed. Reg. 7,287 (Feb. 17, 2026) (hereinafter "RFI"). As time has gone on, and as HRSA has said more about the rebate mechanism during litigation and in the RFI and its related Information Collection Request (ICR), it has become clear that the only possible answer is "no." Because a rebate mechanism of any kind is flawed in both conception and design, the AHA urges HRSA to abandon the idea altogether.[1]

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[1] To avoid repetition, the AHA incorporates all of its previous comment letters addressing HRSA's 340B Rebate Model Pilot Program. *See* American Hospital Association, Comment Letter on Application Process for the 340B Rebate Model Pilot Program (HRSA-2025-14998) (Aug. 27, 2025), https://www.aha.org/system/files/media/file/2025/08/aha-comments-to-hrsa-on-proposed-340b-rebate-model-pilot-program-letter-8-27-2025.pdf; American Hospital Association, Comment Letter on 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-0111 - Extension (Sep. 30, 2025), https://www.aha.org/lettercomment/2025-09-30-aha-letter-hrsa-re-340b-rebate-model-pilot-program. The AHA also incorporates all of its legal filings in the United States District

Since the 340B program first became law, HHS has recognized a single mechanism to make the 340B price available to participating hospitals—upfront discounts. As the United States Court of Appeals for the First Circuit recently observed, an upfront discount mechanism fulfills Congress' purpose in creating the 340B Program: "Since Section 340B's enactment, the pricing agreements have required manufacturers to provide discounts to safety-net hospitals at the time of sale in order 'to stretch scarce federal resources as far as possible.'" *Am. Hosp. Ass'n v. Kennedy*, 164 F.4th 28, 31 (1st Cir. 2026).[2] The First Circuit also recognized that HHS historically determined a rebate mechanism is "both inferior to Section 340B's current upfront-discount model and disruptive to safety-net hospitals." *Id*. at 32; *see also* Compl. ¶¶ 43, 45, 48, 50, *Am. Hospital Ass'n v. Kennedy*, 2:25-cv-600 (D. Me. Dec. 1, 2025).

Yet in this RFI, HRSA has announced that it is still considering whether to move forward with a new version of the 340B Rebate Program. In fact, HRSA has stated that it might *expand* the Rebate Program to include as many as 15 more drugs. *See* Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, 91 Fed. Reg. 9,632 (Feb. 26, 2026) (hereinafter "2026 ICR"). Put another way, HRSA is persisting with a flawed concept that deviates from the purpose of the 340B Program. In so doing, it will inflict *more than a billion dollars* in costs annually on the hospitals that Congress designed the 340B Program to benefit. It will jeopardize access to care for millions of Americans. It will force 340B hospitals to divert their scarce resources away from providing comprehensive services to patients and toward compliance with a new discount mechanism that benefits only drug companies and their third-party vendor, Second Sight Solutions. And it will do so in a way that has inherent and insurmountable design flaws.

HRSA has said it is considering a rebate mechanism because it believes that it "must balance the interests of two industries at loggerheads." Reply in Supp. of Mot. For Stay Pending Appeal at 1, *Am. Hospital Ass'n v. Kennedy*, No. 25-2236 (1st Cir. Dec. 31, 2025) ("Stay Reply Br."); *see* RFI, 90 Fed. Reg. 7,288 ("HRSA sought a balanced and measured approach to allow eligible manufacturers to implement rebate models, at the Secretary's direction and discretion, within certain parameters that would cause minimal impact on 340B covered entities."); Declaration of Chantelle Britton ¶ 4, *Am. Hospital Ass'n v. Kennedy*, 1:25-cv-600 (D. Me. Dec. 15, 2025) ("Britton Decl."). That belief is mistaken. *First*, HRSA's statement draws a false equivalence between some of the

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Courts for the District of Columbia and Maine, and the United States Courts of Appeals for the District of Columbia and First Circuit.

[2] The current RFI recognizes that the purpose of the 340B program is to "enable covered entities 'to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.'" RFI, 91 Fed. Reg. at 7288 (quoting H.R. Rep. No. 102–384(II), at 12 (1992)).

world's most profitable publicly traded companies, and American safety-net providers that rely on razor-thin margins to care for rural and other underserved communities. *Second*, this is the wrong lens through which to view this question. Even if HRSA believes itself to be "positioned between two regulated industries," Stay Reply Br. at 4, *it must give primacy to covered entities on this issue, see* H.R. Rep. 102-384, pt. 2, at 16 (1992). HRSA appears to have done exactly the opposite. *See* RFI, 90 Fed. Reg. 7,288 ("HRSA became interested in testing the merits and shortcomings of a rebate model, including whether *it would be beneficial to manufacturers* participating in the MDPNP as well as to 340B program integrity efforts relating to the prevention of 340B Medicaid duplicate discounts and diversion." (emphasis added)). HRSA's stated goal of "thoroughly balancing competing interests" (and its concomitant failure to privilege covered entities) fails from the start.

Relatedly, no reasonable cost-benefit analysis could justify the astronomical economic and non-economic burdens a Rebate Program will impose. HRSA estimated that its original Program, which included only 10 drugs, would have imposed $200 million in annual administrative costs on 340B hospitals and other covered entities. This prediction was based on HRSA's estimate that a rebate mechanism would require only 2 hours of additional work per week for covered entities. The AHA previously explained that these 2 hour and $200 million numbers—while unjustifiable—vastly underestimated the true administrative costs associated with a 10-drug Rebate Program.

HRSA's recent pronouncements reveal that it has doubled down on its flawed methodology and ensuing underestimations. It now states that the "scope of the potential 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 years 2026 and 2027." 2026 ICR, 91 Fed. Reg. 9632. While couched as a limitation, that is actually an expansion.

Per the ICR, the new Rebate Program could include up to 25 drugs from 13 drug companies. Consistent with this expanded scope, HRSA has increased its preliminary estimate of data collection burden hours from two per covered entity per week to five per covered entity per week. *Id.* at 9633. Using HRSA's original assumption that each extra burden hour will cost a covered entity $132 (based on a pharmacist's 2024 hourly wage and overhead costs), HRSA would now appear to admit that its contemplated Rebate Program will cost covered entities *more than $500 million* each year in labor costs (3,796,000 hours x $132 = $501,072,000). *See id*. The proposed Rebate Program therefore would divert *at least* half a billion dollars away from providing "more comprehensive services" and care for "more eligible patients." H.R. Rep. No. 102-384, pt. 2, at 12 (1992). The previous $200 million labor cost could not justify HRSA's original Rebate Program; a $500 million one certainly cannot either.

To make matters worse, HRSA's estimates drastically understate the Rebate Program's administrative costs. Hospitals have made clear that they will need to devote far more than 2 to 5 hours per week to comply with a rebate mechanism. Our most conservative

estimates are that a Rebate Program will require 340B hospitals, on average, to hire at least one new FTE. Using HRSA's own methodology, that estimate translates into a *$750 million* price tag—just for 340B hospitals, just for one FTE, just for labor costs. An estimate of only one new FTE is almost certainly low, but even at that conservative $750 million number, the decision to move forward with a Rebate Program would be irrational.

But that is not all. When the most conservative estimates of the Rebate Program's other operational costs (*e.g.*, third-party vendors and TPAs, auditors, IT specialists, etc.) are added to that already-conservative labor cost estimate, the total administrative costs to 340B hospitals alone will exceed $1 billion. "[T]hat's billion with a b." *White Stallion Energy Cir., LLC v. EPA*, 748 F.3d 1222, 1259 (D.C. Cir. 2014) (Kavanaugh, J., concurring in part and dissenting in part), *rev'd sub nom. Michigan v. EPA*, 576 U.S. 743 (2015). And this figure does not even include other sizable financial expenses like "float costs" and loss of cost-of-goods-sold (COGS) discounts.

Nor does it include the many downstream, non-economic costs that a rebate mechanism will inflict on patients and communities. These harms are real and inevitable. *See Am. Hosp. Ass'n v. Kennedy,* No. 2:25-cv-600, 2025 WL 3754193, at *8 (D. Me. Dec. 29, 2026) (observing that "the downstream effect" of the Rebate Program will cause hospitals to "cut back services and suspend partnerships with drug distributors," and holding that "[t]hese claims are not unsubstantiated fears of what the future might hold."). Patients will lose access to discounted or free drugs, vital health care services, and much more—all because hospitals will need to divert resources toward complying with an unnecessary rebate mechanism. *See Michigan,* 576 U.S. at 752 ("'[C]ost' includes more than the expense of complying with regulations; any disadvantage could be termed a cost…—including, for instance, harms that regulation might do to human health."). So after this RFI/ICR comment period, when HRSA has a full tally of *all* relevant costs, it will have no choice but to conclude that a Rebate Program cannot justify a multi-billion-dollar-imposition on 340B hospitals and other covered entities. *Id.* at 752–53 (2015) ("Consideration of cost reflects the understanding that reasonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions." (emphasis in original)).

Ultimately, any switch to a rebate mechanism will suffer from the same fundamental defect that the AHA explained when HRSA issued its first Notice: a rebate mechanism is a "solution" in search of a problem.[3] There is nothing wrong with the upfront discount mechanism. HRSA has not identified a single problem with it, and nothing in the past

[3] American Hospital Association, Comment Letter on Application Process for the 340B Rebate Model Pilot Program (HRSA-2025-14998) 2 (Aug. 27, 2025), https://www.aha.org/system/files/media/file/2025/08/aha-comments-to-hrsa-on-proposed-340b-rebate-model-pilot-program-letter-8-27-2025.pdf.

several months has changed that reality. Given covered entities' 30-year reliance on that upfront discount mechanism, the AHA respectfully submits that the "ancient legal principle[,] 'if it ain't broke, don't fix it,'" must govern here.[4]

HRSA cannot avoid this fact by claiming that the Rebate Program is a "test." Not only has HRSA never explained what it is actually testing for, *see infra* at 39-40 n.5, but it is a "test" (or "pilot") in name only. Based on information in the ICR, *all* covered entities will be required to participate in the Rebate Program. This kind of mandatory participation in a government program does not even meet the Pharmaceutical Research and Manufacturers of America's (PhRMA) definition of a "test." *See* Pharmaceutical Research and Manufacturers of America, Comment Letter on Global Benchmark for Efficient Drug Pricing (GLOBE) Proposed Rule (HRSA-2025- 14998) 2 (Feb. 23, 2026), https://cdn.aglty.io/phrma/policy-issues/innovative-medicines/Final%20PhRMA%20Comments%20on%20GLOBE%20NPRM.pdf ("GLOBE is a mandatory funding mechanism, not a "'test.'"); *see also id.* ("GLOBE does not fall within this definition. It is not an experiment. Instead, it will generate—with certainty—billions of dollars in forced, punishing rebates from manufacturers."); *id*. ("Imposing price controls in a nationwide manner, however, and charging manufacturers 25 percent rebates based on such price controls, is hardly a mere "'test.'").

Because there is no sound or lawful reason to abandon the upfront discount model, and because the costs of any switch will massively outweigh any expected benefits, HRSA should not proceed with *any* rebate mechanism. Any other decision would do serious, irreparable harm to 340B hospitals and the patients they serve.

I. A Rebate Program Will Impose Far More Costs On 340B Hospitals Than HRSA Estimates

The AHA appreciates HRSA's attempt, through this RFI, to identify the full range of costs that a rebate mechanism will inflict on 340B hospitals, their patients, and the communities they serve. To list these costs is to admit how quickly they will add up—and thereby divert vital resources away from "reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384, pt. 2, at 12 (1992). For example, the RFI correctly identifies broad categories of costs, including administrative costs, staffing impacts, data infrastructure costs, payment-timing costs (or what the AHA calls "float" costs), and more. It also correctly identifies many of the key cost drivers: new full-time employees, additional labor hours, IT systems, third-party vendors, compliance requirements, claims processing, data submission, reconciliation/tracking down rebates owed, audit support, legal review, consulting services, and more. And it rightly recognizes that these new added costs will result in

[4] Tr. of Oral Arg. at 33, *In re: Grand Jury*, No. 21-1397 (Jan. 9, 2023).

"reduction in services offered" to patients and "medication access concerns." RFI, 90 Fed. Reg. 7,289.

To date, HRSA's calculations of these costs have missed the mark by a wide margin. During the original administrative process, HRSA dramatically undercounted administrative costs and improperly dismissed "float" and other non-economic costs. Now that HRSA expects to include the 2027 Inflation Reduction Act (IRA) drugs, those already-tremendous costs will skyrocket. In fact, many hospitals explain that the financial costs of the Rebate Program are so significant that they will substantially eat away at the benefits that Congress intended for them to receive from the 340B Program.[5] Therefore, as HRSA reviews the AHA's comments, as well as those submitted by its members and other covered entities, it will become unmistakably clear that the costs of any Rebate Program—even a so-called "pilot"—are unjustifiable.

Administrative Costs. The AHA and other stakeholders have explained why HRSA previously underestimated the administrative costs and burdens that the Rebate Program will inflict on 340B covered entities. Given the significance of this issue and the continued severity of HRSA's miscalculations in the ICR, we will explain again.

It is important to acknowledge at the start that even the administrative costs that HRSA has recognized—$200 million for the 2026 IRA drugs and $500 million for the 2027 ones—are enormous. Although we agree with HRSA that "participation in the 340B Program … has always entailed certain compliance, operational, and other costs," Britton Decl. ¶ 34, there is no reason to impose *new* costs if they are unnecessary, are not outweighed by any expected benefits, and are inconsistent with the purpose of the

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[5] *See, e.g.*, Rooks County Health Center, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Mar. 5, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0046 ("These costs would consume an estimated 20–30% of RCHC's 340B margin for the drugs included in the pilot, substantially eroding the program's benefit."); O'Neill Decl. ¶ 18, *Am. Hospital Ass'n v. Kennedy*, 2:25-cv-600 (D. Me. Dec. 1, 2025) ("This administrative cost for a so-called "pilot program" is 20% of our *entire* discount from the 340B Program."); Wheeler Health,, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 3, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0305 ("Wheeler Health reports an average loss of $500,000 to $3 million from entity-owned pharmacy operations and 25% reduction in savings for contract pharmacy arrangements due to the administrative hurdles of manual reconciliation."); Wabash General Hospital District, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-1438 ("Overall, the rebate overhead would consume approximately 30% of our savings for the 10 pilot drugs."); Beth Harwood, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 1, 2026), ("The numbers at [Ammonoosuc Community Health Services] tell the story clearly: … Adding the administrative costs required by a rebate model would erode ACHS' savings by 95% — effectively ending the program's benefit for our patients.… This is not about fraud prevention. Robust oversight mechanisms already exist. This is about making the program so burdensome that safety-net providers cannot sustain participation.").

340B program. HRSA's baseline estimates of $200 to $500 million in costs fail each of these yardsticks. Just because the 340B Program requires *some* administrative spending does not mean that HRSA should impose *more* administrative spending.

As the AHA has previously observed, moreover, HRSA's estimates illustrate the lopsided burden imposed on covered entities as compared to drug companies. HRSA predicts only a few hundred hours of annualized burden on drug companies, while estimating over *5,000 to 12,000 times* the amount of annualized burden hours on 340B covered entities (depending on the number of drugs in the Rebate Program). *See* 2026 ICR, 91 Fed. Reg. 9,632. It is hard to understand why HRSA would want to distribute burdens so unevenly. The AHA can only assume that it is just another indication that HRSA is viewing this issue from the wrong "balance-the-interests-of-two-industries" lens, *see supra* at 2-3, even though these burdens are anything but balanced. Where HRSA should be privileging covered entities on this question, *see id*., these disproportionate burdens confirm that it is favoring drug companies.

It would be bad enough if HRSA was poised to impose "only" $200 or $500 million in new, unjustified administrative costs. But that estimate is dramatically low. As AHA has explained, HRSA's earlier $200 million-estimate incorrectly assumed that each covered entity will have to make 52 responses to the third-party platform and that each response will impose only two hours of burden. Put another way, HRSA assumed that hospitals would submit data only once a week and that each hospital would have to spend only two hours per week to comply with a rebate mechanism. HRSA's updated estimate follows the same flawed methodology, although it increases the number of hours per week to five (to ostensibly reflect that HRSA is contemplating including 2.5 times the number of drugs in its new Rebate Program). *See* 2026 ICR, 91 Fed. Reg. 9,633.

HRSA's methodology is unexplained and unsupported, and it results in a massive understatement in labor hours. Our members have informed the AHA that, on average, *any* Rebate Program will require them to hire new *full-time* employees. Full-time means full time—40 hours per week. Using HRSA's own methodology ($132 hourly wage rate X 40 hours per week X 52 weeks X number of 340B hospitals, this chart illustrates just how widely HRSA's labor and cost calculations miss the mark.[6]

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[6] Although the AHA is relying on HRSA's methodology to illustrate the costs of the Rebate Program, even the assumptions built into HRSA's calculations underestimate the real-world costs. For example, HRSA's estimate for pharmacist wages are based on May 2024 Bureau of Labor Statistics data. *See* Health Resources & Services Administration, *340B rebate Model Pilot Program Application, Implementation, and Evaluation Supporting Statement*, at 6 n.4. That stale data does not reflect wage inflation over the past several years. Even a 3-5% increase in pharmacist wages would cause a significant increase in anticipated administrative costs. Likewise, the AHA's chart only reflects additional pharmacist hours. Our members inform us that a rebate mechanism will require additional weekly work for IT and cybersecurity specialists, lawyers, accounting/revenue cycle employees, and others in their institutions. Because the costs of the Rebate Program are so high when one "only" counts pharmacist hours, we need not to

	Hourly Wage Rate	Hours/ Week	Weeks	340B Hospitals	Annual Burden Hours	Annual Cost
Pharmacist (1 FTE)	$132	40	52	2,728	**5,674,240**	**$748,999,680**
Pharmacist (2 FTE)	$132	80	52	2,728	**11,348,480**	**$1,497,999,360**
Pharmacist (3 FTE)	$132	120	52	2,728	**17,022,720**	**$2,246,999,040**

Information from the AHA's member hospitals supports these calculations. When told that HRSA was predicting only five hours per week for a revised Rebate Model, their reactions alternated between laughter to outrage. Hospitals consistently informed us that even HRSA's $500 million prediction was wrong by an order of magnitude—and this chart reflects that fact. In addition, 340B hospitals disputed HRSA's assumption that the number of hours for the 2027 IRA drugs would increase linearly (*i.e.*, 2.5 times its previous estimates for only 10 IRA drugs). HRSA's back-of-the-envelope math does not reflect the fact that, in reality, many of the 2027 drugs are more frequently prescribed at certain hospitals, and so there are more claims to submit and more rebates to reconcile on the back end by including the 2027 IRA drugs. At any rate, the AHA has chosen to provide a range of potential labor costs here because even at a conservative estimate of only 40 hours per week, the price of the Rebate Program is outrageous. HRSA cannot justify a minimum of $750 million in labor costs alone.

Also consider what this exceedingly conservative $750 million figure omits. It does not include the administrative costs for the remaining estimated 11,900 covered entities that are not hospitals; they, too, have reported the need for new FTEs.[7] It does not account for the fact that, as one hospital commented, "individuals that have the knowledge of the 340B program and the skills required to hold this position are rare. Securing a qualified

include hours estimates for these additional employees to demonstrate that the Rebate Program is unjustifiable. To the extent that HRSA disagrees, however, it must account for hours for these other types of employees as well.

[7] *See, e.g.,* Advocates For Community Health, Comment Letter on 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-0111 - Extension (Nov. 12, 2025),.

candidate and training them properly would take at least one year."[8] Put differently, this sudden demand for a limited supply of 340B talent will not only raise the cost of labor (likely making the $132/hour figure low), but there will be additional training costs for those unfamiliar with 340B. *See, e.g.*, Beauregard Health System, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-1572 ("DeRidder is a small rural town of 10,000 people; it took us 5 months to hire a pharmacist this past winter. Finding a 340b skilled person would be almost impossible, if we were able to hire another person."). And perhaps more important, if hospitals cannot hire employees needed to run a rebate mechanism for up to one year, it raises the serious question of how they will be able to comply with a purported one-year "pilot."

The conservative $750 million estimate also does not include the many other kinds of administrative costs of a rebate mechanism (*e.g.*, vendor and third-party administrator fees, IT support, financial auditing costs, etc.), which we are told will range from $150,000 to over $750,000 per hospital, with costs increasing further if there are significant delays and denials with the rebate payments.[9] Taking an *extremely*

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[8] *E.g.*, MyMichigan Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Feb. 25, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0044 *see* Samaritan, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-0304 ("It will take 6 to 12 months to advertise and find a qualified employee to hire."); Monadnock Community Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 10, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1415 ("Advance notice of at least 6–12 months would be needed to recruit, hire, train, and embed those staff into existing revenue cycle and compliance processes."); Madison Community Hospital d/b/a Madison Regional Health System, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-1447 ("Due to additional administrative burden related to rebates we would have to add FTE's in both our Pharmacy and Finance departments…. Advance notice to hiring any additional staff for this program would be a minimum of 6 months. Due to the rural nature of our community, finding the staff with experience in the 340b program is almost impossible, therefore adding to the delay of having to educate/train a new staff member delaying this at an estimate of another 12 months.").

[9] *E.g.*, St. Tammany Health System, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Mar. 9, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0080 ("Our preliminary analysis indicates that ongoing annual incremental administrative and operational expenses are estimated to be between $340,000 and $950,000, which covers staffing, financial tracking, IT maintenance, reporting updates, vendor fees, and audit or consulting services."); St. Peter's University Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-0111 ("The cost of the rebate billing and tracking software, although difficult to estimate, could reasonably be approximated $500,000 per year."); Elliot Hospital,, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-0317 ("Any rebate program would place significant burden on the covered entity and the administrative burden would be overwhelming for Elliot Hospital. Initial administrative impact is estimated

at $1.5 million annually for Elliot Hospital. This upfront increased cost burden will eat into the benefits of the 340B Program and reduce our available savings by more than 10%. This does not account for the countless hours of labor required to prepare and handle the change."); Bitterroot Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Mar. 9, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0058 ("[W]e estimate a one-time startup investment (interfaces, policy updates, training, accumulator updates) of approximately $95,000–$185,000. Ongoing annual administrative and IT costs for the initial 10-drug scope are estimated at $80,000–$140,000 per year. As the pilot expands to 25 drugs and beyond, ongoing annual administrative costs are expected to escalate toward approximately $120,000–$185,000+ per year at 25 drugs."); Jordan Valley Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Mar. 9, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0085 (estimating an additional $155,000-$285,000 in annual non-labor costs); Memorial Community Hospital and Health System, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Mar. 9, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0105 ("A rebate-based model would significantly increase administrative and compliance costs, require additional staffing that rural hospitals like ours do not have, and force costly changes to IT systems built around an upfront discount framework. Based on national estimates and internal modeling, MCH's annual administrative costs would increase by $75,000 to $250,000, IT implementation costs could reach $300,000, and ongoing system costs would be substantial."); Vermont Health Network Inc., dba University of Vermont Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 17), https://www.regulations.gov/comment/HRSA-2026-0001-1720 ("UVM Health estimates an upfront cost between $3,000,000 to $4,000,000 in third party administration and expenses to operate a rebate model.… UVM Health estimates that ongoing expenses could cost up to $1,000,000 annually to continue to operate a rebate model."); Columbus Regional Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-1422 ("We estimate it could cost us an additional $500,000 in new full-time hires and subscriptions to vendors to manage the new work streams created by a rebate program. These are conservative estimates based on current data available."); Wabash General Hospital District, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-1438 ("Under the rebate program, we estimate the incremental administrative and operation startup costs to be $122,000 to $178,000, including information technology redesign, TPA interface setup and staff training. Ongoing annual costs are estimated at $160,000 to $230,000 including staffing, compliance monitoring, dispute management, and manual reconciliation. These amounts are based on increased staffing for manual claims-level submissions, reconciliation and denials and disputes, TPA charges, IT labor hours for redevelopment, monitoring and audit preparation. In addition, legal review, cybersecurity, and consulting support would range from $27,000 to $41,500 as well as reduced service capacity."); Temple University Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 9, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1396 ("We anticipate additional operational costs of $650,000 that could otherwise be invested in patient care and community health improvement. This includes start-up costs, ongoing staff costs, 3d party platform and associated costs. These represent new administrative layers that do not exist under the current model."); Coffee Regional Medical Center, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 9, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1369 ("Coffee Regional Medical Center estimates that implementation of a 340B rebate model would result in approximately $530,234 in incremental annual administrative and operational costs, effectively doubling our current 340B administrative spend of $265,117. These costs include both one-time startup expenses (IT system redesign, vendor onboarding, staff training, and legal review) and ongoing recurring costs (claims submission, rebate tracking, reconciliation, dispute management, audit preparation, and

conservative estimate of $150,000 a year for each of the 2,728 340B hospitals, these additional operational costs would add more than $400,000,000 to the overall tab. And when that conservative figure is added to the already-conservative one FTE (40 hours/week) of new labor costs, the total administrative costs of a rebate mechanism exceeds *$1 billion for 340B hospitals alone.* Expanded to include all covered entities, the AHA can conservatively estimate that this so-called "pilot" program will cost covered entities *several billions of dollars in administrative costs annually.*

HRSA nonetheless took the position during litigation that the AHA and the other plaintiffs had not "substantiated their assertion" that the rebate mechanism "would require the use of new full-time employees." Reply in Supp. of Mot. For Stay Pending Appeal at 5. We disagree but will take this opportunity to substantiate our calculation again.

The past and present administrative and judicial records are replete with stakeholders directly telling HRSA that they would need to hire new full-time employees to comply with a Rebate Program. Last fall, the AHA and other hospital associations submitted comments explaining that their member-340B hospitals would need to hire new full-time staff to comply with a 10-drug program.[10] Individual 340B hospitals also submitted comments explaining that they would need to hire full-time employees to comply.[11] Plaintiff hospitals submitted declarations in the litigation explaining that they would need to hire full-time employees to comply.[12] Other types of covered entities submitted letters

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compliance oversight)"); University of California Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 20, 2026) ("Vendor support costs are estimated at $100,000–$350,000 per campus annually — costs that are entirely new and incremental to our existing administrative baseline.").

[10] *See, e.g.*, American Hospital Association, Comment Letter on Application Process for the 340B Rebate Model Pilot Program (HRSA-2025-14998) 13-14 (Aug. 27, 2025),; 340B Health, Comment Letter on Application Process for the 340B Rebate Model Pilot Program (HRSA-2025-14998) 6-7 (Sep. 8, 2025).

[11] *E.g.*, United Health Services Hospitals, Inc., Comment Letter on Application Process for the 340B Rebate Model Pilot Program (HRSA-2025-14998) (Sep. 8, 2025); Speare Memorial Hospital, Comment Letter on Application Process for the 340B Rebate Model Pilot Program (HRSA-2025-14998) (Sept. 8, 2025); J. Wallgren on behalf of a KS critical access hospital, Comment Letter on Application Process for the 340B Rebate Model Pilot Program (HRSA-2025-14998) (Sept. 4, 2025).

[12] *See* Fadele Decl. ¶ 22 ("Our pharmacy staff does not have capacity to administer Defendants' planned rebate program. NLH will be hiring a new full-time employee to handle this new administrative burden."); Mantz Decl. ¶ 18 ("We also do not have the staff to track and chase rebates and monitor the impact on our operational budget. DCMC administers the current 340B Program with a single internal employee. But we estimate that Defendants' rebate program will require thirty to sixty hours of staff time each week. Therefore, we will have to hire two additional full-time employees, one in the pharmacy department and another in accounting."); Brown Decl. ¶ 21 ("St. Mary's is a leanly staffed health system, and we do not currently have staff capacity to comply with Defendants' rebate program to track the status of the refunds St. Mary's is owed from the drug companies. This process will take our health system significantly more

explaining that they would need to hire full-time employees to comply with that original Rebate Program.[13] And now, the fraction of 340B hospital comments submitted during *this* RFI period (posted on regulations.gov before April 18, 2026) conclusively prove that 340B hospitals will need to hire one or more FTEs to comply with a Rebate Program.[14]

Clearly, then, the Rebate Program will "require the use of new full-time employees." Reply in Supp. of Mot. For Stay Pending Appeal at 5. That was true for a Rebate Program that involved 10 drugs, and even more so for a so-called "pilot" that includes the 2027 IRA drugs. Those who actually work in 340B hospitals (and will be tasked with complying with any Rebate Program) have consistently told HRSA that they will need to hire new employees because their current staffing structures rely on the 30-year old upfront discount model. These people know best the operational side of the 340B Program, the capacity of their current staffing, and the gaps that will need to be filled to comply with the Rebate Program.

It is unclear why HRSA disregarded this abundant and consistent record evidence. It is even less clear why it continues to disregard this evidence in the 2026 ICR by estimating only 5 hours per week of additional labor to comply with an expanded Rebate Program. In fact, at this point, even the position that further substantiation is needed "runs counter to the evidence before the agency." *State Farm*, 463 U.S. at 43. Put simply, the need for new full-time employees has been substantiated: the Rebate Program's workload will require *far more* labor costs than HRSA estimates.

Although the AHA and others have explained it before, perhaps HRSA seeks further substantiation of what these new full-time employees will be doing to comply with a Rebate Program. Our members have informed us that submitting data and tracking rebates is not as easy as HRSA may believe, or as the drug companies and Second Sight Solutions are telling the agency. The AHA would welcome the opportunity to meet in person to address any specific questions in detail. For now, we summarize several practical complexities inherent in a rebate mechanism that will require additional resource commitments.

First, significant staff hours would be required each week to upload the claims data and verify data integrity across systems with differing package sizes and National Drug

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than two hours per week; I expect that St. Mary's will have to hire a new staff person if the rebate program is implemented.").

[13] *E.g.*, Advocates For Community Health, Comment Letter on 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-0111 - Extension (Nov. 12, 2025), ("According to an internal NACHC assessment, 47% of responding CHCs estimate needing to hire 0.5 to 1 full-time equivalent (FTE), 36% estimate needing 1 to 2 FTEs, and 7% project needing more than two FTEs to meet the anticipated demand of reporting 340B rebate claims.").

[14] *See* Appendix A (listing selected comments regarding the staffing impacts of a Rebate Program).

Code (NDC) configurations. In part, this is because the data is often housed in different systems throughout a hospital, requiring employees to pull data from many places so that they can build and verify separate reports to comply with the required data fields.[15] Likewise, the requirements imposed under the previous Rebate Program are different from anything 340B hospitals have ever had to submit in the past (even under 340B ESP), creating a greater workload simply to submit claims.[16]

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[15] *See, e.g.*, MyMichigan Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Feb. 25, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0044 ("[W]e will have to manually retrieve and report [the information needed]. This would require us to access multiple systems as insurers reimburse claims differently for hospital versus pharmacy."); Maricopa County Special Health Care District DBA Valleywise Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-1399 ("The data collection needed to participate fully in a Rebate Model Pilot would require access and meticulous data management of various reporting elements within the organization. Valleywise Health does not currently have the necessary technology or reporting capabilities needed to ensure that all data requirements are met from a singular source. Any reporting would need to be compiled from information over various platforms (wholesaler, EMR systems, and other database records) and maneuvered to fit the Beacon or other application requirements. This process would be labor intensive, requiring many systems, manhours, and various tools with the knowledge that any missed opportunities would result in a manufacturer denial of claim and at a monetary loss to the organization. This loss of savings would have impact to our programs utilized to support those most vulnerable patients of Valleywise Health."); Graham County Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Mar. 5, 2026), https://www.regulations.gov/comment/HRSA-2025-0001-0012 ("Our hospital currently collects and maintains 340B data through our EHR, pharmacy dispensing system, wholesaler platform, and TPA (PDMI). We use third-party support for program oversight and conduct routine internal reviews along with annual mock audits. 340B ESP is used only for limited manufacturer-required contract pharmacy verification — it is not a rebate invoicing platform.… The data we provide today through 340B ESP and payers for billing purposes does not include the detailed financial reconciliation and rebate tracking elements required under a manufacturer rebate framework. Implementing such a model would create ongoing administrative burden and additional costs for our hospital, which operates on narrow margins as a rural safety net provider.").

[16] It is no answer that Eli Lilly, Novo Nordisk, AstraZeneca, Bristol Myers Squibb have recently unilaterally imposed onerous data requirements on 340B hospitals for them to receive their 340B discounts. At a minimum, those policies do not require back-end reconciliation—the most costly and burdensome part of the process. More fundamentally, Lilly's, Novo's, AstraZeneca's, and Bristol Myers Squibb's policies are unlawful, as AHA has explained to HRSA. *See* Letter from Chad Golder, General Counsel, American Hospital Association to The Hon. Thomas J. Engels, Administrator, HRSA (Jan. 26, 2026), https://www.aha.org/2026-01-26-aha-urges-hrsa-stop-eli-lillys-new-policy-340b-hospitals-going-effect. In fact, the comments submitted in response to this RFI demonstrate the illegality of these policies; the costs associated with complying with either a rebate mechanism or these policies unlawfully raise the effective ceiling price in violation of the 340B statute. Thus, if HRSA relies on those policies to justify its Rebate Program in any way, it must explain why Lilly's and Novo's unilateral actions do not violate the 340B statute. If HRSA fails to do so, it will be ignoring an important aspect of the problem.

In addition, to the extent either the drug companies or HRSA itself relies on covered entity compliance with Lilly's, Novo's, AstraZeneca's, and Bristol Myers Squibb's illegal policies, it must understand that covered entities are complying under duress. Faced with the prospect of losing

What's more, many small and rural hospitals do not have the specialists on staff to deal with the complexity of the Rebate Program submissions. In reliance on 30 years of an upfront discount system, they did not need to expend resources on specialized pharmacy, financial, and data analytics expertise that will be needed for a rebate mechanism. These 340B hospitals informed the AHA that their current staff does not have the capacity or training to absorb this new work.[17]

Second, even more hours will be required to reconcile outbound claims with inbound rebate status (separate from the actual payment reconciliation).[18] This is an entirely new category of labor-intensive work that never had to be done under an upfront discount mechanism. Hospitals will have to track claims on the backend, confirm receipt of payment for a claim, match it to internal reports for outgoing claims requests, allocate the payments to different internal cost centers, and conduct audits to ensure compliance. And denials or delays will introduce their own extra reconciliation

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substantial 340B discounts, and faced with the fact that HHS has not stepped in to address Lilly's, Novo's, AstraZeneca's, and Bristol Myers Squibb's unlawful actions, 340B hospitals are incurring administrative costs to comply with these policies. But make no mistake: those covered entities that are complying are not doing so because it is easy, cheap, or lawful; they are doing so because, as a practical matter, they have no other choice.

[17] While they may seem minor, the following two scenarios illustrate just some of the workload challenges associated with the new data requirements. *First*, our members have informed us that certain data field requirements (*e.g.*, health payer ID, BIN/PCN) create unique challenges for the uninsured. Because covered entities need to keep those fields blank, they need to do certain manual checks, which takes time. FQHCs have identified the same problem. *See* MCR Health, Comment Letter on Application Process for the 340B Rebate Model Pilot Program (HRSA-2025-14998) (Sep. 8, 2025) ("BIN/PCN are limited to retail prescription claims with insurance coverage. They are frequently unavailable for prescriptions filled for uninsured individuals who pay with cash or use a health center's sliding fee scale program. Requiring this data would effectively exclude a core portion of the patient population that health centers serve, creating an operational barrier for a model intended to be transparent and comprehensive."). *Second*, members have informed us that they must manually validate and update the units of measurement to comply with the Rebate Program's data requirements. This creates additional human work. One member explained: "For example, injectables are dispensed in 2 different ways: eaches or in mLs. Enbrel, one of the rebate drugs, comes in a pack of 4 syringes, which are 0.5 mLs each. If you dispense the whole package, then you can dispense it as 4 syringes or 2 mLs. Beacon requires unit of measure to be in eaches, so we need to manually override a mL entry to be in eaches." The time spent to meet these requirements adds up. Only a hospital's on-the-ground perspective demonstrates how difficult this shift from upfront discounts to a rebate mechanism will be in the real world.

[18] It is unclear how the drug companies intend to provide rebates. It is the AHA's understanding that some companies will make lump-sum payments covering a swath of claims, rather than claim-by-claim distributions. That will require additional work so that a hospital can make sure they were fully reimbursed for all claims and then appropriately allocate the rebate to the correct units and departments within their system.

challenges. Many 340B hospitals inform us that this likely will be both the most time-consuming and labor-intensive part of the process.[19]

Third, even before the new claims and reconciliation process begins, many hundreds of staff hours must be spent across the entire hospital organization to prepare for a new discount mechanism. This includes considerable preparatory work across many hospital departments, in all of the cost-driving areas that the RFI lists. It will include work by pharmacy, IT, security risk, government reimbursement, revenue cycle, patient financial services, accounts receivable, legal, and compliance teams. Even these one-time costs are significant. If HRSA is really serious that this is a limited "pilot," one must ask whether these one-time "sunk costs" are worth imposing at all if HRSA's purported "test" will ultimately fail? Just think about how much better these one-time outlays could be spent on patient care and comprehensive health care services if 340B hospitals didn't have to pay these sunk costs for a destined-to-fail rebate "pilot" *See infra* at 34-35 & n. 35.

Yet despite all of this record evidence, HRSA has said in the past that its workload estimates were so low because it assumed that covered entities are already submitting the same type of information to Second Sight Solutions' similar IT platform, 340B ESP, which is only used for contract pharmacy claims. *See* Britton Decl. ¶ 36; Reply in Supp. of Mot. For Stay Pending Appeal at 5; *see also* 91 Fed. Reg. 9632. HRSA believed that the Rebate Program process will be easier because, "since 2021, in connection with manufacturer contract pharmacy policies, many covered entities have been submitting claims data to 340B ESP, an IT platform owned by Second Sight Solutions." *See* Britton Decl. 36 ¶.

Let us be clear: that assumption is wrong. HRSA cannot rely on the incorrect premise that a 340B hospital's cost, workload, labor hours, or any other driver should be lowered because hospitals are already submitting information to 340B ESP. HRSA's assumption was mistaken for several reasons:

- **Far fewer covered entities rely on 340B ESP than HRSA assumes**. HRSA's assumptions about the prevalence of 340B ESP claim submissions are incorrect. Not as many 340B hospitals use it as HRSA may have been told.[20]

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[19] As explained below (at 24,52), moreover, additional staff or services would be needed to address disputes between drug companies and covered entities, including if HRSA intends to: 1) allow drug companies broad authority to deny rebates, *see* RFI, 90 Fed. Reg. 7,290, and 2) rely on the ADR process alone for dispute resolution.

[20] For instance, one AHA member told us that it "submitted data to 340B ESP for approximately one year before discontinuing due to inability of 340B ESP to comply with requests from [its] cyber security team." This member also explained that it "had monthly standing meetings with representatives from 340B ESP

And while information about 340B's exact market penetration is difficult to come by, we believe they process a miniscule amount of claims. Some estimates indicate that they process less than 4% annually; others suggest less than 1% annually. Therefore, the notion that "most covered entities provide the type of claims data they will need to provide" (Britton Decl. ¶ 36) under the Rebate Program because of 340B ESP is incorrect. If HRSA is going to rely on that assumption in any respect—which it should not—it will need to make public more accurate and detailed data from drug companies and Second Sight about 340B ESP usage, as well as a thorough explanation for why any existing use of 340B ESP actually will lead to reduced costs for a Rebate Program.

- **The Beacon IT platform would have imposed more restrictive data qualification criteria than 340B ESP**. On December 10, 2025, Second Sight Solutions sent covered entities a document called "Beacon Rebate Model: Data Validation Criteria." According to our members, these requirements imposed far more restrictive qualification criteria than 340B ESP imposes (*e.g.*, active NPPES, NDC expiration requirements), and it will take far more time for hospital teams to research, validate, and submit claims. In addition, as compared to 340B ESP, there is enhanced documentation and audit risk involved in the Rebate Program.
- **340B ESP does <u>not</u> require post-submission reconciliation**. Validating and reconciling the receipt of rebates likely will be the most time-intensive and costly component of the Rebate Program. 340B ESP for contract pharmacies does not require *any* of that work. Thus, while data submission under the Rebate Program itself is still more time intensive than under 340B ESP for the reasons explained above, a Rebate Program also imposes a greater burden through back-end operational and financial reconciliation requirements.
- **340B ESP is, itself, a burdensome and flawed system**. HRSA believes that workloads will decrease simply because some number of hospitals already submit data to 340B ESP. But that assumes that 340B ESP itself does not create workload or staffing challenges in its own right. That assumption is wrong.

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and were unable to resolve issues around 340B ESP's determination of [managed care plan] claims as eligible or not." After these difficulties, the member "simply gave up trying." Comment letters submitted in response to this RFI reinforce the reality that fewer hospitals use 340B ESP than HRSA may have been told. *See, e.g.*, Electra Memorial Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Mar. 19, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0100 ("We do not currently provide any Data to ESP except for claims at one Contract Pharmacy that accounts for less than 20 prescriptions per month. New restrictions being applied will eliminate this pharmacy at the end of the month."); Beauregard Health System, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-1572 ("This 340b ESP platform is cumbersome and customer service is not very well managed. We use it as little as possible.").

> According to our members, 340B ESP routinely produces a large number of false denials that require extensive staff review. Critically, hospitals often find that the issue originated on the 340B ESP side, creating a large and ongoing operational burden. These problems will be exacerbated if Beacon takes on more responsibility as the drug companies' chosen platform for a Rebate Program. If a rebate mechanism is implemented, Beacon will have to manage *millions* more claims than it already does under 340B ESP for contract pharmacies. Second Sight Solutions cannot handle the work it already has, so we can easily expect more bugs, delays, and incorrect denials in the future.[21]

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[21] *See, e.g*, Pella Regional Health Center, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 3, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0296 ("Our experience with manufacturer data submission platforms (e.g., 340B ESP) has been rife with costly challenges, such as addressing errors, inconsistencies, and opaque requirements, with access to 340B pricing often delayed or denied despite compliance with the manufacturers' policies. We have to dedicate staff just to address these issues. With rebates applying across all hospital settings—not just contract pharmacy—the administrative burden and financial risk would increase greatly."); Blessing Health System (HRSA-2026-03042) (Apr. 15, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1620 (same); Miami Valley Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 20, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1405 (same); Vanderbilt Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 17, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1593 ("Vanderbilt Health's early data from the MTF process indicates a 30% error rate from the third-party administrator matching 340B claims to potential IRA rebates, primarily overpayments requiring deduplication."); *cf*. Premier, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 6, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0662 ("CMS' rebate reconciliation process and validation for initial Inflation Reduction Act (IRA) drugs have presented challenges related to efficiency and accuracy. The platform often misclassifies non-340B eligible claims as 340B eligible, and vice versa, resulting in confusion and delays. Additionally, the appeals process to resolve these issues is complex and time intensive. In response, several hospitals have been forced to redirect existing staff or hire new FTEs to manage errors and appeals."); Kootenai Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr, 15, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1509 ("Our recent experience with the IRA Maximum Fair Price (MFP) rebate program reinforces concerns about the administrative burden these changes would create. Contesting missing MFP rebates in the Beacon platform is an unintuitive, multi-step process that requires substantial time and effort for each incorrectly processed claim. Inquiries must be submitted through one platform, with supporting data uploaded to a separate system for each claim. From identifying errors, submitting a good-faith inquiry, uploading supporting claims data, and validating the response, each claim can take up to 30 minutes to resolve. To date, we have identified hundreds of claims each month requiring this level of manual intervention. While we recognize that this may not be a direct reflection of how the 340B rebate program will ultimately operate, it represents our main experience with the vendor previously selected to operationalize the program. Based on this we believe our concerns are reasonable and warrant consideration."); Johns Hopkins Health System, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 20, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1644 ("Although the manufacturers are subject to a 14-day prompt MFP payment window requirement, many of our MFP rebate payments have been delayed well beyond that window, and these delays have materially affected our cash flow. This is not an

All in all, the record evidence proves that HRSA's prior administrative cost calculations dramatically underestimate what 340B hospitals will actually experience under the Rebate Program. The fact that some hospitals may use the 340B ESP platform does not erase that reality. And it is no answer that HRSA rejected even more costly and onerous demands by the drug companies. *See* Britton Decl. ¶¶ 37-39. The billions of dollars in costs that HRSA actually will impose are colossal in their own right. HRSA must weigh these far-larger-than-previously-estimated administrative costs against any benefits it perceives in imposing an unprecedented rebate mechanism on 340B hospitals.

"Float" Costs. The First Circuit correctly recognized that the Rebate Program would force "safety-net hospitals to pay to the drug manufacturers upfront prices far exceeding the amounts that they actually owe—essentially functioning as an interest-free loan from the hospitals to the manufacturers—and then wait for a rebate." *Am. Hosp. Ass'n*, 164 F.4th at 32. It is beyond dispute that 340B hospitals will have to float gargantuan amounts to drug companies. As a matter of basic arithmetic, the difference between WAC price and the 340B price is considerable; having to pay drug companies the difference, even for a short period of time, leads to eye-popping "float" amounts.

Floating these sums imposes significant costs and burdens on 340B hospitals. HRSA previously minimized them, but on the basis of several faulty premises.

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isolated occurrence. Through mid-March 2026, we identified at least 100 claims that were inaccurately categorized by the Beacon platform and therefore required "Good Faith Inquiries" (GFIs), resulting in approximately $178,000 in erroneously denied MFP rebates in just the first couple months of the MFP program, not including additional claims that appear to have been underpaid by the manufacturer."); Advocate Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 15, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1666 ("Current efforts to avoid 340B/MDPNP Duplicate Discounts via the Beacon IT platform suggest that Beacon's proposed credit process for reversals will ensure inconsistent payments and the inability to accurately track all medication claims for a specific product. A change to a rebate model would not solve the existing issues with the deduplication process and/or would only make those issues worse."); Colquitt Regional Health System and the Hospital Authority of Colquitt County, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-1727 ("The Medicare Maximum Fair Price (MFP) program uses a similar system/setup to the proposal for the rebate pilot program. For the 10 drugs included in the request for MFP, Colquitt Regional had 42 qualifying dispensations in February of this year based on the requirements. Out of the 42, nineteen (45%) processed correctly. Twenty-three (23) processed incorrectly. After reconciliation, we were able to show that 22 of those 23 were in fact 340B drugs and requested they be reversed in the Beacon system. We expect similar results under a rebate model, but with exponentially more qualifying transactions which will affect our cash flow.").

First, HRSA apparently credited the position of drug companies that "the rebate in most instances will be paid before the purchase invoice from a wholesaler for the WAC [wholesale acquisition cost] amount is due." Britton Decl. ¶ 30. Unfortunately, HRSA relied on incorrect information about when hospitals must pay their wholesalers.

For starters, had the original Rebate Program gone into effect, some wholesalers would have required covered entities to deposit large sums of money into their "prepay account," solely in response to the increase in WAC invoice amounts. Essentially, this prepay requirement functions like an escrow or retainer that will be drawn down as drugs inventory is replenished. It therefore does not matter how quickly 340B hospitals will be rebated by drug companies; they will have to "float" large sums as a prepay *regardless* of the repayment timeline.

In addition, our members consistently inform us that it is wrong to assume that covered entities will be rebated before wholesaler payment at the WAC price is due. Comment letters submitted prior to this letter confirm this. Hospitals and health systems anticipate a multi-day gap between payment and rebate given invoicing schedules. As one member told us: "Health systems have varying payment schedules with the wholesalers—some as often as weekly. The turnaround time on the rebate model would never be received by the time we would need to pay our wholesaler. Disputes, denials, [and] appeals would add additional time to payment."

Much like this member, many other members inform us that their wholesaler payments are due in 5 or 7 days, which is obviously less than a 10-day rebate period.[22] Indeed, 340B hospitals of all sizes, large and small, told us that there undoubtedly will be some delta between payment at full price and rebate from the drug companies, and that this gap will be, as one major hospital system called it, "a serious pain point." In particular, that mismatch between WAC payment and rebate timing will create dire cash flow

[22] *See, e.g.*, Kent County Memorial Hospital (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-1624 ("The financial impact of a rebate model would be high, right from the start. If the first 25 drugs of the IRA MFP are approved to the 340B rebate model, Kent Hospital would need to pay approximately $25,713,556.49 in additional upfront costs to purchase the drugs at the wholesale acquisition cost (WAC) price. HRSA has suggested that covered entities will receive the 340B rebate before the WAC invoice is due to be paid, but that is not accurate for Kent Hospital. Due to its volume of purchases, *Kent Hospital is contracted with its primary wholesaler to pay invoices on a weekly basis, therefore, the WAC invoice will be paid at full price prior to the 340B rebate being issued, which will create the addressed cash flow concerns*. The 340B rebate will be processed within 10 days of the claims being reported to Beacon and other drug companies, but Kent Hospital will likely not be able to report claims on a daily basis. *Weekly reporting is more realistic, and this means that rebates could be withheld for up to 17 days depending on the timing of claims reporting*." (emphasis added)).

problems, at least some loss of interest on deferred payments[23], late fees,[24] the need for high-interest lines of credit[25], additional state taxes[26], and additional administrative

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[23] *See. e.g.*, AAMC, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) ("The delayed savings will also result in the loss of interest on deferred savings, which one academic health system estimated at a 4 percent loss on their affected 340B drugs.… One AAMC member institution estimates that these confounding factors—loss of interest, loss of subceiling discounts, rebate denials, and wastage loss—would amount to over $6 million in annual permanent losses, not including any administrative implementation costs."); America's Essential Hospitals, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) ("For hospitals with adequate cash on hand, we estimate the costs of floating funds to pharmaceutical manufacturers would be equal to average interest rates on funds, which the IQVIA study estimates to be 4-5%. In our optimistic scenario, we assumed a 4% interest rate, which would still result in $54.2 million in costs for hospitals for a 340B drug pilot. These costs would grow proportionally if the rebate were extended to all drugs, likely exceeding $155 million a year.").

[24] 340B hospitals inform us that late fees can be steep. If WAC invoices are due before rebates are received and a covered entity does not have enough cash on hand to cover the invoice, hospitals would typically owe simple interest at 15-20% per annum, calculated per each day late, as a late payment penalty. HRSA must account for the likelihood of these extra penalty costs, particularly for small and rural hospitals that lack sufficient cash on hand, in its cost calculations.

[25] *See, e.g.*, Citrus Health Network, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Mar. 31, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0123 ("Under the proposed 340B Rebate Model Pilot, health centers would be required to purchase drugs at full retail price, also known as the Wholesale Acquisition Cost (WAC). This departure from over 30 years of precedent would drastically diminish CHN's ability to purchase drugs, as the uncertainty of waiting for a manufacturer to approve a rebate would constrain cash flow.… This number does not include interest on a line of credit that would be needed to cover this cash flow challenge, which could average about 7% which we would not get back. CHN does not have these cash reserves on hand and line of credits are challenging to obtain and can have high interests."); America's Essential Hospitals, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) ("Unfortunately many essential hospitals cannot afford the added costs of fronting funds to drug manufacturers and may need to take out loans to cover the costs of these payments. **Using estimates for the cost of these loans from the IQVIA study, we estimate that the interest rate on these loans could be 12%.**"); Self Regional Healthcare, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-1495 (""Another concern is that purchasing drugs at full WAC will potentially lead the organizations to exceed wholesaler credit limits, halting our ability to order medications until payments are submitted. For example, having Self Regional Healthcare pay for medications upfront at WAC prices would require dipping into limited financial reserves or taking out loans, thereby defeating the purpose of the 340B program. Self Regional Healthcare asserts that taking out a loan or an extended line of credit to fund drug procurement is a high-risk strategy that places our organization in a state of "financial limbo." This approach fundamentally defeats the purpose of the 340B program—to "stretch" scarce federal resources—by diverting patient-care funds toward interest payments, origination fees, and debt service. Relying on credit to "float" manufacturer rebates is particularly dangerous at a time when all other major revenue sources are unstable.").

burdens for hospitals—particularly for smaller and rural hospitals that have limited cash on hand to absorb the needed "float" costs. HRSA therefore cannot rely on the drug companies' false narrative about payment timing when evaluating "float" costs.

Second, even if a Rebate Program requires a 10-day rebate period, our members inform us (and HRSA) that this is unrealistic. For example, Electra Memorial Hospital's comment letter states: "With the lessons learned over the first two months of the Medicare rebate program it is obvious that there is no way the drug companies could provide reimbursement within 10 days. Often times it takes between 30 and 45 days for any payment to be received. Certainly, they could not provide the rebate in time for us to pay our wholesaler." Electra Memorial Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Mar. 19, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0100. If this is any indication of how quickly 340B hospitals will be rebated in a Rebate Program, it will not only extend the "float costs," but it will increase the number of costly disputes for delays and denials.

Third, HRSA previously disputed the notion that the original 10 Rebate Program drugs may sit on the shelf for a long time before being dispensed. Again, this position ignores on-the-ground realities. In fact, even HRSA's prior statements on this topic contained conspicuous qualifiers. At one point, HRSA stated that "most" or the "majority of drugs" included in the Rebate Program would not sit on the shelves for a period of time. Britton Decl. ¶ 28. By using that language, HRSA necessarily admits that *some* drugs could sit on the shelves for longer periods of time, but HRSA still has never calculated how much that wait time for those drugs will impact 340B hospitals. Our members tell us that floating the full cost while drugs sit on the shelf will have a meaningful adverse impact on their cash flow.

Fourth, HRSA's position relied on the assumption that many of the 10 drugs (which could actually now be up to 25 drugs) are dispensed as a full package size. But as our members explained to us, drugs are often ordered in advance based on anticipated need and variable patient volumes, which can result in inventory sitting on the shelf before use. This is especially true for rural hospitals where utilization can be low and variable. In addition, not *all* use aligns with full-package dispensing—even more so for the 2027 IRA drugs—so HRSA's reliance on full-package sale is not an answer. As one representative member explained: "[W]e fundamentally disagree with the government's

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[26] Lakewood Health System, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-1382 ("Minnesota has a MN Care Tax Rate of 1.8%. With a 340B Drug Rebate Model for IRA drugs needing a MFP rebate, we will never be reimbursed for the higher upfront cost of the tax.").

assumption that drugs in the rebate pilot are dispensed as full packages with high velocity.…[T]he requirement to maintain clinical safety stock for emergent cases necessitates that certain medications remain on our shelves longer than the pilot suggests."

Ultimately, HRSA (again) should rely on the real-world experience of those who work in hospitals and are actually prescribing, purchasing and dispensing the drugs that may be included in the Rebate Program. Through this letter and others, 340B hospitals are conveying that HRSA's full-package assumption is wrong. There will be variable dispensing periods, requiring some drugs to wait on the shelves longer than HRSA has assumed. As a result, there will be significant, harmful "float" costs as 340B hospitals await a rebate they otherwise would have received immediately under an upfront discount mechanism.

Fifth, HRSA previously asserted that it "provided a number of guardrails" to mitigate the risk of improperly delayed or denied rebates. Britton Decl. ¶ 31. Those prior guardrails were insufficient, and so 340B hospitals still expect costly delays and denials that increase "float costs" for several reasons:

- As explained in greater detail below, the absence of a meaningful dispute resolution "guardrail" not only raises the likelihood of delays and denials (leading to longer or full "floats"), but carries its own set of additional administrative costs.

- It is meaningless to require that drug companies have "processes in place for the good faith resolution of disputes," Britton Decl. ¶ 31, if those processes do not yield actual results—*i.e.*, fewer or no disputes. Each dispute means 340B hospitals will not be given a 340B discount they are owed by statute. Each dispute will require additional labor hours, and therefore impose additional costs, to resolve. HRSA cannot simply rely on the "good faith" of drug companies—or the existence of a mere drug company "process"—to ensure that discounts are provided and Congress' intent for the 340B Program is fulfilled.[27]

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[27] *E.g.*, Keck Medicine of the University of Southern California (HRSA-2026-03042) (Apr. 13, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1609 ("We are currently working on a "good faith inquiry" (GFI) for a non-340B dispensation of an MFP drug that was dispensed 1/2/2026 for which we are still owed a rebate on, foreshadowing the long and costly process likely with pharmaceutical companies under a rebate model."); Kootenai Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr, 15, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1509 ("[O]ur prior experience with a similar program, the MFP rebate program, shows that we are typically required to advance payment for approximately two to three months before realizing any rebate recovery. This represents an upfront cash outlay of roughly $5.2 million. *Even then, due to ongoing administrative issues, we have only been able to successfully collect rebates on approximately 25% of eligible drugs to date.*" (emphasis added)); Vermont Health Network Inc., dba University of Vermont Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-

- Even if 340B hospitals could rely on the "good faith" of the drug companies, as many as 13 drug companies will take part in the Rebate Program. This means that there are as many as 13 different "good faith" processes for 340B hospitals to follow. Each one may involve its own unique features and negotiators. That fragmentation itself imposes additional process costs on covered entities.

- HRSA previously did not provide any real means of enforcing the 10-day rebate deadline other than potentially removing drug companies from the Program. Even then, HRSA's FAQs said it would only pursue this option if "HRSA observes trends toward a manufacturer not paying rebates within 10 days of data submissions" or the drug company is "consistently unable to timely resolve rebate reimbursement issues." These undefined terms ("trends toward," "consistently") and unrealistic nuclear penalties (will HRSA *really* kick a drug company out of the rebate program?) leave far too much opportunity for inappropriate and expensive delays and denials.[28]

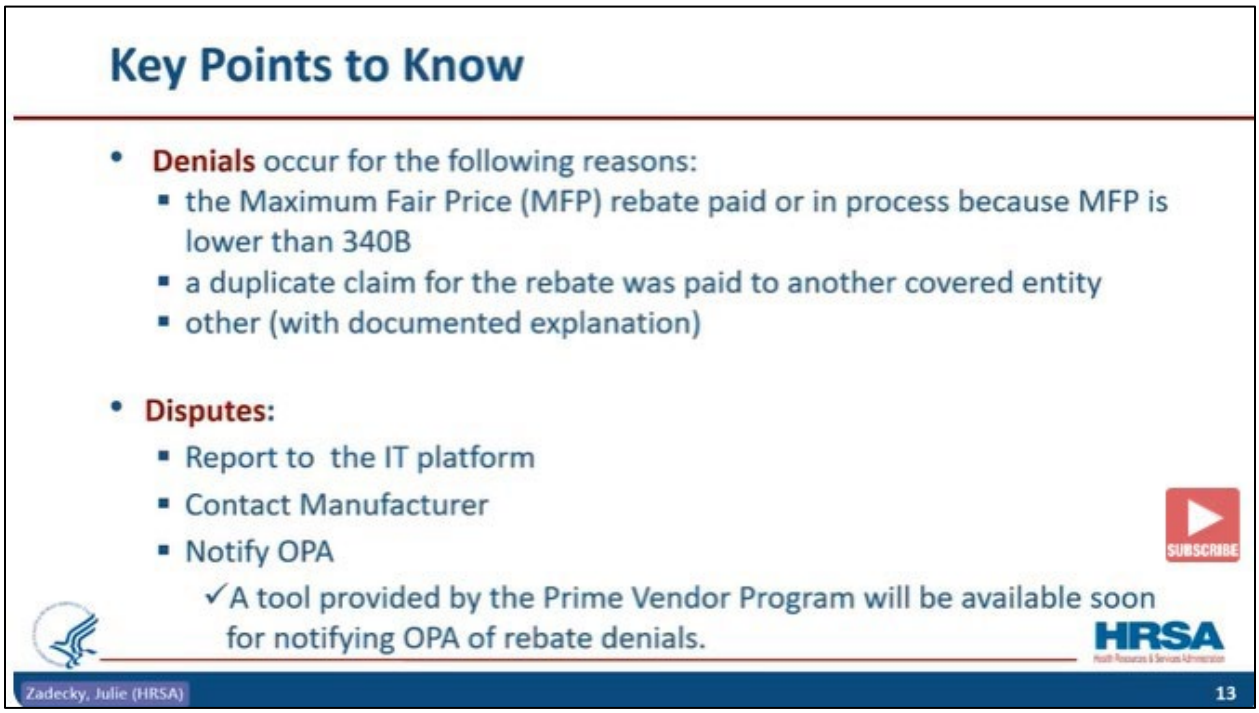
- HRSA previously insisted that it "severely limit[ed] the bases for the denial of claims" under the prior Program. Britton Decl. ¶ 31. But that is not supported by the record. As the screenshot below illustrates, in a brief webinar held for

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2026-03042) (Apr. 17), https://www.regulations.gov/comment/HRSA-2026-0001-1720 ("From our UVM Health pharmacies' experience of the first year of the MDPNP, companies like Amgen, Boehringer Ingelheim, and Johnson & Johnson have denied refund claims, asserting, without evidence, that drugs were dispensed from 340B inventory. In just two months, this has left over $400,000 in unpaid refunds for UVM Medical Center alone. As a result, we paid WAC without receiving either the MDPNP refund or 340B pricing, contrary to legal requirements. To contest denials, manufacturers' agent, Second Sight Solutions, requires uploads to its 340B ESP platform for unrelated purchases, a burdensome process that has yielded no meaningful resolution. Although HRSA OPA and CMS are aware,1 we are not aware that any action has been taken.").

[28] *See generally* Franklin Medical Center, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Feb. 27, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0025 ("[W]e need to be honest about enforcement here. Drug manufacturers have been violating the letter and spirit of the 340B program for years now with absolutely zero consequences outside of a few strongly-worded letters. Rural hospitals have no confidence whatsoever in the fortitude of the federal government to compel Big Pharma to pay the rebates in an accurate and timely manner. The ultimate outcome of a rebate model is going to be rural hospitals begging for their money and drug companies not paying it because they know they can get away with it."); Sanford Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-1635 ("In the three months since MFP rebates were implemented, we have experienced hundreds of incorrectly denied rebates with no path for recoupment. It is not a baseless concern to assume that a shift to a 340B rebate model will result in covered entities paying full WAC price upfront, only to face denied rebates on valid 340B claims. Manufacturers already receive all the information necessary to accurately pay MFP rebates, yet they are not doing so.").

covered entities on December 4, 2025, HRSA admitted that drug companies could deny rebate claims for some undefined category of "other" reasons.



Troublingly, HRSA did not define what constitutes "other" grounds for denial, creating opportunities for drug company abuse—or, at the very least, more disputes over whether claims were appropriately denied for these "other" reasons. Though HRSA's presentation indicated that drug companies are to provide "documented explanation" for such "other" denials, HRSA did not specify what information or detail this explanation must contain, let alone what 340B hospitals can do to appeal to HRSA when they dispute a denial (for any reason, including "other").

The current RFI magnifies this concern. It expressly seeks comments about "Rebate Denials." 90 Fed. Reg. 7,290. In particular, it asks what the "acceptable grounds" should be "for a manufacturer denial of a covered entity rebate request," and it raises the possibility of denials "where a 340B rebate was provided to another covered entity on the same claim." *Id*. Needless to say, the more grounds that HRSA accepts as "acceptable" for denials, the greater the likelihood of delays and disputes and increased "float" costs. And to the extent HRSA is suggesting that a drug company can deny a rebate based on its subjective program integrity concerns, that would invite the possibility of more—and more erroneous—delays and denials. It also would be unlawful. *See infra* at Section IV. "Congress vested authority to oversee compliance with the 340B

Program in HHS and assigned *no auxiliary enforcement role* to" program participants. *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 117 (2011).

- Delays and denials may not only come from drug companies. As explained above, our members inform us that Second Sight's 340B ESP platform often experiences problems, including false denials and delays. Even if the drug companies had the best of intentions, *their chosen IT vendor* may cause 340B hospitals to receive their discounts after 10 days.

Finally, closely related to the "float," hospitals expect to lose the cost-of-goods-sold (COGS) discounts that they negotiate with wholesalers by having to purchase drugs through their WAC accounts instead of their 340B account due to the Rebate Program. These discounts typically vary by product but generally range between 3-10% of the cost of the drug.[29] That translates into *millions of dollars* of added costs of a rebate mechanism—all borne by the covered entities that the 340B program is intended to benefit. HRSA's costs estimates never accounted for the loss of these COGS discounts. Importantly, these discounts often are baked into a hospital's current and future pharmacy budgets. Therefore, losing the COGS discounts will only further disrupt their operations and make it harder for hospitals to afford to acquire these drugs for their patients. HRSA must account for these COGS losses in its cost-benefit analysis as well.

Ultimately, HRSA was incorrect regarding its prior assumptions about "float" costs. It cannot deny that *some* hospitals will be rebated after their payment is due to wholesalers; *some* number of drugs will sit on hospital shelves longer than HRSA has accounted for; *some* number of improper delays and denials will occur; *some* COGS discounts will be lost, and therefore there will be *some* meaningful amount of "float"

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[29] *See, e.g*, Fresno Community Hospital and Medical Center dba Community Health System, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 20, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1479 ("In addition to siphoning resources from patient care to administrative overhead, a rebate program would subject CHS to additional financial pressures by…. eliminating the cost-of-goods discount CHS currently receives from its drug wholesaler when purchasing drugs on its 340B account, which would increase our acquisition costs for drugs included in the rebate pilot by 9.5%."); University of Texas Medical Branch (UTMB), Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr, 15, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1532 ("By requiring covered entities to purchase drugs at WAC instead of receiving upfront discounts, rebate models will significantly reduce the cost of goods sold (COGS) discount received from wholesalers. UTMB would lose these discounts, approximately $9 million a year, again increasing costs and undermining our ability to stretch scarce resources therefore jeopardizing patient care."); Nationwide Children's Hospital (HRSA-2026-03042) (Apr. 17, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1612 ("Transitioning away from upfront 340B discounts eliminates cost of goods sold discounts that covered entities receive from wholesalers. This elimination of wholesaler discounts along with the increased administrative costs is a financial burden on our covered entity. The estimated loss due to the elimination of cost of goods sold discounts would be a permanent loss not recuperated from the manufacturer 340B rebate program.").
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costs. Astonishingly, the ICR does not address these "float" costs at all; it limits its analysis to the incorrect 5 hours of weekly labor costs. Having made no serious effort to study the real costs associated with the interest-free "float," HRSA continues to ignore this important part of the problem.

But when it finally accounts for the "float" costs, HRSA will be unable to deny that they will harm hospitals. 340B hospitals—especially those in rural areas—have limited cash on hand. Consider the following comment from one such hospital, which encapsulates this problem well:

> Perhaps the most consequential concern we must raise is one that may not be immediately apparent to policymakers who are unfamiliar with the capital structure of rural hospitals: the relationship between a rebate-based 340B model and our existing bond covenant obligations. Lexington Regional Health carries outstanding municipal bond obligations subject to financial covenants that require us to maintain minimum debt service coverage ratios and liquidity thresholds on a continuous basis. These covenants are not flexible. Breach triggers default provisions that could accelerate repayment obligations and materially compromise our ability to operate. Under a rebate model, Lexington Regional Health would be required to purchase covered outpatient drugs at wholesale acquisition cost and then wait for manufacturer rebates to arrive weeks or months later. During that float period, our pharmacy is effectively advancing capital we do not have.
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> ….
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> Given our current drug acquisition volumes, the outstanding float at any given time under a rebate model would likely range between $150,000 and $300,000. Carrying that obligation on our balance sheet on a revolving basis would reduce our available liquidity to a point where we risk falling below the coverage ratios specified in our bond indenture. A covenant violation of this nature would not simply create an accounting problem. It would trigger lender notifications, potentially draw scrutiny from rating agencies, and force us into a series of remediation conversations with bondholders that divert leadership attention and resources away from patient care. We want to be direct with HRSA: a rebate model does not merely inconvenience Lexington Regional Health. It places us at genuine risk of a technical default on debt instruments that were issued to finance the very infrastructure we use to serve our community. This is not a risk we can manage internally, and it is not one that should be imposed on covered entities without full recognition of its downstream consequences.

Lexington Regional Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 9, 2026),

https://www.regulations.gov/comment/HRSA-2026-0001-1573. Or consider this comment: "Any disruption in our cash flow puts at grave risk for missing payroll as we are operating with less than 4 days cash on hand and backed by a debtor in possession loan." Jackson Hospital and Clinic, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-1585. Or consider the key fact that emerged in the litigation: the "median number of days of cash on hand for Maine's hospitals was less than 10.6." Austin Dec. ¶ 9.[30]

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[30] *See also* Morris County Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-1435 explaining that the cash flow problems associated with a rebate model "could put us in violation of one of our bond covenants, which requires 1.25" and that "[t]his cash flow squeeze would also greatly diminish our ability to pay for untimely repairs and replacement of needed capital or minor equipment"); Mitchell County Hospital District, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (April 3, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0301 ("Mitchell County Hospital District operates with less than 30 days cash on hand. 340B savings represent 6.5 days of cash and support nearly 10% of charity care. Delayed reimbursement creates immediate liquidity risk."); North Oaks Medical Center, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 9, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1384 ("Our hospital relies on bond financing to raise money for new projects that enhance patient care. Our bonds include covenants requiring us to maintain a certain amount of cash-on-hand. The 'rebate models' would cause cash-on-hand to drop low enough to risk violating our bond covenants. We also have a prompt pay discount with our primary wholesaler of net 7 days. If we are unable to meet this due to an increased payment amount, then we will not have the advantage of the discount. We will also incur fees if outside of that window and this may be cost prohibitive."); UC Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-1637 ("In our hospital system, we estimate the policy would tie up approximately $2.5 million in working capital at any given time, equivalent to 25 patient care positions. This ongoing restriction represents approximately 4% of our annual capital budget, directly constraining our ability to invest in strategic priorities, including expanding access to care for our patients."); Memorial Hospital of Sweetwater County, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 15, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1477 ("By requiring us to pay full price for drugs, under the rebate model, and to float large sums of cash while awaiting a rebate, we may cut into our days of cash on hand. These are funds we have reserved for bond covenants, emergencies, and other patient care needs that will instead need to be diverted to manage this unnecessary rebate model."); El Paso County Hospital District d/b/a University Medical Center of El Paso, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr, 15, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1514 ("UMC El Paso estimates that this policy would reduce our cash on hand by $4 million per month. The proposed rule would result in an estimated reduction of approximately 2 days cash on hand. This deterioration in liquidity and operating revenue would meaningfully constrain our system's ability to fund planned capital infrastructure investments and maintain operational flexibility. A reduction of this magnitude introduces financial uncertainty that could delay medical equipment procurement and workforce investments necessary to sustain patient care delivery."); Hannibal Regional Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 15, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1554 ("We estimate having to front several hundred thousand dollars per month in 'interest-free loans' to drug manufacturers. We do not have the excess liquidity to sustain this gap."); Labette County

Medical Center, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Feb. 25, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0066 ("Cash flow stability is critically important for rural hospitals. Under the current model, we pay our drug wholesaler within approximately 15 days. A rebate model would require our hospital to float approximately $205,000 in drug purchasing costs every 10 days while waiting for rebate payments from manufacturers. This delay would place significant strain on our financial resources and could disrupt our ability to maintain consistent drug purchasing schedules."); Windrose Health Network, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-0083 (explaining that "requiring health centers to purchase medications at full price and wait for a rebate" "would represent an astronomical cost increase to WHN that would disrupt our cashflows to the point where we may have to consider dropping out of the 340B Program"); Los Angeles County Department of Public Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr, 13, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1504 ("A rebate model would require the county to pay full price for medications and wait for reimbursement, creating significant cash-flow strain, and reducing the ability to respond to communicable disease outbreaks."); Electra Memorial Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (March 19, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0100 ("We currently operate with only 40 days' cash on hand. Paying full price for drugs and waiting for the rebate would lower that to only 20 days, risking our ability to make payroll and meet other obligatory timelines. HUD loan covenants require us to maintain financial liquidity ratios that would be impossible to maintain with lower cash on hand and higher receivables."); Glacial Ridge Health System, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr, 13, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1503 ("The most significant concern is the shift in cash flow responsibility.… For a rural Critical Access Hospital, this is not manageable.… Glacial Ridge does not have the financial flexibility to front these costs without impact."); U of L Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (April 1, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0124 ("We operate with approximately 35 days cash on hand, insufficient to absorb the float required for high-cost therapies. Many of the services supported by 340B—oncology, transplant, specialty pharmacy—require significant upfront drug acquisition costs.… Even short-term disruptions in cash flow would force difficult tradeoffs-reducing services, delaying expansion, or limiting access for vulnerable populations."); Columbia Memorial Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 8, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1413 ("While CMH maintains strong financial stewardship, as a Critical Access Hospital, we do not maintain excess cash reserves to absorb sustained delays in reimbursement without impact. The cumulative effect of carrying these costs, particularly across multiple high-cost drugs, could strain liquidity and, depending on scale and duration, may impact compliance with financial covenants or other internal liquidity targets."); Edwards County Medical Center, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 10, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1417 ("We do not have cash on hand to fund the rebate model. We barely have cash on hand to pay our bills!"); Columbus Regional Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-1422 ("Using our utilization projections and differences between the undiscounted (WAC) prices and the 340B prices, the hospital would have approximately $23,000,000 in funds held by manufacturers in 2026 under the rebate model. That is an insurmountable impact to cashflow. County hospitals operate on thin margins and do not have the reserves to carry this financial burden waiting for manufacturers to pay rebates (which they would control the ability to deny)."); Wabash General Hospital District, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042),

Hospitals with such limited reserves cannot afford to front the full WAC price of 340B drugs. Nor can they plan for future projects or services: without some assurance those funds will be available when obligations come due, they cannot afford to earmark that scarce cash today. Simply put, HRSA's cost-benefit analysis must account for the financial and non-economic impacts that will result from forcing 340B hospitals to "float" zero-interest loans to drug companies.

Non-economic Costs. HRSA previously dismissed concerns about the non-economic costs of its Rebate Program, stating:

> 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.

Britton Decl. ¶ 41.

HRSA must rethink this position. The agency has acknowledged that a Rebate Program will impose some costs, including at least $200 or $500 million in annual administrative costs, according to the agency's own (under-) estimate. Even if every rebate is paid on time and in full, that is, at a minimum, $200 or $500 million each year that cannot be spent on patient care. As a matter of basic logic, HRSA has to understand that these new administrative and related costs will have non-economic impacts by diverting resources away from caring for "more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384, pt. 2, at 12 (1992).

But if that commonsense conclusion were not enough, there is ample record evidence showing the deleterious impact on patients and communities. Many commenters have

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https://www.regulations.gov/comment/HRSA-2026-0001-1438 ("We estimate that with the 10 pilot drugs there would be a monthly exposure of $8,400- $15,000 while floating cost purchases. This would severely impact our days-cash-on-hand and could put us at risk with loan covenants."); University of California Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 20, 2026) ("Beyond the administrative and operational costs previously outlined, the most significant additional cost UC Health would incur under a rebate model is the increased drug acquisition cost resulting from drugs purchased at Wholesale Acquisition Cost (WAC) rather than the upfront 340B discounted price. Under a rebate model equivalent to the 2025 pilot program, we would be required to purchase these drugs at WAC and subsequently seek reimbursement of the discount through a manufacturer rebate process. Across all our campuses, we estimate this would result in approximately $120 million in *additional* annual drug acquisition costs for 2025 pilot drugs alone, approximately $10 million per month. This represents a substantial and recurring financial burden that would directly strain our organization's operating capital and budget, diverting resources that currently fund critical care programs and services for our vulnerable patient populations.").

responded to this RFI explaining those harms.[31] Or just take a look at the declarations and other evidence submitted during the litigation. Having reviewed those, the district court identified the non-economic impact of the prior Rebate Program. *E.g., Am. Hosp. Ass'n v. Kennedy,* No. 2:25-cv-600, 2025 WL 3754193, at *8 (D. Me. Dec. 29, 2026) (observing that "the downstream effect" of the Rebate Program will cause hospitals to "cut back services and suspend partnerships with drug distributors"). Again, however, the ICR says nothing about these non-economic costs. *See Council of Parent Att'ys & Advocs., Inc. v. DeVos*, 365 F. Supp. 3d 28, 53–54 (D.D.C. 2019) ("The Delay Regulation is also arbitrary and capricious because the government failed to consider all the relevant factors when considering the cost of the regulation. . . . Here, the government failed to adequately account for two relevant factors—the States' reliance cost and the cost of delay on children, parents, and society."). HRSA's continued failure to acknowledge and account for these downstream non-economic costs to patients "runs counter to the evidence before the agency" and is otherwise unlawful. *State Farm*, 463 U.S. at 43.

The Rebate Program also will *directly* undermine access to care for patients—particularly patients of smaller or mid-size 340B hospitals. These hospitals generally lack sufficient cash-on-hand or borrowing power to pay list price to acquire the 10-25 IRA drugs that may be included in a Rebate Program, some of which cost thousands of dollars. As a result, those hospitals will be forced to either forgo keeping on hand any inventory of these drugs or keep only minimal inventory sufficient to furnish these drugs to select patients in dire need. Several small and mid-size safety net hospitals have confirmed to the AHA that they may be forced to transfer or turn away patients that require one or more of the Rebate Program drugs for their care. Comment letters support that as well.[32] The inability to stock vital medications will harm patient health

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[31] *See* Appendix B (listing selected comments referencing real-world harms to patients and communities).

[32] *E.g.*, Electra Memorial Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Mar. 19, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0100 ("A 340B Rebate Program will force us to remove high cost drugs from our stock because we cannot afford to float the difference between the full price and the 340B price. This will cause our patients to have even greater difficulty accessing the medication they need, and likely result in hospitalizations."); Firelands Regional Medical Center and The Bellevue Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr, 13, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1480 ("This financial risk would be particularly acute for high-cost specialty medications or drugs that remain in inventory for extended periods prior to administration. Firelands Regional Medical Center and The Bellevue Hospital could be required to carry the full acquisition cost of these drugs for weeks or months before a rebate claim could even be submitted, significantly increasing liquidity pressure. As a safety-net provider operating on thin margins, these cash flow disruptions could affect our ability to maintain adequate drug inventories and provide timely access to medications for our patients."); Self Regional Healthcare, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-1495 ("Self Regional Healthcare would possibly

and well-being. Thankfully, HRSA implicitly acknowledged this by asking questions in the RFI about patient "access" to medicine. *See* RFI, 90 Fed. Reg. 7287, 7289. Our answer is straightforward: there will, in fact, be a direct adverse impact to patient access to care because some hospitals cannot stock certain drugs if forced to pay the full WAC price.

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not be able to stock the necessary quantity of medications due to cash flow constraints caused by the entity not being able to afford to float the difference between the WAC and the upfront 340B price."); North Oaks Medical Center, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 9, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1384 ("[N]orth Oaks may be unable to keep certain high-priced oncology, immunology, or specialty drugs in inventory, limiting patient access to life-sustaining therapies and creating longer wait times or care delays."); Abbeville Area Medical Center, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 17, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1652 ("Abbeville Area Medical Center would possibly not be able to stock the necessary quantity of medications due to cash flow constraints caused by the entity not being able to afford to float the difference between the WAC and the upfront 340B price."); University of California Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 20, 2026) ("Additionally, the increased cost of purchasing drugs at list price would necessitate reductions in on-hand drug inventory across our campuses, which could result in dispensing delays and directly impact the continuity and initiation of therapy for patients managing serious or chronic conditions. For example, Stelara (ustekinumab) 90mg prefilled syringe is used to treat serious chronic conditions such as Crohn's disease, ulcerative colitis, and psoriasis. This medication carries a WAC price of over $28,000 per package (over 5 times more than the 340B cost). Under a rebate model, UC Health would be required to purchase this drug at WAC rather than at the 340B discounted price, which would make it financially untenable to maintain adequate inventory levels. Stelara is just one example among the pilot drugs where the financial burden of WAC purchasing would directly translate into reduced inventory and potential delays in patient access to critical therapies."); El Paso County Hospital District d/b/a University Medical Center of El Paso, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr, 15, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1514 ("Ensuring an adequate supply of drugs is important for responding to emergencies and meeting the needs of patients with complex care needs. However, under a rebate model, hospitals would lose access to 340B pricing for stockpiled drugs that are not able to be used because of the everyday realities of patient care. Assuming a 2% rate of purchased drugs that cannot be used, we estimate added costs of $400,000 for our system. The costs of this policy will fall on patients with rare diseases and complex care needs who already have challenges accessing the care they need. High-cost drugs for specialty services like rheumatology, infectious disease, dermatology, and neurology could be negatively impacted. Oncology medications purchased at 340B pricing, affords us the ability to stretch our budget without raising out-of-pocket costs to qualified patients- therefore enabling us to treat more patients. Loss of 340B savings limits the number of patients to be treated and will increase medication costs, putting some treatment options out of reach for many patients."); University of Texas Medical Branch (UTMB), Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr, 15, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1532 ("As a member of the University of Texas System (UTS), UTMB must be able to demonstrate it possess the financial capacity to satisfy its direct financial obligations and UTS cash flow (i.e., minimum cash on hand) requirements by maintaining a satisfactory financial score that is based in part of its debt capacity (i.e., spendable cash and investments relative to operating expenses and debt). This is also required before receiving approval to maintain, improve, or expand capital-intensive infrastructure which puts investments that support patient care at risk for postponement.…");

Patient access to drugs will be harmed in a second important way. In November and December 2025, several national pharmacy chains announced that they would not provide 340B pricing for the 10 IRA drugs included in the original Rebate Program.[33] The AHA has reason to believe that these and other pharmacies (including independent, "mom-and-pop" pharmacies, as well as other large chains) will again deny 340B pricing if a new Rebate Program is implemented. But as HRSA has repeatedly recognized, contract pharmacy relationships enhance patient access to vital medications and promote the continuum of care to ensure that patients receive their prescribed medication. If pharmacies like Walmart, Walgreens, CVS, and others are not processing 340B claims for IRA drugs, patients may be forced to travel long distances to obtain their medications at in-house pharmacies or elsewhere. This is particularly problematic in rural areas where patients may live far from their hospitals and depend on contract pharmacy relationships for easier access to their medications.

In sum, a Rebate Program will harm patients in multiple, concrete ways. It will jeopardize essential service lines—including oncology, labor and delivery, behavioral health, opioid treatment, and more. It will undermine patient assistance programs that subsidize 340B drugs for vulnerable patients. And in some cases, it will directly restrict access to needed medications. These are not speculative or peripheral effects; they are predictable consequences of a rebate mechanism that bears directly on patient health. As HRSA evaluates the many different cost streams associated with any future Rebate Program, it must account for these non-economic impacts on patients as part of its overall cost-benefit analysis.

For all of these reasons, the AHA respectfully submits that the total costs of the Rebate Program are far greater than what HRSA has previously accounted for. Once it appropriately accounts for them, it will be indisputable that those billions of dollars in administrative, "float," and non-economic costs far outweigh the benefits of moving forward with any new Rebate Program, even in so-called "pilot" form.

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[33] *See, e.g.*, William Newton, *Walgreens to Carve Out 340B Rebate Pilot, IRA Drugs from Contract Pharmacies*, 340B Report (Nov. 21, 2025), https://340breport.com/walgreens-to-carve-out-340b-rebate-pilot-ira-drugs-from-contract-pharmacies/; Declaration of Chad Golder ¶ 4, *Am. Hospital Ass'n v. Kennedy*, 1:25-cv-600 (D. Me. Dec. 18, 2025) ("Walmart provided that it will block all MFP drugs dispensed to patients under Medicare Part D from inclusion under covered entities' 340B Pharmacy Services Agreement with Walmart, effective January 1, 2026. Walmart identified the "new reimbursement mechanism" and "operational constraints" as motivating its exclusion and did not indicate that its exclusion was temporary.").

II. HRSA Has Not Calculated, Quantified, Articulated, Or Accounted For Any Perceived Benefits of The Rebate Program

To date, HRSA's analysis of any purported benefits of its Rebate Program has been riddled with errors. For the most part, these have been errors of *omission*. HRSA has never identified any actual or expected benefits of switching from an upfront discount mechanism to a rebate mechanism. Or as one hospital commenter rightly put it: "At a fundamental level, HRSA has not provided a clear rationale for why a rebate model is necessary." Sanford Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-1635. At best, HRSA has said it wants to "test" a rebate mechanism. But HRSA must identify some benefit in testing the rebate model beyond simply conducting a test. Otherwise, agencies could justify every new policy program by saying they wish to learn more about its merits and shortcomings.

It is first important to address an argument that HRSA made during the litigation that "HHS is not required to quantify … benefits to conclude that they outweigh the compliance burdens." Stay Reply Br. at 8. Neither law nor logic supports that position. When considering a new policy like the Rebate Program, an agency must compare costs *and* benefits. *See Michigan,* 576 U.S. at 752–53. The purpose of a cost-benefit analysis is to guide the agency's exercise of authority and discretion. If an agency does not calculate the benefits in roughly the same way it compares costs, the exercise is largely meaningless. Without even trying to quantify costs and benefits, the agency's analysis will be little more than a pretense, permitting HRSA to justify any outcome by overstating some abstract benefits. (In fact, HRSA may try to do that here by saying there is some abstract, hypothetical benefit in conducting a "test," when in fact the costs of any rebate program make such an expensive, burdensome test unjustifiable.) Thus, as HRSA considers whether to move forward with a new, expanded Rebate Program, it must attempt to quantify the benefits of the Program and clearly explain those benefits to stakeholders and the public.[34]

A key reason why HRSA failed to calculate the benefits of the Rebate Program is that it has never been clear about what it believes those benefits will be. It previously stated that "testing the rebate methodology to effectuate the 340B ceiling price was OPA's

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[34] *See* Jeffrey B. Clark, Acting Adm'r, Off. of Info. & Regul. Affs., *Interim Guidance Implementing Section 3 of Executive Order 14215, Ensuring Accountability for All Agencies* (Apr. 17, 2025), https://www.whitehouse.gov/wp-content/uploads/2025/02/M-25-24-Interim-Guidance-Implementing-Section-3-of-Executive-Order-14215-Titled-Ensuring-Accountability-for-All-Agencies.pdf ("In deciding whether and how to regulate, to the extent permitted by law and where applicable, agencies should assess both the costs and benefits of an intended regulatory action, as well as available regulatory alternatives, including the alternative of not regulating.… Further agencies' analysis submitted to OIRA should include both quantifiable measures and qualitative measures of costs and benefits that are difficult to measure." (citing *Michigan v. EPA*, 576 U.S. 743 (2015))).

chief aim" in implementing the Rebate Program. Britton Decl. ¶ 21; *see id*. ¶ 4 ("OPA recently became interested in testing the merits and shortcomings of a rebate model."). But this kind of statement does not answer an important question: what is HRSA testing for? Without that answer, it is impossible to know whether its test will be beneficial.

The current RFI perpetuates this problem. At most, the RFI explains the purpose and expected benefits of a rebate model with a handful of vague, conclusory statements:

- "HRSA is now requesting comments from stakeholders to further evaluate the potential benefits and costs of a rebate model, among other topics."
- "… appropriately balance stakeholder concerns regarding implementation of a rebate model against the agency's goal of testing rebates in the 340B Program";
- "With the information collected from this RFI, HRSA will evaluate if a potential 340B Rebate Model Pilot Program is in the public's interest."

These statements, like HRSA's earlier ones, are no different from saying that HRSA wants to test a rebate model so that it can test a rebate model. Such circular reasoning makes it impossible to answer critical questions like: (1) would alternative test designs provide better information about whatever it is that HRSA is testing for; (2) are there cheaper or less burdensome ways to perform this test or gather the information it is looking for from the test; (3) what would convince HRSA that the merits outweigh the shortcomings (of whatever it is testing for); and (4) will the best case scenario for whatever HRSA is testing for *ever* justify the astronomical costs that are being imposed by this test, and what is the likelihood that this best case scenario will come to pass?[35] These questions persist, moreover, because HRSA has never explained what is wrong with the upfront-discount mechanism (other than the drug industry's self-interested desire to impose a rebate mechanism) that might require a change of 30 years of precedent.

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[35] For instance, if covered entities are facing billions of dollars in cost for the 2026 and 2027 IRA drugs, the agency should consider what the cost might be if the rebate mechanism would be expanded following the "test." *E.g.*, Temple University Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 9, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1553 ("We estimate that the fiscal impact of the 340B rebate model pilot program will be about $5.7 million for TUH in 2026. This figure includes direct start-up costs, operational expenses, thirdparty processing fees, legal advice, training, and consulting expenditures, as well as the anticipated negative effect on cash flow and the expectation of manufacturer denials. If the rebate program is expanded in subsequent years to cover an additional 15 drugs each year within the drug negotiation program, projected costs would increase to about $13 million in 2027 and $20 million in 2028. Notably, these costs are not associated with improvements in patient care or program integrity, but rather with administrative restructuring required by the rebate model.").

If we already know that the best-case scenario of whatever HRSA is looking for would impose *many more* billions of dollars in costs, is it really worth conducting the test in the first place? Put another way, if it would be irrational to adopt a rebate mechanism after conducting a test, why conduct that test at all?

HRSA must justify its performance of a test, just like it must justify any other agency action. A desire to test for testing's sake is not sufficient. Without explaining *why* HRSA is conducting such a test beyond using the nebulous language above (*e.g.*, "evaluate the potential benefits and costs of a rebate model," "public's interest") there is no way to balance the potential benefits of conducting a test against the manifest costs and burdens that conducting this test will impose on covered entities and their patients.[36] Thus, before initiating a new Rebate Program, HRSA must offer a reasoned explanation for *why* it is conducting this "test." We are confident that once HRSA's goals or anticipated benefits are clearly articulated, it will be clear that the Rebate Program involves too much guaranteed wasteful expenditure for too little potential gain.

Finally, as HRSA weighs the costs of the Rebate Program against any benefits, it also must consider the question of timing. This, too, is an important aspect of the problem. If HRSA wants to test a rebate mechanism, it must evaluate and address whether *now is the time* to conduct such a test?

It is not. If HRSA moves forward with a new Rebate Program, it will be doing so at a perilous moment for safety-net hospitals. 2026 has not gotten off to a strong start. According to Strata's Monthly Healthcare Industry Financial Benchmarks report, "[p]atient demand and revenue growth slowed while expenses intensified, leading to an operating margins dip." Laura Dydra, *Hospital margins take a dive*, Becker's Hospital Review (Mar. 12, 2026), https://www.beckershospitalreview.com/finance/hospital-margins-take-a-dive. In particular, "[t]otal expenses increased 5.4% year over year in January while gross operating revenue rose 3.9%, leaving a significant gap for many organizations." *Id*. "Non-labor expenses drove expense growth, at 6.4%," with drug expenses up 6.8%. *Id*. As a result, "[h]ospitals with less than 100 beds reported a 3.9 percentage point margin drop while hospitals with 500-plus beds reported a 2.5 percentage point decrease." *Id*.

A second recent study corroborates these figures. According to Kaufman Hall, between January 2025 and January 2026, total expenses rose 5 percent, driven by increases in labor and supply costs, with drug expenses growing by 7 percent. *See* Kaufman Hall, National Hospital Flash Report: January 2026, https://www.kaufmanhall.com/sites/default/files/2026-03/KH-NHFR-Report_January-2026-Metrics.pdf. The study also found that bad debt and charity care increased by 8% from January 2025 to January 2026, continuing trends that were present throughout 2025. Summarizing this analysis and looking ahead to the remainder of 2026, a Kaufman Hall representative explained: "Increased expenses, especially in labor, and

[36] HRSA's failure to identify a real purpose or benefit of the rebate mechanism makes it difficult to answer RFI questions about what data drug companies should submit to the agency. Unless we know what HRSA is trying to accomplish, we do not know what data it needs. At the very least, drug companies should regularly make public: 1) delay or denial rates; and 2) information about their financial relationships with any third-party vendors like Second Sight Solutions.

the persistent increase in bad debt and charity care are not likely to ease this year. Overall structural costs are poised to go up. Hospitals will need to be strategic about where to allocate resources and how to manage spending in what could be a challenging economic environment." Kaufman Hall, Hospitals begin 2026 challenged by expenses and bad debt (Mar. 19, 2026), https://www.kaufmanhall.com/news/hospitals-begin-2026-challenged-expenses-and-bad-debt.

These early 2026 figures mirror the longer-term trends for hospitals. Labor, drug, and supply costs continue to increase.[37] Hospitals face continuing cybersecurity threats and associated expenditures to prevent them.[38] "An aging population and the increasing prevalence of chronic disease continue to raise the level of complexity and intensity of hospital care."[39] And inpatient volumes continue to increase, meaning hospitals must take care of sicker patients, while still maintaining a "fully staffed, 24/7 care environment that remains ready for anything, including disasters and large-scale emergencies."[40]

The policy environment isn't any better. Hospitals will suffer new cuts under the 2026 OPPS final rule, which will pay for drug administration services furnished in grandfathered off-campus hospital outpatient departments at the site-neutral rate of 40% of the full OPPS rate. If past is prologue, moreover, 340B hospitals face potential cuts to their reimbursement rates in the 2027 OPPS rule following HHS' recently concluded OPPS Outpatient Drug Acquisition Cost Survey. Changes in a variety of other federal policies—from tariffs to the expiration of the enhanced premium tax

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[37] *See* American Hospital Association, *Costs of Caring Challenges Facing America's Hospitals as They Care for Patients in 2026* (Mar. 11, 2026), ("2026 Cost of Caring Report"); *see also* Laura Dydra, *Hospital labor expenses escalate as C-suites rethink long-term strategy, Becker's Hospital Review* (Nov. 26, 2025), ("Hospital labor costs may not be spiking the way they did during the height of the staffing crisis, but recent data shows the pressure isn't letting up.… [W]orkforce inflation has become a defining feature of the operating environment. The challenge for the C-suite isn't reacting to sudden shocks but leading through a prolonged period of steady, structural cost escalation."); Kaufman Hall, *2025 Health System Performance Outlook:Redefining performance in an era of financial pressure* (Dec. 2025), https://www.kaufmanhall.com/sites/default/files/2025-12/KH-Report_2025%20Health-System-Performance-Outlook.pdf ("[N]on-labor expenses (8%), supply expense (8%), drugs expense (11%) and purchased services expense (9%) per calendar day increased in 2025 through September compared to the same time frame in 2024. This data aligns with what survey respondents reported—nearly 60% of whom reported non-labor cost increases of 6% to 10% over the past year.").

[38] *See* 2026 Cost of Caring Report ("For example, hospitals spent roughly $30 billion in 2025 on the technology and services needed to protect their systems, data, and operations from cyber threats. That infrastructure is essential to keeping doors open in the community, but it adds real ongoing cost.").

[39] *Id*.

[40] *Id*.

credits—will reduce hospital margins.[41] And most important, a new Rebate Program would launch just as hospitals are beginning to feel the impact of the One Big Beautiful Bill Act (OBBBA) (Public Law 119-21).

Although individual hospitals across the country are still assessing exactly how the OBBBA will affect their finances, "[a]ll providers will be affected," and "[f]or some, the magnitude of change could threaten their ability to sustainably serve their local population."[42] According to one recent study by an independent firm, Premier, the law will trigger a $68 billion adverse revenue impact for hospitals in 2026 and 2027[43]—exactly when HRSA's "test" will be conducted and the new costs of any Rebate Program will be imposed on hospitals. Likewise, McKinsey & Company recently reported:

> After recovering in 2024–25, EBITDA is expected to decline by about 2 percent in 2027 compared with 2025. This drop will largely reflect the impact of ACA and Medicaid disenrollment. The disenrollment is expected to increase the uninsured population and lead to higher levels of uncompensated care along with a potential reduction in Medicaid reimbursement due to provider tax changes (not yet reflected in current estimates).[44]

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[41] Neha Patel and Shubham Singhal, *McKinsey: What to expect in US healthcare in 2026 and beyond* (Jan. 12, 2026), https://www.mckinsey.com/industries/healthcare/our-insights/what-to-expect-in-us-healthcare ("Between 2025 and 2027, hospitals will face headwinds from the impact of tariffs, subsidy expirations, and changes in federal policy, all of which are expected to reduce EBITDA margins by 40 to 100 basis points.").

[42] Kaufman Hall, *The more things change: Navigating the next healthcare crisis under the One Big Beautiful Bill* (July 17, 2025), https://www.kaufmanhall.com/insights/article/more-things-changenavigating-next-healthcare-crisis-under-one-big-beautiful-bill; PWC, *The One Big Beautiful Bill Act (OBBBA): A trillion-dollar turn in US health policy* (July 10, 2025), https://www.pwc.com/us/en/industries/health-industries/library/impact-of-obbba-on-ushealth-system.html ("Hospitals, especially rural providers, will face growing financial pressure. With more uninsured patients and fewer Medicaid dollars, providers may see increases in uncompensated care, with rural hospitals being particularly vulnerable despite a $50 billion funding provision."); *id*. ("Healthcare providers, especially hospitals and health systems, may experience significant pressures as federal Medicaid funding shrinks, and the number of uninsured patients grows.").

[43] Premier, *Premier Data Shows OBBBA Will Trigger a $68 Billion Hospital Revenue Impact* (Dec. 15, 2025), https://premierinc.com/newsroom/blog/premier-data-shows-obbba-will-trigger-a-68-billion-hospital-revenue-impact.

[44] Neha Patel and Shubham Singhal, *What to expect in US healthcare in 2026 and beyond* (Jan. 12, 2026), https://www.mckinsey.com/industries/healthcare/our-insights/what-to-expect-in-us-healthcare.

Critically, the costs of the OBBBA and other recent policy changes will hit many of America's 340B hospitals the hardest because they treat large Medicaid populations while operating operate on the thinnest of margins.

Thus, as HRSA evaluates the financial impact of its program, it must do so in the context of the overall financial picture facing hospitals ***at this time***. HRSA must provide a reasoned explanation for imposing the costs of the Rebate Program *on top of* the costs of the OBBBA and other developments. Even if HRSA anticipates some benefits from conducting a test at some point, ***now is not that time*** given the squeeze that 340B hospitals will face in 2026, 2027, and beyond. HRSA cannot ignore the important timing aspect of the problem.

III. The RFI Incorrectly Frames 340B Hospitals' Reliance Interests

The RFI invites comment on "reliance interests in continuing to obtain the 340B ceiling prices through upfront discounts and whether such reliance interests are reasonable in light of the Secretary's express statutory authority to provide for discounts via 'rebate or discount.'" 90 Fed. Reg. 7,289. Respectfully, that framing rests on a flawed premise and would not fulfill HRSA's obligations under the law to properly account for reliance interests. *E.g.*, *DHS v. Regents of the Univ. of Cal.*, 591 U.S. 1, 33 (2020)*; Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 106 (2015). The AHA does not dispute that, in general, HRSA has the statutory authority to authorize a rebate mechanism in an appropriate situation. But the mere existence of statutory authority does not imply that the agency will exercise it in a particular way or that a hospital must continually assume that an agency will change how it previously exercised authority.

Nor does statutory authority alone render irrelevant 30 years of consistent agency practice and repeated agency statements favoring an upfront discount model. HRSA has authorized an upfront discount model for 340B hospitals from the beginning of the 340B Program. It has departed from that practice only once, authorizing a rebate mechanism for a single category of covered entities—AIDS Drug Assistance Programs—and only for reasons unique to that category. In fact, even when HRSA approved rebates as a permissible mechanism for ADAPs, it declined to authorize rebates for all other covered entities. HRSA specifically found that "the [upfront] discount system is *functioning successfully for most covered entities*[.]" 62 Fed. Reg. 45,824 (emphasis added).

More recently, as drug companies began their relentless, coordinated effort to press HRSA to adopt a rebate mechanism, HRSA continued to publicly favor an upfront discount model. For example, in its March 17, 2025, motion for summary judgment in *Eli Lilly & Co., et al. v. Becerra*, No. 24-cv-3220 (D.D.C. Nov. 14, 2024), HRSA explained that "widespread adoption of rebate models would cause unprecedented disruption to the program." Dkt. 35-1 at 20. Likewise, in HRSA's April 2, 2025 motion for summary judgment in *J&J Health Care Sys. Inc. v. Kennedy*, No. 24-cv-3188 (D.D.C. Nov. 12, 2024), it noted that HRSA "has long envisioned upfront discounts as the preferred price

reduction mechanism, explaining that '[c]overed entities generally preferred a discount system, because they could negotiate lower prices and needed less initial outlay of drug purchasing money.'" Dkt. 41-1 at 18. And in an August 1, 2025, brief filed with the D.C. Circuit, HRSA further defended the upfront discounts and flagged concerns with rebates in the 340B Program: "Unlike discounts, rebates require covered entities to spend more money upfront and put greater financial pressure on those safety-net programs." Doc. 2128443 at 2, *Novartis Pharms. Corp. v. Kennedy*, No. 25-5177.

340B hospitals reasonably relied on this three-decade consistency and these agency representations when designing their internal operations, staffing, third-party contractual relationships, and financial planning for the use of 340B savings. A switch to a rebate mechanism, even in so-called "pilot" form for 10 to 25 drugs, would disrupt the settled reliance interests engendered by the agency's prior policy. Comment letters submitted in response to this RFI explain how covered entities have relied on this consistent practice to design their internal operations and just how problematic this forced transformation would be. Meanwhile, HRSA has never explained why the purported benefits of a rebate mechanism justify the "unprecedented disruption." Dkt. 35-1 at 20, *Eli Lilly & Co., et al. v. Becerra*, No. 24-cv-3220; *see also Am. Hosp. Ass'n v. Kennedy*, No. 2:25-cv-600, 2025 WL 3754193, at *6 (D. Me. Dec. 29, 2025) (faulting HRSA for not "weigh[ing] any reliance interest against the competing de-duplication policy concern or the proposed de-duplication approach favored by the participating manufacturers."). Thus, absent any problems with the upfront discount mechanism, and given the massive costs and burdens that a shift from that mechanism will impose on covered entities, there is no reason to upset settled reliance interests by pursuing this Rebate Program, even in so-called "pilot" form.[45]

IV. A Rebate Model Is ***Not*** Necessary For 340B/IRA Deduplication

HRSA previously suggested that one goal of its original Rebate Program was to facilitate deduplication between 340B discounts and maximum fair price discounts under the IRA. The RFI is not as clear about whether that remains a goal of any future Rebate Program, but it does 1) briefly note that 340B/IRA deduplication was an earlier goal and 2) ask a few questions about the issue. *See* RFI, 91 Fed. Reg. 7,288, 7,290.

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[45] The AHA has explained why the proposed Rebate Program is not a "pilot" in any traditional sense of the word. *See Am. Hosp. Ass'n v. Kennedy*, No. 2:25-cv-600, 2025 WL 3754193, at *6 n.4 (D. Me. Dec. 29, 2025) ("Plaintiffs dispute Defendants' characterization of the Rebate Program as 'limited' or a 'pilot.'"). Ordinarily, pilot programs are limited in scope, whereas the anticipated Rebate Program is not. Every indication is that HRSA will (again) require *all* 340B hospitals to operate under a rebate mechanism for the 2026 or 2027 IRA drugs. *See* 2026 ICR, 91 Fed. Reg. at 9,633 (listing 14,000 covered entities). Mandatory participation for all, even for a limited time frame, does not make something a "pilot." *See supra* 5 (citing Pharmaceutical Research and Manufacturers of America, Comment Letter on Global Benchmark for Efficient Drug Pricing (GLOBE) Proposed Rule (HRSA-2025- 14998) 2 (Feb. 23, 2026)). HRSA cannot hide behind such labeling when imposing onerous requirements on the hospitals that serve America's most vulnerable populations, especially when more limited, pilot-like alternatives are available.

In addition, the fact that the ICR assumes that the program will include the 2026 and 2027 IRA drugs further suggests that deduplication remains a goal.

Regardless, there is no dispute that drug companies have other ways to ensure such deduplication. In repeated court filings, HRSA made clear that a rebate mechanism is not the only way to promote 340B/IRA deduplication. (Interestingly, HRSA has never stated that a rebate model is the *best* method for deduplication.) For example, on February 10, 2026, HRSA submitted a letter to the D.C. Circuit stating: "while the government seeks to enable manufacturers to avoid paying 340B discounts on drug dispenses subject to the Maximum Fair Price under the Negotiation Program through rebates, plaintiffs [drug companies] in this litigation have other options available to them." Previously, on December 31, 2025, the government told the D.C. Circuit: "While the government seeks to enable manufacturers to deduplicate 340B and Negotiation [Program] discounts through rebates, plaintiffs have other deduplication options available to them." And it told the First Circuit on December 30, 2025 that "[m]anufacturers have alternate means to deduplicate discounts."

Given these other options for 340B/IRA deduplication, HRSA should not pursue a rebate mechanism, particularly since it is almost certainly costlier and more burdensome for 340B hospitals. In fact, even if there is a legitimate reason to believe that the rebate model is the most effective at ensuring 340B/IRA deduplication (again, something HRSA has never said), that does not mean that it is the best mechanism, all things considered, for providing 340B discounts. HRSA must account for other policy goals, including those of the 340B Program, and consider whether any isolated 340B/IRA deduplication benefits outweigh the massive costs that a rebate model imposes on 340B hospitals, their patients, and the communities they serve.

In short, HRSA cannot let this one possible deduplication benefit overshadow other benefits of an upfront discount model, especially when there are other ways to achieve that deduplication goal. HRSA has never made clear whether these other deduplication alternatives will impose $200 million, $500 million, $750 million, or billions in costs on covered entities. It must do so. At a minimum, HRSA must 1) explain to the public what these other deduplication options are; 2) conduct a cost analysis for those options, especially the costs they impose on covered entities; 3) compare those deduplication options against each other; and 4) provide a reasoned explanation for why the rebate mechanism is the best approach considering *all* relevant policy aims, including Congress' intent to help covered entities stretch scarce federal resources to provide more comprehensive care to patients. *See* H.R. Rep. No. 102-384, pt. 2, at 12 (1992).

In so doing, HRSA should be highly skeptical of any cost figures that drug companies provide because those estimates have proven to be wildly overstated. For example, during the litigation over the original Rebate Program, certain drug companies and their trade association PhRMA told the First Circuit that they would face "$4 billion in financial losses in 2026 alone" if they could not use a rebate model for deduplication. Mot. to Intervene on Appeal at 1, *Am. Hospital Ass'n v. Kennedy*, No. 25-2236; *see id*. at 22

("Absent a stay, the manufacturer-movants and several PhRMA members will be subject to conflicting statutory obligations and will incur drastic financial losses beginning on January 1, when the drugs approved for the Pilot Program will be subject to competing 340B and MFP discounts. Those losses will total $4 billion in 2026 alone—absent the Pilot Program."). They also insisted that it would "plunge a novel federal drug-pricing program into chaos on January 1, 2026, the first day of its operation." But contrary to these assertions, there has not been "chaos" over the past three-plus months. And as time has gone on, drug companies have been forced to acknowledge in litigation that their first estimates of cost were too high by orders of magnitude, explaining most recently to the D.C. Circuit that "[n]ow [] the Drug Price Negotiation Program is in full force—subjecting manufactures to *potentially millions* in unchecked unlawful rebates and civil monetary penalties if they incorrectly deem rebates duplicative." Letter from Catherine Stetson, Counsel for Appellants, to Clifton Cislak, Clerk of Court at 2, *Novartis Pharmaceuticals Corporation v. Kennedy*, No. 25-5177 (Feb. 12, 2026) (emphasis added).

As "billions" have become "millions," and as certainty has become "potentially," one thing remains clear: manufacturers habitually overestimate the financial benefits (to them, of course) of a rebate mechanism for purposes of deduplication. HRSA should not make the same mistake. Given the inaccuracy of prior numbers offered by the drug companies, the only rational response is for HRSA to discount any future estimates of financial impact that they offer. At a minimum, HRSA must demand an explanation of the methodology behind any drug company estimates, and a full explanation of why numbers they submitted during litigation were so faulty, why their revisions are *a tenth* of what they previously offered, and why their confidence in those numbers has fallen now to "potentially." If it turns out that a rebate mechanism will impose billions of dollars of costs on covered entities while potentially saving far less for drug companies, there is no way a Rebate Program can survive scrutiny.

More fundamentally, as long as other options remain for 340B/IRA deduplication, HRSA cannot allow the narrow interests of drug companies in avoiding "potentially millions of dollars" in costs outweigh the hundreds of millions of dollars that a rebate mechanism will inflict on 340B hospitals and other covered entities. That, again, will be privileging drug companies at the expense of covered entities—exactly the opposite of how Congress intended for this issue to be evaluated. *See supra* at 2-3.[46]

IV. HRSA May Not Use A Rebate Model As A Program Integrity Measure

[46] *E.g.*, Firelands Regional Medical Center and The Bellevue Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr, 13, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1480 ("WHY DOES A MANUFACTURER'S INTEREST IN DEDUPLICATION OUTWEIGH FIRELANDS REGIONAL MEDICAL CENTER AND THE BELLEUVE HOSPITAL'S INTEREST IN CARING FOR ITS PATIENTS?).

Although HRSA has not clearly explained why it wishes to test a rebate model (other than for testing's sake or, perhaps, for IRA/340B deduplication purposes), at times the RFI suggests that it views the rebate mechanism as a generalized program integrity measure. For example, the RFI invites comments on how to design a rebate model with "safeguards to promote the integrity of the 340B Program, and avoid duplicate discounts," and it includes a series of questions on "340B Program Integrity and Other Potential Benefits of A Rebate Pilot." RFI, 91 Fed. Reg. at 7289, 7290. Likewise, the drug industry has (wrongly) argued that a rebate mechanism can be used "to demonstrate program compliance prior to manufacturers providing rebates on medicines." PhRMA, Rebate Model: Addressing Long-term Fraud and Abuse in the 340B Program (Mar. 19, 2026), https://phrma.org/resources/rebate-model-addressing-long-term-fraud-and-abuse-in-the-340b-program. If the purpose of the Rebate Program is to enforce general program compliance, HRSA must provide a reasoned explanation for why it has the legal authority to use a rebate mechanism to achieve those ends.[47]

The AHA has previously explained why the agency lacks the legal authority to approve a rebate mechanism as a generalized program integrity measure. *See, e.g.*, Br. of the American Hospital Association, et al., *Novartis Pharmaceuticals Corporation, et al., v. Kennedy*, Nos. 25-5177, 25-5179, 25-5220, 25-5221, 255236 (D.C. Cir. Aug. 5, 2025), https://www.aha.org/amicus-brief/2025-08-05-aha-others-defend-hhsdecision-reject-340b-rebate-models-drug-companies; American Hospital Association, Comment Letter on Application Process for the 340B Rebate Model Pilot Program (HRSA-2025-14998) (Aug. 27, 2025) 9-10, https://www.aha.org/system/files/media/file/2025/08/aha-comments-to-hrsa-on-proposed-340b-rebate-model-pilot-program-letter-8-27-2025.pdf.

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[47] The AHA has previously explained why the drug companies' assertions about the amount of diversion and duplicate discounts are overstated. *See* American Hospital Association, Comment Letter on Application Process for the 340B Rebate Model Pilot Program (HRSA-2025-14998) 8-12 (Aug. 27, 2025), https://www.aha.org/system/files/media/file/2025/08/aha-comments-to-hrsa-on-proposed-340b-rebate-model-pilot-program-letter-8-27-2025.pdf; *see also* Columbia Memorial Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 8, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1413 ("Over the past 15 years, we have built a highly compliant program with robust internal and external auditing processes. In the past 6 years, we have undergone a HRSA audit, two external audits, and annual full-program audits with no findings, demonstrating our strong commitment to program integrity. Based on this experience, we believe that broad allegations of duplicate discounts and program abuse do not accurately reflect how compliant hospitals manage the 340B Program."); Providence, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 15, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1496 ("In the RFI, HRSA describes its concern that the current 340B payment process may be permitting entities to collect duplicate discounts on their 340B covered drugs from the drug manufacturer and their state Medicaid program. HRSA believes a rebate model would help prevent that duplication, but Providence urges HRSA to investigate further the true magnitude of the suspected duplicate discounts. The publicly reported 340B covered entity audit results include findings of inaccurate or incomplete information in the HRSA Medicaid Exclusion File (MEF) that could lead to duplicate discounts, but crucially, the appearance of this finding does not mean that a second discount was actually obtained.").

HRSA has *never* addressed this legal analysis. The AHA need not repeat all of the reasons it has offered for why a rebate model cannot be lawfully used as a program integrity measure. We instead incorporate these documents by reference and offer a brief summary below.

The text, structure, history and purpose of the 340B statute reveal a carefully calibrated regime in which "Congress vested authority to oversee compliance with the 340B Program in HHS and assigned *no auxiliary enforcement role* to" program participants. *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 117 (2011). The statute contains several provisions addressing audits, compliance and dispute resolution that are incompatible with a rebate mechanism that is designed to address diversion and duplicate discounts—even in a so-called "pilot" form. Consider the following provisions:

- 42 U.S.C. § 256b(a)(5)(C) provides for audits to enforce the statute's prohibitions on diversion and duplicate discounts.

- 42 U.S.C. § 256b(a)(5)(D) relatedly provides for "[a]dditional sanction for noncompliance" with the diversion and duplicate discount provisions, but only *after* an audit is completed and only *after* the covered entity is given an opportunity for "notice and hearing." *Id.*

- 42 U.S.C. § 256b(d)(3) formalizes a statutory ADR process, whereby an authorized audit is a "prerequisite to initiating administrative dispute resolution proceedings against a covered entity."

These structural features make clear that Congress did not authorize drug companies to engage in self-enforcement, which is exactly what a rebate mechanism will encourage. The Supreme Court has recognized this statutory design. As the Court held in *Astra*, Congress "centralized" 340B "enforcement in the "government," creating a "unitary administrative and enforcement scheme." 563 U.S. at 119-120 (quotation marks and citations omitted); *see also Am. Hosp. Ass'n v. HHS*, No. 4:20-cv-08806, 2021 WL 616323, at *6 (N.D. Cal. Feb. 17, 2021) ("Congress made explicit that alleged 340B Program violations are to be first adjudicated by HHS through an established ADR process."). The drug industry knows this. Several of the world's largest drug companies submitted a brief arguing that "*Astra* forbids[ ] the *private* enforcement of 340B program requirements *in all forms*." Pls.' Joint Opp'n to Mot. to Intervene (Dkt. 22) at 10, *Novartis Pharm. Corp. v. Becerra*, No. 25-cv-117 (D.D.C. filed Jan. 15, 2025) (second emphasis added and quotation marks omitted); *see id.* at 9–10 (quoting *Astra* twice more for same proposition).

Relatedly, the 340B statute does not contemplate audits or other enforcement *before* payment at discounted 340B pricing. The 340B statute contemplates: 1) some awareness of a *past* violation, which then kicks off; 2) a review of completed transaction records, followed by; 3) a determination and remedy by HHS, either under the ADR process, *see* 42 U.S.C. § 256b(d)(3)(B)(i), or through agency-imposed sanctions and

civil monetary penalties, *see id*. §§ 256b(a)(5)(D), 256b(d)(2)(B)(v). *See Am. Hosp. Ass'n v. HHS*, No. 20-cv-8806, 2021 WL 616323, at *6 (N.D. Cal. Feb. 17, 2021) ("Congress made explicit that alleged 340B Program violations are to be first adjudicated by HHS through an established ADR process."). Neither the audit nor the ADR process contemplates a regime where drug companies can conduct their own free-wheeling self-enforcement *before* providing 340B discounts, with the authority to refuse such pricing based on a drug company's unilateral belief that violations of the statute are occurring.

"[C]onsidered and consistent" HRSA practice "buttresses" this interpretation of the statute. *Kennedy v. Braidwood Mgmt., Inc*., 606 U.S. 748, 783 (2025). For example, in 1993, HRSA sought public comment to inform its superintendence of the 340B Program, particularly with regard to the statutory bars on diversion and duplicate discounts. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 58 Fed. Reg. 68,922 (Dec. 29, 1993). Five months later, the agency issued a Final Notice stating: "A manufacturer may not condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions." Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110, 25,113 (May 13, 1994).

In 1996, moreover, the Secretary promulgated a final notice entitled "Manufacturer Audit Guidelines and Dispute Resolution Process" after notice and comment. 61 Fed. Reg. 65,406 (Dec. 12, 1996). Among other things, the Guidelines require government approval for drug companies to initiate audits. It states: "If the matter is not resolved and the manufacturer desires to perform an audit, the manufacturer must file an audit work plan" and "sufficient facts and evidence in support of the belief" with HRSA. *Id*. at 65410. HRSA requires this approval "ensure that the audits are performed where there are valid business concerns ... *with the least possible disruption to the covered entity*." *Id.* at 65406 (emphasis added).

The 1996 Guidelines also addressed public comments insisting that "[m]anufacturers should not be required to continue to sell to a covered entity at the mandated price once an audit has been initiated, particularly since reasonable cause has already been demonstrated." Manufacturer Audit Guidelines and Dispute Resolution Processes, 61 Fed. Reg. 65,406, 65,408 (Dec. 12, 1996). HHS rejected that proposal:

> Manufacturers must continue to sell at the statutory price during the audit process. Once the audit has been completed and the manufacturer believes that there is sufficient evidence to indicate prohibited entity activity, then the manufacturer may bring the claim to the Department through the informal dispute process. Not until the entity is found guilty of prohibited activity and a decision is made to remove the entity from the covered entity list, will the manufacturers no longer be required to extend the discount.

Id.; *see also Or. Health & Sci. Univ. v. Engels*, No. 24-cv-2184, 2025 WL 1707630, at *3 (D.D.C. June 17, 2025).

Taken together, the statutory and regulatory history is clear: 1) the law sets forth specific program integrity measures that preclude *unilateral* drug company denials; 2) covered entities must be provided their statutory discounts *even while* investigations of program integrity violations are ongoing; and 3) those investigations must cause *as little* disruption as possible to covered entities. By contrast, using a rebate mechanism to police suspected program integrity violations will cause massive disruption to 340B hospitals, delay discounts for a meaningful period of time, and operate outside the HRSA-led processes that Congress created. Thus, if promoting generalized program integrity remains one of HRSA's goals in adopting a rebate model, HRSA must explain why it is permitted to authorize this extra-statutory regime.

It is no answer that drug companies seek to gather information from covered entities via a rebate mechanism to support their potential audit requests. As the AHA has explained, HRSA's Audit Guidance and historical practice confirm that the threshold that a drug company must meet before auditing a 340B entity is modest and does not require a rebate mechanism. In fact, HRSA itself has stated that the standards for initiating an audit "are *not overly burdensome*" and do not "present *any barriers* to a manufacturer's ability to perform an audit of a covered entity." ADR Rule, 89 Fed. Reg. 28,646 (emphasis added). As evidence, HRSA has noted that "[i]n the last 5 years," it "has not denied a request for a manufacturer audit of a covered entity." *Id.* Nor is it an answer that some isolated covered entities have challenged certain audit requests; that is rare, not representative of the full hospital field, and the courts have already addressed that issue. *E.g., Or. Health & Sci. Univ. v. Engels*, No. 24-cv-2184, 2025 WL 1707630, at *3 (D.D.C. June 17, 2025).

The standard itself, "reasonable cause," is defined broadly to mean "that a reasonable person *could* believe that a covered entity *may have* violated [certain provisions of the 340B statute]." HRSA, Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65,406, 65,409 (Dec. 12, 1996). Drug companies can meet this standard in various ways that do not require a rebate mechanism. For example, drug companies can point to "[s]ignificant changes in quantities of specific drugs ordered by a covered entity," or by cite "complaints from patients/other manufacturers about activities of a covered entity[.]" *Id. at 65* ,406. In fact, the standard is so modest that "there are apparently no cases where a manufacturer requested but was denied an audit due to a lack of relevant claims data." *PhRMA v. Frey*, 1:25-cv-00469-JCN, 2026 WL 184504, at *14 (D. Me. Jan. 23, 2026).[48]

[48] Likewise, as HRSA itself has recognized, drug companies seldom ask to conduct audits, and even when they do, manufacturers frequently fail to follow through with them. *See* Decl. of Chantelle Britton at ¶ 15, *Or. Health & Sci. Univ. v. Engels*, Case No. 1:24-cv-2998-RC (D.D.C.) (noting that, "over the past decade-plus," HRSA approved 37 manufacturer audit requests, but only 18 audits were conducted).

Given these statutory and regulatory realities, drug companies *cannot* unilaterally deny 340B discounts based on their own subjective assessment of whether a covered entity complied with the law. HRSA's original Rebate Program acknowledged this when it provided that 340B rebates could not be "denied based on compliance concerns with diversion or Medicaid duplicate discounts." 90 Fed. Reg. 38,165, 38,166 (Aug. 7, 2025). Thus, if drug companies must provide 340B discounts regardless of suspected program integrity concerns, it is unclear how a rebate model can advance any purported program integrity goals. Likewise, if drug companies view a rebate mechanism as a way to aid the existing, statutory audit and ADR processes, then the modest standard discussed above shows that it is not needed. Drug companies already have access to those statutory processes under an upfront discount mechanism, but they simply choose not to use them. Any incremental benefits a rebate mechanism might offer for the audit process cannot outweigh the billions of dollars in costs to covered entities.

Finally, it is no answer that a rebate mechanism will increase transparency into the 340B Program. The only entities that will see covered entity data are drug companies, their third-party IT platform, and whoever that third-party chooses to sell data to (if that is permitted, *see infra* at 51). That is not real transparency. By contrast, there are many ways to gather relevant data that will allow for *effective* program transparency. As we explain below, a neutral third-party clearinghouse will enhance HHS' own visibility into the 340B program and thus its ability to strengthen program integrity—exactly what Congress intended. *Astra USA, Inc.,* 563 U.S. 117 ("Congress vested authority to oversee compliance with the 340B Program in HHS…."). Most important, a neutral third-party clearinghouse is a cheaper, less burdensome way to do so, and it is fairer to all stakeholders. *See infra* at 47-49. A rebate model, by contrast, is more expensive and wrongly privileges the pecuniary interests of drug companies over 340B hospitals, their patients, and the communities they serve.

For all of these reasons, HRSA cannot rely on program integrity as a valid reason for (or expected benefit of) pursuing a rebate mechanism. Put another way, HRSA cannot include program integrity in its required cost-benefit analysis.

V. HRSA Should Adopt A Less Burdensome Alternative

To be clear: HRSA should abandon its misguided pursuit of a rebate mechanism because there is no sensible reason to impose billions of dollars of administrative, "float," and non-economic costs on 340B hospitals and the vulnerable patients they serve. If, however, HRSA is committed to going down this problematic path, there are significant, viable and less burdensome alternatives it should adopt instead.

The proposed alternatives can be divided into two categories: (1) less burdensome so-called "pilot" programs; and (2) less burdensome alternatives to a rebate mechanism that would help facilitate 340B/Inflation Reduction Act deduplication or program integrity goals.

To the extent that HRSA now claims that "evaluat[ing] the potential benefits and costs of a rebate model" is the goal of any future Rebate Program, it can design a much less burdensome version. *First*, HRSA could create a volunteer-only program that would allow covered entities to opt-in. This is consistent with typical pilot programs and would limit the costs and burdens to only those covered entities that are prepared to bear them. HRSA has said that it rejected this concept because it wanted to "collect information on the experience of a wide variety of covered entity types with a rebate model." Britton Decl. ¶ 24. But HRSA took no steps to determine whether a "wide variety of covered entity types" would volunteer. It can—and should—put out a request for volunteers before it dismisses this concept. And it can—and should—incentivize participation in the Rebate Program by requiring drug companies to cover *all* costs for those volunteers. If the drug companies believe that a rebate mechanism will pass HRSA's "test," then they should be eager to put their money where their mouths are and fund covered entity participation. Only if HRSA does not receive enough volunteers (after this incentivization) should it consider other options.

Second, HRSA should consider alternative ways of achieving whatever goals it believes could be accomplished by a rebate mechanism. One example that would obviate the need for a rebate mechanism would be to have drug companies prospectively publish both the 340B price of drugs and the MFP price. Covered entities could then have two accounts with their wholesaler, one loaded with 340B pricing and another loaded with MFP pricing. As prescriptions are filled, the covered entities, in coordination with their third-party administrators, could track those purchases, and when it is time to reorder the drug, the covered entity would simply replenish the drug at the lower of the two prices for that drug. The claims data could be submitted to a neutral third-party clearinghouse that could verify that the covered entity purchased the drug at the correct price. In the event that the incorrect price was used, the clearinghouse could help facilitate payment reconciliation between the covered entity and the manufacturer to ensure the drug is purchased at the lower of the MFP and 340B price.

Relatedly, the AHA also suggested—and HHS rejected—that HRSA administer its own clearinghouse. Others have suggested a HRSA clearinghouse, too.[49] It is therefore

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[49] *E.g.*, National Association of Chain Drug Stores, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Mar. 19, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0042 ("NACDS implores HRSA to consider alternative methodologies for achieving the stated manufacturer goals of avoiding duplicate discounts. The agencies should consider the development of a centralized clearinghouse run by a conflict-free vendor that would use 340B claims data retrospectively submitted by covered entities to remove those claims from the claims on which manufacturers must pay MFP refunds. In fact, CMS has already stated it plans to develop and test such a model to prevent duplicate discounts for 340B and Medicare Part D inflation rebates."); Walgreens, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 15, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-

important to address HRSA's prior explanation for why it rejected this option, even though HHS adopted a similar framework for a clearinghouse in connection with Medicare Part D drugs.

HRSA has asserted that there is "no clear legal authority in the 340B statute for OPA to create" that type of clearinghouse. *Id*. ¶ 21. HHS has not, however, publicly presented its legal reasoning, and there is serious reason to question it. After all, if HHS can create a clearinghouse in the Part D context to deduplicate 340B drugs, why is it legally forbidden from doing so elsewhere? Put differently, if 340B/IRA deduplication remains a goal of a Rebate Program, and if HHS relied on the IRA's statutory authority for the Part D clearinghouse, then there is no reason why the same authority couldn't be relied upon here. At the very least, HRSA must subject its legal analysis to public scrutiny. HRSA's failure to adopt a less costly, equally (or more) effective, fairer-to-***all***-stakeholders alternative because of a perceived (but dubious) legal impediment is surely an important aspect of the problem that the agency must consider (and present to the public for further comment).

This is especially important because drug companies have not questioned the lawfulness or effectiveness of a clearinghouse for IRA/340B deduplication. In their briefing before the district court in Maine and First Circuit, their only objection to a clearinghouse was timing. The companies insisted that such a clearinghouse could not be "created and implemented before the MFP goes into effect on January 1[, 2026]" and that "the earliest any such clearinghouse allegedly could be available (on a voluntary basis and for testing only) is the fall of 2026." Proposed Intervenors' Br. in Opp'n to Pls.' Mot. for TRO 13, *Am. Hosp. Ass'n v. Kennedy*, No. 2:25-cv-600 (D. Me. Dec. 1, 2025); *see id*. ("Because the clearinghouse will not be operational before January 1, it is not a viable alternative that HRSA needed to consider.").

But with the withdrawal of that original Rebate Program, those timing concerns are moot. If HRSA can get a clearinghouse up and running by the fall of 2026, then the only possible reason not to use such a clearinghouse is the legal argument HRSA has alluded to with its conclusory statement in a litigation filing. And if that legal argument does not hold water because HHS has legal authority under the IRA, this neutral

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1548 ("Instead of proceeding with the rebate pilot or expanding the use of 340B rebates more broadly, one option that HRSA could pursue is the development of a clearinghouse run by a federal government contractor, to which covered entities, third-party administrators, and/or contract pharmacies retrospectively submit 340B claims data to prevent duplicate discounts. Manufacturers would only pay MFP rebates on non340B claims, thereby preventing duplicate discounts. This approach is not without precedent. CMS has already proposed testing a clearinghouse-like model that the agency is calling a "340B repository" to prevent 340B-Medicare Part D inflation rebate duplicate discounts. A clearinghouse approach could also be used to prevent 340B-MFP duplicate discounts and 340B-Medicad rebate duplicate discounts.").

clearinghouse alternative is viable, less burdensome, and fairer to covered entities (whose interests must be, as noted, paramount here). It should be adopted instead.

VI. HRSA Must Exercise Greater Authority Over The Chosen IT Platform

The AHA and others have identified a host of problems with the Beacon IT platform that the drug companies selected for the original Rebate Program. For example, we have explained that HRSA should have insisted on a *neutral* IT platform provider—not Second Sight Solutions, which is a wholly owned subsidiary of a consulting firm with a long history of working for drug companies and their trade association, PhRMA. Our concerns about the excessive entanglements between the drug industry and Second Sight Solutions have only grown, as Second Sight Solutions submitted a misleading, error-laden declaration supporting the drug companies in the litigation. We do not know if HRSA will still bless the use of that platform following this RFI. It should not. But if it does, it must address these many problems with Beacon and Second Sight Solutions.

Beacon's Terms and Conditions both illustrate this bias-problem and are highly problematic in their own right. Just as numerous commenters previously warned HRSA during the 2025 comment period, Beacon would have required covered entities to sign a one-sided, nonnegotiable contract that covered entities would not have otherwise signed if their hands weren't tied. This contract included several intolerable provisions, including those that (a) limited Beacon's liability for direct damages under the Rebate Program to $1,000, including for cybersecurity and data breach incidents; (b) allowed Beacon to sell covered-entity data to any purchaser (including drug companies themselves); and (c) permitted Beacon to unilaterally change contract terms at any point in time or cancel the contract for any reason.

Beacon's contract also did not align with the scope of the original Rebate Program. For instance, the Preamble to the contract stated: "The Rebate Platform further enables analysis of this claims data for Manufacturers in order to identify Medicaid, Medicare, TriCare, commercial payer, or other discounts that are ineligible for reimbursement by Manufacturers." Similarly, Section 3(d), (e) (Data License) allowed Second Sight to verify "compliance with 340B program requirements." This is inconsistent with how HRSA itself viewed the Rebate Program. As HRSA previously articulated it, the Rebate Program was *not* intended to verify program integrity—a function the drug companies strongly favored—yet that is exactly how Beacon viewed its remit.

In addition, numerous AHA members reported that in the run-up to the previous January 1 deadline, Beacon refused to provide basic customer service to help 340B hospitals work through technical problems. See, e.g., Columbia Memorial Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 8, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1413 ("Customer support and communication were limited and insufficient given the complexity of the program."). Beacon would not provide a contact person to discuss problems, and it refused to answer questions from hospital IT teams on data security. To

take one example among many, multiple AHA members reported that Beacon refused to complete data security questionnaires or allow standard vendor assessments related to the security of the data that hospitals were required to submit under the Rebate Program. As you know, hospitals complete these security assessments to comply with the HIPAA Security Rule (45 C.F.R. § 164.308). Because Beacon refused to provide this data security information to the AHA's 340B members, it was essentially forcing covered entities to either forfeit access to 340B discounts for the drugs in the Rebate Program or risk violating HIPAA and other data privacy laws. Likewise, Beacon was constantly adding new technical requirements to use its platform. Hospitals reported to the AHA that they felt like these new requirements were coming on a daily basis. This made it impossible for 340B hospitals to prepare to use the platform, adding even more costs and burdens to the Rebate Program.

Faced with all of these troubling developments, HRSA stated that "Beacon is a private company that is an ancillary stakeholder in the 340B space, but OPA has no legal authority over Beacon." Britton Decl. ¶ 44; *see id*. ("OPA cannot compel Beacon to act in a certain manner."); *id*. ¶ 45 ("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."). This is a troubling abdication of responsibility over its own Rebate Program, and one HRSA cannot repeat if it decides to move forward with another version of its misguided Rebate Program.

However, HRSA did, in fact, impose conditions on manufacturers' choice of IT platform. *E.g.*, *id*. ¶ 43(5) (noting that manufacturers were required to "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"). Regardless of its legal authority over the IT platform, HRSA has authority over its own Rebate Program. And there is no reason why, as a condition of participation in that Rebate Program, HRSA could not similarly require drug companies to choose:

- a *neutral* IT platform of HRSA's selection, *i.e*., <u>*not*</u> Second Sight Solutions or Beacon;
- an IT platform that would not include objectionable, unfair, one-sided contract provisions, including those discussed above;
- an IT platform that provided necessary support and customer service to covered entities, including specified representatives to resolve problems with the rebate mechanism;
- an IT platform that would complete data security questionnaires to comply with HIPAA; and
- an IT platform that would not add new data or other requirements after a certain date so covered entities could adequately prepare for implementation.

HRSA also could have insisted on the ability to test the functionality and operation of the IT platform *before* implementation—something HRSA shockingly did not do last December.

The AHA urges HRSA to take these steps before moving forward with any new Rebate Program. It must not outsource all management and oversight of the IT platform to the participating drug companies or their biased third-party business partners.

VII. HRSA Must Create A Dedicated Process To Resolve Disputes Between Drug Companies and Covered Entities

HRSA also abdicated its responsibility to resolve disputes between drug companies and covered entities over delays and denials, as well as other potential operational issues. Before it was taken down, HRSA's FAQ webpage stated:

> Covered entities who are not receiving rebates within the 10-day timeframe after submitting complete and accurate data, should first contact the manufacturer and IT platform vendor to report concerns. If after attempting to work with the manufacturer a covered entity cannot resolve the issue with the manufacturer, the covered entity should email with the details of its concern. A manufacturer that is consistently unable to timely resolve rebate reimbursement issues may have its participation in the pilot program revoked.

This is insufficient. If HRSA itself does not play an active role in resolving disputes—apart from merely receiving complaints at a general email inbox—then there is little hope that disputes will actually get resolved (and in a timely manner). That, in turn, will only incentivize drug company misbehavior and leave hospitals with no viable path to effectively challenge rebate delays or denials. All of this raises the risk that drug companies can delay or deny rebates without recourse, and that hospitals will have to spend *even more* time and money chasing down the discounts they are owed by statute.

HRSA also stated in the litigation that "covered entities will be able to raise these types of issues through the 340B Administrative Dispute Resolution process." Britton Decl. ¶ 32. By this, we assume HRSA will not specifically resolve disputes over the Rebate Program and will force 340B hospitals to bring their complaints about delay and denial through the ADR process. This is a different form of abdication, but one that is highly problematic as well.

Under the regulations, the ADR process can take up to one year before a decision is rendered. But in reality, the ADR process is severely backlogged, with decisions

pending far longer than a year.[50] Either way, a resort to the ADR process would mean that hospitals would have to forgo a rebate and float large sums of cash for an extended period—hundreds of days more than the 10 days allowed under the original Rebate Program. Plus, resolution through the ADR process can be expensive for 340B hospitals, adding further administrative costs that HRSA has not accounted for in any of its cost estimates. (HRSA did not even raise the prospect of ADR until the litigation and does not discuss it in the new RFI or ICR).[51] And it is not clear that the existing ADR system can handle the avalanche of disputes that may arise over rebate delays and denials, especially if drug companies realize that they can hold on to discount dollars longer by forcing hospitals to go through that backlogged process to resolve claims. Finally, it is not clear that all problems that may arise under the Rebate Program (*e.g.*, administrative or logistical issues) can be resolved through the ADR process since some may not qualify as overcharges.

For all of these reasons, HRSA must create a dedicated dispute resolution process for any Rebate Program. This separate process should allow for expedited review and timely decisions of any rebate-related disputes. Most important, the agency should provide (1) a designated *human* point-of-contact to receive complaints (and follow-ups on those complaints); (2) a clear, specified process by which disputes will be addressed; and (3) a specific timeline (no longer than 30 days) for when those complaints will be resolved.[52] HRSA should provide the public with the cost of creating such a process, and it should ask itself whether the need to stand up a fair dispute resolution process just for a rebate mechanism is a responsible use of taxpayer resources.

That said, the failure to create such a process unfairly shifts the costs of policing rebate delays and denials to America's safety-net hospitals—yet again, an example of HRSA impermissibly privileging drug companies over covered entities on this issue under the

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[50] Thus, if HRSA is serious about this being a one-year "pilot," it is almost certain that the ADR disputes would outlast the Program itself.

[51] Even if HRSA believes that drug companies will largely comply with the Rebate Program's rules—a questionable proposition—it has to realistically account for *some* legitimate disputes. It therefore must build into its estimates the costs that covered entities will incur for hiring attorneys to pursue the ADR process and the delays in receiving discounts.

[52] To aid this process and to minimize disputes between drug companies and covered entities, HRSA should require drug companies to document the reasons for any denial. Documentation must include: 1) a narrative description of why a rebate claim is being denied, and not just a conclusory statement (*e.g.*, "deduplication for MFP or 340B provided to another covered entity on the same claim"); 2) supporting primary source materials justifying such a denial (*e.g.*, claims information, indication of which other covered entity received a rebate); and 3) a signature or attestation by a drug company employee, along with their telephone number or email address, so that covered entities can reach them to address any incorrect denials. In fact, HRSA also should consider creating a standard denial form to streamline the administrative process and provide covered entities with sufficient information to understand (and potentially challenge) a denial.

mistaken mission of achieving "balance." *See supra* at 2-3. If HRSA decides to reject these commonsense suggestions, it cannot offer conclusory statements like "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." Britton Decl. ¶ 32. It must instead provide a thorough explanation for why the suggestions were "unnecessary" and why the agency was willing to impose on hospitals the added costs associated with a toothless or inefficient dispute resolution process.

VIII. If HRSA Proceeds With A New Rebate Program, It Must Provide Additional Opportunity For Comments

The current RFI does not address many important details of a Rebate Program—exactly which drugs will be included, what kinds of data the drug companies will be permitted to require from covered entities, what guardrails will be in place, which third-party vendors it has approved, which design features HRSA has accepted and rejected, and so on. Therefore, if HRSA chooses to move forward with a new Rebate Program, it should allow stakeholders to comment on any specifics of its new program before any drug company applications are submitted or approved.[53] Only then will HRSA be able to fully evaluate the true costs and benefits of its new program. Put another way, a failure to permit additional comments on the *specific* features of the program will be, in effect, a wholesale failure to consider potentially important aspects of the problem. We therefore look forward to the opportunity to comment again, if necessary.

* * * *

We appreciate your careful consideration of these issues. The AHA is eager to meet with you at your earliest convenience to discuss our members' concerns and to provide you with accurate information about the real-world, on-the-ground impacts of a Rebate Program. Please contact me if you have any questions.

Sincerely,

/s/

Chad Golder
General Counsel & Secretary

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[53] In fact, it also should make public those applications and allow public comment on those applications. The prior administrative record (including documents that the drug companies tried to introduce during the litigation) revealed that drug companies were in frequent contact with HRSA, negotiating by the exact terms of their participation in the Rebate Program, while certain covered entities were left out entirely. We hope that this does not happen again.

Appendix A
Selected Comments Referencing Staffing Impacts

St. Tammany Health System, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (March 9, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0080 ("STHS currently lacks adequate staffing to support a rebate-based program. To effectively administer the rebate process—including submission management, reconciliations, and handling any delays or denials—an additional 2.0 FTEs would be required. Furthermore, significant lead time would be necessary for recruiting and training these employees, especially given ongoing challenges in pharmacy hiring; several positions have remained unfilled for months due to a shortage of qualified candidates.").

St. Peter's University Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-0111 ("At least two full-time employees will be needed initially").

MyMichigan Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Feb. 25, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0044 ("MyMichigan Health does not currently have the staff needed to comply with a Rebate Program. Rural safety net hospitals operate on limited budgets and the intent of the 340B program was to stretch scarce federal resources.… HRSA has grossly underestimated the labor burden of implementing a rebate model. This model would require a completely different workflow and as it would be implemented gradually, and covered entities would essentially be operating under multiple models and workflows. This would require an additional 1-2 full time employees initially, and more as the program expanded.").

Graham County Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (March 5, 2026), https://www.regulations.gov/comment/HRSA-2025-0001-0012 ("As indicated before, a rebate model pilot program would require additional full-time employees and has the potential to cause current medical providers to reallocate work hours away from direct patient care to perform administrative functions. A minimum of 1.5 additional FTE's would be required as noted before to track, reconcile, work to ensure IT network administration, and legal framework for difficult to obtain rebates. HRSA's prior estimate of 2 additional work hours per week is a gross underestimation of the time it takes to file, reconcile, administer from an IT standpoint, and legal pressure for rebates we are duly owed.").

Mccurtain Memorial Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (March 12, 2026), https://www.regulations.gov/comment/HRSA-2025-0001-0817 ("We anticipate needing at least one additional full-time employee, and this role would likely be permanent, not temporary, because the work would be ongoing.").

Equitas Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Mar.ch12, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0073 ("Under the proposed 340B rebate model [for only 10 drugs], we estimate an exponential rise in the administrative costs related to this program, and specifically, we would need to expand our auditing team by an additional 2 to 3 FTEs and 2 more FTEs for our front-line focused work. Further, the system changes would require dedicated personnel from our finance team, which would require an additional 2 FTEs in that unit. In short, we would need to expand from our current staffing of 9 FTEs to 15 to 16 FTEs, which means our staffing costs alone would rise by an estimated 40%.").

Labette County Medical Center, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Feb. 25, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0066 ("Implementation of a rebate model would require doubling our current staffing dedicated to 340B program administration. These additional personnel would be responsible for rebate submission, reconciliation, dispute resolution, and expanded compliance reporting. These positions would be permanent roles due to the ongoing administrative demands of the program.").

West Calcasieu Cameron Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (March 5, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0026 ("Hospitals would need additional personnel and infrastructure to manage claim-level tracking, reconciliation, dispute resolution, and audit preparation. These expanded responsibilities would involve coordination across pharmacy, finance, IT, compliance, and revenue cycle departments, resulting in structural cost increases, particularly for rural and community DSH hospitals.").

Heart of America Medical Center, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (March 5, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0037 (explaining that for only 10 medications: "Heart of America Medical Center in Rugby, North Dakota does not currently have the staff needed to comply with a Rebate Program. To maintain this rebate program, Heart of America Medical Center would have to reallocate 30 hours per month from important medical care to administrative functions. This would also divert our already minimal current pharmacy staff from tending to the needs of our patients in the retail and hospital settings.").

Iroquois Healthcare Alliance, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Feb. 25, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0018 ("Across our membership, hospitals have identified potential cost increases including: new or upgraded IT systems and data infrastructure, additional staffing or reallocation of existing clinical and administrative staff to compliance functions, new contracts with third-party administrators or vendors, legal and consulting costs associated with

program implementation, and ongoing reconciliation and dispute resolution functions that do not exist under the current model. For smaller rural hospitals with lean administrative teams, even modest increases in compliance workload can have outsized impacts. HRSA's prior estimate of two additional hours per week bears no relationship to what our members have experienced or anticipate. If the pilot program were to expand beyond the original 10 drugs, these costs would multiply accordingly."); *id*. ("IHA member hospitals, particularly those in rural areas, consistently face workforce shortages. Most do not have excess administrative capacity to absorb new compliance obligations without either hiring additional staff or diverting existing employees from clinical and operational functions. A rebate model would require both. Hospitals have indicated they would need dedicated staff to manage claims submission, data validation, rebate tracking, and dispute resolution under a rebate model. In some cases, this would require diverting pharmacy staff or billing personnel who are currently focused on patient care activities. In rural communities where hiring qualified staff is already difficult and expensive, those transitions take time and come at a real cost. HRSA should not underestimate how disruptive that reallocation would be for hospitals that are already stretched thin.").

Jefferson Community Health & Life, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-0075 ("These processes would require additional staff time and potentially additional personnel.… Jefferson Community Health & Life does not currently employ staff dedicated solely to managing manufacturer rebates. Implementing such a system would require staff to divert time from patient-centered responsibilities to perform administrative functions related to claims submission, reconciliation, and manufacturer communications. HRSA's estimate that these processes would require only minimal additional hours significantly underestimates the complexity of implementing and maintaining a rebate-based program, particularly if as many as 25 drugs are included in the pilot.").

Jordan Valley Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (March 9, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0085 (estimating an additional 1-2 FTEs in pharmacy, finance, and compliance).

Massac Memorial Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (March 9, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0087 ("We would need an additional FTE in addition to current staff additional training and education. This hiring process is concerning because we already live in a rural community where Information Analyst positions are proving difficult to fill.").

Electra Memorial Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (March 19, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0100 ("Additional staff of 1 administration and 1.5 operational staff will be needed to complete additional duties.").

The Richland Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (March 19, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0093 ("We would estimate the incremental administrative and operational costs our organization would incur under a 340B Model Rebate Pilot Program: … ongoing costs of at least 40 hours and thousands of dollars per month. Key cost drivers would include increased staffing requirements, diverting current staff. We currently contract out for 340b management services, despite this, we would expect contract expenses to increase under a rebate model and reallocation of pharmacist work hours from medical care to perform administrative functions. (approximately 20-40 hours per month.").

Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (March 19, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0096 ("Our organization, located in New York State, is comprised of a DSH, a CAH, and a SCH registration on the Office of Pharmacy Affairs 340B OPAIS.… Additional staff required to manage the rebate programs for the network would exceed $500,000 in upfront costs.").

Randolph Hospital District dba Memorial Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-0110 ("The proposed model's impact on our mixed-use and retail operations creates a need for an additional full-time 340B Account Manager at an annual salary of $95,000. Due to our rural location in Southern Illinois, we anticipate a one-time cost of $20,000 for specialized recruitment and training.").

Bothwell Regional Health Center, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (April 2, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0156 ("I believe each rebate claim would require approximately 30 minutes of additional attention. With an estimate of 4,000 affected claims, there is no way we could absorb this into our current workload. An additional full time employee is required to ensure we receive full compensation from our WAC purchases. This burden placed on hospitals operating on a shoestring budget is unacceptable. Our hospital was just forced to do a reduction in force and expenses, with another round expected by summer. The rebate model would require us to create and fill additional 340B role(s).").

Mitchell County Hospital District, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (April 3, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0301 ("The rebate model would require approximately 1.0 FTE to manage claims submission, reconciliation, and appeals.").

Citrus Health Network, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (March 31, 2026),

https://www.regulations.gov/comment/HRSA-2026-0001-0123 ("The administrative costs alone in this 340B model are projected to be at least $300,000 a year because at least 3FTEs would be needed to administer the tracking of data, billing, rebates, compliance and appeals.").

AAMC, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) ("Based on feedback provided by AAMC member hospitals, depending on the institution-specific circumstances and their current staffing levels, a hospital would need to hire from one to more than six FTEs spanning not just the pharmacy department but including legal, compliance, revenue cycle, and finance roles as well.… Many hospitals also reported that they would have to realign existing staff time to prioritize rebate model compliance, with one hospital citing approximately 12,240 hours of redistributed staff time annually across pharmacy, finance, revenue cycle, and compliance teams."); *see id*. ("Staff time related to submitting and reconciling claims and managing disputes and discrepancies is estimated to require 25 to 40 hours per week.").

America's Essential Hospitals, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) ("According to our members' experience preparing for the implementation of the rebate pilot, hospitals noted that they would need to hire at least one FTE employee to work on this model full time (40 hours a week). Many of our largest members have indicated that they would need to hire at least three FTE employees to manage the new process. These staff would be needed to conduct ongoing monitoring of claim determinations, investigate of denials, and initiate formal appeals processes to ensure access to their statutorily required discounts. **Based on these data, we estimate that the rebate pilot would impose $1.2 billion in total direct staffing costs on all hospitals, including $135.9 million in costs on essential hospitals.**").

Elliot Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-0317 ("Elliot Hospital does not currently have the staff needed to comply with a Rebate Program. We estimate it would require the following adjustments to our team: Additional 2 full time employees would be required to handle data processing, rebate tracking and validation, and manufacturer communication. Hiring would require 3-6 months to find qualified individuals with necessary niche skill set.").

Ammonoosuc Community Health Services, Inc., Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Mar. 30, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0304 ("ACHS anticipates adding 1-2 FTE that alone would put the program out of existence for all intents and purposes where the cost of administration will exceed the cost of any savings.").

Samaritan, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-0653 ("It will either require us to hire an additional FTE or contract with a company to provide those support hours. It would require 1 FT employee to reconcile payments

against cost, upload data to Beacon and work denials, etc. It will take 6 to 12 months to advertise and find a qualified employee to hire.").

Sierra View Medical Center, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-1389 ("Sierra View Medical Center does not currently have the staff needed to comply with a Rebate Program. This new rebate pilot would cause us to incur hiring another full-time employee to just handle the claims data submissions, on top of our already newly created 340B Program Coordinator position. This additional 40 hour per week FTE would be responsible for data claim submissions, IT data feeds, TPA interfacing, reconciliation of rebates and denials, and auditing of these new data claims. HRSA's current estimate of only 5 hours per week to manage the details of this rebate program are very underestimated. This new position would cost us up to 30% of our current 340B contract pharmacy savings.").

Columbia Memorial Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 8, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1413 ("We estimate the need for at least on additional FTE (340B coordinator) to manage data submission, rebate tracking and reconciliation, and the investigation and appeal of denied rebates. This would be in addition to recent increases in staffing required to track claims associated with the MFP program.… Given the specialized nature of 340B program administration, we would require approximately 3-6 months of advance notice to recruit, hire, and train appropriate staff.").

Rady Children's Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 14, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1444 ("A new rebate model will require new and additional resources and processes, imposing considerable additional costs and burdens on our institution that go far above and beyond what we had expected and planned for as a pediatric health system, including adding at least one full-time equivalent employee to track compliance to a dual claims system, and at least $100,000 annual investment in a custom design platform identify, submit and track claims.").

Mount St. Mary's Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 13, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1430 ("We anticipate needing to hire at least one full-time employee at an estimated annual cost of $80,000, in addition to engaging an external vendor at approximately $60,000 per year. Existing staff would also need to be reallocated from compliance and auditing functions, weakening—rather than strengthening—program integrity.").

Liberty Dayton Regional Medical Center, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 13, 2026),

https://www.regulations.gov/comment/HRSA-2026-0001-1400 ("[A] 1.0 FTE is totally required to run the program.").

Woman's Hospital Foundation, dba Woman's Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 10, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1408 ("Implementation of a rebate model would result in incremental and ongoing costs, including: A minimum of 1.5 additional FTEs.").

Monadnock Community Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 10, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1415 ("Depending on the final program rules, MCH would likely need at least 1–2 additional fulltime equivalents to manage the workflow, with more support possibly required during implementation and audit periods. Advance notice of at least 6–12 months would be needed to recruit, hire, train, and embed those staff into existing revenue cycle and compliance processes.").

Edwards County Medical Center, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 10, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1417 ("An estimated 20 additional hours a week will be needed to administer this new program model. Though this may be insignificant to some organizations, it is a substantial amount of additional time for my staff, which already has multiple tasks beyond 340B administrative functions. This will require more dollars to be spent on staff and administrative work, thus cutting into the benefits we are supposed to fund with these dollars. The reality is Edwards County Medical Center could close its doors if 340B dollars cannot continue to help us on our bottom line.").

Sisters of Charity Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 13, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1429 ("We anticipate needing to hire at least one full-time employee…. Existing staff would also need to be reallocated from compliance and auditing functions, weakening— rather than strengthening—program integrity.").

Wabash General Hospital District, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-1438 ("In our estimate, we would need to shift current responsibilities and hire the following staff members to ensure program success: 1.0 FTE - 340B Program Analyst; 0.5 FTE - Pharmacy Technician; 0.25 FTE - Finance Specialist; 0.1-0.2 FTE - Compliance Office.").

Madison Community Hospital d/b/a Madison Regional Health System, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-1447 ("Due to additional administrative burden related to rebates we would have to add FTE's in both our

Pharmacy and Finance departments…. Advance notice to hiring any additional staff for this program would be a minimum of 6 months. Due to the rural nature of our community, finding the staff with experience in the 340b program is almost impossible, therefore adding to the delay of having to educate/train a new staff member delaying this at an estimate of another 12 months.").

Maricopa County Special Health Care District DBA Valleywise Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-1399 ("Valleywise Health estimates that, at a minimum, the addition of three Fulltime Employees will be needed to monitor, reconcile, and gather information for disputed claims. These employees would be required to be well versed in purchasing, 340B regulatory processes, and have a working familiarity with the Beacon platform and any other associated applications utilized by any manufacturer.").

Temple University Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 9, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1396 ("[T]o implement the rebate model, 2 full-time employees (FTEs) are required: one will join the 340B team to oversee $15 million in spending on 10 MFP 2026 drugs, and another IT/accounting professional to provide ongoing support. If more drugs are added in in 2027, annual drug costs will rise by $27 million and $29 million, which will require 2 additional FTEs each year to manage at an additional $302,000 per year.").

North Oaks Medical Center, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-1384 ("[W]e anticipate an addition 1.0 FTE will be needed to facilitate the additional requirements of the rebate program.").

Lakewood Health System, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-1382 ("We anticipate adding at minimum a 1.0 FTE to manage a drug rebate model with all the added complexity to an already extremely complex program, which we take pride in our 340B compliance.").

Coffee Regional Medical Center, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 9, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1369 ("Currently, Coffee Regional Medical Center operates its 340B program with one full-time equivalent employee. A rebate model would require at least one to two additional full-time employees, including a dedicated rebate analyst and compliance specialist. Additionally, clinical and pharmacy staff would be required to divert time away from patient care to support administrative functions.").

University of California Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 20, 2026) ("On an ongoing basis, we estimate an increase of 3–4 hours per day per campus, plus approximately one additional FTE per campus to manage rebate-related functions. Even with a third-party vendor, internal staff will still be required to oversee and validate that work.").

Baylor Scott & White Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 20, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1485 ("HRSA estimates that implementation of a rebate model would require approximately five additional hours per week of program compliance and operations burden. Based on BSWH's direct operational experience with existing claims-based compliance platforms, this estimate is not accurate. A rebate model would require the creation of entirely new workflows, including claims extraction, validation, submission, tracking, reconciliation, dispute resolution, and audit support. These activities are labor-intensive, highly manual, and ultimately require BSWH to hire seven to eight FTEs and spend hundreds of hours a month on program compliance and operations.").

Fresno Community Hospital and Medical Center dba Community Health System, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 20, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1479 ("Should HRSA go forward with the proposed rebate pilot, CHS anticipates needing to hire multiple additional Full-Time Equivalents (FTE) to prepare data submissions to manufacturers, submit and track rebate submissions, adjudicate rebate payments, challenge denials, and resubmit rebates when manufacturers deny them, which could occur for any number of reasons having nothing to do with program integrity or preventing duplicate discounts.").

Self Regional Healthcare, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-1495 ("The organization at a minimum would have to hire 5 full-time employees to accurately track and submit rebate requests.… The new 5 FTEs mentioned previously would need to be trained in 340B and the rebate model.").

Firelands Regional Medical Center and The Bellevue Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr, 13, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1480 ("Implementation of a rebate-based model would require Firelands Regional Medical Center and The Bellevue Hospital to significantly expand staffing devoted to 340B program administration. A rebate model would require entirely new operational functions, including claims-level tracking, rebate request submission, payment monitoring, reconciliation, and dispute resolution.").

Yale New Haven Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr, 14, 2026),

https://www.regulations.gov/comment/HRSA-2026-0001-1473 ("Based on preliminary, scenario-dependent estimates, a rebate model could require up to approximately 120 additional staff hours per week across multiple functions.… YNHH does not currently maintain excess staffing capacity for rebate-based claims processing. Under a potential rebate model, YNHHS may need to hire additional full-time employees and/or reallocate existing staff from other operational or compliance activities. Early estimates contemplate the possible addition of approximately three full-time employees, though actual staffing needs would depend on final program details and manufacturer implementation practices.").

Providence, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 15, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1496 ("[A] rebate model will cost entities well above the estimated 5 hours per week that HRSA estimates for a 25-drug model. We expect an annual cost of over $3 million to appropriately staff our program for rebate processing. These administrative changes will not be linear, especially as the program expands from 10 to 25 drugs or beyond.").

Memorial Hospital of Sweetwater County, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 15, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1477 ("As we set up our 340B program operations, we initially planned to allocate 1 FTE to manage it. However, under a rebate model, we anticipate needing additional FTEs or contract management assistance to manage the 340B program. These are additional costs we did not plan for and are difficult to incur, given our financial situation as a rural CAH.").

Marion General Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 15, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1497 ("Implementation of a rebate-based model would require Marion General Hospital to significantly expand staffing devoted to 340B program administration. Current compliance activities are largely focused on maintaining purchasing records, monitoring contract pharmacy activity, and preparing for potential audits. A rebate model would require entirely new operational functions, including claims-level tracking, rebate request submission, payment monitoring, reconciliation, and dispute resolution. Marion General Hospital's current staffing model includes one full-time 340B Specialist and a Pharmacy Systems Manager who devotes approximately 40% of their time to 340B monitoring and compliance. If the Rebate Model Pilot Program is implemented and subsequently expanded, we anticipate the need to add an additional full-time 340B Specialist and increase the oversight time required from our Pharmacy Systems Manager. This added staffing and oversight burden would ultimately erode 340B savings, as Marion General Hospital would incur increased operational costs to manage and sustain a rebate-based model.").

Rutland Regional Medical Center, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 15, 2026),

https://www.regulations.gov/comment/HRSA-2026-0001-1502 ("HRSA's estimate of only 5 hours per week in additional work is a gross underestimate of the staff time we would need to dedicate to a rebate program.… If HRSA implements a rebate program, we anticipate a need to hire an additional 2 FTEs.").

Kootenai Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr, 15, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1509 ("Additional FTE responsibilities would include data submission, rebate tracking, auditing and validation of received rebates, and ongoing coordination with manufacturers' vendors to resolve missing or delayed payments. We anticipate requiring between 1-2 additional FTE to manage these tasks.").

Cook County Hospital District d/b/a North Shore Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr, 15, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1522 ("NSH does not currently have sufficient staff to comply with a rebate-based system. Our pharmacy services are provided by two pharmacists who already operate at capacity. Even a modest increase in workload would be unsustainable. Recruiting additional qualified professionals in our rural location is extremely challenging and additional burdens could lead to staff attrition, further limiting available services.").

University of Texas Medical Branch (UTMB), Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr, 15, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1532

UTMB anticipates that it will be required to invest in additional staff resources to maintain a rebate model. Resources at a minimum will be required in pharmacy, finance, IT, and operations and will rely on enhanced coordination between departments such as compliance, pharmacy, operations, finance, IT, 340B Team, and treasury. The estimated ongoing cost is $792,000, increasing costs and undermining our ability to stretch scarce resources.

Table 3: Additional Staff Resources

Role	Description
Pharmacy Senior Buyer (2)	Manage WAC purchases, track dispensing, ensure only eligible purchases are submitted for rebates, prepare purchase-level data for rebate invoicing
Financial Analyst (2)	Monitor cash flow impacts, reconcile rebate payments, and maintain audit-ready records
IT Software System Specialist (1)	Support platform registrations, data integration, and troubleshooting
340B Program Analyst (1)	Monitor claims submission, monitor pricing and process, flag anomalies, audit
Pharmacy Technologist Specialist (2)	Manage and dispute denials, track denial rates, monitor BCMA compliance, and review claims level data

Vandalia Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 7, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1543 ("To operationalize a rebate model effectively, we would require at least two additional FTEs, diverting focus from existing compliance efforts and potentially increasing short-term compliance risk.").

Hannibal Regional Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 15, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1554 ("We anticipate needing two additional administrative specialists to manage the increased volume of data submission and dispute resolution. We would require at least six months of lead time to recruit and train these individuals in the specialized nuances of 340B compliance.").

Indiana University Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 16, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1560 ("Based on our preliminary internal assessment, IU Health expects that a full rebate model would require significant incremental FTE dedicated to rebate administration and reconciliation, representing substantial new annual personnel costs. These costs are not offset by any efficiency gain under the proposed model; they represent a net new administrative burden imposed on IU Health's operations.").

Knox Community Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-1564 ("As previously stated, Knox Community Hospital would need to hire an additional 2 full-time employees to meet the demands of a Rebate pilot Program. This is because HRSA's estimate of 5 hours per week needed to navigate said program is ludicrously low for the suggested 25 total drugs. This program will require extensive monitoring which we cannot do with our current staff of one full-time 340B employee.").

Jackson Hospital and Clinic, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-1585 ("We estimate the need for an additional two FTEs to analyze submission, track rebates, refile denials and reconcile deposits.").

Vanderbilt Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 17, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1593 ("The February 2026 ICR estimated that Covered Entities would experience an average weekly burden of five (5) hours of staff labor to comply with the Rebate Model. **Our projection of hiring six (6) new full-time employees equates to a weekly burden of 240 hours, or 48 times greater than HRSA's estimate for ongoing burdens on Covered Entities. Expanding the Rebate Model from 10 drugs to 25 would increase the above estimated costs considerably.**").

Clark Fork Valley Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 17, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1601 ("Clark Fork Valley Hospital, Plains, MT does not currently have the staff needed to comply with a Rebate

Program. We currently struggle to fill vacancies throughout our hospital, from housekeepers to cooks to nurses' aides to therapists to medical professionals. We can't even employ a full-time pharmacist.").

Keck Medicine of the University of Southern California, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (HRSA-2026-03042) (Apr. 13, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1609 ("Keck Medicine of USC does not currently have the stac needed to comply with a Rebate Program. We estimate a 20% increase on FTEs, additional IT fees, and potentially a new third-party vendor will be needed to manage and track the rebates expected.").

Nationwide Children's Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 17, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1612 ("Our covered entity would require one additional full-time equivalent employee to be added as a permanent employee. This FTE would be responsible for data submission, rebate dispute resolution, rebate reconciliation, and 340B program auditing.").

Blessing Health System, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 15, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1620 ("At least 2 additional Full-Time Employees.").

Kent County Memorial Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-1624 ("Kent Hospital does not currently have the staff needed to comply with a rebate program. Kent Hospital will need to hire and train an additional staff member in order to implement and maintain the 340B rebate model. It would take a minimum of 4-6 weeks to train a new employee to be proficient in the 340B rebate model and it would take 2-3 months to post a position, interview candidates, and onboard the employee. Kent Hospital expects it to take 3-4 months from the time the rebate model is announced to hire, onboard and train a new employee. Furthermore, additional new staff may be needed to be hired and trained, to comply with an entirely new, and more burdensome, model of reimbursement-so these estimates are conservative.")

University Hospitals of Cleveland, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 17, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1651 ("The organization at a minimum would have to hire 2 full-time employees to accurately track and submit rebate requests. If full-time employees were not hired, then a third-party administrator would need to be contracted to track rebates but a person at the organization would need to take 20 hours per week making sure that we are receiving the rebates and everything is correct with the third-party administrator. Total increase in administrative costs with either option would be at a minimum of $200,000 per year.").

Abbeville Area Medical Center, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 17, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1652 ("The organization at a minimum would have to hire 2 full-time employees to accurately track and submit rebate requests. If full-time employees were not hired, then a third-party administrator would need to be contracted to track rebates but a person at the organization would need to take 20 hours per week making sure that we are receiving the rebates and everything is correct with the third-party administrator. Total increase in administrative costs with either option would be at a minimum of $200,000 per year.").

Edgefield County Healthcare, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-1655 ("Abbeville Area Medical Center would possibly not be able to stock the necessary quantity of medications due to cash flow constraints caused by the entity not being able to afford to float the difference between the WAC and the upfront 340B price.").

Freeman-Oak Hill Health System, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 16, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1638 ("Freeman's current estimate additional weekly administrative hours to participate successfully in the proposed 340B Rebate Model is not five (5), but rather eighty (80).").

Unity Medical Center, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 17, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1690 ("We simply do not have the staff needed to comply with a Rebate Program. At small locations such as ours, each staff member necessarily wears multiple hats—very few roles are dedicated to simply managing "one job" as larger organizations may. We cannot afford to maintain ever-increasing specialized staff and services to manage a program whose entire purpose is to help us maintain and expand for the good of the patient. With ongoing attacks from heightened regulations and manufacturer push backs, a highly trained role will be necessary to effectively manage the intricacies of the suggested program. Unity estimates a requirement of 1.0 to 2.0 specialized FTEs to manage daily data scrubbing, reconciliation, and the 10-day dispute window, not to mention the already rigorous standards required to maintain program compliance.").

Neshoba County General Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-1704 ("As mentioned above, NCGH would require hiring an additional staff member to efficiently comply with and monitor rebates in the proposed program. Additional training and software would be needed to manage the program.").

Appendix B
Selected Comments Referencing Impact On Services, Patients, and Communities

Graham County Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (March 5, 2026), https://www.regulations.gov/comment/HRSA-2025-0001-0012 ("We will likely shut down our patient assistance program. This program allows us to directly pass 340B savings to patients.").

Bitterroot Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (March 9, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0058 ("A particularly serious concern for Bitterroot Health Daly Hospital is the impact of the rebate model on our SunRx cash-card program. Our SunRx cash-card program provides medications to patients at the 340B acquisition cost plus a small dispensing fee and generates no revenue for the hospital; it exists solely to improve medication affordability for patients who might otherwise forgo needed treatment.… This means the rebate model converts a zero-margin, patient-benefit program into a high-risk financial loss center for our rural hospital and directly threatens our ability to continue offering this critical access program."); *id*. ("The 340B program enables Bitterroot Health Daly Hospital to sustain services that would otherwise be financially unsustainable in a rural market, including oncology infusion services; outpatient specialty clinics such as cardiology, orthopedics, urology, and behavioral health; medication access and assistance programs; chronic disease management and care coordination; and emergency and urgent care medication availability. The combination of new structural costs (startup and ongoing), large WAC exposure in our SunRx cash-card program, potential permanent rebate losses, and significant cashflow delays directly threatens the viability of these service lines.").

Heart of America Medical Center, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (March 5, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0037 (explaining that for only 10 medications: "Heart of America Medical Center in Rugby, North Dakota uses our 340b funds to help support programs, such as cardiac rehab program and diabetes education. If 340b funds are reduced due to the Rebate Program, these patients may have to travel at least 60 miles to access programs such as these.").

Iroquois Healthcare Alliance, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Feb. 25, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0018 ("The cumulative effect of increased administrative costs, staffing burdens, and cash flow risk is straightforward: IHA member hospitals would have less money available for patient care. For hospitals that are already making difficult decisions about which services they can sustain, that reduction is not abstract. It translates directly into program cuts, service line reductions, and in some cases potential facility closures. Several IHA member hospitals use 340B

savings to cross-subsidize services that are financially unsustainable on their own, including labor and delivery units, behavioral health programs, and outpatient clinics serving uninsured patients. These are services that exist because 340B savings make them possible. A rebate model that erodes those savings puts those services in jeopardy. In communities where IHA members are the only hospital within a reasonable distance, the consequences of service reductions are severe.").

MyMichigan Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Feb. 25, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0044 ("Our charity care program to support underinsured and uninsured patients will be severely impacted. The money spent on implementing and maintaining this rebate model will directly impact our ability to serve our most vulnerable community members.").

Jefferson Community Health & Life, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-0075 (listing numerous programs supported by 340B discounts at risk if a rebate mechanism is imposed, including a "home health agency [that] allows patients to receive skilled care in their homes rather than traveling long distances for treatment," a "long-term care facility [that] provides a home for up to 40 individuals who require skilled or long-term care," charity care, bad debt write-offs, "reduced cost health screenings and community health education programs," hosting students for rural clinical health rotations, and "supporting scholarships for students pursuing careers in health care.").

Electra Memorial Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (March 19, 2026), *at* https://www.regulations.gov/comment/HRSA-2026-0001-0100 ("The impact of these incremental costs will be devastating to our facility.… Clinical staff will have to be cut to increase the number of administrative staff required to track and recover rebates. Replacement of radios and purchase of a ventilator for our EMS service along with purchase of new monitors for the emergency room and inpatient services have all been paused in anticipation of this drain on cash flow.").

Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (March 19, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0096 ("Our organization, located in New York State, is comprised of a DSH, a CAH, and a SCH registration on the Office of Pharmacy Affairs 340B OPAIS.… Community give back programs, medication assistance programs and free or discounted medications would be in jeopardy of dissolution. 340B savings fund Oncology services, Behavioral Health, Mental Health and Harm Reduction services, Women's and Children's programs and Heart Health clinics. When cash flow becomes unpredictable, the organization will need to assess the high overhead services: specifically Oncology and Specialty Pharmaceutical care.").

Memorial Community Hospital and Health System, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (March 9, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0105 ("These added burdens would directly reduce the resources available for patient care in the Blair community. MCH's 340B savings are not excess revenue-they are essential to sustaining services that would otherwise be unavailable in a rural setting. Over the past several years, those savings have enabled us to expand oncology, infusion, and specialty services so patients can receive care close to home. Diverting those dollars to administrative overhead, IT systems, and cash-flow management would threaten the continued availability of these services and negatively affect patient access and outcomes.").

Randolph Hospital District dba Memorial Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-0110 ("In our most recent fiscal year, Memorial Hospital of Chester, IL, saved retail pharmacy customers $106,000 through loyalty pricing and pharmacy financial assistance programs. The complexities and pricing uncertainties of the proposed rebate model threaten to diminish these savings, potentially leading to non-compliance for patients who rely on this assistance to afford life-saving medications.").

Wheeler Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 3, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-0305 ("To offset the upfront cost of drugs, we would be forced to scale back non-revenue-generating but essential services, such as mobile medical services and community events promoting blood pressure monitoring and other risk factors.… Our ability to provide medications at "zero-pay" or deeply discounted rates under our sliding fee scale will be compromised. If the cash is not in our accounts because it is being held by a manufacturer, we cannot provide the "bridge" support that prevents our 1,100 uninsured patients from rationing their insulin or heart medication.").

Sierra View Medical Center, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-1389 ("We also have been currently using our 340B savings to support our new OB Clinic at Sierra View. Without our 340B savings, our charity care, OB Clinic beginnings, and future rural health initiatives would be thwarted. Our community and the people we serve would be negatively affected by the rebate program.").

Columbia Memorial Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 8, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1413 ("Funds to support this additional FTE will come directly from the 340B resources that the hospital currently receives as a result of the savings. Funds that are currently used to support programs like the only inpatient maternity department in Clatsop County.").

Knox Community Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042), https://www.regulations.gov/comment/HRSA-2026-0001-1564 ("With these additional costs, our facility may have to delay or cancel capital improvements. Over the last few years, we have had to close our Allergy Clinic and Home Health Department due to cash flow and viability, and that is with 340B savings. We would not be able to offer the same amount of patient assistance as we currently do, and we would not be able to grow our patient's access to affordable medications. Any patient assistance copay options funded by 340B savings we have planned are off the table, as we would be unable to offer discounts on medications for which we do not know if we will be paid. Our facility would not be able to attract and maintain specialist that benefit our rural community, meaning patients would have to travel up to an hour to find comparable services. Many of our patients struggle with transportation costs, and this would only make it harder for them to receive care.").

Woman's Hospital Foundation, dba Woman's Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 10, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1408 ("The 340B Program enables Woman's Hospital to sustain essential services, including mobile mammography, perinatal mental health services, bedside prescription delivery, specialty gene therapy, HIV post-exposure prophylaxis, and care for low-income patients through Louisiana State University affiliated clinics. Policies that delay or reduce access to 340B savings will directly affect patient care in the communities we serve.").

Baylor Scott & White Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 20, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1485 ("The cumulative effect of the proposed rebate model requirements is a meaningful diversion of resources away from patient care. 340B program savings that currently support patient assistance programs, clinical operations, and pharmacy services would be reassigned to administrative compliance functions. Financial resources would be redirected toward staffing, consultants, and IT systems rather than community benefit programs and expanded access to care.").

Adams County Memorial Hospital and Adams Community Pharmacy, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr, 13, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1508 ("Adams Community Pharmacy serves patients who often struggle to afford medications, and we provide assistance that is not otherwise readily available in our community. If covered entities must absorb higher upfront drug costs and devote more resources to administrative rebate functions, fewer resources will remain available for medication assistance, care coordination, and other community benefit activities supported by 340B savings. The result could be reduced access to medications, delayed therapy, greater financial hardship for patients, and worsening health outcomes. Those harms would fall most heavily on rural, low income, elderly, and uninsured populations.").

Hannibal Regional Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 15, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1554 ("These administrative burdens will effectively reduce our 340B net benefit by an estimated 20-25% for these specific drugs, money that is currently used to subsidize our sliding-fee scale for uninsured patients in northeast Missouri.… The uncertainty of this pilot has already led us to pause a planned upgrade to our rural health clinic equipment.").

Clark Fork Valley Hospital, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 17, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1601 ("One of the more important and visible impacts of our program is our Cash Program which allows uninsured patients to benefit from the hospital's 340B pricing and receive a significant discount when obtaining prescriptions at our contract pharmacy. If we are unable to sustain our participation in 340B, that program will go away. At the same time, the numbers of uninsured people in our county are increasing due to the increased cost of insurance on the exchange and cutbacks to Medicaid eligibility.").

CaroMont Regional Medical Center, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 16, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1643 ("CaroMont Regional Medical Center operates the only two acute care hospitals in Gaston County. Without the upfront, reliable savings from the 340b drug program, the hospital might have to close two of its most unprofitable services – Labor and Delivery and Inpatient Behavioral Health. This would mean that patients would have to travel outside their home county to deliver their babies, putting themselves and their unborn child at higher risk. There currently is a shortage of behavioral health inpatient beds in North Carolina so closing our 63 licensed beds would cause further challenges for these patients to obtain the care they need when they are the most vulnerable and potentially a danger to themselves and those around them.").

Johns Hopkins Health System, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 20, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1644 ("The Johns Hopkins Hospital System partners with community members to identify the most important health needs in the community. For many years, 340B savings have contributed to addressing those and many other needs through innovative programs such as our Community Health Needs Assessment Small Grants program, supportive housing for drug treatment, wraparound social services for unhoused individuals through Maryland's Assistance in Community Integration Services, and Break the Cycle Hospital Violence Intervention Program. For example, JHH's total Community Benefit activity in FY25 was $412 million, which is substantially more than JHH's estimated 340B savings of $285.7 million that same year. Additive costs and burdens to the 340B program could force Johns Hopkins to offer fewer comprehensive services, pause or terminate innovative programming, and reduce community support efforts.").

University Hospitals of Cleveland, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 17, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1651 ("The majority of outpatient pharmacy services, including clinical and financial support programs were funded mainly by 340B savings. The programs listed below would be significantly reduced or eliminated if a 340B rebate model is implemented: ▪ Financial assistance for patients unable to afford medication ▪ Medication access team- navigate insurance requirements/remove financial barriers ▪ Patient engagement team- outreach to manage refills and drive adherence to therapy ▪ Clinical services- pharmacists in provider's offices, ongoing care management."); id. ("The combination of increased administrative costs and decreased cash flow will likely lead to reductions in workforce and in the comprehensive services we currently offer to our community.").

Abbeville Area Medical Center, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Apr. 17, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-1652 ("To offset the upfront cost of drugs, we would be forced to scale back non-revenuegenerating but essential services, such as our medication management clinic that helps patients manage complex disease states such as diabetes and heart failure. Abbeville Area Medical Center in Abbeville, SC anticipates reducing clinic and pharmacy hours specifically impacting the working class. The administrative burden of this pilot requires us to divert funds away from clinical staff. For every 'Rebate Coordinator' we are forced to hire, we lose the ability to fund appropriate clinic and pharmacy staff directly increasing wait times for patients and prescriptions. Our ability to provide medications at 'zero-pay' or deeply discounted rates under our sliding fee scale will be compromised. If the cash is not in our accounts because it is being held by a manufacturer, we cannot provide the 'bridge' support that prevents our uninsured or underinsured patients from rationing their diabetic or heart medications such as insulin. This could cause needless admissions to the hospital that could cost government-sponsored Medicare plans more money in the long run.").

Public Comments for ICR 202606-0906-001

Author Full Name : Lisa Henry **Received Date :** 07/15/2026 11:43 AM

Comments Received :

On behalf of our more than 2,000 member hospitals and health systems that participate in the 340B Drug Pricing Program, the American Hospital Association appreciates the opportunity to respond to this Information Collection Request about the Health Resources and Services Administration’s proposed 340B Rebate Model Program. See the attached document for full comments.

340B Health

340B HEALTH

July 15, 2026

Submitted to: https://www.reginfo.gov/public/do/PRAMain

Russell Vought
Director
Office of Management and Budget
725 17th Street NW
Washington, DC 20503

Re: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906–NEW

Dear Director Vought:

On behalf of our more than 1,600 hospital and health system members, 340B Health appreciates the opportunity to respond to the notice published in the Federal Register on June 15, 2026, requesting public comment on the Health Resources and Services Administration's (HRSA) proposed information collection pertaining to a 340B rebate program.[1] Congress created the 340B program in 1992 to "reduce the cost of operations" for safety-net providers, allowing them to "stretch scarce Federal funding as far as possible" so that they could reach more eligible patients.[2]

340B Health urges OMB not to approve HRSA's proposed information collection. As detailed in the comments below, HRSA's estimated burden of more than $500 million in additional costs on 340B covered entities (CEs) to submit rebate claims data to drugmakers significantly understates the actual costs CEs would likely incur under a rebate model. **HRSA's underestimate rests on unfounded and heavily contradicted assumptions that the data is comparable to information CEs already collect, maintain, and transmit through existing third-party vendor relationships.[3] In reaching this incorrect conclusion, HRSA appears to have relied primarily on assertions from pharmaceutical manufacturers and their vendors that stand to process the rebate data, while discounting information from hospitals.[4] By crediting speculative claims from industry that would not bear the reporting burden over firsthand evidence from hospitals that would, HRSA materially understated the administrative,**

[1] Health Resources and Services Administration, 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906–NEW, 91 Fed. Reg. 35989 (June 15, 2026).
[2] H.R. Rep. No. 102-384(II), at 12 (1992), 1992 WL 239341.
[3] 91 Fed. Reg. 35989, 35990-91 (June 15, 2026) (describing the data as "commonly available and already generated, maintained, and transmitted by CEs or their vendors.").
[4] 340B Health reviewed the publicly available comments that we could locate from drugmakers (20 reviewed), their vendors that have announced platforms for processing rebate data (2), and comments from hospitals (261) in response to the Health Resources and Services Administration, Notice, Request for Information: 340B Rebate Model Pilot Program, 91 Fed. Reg. 7287 (Feb. 17, 2026)

operational, technology, and staffing burdens associated with the proposed information collection. At a minimum, OMB should require HRSA to recalculate the burden using evidence provided by the entities subject to the proposed collection and to disregard unsupported and conflicting assertions from those that are not.

In addition to "establish[ing] and oversee[ing] standards and guidelines by which agencies are to estimate the burden to comply with a proposed collection of information, the OMB is also responsible for "minimiz[ing] the Federal information collection burden."[5] **If HRSA proceeds with a rebate program, we recommend changes to the proposed data collection to minimize the burden on 340B CEs by prohibiting all rebate denials by manufacturers.**

I. HRSA's Method for Estimating the Burden for 340B CEs is Significantly Flawed and Resulted in a Material Understatement of the Burden

A. HRSA Improperly Relies on Drug Manufacturer Comments and Discounts Hospital Evidence to Conclude That Hospitals Already Transmit Comparable Data

HRSA estimates that CEs would incur at least $523 million in additional annual costs, driven by more than 3.9 million hours of labor that pharmacists would spend solely on submitting data to a third-party vendor (TPA) to obtain rebates for 340B drugs.[6] HRSA says it estimated the "burden"[7] using a task-based methodology focused on discrete reporting activities, such as identifying and extracting eligible claims data, formatting and validating data, submitting information to manufacturers, reconciling submissions, tracking rebate status, and responding to errors or denials.[8] HRSA "normalized" into a per-response estimate the "higher-end estimates" commenters provided, reflecting total operational workload and "lower-end estimates" reflecting use of existing systems and automation.[9] The lower-end estimates appear to be derived from

[5] 44 U.S.C. § 3504(c)(3).
[6] *See* 91 Fed. Reg. at 35991 (June 15, 2026) (maintaining the estimated burden of 5 hours per week per CE, totaling more than 3.9 million total hours CEs would spend on data submission requirements.); *see also* 340B Rebate Model Pilot Program Application, Implementation, and Evaluation Notice, OMB Control No. 0906-NEW, Supporting Statement, page 12, (calculating each hour of burden pertaining to CE data submission under HRSA's rebate program as imposing $132 (a pharmacist's hourly wage rate). Under this assumption, HRSA estimates that CEs would incur more than $523 million in annual labor costs just to submit rebate claims data to 11 drugmakers for their drugs subject to Medicare Part D negotiated pricing in 2026 and 2027).
[7] The Paperwork Reduction Act (PRA) defines "burden" as the "total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency." The PRA expressly includes the total time, effort, or financial resources expended to review instructions, develop systems and acquire technology for the purpose of processing and maintaining information, verifying and validating information, and disclosing and providing information, in addition to training personnel to be able to respond to the collection, searching data sources, completing and reviewing the collection, and transmitting the information.
[8] 91 Fed. Reg. at 35990.
[9] *Id.*

comments submitted by pharmaceutical manufacturers and their vendors that would administer rebate data submissions.[10]

- Eli Lilly commented: "[c]laims that a rebate requirement imposes new or additional administrative burdens are overstated and inaccurate. The data elements necessary are already maintained in covered entities' pharmacy management systems as a routine part of their operations."[11]

- Novartis commented: "we do not believe that data collection associated with rebate model requests will constitute an added burden on CEs. These data … must already be collected to verify 340B eligibility under the existing replenishment model and maintained for future compliance and audit purposes, resulting in any incremental costs associated with the rebate model to be limited."[12]

- Sanofi commented: "[t]he data requirements proposed under a rebate model would not represent a significant new burden because covered entities already collect, maintain, and submit this information for other purposes."[13]

- Amgen commented that "[c]overed entities already maintain this information in readily shareable formats."[14]

- GlaxoSmithKline commented that "most of these data elements are captured in electronic health records, must be maintained to comply with 340B audit requirements or submitted in connection with contract pharmacy policies or are necessary to meet other billing and inventory management requirements. Thus, transmitting data for a Rebate Pilot should not substantially increase burden on covered entities."[15]

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[10] *Id.* at 35990. HRSA references comments that asserted that "CEs already collect the required data elements as part of routine billing, compliance, and audit processes." At least 17 manufacturers and two rebate vendors - Second Sight Solutions (Beacon and 340B ESP) and Kalderos - asserted this in their comments on HRSA's Rebate RFI. HRSA also apparently "normalized" estimates from commenters that said existing systems, including existing manufacturer claims platforms used to administer manufacturer contract pharmacy restrictions, could be leveraged to support rebate reporting. At least 12 manufacturers, Second Sight Solutions, and Kalderos asserted this in their comments. HRSA also considered comments that reporting activities could be automated or integrated into existing workflows, thereby minimizing incremental burden on CEs. At least 4 manufacturers and Kalderos asserted this in their comments on HRSA's Rebate RFI.

[11] Eli Lilly's Comments on HRSA's Rebate RFI, pages 3-4, https://www.regulations.gov/comment/HRSA-2026-0001-2394, (stating that

[12] Novartis Comments on HRSA's Rebate RFI, page 7, https://www.regulations.gov/comment/HRSA-2026-0001-1661

[13] Novartis Comments on HRSA's Rebate RFI, page 11, https://www.regulations.gov/comment/HRSA-2026-0001-2020

[14] Amgen's Comments on HRSA's Rebate RFI, page 4, https://www.regulations.gov/comment/HRSA-2026-0001-2131

[15] GlaxoSmithKline's Comments on HRSA's Rebate RFI, pages 5-6, https://www.regulations.gov/comment/HRSA-2026-0001-1667,

- Bristol Myers Squibb commented: "[t]o facilitate implementation, BMS would leverage established third-party platforms operated by Berkely Research Group, including 340B ESP and the Beacon Platform, which is currently utilized by all nine manufacturers of drugs subject to MFPs for IPAY 2026. Covered entities are already familiar with these platforms, given their role in existing 340B and federal drug pricing program operations. As a result, leveraging this existing infrastructure would substantially reduce the need for new system development and mitigate concerns regarding IT burden and staffing requirements. More fundamentally, the asserted burdens are overstated because a 340B rebate model would rely on data that covered entities already collect in the ordinary course of 340B Program compliance."[16]

- Boehringer Ingelheim's commented that "[t]he only additional administrative task presented by the 340B Rebate Model would be the submission of these data to manufacturers—a process some covered entities undertake through the 340B ESP platform to comply with Boehringer's contract pharmacy policy. The added cost and administrative burden of this one additional task would be marginal."[17]

- AbbVie commented that "arguments from covered entities that they will incur significant additional costs to collect and process claims data under a Rebate Model are suspect as the collection and processing of such data by covered entities and their vendors is already required for covered entities to ensure they are compliant with 340B program requirements."[18]

- Second Sight Solution commented that "[t]he required data fields and utilization data that entities would submit to Beacon Rebate Model are exactly the same as those submitted to 340B ESP. Thus, for the 7,000 covered entities that have already submitted data to 340B ESP, the incremental work necessary to submit data to Beacon Rebate Model is very limited."[19]

Under OMB regulations, the "time, effort, and financial resources necessary to comply with a collection of information" constitute burden unless the agency demonstrates that the activities are

[16] Bristol Myers Squibb's Comments on HRSA's Rebate RFI, pages 8-9, https://www.regulations.gov/comment/HRSA-2026-0001-2112. 340B Health strongly disagrees with the manufacturer's comment that CEs' familiarity with Second Sight Solutions' 340B ESP and Beacon platforms would reduce IT burdens and staffing requirements for CEs under a rebate model. Hospitals have reported to 340B Health hiring additional staff or reassigning existing employees simply to manage claim submissions and the many other issues that arose during submissions to 340B ESP.
[17] Boehringer Ingelheim's Comments on HRSA's Rebate RFI, page 12, https://www.regulations.gov/comment/HRSA-2026-0001-2323. 340B Health strongly disagrees with manufacturers' comments that CEs' familiarity with Second Sight Solutions' 340B ESP and Beacon platforms would reduce IT burdens and staffing requirements for CEs under a rebate model.
[18] AbbVie's Comments on HRSA's Rebate RFI, page 26, https://www.regulations.gov/comment/HRSA-2026-0001-2374
[19] Second Sight Solution's Comments on HRSA's Rebate RFI, page 2, https://www.regulations.gov/comment/HRSA-2026-0001-2149. 340B Health notes that data for medical claims has never been routinely submitted by 340B hospitals to 340B ESP, nor to any drugmaker or other drugmaker vendor.

"usual and customary."[20] HRSA has not made that showing. Instead, by "normalizing" unsupported inputs provided by manufacturers and their vendors, HRSA's methodology gives disproportionate weight to manufacturers' generalized assumptions while minimizing information from the hospital industry that would be reporting the data. Manufacturers lack firsthand knowledge of CEs' information systems, workflows, staffing, and data capabilities. Hospitals, by contrast, are best positioned to explain what data they currently maintain, how those data are stored, what information must be created or validated, and what operational changes would be necessary to comply.

Many of the more than 250 hospitals that commented on HRSA's Rebate Request for Information (RFI) notice provided information that directly refuted assumptions that CEs already maintain and provide the data that would be required for rebates. Hospitals explained that the data are not always routinely available, and although *some* data elements may already exist within hospitals' systems, transmitting those data to manufacturers to request rebates would require new operational processes, particularly for medical claims associated with drugs administered in hospital outpatient departments. [21] Data for medical claims, which account for most 340B drug spend, has never been routinely submitted to manufacturers by the 340B hospital industry and any medical data hospitals currently submit to TPAs to distinguish 340B (outpatient) drugs from inpatient drugs is significantly more limited. Rebates would effectively require significant new data reporting infrastructure, and systems developments, including interfaces across disparate technology platforms just to identify, prepare, and submit the data - burdens and costs that were not fully accounted for under HRSA's flawed method.[22]

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[20] 5 C.F.R. § 1320.3(b)(2).

[21] UNC Comments on HRSA Information Collection Request, Consolidated Group 5, https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=202606-0906-001 (stating that"UNC Health does not currently collect many of the claims-level data elements contemplated under a rebate model ... [i]n particular, UNC Health does not consistently maintain complete health plan identifiers for all outpatient encounters."); Adventist Health White Memorial, Request for Information: 340B Rebate Model Pilot Program, https://www.regulations.gov/comment/HRSA-2026-0001-1829 (stating that "[s]ome stakeholders have suggested that covered entities already provide the information that would be required under a rebate model through the 340B ESP. That characterization is inaccurate. A rebate model would impose new [] data-collection, validation, and submission requirements on covered entities."; Salinas Valley Health, Request for Information: 340B Rebate Model Pilot Program, https://www.regulations.gov/comment/HRSA-2026-0001-0063 (stating that "[c]overed entities already collect and retain substantial data to support 340B compliance, but a rebate model would require more granular … and often non-routinely-available data."); Jefferson Health, Request for Information: 340B Rebate Model Pilot Program, https://www.regulations.gov/comment/HRSA-2026-0001-2082 (stating that "A rebate model would significantly expand the volume, elements, and complexity of data that Covered Entities must collect and submit. Instead of maintaining internal compliance records, Jefferson Health would be required to generate new claims-level datasets for submission to manufacturers or third-party platforms.").

[22] Nor does HRSA's burden estimate account for costs of submitting data from locations in the hospital for which data has not previously been shared with TPAs or manufacturers. A rebate model would require data for all hospital dispenses of a unique drug, which hospitals currently do not do. Hospitals submit data to their third-party administrators (TPAs) only for certain locations – those where some of the patients seen are not likely to be 340B-eligible. Rebates would impose ongoing costs on hospitals to submit data to third party vendors from locations that do not currently do so, such as "clean sites" that use only 340B drugs and thus have no standard business reason to send data to their split-billing vendors. CEs would also incur continuing costs related to maintaining the equipment and regularly auditing each location to ensure that the systems are working correctly.

> *Memorial Health System, a DSH hospital in Colorado, commented: "One of the most significant operational challenges relates to the collection and transmission of medical claims data necessary to support rebate submissions. Our hospital's systems were not designed to automatically transmit all of the required data elements directly to our third-party administrator (TPA) or other rebate-processing entities. In many cases, the necessary data elements exist in different internal systems, including our EHR, pharmacy dispensing records, billing systems, and financial reporting systems. These systems do not currently operate through a single automated data feed that can easily generate the information required to support rebate submissions."*[23]

> *"Allina Health's current systems and protocols are designed to support upfront discount purchasing and do not currently capture or transmit all data elements required under a rebate model. Any shift to a rebate mechanism will force us to incur significant costs to change those systems … "[n]ew or significantly modified IT infrastructure to support data extraction, claims submission, tracking, and reconciliation, [and] [d]evelopment of new interfaces with third-party administrators and manufacturers … [a] key challenge is that required data elements are often dispersed across multiple systems and are not currently integrated into vendor platforms. As a result, compliance would likely require significant manual intervention, increasing both cost and risk of error. This existing format is a product of how the existing 340B program is structured, and further underscores how disruptive a rebate model would be to existing workflows."*[24]

Virtually no hospitals commented that rebate reporting could simply be incorporated into existing workflows or automated.[25] It is not surprising that hospitals report workloads that far

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[23] Memorial Health System, Comment Letter on Request for Information: 340B Rebate Model Pilot Program, https://www.regulations.gov/comment/HRSA-2026-0001-2013

[24] Allina Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042) (Mar. 9, 2026), https://downloads.regulations.gov/HRSA-2026-0001-2398/attachment_1.pdf; *see also* University of Cincinnati Hospital, Commented Letter on Request for Information: 340B Rebate Model Pilot Program, https://www.regulations.gov/comment/HRSA-2026-0001-1637 (stating that "[t]he 340B Rebate Model … requir[es] health systems to submit, track, and reconcile every eligible transaction across multiple disconnected systems (HER, split-billing and revenue cycle.) This creates substantial compliance challenges and administrative burden, including data integration challenges, high reconciliation workload, and the need for new denial management and appeal processes, all while operating under strict timing requirements that increase the risk of missed claims and savings opportunities. Additionally, the model … demands new and highly specialized staffing capabilities that blend pharmacy, finance, and analytics expertise."); Labette County Medical Center, Comment Letter on Request for Information: 340B Rebate Model Pilot Program, https://www.regulations.gov/comment/HRSA-2026-0001-0066, (commenting that "[c]urrently, Labette County Medical Center uses third-party vendors to assist with 340B compliance tracking, reconciliation, and auditing. A rebate model would require additional pharmacy and medical claims data that are not currently captured in formats readily available for submission to manufacturers. Much of this data would likely require manual extraction from different systems, increasing administrative workload and risk of error.").

[25] *Cf.* Legacy Health, Request for Information: 340B Rebate Model Pilot Program, https://www.regulations.gov/comment/HRSA-2026-0001-1710 (alluding to data submission burdens possibly being minimized by automation in only some cases, but noting that the covered entity is still responsible for manually pulling and submitting data in cases where there are issues with the reports or the data feed, and based on the hospital's experience, data validation is still necessary for automated data submission and noting that notwithstanding potential automation, "the new labor hours required to audit claims submissions to ensure they were

exceed HRSA's estimate of just five hours per week per CE. Multiple hospitals commented that rebates would require hiring additional full-time staff, diverting existing personnel, and/or hiring third-party vendors to manage aspects of the rebate claims process:

> *University of Washington, which operates two 340B hospitals, commented: "UW Medicine anticipates the need for seven additional FTEs in the initial year of the pilot, with an additional seven FTEs required annually as more drugs are incorporated into the 340B rebate model. These resources would support data submission, rebate tracking, payment validation, dispute management, and escalation through HRSA's Administrative Dispute Resolution (ADR) process."*[26]
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> *Baylor Scott White & Health, which operates six CEs that participate in 340B commented: "Each covered entity facility would require at least one additional full-time employee dedicated to rebate administration, including claims submission, tracking, and dispute resolution management. Additional centralized financial and administrative staff (estimated 1–2 FTEs) would be required to manage reconciliation, accounting, and compliance oversight."*[27]
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> *Memorial Hospital of Sweetwater County, a critical access hospital commented: "As we set up our 340B program operations, we initially planned to allocate 1 FTE to manage it. However, under a rebate model, we anticipate needing additional FTEs or contract management assistance to manage the 340B program. These are additional costs we did not plan for and are difficult to incur, given our financial situation as a rural CAH."*[28]
>
> *University of Texas Medical Branch (UTMB), a DSH, commented: "UTMB anticipates that it will be required to invest in additional staff resources to maintain a rebate model. Resources at a minimum will be required in pharmacy, finance, IT, and operations and will rely on enhanced coordination between departments such as compliance, pharmacy,*

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accepted, to investigate why claims were rejected, and to submit claim denial disputes would be extremely burdensome as demonstrated through our work with 340B ESP … [w]e expect that the 340B rebate model platform(s) would be as or more labor-intensive to work with and require the same focus on claims status monitoring and claims denial management.").

[26] UW Medicine Comment Letter on Request for Information: 340B Rebate Model Pilot Program, https://downloads.regulations.gov/HRSA-2026-0001-1860/attachment_1.pdf

[27] Baylor Scott White & Health, Comment Letter on Request for Information: 340B Rebate Model Pilot Program, https://www.regulations.gov/comment/HRSA-2026-0001-1485

[28] Memorial Hospital of Sweetwater County, Comment Letter on Request for Information: 340B Rebate Model Pilot Program, https://www.regulations.gov/comment/HRSA-2026-0001-1477; see also Rutland Regional Medical Center, Comment Letter on Request for Information: 340B Rebate Model Pilot Program, https://www.regulations.gov/comment/HRSA-2026-0001-1502 (commenting that "HRSA's estimate of only 5 hours per week in additional work is a gross underestimate of the staff time we would need to dedicate to a rebate program.… If HRSA implements a rebate program, we anticipate a need to hire an additional 2 FTEs."); St. Tammany Health System Comment Letter on Request for Information: 340B Rebate Model Pilot Program, https://www.regulations.gov/comment/HRSA-2026- 0001-0080 (stating that "[o]ur preliminary analysis indicates that ongoing annual incremental administrative and operational expenses are estimated to be between $340,000 and $950,000, which covers staffing, financial tracking, IT maintenance, reporting updates, vendor fees, and audit or consulting services.").

> *operations, finance, IT, 340B Team, and treasury. The estimated ongoing cost is $792,000, increasing costs and undermining our ability to stretch scarce resources."*[29]

HRSA acknowledged in its information collection notice that "commenters consistently indicated that the proposed data submission requirements would impose substantial administrative, operational, and systems-related burdens" and that compliance would require "additional staffing, new or modified information technology systems, increased data tracking and reconciliation efforts, and ongoing auditing and reporting activities."[30] These activities fall squarely within the Paperwork Reduction Act's definition of "burden", which includes the time, effort, and financial resources expended to generate, maintain, retain, and provide the information necessary to comply with the proposed information collection.[31] Giving far greater weight to unsupported manufacturer assertions, HRSA concluded that "higher" cost estimates provided by CEs, including those based on full-time equivalent staffing or total weekly workload reflected "broader operational impacts" rather than the incremental burden associated with submitting rebate data.[32]

CEs would also be forced to expend significant additional time and financial resources to develop, implement, and maintain the systems required to support data submissions. Hospitals would need to build and rigorously test new software to ensure integration with existing electronic medical record (EMR) systems. Hospitals have hundreds of different accounts for their main hospital, various clinics and the pharmacies that they own and operate whose billing systems could be significantly disrupted because of changes hospitals may need to make to have the required information to request rebates.

The ongoing demands of routinely maintaining and auditing these systems to ensure they are working properly further compound the burden. Even minor changes to an EMR system can unintentionally disrupt connections or data flows under a new rebate system, introducing risks of data errors or failures. To mitigate these risks, hospitals must implement regular maintenance and auditing processes. This creates a sustained operational obligation that is technically complex and resource intensive. HRSA's flawed methodology for estimating the burden did not fully account for these burdens.

Finally, HRSA's estimates do not adequately reflect the significant administrative burden associated with interacting with manufacturers and their rebate vendors after data submission. HRSA is well aware of the substantial operational challenges hospitals have experienced under existing manufacturer claims platforms used to administer contract pharmacy restrictions.[33]

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[29] University of Texas Medical Branch (UTMB), Comment Letter on Request for Information: 340B Rebate Model Pilot Program, https://www.regulations.gov/comment/HRSA-2026-0001-1532

[30] 91 Fed. Reg. at 35989-35990 (stating that "[s]everal commenters also raised concerns about the complexity of claims-level data submission, potential for errors, and the need to manage denials and disputes, all of which would increase burden. In addition, some commenters highlighted privacy and data-sharing concerns associated with transmitting patient-level information to manufacturers.").

[31] 5 C.F.R. § 1320.3(b)(1).

[32] 91 Fed. Reg. at 35990 (June 15, 2026).

[33] See e.g., 340B Health Letter to HHS and HRSA, Significant Administrative and Financial Burdens Imposed on Hospitals Sharing 340B Claims Data Under Manufacturer Contract Pharmacy Restrictions, May 10, 2022,

Many hospitals have reported hiring additional staff or reassigning existing employees simply to manage claim submissions and the many other issues that arose in this process.[34] A rebate model would extend these same administrative challenges to virtually every covered dispense of affected drugs across all care settings, dramatically increasing the scale of those burdens.

HRSA does not acknowledge its reliance on manufacturers' reports *of how data is handled internally by hospitals,* to the exclusion of hundreds of comments from the hospitals themselves. We believe this approach fails to take into account hospital comments as required under the Administrative Procedure Act and the Paperwork Reduction Act.[35]

OMB should therefore reject HRSA's burden estimate. At a minimum, OMB should require HRSA to recalculate the burden using evidence provided by the entities that will actually respond to the information collection and to disregard unsupported assertions that the required activities are already "usual and customary"[36] unless HRSA can demonstrate, with evidence, that CEs presently perform those activities in the ordinary course of business.

II. Prohibiting All Manufacturer Rebate Denials Would Improve Clarity and Minimize the Burden of the Rebate Pilot on CEs

Documentation submitted to OMB in connection with HRSA's proposed data collection for a rebate program indicates that manufacturers will be permitted to deny rebates for reasons unrelated to diversion or Medicaid duplicate discounts. HRSA lists the following reasons for rebate denials: MFP rebate, rebate claimed by another CE, and other.[37] These would be very difficult for a CE to understand or challenge, as would any other denials that could be permitted under "other." Prohibiting manufacturers from issuing any rebate denials would improve the clarity of the collection. A no-denial policy would also help limit a portion of the new costs providers would be expected to incur to challenge denials and would reduce a source of

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https://www.340bhealth.org/files/340B-Health-Letter-to-HHS-on-Burdens-of-Manufacturer-ClaimsDataConditions5.10.22.pdf; 340B Health, 340B Rebate Pilot Program (HHS Docket No. HRSA–2025–14619), Sept. 8, 2025, https://www.340bhealth.org/files/FINAL-340B-Health-Comments-Rebate-Pilot9.8.25.pdf

[34] 340B Health Member Survey – Costs and Burdens of Submitting 340B Claims Data to Pharmaceutical Companies, Summary Results, Apr. 1, 2026. These issues include delayed responses or errors by 340B ESP and/or the manufacturer(s) resulting in the hospital not receiving 340B discounts that they were otherwise entitled to, thereby harming the hospital (85%) and having to conduct follow-up with TPAs, wholesalers, and 340B ESP after pricing dropped for NDCs and contract pharmacies without explanation (95%).

[35] *See* 340B Rebate Model Pilot Program Application, Implementation, and Evaluation Notice, OMB Control No. 0906-NEW, Supporting Statement, pg. 19 (stating that "[u]nder the Pilot, covered entities are not required to submit any new pharmacy elements beyond what most covered entities are already submitting either as part of the manufacturer contract pharmacy claims submission process or what most covered entities already have readily available through TPAs."). This is incorrect. HRSA's proposed data collection would require hospitals to submit BIN and PCN information for all retail claims. Hospitals have not been required to submit that information to manufacturers and TPAs in the past. Importantly, this information is not regularly available for drugs dispensed by contract pharmacies.

[36] 5 C.F.R. § 1320.3(b)(2).

[37] Manufacturers: 340B Program Rebate Model Pilot Program Plan Submission & Monthly Purchase Reports, https://www.reginfo.gov/public/do/PRAViewIC?ref_nbr=202606-0906-001&icID=280967. These are the same denial codes that HRSA would have permitted under its withdrawn rebate program.

administrative burden and cost for safety-net providers under rebate models that is expected to stem from having to interface with the manufacturers' vendor that would administer approved rebate models.

If any rebate denials are permitted, at a minimum, all denial reasons should receive prior approval from HRSA. Manufacturers should be required to submit detailed explanations describing how and why a denial would occur, as well as the specific information they would provide to CEs in support of the denial. This information should then be made available for public notice and comment. HRSA should also make clear that manufacturers may not deny rebate claims for drugs dispensed by contract pharmacies on the basis that the arrangements are not approved under drugmakers' contract pharmacy restrictions. 340B Health believes that such denials would violate the 340B statute and that HRSA lacks the legal authority to enforce manufacturer-imposed contract pharmacy restrictions.

***

Thank you for considering our comments. Please contact Maureen Testoni, President and Chief Executive Officer, at maureen.testoni@340bhealth.org, or Amanda Nagrotsky, Vice President of Legal and Policy, at amanda.nagrotsky@340Bhealth.org, if you have questions or would like to discuss our comments.

Sincerely,





Maureen Testoni
President and Chief Executive Officer
340B Health

Amanda Nagrotsky
Vice President of Legal and Policy
340B Health

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July 15, 2026

The Honorable Thomas J. Engels
Administrator Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20852

Subject: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-NEW (Federal Register, Vol. 91, No. 114, Monday, June 15, 2026, Notices, pp. 35989-35991)

Dear Administrator Engels,

The Allegheny Health Network (AHN) appreciates this supplemental opportunity to provide comments on the Health Resources and Services Administration's (HRSA) proposed 340B Rebate Model Pilot Program, as published in the Federal Register (Vol. 91, No. 114, June 15, 2026, Notices, pp. 35989-35991). These comments explicitly address HRSA's responses to previous public input, building upon our detailed RFI submission (HHS Docket No. HRSA-2026-03042) and our initial ICR comments.

As a non-profit health network, AHN is deeply concerned that HRSA's proposed rebate model, and its interpretation of "burden" as outlined in the Federal Register notice, fundamentally misunderstands the operational realities and critical importance of the 340B Program. We firmly believe that the proposed model will undermine our ability to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services" for the vulnerable populations across our service areas.

1. HRSA's Dismissal of Substantive Concerns Undermines Stakeholder Engagement and Program Integrity

HRSA acknowledges receiving comments expressing "general opposition to implementing a rebate model," "requests to maintain the current upfront discount structure," and "concerns about financial impacts such as cash flow constraints, increased drug acquisition costs, and loss of 340B savings; potential downstream effects on patient care, including reduced access to medications and elimination of services supported by 340B savings."



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However, HRSA dismisses these vital concerns by stating they "do not directly address the necessity, practical utility, or burden of the information collection under the PRA." This response is deeply troubling and demonstrates a critical misunderstanding of the interwoven nature of program necessity, practical utility, and burden. The core utility of the 340B Program for covered entities *is* its upfront discount, which directly supports patient services. Any change that erodes this utility, increases costs, or constrains cash flow *is* a direct measure of burden and impacts the program's necessity and utility.

A rebate model, by definition, shifts immediate financial relief to a delayed, uncertain payment. This change has direct and profound implications for a covered entity's ability to operate and deliver services. To separate these practical and financial impacts from the "burden" of information collection ignores the fundamental purpose of the 340B Program and the real-world consequences for healthcare providers and their patients. Furthermore, we question the underlying premise for such a radical shift: **What findings in HRSA audits prompted this theory of widespread theft within the 340B program that necessitates this complete overhaul? This critical context is missing from HRSA's justification.**

2. Gross Underestimation of Burden and Costs Persists

HRSA's continued insistence on an estimated burden of **5 hours per response for Covered Entities reporting claims data** is woefully inadequate and a severe underestimation of the actual administrative, operational, and financial impact. While HRSA states this estimate "reflects a reasonable median burden across this range of entities" and considers a "task-based methodology" and "limited scope of the Pilot" (25 drugs), it still fails to capture the true cost and complexity:

- **Discrepancy with Real-World Estimates:** AHN, along with many other commenters, provided "substantially higher burden estimates," including:
- **One-Time Startup Costs: 620-1,240 hours** (15.5 to 31 full-time weeks) for initial setup, including legal review, IT build-out, operational workflow changes, training, accrual calculation development, and analytics.
- **Specialized Software Implementation:** Estimated one-time costs of **$1.2M - $1.5M+** for specialized 340B software implementation and IT system development.
- **Ongoing Staffing Costs: 120-160 hours per week** (3 to 4 full-time equivalent employees), totaling **$390,000 - $625,000 annually** in new, permanent staff salaries.
- **Additional Costs: $500K – $900K** for legal review, staff training, and consulting services.
- **Misinterpretation of "Limited Scope" and "Existing Systems":** While the pilot is limited to 25 drugs, it introduces an entirely *new* system and workflow that runs *parallel* to the existing 340B upfront discount model. This does not reduce complexity; it duplicates it. Leveraging "existing systems and processes" is insufficient when the fundamental nature of the transaction (upfront discount vs. post-purchase rebate) changes, requiring:

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- ✓ Extensive legal review and data governance.
- ✓ Complex IT build-out and integration with disparate internal systems (claims, pharmacy, EHR, purchasing).
- ✓ Entirely new operational workflows for claims processing, data submission, reconciliation, audit support, denial tracking, appeals management, and manufacturer portal logins.
- ✓ Complex accrual calculations and labor-intensive reconciliation and denial management.
- ✓ The creation of a quarterly 340B price file for CEs, which would be an **"operational nightmare"** as current pharmacy billing software lacks the ability to load this type of file. This critical aspect, vital for AHN's Disproportionate Share Hospital (DSH) status, is a significant, unaddressed burden.

- **The 5-hour estimate reflects an assumption that Covered Entities will simply extract and submit data, which is a gross oversimplification.** It ignores the full lifecycle of a rebate process, from initial data mapping and IT integration to ongoing reconciliation, denial management, and financial accounting. Furthermore, the assumption that existing IT costs are becoming redundant with a rebate model is flawed; these are parallel systems, and a lack of data modification for reversals makes results inaccurate and costly.

3. Financial Liquidity Threat and Compromised Patient Services Remain Critical

The Federal Register notice confirms that the pilot will require covered entities to submit data to manufacturers to request rebates. This solidifies our concern regarding the direct and severe impact on AHN's cash flow. The current upfront discount model provides immediate financial relief. Shifting to a rebate model, even for a limited set of 25 drugs under the pilot, would force AHN to pay full Wholesale Acquisition Cost (WAC) upfront and await delayed reimbursement.

- **Cash Flow Float:** Our estimated cash flow float of approximately **$10M+** would significantly reduce liquidity, increase borrowing costs, and risk violating bond covenants. This effectively forces AHN to provide interest-free loans to drug manufacturers for extended periods (estimated 14 to 180+ days, given actual wholesaler payment terms of less than 15 days). HRSA's proposed 10-day payment window for manufacturers after data submission is insufficient to mitigate this.
- **Impact on Vulnerable Patient Populations:** These new, unbudgeted costs and financial strains will directly reduce AHN's capacity to deliver essential patient services and support community health initiatives. This includes, but is not limited to:
  - ✓ Reduced access to free/reduced-cost medications and financial assistance for vulnerable patients.
  - ✓ Cuts to vital community health programs.
  - ✓ Compromised quality and innovation in patient care.

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- ✓ Limited ability to stock high-priced drugs due to liquidity constraints.

HRSA's statement that these concerns do not "directly address the necessity, practical utility, or burden of the information collection" is a failure to acknowledge the direct link between financial viability, operational capacity, and the very existence of the comprehensive services the 340B program enables.

4. Recommendations for a Less Burdensome and More Effective Approach

Given HRSA's continued pursuit of information collection related to duplicate discounts, AHN reiterates its primary recommendation to **abandon the rebate model concept entirely.** If, however, HRSA insists on proceeding, it must drastically revise its approach to genuinely minimize burden and protect program integrity.

- **Revise Burden Estimates Accurately:** HRSA must engage in a thorough re-evaluation of its burden estimates, taking into account the full scope of activities and costs as reported by covered entities. The current 5-hour estimate is scientifically unsound and practically unsustainable.
- **Prioritize a Neutral, Third-Party Clearinghouse:** As AHN previously recommended, a neutral, third-party clearinghouse offers a significantly less burdensome and more effective alternative to address duplicate discounts, without the profound negative impacts of a rebate model on covered entity operations and patient care. This approach would centralize data, ensure consistency, and maintain the upfront discount structure.
- **Mandate Clear IT Functionality and Manufacturer Bearing of IT Costs:**
- **IT Platform Costs must be borne by the manufacturer.** We recommend that internal IT costs for covered entities can be billed to manufacturers.
- Any online platforms for data submission must have basic functionality including **file deletion, modification, and reporting capabilities.**
- All parties need to provide technical assistance/customer service to users, with communication of new releases and updated functionality. It would be helpful to assign an account representative for vendor support. User groups for new recommendations should be established.
- **The rebate model fails to factor in a mechanism for wholesalers to stay viable,** as their business model relies on chargebacks to manufacturers, which would be impacted by a rebate system.
- **Data Minimization and Standardization:** Implement strict controls to collect only the minimum necessary, de-identified data in a standardized format, leveraging existing data exchange standards (e.g., HL7, FHIR, EDI). IT platform assurance for data security and data elements should be limited to only what is necessary.



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- **Robust Privacy and Security Guardrails:** Mandate clear, negotiable data use agreements explicitly prohibiting commercial use of covered entity data, along with independent third-party auditing of any platform technology.
- **Manufacturer Accountability and Rebate Processing:** Shift the primary reporting burden to manufacturers, requiring them to provide real-time updates on claim status, detailed rationales for all denials, and itemized payment details.
- **Rebates must be paid at the unit level,** and detailed rebate calculations provided.
- **340B rebates cannot be denied based on eligibility or compliance concerns with diversion or Medicaid DD, or perceived lack of WAC purchases.** Such issues must go through a proper dispute resolution process or audit, and there should be **no contract pharmacy restrictions on these.**
- Manufacturers should provide sufficient details to accommodate up to 2 unreplenished accumulated packages during implementation and a 15-day grace period for CE submission.
- All rebates paid or documented denials must be submitted within 10 days.
- HRSA should publicly share aggregated manufacturer performance metrics to ensure transparency and accountability.
- **Enhanced Real-Time Solutions:** Invest in strengthening existing real-time claims adjudication flags within PBM systems to identify potential duplicate discounts *before* they occur, a far more efficient method than a post-purchase rebate.
- **Adequate Timeframes and Advance Notice:**
- Allow for a minimum of **45 days after dispense** for submission of claim information, with allowances for extenuating circumstances or other exceptions, including when 340B status changes.
- Provide at least **90 calendar days' notice** to CEs and stakeholders for any changes, allowing adequate time for review and implementation.

The Allegheny Health Network urges HRSA to critically reconsider its path forward. The Federal Register notice indicates a concerning disregard for the substantive feedback provided by covered entities regarding the profound negative impacts of a rebate model. AHN reiterates that the proposed 340B Rebate Model Pilot Program, with its inherent delays, increased administrative burden, and severe cash flow constraints, will directly harm our ability to serve vulnerable patients and uphold the core mission of the 340B Program.

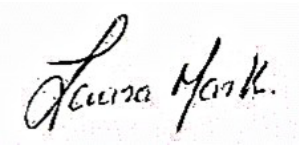
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We believe that our detailed comments, consistently highlighting the significant understatement of burden and the detrimental impact on patient services, warrant a comprehensive re-evaluation of this proposal. AHN remains committed to collaborating with HRSA to find constructive solutions that genuinely protect the integrity and life-saving mission of the 340B Program.

Thank you for your careful consideration of these critical comments.

Sincerely,



Laura Mark
Vice President, Pharmacy

cc: Mark Sevco, President, AHN
Jacqueline M. Bauer, General Counsel and Chief Administrative Officer, AHN
Daniel A. Onorato, Executive Vice President, Corporate Affairs, Highmark Health

Public Comments for ICR 202606-0906-001

Author Full Name : Anonymous **Received Date :** 07/15/2026 08:27 PM

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ICR REFERENCE NUMBER: 202606-0906-001
340B Rebate Model Pilot Program Application, Implementation, and Evaluation
Allegheny Health Network Comments

Boston Medical Center Health System

Boston Medical Center
HEALTH SYSTEM

July 15, 2026

Electronically filed: https://www.reginfo.gov/public/do/PRA/icrPublicCommentRequest?ref_nbr=202606-0906-001

The Honorable Thomas J. Engels
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane Rockville, MD 20852

Re: HHS-HRSA Notice: Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation. 91 Fed. Reg. 35989 (published June 15, 2026). OMB Number 0906-NEW. FR Doc. 2026-11989. ICR Reference: 202606-0906-001

Dear Administrator Engels,

On behalf of **Boston Medical Center Health System (BMCHS),** we are grateful for the opportunity to comment on the Department of Health and Human Services' (HHS) "Request for Information: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation."

BMC Health System is New England's largest safety-net health system, which includes Boston Medical Center, our flagship academic medical center, two community teaching hospitals (BMC-Brighton and BMC-South), and WellSense Health Plan, which serves almost 700,000 members across Massachusetts and New Hampshire. Each year, BMC Health System provides care across more than one million patient visits, including 25,000 inpatient admissions and 120,000 emergency department visits. BMC Health System serves a disproportionately low-income, racially and ethnically diverse patient population from across the region – roughly half live at or below the federal poverty level, 70% identify as Black or Hispanic, and approximately one-third are best served in a language other than English. The overwhelming majority of our patients and members are enrolled in MassHealth (combined program for Medicaid and the Children's Health Insurance Program), Medicare, or subsidized Marketplace coverage. Our hospitals are just the type of entities for which the 340B program was designed and without it, we could not provide the care we do to hundreds of thousands of low-income patients in our region.

BMCHS fundamentally opposes any form of 340B rebate model. **We believe widespread use of rebates would put BMCHS at risk of insolvency. Essential systems like ours are operating at negative margins already; we would have no choice but to take immediate, drastic survival measures.** These could include closing both of our community hospitals entirely and severely shrinking essential but chronically unprofitable services—such as psychiatry, substance use disorder,

maternity care and trauma care —that we are currently able to sustain because of 340B savings. **Any rebate mechanism will impose enormous costs and burdens on health systems of our size that far outweigh any benefits that might come from it:** (1) the proposed rebate model will put a significant strain on our cash flow due to upfront costs and lack of standardization, (2) HRSA is underestimating the covered entities administrative burden to implement the 340B rebate model, (3) by allowing manufacturers to approve and process rebate claims, the rebate model effectively shifts claim eligibility determination from HRSA to manufacturers, and (4) there is federal 340B legislation under consideration by Congress that would provide meaningful reforms and further enhance HRSA's regulatory authority to oversee the program in the future.

1) The proposed 340B rebate model will significantly impact our cash flow.

Since its inception, the 340B Program has consistently provided discounts through upfront pricing rather than post-sale rebates. BMCHS reasonably relied on this history when designing its internal operations, staffing, third-party contractual relationships, and financial planning for the use of 340B savings—all based on an upfront-discount model. Changing that would not only create short-term operational disruption for safety net health systems, but also fundamentally alter the economics that these health systems rely on. **The rebate model creates a hidden tax on safety-net providers through forced working capital financing.** We would be required to finance up to 60 days of inflated prices for our pharmaceutical inventory before reimbursement, which would constitute a substantial burden given that drug spend represents one of our largest cash outflows. Financing this gap through increased debt introduces recurring interest expenses that directly degrade our operating margin. For organizations already operating on thin margins, this permanent interest drain reduces capacity for clinical expansion, graduate medical education, and charity care - the very missions that justify the 340B program.

Without clearly defined appeal rights, documentation requirements, decision criteria, and mandatory resolution timelines, covered entities face prolonged uncertainty regarding reimbursement for drugs that have already been purchased and dispensed to eligible patients. **This shifts significant financial risk to safety-net providers, creating additional cash-flow instability, and undermining the purpose of the 340B program by delaying resources that are intended to support patient care.** HRSA's expansion pathway raises broader concerns about the long-term sustainability of this model for BMCHS. While framed as a limited pilot, HRSA's Federal Register notice signals intent to expand to "other drugs purchased under the 340B Program", meaning this could extend to the whole 340B portfolio. The fact that HRSA has already expanded the pilot from 10 drugs to 25 drugs between the initial announcement and the current ICR confirms this pattern and validates our concerns that scope creep will continue.

Our experience with the Medicare Negotiated Price program demonstrates that rebate processing timelines far exceed HRSA's assumptions—we experienced months' long delays for rebates due in January 2026 and are experiencing ongoing reconciliation issues between submitted claims and received payments.

Early manufacturer rebate programs have demonstrated significant operational failures that indicate the risks BMCHS would face under the proposed 340B Rebate Model Pilot Program. Real-world rebate administration data reveals systemic problems in claim processing and payment:

- Approximately 10% of claims eligible for payment were incorrectly rejected after being identified as 340B claims
- Approximately 30% experienced payment delays because of missing or inconsistent data elements
- Approximately 40% of submitted claims required manual intervention or experienced processing issues

These failure rates demonstrate that **manufacturer-administered rebate systems are inherently unreliable and create unacceptable risk for covered entities.** Our experience thus far proves that, if a rebate model is implemented and expanded, the problems would be far worse than what has been modeled. Given that BMCHS already operates on negative margins and thin liquidity, subjecting our 340B program to this level of processing failure would materially jeopardize our ability to fund patient care programs and maintain bond covenant compliance.[1]

2) **HRSA is materially and broadly underestimating the administrative burden of the rebate model for all stakeholders, especially for large, multi-site health systems like BMCHS.**

HRSA estimated five hours per week for covered entities to submit claims data to manufacturers. The estimate is not realistic, is not achievable without substantial staffing increases, and does not reflect the actual operational and systems integration burden that a large system must absorb to implement the 340B Rebate Model Pilot Program. While the 60-day comment period was closed, our assessment of the burden estimate has not changed; HRSA's response to commenter concerns neither addressed the specific operational complexities facing large systems nor provided evidence supporting the 5-hour estimate's applicability to systems of our scale.

HRSA's burden estimate fails to account for the fundamental operational reality facing large, multi-site health systems**:** This isn't isolated to "submitting claims"; we must build enterprise infrastructure that does not currently exist. BMCHS operates across multiple service lines and locations with heterogeneous legacy pharmacy systems, electronic health records, and third-party administrator platforms that were designed and contracted on the assumption of upfront discounts. The rebate model requires three additional critical capabilities we do not currently have: (a) real-time identification and extraction of 340B-eligible claims; (b) J-code-to-NDC mapping to connect medical claims data with pharmaceutical rebate data – currently manual and error prone; and (c) new TPA software or functionality implementation and integration with multiple manufacturers' platforms or a new centralized platform. These are not marginal additions to existing processes—they require dedicated full-time staff in data analytics, revenue cycle reconciliation, eligibility management, and IT systems integration, supported by substantial one-time technology

[1] 340B Report, "40% of Claims Miss the Mark," available at https://340breport.com/40-of-claims-miss-the-mark-sponcon-rxparadigm/

investment. HRSA's estimate assumes this infrastructure already exists or can be absorbed into existing capacity; neither assumption is accurate for a system of BMCHS's scale and complexity.

As stated in the previous comments submitted by BMCHS, **to operationalize the rebate model, BMCHS requires incremental permanent staffing of 6.5 full-time equivalents across five critical functions**:

- data and analytics (2 FTEs) to manage the new process for claims submission, data validation, and system integration;
- revenue cycle reconciliation (1 FTE) to track and verify 340B rebate payments on over 1,000 claims per week;
- eligibility and dispute management (2 FTEs) to handle ongoing claim disputes, manufacturer denials, and coordination with multiple manufacturers;
- compliance and audit (1 FTE) to manage regulatory requirements and risk mitigation; and
- IT systems integration (0.5 FTE) to support ongoing platform troubleshooting and vendor management.

These positions represent a permanent shift of specialized personnel and resources away from direct patient care, clinical quality improvement, and other strategic initiatives. At a fully loaded cost of approximately $650,000 to $750,000 annually—plus an additional $150,000 to $200,000 in ongoing technology licensing and maintenance—this represents a permanent drain on organizational resources that cannot be absorbed into existing capacity. HRSA's five-hour-per-week estimate does not account for the need to hire, train, manage, and sustain these dedicated positions, nor does it acknowledge the opportunity cost of diverting this capacity from the organization's core clinical mission.

Moreover, HRSA's estimate fundamentally misunderstands the nature of implementation burden. First, the rebate model cannot be layered onto existing 340B processes; it requires parallel infrastructure and workflows that will operate simultaneously with current upfront discount operations. Through this new process, covered entities will transition a limited scope of 340B drugs to rebate submission, meaning they must maintain dual processes (upfront discount tracking and rebate submission tracking) during the pilot phase and potentially indefinitely. This means the burden is not absorbed into existing staff capacity; it requires incremental staffing to manage the parallel workflows, systems reconciliation, and governance across two fundamentally different operational models.

Second, the operational burden is not proportional to the claim count. The burden is driven by the infrastructure required to support a new process: data pipeline development, vendor integration, eligibility determination, denials management, and reconciliation protocols. Whether BMCHS processes 50,000 rebate-eligible claims or 500,000 claims annually, the fixed cost of standing up this infrastructure is nearly identical. HRSA's assumption that a "limited pilot" of 25 IRA drugs justifies

minimal burden is operationally false—we must build enterprise-grade infrastructure to support claims-level submission and tracking, regardless of whether that infrastructure initially serves 5% or 100% of our 340B volume. Even a low erroneous denial rate can create substantial operational burden. For example, our health systems submits 500,000 rebate claims annually; an erroneous denial rate of just 1% would generate 5,000 individual disputes requiring investigation, documentation, follow-up, and potential appeals. Without a standardized, binding dispute resolution process and defined timelines, these disputes could delay access to 340B savings and increase administrative costs for both covered entities and manufacturers.

3) **By allowing manufacturers to approve and process rebate claims, the rebate model effectively shifts claim eligibility determination from HRSA to manufacturers.**

The 340B statute expressly delegates authority over the program eligibility and discounts to the HHS Secretary, not manufacturers. Under the current regulations, manufacturers cannot require covered entities to sign agreements or make assurances as a condition of receiving 340B discounts. Specifically, manufacturers cannot demand assurances about: eligibility status, authorized use of drugs, confidentiality of pricing, audit access, or submission of acquisition and inventory data. Manufacturers may only request whether an entity participates in 340B (which the entity must answer truthfully). This prohibition protects covered entities from being coerced into onerous compliance commitments as a price for accessing statutory discounts. **By allowing manufacturers to approve and process rebate claims, the rebate model effectively shifts claim eligibility determination from HRSA, where statutory authority resides, to manufacturers.** Although HRSA maintains that manufacturers cannot unilaterally deny 340B access, the rebate model structure effectively empowers them to do so. By allowing manufacturers to receive, verify, and approve claims, the model creates opportunities for selective denials, delayed processing, and refusals to pay claims manufacturers deem 'ineligible.' These manufacturer-developed eligibility criteria operate without HRSA oversight or covered entity appeal rights, shifting gatekeeping authority away from the statutory administrator. This fundamentally undermines HRSA's enforcement authority under the 340B Administrative Dispute Resolution (ADR) process. Manufacturers should be required to submit claims for rebate processing to HRSA-designated administrators, with HRSA—not manufacturers—determining eligibility and making denial decisions.

HRSA has already made clear that drug companies have other available options to address the need to deduplicate 340B and MDPNP pricing. Given the tremendous costs that a rebate mechanism will impose on BMCHS, HRSA should rely on those other options. Any other decision would impermissibly privilege the interests of drug companies over those of covered entities, their patients, and the communities they serve.

Drug manufacturers, understandably, have consistently expressed discontent with a program requiring them to sell their products at a discount. But that discontent is the basis and reason for the law. Consequently, manufacturers have demonstrated consistent hostility toward program components they cannot control, particularly contract pharmacy arrangements, and sought ways to limit the use of the components to which they object. Giving manufacturers the authority and

flexibility to establish parameters around which claims warrant a rebate is the broad, exploitable opening that manufacturers have long sought to curtail use of this hugely successful program. One consequence of the proposed rebate model is that it would provide the perfect mechanism for manufacturers to eliminate contract pharmacies by simply denying rebates for these arrangements.

Multiple ongoing court cases demonstrate manufacturers' determination to limit the use of the 340B Program, often through the unauthorized and illegal imposition of rebate models, despite administrative denial of those requests. We fear that granting this authority to manufacturers will encourage new avenues of manufacturer-imposed hurdles forcing covered entities to spend countless time and dollars chasing discounts or rebates that were inappropriately denied.

The 340B Rebate Model grants pharmaceutical manufacturers unprecedented authority over a federal program specifically designed to limit their pricing power. Section 340B of the Public Health Service Act's plain text creates a drug discount program, not the framework for a rebate program. Not only does HRSA's proposal to significantly alter the fundamental premise of the program fly in the face of the statutory text, but potentially violates the Constitutional principle of non-delegation, making manufacturers the arbiters of claim eligibility and inverting the program's fundamental structure and purpose.

4) **There is federal 340B legislation under consideration by Congress that would provide meaningful reforms and further enhance HRSA's regulatory authority to oversee the program in the future.**

As Congress actively considers comprehensive legislation to strengthen program integrity, clarify eligibility standards, enhance HRSA oversight, and establish a durable statutory framework for the 340B program, **OMB and HRSA should defer implementation of a nationwide rebate model until these legislative efforts have been fully evaluated.** Advancing significant regulatory changes while Congress is considering comprehensive reforms risks creating conflicting requirements, increasing administrative burden, and undermining the long-term regulatory certainty that providers, manufacturers, and patients need. Durable, bipartisan legislative solutions remain the most appropriate path to preserving the integrity and sustainability of the 340B program while ensuring continued access to high-quality, affordable care.

Likewise, we support the common position that there are viable, lawful, and less burdensome alternatives that could achieve the same potential benefits as a rebate mechanism. In particular, we urge HRSA to adopt a third-party clearinghouse not funded by manufacturers, rather than a rebate mechanism, to advance 340B/MDPNP deduplication, program integrity, and any other potential benefits**.** At a minimum, HRSA must provide a reasoned explanation for why the third-party clearinghouse is neither viable nor less costly than a rebate mechanism.

For all of these reasons, BMCHS respectfully submits that the costs of any Rebate Program will outweigh any expected benefits. HRSA therefore should preserve the current 340B model and adopt existing and viable proposals to address program concerns. Our organization urges policymakers and program stakeholders to prioritize the establishment of an independent third-party

clearinghouse model as a fundamental prerequisite for meaningful 340B program improvement. While a rebate-based model is positioned as a mechanism to improve program integrity, in practice it would provide limited incremental benefit over existing 340B safeguards in addressing duplicate discounts, diversion, or pricing transparency. On the contrary, the Rebate Model likely increases risks, administrative burden, and cash-flow issues for covered entities, shifting benefit to manufacturers over covered entities.

BMCHS is deeply concerned that the proposed 340B Rebate Model Pilot Program is operationally infeasible, statutorily misaligned, and threatens the core mission of the 340B program. The burden estimate is unsupported, the infrastructure requirements are substantial and permanent, and the shift of claim adjudication authority to manufacturers contradicts the statutory delegation of that authority to HRSA.

We support legislation that strengthens, stabilizes, and preserves the 340B Drug Pricing Program for eligible hospitals and federally qualified health centers serving our nation's most vulnerable patients. At BMC Health System, 340B savings are reinvested directly into services that expand access to care, improve health outcomes, and strengthen the healthcare safety net for underserved communities. We recognize that sustaining the 340B program—including addressing concerns related to the proposed rebate model—requires balancing the needs of patients, providers, manufacturers, and taxpayers.

We appreciate your consideration of these comments and look forward to working with HRSA on this important issue, which has profound implications for the millions of patients who rely on the 340B Program. Please contact me if you have questions.

Sincerely, DocuSigned by: Bhavesh Shah 8FDB74AD126247E...

Bhavesh Shah R.Ph, BCOP

VP of Pharmacy

Boston Medical Center Health System

Bhavesh.shah@bmc.org

CC: Authorized Official: Alastair Bell MD and

Primary contact: Noreen Palinkas

Public Comments for IFR 202606-0906-001

Author Full Name : Bhavesh Shah **Received Date :** 07/15/2026 05:17 PM

Comments Received :

Thank you for the opportunity to provide comments on 340B Rebate Model Pilot Program Application, Implementation, and Evaluation

Holton Community Hospital

HOLTON COMMUNITY HOSPITAL

July 8, 2026

The Honorable Thomas J. Engels
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane Rockville, MD 20852

Re: Information Collection Request: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-NEW.

Dear Administrator Engels:

On behalf of the Holton Community Hospital, 340B ID CAH171319-00, a340B participating hospital, I appreciate the opportunity to comment on the Department of Health and Human Services' (HHS) Information Collection Request: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-NEW.

Question 1: Does the entity already collect all data elements required under a rebate model?
No. Holton Community Hospital does not hold the data a rebate model demands. Nothing in our systems connects an individual dispensed claim back to the specific wholesaler invoice and purchase date it drew from, and the patient-level detail these proposals contemplate is information a covered entity should not be transmitting to drug manufacturers at all.
The burden estimate also rests on a claim that defeats itself. Manufacturers assert that entities already possess this information, and use that assertion to call the lift minimal. If the data already existed and already flowed, manufacturers could verify eligibility through the channels built for exactly that purpose and no submission model would be necessary. Either the data is already available to them, in which case this model is redundant, or it is not, in which case creating it from scratch every cycle is real work performed by real staff. Both cannot be true, and that work appears nowhere in the estimate.

Question 2: Does the entity submit this on the same timeline to Medicare, Medicaid, and commercial payers?
No, because nothing like this submission exists anywhere in the payer world. Claims to Medicare, Medicaid, and commercial plans adjudicate electronically at the point of sale through the pharmacy switch. A rebate model replaces that with retrospective file assembly, transmission through a third-party platform, and a waiting period during which we hope the data matched, the platform functioned, and the manufacturer agrees it owes us anything. Our experience with the data platforms already operating in this space is that files reject, claims sit unmatched, and the cleanup falls to hospital staff. The estimate assumes the automation works every time. No system in this program has earned that assumption.

Question 3: Additional information rebutting HRSA's burden estimate.
HRSA puts the burden at five hours. That figure is unrecognizable to anyone operating this program at a critical access hospital, and it ignores what 340B's mounting complexity has already cost this community. Manufacturer restrictions have already forced this hospital into a choice no community should have to make. When designations were limited, we used ours to protect the independent pharmacy that serves the largest share of our patients, because if 340B does not help keep that pharmacy's doors open, our town

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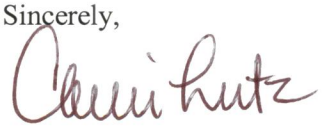
loses it. That decision meant giving up the opportunity to designate the chain pharmacy, the biggest pharmacy in town, and the savings and access that went with it.
The savings that survive those restrictions no longer stretch far enough. We have already had to significantly reduce our cash card program, a benefit that put affordable medications directly into patients' hands, because the cumulative changes to this program eroded the savings that funded it.
And the complexity keeps compounding. To participate in 340B at all, a hospital our size pays for a third-party administrator, split-billing software, outside consultants, audit preparation, and staff hours devoted to manufacturer data platforms. Every one of those costs exists because the program keeps getting harder to run, and every one is paid out of the savings the program is supposed to produce. Our margin from 340B has been eroded to the point where continued viability is a live question.

A rebate model would be one more layer on a structure already buckling. It converts an upfront discount into money we front and hope to recover. We would purchase at full price, assemble and submit data, and then reconcile results without a line-by-line accounting of which claims were paid. Verifying payment claim by claim, chasing rejections, and resubmitting failures is recurring weekly work, not a one-time task, and every unmatched claim is cash this hospital has already spent and may never see again.

Manufacturers have spent years narrowing this program, and now the rebate model would stack one more obligation on the entities least equipped to carry it. HRSA's estimate does not just undercount the hours. It fails to account for the real possibility that this final layer ends 340B participation for hospitals like ours, and for the patients and pharmacies that depend on it.

I appreciate your time and consideration into my comments offered, and am available to be reached if you have further questions.

Sincerely,



Carrie Lutz, CEO
Holton Community Hospital
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Public Comments for ICR 202606-0906-001

Author Full Name : Carrie Lutz **Received Date :** 07/10/2026 10:19 AM

Comments Received :

On behalf of the Holton Community Hospital, 340B ID CAH171319-00, a340B participating hospital, I appreciate the opportunity to comment on the Department of Health and Human Services' (HHS) Information Collection Request: 340B Rebate Model Pilot Program Application, OMB No. 0906-NEW.

Question 1: Does the entity already collect all data elements required under a rebate model?

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The burden estimate also rests on a claim that defeats itself. Manufacturers assert that entities already possess this information, and use that assertion to call the lift minimal. If the data already existed and already flowed, manufacturers could verify eligibility through the channels built for exactly that purpose and no submission model would be necessary. Either the data is already available to them, in which case this model is redundant, or it is not, in which case creating it from scratch every cycle is real work performed by real staff. Both cannot be true, and that work appears nowhere in the estimate.

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Question 3: Additional information rebutting HRSA's burden estimate.

HRSA puts the burden at five hours. That figure is unrecognizable to anyone operating this program at a critical access hospital, and it ignores what 340B's mounting complexity has already cost this community.

Manufacturer restrictions have already forced this hospital into a choice no community should have to make. When designations were limited, we used ours to protect the independent pharmacy that serves the largest share of our patients, because if 340B does not help keep that pharmacy's doors open, our town loses it. That decision meant giving up the opportunity to designate the chain pharmacy, the biggest pharmacy in town, and the savings and access that went with it.

The savings that survive those restrictions no longer stretch far enough. We have already had to significantly reduce our cash card program, a benefit that put affordable medications directly into patients' hands, because the cumulative changes to this program eroded the savings that funded it.

Please find an enclosed full response.

Carrie Lutz, CEO Holton Community Hospital

Kansas Hospital Association

Kansas Hospital ASSOCIATION

July 8, 2026

The Honorable Thomas J. Engels
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane Rockville, MD 20852

Re: Information Collection Request: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-NEW.

Dear Administrator Engels:

On behalf of the Kansas Hospital Association (KHA) and our ninety-three KHA member 340B participating hospitals, we appreciate the opportunity to comment on the Department of Health and Human Services' (HHS) Information Collection Request: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-NEW.

This information collection request (ICR) refers to HRSA's estimated burden of 5 hours per week for covered entities to comply with data submission requirements of a 340B rebate model. HRSA's estimate **grossly underestimates** the time and level of effort hospitals will be required to expend to support a rebate model.

HRSA maintains in its ICR that "These standardized data elements are commonly available and already generated, maintained and transmitted by covered entities or their vendors." KHA member 340B hospitals have provided detailed information that demonstrates HRSA misunderstands how and where this data resides and the onerous burden a 340B rebate model would require. Covered entities' existing processes and systems were designed around the current upfront discount model. A rebate model would require additional tracking and reporting capabilities, including claim-level data collection, manufacturer-specific utilization tracking, reconciliation of rebate amounts, identification of unpaid or disputed rebates, and retention of supporting documentation for audit purposes. These functions are not currently part of the normal 340B workflow and would require significant modifications and expenditures to existing systems and processes.

Further, HRSA states in its ICR that "The data submitted to covered entities to manufacturers is comparable to data already being collected and maintained by covered entities through existing third-party relationships." However, HRSA does not consider in its current estimates and position that dispensing data, wholesaler invoices and order dates, and claims adjudication data all reside in disparate systems. HRSA's estimate and description of the administrative aspect of a 340B rebate model for covered entities does not take into account the hours of work required daily to assemble data from separate systems and stitch those into a record that does not exist today.

Additionally, there would be significant systems and infrastructure impacts caused by a 340B rebate program. Kansas 340B hospitals' current technological systems and operational infrastructure to support 340B is based on an upfront discount model. Any shift to a rebate mechanism forces hospitals to incur significant costs to change those systems. Such changes include new or modified IT systems, software, and data infrastructure that would be required to implement a potential 340B Rebate Model Pilot Program.

In its ICR, HRSA also states that "other commenters asserted that the cost estimates by covered entities are overstated or unsupported and noted that many of the required data elements are already collected

and maintained by covered entities as part of routine billing, compliance, and audit processes, and that existing systems and third-part administrators may be leveraged to support data submission and reporting. In their view, the data sharing requirements contemplated with rebates are materially similar to existing obligations imposed by Medicare, Medicaid, and commercial payers."

Although claims are submitted to various payers for adjudication, covered entities are not currently transmitting or reconciling manufacturer-specific prescription data in the manner contemplated under a rebate model. Existing claims processes are intended to secure payment for services and prescriptions, not to support an additional layer of manufacturer rebate administration. The proposed rebate model creates entirely new reporting and reconciliation requirements that vary from current billing processes.

KHA member 340B hospitals emphasize that ordinary payer claims clear through a pharmacy switch in real time at point of sale. A rebate model does not operate in real time, rather requires covered entities to stitch data together from the disparate sources listed above. Covered entities also point out that third party vendor automation does not always work, and point to 340B ESP glitches, TPA glitches, and concerns regarding Beacon. When the process flow is interrupted, the manual clean up and reconciliation that falls to covered entity staff is also not accounted for in HRSA's underestimate. The data sharing requirements contemplated in a rebate model are not materially similar to existing obligations imposed by Medicare, Medicaid, and commercial payers as HRSA asserts in their ICR.

HRSA's underestimate of 5 hours weekly also does not take into account the reconciliation process that covered entities perform. Our member covered entities state that reconciliation alone takes longer than 5 hours weekly. Beacon does not return a line-by-line accounting of which claims paid, so covered entities must verify payment by manually reviewing each claim individually for every cycle. Just the reconciliation time far exceeds 5 hours per week.

Many covered entities report that contract pharmacies on the same MTF/ESP infrastructure report that it takes 10 – 20 hours per week of staff time to complete data submission, troubleshooting, and reconciliation. Supporting the rebate model for covered entity staff is estimated to be far greater than HRSA's five hours per week. Many member hospitals have reported to KHA that they are hiring partial to full time staff just to respond to manufacturer data requests and anticipate that they would have to hire additional staff to support a rebate model.

As KHA has shared with HHS and HRSA previously, any rebate mechanism will impose enormous costs and burdens on hospitals, especially critical access hospitals, that far outweigh any benefits that might come from it. The administrative burden to implement a rebate model will consume a sizable portion of 340B savings, further reducing 340B supported patient care access.

HRSA's previously expressed desire to test a rebate model appears to be based on the incorrect premise that it must balance the interests of 340B hospitals and drug companies when choosing a discount mechanism. We reiterate the American Hospital Association's prior point that HRSA must give primacy to the needs of patients and covered entities that serve them so that the covered entities can "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Preserving the upfront discount mechanism, which Kansas 340B hospitals have relied on for decades, is the most efficient way to fulfill the intended purpose of the 340B program.

The additional funds needed to cover the increased administrative costs of a rebate model will significantly reduce 340B funding available to serve patients, especially in rural communities, where the vast majority of hospitals and pharmacies are already struggling financially. Hospitals' current 340B administration program hiring, operations, and processes support an upfront discount model. A shift to a

Kansas Hospital ASSOCIATION

rebate model demands added resources, imposing considerable additional costs and burdens on hospitals that go far beyond what is budgeted and planned for as a 340B hospital.

Besides additional staffing and administrative costs, other key cost drivers to hospitals include paying list price for medications with no guarantee that the 340B price will be honored by manufacturers; additional IT expenditures and support, third-party vendors, compliance activities, and denials and delays on rebate payment by pharmaceutical manufacturers.

Most of our critical access hospitals operate on a negative margin and are in financially challenging positions. Conversion to a rebate model which forces struggling hospitals to pay list price for medications will mean that many hospitals will not be able to make these payments and will further reduce 340B covered services to their patients. Some hospitals have expressed concern that they may not be able to increase their line of credit with their wholesaler/distributer in order to purchase 340B medications at list price.

Today, the 340B discounted price is available to covered entities at time of purchase. A rebate model requires that covered entities pay full list price and places all financial risk on the backs of safety net hospitals, essentially making hospitals the unsecured creditors of drug manufacturers for every 340B claim.

HRSA also mentions deduplication in its ICR, however the agency has already made clear that drug companies have other available options to address the need to deduplicate 340B and MDPNP pricing. Given the tremendous costs that a rebate mechanism will impose on 340B hospitals, HRSA should rely on those other options. Any other decision would impermissibly privilege the interests of drug companies over those of covered entities, their patients, and the communities they serve.

KHA supports the American Hospital Association's position that there are viable, lawful, and less burdensome alternatives that could achieve the same potential benefits as a rebate mechanism. We again urge HRSA to adopt a third-party clearinghouse, rather than a rebate mechanism, to advance 340B/MDPNP deduplication, program integrity, and any other potential benefits. At a minimum, HRSA must provide a reasoned explanation for why the third-party clearinghouse is neither viable nor less costly than a rebate mechanism.

Importantly, unlike the existing upfront discount mechanism, any rebate mechanism will not only force our member 340B hospitals to hire or reallocate staff, increase expenditures and administrative tasks and systems, it also forces hospitals to effectively provides drug companies interest-free loans as they await the discounts that they are owed under the 340B statute. Even if drug companies paid within a 10-day period as required under the prior iteration of the Rebate Program, that delayed discount to our hospitals is financially untenable and will result in reduced services for their patients.

In Kansas, hospital operating margins in 2024 averaged -7 percent. While the national average for hospital days cash on hand is 218 days, in Kansas, that number is 62 days. Sixty rural Kansas hospitals are at risk of closing. They cannot afford to give drug companies interest-free loans. A rebate model could result in more rural hospital closures, further reducing access to care in rural areas.

We have assumed that any future Rebate Program will include the ten drugs that HRSA previously approved for its original Program and those that have been approved under the Medicare Drug Price Negotiation Program (MDPNP) for 2027, per HRSA's February 25, 2026, Information Collection Request. With the addition of the 2027 drugs, our members' cost estimates have increased significantly over the estimates calculated for the 2026 drugs alone. As the rebate model grows, there will be less 340B savings for hospitals to dedicate to patient care and comprehensive health care services.

Kansas Hospital ASSOCIATION

For all of these reasons, the Kansas Hospital Association respectfully submits that the 5 hour weekly administrative burden is a gross underestimate by HRSA and that the costs of *any* Rebate Program will outweigh any expected benefits. HRSA therefore should abandon the concept altogether and embrace a neutral, third-party clearinghouse.

If, however, HRSA chooses to move forward with this ill-conceived effort, we continue to implore HRSA to allow participating 340B hospitals and other covered entities to comment on the specifics of its new program. While we have endeavored to address the issues in HRSA's latest ICR and have encouraged our member 340B hospitals to provide the most detailed information possible, our comments are without having precise knowledge of many critical details (*e.g.*, data required, possible grounds for denial of rebates, dispute resolution processes, other guardrails). A failure to permit additional comments on the specific features of the program will be, in effect, a wholesale failure to consider important aspects of the problem that will ultimately reduce or eliminate patients' access to care.

We appreciate your consideration of these comments and look forward to working with HRSA on this critical issue, which has profound implications for Kansas patients, especially in rural communities, who rely on the 340B Program for access to critical health care. Please contact us if you have questions.

Sincerely,

Karen Braman, RPh, MS
Senior Vice President, Clinical and Strategic Initiatives

Mohawk Valley Health System

Mohawk Valley Health System
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July 13, 2026

VIA ELECTRONIC SUBMISSION TO
https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202606-0906-001

Ms. Samantha Miller
Health Resources and Services Administration
Information Collection Clearance Officer
5600 Fishers Lane, Room 13N82
Rockville, MD 20857

RE: Public Comment Response to HRSA's Request for Information Collection under OMB Number 0906-NEW

Dear Ms. Miller:

On behalf of Mohawk Valley Health System ("MVHS, INC."), we respectfully submit this comment regarding the proposed collection of information described in *340B Rebate Model Pilot Program Application, Implementation, and Evaluation under OMB Number 0906-NEW* ("Proposed ICR").[1] We appreciate the opportunity to provide feedback during the 30-day comment period.

As a 340B Covered Entity, MVHS, INC. is particularly interested in ensuring that any future rebate model can be administered in a manner that is operationally feasible, appropriately tailored, and does not create unnecessary administrative burden for providers serving vulnerable patient populations. Considering that Covered Entities will ultimately be responsible for collecting, validating, submitting, and reconciling the information contemplated by the Proposed ICR, it is important that HRSA's burden estimates and reporting assumptions accurately reflect the realities of day-to-day program administration. The comments below reflect our concerns regarding (i) the lack of specificity surrounding required data elements, (ii) the continuing inconsistencies regarding future reporting obligations, and (iii) the significant administrative and technological burdens that may be imposed upon Covered Entities.

HRSA's Data Submission Requirements Are Not Only Ambiguous, They Are Contradictory.

One of the most significant challenges the Proposed ICR presents is that MVHS, INC. still does not know what information will ultimately be required under a future rebate model. Not only is HRSA's ambiguity contrary to the intent of the Paperwork Reduction Act, but from an operational perspective, it is difficult for MVHS, INC. to evaluate staffing needs, technology requirements, vendor support needs, or reporting burden when the specific data elements have not yet been identified.

[1] *340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-NEW,* 91 Fed. Reg. 35989 (Jun. 26, 2026).

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Notably, the Proposed ICR does not contain definitions that describe the specific data elements that MVHS, INC. would be required to submit, nor does it identify any standardized format or scope for such submissions. This lack of clarity is particularly problematic because HRSA has stated in the Proposed ICR that it has not approved nor reviewed any manufacturer rebate model proposals, and therefore cannot articulate what information would actually be required under a future rebate model.[2] The only confirmation Covered Entities have received from HRSA is that it will publish manufacturer plans in the Federal Register. Further, the Proposed ICR does not offer any general description of the type of data MVHS, INC. will be required to submit. Once again, the Proposed ICR states that the type and frequency of such submissions will be published in the Federal Register notice and that the data will be "comparable to data currently maintained through third-party vendors or previously provided to manufacturers under unrelated pharmacy or claims programs."[3] This expectation is entirely speculative and ambiguous.

This ambiguity is particularly concerning because it creates a fundamental inconsistency regarding the information MVHS, INC. may eventually be required to submit. HRSA repeatedly suggests that the necessary data elements are already generated and maintained by Covered Entities or their vendors, yet simultaneously acknowledges that it has not identified the specific data elements that will be required and that those requirements will be defined in a future Federal Register notice. If the required data elements are already standardized and commonly maintained, HRSA should be able to identify them now. Conversely, if HRSA cannot identify the data elements until after manufacturer proposals are received and evaluated, then there is no basis for concluding that such information is readily available or can be produced with minimal burden. This contradiction makes it difficult for MVHS, INC. to understand what we are being asked to prepare for and further underscores the lack of clarity surrounding the Proposed ICR.

HRSA's ambiguity and contradictory language is not entirely new. In the February 2026 ICR, Covered Entities raised similar objections regarding the inconsistencies between HRSA's claim that it would publish the standard data elements and that Covered Entities already maintained those data elements.[4] Since HRSA did not materially answer to these concerns in February, MVHS, INC. (and Covered Entities in general) remains in the same position it occupied in prior comment periods: to evaluate an information collection request without knowing what information will ultimately be collected or how such information will be used. Due to the above-mentioned ambiguities and inconsistencies, the Proposed ICR does not resolve the central uncertainty that has characterized each previous iteration of HRSA's rebate model information collection and instead perpetuates it.

[2] *See* 91 Fed. Reg. at 35990.
[3] *Id.*
[4] *See 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-NEW,* 91 Fed. Reg. 9632, 9633.

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This uncertainty is particularly challenging because health systems cannot build compliance processes overnight. New reporting requirements often require coordination among MVHS, INC.'s own internal pharmacy department and its third party vendors. Without knowing what information will ultimately be collected, MVHS, INC. cannot meaningfully assess the resources necessary to comply nor comment on the Proposed ICR.

The Proposed ICR Is More Burdensome Than Necessary.

HRSA has not offered an accurate estimate of the average burden upon Covered Entities, nor has it demonstrated that it has selected the least burdensome means of collecting covered entities' information – because it cannot, for the reasons noted above. HRSA states that it employs a task-based methodology to estimate respondent burden and that its calculation accounts for "(1) identifying and extracting eligible claims data, (2) formatting and validating data to meet manufacturer specifications; (3) submitting the data; (4) reconciling submissions and tracking rebate status; and (5) addressing errors, denials, or follow-up requests."[5] Despite acknowledging the breadth of these operational functions, HRSA concludes that Covered Entities will only require approximately five hours per week to satisfy these obligations.[6]

That estimate is not—and again cannot be given the current lack of information—accompanied by sufficient explanation to permit meaningful public review. HRSA does not identify the assumptions that underlie its calculations, including the volume of expected claims transactions, the anticipated frequency of data submissions, the number of reconciliation events, the extent of staff involvement necessary to resolve disputes or denials, the processes for such disputes, or the costs associated with implementing and maintaining systems capable of complying with manufacturer reporting requirements.

To better inform HRSA and OMB of the actual burden associated with these activities, MVHS, INC. should be permitted to describe our operational experience. Accordingly, MVHS, INC. estimates that compliance with claims data reporting and rebate administration requirements currently requires approximately, at a minimum, 15 hours per week. This estimate is based on our experience working through the similar process of submitting for MFP rebates for the current list of affected products. We anticipate this time commitment to increase by an additional five hours per week as more products are affected and the product list more than doubles in 2027. With the addition of even more products in 2028, there will be again be increased time requirements that are difficult to approximate at this point, but a reasonable assumption might be that we will have to dedicate additional employees to manage all aspects of the rebate programs.

We now have six months of experience working with Beacon and the MTF and have experienced significant setbacks and struggles. We have endured several cases of denial of rebates for eligible Medicare claims, and our concern is that if a similar process to submit for 340B rebates goes into effect we will lose the ability to ultimately obtain the 340B price for eligible claims even after pursuing a good

[5] 91 Fed. Reg. at 35990.
[6] *Id.*

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faith inquiry with Beacon, the MTF, and manufacturers directly. These denials have resulted in financial losses for our organization that we have been unable to resolve going back to the inception of this program in January 2026. We can only anticipate this to continue and, in fact, become more burdensome after the additional requirements needed to submit for 340B rebates and follow affected claims through the entire process.

Additionally, we are hoping HRSA can provide more guidance on the most appropriate ways for Covered Entities to resolve any self-audit findings that result in the need to update claim status retroactively. For instance, if a claim is not initially assigned 340B status but later determined to meet all eligibility requirements, but the manufacturer ultimately declines to issue a 340B rebate. Although Beacon has repeatedly insisted that their platform is capable of carrying out the requirements of both MFP and 340B rebates, this has not consistently been our experience, at least for MFP rebates. This is highly concerning with the anticipated increase in reliance on Beacon if 340B rebates go into effect. Unfortunately, Beacon seems to be limited to simply reporting which claims manufacturers deem eligible for rebates even in cases where the Covered Entity has determined that they are owed a rebate.

The Proposed Rebate Model May Lead to Overcharges.

On a separate note, should MVHS, INC. be required to submit claims-data under a future rebate model, it may trigger overcharges under the 340B statute. Through manufacturer all-claims policies, Covered Entities are increasingly being required to provide extensive claims-level data as a condition of accessing 340B drugs. Under these arrangements, Covered Entities are required to submit more data than is necessary for platforms such as 340B ESP to match Covered Entities' claims with manufacturer's rebate data.[7] For example, CMS's Part D repository will only require Covered Entities to submit: (i) 340B ID, (ii) Date of Service, (iii) Prescription Number, (iv) Fill number, (v) NDC-11, (vi) Dispensing Pharmacy NPI, and (vii) Claim Record Indicator. If CMS has determined that it only needs these seven data elements to remove 340B claims from its Part D inflation rebate requests, it would be highly irregular for its sister agency to require Covered Entities to disclose more or different data to a private, for-profit data aggregator.

Any such requirement would raise immediate concerns under the 340B statute's prohibition against overcharges. While manufacturers may characterize these data-submission obligations as administrative requirements rather than part of the purchase price, the practical effect would be that MVHS, INC. could not obtain the full value of the 340B discount without providing valuable claims data and absorbing the significant costs associated with maintaining and submitting that information. MVHS, INC. also will not receive compensation for either the data itself or the resources required to support these activities. As a result, a future rebate model may effectively require MVHS, INC. to provide additional consideration beyond payment of the of the 340B ceiling price in order to access the 340B discount, which would result in an overcharge.

[7] Bradley Malin, Expert's Assessment of Second Sight 340B ESP™ De-Identification Procedures for Medical Benefits Claims Data, 19 (2026).

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Conclusion

MVHS, INC. appreciates HRSA's efforts to gather stakeholder feedback regarding reporting requirements for a future Rebate Model Pilot Program. As an organization committed to serving patients and maintaining compliance with the 340B Program, we support efforts to develop processes that are defined, operationally feasible, and tailored to the realities Covered Entities face.
At this time, however, we believe that additional information is needed regarding the data elements that may be required, the operational structure of the of future rebate models, and the assumptions underlying HRSA's burden estimates. We respectfully encourage HRSA to revise the Proposed ICR and provide stakeholders with additional detail before seeking final approval from OMB.

Respectfully submitted,



Louis Aiello
Sr. Vice President/Chief Financial Officer

MultiCare Health System

MultiCare Health System
820 A Street, Tacoma, WA 98402
PO Box 5299, Tacoma, WA 98415-0299 ~ multicare.org

July 14, 2026

The Honorable Thomas J. Engels
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane Rockville, MD 20852

Re: Information Collection Request – 340B Rebate Model Pilot Program Application, Implementation, and Evaluation (OMB No. 0906-NEW)

Dear Administrator Engels:

On behalf of MultiCare Health System, we appreciate the opportunity to comment on the information collection request regarding the revised 340B rebate model pilot program from the Office of Management and Budget (OMB).

MultiCare is a nonprofit health system serving patients across the Pacific Northwest. MultiCare includes nine 340B-covered entities in Washington state and processed over 5.1 million 340B-eligible claims in 2025. We maintain a mature, system-level 340B compliance infrastructure designed to meet the audit expectations from the Health Resources and Services Administration (HRSA) under the longstanding upfront discount model.

If HRSA must move forward with a rebate-based 340B purchasing model, we urge the agency to revise its burden analysis as it significantly understates the actual effort required to operationalize and administer such a model. The proposed estimate of five hours of burden per week considers only the act of transmitting information and fails to account for the substantial operational infrastructure necessary to generate, validate, reconcile, dispute, monitor and audit the underlying data. Each of these activities requires significant staff time, specialized expertise, technology investments and ongoing oversight.

Our comments below focus on the requirements necessary for rebate implementation and administration as well as recommended revisions to HRSA's burden analysis.

Program design and implementation

HRSA's five-hour burden estimate appears to assume that covered entities can leverage existing systems and processes with minimal modification, and that rebate administration functions are largely automated. Based on MultiCare's direct experience administering manufacturer rebate programs, neither assumption is accurate.

Prior to submitting a single claim, covered entities would need to:

- Design new operational workflows
- Develop policies and procedures
- Configure 340B software systems
- Establish or substantially modify data feeds between pharmacy, billing, wholesaler and manufacturer platforms
- Develop auditing and monitoring procedures
- Train pharmacy, revenue cycle, compliance, finance, information technology, and operational staff

These implementation activities would require hundreds of hours of one-time effort and are not reflected anywhere in HRSA's burden estimate.

Ongoing data collection and validation

Unlike the traditional upfront discount model, rebate administration requires continuous aggregation and validation of information from multiple independent systems.

Covered entities must collect and reconcile data from:

- Electronic health records
- Pharmacy management systems
- Split-billing software
- Wholesaler purchasing data
- Claims processing systems
- Manufacturer rebate platforms
- Contract pharmacy reports

Each data source uses different formats, timing conventions and identifiers. Significant manual intervention is frequently necessary to resolve discrepancies before data can be submitted. No existing infrastructure or vendor platform currently integrates these disparate data sources in a manner that meaningfully reduces the manual effort required. HRSA’s five-hour estimate does not appear to include the time necessary to validate data accuracy before submission or to investigate variances identified after submission.

Rebate adjudication monitoring and dispute resolution

HRSA's estimate also fails to account for the substantial effort associated with monitoring rebate determinations and correcting errors.

Our experience demonstrates that rebate platforms routinely generate claim classifications that require manual review. When a claim is improperly designated as ineligible, covered entities must:

- Research the claim using multiple systems and data sources
- Collect supporting documentation
- Prepare and submit inquiries
- Communicate with manufacturers or administrators
- Track dispute status
- Review responses
- Resubmit information when necessary

These activities occur continuously and require dedicated personnel. The effort associated with dispute resolution often exceeds the time required for the initial data submission.

MultiCare's experience with the Medicare rebate program demonstrates that researching a disputed claim, collecting supporting documentation, tracking status, reviewing responses, and documenting the outcome requires an average of 40 minutes per claim. Because this work is performed almost entirely through manual processes, it requires substantial staff resources and ongoing administrative oversight. Expansion of rebate administration across additional programs would further increase this administrative burden.

Financial reconciliation

A rebate model transforms what is currently a straightforward purchasing transaction into an ongoing accounts receivable function. This means covered entities must:

- Track expected rebate payments
- Match payments to submitted claims
- Resolve partial payments and denials
- Investigate underpayments
- Reconcile manufacturer remittances
- Monitor aging balances
- Support internal and external audits

These financial activities do not exist under the traditional upfront discount model and represent entirely new administrative burdens. MultiCare's experience with Beacon MFP (drug manufacturers' technology platform for managing rebates) and the Medicare rebate program over the past six months demonstrates that financial reconciliation processes require substantial development, testing, and refinement. Significant gaps remain and are already affecting cash flow and hospital financial operations.

Compliance monitoring and audit readiness

Beyond its financial impacts, HRSA's estimate appears to overlook the compliance burden created by the rebate model.

Covered entities remain subject to all existing 340B program requirements, including:

- Diversion prevention
- Duplicate discount prevention
- Internal auditing
- Independent audits
- HRSA audit preparation

Rebate administration does not replace any existing compliance obligations. Instead, it creates an additional layer of documentation, monitoring, reconciliation and audit support activities that must be maintained simultaneously.

As a result, rebate-related work is additive rather than substitutive. MultiCare's experience with the initial 10 Medicare rebate drugs demonstrates that this incremental workload required the addition of a dedicated full-time employee to support rebate administration activities.

Information technology and vendor management

The burden estimate also excludes the substantial information technology efforts necessary to maintain rebate operations. Covered entities will be required to:

- Build and maintain new data interfaces
- Modify existing software configurations
- Test system changes
- Monitor data integrity
- Manage third-party vendors
- Respond to manufacturer platform updates
- Address system outages and transmission failures

These activities require ongoing support from information technology personnel and external vendors. Based on MultiCare's experience, the level of technology and vendor support required to administer a rebate pilot program would exceed existing internal capacity.

Successful implementation would require onboarding at least one additional software vendor and expanding services provided by third-party administrators. These requirements would result in significant implementation and ongoing maintenance costs for hospitals.

Recommended revisions to the burden estimate

MultiCare's experience administering rebate programs indicates that the actual burden substantially exceeds HRSA's estimate. For the Medicare rebate program involving only ten drugs, MultiCare currently devotes approximately 18 hours per week to:

- Data collection and preparation
- Submission activities
- Claim validation
- Rebate platform review
- Identification of 340B claims
- Good-faith inquiry management
- Financial reconciliation

This effort already exceeds HRSA's estimated burden by more than threefold, despite being limited to a relatively small number of products. Based on our experience, expanding rebate administration to approximately 25 drugs across multiple payers would require:

- Three additional full-time employees dedicated to rebate administration
- Significant technology investments
- Enhanced auditing and compliance resources
- Ongoing financial reconciliation and dispute management activities

For large health systems processing millions of annual 340B transactions, **the administrative burden is measured in thousands of labor hours annually** rather than the 260 hours per year implied by HRSA's estimate of five hours per week.

IF HRSA proceeds with a rebate-based approach, we urge the agency to revise its burden analysis to include:

- Initial implementation and system configuration activities
- Data extraction, validation and submission activities
- Rebate adjudication review and dispute resolution
- Financial reconciliation and accounts receivable management
- Compliance monitoring and audit support
- Information technology support and vendor management
- Ongoing staff training and policy maintenance

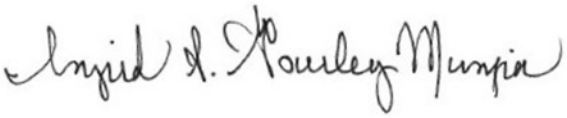
Without inclusion of these operational functions, the burden estimate substantially understates the true administrative impact of the rebate model and does not provide OMB with a reasonable basis for evaluating covered entity burden under the Paperwork Reduction Act.

The current five-hour estimate appears to measure only the act of submitting data. However, covered entities do not incur burden simply by transmitting information; they incur burden by creating a compliant operational infrastructure capable of producing, validating, defending, reconciling and auditing that information.

MultiCare's experience demonstrates that when these functions are not fully developed and integrated, financial harm can occur through delayed payments, unresolved underpayments, disputed claims, and cash flow disruption. Without the personnel, technology, vendor support, reconciliation processes, and audit controls necessary to manage these activities, covered entities face a substantial risk of unrecovered 340B savings and significant financial loss. Excluding these functions from the burden estimate materially understates the true administrative and financial impact of the proposed rebate model.

Thank you for considering these comments. Please let us know if you would like additional information.

Sincerely,



Ingrid Gourley Mungia, JD
VP Public Policy and Advocacy

Public Comments for ICR-202606-0906-001

Author Full Name : Mary McManus **Received Date :** 07/14/2026 02:58 PM

Comments Received :

File Attached

Wayne Community Health Centers

HRSA's Task-Based Burden Estimate Significantly Underestimates the Operational Workload

HRSA estimates reporting burden by dividing the process into five discrete activities. Based on Wayne Community Health Centers' real-world experience administering the Medicare Maximum Fair Price (MFP) rebate program over the past six months, we believe each of these activities requires substantially more time than estimated. Our experience demonstrates that the majority of the burden occurs after the initial data submission through ongoing reconciliation, financial tracking, and dispute resolution.

The estimates below assume a monthly reporting cycle for our organization and are based on actual operational experience wherever possible.

Basis for Burden Estimates

The burden estimates presented throughout these comments are derived from Wayne Community Health Centers' operational experience administering rebates associated with manufacturers participating in the Medicare Drug Price Negotiation Program Agreements with the Centers for Medicare & Medicaid Services (CMS) for Initial Price Applicability Years (IPAY) 2026 and 2027. These estimates reflect actual staff time spent identifying eligible claims, preparing submissions, reconciling rebate payments, resolving discrepancies, communicating with manufacturers and third-party administrators, and completing associated compliance activities during the first six months of program implementation.

These estimates should **not** be interpreted to mean that the same level of effort would be required if a similar rebate model were expanded to all manufacturers participating in the 340B Program. The current Medicare Drug Price Negotiation Program involves a limited number of participating manufacturers and negotiated drugs. Expanding a rebate-based reporting model across the broader 340B Program would substantially increase the number of manufacturers, reporting relationships, submission requirements, payment streams, reconciliation activities, dispute resolution processes, and audit responsibilities.

Accordingly, the burden estimates presented in these comments should be viewed as a **baseline minimum estimate** derived from administering a rebate process involving a limited subset of manufacturers. If a comparable rebate model were implemented across the entire 340B Program, the associated administrative burden, staffing requirements, operational

complexity, and compliance costs would reasonably be expected to increase proportionally—and potentially disproportionately—as covered entities would be required to navigate numerous manufacturer-specific reporting requirements, timelines, and reconciliation processes simultaneously.

Existing Data Does Not Eliminate the Administrative Burden

HRSA notes that some commenters believe the burden estimates are overstated because many of the required data elements are already collected and maintained by covered entities during routine pharmacy operations. While individual data elements such as prescription claims, patient information, National Drug Codes (NDCs), prescriber information, and billing records are generally maintained within pharmacy management systems, the existence of these data elements does not mean they are readily available in the format or relationships necessary to support a manufacturer rebate model.

The existence of data should not be confused with the effort required to prepare that data for submission. An appropriate analogy is the federal income tax process. Most taxpayers already possess the information needed to file their tax return—including W-2s, 1099s, bank statements, and receipts—yet preparing an accurate tax return still requires significant time to gather records, organize information, validate accuracy, reconcile discrepancies, and complete the required submission. The burden lies not in creating the information, but in collecting, organizing, validating, and presenting it in the manner required by the receiving entity. The same principle applies to a 340B rebate reporting model.

The primary administrative burden is not collecting the underlying data—it is integrating, validating, reconciling, and maintaining that data across multiple independent systems and reporting requirements. Current pharmacy management systems were designed to adjudicate prescription claims and maintain patient records, not to establish permanent relationships between individual dispensations, wholesaler purchase invoices, manufacturer rebate eligibility, payment status, dispute resolution, and audit documentation. If future rebate reporting requires invoice-level traceability or manufacturer-specific validation requirements, as contemplated by recently proposed legislation such as the SECURE 340B Act, significant system modifications or

manual processes will be required regardless of whether the underlying data already exist.

Similarly, while third-party administrators may assist with portions of the reporting process, they do not eliminate the covered entity's responsibility for ensuring the accuracy of submitted data, maintaining supporting documentation, responding to manufacturer inquiries, resolving disputed claims, reconciling payments, and demonstrating compliance during audits. These activities remain the responsibility of the covered entity and require dedicated staff time regardless of the level of automation available.

We also disagree with the assertion that manufacturer rebate reporting is materially similar to existing Medicare, Medicaid, or commercial payer billing requirements. Traditional pharmacy claims are adjudicated electronically in real time using standardized transaction formats with immediate payment determinations. By contrast, a rebate model creates an entirely separate administrative workflow after the claim has already been adjudicated and the medication dispensed. Covered entities must then prepare and submit data, monitor submission status, reconcile payments, investigate discrepancies, communicate with manufacturers and third-party administrators, and resolve denials. Our experience administering the Medicare Maximum Fair Price rebate process over the past six months has demonstrated that these post-adjudication activities represent the overwhelming majority of the administrative burden and cannot reasonably be characterized as routine billing functions.

Accordingly, while covered entities may already possess many of the underlying data elements, the operational burden associated with collecting, organizing, validating, submitting, reconciling, and defending those data for a rebate model represents a substantial new administrative responsibility that is not reflected in routine pharmacy operations today.

Time Estimations Based on Experience

(1) Identifying and Extracting Eligible Claims Data

The time required to identify and extract eligible claims is highly dependent upon the data elements required by HRSA and manufacturers.

For example, if covered entities must associate individual dispensed prescriptions with specific wholesaler invoices—as contemplated in recently proposed legislation such as the SECURE 340B Act—the burden increases

dramatically. Pharmacy management systems do not currently maintain this relationship in a readily reportable format.

If pharmacy management systems are modified to automate invoice-to-dispensation matching, we estimate this process would still require approximately **0.65 additional minutes per eligible prescription** to ensure invoice data is accurately captured and maintained throughout the dispensing workflow.

If this process must instead be completed manually, staff would spend an average of **2.85 minutes per eligible prescription** identifying and documenting the required purchase information.

Based on our current dispensing volume of manufacture products currently in the Medicare Drug Price Negotiation Program Agreements with the Centers for Medicare & Medicaid Services, this activity alone would require approximately **3 to 12 hours per monthly reporting cycle**, depending on the level of automation available.

(2) Formatting and Validating Data to Meet Manufacturer Specifications

If invoice matching and data extraction must be performed manually, the formatting and validation activities are largely incorporated into the time estimates above because staff must simultaneously validate data while creating the reporting dataset.

If automated reporting is available, additional staff time will still be required to:

- develop and maintain reporting queries;
- validate extracted data;
- perform quality assurance;
- verify manufacturer-specific formatting requirements; and
- ensure report accuracy prior to submission.

This burden will increase substantially if manufacturers continue to require different reporting formats, data elements, or submission standards.

(3) Submitting the Data

Submission burden depends almost entirely upon the number of reporting platforms required.

If covered entities must submit data through multiple manufacturer or third-party portals (for example, Truzo, Beacon, 340B ESP, the Medicare 340B Repository, and additional manufacturer-specific systems), each submission requires:

- preparing upload files;
- logging into separate platforms;
- completing submission workflows;
- confirming successful transmission;
- documenting submission confirmation; and
- maintaining records to prevent duplicate reporting during future submission cycles.

Assuming consistent formatting across platforms, we estimate approximately **15.34 minutes per reporting platform per submission**, resulting in approximately **one hour of administrative time per monthly response**.

(4) Reconciling Submissions and Tracking Rebate Status

This has proven to be the single most resource-intensive component of the current Medicare Maximum Fair Price rebate program.

Unlike traditional claims processing, rebate payments require continuous monitoring to determine whether claims have been accepted, rejected, partially paid, delayed, or remain pending. Staff must routinely compare submitted claims against manufacturer responses, identify discrepancies, research payment variances, and reconcile outstanding balances.

Through these reconciliation efforts, Wayne Community Health Centers has identified **thousands of dollars in improperly processed rebate claims** that otherwise would have gone unnoticed.

Based on six months of operational experience, reconciliation activities require approximately **3.8 minutes per eligible prescription**, equating to approximately **5 hours per monthly reporting cycle**.

(5) Addressing Errors, Denials, and Follow-Up Requests

HRSA significantly underestimates the burden associated with correcting rebate determinations.

When rebate claims are denied or questioned, staff must:

- research individual transactions;
- compile supporting documentation;
- retrieve dispensing and purchasing records;
- communicate with manufacturers and their vendors;
- communicate with CMS when necessary;
- submit Good Faith Inquiries and other formal dispute documentation;
- monitor responses; and
- repeat these activities until claims are resolved.

Our experience under the Medicare Maximum Fair Price rebate program indicates that approximately **10 percent of claims require additional follow-up**, consistent with current operational error rates.

For affected claims, these activities average approximately **26.69 minutes per prescription**, resulting in approximately **4 hours of additional administrative time per monthly reporting cycle**.

Total Estimated Monthly Reporting Burden

Based on our operational experience with the Medicare Maximum Fair Price rebate program, Wayne Community Health Centers estimates that a single monthly reporting cycle would require approximately:

Activity	**Estimated Hours**
Identify & Extract Claims	3-12
Format & Validate Data	Included above (manual) / additional with automation
Submit Data	~1
Reconcile & Track Rebates	5
Resolve Errors & Denials	4
Total Estimated Burden	**13-23 hours per response**

These estimates are based on actual operational experience administering the Medicare Maximum Fair Price rebate program over the past six months and closely align with our previously submitted estimate that implementation of a rebate model would require an additional **0.5-0.75 full-time equivalent employee per pharmacy** solely to administer rebate reporting, reconciliation, and compliance activities. The majority of this burden arises not from the initial submission of data, but from the ongoing financial reconciliation and dispute-resolution processes that continue long after a reporting file has been transmitted.

National Jewish Health

The Honorable Thomas J. Engels
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20852

Re: Request for Information: 340B Rebate Model Pilot Program, HHS Docket No. HRSA-2026-03042

Dear Administrator Engels:

On behalf of National Jewish Health (NJH) in Denver, Colorado, we appreciate the opportunity to comment on the Department of Health and Human Services' Request for Information regarding the proposed 340B Rebate Model Pilot Program.

National Jewish Health is a small specialty hospital focused on the treatment of respiratory, cardiovascular, rheumatologic, autoimmune, and immunologic diseases. We serve patients from across the country, many of whom have complex, chronic conditions. Our care is primarily delivered in the outpatient setting, with the goal of preventing hospitalizations whenever possible. We treat all patients regardless of payer mix and operate on extremely thin margins, without the benefit of significant cash reserves. Many of our programs rely on uncompensated support from nurses, social workers, and care managers—services that are rarely reimbursed in outpatient care.

The 340B program is critical to sustaining these services. The proposed shift from an upfront discount model to a rebate model would fundamentally undermine our ability to operate and care for patients.

We have based our analysis on direct experience with existing rebate processes, including those associated with the Medicare Drug Price Negotiation Program. Based on this experience, we can state clearly: the rebate model does not function effectively today at small scale and would be unworkable if expanded across the 340B program. This proposal would not merely add complexity—it would overwhelm pharmacy operations, divert clinical resources, and materially impair patient care.

The current rebate infrastructure is fragmented, manual, and inefficient. Staff must navigate multiple disconnected systems (e.g., MTF, Beacon, ESP) to track a single claim. Even within today's limited rebate environment, we routinely encounter conflicting claim data that must be manually corrected. While providers like NJH maintain complete patient insurance information and have implemented safeguards to prevent duplicate discounts, manufacturers lack reliable mechanisms to accurately identify 340B claims.

As a result, every claim must be manually reviewed to ensure proper classification. Errors are common in both directions—manufacturers issue rebates on ineligible claims and fail to issue rebates on eligible ones. NJH is then required to identify and reverse incorrect payments. While manufacturers can quickly recoup funds, providers are forced into lengthy Good Faith Inquiry (GFI) processes that often take two to three months or longer and may not result in resolution.

In a sample of 36 prescriptions, 6 were incorrectly rebated despite being 340B-eligible, while other eligible claims remained misclassified and unresolved. This is not a system that can be optimized; it is a system that does not function reliably.

Rebate timelines further compound these issues. Rebates are never issued within 10 days; claims are not even eligible for evaluation for at least that long, and resolution frequently takes months. Disputes are frequent, repetitive, and often reset or disappear without explanation. In our small sample, staff spent more than 20 hours resolving issues, approximately one hour for every two prescriptions.

Scaling this across our operations illustrates the magnitude of the burden. NJH processed more than 6,750 prescriptions for the 25 drugs identified for the program through 2027. With refills, this equates to approximately 22,000 transactions annually requiring rebate adjudication (excluding Medicaid and unaffiliated pharmacies). At current efficiency levels, this would require approximately 11,000 staff hours annually—equivalent to five full-time employees. Even assuming substantial process improvements, we estimate a minimum of three full-time staff dedicated solely to rebate management.

These are not administrative roles; they require pharmacists and other healthcare professionals, diverting them from direct patient care to perform manual, repetitive reconciliation work. In addition, at least one full-time accounting resource would be required to reconcile invoices, payments, and rebate activity.

National Jewish Health operates on margins below 2 percent. The incremental staffing and system costs associated with a rebate model are estimated at no less than $824,045 annually, excluding financing costs related to delayed cash flow. In many years, this would eliminate our entire operating margin. These costs cannot be absorbed without negatively impacting patient care.

NJH takes its compliance responsibilities seriously and has implemented rigorous safeguards to prevent duplicate discounts, including:

- Use of Submission Clarification Codes (420-DK and 423-DN) to identify 340B claims with Colorado Medicaid

- Third-party administrator validation of every prescription prior to 340B accumulation
- A closed-door pharmacy model, limiting dispensing to NJH patients and employees
- Monthly audits of all 340B activity, with immediate investigation and correction of discrepancies

The proposed rebate model disregards these safeguards and replaces them with an error-prone, externally driven process.

In addition, the rebate model would significantly strain cash flow. NJH would be required to purchase drugs at full price while waiting months for reimbursement. At the same time, we already experience payment delays from payers ranging from 45 to 180 days and provide care to patients whose coverage does not meet the cost of care. Pharmaceutical distributor invoices must often be paid within 15 days to avoid penalties.

Even under a limited implementation involving only 25 drugs, we would likely need to draw on lines of credit to cover routine expenses. For providers operating on thin margins in an already inefficient system, absorbing additional cash flow delays is not feasible. Shifting financial burden from manufacturers and insurers—entities with significantly greater margins and liquidity—to safety-net providers is inequitable and unsustainable.

For these reasons, we strongly urge HRSA to reject a rebate-based approach and maintain the current upfront discount structure, which has provided stability and predictability for more than 30 years.

If changes are deemed necessary, we recommend an alternative approach in which providers continue to purchase drugs at discounted prices but reconcile and remit payments for ineligible claims within a defined timeframe (e.g., 10 days). While not without challenges, this approach would better align cash flow and reduce operational risk without jeopardizing the financial viability of providers like NJH.

Thank you for your consideration of our comments.

Sincerely,

Christine Forkner

Executive Vice President of Corporate Affairs & Chief Financial Officer

National Jewish Health

Minneola Healthcare

July 10, 2026

The Honorable Thomas J. Engels
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane Rockville, MD 20852

Re: Information Collection Request: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-NEW.

Dear Administrator Engels:

On behalf of Minneola Healthcare and the communities we serve, I appreciate the opportunity to comment on the Department of Health and Human Services' (HHS) Information Collection Request: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-NEW.

This information collection request (ICR) refers to HRSA's estimated burden of 5 hours per week for covered entities to comply with data submission requirements of a 340B rebate model. HRSA's estimate **grossly underestimates** the time and level of effort hospitals will be required to expend to support a rebate model.

HRSA maintains in its ICR that "These standardized data elements are commonly available and already generated, maintained and transmitted by covered entities or their vendors." MHC does not currently collect the data elements a rebate model would require. The proposal contemplates patient-level and claim-level detail we do not hold, including patient data no covered entity should be handling for this purpose, and the link tying a dispensed claim back to its specific wholesaler invoice and order date. There is a contradiction in the manufacturer's burden estimate. It is claimed entities already have all this information and use that claim to argue the lift is minimal. If that were true, there would be no need for a rebate model at all, and they could simply pull the information they need from existing infrastructure like 340B ESP or the proposed CMS repository. It is our position that they cannot have it both ways: telling HRSA the data already exists while building a model premised on entities submitting data they do not maintain. Assembling the data is precisely the burden the estimate ignores.

MHCs and all covered entities' existing processes and systems were designed around the current upfront discount model. A rebate model would require additional tracking and reporting capabilities, including claim-level data collection, manufacturer-specific utilization tracking, reconciliation of rebate amounts, identification of unpaid or disputed rebates, and retention of supporting documentation for audit purposes. These functions are not currently part of the normal 340B workflow and would require significant modifications and expenditures to existing systems and processes.

Further, HRSA states in its ICR that "The data submitted to covered entities to manufacturers is comparable to data already being collected and maintained by covered entities through existing third-party relationships." However, HRSA does not consider in its current estimates and position that dispensing data, wholesaler invoices and order dates, and claims adjudication data all reside in disparate systems. HRSA's estimate and description of the administrative aspect of a 340B rebate model for covered entities does not take into account the hours of work required daily to assemble data from separate systems and stitch those into a record that does not exist today.

Minneola Healthcare
PO Box 127
Minneola, Kansas 67865
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Additionally, there would be significant systems and infrastructure impacts caused by a 340B rebate program. Kansas 340B hospitals' current technological systems and operational infrastructure to support 340B is based on an upfront discount model. Any shift to a rebate mechanism forces hospitals to incur significant costs to change those systems. Such changes include new or modified IT systems, software, and data infrastructure that would be required to implement a potential 340B Rebate Model Pilot Program.

MHC emphasizes that ordinary payer claims clear through a pharmacy switch in real time at point of sale. A rebate model does not operate in real time, rather requires covered entities to stitch data together from the disparate sources listed above. It is also important to note that third party vendor automation does not always work as we have learned from experience through 340B ESP glitches, TPA glitches, and concerns regarding Beacon. When the process flow is interrupted, the manual clean up and reconciliation that falls to covered entity staff is also not accounted for in HRSA's underestimate. The data sharing requirements contemplated in a rebate model are not materially similar to existing obligations imposed by Medicare, Medicaid, and commercial payers as HRSA asserts in their ICR.

HRSA's underestimate of 5 hours weekly also does not consider the reconciliation process that MHC, as well as all other covered entities, will be required to perform. Reconciliation alone takes longer than 5 hours weekly. Beacon does not return a line-by-line accounting of which claims paid, so covered entities must verify payment by manually reviewing each claim individually for every cycle. Just the reconciliation time far exceeds 5 hours per week.

MHC, along with many covered entities, report that contract pharmacies on the same MTF/ESP infrastructure report that it takes 10 – 20 hours per week of staff time to complete data submission, troubleshooting, and reconciliation. Supporting the rebate model for covered entity staff is estimated to be far greater than HRSA's five hours per week. MHC has had to increase its Pharmacy hours, as well as hire a consulting company, just to respond to manufacturer data requests and anticipate that we will have to increase human resource expenses to manage the additional burden.

As a critical access hospital, any rebate mechanism is expected to significantly increase costs and burdens to the point that the additional administrative work will consume a sizable portion of the 340B savings, further reducing 340B supported patient care services.

HRSA's previously expressed desire to test a rebate model appears to be based on the incorrect premise that it must balance the interests of 340B hospitals and drug companies when choosing a discount mechanism. We reiterate the American Hospital Association's prior point that HRSA must give primacy to the needs of patients and covered entities that serve them so that the covered entities can "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Preserving the upfront discount mechanism, which Kansas 340B hospitals have relied on for decades, is the most efficient way to fulfill the intended purpose of the 340B program.

The additional funds needed to cover the increased administrative costs of a rebate model will significantly reduce 340B funding available to serve patients, especially in rural communities, where the vast majority of hospitals and pharmacies are already struggling financially. Hospitals' current 340B administration program hiring, operations, and processes support an upfront discount model. A shift to a rebate model demands added resources, imposing considerable additional costs and burdens on hospitals that go far beyond what is budgeted and planned for as a 340B hospital.

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Besides additional staffing and administrative costs, other key cost drivers to hospitals include paying list price for medications with no guarantee that the 340B price will be honored by manufacturers; additional IT expenditures and support, third-party vendors, compliance activities, and denials and delays on rebate payment by pharmaceutical manufacturers.

Today, the 340B discounted price is available to covered entities at time of purchase. A rebate model requires that covered entities pay full list price and places all financial risk on the backs of safety net hospitals, essentially making hospitals the unsecured creditors of drug manufacturers for every 340B claim.

HRSA also mentions deduplication in its ICR, however the agency has already made clear that drug companies have other available options to address the need to deduplicate 340B and MDPNP pricing. Given the tremendous costs that a rebate mechanism will impose on 340B hospitals, HRSA should rely on those other options. Any other decision would impermissibly privilege the interests of drug companies over those of covered entities, their patients, and the communities they serve.

MHC supports the American Hospital Association's position that there are viable, lawful, and less burdensome alternatives that could achieve the same potential benefits as a rebate mechanism. We again urge HRSA to adopt a third-party clearinghouse, rather than a rebate mechanism, to advance 340B/MDPNP deduplication, program integrity, and any other potential benefits. At a minimum, HRSA must provide a reasoned explanation for why the third-party clearinghouse is neither viable nor less costly than a rebate mechanism.

Importantly, unlike the existing upfront discount mechanism, any rebate mechanism will not only force 340B hospitals to hire or reallocate staff, increase expenditures and administrative tasks and systems, it also forces hospitals to effectively provide drug companies interest-free loans as they await the discounts that they are owed under the 340B statute. Even if drug companies paid within a 10-day period as required under the prior iteration of the Rebate Program, that delayed discount to hospitals is financially untenable and will result in reduced services for their patients.

In Kansas, hospital operating margins in 2024 averaged -7 percent. While the national average for hospital days cash on hand is 218 days, in Kansas, that number is 62 days. Sixty rural Kansas hospitals are at risk of closing. We cannot afford to give drug companies interest-free loans. A rebate model could result in more rural hospital closures, further reducing access to care in rural areas.

We have assumed that any future Rebate Program will include the ten drugs that HRSA previously approved for its original Program and those that have been approved under the Medicare Drug Price Negotiation Program (MDPNP) for 2027, per HRSA's February 25, 2026, Information Collection Request. With the addition of the 2027 drugs, hospital's cost estimates have increased significantly over the estimates calculated for the 2026 drugs alone. As the rebate model grows, there will be less 340B savings for hospitals to dedicate to patient care and comprehensive health care services.

For all these reasons, Minneola Healthcare respectfully submits that the 5 hour weekly administrative burden is a gross underestimate by HRSA and that the costs of *any* Rebate Program will outweigh any expected benefits. HRSA therefore should abandon the concept altogether and embrace a neutral, third-party clearinghouse.

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If, however, HRSA chooses to move forward with this effort, I continue to implore HRSA to allow participating 340B hospitals and other covered entities to comment on the specifics of its new program. While hospitals have endeavored to address the issues in HRSA's latest ICR with the Kansas Hospital Association encouraging its member 340B hospitals to provide the most detailed information possible, these comments are without having precise knowledge of many critical details (*e.g.*, data required, possible grounds for denial of rebates, dispute resolution processes, other guardrails). A failure to permit additional comments on the specific features of the program will be, in effect, a wholesale failure to consider important aspects of the problem that will ultimately reduce or eliminate patients' access to care.

I appreciate your consideration of these comments and look forward to working with HRSA on this critical issue, which has profound implications for Kansas patients, especially in rural communities, who rely on the 340B Program for access to critical health care. Please contact me if you have questions.

Sincerely,

Deborah A. Bruner
Chief Executive Officer

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Public Comments for IGR202606-0906-001

Author Full Name : Debbie Bruner **Received Date :** 07/13/2026 03:33 PM

Comments Received :

Please see attached for MHC.

American Society of Health-System Pharmacists

pharmacists advancing healthcare®

July 15, 2026

The Honorable Thomas J. Engels
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20852

Re: 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-NEW

Dear Administrator Engels:

On behalf of our over 65,000 pharmacist, pharmacy technician, and pharmacy student members practicing in all settings across the United States, the American Society of Health-System Pharmacists (ASHP) appreciates the opportunity to comment on the Health Resources and Services Administration's (HRSA) information collection request (ICR) regarding the agency's burden estimate for the 340B Rebate Model Pilot Program (the "pilot program" or "model").

ASHP continues to oppose the imposition of any rebate model in the 340B Drug Pricing Program. Payment under the 340B program has always been prospective.[1] Shifting to a rebate model, even for a small number of drugs, creates serious risks to a high-functioning program and the patient services that it supports. We believe that manufacturers are using the implementation of the Inflation Reduction Act (IRA) negotiated drug pricing framework as an improper justification for seeking rebates in the 340B program. Structuring both the 340B program and the IRA negotiated pricing programs as prospective discounts would make them more efficient, more consistent with congressional intent, and less prone to manufacture abuse.

I. HRSA's Burden Estimate Fails to Account for Data Extraction and Reconciliation and Denial Management Processes

HRSA's burden estimate of 5 hours per week per claim vastly underestimates the administrative burden associated with a rebate model. In the ICR notice, HRSA recognizes that the rebate program will create burden, but focuses largely on the estimates associated with the initial claims data submission, ignoring both data extraction and reconciliation management. As evidenced by the IRA reconciliation process, the

[1] *See* 58 Fed. Reg. 27289, 27291 (May 7, 1993); *see also* 63 Fed. Reg. 35239 (June 29, 1998)(allowing a sole exception to the prospective discount for AIDs programs that are structured differently than other covered entities).

initial submission is merely a fraction of a time required to manage the process, with the bulk of the burden coming from managing the reconciliation process and claims denials.

As noted in our previous comments on the proposed 340B rebate model pilot program, the rollout of the IRA negotiated drug pricing framework illustrates the high costs – both in terms of financial and administrative resources – of retrospective rebates. Under the IRA framework, hospitals and health systems are seeing delayed rebate and claims payments, forcing them to float purchasing and administrative costs. Our members are reporting that they are currently waiting on, collectively, millions of dollars in rebates for just the first few months of IRA. These unpaid rebate claims are in addition the costs of purchasing the drugs at a higher price (Wholesale Acquisition Cost [WAC] versus 340B discounts). Further, because claims issues are reported to both the Centers for Medicare and Medicaid Services (CMS) and manufacturers, organizations have reconfigured workflows and added personnel (i.e., full-time equivalent [FTE]) to cover management of the rebates.

Imposing a second reconciliation process via the proposed rebate model is certain to further increase the administrative burden. As previously noted in our comments, members have reported numerous problems with the IRA maximum fair price (MFP) rebates, including mismatched data fields, requests for invoice pricing for all purchases (not just 340B inventory), and a lack of responsiveness from both CMS and certain manufacturers regarding these issues. There are also ongoing concerns regarding data integrity and security, which require review and oversight by information technology specialists, further adding to administrative burden and labor demand associated with the program. Allowing manufacturers to expand these problems into the 340B environment via a rebate pilot program is both unnecessary and fiscally irresponsible, especially considering the existence of a much simpler, cost-effective option — the third-party clearinghouse.

Even with aggressive automation of data extraction and submission, HRSA's burden estimate is low. Reconciliation and claims denial management add hours of weekly burden per covered entity. Members have reported that addressing these issues through Beacon is hugely time-consuming, with AI-generated responses that necessitate human intervention (and additional FTEs) to resolve issues. The time associated with these activities matches or exceeds HRSA's entire burden estimate.

To accurately estimate the administrative burden associated with the rebate pilot, HRSA must consider the administrative burden associated with each step of the process: data extraction, data submission, and reconciliation and claims denial management. Given that the current estimate appears to focus solely on data submission, the agency must revisit its estimate and revise it upward to account for *all* administrative burden associated with the proposed pilot program.

II. HRSA Should Scrap the Pilot Program in Favor of a Cost-Effective, Patient-Focused Solution

Although we appreciate HRSA's efforts to collect detailed feedback on a rebate model, HRSA must consider alternatives. From its inception, the 340B program has operated as an upfront discount. Covered entities have relied on that program design for almost 40 years, setting up care models and community outreach programs around it that have greatly expanded patient access to care services. Although the previously proposed rebate model pilot was explicitly not premised on addressing

duplicate discounts, they are a chief manufacturer complaint and almost certainly underpin the manufacturer push for a refund model. However, covered entities do not have a program integrity problem — ample safeguards already exist to address duplicate discounts, including HRSA and manufacturer audits.

If HRSA determines that these mechanisms are inadequate, a claims clearinghouse run by an independent third party could help mitigate manufacturer concerns about duplicate discounts while preserving prospective discounts. Under this arrangement, 340B covered entities would continue to receive the upfront 340B price, with any necessary reconciliation done post-payment, thereby ensuring that manufacturers bear the costs as intended by Congress. This option would also obviate the need for manufacturer-imposed claims data requirements (e.g., the recent Eli Lilly and Novo Nordisk policies that attempt to unilaterally impose extra-statutory program requirements).

As the IRA rollout demonstrates, when pharmaceutical manufacturers are given too much control over the design and implementation of a program, they will choose to delay payment obligations through a drawn-out rebate scheme— leaving health care providers and their patients to suffer. We urge HRSA to examine the unsuccessful rollout of the IRA rebate process and rethink the imposition of a rebate model for the 340B program. Both IRA Medicare discounts and 340B would be administratively simpler and less prone to manufacturer abuse if implemented as prospective discounts.

We appreciate the opportunity to offer our feedback on the ICR. ASHP continues to urge HRSA to abandon the pilot program in favor of other practical, less damaging options. HRSA's burden estimates substantially understate the true administrative, operational, technological, and financial burden that implementation would impose on covered entities, calling into question whether the agency has fully assessed the scope and impact of the model. No pilot program should be proposed until HRSA has time to adequately address stakeholder feedback and fully gauge the potential damage to covered entities and their patients from such a precipitous and catastrophic policy shift.

We look forward to working with HRSA to identify practical policy solutions that protect the 340B program and the patients it serves. Please do not hesitate to contact me at 301-664-8698 or jschulte@ashp.org if ASHP can provide any further information or assist the agency in any way.

Sincerely,



Jillanne Schulte Wall, J.D.
Senior Director, Health & Regulatory Policy

Henry Ford Health

July 9, 2026

The Honorable Russell Vought
Administrator
The Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Submitted electronically to https://RegInfo.gov

Re: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation (OMB No. 0906-NEW)

Dear Administrator Vought:

On behalf of Henry Ford Health, we appreciate the opportunity to provide comments in response to the Health Resources and Services Administration's (HRSA) proposed Information Collection Request (ICR) related to the 340B Rebate Model Pilot Program.

Henry Ford Health is a large, Michigan-based, non-profit corporation and integrated healthcare delivery system headquartered in Detroit. We have been committed to improving the health and wellbeing of the community for over 110 years. Henry Ford Health offers healthcare services across the continuum through a diverse network of facilities in the greater Detroit, Flint, and Jackson regions. The system has approximately 50,000 valued employees, more than 550 care delivery locations, and 13 acute care hospitals—including our flagship Henry Ford Hospital, a large academic safety net hospital located within the city of Detroit.

Several of our hospitals qualify for 340B as disproportionate share hospitals or rural referral centers. This includes Henry Ford Hospital, our main hospital, which operates in Detroit. There are no public hospitals in Detroit, so the few private hospitals in the region are responsible for providing charity care and other forms of uncompensated care in the community. All of our qualifying hospitals meet the high disproportionate share adjustment percentage required to qualify for 340B, meaning they provide healthcare services to a large proportion of low-income and financially vulnerable patients.

For Henry Ford Health, the 340B program is immensely valuable. It is an essential part of the delicate balance of benefits and expenses that allows our health system to provide uncompensated care—including charity care and care for patients with Medicare and Medicaid where reimbursement does not fully cover the costs—and other community benefits. Collectively, **for Henry Ford Health, we provided $1.1 billion in uncompensated care in 2025**. While 340B savings offset only a portion of our total uncompensated care costs, without these savings, Henry Ford Health would not be able to provide the breadth of charity care, other uncompensated care, and community benefit services that we currently provide.

We are concerned that the proposed ICR understates the administrative, operational, financial, and technological burden that participating covered entities would incur under the proposed rebate model. HRSA estimates that covered entities will require five hours per weekly reporting response to identify, format, and submit data to drug manufacturers as well as conduct claim reconciliation

and follow-up activities. Based on Henry Ford Health's operational scale and current Maximum Fair Price (MFP) rebate experience, we believe the actual burden is 8 to 13 times higher than HRSA's estimate; and the administrative burden and related labor costs will grow as more drugs are added to the rebate model over time. Below is a detailed explanation of the time and resource requirements for each activity that HRSA identified in the ICR for covered entities.

Identifying and extracting eligible claims data

Henry Ford Health's experience with MFP rebates shows that claim identification and extraction is labor-intensive, continuous, and requires dedicated staff. This step alone requires multiple full-time equivalents (FTE) and require 10–15 hours per week at minimum, exceeding HRSA's estimate for all reporting activities.

Henry Ford Health processes over eight million 340B-eligible transactions annually, across multiple hospitals, outpatient departments, retail pharmacies, and contract pharmacies. Identifying eligible claims under a rebate model requires:

- Extracting data from multiple systems including electronic health records, pharmacy dispensing systems, billing platforms, split-billing software, and third-party vendors
- Applying patient eligibility, prescriber eligibility, and encounter-level rules
- Cross-referencing state-specific billing rules and managed care encounter data to prevent Medicaid duplicate discounts
- Validating National Drug Code-level accuracy across mixed-use settings
- Reconciling data across six separate systems already used for MFP and 340B compliance

These activities require extensive manual review, complex systems integration, and coordination across multiple data sources and regulatory requirements. The identification and extraction of rebate-eligible claims is a highly resource-intensive process that demands significant staff time to ensure accurate reporting and program compliance.

Formatting and validating data to meet manufacturer specifications

HRSA's estimated burden association with data formatting and validation does not account for the complexity and variability of manufacturer-specific requirements. Formatting and validation would require 5–10 hours per week, depending on claim volume and manufacturer variability.

Under a rebate model, each manufacturer may require different file layouts, data fields, and validation rules. Henry Ford Health would need to maintain multiple data-mapping templates and update them as manufacturers change requirements. We would then validate data for completeness, accuracy, and internal consistency before submission. We have already contracted for a $600,000 annual rebate reconciliation tool, plus $880,000 in split-billing software updates, demonstrating the scale of work required.

Without a more uniform reporting process, or one conducted through a clearinghouse, the unique requirements of each manufacturer introduce instability and inefficiency to the reporting process. Those inefficiencies could also increase over time if additional drugs, and manufacturers, are integrated into a rebate model.

Submitting the data

Henry Ford Health's experience with MFP rebates shows that data submission is manual, repetitive, and error-prone, requiring continuous monitoring. This step would require 3–5 hours per week, depending on the number of participating manufacturers. Specifically, data submission under a rebate model requires:

- Navigating multiple manufacturer portals or a federal clearinghouse
- Ensuring secure transmission of protected health information and compliance with Business Associate Agreements
- Tracking submission deadlines across all participating manufacturers
- Maintaining documentation for audit readiness
- Coordinating with information technology (IT) and compliance teams to ensure successful transmission

Reconciling submissions and tracking rebate status

Based on our MFP experience, reconciliation in the context of a rebate model is extremely resource-intensive because Henry Ford Health would need to:

- Monitor manufacturer acknowledgments and payment confirmations
- Track each claim through approval, denial, or pending status
- Reconcile rebate payments against submitted claims at the claim level, not the invoice level
- Investigate discrepancies, underpayments, or missing rebates
- Integrate reconciliation data with the general ledger and purchasing systems
- Manage denial rates conducting appeals
    - Note: denial rates under MFP have been 10–15%

Henry Ford Health has already budgeted $120,000 annually for third-party reconciliation vendor expansion and three additional FTEs dedicated to rebate reconciliation and dispute management. This activity alone would require 10–20 hours per week, depending on denial volume and manufacturer responsiveness.

Addressing errors, denials, or follow-up requests

Following up with manufacturers regarding errors and denials is time-consuming and unpredictable. Addressing errors and denials would require 10–15 hours per week, depending on claim volume and manufacturer behavior. We know, based on our MFP experience, that manufacturers have been aggressive in denying claims. Specifically, manufacturers have denied MFP claims due to missing or inconsistent data, eligibility disputes, formatting errors, duplicate discount concerns, and manufacturer-imposed restrictions. Henry Ford Health's MFP experience has shown that:

- 10–15% of valid claims are denied, requiring extensive appeal
- Manufacturers often request additional documentation, which must be gathered from multiple systems

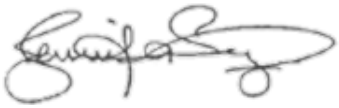
- Each denial requires coordination across pharmacy, finance, compliance, and IT
- Some manufacturers use third-party administrators with non-negotiable contract terms and operational issues, increasing administrative burden

Because each error or denial may require extensive research, manufacturer communication, and audit documentation, the time required to resolve exceptions is likely to far exceed HRSA's estimated burden and may become one of the most resource-intensive aspects of the rebate model.

Conclusions and recommendations

Henry Ford Health appreciates HRSA's consideration of stakeholder input regarding the proposed information collection. Given the significant operational complexity associated with claim-level reporting, rebate reconciliation, systems modifications, and compliance oversight, HRSA should revise its burden assumptions and provide additional transparency before seeking final OMB approval. We request that HRSA and OMB reconsider the proposed burden estimates and work with covered entities to develop a reporting framework that minimizes administrative burden.

Sincerely,



Jennifer Tryon
Chief Pharmacy Officer



Alexander Mansour
340B Compliance Officer
Director, Financial Services, Inventory, Audits & Contracts
Ambulatory Pharmacy Services

Southwest Mississippi Regional Medical Center

Southwest Mississippi Regional Medical Center
Southwest Health

April 27, 2026

HRSA Information Collection Clearance Officer
paperwork@hrsa.gov

Re: Information Collection Request – 340B Rebate Model Pilot Program (OMB No. 0906–NEW)

Dear Sir or Madam:

On behalf of Southwest Mississippi Regional Medical Center (SMRMC), I am submitting these comments in response to HRSA's Information Collection Request (ICR) associated with the proposed 340B Rebate Model Pilot Program. These comments supplement our previously submitted response to the Request for Information (RFI).

Our comments are focused specifically on the burden estimates and operational realities associated with the proposed data collection requirements, as required under the Paperwork Reduction Act.

1. HRSA's Estimated Burden is Materially Understated

HRSA estimates that covered entities would require approximately 5 hours per week to submit claims-level data.

Based on our direct operational experience with existing platforms (including ESP and Beacon-related workflows), **this estimate is not reflective of real-world conditions**.

At SMRMC, we estimate the following ongoing burden under a rebate model:

- Pharmacy (data validation, claim integrity, resubmissions): 10–15 hours/week
- Finance (rebate tracking, reconciliation, variance analysis): 8–12 hours/week
- IT/Reporting (data extraction, formatting, system interfacing): 6–10 hours/week
- Vendor coordination and dispute resolution: 5–8 hours/week

SMRMC Total Estimated Burden*: 29–45 hours per week (1.5–2.5 FTEs minimum)
*This estimate does not include initial build costs, system configuration, or implementation-phase workload, which would be substantial. Accordingly, SMRMC does not agree with HRSA's assertion that the proposed data collection burden is minimal or comparable to existing practices.

2. Data Required is Not "Readily Available" or Standardized

The ICR assumes that required data elements are comparable to data already maintained or submitted through existing processes.
This assumption is inaccurate.

At SMRMC:



- Required data elements reside across multiple non-integrated systems (EHR, pharmacy systems, billing, contract pharmacy platforms)
- These systems are subject to ongoing vendor-driven updates and changes in data structure, often without advance notice to the CE, requiring continuous revalidation and reconciliation of reporting outputs.
- Data must be manually extracted, normalized, and reformatted
- There is no standardized format across manufacturers or third-party platforms
- Significant manual intervention is required to ensure claim eligibility

We do not currently submit complete claims-level data sets to all manufacturers across all dispensing channels, and doing so would require new infrastructure, workflows, and staffing.

3. Ongoing Operational Burden Extends Far Beyond Initial Submission

The burden associated with the proposed model is not limited to initial data submission. It includes continuous, iterative processes:

- Manual claim review and eligibility validation
- Correction and resubmission of rejected claims
- Monitoring of platform errors and system logic discrepancies
- Coordination with multiple TPAs and manufacturers
- Tracking and managing 45-day submission windows
- Reconciliation of expected vs. received rebate payments
- Initiation and tracking of credit/rebill processes

Our experience demonstrates that even when claims are submitted correctly, system-level errors and opaque adjudication processes can delay or prevent reimbursement. To date, despite significant resource investment, SMRMC has not successfully resolved a single denied claim through existing rebate-related infrastructure.

4. Financial Burden and Cash Flow Impact

The rebate model introduces a material financial burden tied directly to the data collection process.

SMRMC projects:

- $1.25 million increase in upfront drug spend (2026)
- Up to $6 million annual exposure by 2028

In addition:

- Delays in rebate payment create cash flow strain
- Denied or disputed claims result in permanent financial loss
- Additional administrative burden requires new staffing and/or vendor contracts

Southwest Mississippi Regional Medical Center
Southwest Health

These financial risks are inseparable from the data submission requirements and must be considered part of the total burden under the PRA. These financial exposures are directly contingent upon successful data submission, validation, and adjudication, and therefore are inseparable from the information collection burden itself.

5. Response to PRA Evaluation Criteria

Under the Paperwork Reduction Act, agencies are required to ensure that information collection burdens are accurately estimated and minimized to the extent practicable.

- (1) Necessity and Utility
  The proposed data collection is duplicative of existing processes and does not justify the operational burden imposed.
- (2) Accuracy of Burden Estimate
  HRSA's estimate of 5 hours/week is significantly understated. Based on real-world experience, the burden is 6–9 times higher.
- (3) Quality and Clarity of Data Collection
  Current systems lack standardization, transparency, and reliability, limiting the utility of collected data.
- (4) Use of Automation
  Automation is not feasible given:
  - Fragmented data sources
  - Lack of standardized formats
  - Dependence on external vendor platforms

In conclusion, based on our operational experience, the data collection requirements associated with the proposed rebate model would impose a substantial and ongoing administrative burden that is not accurately reflected in the ICR.

We respectfully request that HRSA revise its burden estimates to reflect real-world conditions and reconsider the feasibility of the proposed data collection framework.

Thank you for the opportunity to provide these comments.

Sincerely,

Robert Weathersby, COO
Southwest Mississippi Regional Medical Center

National Association of Community Health Centers

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS®

July 15, 2026

Chantelle Britton
Director
Office of Pharmacy Affairs
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, Maryland 20857
Submitted electronically via www.reginfo.gov

RE: Agency Information Collection Activities: Proposed Collection: Public Comment Request (30-Day Notice); Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906-NEW (FR Doc. 2026-11989, 91 Fed. Reg. 35989, June 15, 2026)

Dear Director Britton:

For the past 55 years, the National Association of Community Health Centers (NACHC) has been the leading national, nonpartisan organization dedicated to supporting Community Health Centers (CHCs), also known as Federally Qualified Health Centers. As our nation's largest primary care system, CHCs save lives and money across 17,000 locations that serve as affordable, comprehensive, and effective primary care homes for 52 million patients. For more than 60 years, CHCs have provided high-quality, affordable, comprehensive care, including primary, preventive, dental, behavioral health, pharmacy, vision, and other essential health services at over 17,000 locations across rural and nonrural communities. This includes 1 in 3 rural Americans and 1 in 2 in poverty. As our nation's largest primary care system, there is strong evidence, including from the Congressional Budget Office, that our work saves lives and saves Medicaid and Medicare billions annually by reducing costly emergency, inpatient, and specialty care.[1] Research shows that every dollar invested in primary care yields a 13-to-1 return in overall health system savings.[2]

The 340B program is foundational to CHCs' ability to serve the most vulnerable members of our community. However, the proposed shift of responsibility from manufacturers to safety-net providers directly serving patients through a rebate model threatens to destabilize CHC pharmacy operations nationwide. Based on information from CHCs, the hours and dollars spent complying with a rebate program would be significant. Our focus in this letter is on the practical utility, accuracy of the burden estimate, and minimization of burden of the proposed collection, consistent with 44 U.S.C. 3506(c)(2)(A). NACHC appreciates the opportunity to comment on this Information Collection Request (ICR).

I. Summary of NACHC Recommendations

1. NACHC strongly urges HRSA to exempt CHCs from any 340B Rebate Model Pilot Program since the additional compliance burden would be overwhelming for safety-net providers operating on an average margin of negative two percent, with one quarter of CHCs operating below negative five percent.
2. NACHC urges HRSA to revise the covered-entity per-response burden estimate upward to reflect the full range of task-based activities. Our estimates from a sample of 24 CHCs (outlined below) indicate

[1] Volerman A, Carlson B, Wan W, Murugesan M, Asfour N, Bolton J, Chin MH, Sripipatana A, Nocon RS. Utilization, quality, and spending for pediatric Medicaid enrollees with primary care in health centers vs non-health centers. BMC Pediatr. 2024 Feb 8;24(1):100. doi: 10.1186/s12887-024-04547-y. PMID: 38331758; PMCID: PMC10851548. https://pubmed.ncbi.nlm.nih.gov/38331758/

[2] https://www.oregon.gov/oha/HPA/dsi-pcpch/Documents/PCPCH-Program-Implementation-Report-Final-Sept-2016.pdf

that a representative CHC would have a burden between 784 and 2,064 burden hours per year under the rebate model. That's an additional $103,000 to $272,000 additional cost per CHC per year, and between $150 million to $395 million additional cost per year for all CHCs, significantly higher than HRSA's initial estimate.

3. NACHC recommends HRSA requires a single uniform set of data fields, formats, and submission timelines across all manufacturers, and prohibits manufacturers from requesting additional data fields from covered entities, unless first approved by HRSA.
4. NACHC recommends that covered entities be permitted to submit data through a single neutral-party platform, ensuring consistent processes and eliminating duplicative system interactions.
5. NACHC requests that HRSA make all approved manufacturer plans and manufacturer-reported data publicly available in their entirety on OPA's website.
6. NACHC recommends HRSA's burden analysis account for covered entities already reporting duplicative data necessary in a 340B rebate pilot program to the existing CMS Medicare Part D 340B Data Repository.

II. HRSA Has Materially Underestimated the Burden on Community Health Centers to Submit Claims Data to Manufacturers

The ICR estimates an average of **5 hours per response** for covered entities reporting claims data to a third-party platform, applied across 15,249 covered entities, filing 52 responses each (792,948 total responses; 3,964,740 total burden hours, costing $523,345,680 annually).[3] HRSA's burden logic[4] assumes that each CHC will complete a 5 hour, data reporting cycle, weekly for the entire covered entity. The Office of Pharmacy Affairs Information System (OPAIS) reflects that there are 1,452 active CHCs and CHC Look-Alikes (CHC-LAs), with 13,805 active grantee sites, as of June 29th, 2026.[5] Utilizing HRSA's burden logic calculations, this equates to 377,520 burden hours at a cost of $49,832,640.

NACHC respectfully requests that HRSA address the inconsistencies in the methods used to estimate the burden of the proposed 340B rebate pilot on CHCs. HRSA has asked covered entities to comment on the "burden in the context of this information collection means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested." This comment request does not appear to include time spent reconciling submissions and tracking rebate status, and addressing errors, denials, or follow-up requests, which CHCs expect to be the most burdensome steps. Additionally, the methodology does not consider the burden of new financial tasks the rebate model would impose on CHCS, such as applying for new lines of credit or changing payment management with wholesalers.

Because each grantee site functions as a separate reporting unit, NACHC's calculated burden estimate for CHCs is from 15.09 to 39.7 hours per week, representing 0.4-1.0 additional FTE, or $103,552 to $272,518 annual cost. For all CHCs, the total burden cost would be $150,000,000 to $395,000,000. NACHC calculated these figures using HRSA's own task-based methodology and included ranges to account for different assumptions about the rate of errors, denials, or follow up requests.

The Task-Based Methodology HRSA Used Supports a Higher Estimate

The ICR states "HRSA applied a task-based methodology that considers the discrete activities required to complete a reporting cycle, including:

1. Identifying and extracting eligible claims data;

[3] 340B Rebate Model Pilot Program ICR, Table 1, FR Doc. 2026-11989, 91 Fed. Reg. 35989 (June 15, 2026), https://www.federalregister.gov/d/2026-11989.
[4] Supporting Statement A - OPA - 340B Rebate Model Pilot - 0906-NEW https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=202606-0906-001
[5] https://340bopais.hrsa.gov/SearchCe

2. Formatting and validating data to meet manufacturer specifications;
3. Submitting the data;
4. Reconciling submissions and tracking rebate status; and
5. Addressing errors, denials, or follow-up requests."[6]

Working within HRSA's five-element methodology, the cumulative per-response time for a CHC greatly exceeds five hours. HRSA's covered entity-level assumption does not accurately reflect how CHCs participate in the 340B Program. In contrast to hospital covered entities whose child sites obtain their 340B-eligibility from the hospital itself, each CHC location is individually 340B eligible and operates as a "parent" site for purposes of purchasing and data reporting. Accordingly, CHCs must separately register contract pharmacies under grantee sites on OPAIS by obtaining separate HINs for each 340B ID (reflecting individual pharmacy relationships), aligning wholesaler accounts to the associated site 340B IDs to ensure the purchases are properly aligned to a specific site, making the necessary designations in the manufacturer chosen platform, submitting utilization data for each designated site (which entails manipulating TPA reports, since most systems do not accommodate this nuance of CHC reporting), reconciling submission data, and troubleshooting any discrepancies. This is all at the individual site or 340B ID level.

340B Rebate Model Burden Considerations

The burden of a 340B rebate model is driven primarily by fragmentation in data standards, submission pathways, and platform requirements by drug manufacturers, forcing covered entities to duplicate data mapping, submission, and reconciliation efforts across systems. **To address this burden at its source, NACHC recommends HRSA require a single uniform set of data fields, formats, and submission timelines across all manufacturers, and prohibit unapproved additional data requests.** In the absence of standardization, these parallel workflows significantly expand the administrative workload beyond HRSA's assumptions.[7] **NACHC further recommends covered entities be permitted to submit data through a single neutral-party platform, ensuring consistent processes and eliminating duplicative system interactions.**

We have outlined several of these burdens in more detail for consideration:

- **Rebate processes mirror existing data submissions to manufacturers.** HRSA is correct that many CHCs are already submitting the majority of the requested data elements (except for BIN & PCN) regularly through the 340B ESP platform. At present, Teva is the only manufacturer included in the proposed rebate pilot that does not request data from CHCs for contract pharmacies. Furthermore, six of the manufacturers also require entity-level claims as a condition of sale to covered entity sites and pharmacies listed as 340B-eligible on OPAIS. NACHC respectfully disagrees that program transparency will improve since identical data is already being submitted through 340B ESP. The proposed rebate pilot would replicate existing processes, while significantly increasing the burden on covered entities through an exponential increase in the volume, complexity, and financial risk, with little evidence it will improve 340B Program operations.
- **Lack of standardization across manufacturer platforms.** Today, covered entities already submit manufacturer-restriction claims data through Second Sight Solutions' 340B ESP and Truzo (Kalderos / Model N) platforms. Under the anticipated rebate model, there is potential for manufacturer participants to use multiple, non-interoperable platforms with different data specifications. The result: covered entities may need to identify, format, validate, submit, reconcile, and pursue denials for the selected-drug claims across multiple manufacturer platforms, each with its own registration, data specifications, file layouts, and workflows. Variation across manufacturer platforms will require multiple logins, repeated mapping, and duplicate submission of the same underlying claim data. Presently, Truzo's platform is highly manual, requiring individual, customized submissions tailored to each participating

[6] Internal NACHC survey data
[7] Supporting Statement A - OPA - 340B Rebate Model Pilot - 0906-NEW

manufacturer rather than a single standardized file. Potentially maintaining claims data in parallel across multiple manufacturer IT platforms (e.g., 340B ESP, Beacon, and Truzo), and tracking rebate status and denials separately in each, multiplies the CHCs burden.

- **TPA automation is not a consistently viable solution.** A significant volume of CHC 340B activity, including clinic-administered drugs and entity-owned pharmacies, occurs outside the TPA workflow that HRSA has assumed is standard. For many CHCs, there is no existing automated TPA "extract-and-submit" pipeline for these claims. Therefore, identification, formatting, and submission for these areas will be predominantly manual. Many existing TPAs' automated data upload processes are designed for hospitals, uploading all data through the parent-site 340B ID. For CHCs utilizing TPAs for entity-owned or contract pharmacies, this means their TPAs' automated data submission processes are not designed for the CHCs grantee site specific data upload needs. If the CHC did use the TPA's hospital-centric automated data upload process, it would create submission errors. On average, CHCs, even with TPAs, must upload data manually to the manufacturer IT platforms. The few TPAs with CHC-specific data upload processes charge CHCs extra for this, reducing 340B savings that could otherwise be used to expand services, increase access to affordable medications, and improve patient care. Many CHCs operate across contract pharmacies, entity-owned pharmacies, and Clinic Administered Drugs (CADs) workflows, and those activities do not reside in a single data stream that can be exported once and sent to manufacturer IT platforms.[8]
- **Clinic-administered drugs (CAD) and paper records.** The majority of CADs are bundled into the CHCs' Prospective Payment System and are not separately billed. For many CHCs, administration logs are maintained on paper or in visit notes rather than in discrete reportable fields within electronic medication administration records (eMAR). Converting these records into the claims-level electronic data elements required for rebate submission is a manual process that imposes additional burden not captured by HRSA's "automated-extract" assumptions.
- **Reconciliation and denial management.** Tasks (4) and (5) of HRSA's methodology[9] are recurring and resource intensive. A time study of current CHC submission processes, conducted by NACHC's 340B Technical Advisors, FQHC 340B Compliance, found that, even at maximum efficiency, an experienced individual requires at least 20 minutes to investigate and resolve a denial or erroneous claim.[10] Because no empirical study currently exists for the proposed 340B rebate model, NACHC estimated reasonable range of claim classification error and claim denial rates using available proxy measures. Improper payment rates reported across CMS programs provide a reasonable lower-bound benchmark for claims requiring staff investigation, appeals, or reconciliation, while reported implementation experience from the Beacon Maximum Fair Price (MFP) rebate program provides an upper-bound benchmark during the launch of a new national rebate infrastructure.
    - **Together, these data suggest claim classification rates provide a reasonable range from approximately 10% to 40% while claim denial rates could range from approximately 5% to 20%.**[11] Additional evidence from Medicare Advantage further demonstrates the administrative burden associated with claim denials.[12] The study found approximately 17% of prior authorization denials meeting Medicare coverage rules were ultimately overturned upon appeal, illustrating that claim denials frequently require extensive provider review, documentation, and follow-up before payment is received. Even assuming a minimum claim

[8] 340B Rebate Model Pilot Program ICR, 91 Fed. Reg. 35989 (June 15, 2026), https://www.federalregister.gov/d/2026-11989.
[9] This includes reconciling submissions, tracking rebate status, and addressing errors, denials, or follow-up requests
[10] Time estimates to complete each task were based on time studies of gathering, formatting and uploading claims to 340B ESP to reconcile and remediate issues in 340B ESP and Beacon MFP. Highly skilled staff that perform these tasks for nearly 100 community health centers on an ongoing basis conducted timed trials across health centers ranging in size and complexity (patient size, payer mix, number of pharmacies (entity owned vs contract pharmacy), number of Third Party Administrators, presence of CAD and method, and rural vs urban). These time per tasks are an average.
[11] https://340breport.com/denied-disputed-delayed-sponcon-rxparadigm/
[12] Medicare Advantage Denies 17 Percent Of Initial Claims; Most Denials Are Reversed, But Provider Payouts Dip 7 Percent | Health Affairs

classification error rate of 10% and a claim denial rate of 5%, both of which require CHC staff investigation, the estimated burden for claim error and denial is associated with claim investigation ranges from 4 hours for smaller CHCs to more than 50 hours weekly for larger CHCs. Although Beacon MFP's performance is expected to improve as the program matures, the timeframe for resolving technical, operational, and system integration challenges remains uncertain. Accordingly, the estimates range provide a reasonable basis for estimating the administrative burden CHCs can expect during implementation of the 340B rebate model.

- **Medical-claims data elements differ from pharmacy fields.** Proposed medical claims data elements, including claim line number, claim number, health plan name, health plan ID, and health plan ID qualifier, are not standardized across health care systems and may not be available at the time of claim submission. Assembling and validating these distinct data field sets adds burden beyond a routine pharmacy extract.

In summary, each entity-owned pharmacy, TPA platform, and electronic health record will constitute a discrete data set that must flow through all five claim-cycle elements. HRSA estimates appear to envision one data upload per week; operational realities dictate that CHCs will have numerous disparate data sets to address each week. While TPAs do offer the potential to improve efficiency, they also drive added cost and are typically not utilized by CHCs for clinic-administered drugs or entity-owned pharmacies.

III. Covered Entity Burden Estimate

To assist HRSA in developing a more accurate, evidence-based, per-response estimate, individual covered entities' burden for providing requested data is provided below. The burden estimate components reflect time studies conducted of HRSA's five task-based activities and capture the entity-specific drivers, including number of impacted claims, number of TPAs, and claim types reported without a TPA, that materially affect burden.

Figure 1. Time Study of HRSA's Task Based Activities

HRSA Task Cycle Area	Platform	Time per Tasks (Min)
1. Identify and extract eligible claims data	In-house	3.00
	CAD	3.00
	CAD Paper Log	5.00
	TPA	3.25
2. Format and validate data to meet manufacturer specifications	In-house	6.50
	CAD EHR Report	3.00
	CAD Paper Log	15.00
	Sites Specific Formatting	2.00
	TPA	2.00
3. Submit the data	Manufacturer Platform	5.00
4. Reconcile submissions & track rebate status	Manufacturer Platform	30.00
5. Address errors, denials, or follow-up requests	Manufacturer Platform	20.00

Time estimates to complete each task were based on time studies of gathering, formatting, and uploading claims to 340B ESP to reconcile and remediate issues in 340B ESP and Beacon MFP. Claim issues and denial rates were estimated at 10% and 5% respectively, based on a publication from Rx Paradigm reporting

on error (40%) and denial (18%) rates, applying a 4-fold decrease to account for system improvements hoped to be gained over 2026.[13] **As mentioned on the previous page, taken together, these data suggest claim classification rates provide a reasonable range from approximately 10% to 40% while claim denial rates could range from approximately 5% to 20%.[14]**

NACHC collected time estimate data from 24 CHCs with patient sizes between 6,000 and 118,000 per the UDS to calculate burden on different sized health centers. Average hours per week under both the low-end assumption (10% claim classification rates and 5% denial rates) and high-end assumption (40% claim classification rates and 5% denial rates) were calculated to show a range of scenarios. Figures 2 and 3 show the results below.

Figure 2. Average Hours Per Weekly Cycle Under High End and Low End Assumptions

Task-Based Activity (per HRSA methodology)	**Average Hours Per Cycle Assuming 10% Claim Classification Rates and 5% Claim Denial Rates**			**Average Hours Per Cycle Assuming 40% Claim Classification Rates and 10% Claim Denial Rates**		
	Average	Max	Min	Average	Max	Min
1. Identify and extract eligible claims data	0.50	4.00	0.05	0.50	4.00	0.05
2. Format and validate data to meet manufacturer specifications	0.64	4.51	0.03	0.64	4.51	0.03
3. Submit the data	0.82	6.67	0.08	0.82	6.67	0.08
4. Reconcile submissions and track rebate status	4.92	40.00	0.50	4.92	40.00	0.50
5. Address errors, denials, or follow-up requests	8.21	49.08	0.09	32.82	196.31	0.36
Subtotal: Estimated hours per response cycle (weekly)	**15.09**	**62.34**	**1.12**	**39.70**	**201.09**	**2.39**

Figure 3. Annualized Burden Calculations in Hours and FTE costs

Annualized Burden	**Low End Calculation**			**High End Calculation**		
	Avg	Max	Min	Avg	Max	Min
Estimated Hours Per Response	15.09	62.34	1.12	39.70	201.09	2.39
Number of Responses (Task Cycles)	511.33	4,160.00	52.00	511.33	4,160.00	52.00
Estimated Annual Burden Hours	784.49	3,241.82	58.38	2,064.53	10,456.52	124.10
Cost of Responsible Staff	$ 103,552.50	$427,919.80	$7,706.60	$ 272,518.50	$1,380,260.00	$16,381.20

[13] https://340breport.com/denied-disputed-delayed-sponcon-rxparadigm/
[14] https://340breport.com/denied-disputed-delayed-sponcon-rxparadigm/

(Using $132/hour for a pharmacist)						

NACHC's survey suggests that CHCs employees would have to spend between 15.09 to 39.70 hours a week to comply with the rebate model. Using OPA's assigned rate of $132/hour for a pharmacist, the annual financial burden on the CHC will be between $103,552.50 and $272,518.50. There are 1,452 CHCs registered as covered entities with OPA, resulting in an average annual burden between $150,358,230 - $395,696,862.

IV. Burden Associated with the Manufacturer Collections Should Address Downstream Effects on Covered Entities

A. Manufacturer Plan Submissions (Estimated 8 Hours; 11 Respondents)

The ICR estimates 8 hours per manufacturer plan submission across 11 manufacturers, totaling 88 total burden hours.[15] NACHC does not opine on the time a manufacturer needs to draft a plan but emphasizes that the *content* of these plans directly determines covered-entity burden. **NACHC respectfully requests all approved manufacturer plans be publicly published in their entirety on OPA's website.** Published manufacturer plans should include complete descriptions of "dispense to rebate" calculation logics to be used by manufacturers' IT platform vendors, including any conditions such as reasonable use timeframes (e.g., rebate requests must be made within X days of a WAC purchase), to alleviate participation burden. This would also align with the 340B rebate pilot's stated intent to improve program transparency.

B. Manufacturer Monthly Purchase Reports (Estimated 2 Hours; 132 Responses)

The ICR estimates 2 hours per monthly purchase report, 12 reports per manufacturer across 11 manufacturers, totaling 264 total burden hours.[16] **NACHC supports robust manufacturer reporting to OPA and the 340B Prime Vendor as a program-integrity measure. We also recommend that HRSA make manufacturer-reported performance data publicly available on OPA's website.** For transparency purposes, NACHC strongly suggests the following metrics be made publicly available, both by drug and by manufacturer:

- Average days from claim submission to rebate payment
- Percentage of rebates paid after 10 days
- Percentage of rebates denied by denial reason
- Aggregate volume of rebates requested and rebates approved.

V. The Pilot Duplicates Reporting Already Being Requested Under the CMS Medicare Part D 340B Data Repository

HRSA's covered entity burden estimate fails to account for the substantial duplication of effort between the anticipated Rebate Model Pilot and the new Medicare Part D Claims Data 340B Repository (the "340B repository"). The Centers for Medicare and Medicaid Services (CMS) finalized the 340B repository in the Calendar Year 2026 Physician Fee Schedule final rule (90 Fed. Reg. 49266) as part of its implementation of the Medicare Part D Drug Inflation Rebate Program under the Inflation Reduction Act. Although repository participation is currently voluntary, CMS proposed making participation mandatory in the 2027 Physician Fee Schedule Notice of Proposed Rulemaking. Both collections require covered entities to identify, extract, format, and transmit claims-level data on the very same 340B dispenses, including date of service, prescription number, fill number, dispensing pharmacy NPI, and NDC-11, and the covered entity's

[15] Id., Table 1, row 1 (Plan Submission: 11 respondents × 8 hours = 88 hours).
[16] Id., Table 1, row 2 (Monthly purchase reports: 11 respondents × 12 responses × 2 hours = 264 hours).

340B ID. Yet they are being built as separate, parallel systems with different operators, specifications, and workflows.

As a result, covered entities will likely be required to maintain two distinct claims data pipelines for the same underlying claims, each with distinct validation rules, submission processes, reconciliation activities, and record-retention requirements. This is precisely the type of information collection burden that the Paperwork Reduction Act directs agencies to identify and avoid under 44 U.S.C. 3506(c)(3)(A) and 3506(c)(3)(B). **HRSA's burden analysis should expressly account for the fact that covered entities are simultaneously standing up the processes and systems needed for the 340B repository, and that the Pilot adds a second, non-interoperable reporting obligation on top of it**

To mitigate these concerns, NACHC recommends that HRSA:

1. Expressly account for the duplicative burden of the 340B repository in its per response and annual burden estimates rather than treating the Pilot reporting as a standalone, first-time data exercise;
2. Coordinate with CMS so that the data elements, formats, and submission timelines for the Pilot align with the 340B repository to the greatest extent possible, ideally allowing a single, standardized covered entity submission to serve both purposes; and
3. Leverage the 340B repository as the source of truth for deduplication wherever feasible, rather than requiring covered entities to construct an additional, parallel reporting channel to each manufacturer's chosen platform.

VI. Conclusion

NACHC strongly urges HRSA to exempt CHCs from any 340B Rebate Model Pilot Program. As discussed in previous comment letters, a rebate model represents a substantial departure from the original intent of the 340B program; to allow safety-net providers to "stretch scarce Federal resources" and provide more comprehensive care. This pilot would create significant cash flow challenges, forcing CHCs to make difficult decisions about staffing, services, and the range of drugs they can afford to stock. Additionally, many CHCs would need to make significant investments in IT infrastructure and staff to comply with rebate requirements and track rebates. It would also create a new barrier for patients, especially uninsured patients, who depend on the up-front 340B discount, making it operationally impossible to provide the sliding fee scale and steeply discounted medications required by law. **NACHC believes that a 340B rebate pilot would cause disproportionate harm to 52 million patients served by CHCs.**

NACHC appreciates the opportunity to respond to this ICR on the 340B Rebate Model Pilot Program and looks forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please contact Elizabeth Linderbaum, Director of Regulatory Affairs, at elinderbaum@nachc.org.

Sincerely,



Joe Dunn
Chief Policy Officer

Supplemental Supporting Data (See accompanying Excel file for tables describing NACHC's calculations)

Figure 4: HRSA Estimated Data Burden Hours (All CEs)

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Covered Entities reporting claims data to third party platform	15,249	52	792,948	5	3964740
Total	15,260		793,091		**3,965,092**

Figure 5: HRSA Estimated Cost (All CEs)

Type of Respondent	Instrument	Total Estimated Burden Hours	Hourly Wage Rate	Total Respondent Costs
Pharmacist	**Covered Entities reporting claims data to third party platform**	**3,964,740**	**$132.00**	**$523,345,680**

Figure 6: HRSA Estimated CHC Data Burden Hours

Health Center By CE reporting claims data to third party platform	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
CHC	1302	52	67,704	5	338,520
FQHC-LAL	150	52	7,800	5	39,000
Total	1,452		75,504	10	**377,520**

Figure 7: HRSA Estimated CHC Data Burden Cost

Type of Respondent	**Instrument**	**Total Estimated Burden Hours**	**Hourly Rate**	**Total Respondent Costs**
Pharmacist	Covered Entities reporting claims data to third party platform	377,520	$132.00	$49,832,640
Estimated Total		**3,965,356**		**$49,832,640**

Figure 8: Proposed Pilot Manufacturers Current Data Conditions for Sale at 340B Pricing

Manufacturer	**Drug**	**CHC Contract Pharmacy Data Requirements**	**CHC Entity Claims Data Requirements (Effective)**	**Platform**
AbbVie	Imbruvica, Linzess, Vraylar	Yes		340B ESP
Amgen	Enbrel, Otezla; Otezla XR	Yes	Yes (6/1/2026)	340B ESP
Astellas	Xtandi	Yes		340B ESP

AstraZeneca	Calquence, Farxiga	Yes	Yes (5/1/2026)	340B ESP
BI	Jardiance, Ofev, Tradjenta	Yes	Yes (7/6/2026)	340B ESP
BMS	Eliquis, Pomalyst	Yes	Yes (5/1/2026)	340B ESP
GSK	Breo Ellipta, Trelegy Ellipta	Yes	Yes (7/1/2026)	340B ESP
Merck	Janumet, Januvia	Yes		340B ESP
Novo Nordisk	Ozempic, Rybelsus, Wegovy	Yes	Yes (4/1/2026)	340B ESP
Pfizer	Ibrance	Yes		340B ESP
Teva	Austedo; Austedo Xr	Hospitals Only		340B ESP

Public Comments for ICR 202606-0906-001

Author Full Name : Elizabeth Linderbaum **Received Date :** 07/15/2026 07:25 PM

Comments Received :

On behalf of the National Association of Community Health Centers, please see the attached comment letter and Excel spreadsheet in response to the 340B Rebate Model Pilot Program ICR. Thank you in advance for your consideration and review.

Task-Based Activity (per HRSA methodology)	Est. Weekly Burden Hours (10%/5% Burden)	Est. Weekly Burden Hours (40%/20% Burden)	UDS Patient Count (Rounded to Nearest 1,000)	Percent Below 200% FPL	Percent Below 100% FPL	Uninsured	Medicaid	Medicare	Commercial
CHC 1	**53.86**	**201.09**	**119,000**	93.20%	65.74%	10.94%	37.59%	17.83%	33.64%
CHC 2	**11.73**	**24.94**	**36,000**	78.30%	49.24%	23.95%	37.76%	10.58%	27.71%
CHC 3	**12.89**	**33.96**	**115,000**	88.45%	50.70%	13.55%	37.66%	7.08%	41.71%
CHC 4	**19.40**	**38.57**	**38,000**	87.74%	74.39%	28.71%	24.22%	13.21%	33.86%
CHC 5	**7.82**	**23.19**	**52,000**	92.78%	86.65%	7.68%	57.37%	15.74%	19.21%
CHC 6	**12.28**	**34.19**	**35,000**	75.99%	60.54%	10.04%	25.40%	25.87%	38.69%
CHC 7	**4.49**	**5.51**	**23,000**	92.92%	74.35%	10.31%	64.03%	8.49%	17.17%
CHC 8	**62.34**	**83.83**	**54,000**	83.00%	57.71%	9.52%	33.11%	18.25%	39.13%
CHC 9	**8.34**	**14.61**	**88,000**	85.13%	41.54%	16.09%	19.44%	31.24%	33.23%
CHC 10	**9.65**	**23.84**	**46,000**	93.90%	69.33%	27.26%	37.67%	9.10%	25.97%
CHC 11	**8.91**	**25.43**	**11,000**	72.36%	UNKNOWN	11.90%	28.10%	27.70%	32.20%
CHC 12	**24.97**	**80.89**	**46,000**	95.90%	54.38%	20.37%	29.53%	26.01%	24.09%
CHC 13	**6.13**	**14.19**	**12,000**	63.35%	38.75%	6.80%	25.13%	34.36%	33.71%
CHC 14	**12.08**	**29.55**	**27,000**	71.00%	37.26%	3.85%	20.77%	29.37%	46.01%
CHC 15	**19.10**	**66.14**	**16,000**	97.01%	75.12%	51.02%	11.93%	12.40%	24.66%
CHC 16	**10.68**	**27.95**	**15,000**	75.48%	38.42%	21.86%	17.61%	15.36%	45.16%
CHC 17	**2.12**	**2.39**	**17,000**	92.01%	66.50%	17.59%	45.89%	7.83%	28.69%
CHC 18	**1.12**	**2.48**	**7,000**	91.74%	68.28%	30.86%	28.47%	16.32%	24.35%
CHC 19	**3.74**	**10.74**	**17,000**	82.62%	54.25%	26.89%	33.78%	7.87%	31.46%
CHC 20	**8.92**	**25.19**	**24,000**	75.61%	49.60%	8.87%	43.22%	15.91%	32.00%
CHC 21	**2.47**	**5.86**	**10,000**	71.86%	32.26%	12.74%	31.40%	16.43%	39.42%
CHC 22	**18.84**	**33.88**	**24,000**	98.83%	91.69%	15.14%	78.18%	3.15%	3.53%
CHC 23	**7.37**	**23.44**	**17,000**	89.88%	43.82%	17.05%	34.61%	14.33%	34.00%
CHC 24	**32.82**	**121.00**	**19,000**	79.85%	31.99%	19.62%	6.71%	50.00%	23.67%
Average	**15.09**	**39.70**	**36,167**	84.16%	56.67%	17.90%	33.73%	18.10%	30.55%

Total Claims	CHC 1	CHC 2	CHC 3	CHC 4	CHC 5	CHC 6	CHC 7	CHC 8	CHC 9	CHC 10	CHC 11	CHC 12	CHC 13	CHC 14	CHC 15	CHC 16	CHC 17	CHC 18	CHC 19	CHC 20	CHC 21	CHC 22	CHC 23	CHC 24
Total Claims	313462	4,730	98300	27481	577	24925	7496	148412	**68,428**	90868	44372	49019	5480	90545	22136	6386	137845	492	3720	108151	37327	8863	266	**19,433**
Selected Drug Claims	25520	410	2290	5095	47	2997	1393	7913	**3,027**	6647	2664	8573	180	3725	3162	1181	9693	235	202	16305	2994	470	98	**1,398**
	8%	9%	2%	19%	8%	12%	19%	5%	4%	7%	6%	17%	3%	4%	14%	18%	7%	48%	5%	15%	8%	5%	37%	7%

Selected Drug	CHC 1	CHC 2	CHC 3	CHC 4	CHC 5	CHC 6	CHC 7	CHC 8	CHC 9	CHC 10	CHC 11	CHC 12	CHC 13	CHC 14	CHC 15	CHC 16	CHC 17	CHC 18	CHC 19	CHC 20	CHC 21	CHC 22	CHC 23	CHC 24	Total	% Impact of Total
IMBRUVICA	5	-	0	0	0	0	0	0	-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	6	0%
LINZESS	482	-	0	115	0	5	0	7	5	25	0	16	0	4	3	0	10	0	6	0	0	0	0	-	678	1%
OTEZLA; O	-	-	0	25	0	0	0	0	-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-	25	0%
ENBREL	110	15	23	15	0	0	5	24	6	40	63	146	0	28	53	3	149	0	6	4028	112	2	0	1	4,829	5%
VRAYLAR	3,632	43	433	30	0	6	48	840	396	1137	204	261	5	648	68	118	1021	8	7	252	150	70	5	206	9,588	9%
XTANDI	3	-	0	0	0	0	0	0	-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-	3	0%
FARXIGA	1,533	7	30	743	0	26	93	93	55	30	1	66	10	4	131	18	208	3	4	0	169	8	28	148	3,408	3%
CALQUENC	43	1	0	0	0	0	0	0	-	0	6	0	0	1	1	0	0	39	1	0	7	0	0	4	103	0%
ELIQUIS	9	-	0	1137	0	13	0	0	-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-	1,159	1%
POMALYST	76	61	11	0	0	0	10	249	44	125	71	115	3	74	28	13	129	0	7	1086	26	6	0	13	2,147	2%
TRADJENTA	7	-	0	125	0	4	0	0	-	0	0	0	1	0	0	0	0	0	0	0	0	0	0	-	137	0%
OFEV	463	8	53	0	0	0	10	224	34	44	99	53	1	100	21	6	252	0	0	2	53	14	1	42	1,480	1%
JARDIANCE	1,176	9	66	722	16	446	88	280	70	115	149	1054	6	125	46	55	284	24	3	32	120	1	4	60	4,951	5%
BREO ELLI	-	-	0	44	0	0	0	0	-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-	44	0%
TRELEGY E	1,861	12	129	566	0	4	104	407	91	566	85	331	13	184	82	47	554	24	5	0	76	33	4	41	5,219	5%
JANUMET;	537	20	123	40	0	148	41	1014	101	139	227	230	8	356	89	19	825	8	2	1434	460	4	0	63	5,888	6%
JANUVIA	4,758	124	371	139	0	303	312	1727	1,146	722	762	665	71	896	273	233	1520	22	96	6468	431	77	5	135	21,256	21%
OZEMPIC;	7,816	88	711	1394	31	1651	554	2679	983	1394	954	4569	56	1092	502	648	3624	107	58	1167	1047	236	50	545	31,956	31%
IBRANCE	1,439	-	4	0	0	0	0	8	17	15	0	0	0	0	7	0	7	0	4	31	3	1	0	-	1,536	1%
AUSTEDO;	1,570	22	336	0	0	0	128	361	79	743	43	1067	6	213	73	21	1110	0	3	1805	340	18	1	139	8,078	8%
Total	**25,520**	**410**	2290	5095	47	2606	1393	7913	3027	5095	2664	8573	180	3725	1377	1181	9693	235	202	16305	2994	470	98	1398	102,491	100%

Task-Based Activity (per HRSA methodology)	Est. Hours / Cycle (Low End)			Est. Hours / Cycle (High End)		
	Max	Min	Avg	Max	Min	Avg
1. Identify and extract eligible claims data	4.00	0.05	0.50	4.00	0.05	0.50
2. Format and validate data to meet manufacturer specifications	4.51	0.03	0.64	4.51	0.03	0.64
3. Submit the data	6.67	0.08	0.82	6.67	0.08	0.82
4. Reconcile submissions and track rebate status	40.00	0.50	4.92	40.00	0.50	4.92
5. Address errors, denials, or follow-up requests	49.08	0.09	8.21	196.31	0.36	32.82
Subtotal: Estimated hours per response cycle (weekly)	62.34	1.12	15.09	201.09	2.39	39.70

Annualized Burden Calculation	Low End Calculation			High End Calculation		
	Max	Min	Avg	Max	Min	Avg
Estimated hours per response / cycle (per week)	62.34	1.12	15.09	201.09	2.39	39.70
Number of responses (Task Cycles) per year (HRSA used 52, assuming 1 per week)	4,160.00	52.00	511.33	4,160.00	52.00	511.33
Estimated ongoing annual burden hours (hours/cycle x responses/year)	3,241.82	58.38	784.49	10,456.52	124.10	2,064.53
Responsible staff roles (OPA assigned hourly rate of $132/hour for a pharmacist)	$ 427,919.80	$ 7,706.60	$ 103,552.50	$ 1,380,260.00	$ 16,381.20	$ 272,518.50

Not in tables, but for context: Added FTEs -->	1.56	0.03	0.38	5.03	0.06	0.99

Beth Israel Lahey Health System — Including Beth Israel Deaconess Medical Center and Northeast Hospital Corp.

Beth Israel Lahey Health

July 15, 2026

VIA ELECTRONIC SUBMISSION TO https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202606-0906-001

Ms. Samantha Miller
Health Resources and Services Administration
Information Collection Clearance Officer
5600 Fishers Lane, Room 13N82
Rockville, MD 20857

RE: Public Comment Response to HRSA's Request for Information Collection under OMB Number 0906-NEW

Dear Ms. Miller:

On behalf of Beth Israel Deaconess Medical Center DSH220086 (BIDMC) and Northeast Hospital Corp. DSH220033 (NHC), both members of the Beth Israel Lahey Health system ("BILH"), we respectfully submit this comment regarding the proposed collection of information described in *340B Rebate Model Pilot Program Application, Implementation, and Evaluation under OMB Number 0906-NEW* ("Proposed ICR").[1] We appreciate the opportunity to provide feedback during the 30-day comment period.

As 340B Covered Entities, BIDMC and NHC are particularly interested in ensuring that any future rebate model can be administered in a manner that is operationally feasible, appropriately tailored, and does not create unnecessary administrative burden for providers serving vulnerable patient populations. Considering that Covered Entities will ultimately be responsible for collecting, validating, submitting, and reconciling the information contemplated by the Proposed ICR, it is important that HRSA's burden estimates and reporting assumptions accurately reflect the realities of day-to-day program administration. The comments below reflect our concerns regarding (i) the lack of specificity surrounding required data elements, (ii) the continuing inconsistencies regarding future reporting obligations, and (iii) the significant administrative and technological burdens that may be imposed upon Covered Entities.

I. HRSA's Data Submission Requirements Are Not Only Ambiguous, They Are Contradictory.

One of the most significant challenges the Proposed ICR presents is that BIDMC and NHC still does not know what information will ultimately be required under a future rebate model. Not only are HRSA's ambiguous requirements contrary to the intent of the Paperwork Reduction Act, but from an operational perspective, it is difficult for BIDMC and NHC to evaluate staffing needs,

[1] *340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-NEW,* 91 Fed. Reg. 35989 (Jun. 26, 2026).

technology requirements, vendor support needs, or reporting burden when the specific data elements have not yet been identified.

Notably, the Proposed ICR does not contain definitions that describe the specific data elements that BIDMC and NHC would be required to submit, nor does it identify any standardized format or scope for such submissions. This lack of clarity is particularly problematic because HRSA has stated in the Proposed ICR that it has not approved nor reviewed any manufacturer rebate model proposals, and therefore cannot articulate what information would actually be required under a future rebate model.[2] The only confirmation Covered Entities have received from HRSA is that it will publish manufacturer plans in the Federal Register. Further, the Proposed ICR does not offer any general description of the type of data BIDMC and NHC will be required to submit. Once again, the Proposed ICR states that the type and frequency of such submissions will be published in the Federal Register notice and that the data will be "comparable to data currently maintained through third-party vendors or previously provided to manufacturers under unrelated pharmacy or claims programs."[3] This expectation is entirely speculative and ambiguous.

This ambiguity is particularly concerning because it creates a fundamental inconsistency regarding the information BIDMC and NHC may eventually be required to submit. HRSA repeatedly suggests that the necessary data elements are already generated and maintained by Covered Entities or their vendors, yet simultaneously acknowledges that it has not identified the specific data elements that will be required and that those requirements will be defined in a future Federal Register notice. If the required data elements are already standardized and commonly maintained, HRSA should be able to identify them now. Conversely, if HRSA cannot identify the data elements until after manufacturer proposals are received and evaluated, then there is no basis for concluding that such information is readily available or can be produced with minimal burden. This contradiction makes it difficult for BIDMC and NHC to understand what we are being asked to prepare for and further underscores the lack of clarity surrounding the Proposed ICR.

HRSA's ambiguity and contradictory language is not entirely new. In the February 2026 ICR, Covered Entities raised similar objections regarding the inconsistencies between HRSA's claim that it would publish the standard data elements and that Covered Entities already maintained those data elements.[4] Because HRSA did not meaningfully address these concerns in February, BIDMC, NHC, and covered entities generally remain in the same position they occupied during prior comment periods: being asked to evaluate an information collection request without knowing what information ultimately will be collected or how that information will be used. Due to the above-mentioned ambiguities and inconsistencies, the Proposed ICR does not resolve the central uncertainty that has characterized each previous iteration of HRSA's rebate model information collection and instead perpetuates it.

[2] *See* 91 Fed. Reg. at 35990.
[3] *Id.*
[4] *See 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-NEW,* 91 Fed. Reg. 9632, 9633.

This uncertainty is particularly challenging because health systems cannot build compliance processes overnight. New reporting requirements often require coordination among BIDMC and NHC's own internal pharmacy department and its third-party vendors. Without knowing what information will ultimately be collected, BIDMC and NHC cannot meaningfully assess the resources necessary to comply nor comment on the Proposed ICR.

II. The Proposed ICR Is More Burdensome Than Necessary.

HRSA has not offered an accurate estimate of the average burden upon Covered Entities, nor has it demonstrated that it has selected the least burdensome means of collecting covered entities' information – because it cannot, for the reasons noted above. HRSA states that it employs a task-based methodology to estimate respondent burden and that its calculation accounts for "(1) identifying and extracting eligible claims data, (2) formatting and validating data to meet manufacturer specifications; (3) submitting the data; (4) reconciling submissions and tracking rebate status; and (5) addressing errors, denials, or follow-up requests."[5] Despite acknowledging the breadth of these operational functions, HRSA concludes that Covered Entities will only require approximately five hours per week to satisfy these obligations.[6]

That estimate is not—and again cannot be given the current lack of information—accompanied by sufficient explanation to permit meaningful public review. HRSA does not identify the assumptions that underlie its calculations, including the volume of expected claims transactions, the anticipated frequency of data submissions, the number of reconciliation events, the extent of staff involvement necessary to resolve disputes or denials, the processes for such disputes, or the costs associated with implementing and maintaining systems capable of complying with manufacturer reporting requirements.

To better inform HRSA and OMB of the actual burden associated with these activities, BIDMC and NHC should be permitted to describe our operational experience. Accordingly, BIDMC and NHC estimate that compliance with claims data reporting and rebate administration requirements currently requires approximately, at a minimum 120 hours per week. These include financial resources to track, manage and dispute rebate processing and to true up open AR against received rebates. Data analytics resources to support data submissions and additional 340B staff to manage the growing program complexities.

On a separate note, should BIDMC and NHC be required to submit claims-data under a future rebate model, it may trigger overcharges under the 340B statute. Through manufacturer all-claims policies, Covered Entities are increasingly being required to provide extensive claims-level data as a condition of accessing 340B drugs. Under these arrangements, Covered Entities are required to submit more data than is necessary for platforms such as 340B ESP to match Covered Entities' claims with manufacturer's rebate data.[7] For example, CMS's Part D repository will only require Covered Entities to submit: (i) 340B ID, (ii) Date of Service, (iii) Prescription Number, (iv) Fill

[5] 91 Fed. Reg. at 35990.
[6] *Id.*
[7] Bradley Malin, Expert's Assessment of Second Sight 340B ESP™ De-Identification Procedures for Medical Benefits Claims Data, 19 (2026).

number, (v) NDC-11, (vi) Dispensing Pharmacy NPI, and (vii) Claim Record Indicator. If CMS has determined that it only needs these seven data elements to remove 340B claims from its Part D inflation rebate requests, it would be highly irregular for its sister agency to require Covered Entities to disclose more or different data to a private, for-profit data aggregator.

Any such requirement would raise immediate concerns under the 340B statute's prohibition against overcharges. While manufacturers may characterize these data-submission obligations as administrative requirements rather than part of the purchase price, the practical effect would be that BIDMC and NHC could not obtain the full value of the 340B discount without providing valuable claims data and absorbing the significant costs associated with maintaining and submitting that information. BIDMC and NHC also will not receive compensation for either the data itself or the resources required to support these activities. As a result, a future rebate model may effectively require BIDMC and NHC to provide additional consideration beyond payment of the of the 340B ceiling price in order to access the 340B discount, which would result in an overcharge.

III. Conclusion

BIDMC and NHC appreciate HRSA's efforts to gather stakeholder feedback regarding reporting requirements for a future Rebate Model Pilot Program. As an organization committed to serving patients and maintaining compliance with the 340B Program, we support efforts to develop processes that are defined, operationally feasible, and tailored to the realities Covered Entities face.

At this time, however, we believe that additional information is needed regarding the data elements that may be required, the operational structure of the of future rebate models, and the assumptions underlying HRSA's burden estimates. We respectfully encourage HRSA to revise the Proposed ICR and provide stakeholders with additional detail before seeking final approval from OMB.

Respectfully submitted,

Jennifer J Rossi

Jennifer J Rossi 340B Director of Compliance and Advocacy

University of Arkansas for Medical Sciences

July 14th, 2026

VIA ELECTRONIC SUBMISSION TO
https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202606-0906-001

Ms. Samantha Miller
Health Resources and Services Administration
Information Collection Clearance Officer
5600 Fishers Lane, Room 13N82
Rockville, MD 20857

RE: Public Comment Response to HRSA's Request for Information Collection under OMB Number 0906-NEW

Dear Ms. Miller:

On behalf of the University of Arkansas for Medical Sciences, UAMS, we respectfully submit this comment regarding the proposed collection of information described in *340B Rebate Model Pilot Program Application, Implementation, and Evaluation under OMB Number 0906-NEW* ("Proposed ICR").[1] We appreciate the opportunity to provide feedback during the 30-day comment period.

As a 340B Covered Entity, UAMS is particularly interested in ensuring that any future rebate model can be administered in a manner that is operationally feasible, appropriately tailored, and

[1] *340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-NEW,* 91 Fed. Reg. 35989 (Jun. 26, 2026).

does not create unnecessary administrative burden for providers serving vulnerable patient populations. Considering that Covered Entities will ultimately be responsible for collecting, validating, submitting, and reconciling the information contemplated by the Proposed ICR, it is important that HRSA's burden estimates and reporting assumptions accurately reflect the realities of day-to-day program administration. The comments below reflect our concerns regarding (i) the lack of specificity surrounding required data elements, (ii) the continuing inconsistencies regarding future reporting obligations, and (iii) the significant administrative and technological burdens that may be imposed upon Covered Entities.

I. HRSA's Data Submission Requirements Are Not Only Ambiguous, They Are Contradictory.

One of the most significant challenges the Proposed ICR presents is that UAMS still does not know what information will ultimately be required under a future rebate model. Not only is HRSA's ambiguity contrary to the intent of the Paperwork Reduction Act, but from an operational perspective, it is difficult for UAMS to evaluate staffing needs, technology requirements, vendor support needs, or reporting burden when the specific data elements have not yet been identified.

Notably, the Proposed ICR does not contain definitions that describe the specific data elements that UAMS would be required to submit, nor does it identify any standardized format or scope for such submissions. This lack of clarity is particularly problematic because HRSA has stated in the Proposed ICR that it has not approved nor reviewed any manufacturer rebate model proposals, and therefore cannot articulate what information would actually be required under a future rebate model.[2] The only confirmation Covered Entities have received from HRSA is that it will publish manufacturer plans in the Federal Register. Further, the Proposed ICR does not offer any general description of the type of data UAMS will be required to submit. Once again, the Proposed ICR states that the type and frequency of such submissions will be published in the Federal Register notice and that the data will be "comparable to data currently maintained through third-party vendors or previously provided to manufacturers under unrelated pharmacy or claims programs."[3] This expectation is entirely speculative and ambiguous.

This ambiguity is particularly concerning because it creates a fundamental inconsistency regarding the information UAMS may eventually be required to submit. HRSA repeatedly suggests that the necessary data elements are already generated and maintained by Covered Entities or their vendors, yet simultaneously acknowledges that it has not identified the specific data elements that will be required and that those requirements will be defined in a future Federal Register notice. If the required data elements are already standardized and commonly maintained, HRSA should be able to identify them now. Conversely, if HRSA cannot identify the data elements until after manufacturer proposals are received and evaluated, then there is no basis for concluding that such information is readily available or can be produced with minimal burden. This contradiction makes

[2] *See* 91 Fed. Reg. at 35990.
[3] *Id.*

it difficult for UAMS to understand what we are being asked to prepare for and further underscores the lack of clarity surrounding the Proposed ICR.

HRSA's ambiguity and contradictory language is not entirely new. In the February 2026 ICR, Covered Entities raised similar objections regarding the inconsistencies between HRSA's claim that it would publish the standard data elements and that Covered Entities already maintained those data elements.[4] Since HRSA did not materially answer to these concerns in February, UAMS (and Covered Entities in general) remains in the same position it occupied in prior comment periods: to evaluate an information collection request without knowing what information will ultimately be collected or how such information will be used. Due to the above-mentioned ambiguities and inconsistencies, the Proposed ICR does not resolve the central uncertainty that has characterized each previous iteration of HRSA's rebate model information collection and instead perpetuates it.

This uncertainty is particularly challenging because health systems cannot build compliance processes overnight. New reporting requirements often require coordination among UAMS's own internal pharmacy department and its third party vendors. Without knowing what information will ultimately be collected, UAMS cannot meaningfully assess the resources necessary to comply nor comment on the Proposed ICR.

II. The Proposed ICR Is More Burdensome Than Necessary.

HRSA has not offered an accurate estimate of the average burden upon Covered Entities, nor has it demonstrated that it has selected the least burdensome means of collecting covered entities' information – because it cannot, for the reasons noted above. HRSA states that it employs a task-based methodology to estimate respondent burden and that its calculation accounts for "(1) identifying and extracting eligible claims data, (2) formatting and validating data to meet manufacturer specifications; (3) submitting the data; (4) reconciling submissions and tracking rebate status; and (5) addressing errors, denials, or follow-up requests."[5] Despite acknowledging the breadth of these operational functions, HRSA concludes that Covered Entities will only require approximately five hours per week to satisfy these obligations.[6]

That estimate is not—and again cannot be given the current lack of information—accompanied by sufficient explanation to permit meaningful public review. HRSA does not identify the assumptions that underlie its calculations, including the volume of expected claims transactions, the anticipated frequency of data submissions, the number of reconciliation events, the extent of staff involvement necessary to resolve disputes or denials, the processes for such disputes, or the costs associated with implementing and maintaining systems capable of complying with manufacturer reporting requirements.

To better inform HRSA and OMB of the actual burden associated with these activities, UAMS should be permitted to describe our operational experience. Accordingly, UAMS estimates that

[4] *See 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-NEW,* 91 Fed. Reg. 9632, 9633.
[5] 91 Fed. Reg. at 35990.
[6] *Id.*

compliance with claims data reporting and rebate administration requirements currently requires approximately, at a minimum, 40 to 60 hours per week. This large burden is due to large data pulls needed for several pre-existing report types. As these are separate systems, all the data will have to be gathered, sorted, filtered to the requested components, formatted to the requested specifications, tested, and submitted. All data extracts when then needed to be checked for correct ingestion into the assigned portal, with follow-up corrections as needed. The largest estimated time burden will be on the constant monitoring for incorrectly denied claims within the portal and completing the multi-step process to attempt to get these remedies. Our experience in the current MFP portal shows incorrect denials in over 40% of claims.

III. The Proposed Rebate Model May Lead to Overcharges.

On a separate note, should UAMS be required to submit claims-data under a future rebate model, it may trigger overcharges under the 340B statute. Through manufacturer all-claims policies, Covered Entities are increasingly being required to provide extensive claims-level data as a condition of accessing 340B drugs. Under these arrangements, Covered Entities are required to submit more data than is necessary for platforms such as 340B ESP to match Covered Entities' claims with manufacturer's rebate data.[7] For example, CMS's Part D repository will only require Covered Entities to submit: (i) 340B ID, (ii) Date of Service, (iii) Prescription Number, (iv) Fill number, (v) NDC-11, (vi) Dispensing Pharmacy NPI, and (vii) Claim Record Indicator. If CMS has determined that it only needs these seven data elements to remove 340B claims from its Part D inflation rebate requests, it would be highly irregular for its sister agency to require Covered Entities to disclose more or different data to a private, for-profit data aggregator.

Any such requirement would raise immediate concerns under the 340B statute's prohibition against overcharges. While manufacturers may characterize these data-submission obligations as administrative requirements rather than part of the purchase price, the practical effect would be that UAMS could not obtain the full value of the 340B discount without providing valuable claims data and absorbing the significant costs associated with maintaining and submitting that information. UAMS also will not receive compensation for either the data itself or the resources required to support these activities. As a result, a future rebate model may effectively require UAMS to provide additional consideration beyond payment of the of the 340B ceiling price in order to access the 340B discount, which would result in an overcharge.

IV. Conclusion

UAMS appreciates HRSA's efforts to gather stakeholder feedback regarding reporting requirements for a future Rebate Model Pilot Program. As an organization committed to serving patients and maintaining compliance with the 340B Program, we support efforts to develop processes that are defined, operationally feasible, and tailored to the realities Covered Entities face.

At this time, however, we believe that additional information is needed regarding the data elements that may be required, the operational structure of the of future rebate models, and the assumptions

[7] Bradley Malin, Expert's Assessment of Second Sight 340B ESP™ De-Identification Procedures for Medical Benefits Claims Data, 19 (2026).

underlying HRSA's burden estimates. We respectfully encourage HRSA to revise the Proposed ICR and provide stakeholders with additional detail before seeking final approval from OMB.

Respectfully submitted,

Brian Jolly

Digitally signed by Brian Jolly
Date: 2026.07.15 15:48:21 -05'00'

Pikeville Medical Center, Inc.

PIKEVILLE MEDICAL CENTER
911 Bypass Road, Pikeville, KY 41501 | 606-430-3500 | www.pmcky.org

July 15, 2026

VIA ELECTRONIC SUBMISSION TO
https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202606-0906-001

Ms. Samantha Miller
Health Resources and Services Administration
Information Collection Clearance Officer
5600 Fishers Lane, Room 13N82
Rockville, MD 20857

RE: Public Comment Response to HRSA's Request for Information Collection under OMB Number 0906-NEW

Dear Ms. Miller:

On behalf of Pikeville Medical Center, Inc. ("PMC"), we respectfully submit this comment regarding the proposed collection of information described in *340B Rebate Model Pilot Program Application, Implementation, and Evaluation under OMB Number 0906-NEW* ("Proposed ICR").[1] We appreciate the opportunity to provide feedback during the 30-day comment period.

As a 340B Covered Entity, PMC is particularly interested in ensuring that any future rebate model can be administered in a manner that is operationally feasible, appropriately tailored, and does not create unnecessary administrative burden for providers serving vulnerable patient populations. Considering that Covered Entities will ultimately be responsible for collecting, validating, submitting, and reconciling the information contemplated by the Proposed ICR, it is important that HRSA's burden estimates and reporting assumptions accurately reflect the realities of day-to-day program administration. The comments below reflect our concerns regarding (i) the lack of specificity surrounding required data elements, (ii) the continuing inconsistencies regarding future reporting obligations, and (iii) the significant administrative and technological burdens that may be imposed upon Covered Entities.

I. HRSA's Data Submission Requirements Are Not Only Ambiguous, They Are Contradictory.

[1] *340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-NEW*, 91 Fed. Reg. 35989 (Jun. 26, 2026).

One of the most significant challenges the Proposed ICR presents is that PMC still does not know what information will ultimately be required under a future rebate model. Not only is HRSA's ambiguity contrary to the intent of the Paperwork Reduction Act, but from an operational perspective, it is difficult for PMC to evaluate staffing needs, technology requirements, vendor support needs, or reporting burden when the specific data elements have not yet been identified.

Notably, the Proposed ICR does not contain definitions that describe the specific data elements that PMC would be required to submit, nor does it identify any standardized format or scope for such submissions. This lack of clarity is particularly problematic because HRSA has stated in the Proposed ICR that it has not approved nor reviewed any manufacturer rebate model proposals, and therefore cannot articulate what information would actually be required under a future rebate model.[2] The only confirmation Covered Entities have received from HRSA is that it will publish manufacturer plans in the Federal Register. Further, the Proposed ICR does not offer any general description of the type of data PMC will be required to submit. Once again, the Proposed ICR states that the type and frequency of such submissions will be published in the Federal Register notice and that the data will be "comparable to data currently maintained through third-party vendors or previously provided to manufacturers under unrelated pharmacy or claims programs."[3] This expectation is entirely speculative and ambiguous.

This ambiguity is particularly concerning because it creates a fundamental inconsistency regarding the information PMC may eventually be required to submit. HRSA repeatedly suggests that the necessary data elements are already generated and maintained by Covered Entities or their vendors, yet simultaneously acknowledges that it has not identified the specific data elements that will be required and that those requirements will be defined in a future Federal Register notice. If the required data elements are already standardized and commonly maintained, HRSA should be able to identify them now. Conversely, if HRSA cannot identify the data elements until after manufacturer proposals are received and evaluated, then there is no basis for concluding that such information is readily available or can be produced with minimal burden. This contradiction makes it difficult for PMC to understand what we are being asked to prepare for and further underscores the lack of clarity surrounding the Proposed ICR.

HRSA's ambiguity and contradictory language is not entirely new. In the February 2026 ICR, Covered Entities raised similar objections regarding the inconsistencies between HRSA's claim that it would publish the standard data elements and that Covered Entities already maintained those data elements.[4] Since HRSA did not materially answer to these concerns in February, PMC (and Covered Entities in general) remains in the same position it occupied in prior comment periods: to evaluate an information collection request without knowing what information will ultimately be collected or how such information will be used. Due to the above-mentioned ambiguities and inconsistencies, the Proposed ICR does not resolve the central uncertainty that has characterized each previous iteration of HRSA's rebate model information collection and instead perpetuates it.

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[2] *See* 91 Fed. Reg. at 35990.
[3] *Id.*
[4] *See 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-NEW*, 91 Fed. Reg. 9632, 9633.

This uncertainty is particularly challenging because health systems cannot build compliance processes overnight. New reporting requirements often require coordination among PMC's own internal pharmacy department and its third party vendors. Without knowing what information will ultimately be collected, PMC cannot meaningfully assess the resources necessary to comply nor comment on the Proposed ICR.

II. The Proposed ICR Is More Burdensome Than Necessary.

HRSA has not offered an accurate estimate of the average burden upon Covered Entities, nor has it demonstrated that it has selected the least burdensome means of collecting covered entities' information – because it cannot, for the reasons noted above. HRSA states that it employs a task-based methodology to estimate respondent burden and that its calculation accounts for "(1) identifying and extracting eligible claims data, (2) formatting and validating data to meet manufacturer specifications; (3) submitting the data; (4) reconciling submissions and tracking rebate status; and (5) addressing errors, denials, or follow-up requests."[5] Despite acknowledging the breadth of these operational functions, HRSA concludes that Covered Entities will only require approximately five hours per week to satisfy these obligations.[6]

That estimate is not—and again cannot be given the current lack of information—accompanied by sufficient explanation to permit meaningful public review. HRSA does not identify the assumptions that underlie its calculations, including the volume of expected claims transactions, the anticipated frequency of data submissions, the number of reconciliation events, the extent of staff involvement necessary to resolve disputes or denials, the processes for such disputes, or the costs associated with implementing and maintaining systems capable of complying with manufacturer reporting requirements.

To better inform HRSA and OMB of the actual burden associated with these activities, PMC should be permitted to describe our operational experience. Accordingly, PMC estimates that compliance with claims data reporting and rebate administration requirements currently requires approximately, at a minimum, 25.7 hours per week—more than five times HRSA's five-hour estimate, and nearly 1,335 hours annually. Based on PMC's claims volume for the pilot drugs, this burden is driven primarily by formatting and validating claims data to meet manufacturer-specific submission requirements, a process complicated by inconsistent data extraction from PMC's existing systems, as well as by managing rebate denials and disputes, where the information manufacturers and their vendors provide is frequently incomplete or inaccurate.

III. The Proposed Rebate Model May Lead to Overcharges.

On a separate note, should PMC be required to submit claims-data under a future rebate model, it may trigger overcharges under the 340B statute. Through manufacturer all-claims policies, Covered Entities are increasingly being required to provide extensive claims-level data as a condition of accessing 340B drugs. Under these arrangements, Covered Entities are required to submit more data than is necessary for platforms such as 340B ESP to match Covered Entities'

[5] 91 Fed. Reg. at 35990.
[6] *Id.*

claims with manufacturer's rebate data.[7] For example, CMS's Part D repository will only require Covered Entities to submit: (i) 340B ID, (ii) Date of Service, (iii) Prescription Number, (iv) Fill number, (v) NDC-11, (vi) Dispensing Pharmacy NPI, and (vii) Claim Record Indicator. If CMS has determined that it only needs these seven data elements to remove 340B claims from its Part D inflation rebate requests, it would be highly irregular for its sister agency to require Covered Entities to disclose more or different data to a private, for-profit data aggregator.

Any such requirement would raise immediate concerns under the 340B statute's prohibition against overcharges. While manufacturers may characterize these data-submission obligations as administrative requirements rather than part of the purchase price, the practical effect would be that PMC could not obtain the full value of the 340B discount without providing valuable claims data and absorbing the significant costs associated with maintaining and submitting that information. PMC also will not receive compensation for either the data itself or the resources required to support these activities. As a result, a future rebate model may effectively require PMC to provide additional consideration beyond payment of the of the 340B ceiling price in order to access the 340B discount, which would result in an overcharge.

IV. Conclusion

PMC appreciates HRSA's efforts to gather stakeholder feedback regarding reporting requirements for a future Rebate Model Pilot Program. As an organization committed to serving patients and maintaining compliance with the 340B Program, we support efforts to develop processes that are defined, operationally feasible, and tailored to the realities Covered Entities face.

At this time, however, we believe that additional information is needed regarding the data elements that may be required, the operational structure of the of future rebate models, and the assumptions underlying HRSA's burden estimates. We respectfully encourage HRSA to revise the Proposed ICR and provide stakeholders with additional detail before seeking final approval from OMB.

Respectfully submitted,

Signed by:
Michelle Hagy
FE5394A6AFBE42E...

Michelle Hagy
EVP/Chief Financial Officer

[7] Bradley Malin, Expert's Assessment of Second Sight 340B ESP™ De-Identification Procedures for Medical Benefits Claims Data, 19 (2026).

Public Comments for ICR 202606-0906-001

Author Full Name : Michelle Hagy **Received Date :** 07/15/2026 05:42 PM

Comments Received :

Pikeville Medical Center, Inc. submits this comment to highlight that HRSA's burden estimate for the proposed 340B Rebate Model Pilot Program ICR is significantly understated. Based on PMC's own operational data, compliance would require approximately 25.7 hours per week—over five times HRSA's estimate—due to claims data formatting, submission, and rebate dispute management. Full details are provided in the attached letter.

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SUBMITTED VIA EMAIL (paperwork@hrsa.gov)

April 20, 2026

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

Re: Johnson & Johnson Health Care Systems Inc. Comments on Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906-NEW

Dear Administrator Engels:

I write on behalf of Johnson & Johnson Health Care Systems Inc. ("J&J") in response to the Health Resources & Services Administration ("HRSA") Request for Information: 340B Rebate Model Pilot Program (HHS Docket No. HRSA-2026-03042) (the "RFI")[1] and the accompanying Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation ("ICR").[2] J&J appreciates the opportunity to provide feedback regarding the RFI and ICR.

J&J has sought to work transparently and constructively with HRSA on implementation of a rebate model since July 2024. Most recently, in September 2025, J&J submitted comments in response to HRSA's announcement of the application process for the initial 340B Rebate Model Pilot Program ("Pilot"),[3] and HRSA approved J&J's application for initial price applicability year ("IPAY") 2026 drugs STELARA®[4] and XARELTO®. J&J planned to participate in the Pilot until HRSA terminated the program earlier this year pursuant to a court order. Although J&J maintains that the 340B statute authorizes manufacturers to implement rebate models without HRSA's prior approval, we nevertheless commend HRSA for re-starting the pilot process and seeking stakeholder input on a new 340B rebate model pilot program. HRSA's support for a rebate model offers a practical mechanism that allows manufacturers to more effectively deduplicate discounts and address ongoing 340B program integrity concerns. We welcome the opportunity to contribute to the success of a rebate model pilot program and support its expansion to all covered outpatient drugs and broader use for 340B Program compliance purposes.

Since 2024, J&J has corresponded extensively with HRSA regarding the use of a rebate model and J&J's attempts to conduct statutorily authorized audits of various covered entities due to documented concerns of potential diversion and duplicate discounting. Although HRSA approved our audit requests and associated work plans nearly two years ago, we continue to encounter substantial resistance from certain covered entities, causing those audits to remain incomplete and to result in extraordinary expense, despite the fact that covered entity compliance with HRSA-approved manufacturer audits is a condition of

[1] Request for Information: 340B Rebate Model Pilot Program, 91 Fed. Reg. 7287 (Feb. 17, 2026).
[2] 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–NEW, 91 Fed. Reg. 9632 (Feb. 26, 2026).
[3] 90 Fed. Reg. 38165 (Aug. 7, 2025).
[4] We note that J&J's drug USKETINUMAB (unbranded STELARA) is a selected drug for IPAY 2026 and would also be included in a pilot covering IPAY 2026 selected drugs if J&J's rebate model plan were to be approved.

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participation in the 340B Program.[5] Our experience with the audit process reinforces the need for a rebate model.

Below we have provided our comments in response to the RFI. **Section I** outlines J&J's advocacy efforts regarding a rebate model, frustrated pursuit of HRSA-approved covered entity audits, and initial participation in the Pilot. **Section II** describes the 340B Program's widespread issues with abuse, including duplicate discounting, diversion, the replenishment model, and covered entity audits. Sections III and IV respond to HRSA's questions raised in the RFI. **Section III** outlines how a rebate model would address program integrity concerns, including through real-time claim and program reporting. In conclusion, **Section IV** clarifies the limited impact a rebate model would have on covered entities.

I. J&J's Advocacy for a Rebate Model, Frustrated Audit Efforts, and Participation in HRSA's Initial Pilot.

Since 2024, J&J has advocated for a 340B rebate model that would support program integrity and facilitate deduplication of discounts under Section 340B and the Medicare Drug Price Negotiation Program ("MDPNP") created by the Inflation Reduction Act ("IRA").[6] J&J first proposed a rebate model for sales to Disproportionate Share Hospital ("DSH") covered entities of its two IRA-selected drugs (STELARA and XARELTO) in mid-2024, explaining that the deduplication procedure directed by the IRA presented serious logistical hurdles that a rebate model would best address.

J&J's advocacy for a rebate model proceeded alongside its efforts to conduct a series of HRSA-approved audits of covered entities. For nearly two years, however, J&J has faced fervent resistance from several covered entities, making clear that audits are not an adequate means to address longstanding program integrity concerns.

a. J&J's Pre-Pilot Advocacy for a 340B Rebate Model

J&J's interest in pursuing a 340B rebate model arose from concerning trends it observed in the volume of purchases of its products at 340B prices. Across its portfolio, purchases of J&J's drugs at 340B prices have increased at least twice as fast as its overall sales, and 340B purchases of certain of its products increased even faster. For example, from the second quarter of 2023 to the second quarter of 2024, 340B purchases of STELARA increased by 56%—about five times as fast as STELARA's overall sales. Likewise, 340B purchases of XARELTO increased by 33%—about eight times as fast as XARELTO's overall sales. These significant increases in 340B sales occurred even though the population of patients either uninsured or living in poverty—the patients who should be benefiting from 340B discounts—has actually declined by almost half, from 15.7% of the U.S. population in 2013 to 8.7% in 2021.[7] These aberrant purchasing patterns were a key factor that prompted J&J to pursue covered entity audits and to consider a rebate model.

J&J first met with HRSA to discuss 340B rebate models in mid-2024, explaining that under the current structure of the 340B Program, it has little to no visibility into the claims-level data necessary to validate 340B claims—in particular, whether covered entities are unlawfully causing duplicate discounts on 340B-priced drugs. Offering the 340B price through a rebate, J&J explained, would improve the integrity

[5] 42 U.S.C. § 256b(a)(5)(C).
[6] Pub. L. No. 117-169, 136 Stat. 1818 (2022).
[7] *See* Rory Martin et al., IQVIA, *Unintended Consequences: How the Affordable Care Act Helped Grow the 340B Program*, at 8 (Aug. 30, 2024), https://bit.ly/3XFDWh8.

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of the 340B Program by helping to mitigate the risk of duplicate discounts, which HRSA's own audits demonstrate occur frequently year after year.[8]

J&J also described the challenges it faced in attempting to comply with its obligations under the IRA's MDPNP. Under the IRA, covered entities are entitled to the lesser of the 340B price or the maximum fair price ("MFP") for drugs selected for "negotiation" by CMS. For calendar year 2026, this includes two J&J products, STELARA and XARELTO. Because the IRA's nonduplication provision protects manufacturers from providing both the 340B ceiling price and the "MFP" on the same drug unit and requires manufacturers to make this determination within 14 days of the transaction, effectuating the "MFP" requires manufacturers to identify when 340B-priced drugs are dispensed to Medicare beneficiaries in real-time. However, CMS had not yet (and to date, still has not) developed a mechanism that would enable manufacturers to identify 340B-eligible "MFP" claims. Offering the 340B price through a rebate, J&J explained, would be the most effective means for J&J to fill the gap left by CMS, enabling J&J to identify Medicare claims in real-time and comply with the IRA's nonduplication requirement.

In light of these challenges, J&J informed HRSA that it was contemplating a shift to a rebate model. Under the model, DSH covered entities—which J&J's data showed were particularly prone to abuse—would acquire STELARA and XARELTO from wholesalers at commercial prices and then receive a rebate to realize the 340B ceiling price promptly after submitting commercially standard claims data, which could occur before payment is due under standard wholesaler terms. J&J stressed that the rebate model would utilize standard claims data that covered entities already collect in the normal course of business, retain for 340B compliance purposes, and submit to payers in the reimbursement process.

After further correspondence between J&J and HRSA, however, HRSA concluded that Section 340B grants HRSA authority to require its pre-approval before a manufacturer may adopt a rebate model and warned J&J that penalties for proceeding with an unapproved rebate model could include termination from the program. HRSA provided similar responses to other manufacturers that proposed their rebate models. Faced with the threat of termination, J&J paused its plan to implement a rebate model and brought litigation against HRSA. That case, along with other cases brought by other manufacturers, remains pending before the U.S. Court of Appeals for the District of Columbia Circuit.

b. J&J's Stymied Audits of Covered Entities

In parallel with its efforts to adopt a limited-scope rebate model, J&J sought and obtained HRSA's approval to conduct audits of a dozen covered entities. Instead of cooperating with the duly authorized audits—as the 340B statute required them to do[9]—many of the covered entities resisted, obfuscated, and delayed. Six of the covered entities filed suit against HRSA seeking to halt the audits altogether. All six suits were dismissed.[10]

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[8] *See* U.S. Gov't Accountability Off., GAO-21-107, *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, at 13–14 (Dec. 14, 2020), https://www.gao.gov/assets/gao-21-107.pdf (finding nearly 35% of HRSA's 2012-2019 audits resulted in a finding of duplicate discounting, and 44% resulted in a finding of diversion); *see also* HRSA, Program Integrity: FY22 Audit Results, https://www.hrsa.gov/opa/program-integrity/fy-22-audit-results (last updated Feb. 23, 2026) (finding duplicate discounts at nearly two dozen of the 199 covered entities HRSA audited in 2022); HRSA, Program Integrity: FY23 Audit Results, https://www.hrsa.gov/opa/program-integrity/fy-23-audit-results (last updated Mar. 30, 2026) (finding duplicate discounts at nearly two dozen of 176 entities audited in 2023); HRSA, Program Integrity: FY24 Audit Results, https://www.hrsa.gov/opa/program-integrity/fy-24-audit-results (last updated Mar. 30, 2026) (finding duplicate discounts at nearly two dozen of the 179 entities audited in 2024); HRSA, Program Integrity: FY25 Audit Results, https://www.hrsa.gov/opa/program-integrity/fy-25-audit-results (last updated Mar. 30, 2026) (finding duplicate discounts at nearly two dozen of the 115 entities with completed audits conducted in 2025).

[9] 42 U.S.C. § 256b(a)(5)(C).

[10] *Or. Health & Sci. Univ. v. Engels*, No. 24-cv-2184, 2025 WL 1707630 (D.D.C. Jun. 17, 2025).

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Even now, *two years* after J&J began its good-faith outreach to covered entities and almost one year since the district court dismissed their lawsuits, some of the entities that brought suit continue to resist J&J's audits—despite multiple reminders from HRSA that they are required to comply as a condition of their 340B Program eligibility. These covered entities have developed a playbook to vitiate J&J's rights by dramatically increasing the costs and time required even to *initiate* an audit, let alone complete one and take any disputes to administrative dispute resolution ("ADR").

Moreover, even when audits can be effectively conducted, they serve a different purpose than rebate models. Audits are backward-looking and cannot ensure future compliance; they address only a narrow subset of historical claims; they can take months or, in our experience, years to complete; they can be conducted only for a handful of entities per year at most; and they do not require covered entities to address the full scope of identified noncompliance or revise the policies or procedures that led to any identified violations. As a result—and especially in light of covered entities' ability to resist them without apparent consequence—audits are a profoundly inefficient and ineffective tool for addressing program abuse and only serve to reinforce the need for a rebate model.

c. HRSA's 340B Rebate Model Pilot Program and J&J's IRA Compliance Without a Rebate Model

J&J appreciates HRSA's willingness to explore practical solutions to ensure greater program integrity and address challenges manufacturers face in implementing their overlapping statutory obligations. J&J was prepared to participate in the initial Pilot after HRSA approved its application and applauded HRSA for taking an important first step toward structured and transparent rebate models. J&J is pleased to share responses to the questions posed in HRSA's RFI, along with related information that J&J believes will be useful as HRSA considers the potential for another rebate model pilot.

Without a rebate model, J&J has been grappling with its limited ability to implement the deduplication provisions of the IRA since the "MFP" became effective on January 1, 2026. J&J has relatively little access to real-time data needed to deduplicate 340B and "MFP" discounts consistent with its obligations under the IRA. Without the claims data that a rebate model would make available for all "MFP" claims across all covered entities, J&J must rely on limited and imperfect data and analytics to reasonably identify units of STELARA or XARELTO dispensed to Medicare Part D beneficiaries that were eligible for 340B pricing. This is, in part, because J&J's current contract pharmacy policy applies only to hospital covered entities, many of which have opted out and submit no data to J&J. As of this time, a very limited subset of dispensing entities self-identify 340B-eligible "MFP" claims to J&J. To date, pharmacies have classified "fewer than 0.5 percent of "MFP" claims" as 340B, despite estimates suggesting 10% to 12% of "MFP" claims are 340B.[11] In the absence of a mechanism to identify all 340B-eligible "MFP" claims, J&J estimates that it faces increased risk of paying duplicate discounts on up to 40% to 50% of 340B-eligible "MFP" claims and estimates that it has already paid approximately $80 million in duplicate discounts on 340B-eligible "MFP" claims for STELARA and XARELTO since January 1, 2026.

[11] BRG, Update on Effectuation of the Maximum Fair Price in 2026 and Outlook for 2027, at 2 (Apr. 2026), https://media.thinkbrg.com/wp-content/uploads/2026/04/03101442/Effectuation-of-the-Maximum-Fair-Price-in-2026-and-Outlook-to-2027.pdf.

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II. The 340B Program Suffers from Pervasive Program Integrity Abuse.

The 340B Program is rife with abuse and has increasingly operated beyond its narrow statutory purpose. The legislative history of the 340B statute confirms the program's intent: to "reduce pharmaceutical costs for safety-net medical providers and the indigent populations they serve."[12] Over time, however, the Program has expanded in scope and complexity without necessary guardrails or transparency. This expansion has contributed to persistent compliance concerns, including duplicate discounts between Medicaid and 340B, diversion of discounted drugs to ineligible individuals, and the inability to verify program integrity in a timely manner. This section discusses these concerns in more detail.

a. Duplicate Discounting is Widespread Under the 340B Program.

Covered entities may receive improper duplicate discounts in two ways. *First*, the 340B statute expressly prohibits a covered entity from obtaining a 340B discount on the same units of a covered outpatient drug that generate a Medicaid rebate.[13] Despite this prohibition and well documented risks of manufacturers paying duplicate discounts, manufacturers are significantly limited in their ability to access Medicaid and 340B claims data to prevent duplicate discounts. With respect to accessing 340B claims data, we note that J&J's 340B contract pharmacy policy currently applies only to hospital covered entities (*i.e.*, it excludes grantee covered entities) that opt to submit claims data to 340B ESP, and, even then, only to self-administered drugs that were billed through pharmacy claims. On the Medicaid side, only a subset of states currently provide J&J access to Medicaid claims data that allows for matching against 340B claims to identify potential duplicate claims. Notwithstanding these data limitations, J&J analyzed 340B claims that hospital covered entities submitted to the ESP platform for the most recent nearly three-year period and found more than 16,500 340B claims that were potentially duplicated with Medicaid rebate claims. This amounted to more than $22.4 million in potentially duplicated Medicaid rebate requests during the period. Given the data limitations described above, this estimate likely dramatically understates the true scope of J&J's potential Medicaid duplicate discount exposure.

More broadly, however, a 2020 report issued by the Government Accountability Office ("GAO") found that, in the 1,242 audits HRSA conducted from fiscal years 2012 through 2019, HRSA had identified 429 findings related to duplicate discounts.[14] In other words, nearly 35% of HRSA's audits found evidence of prohibited duplicate discounting. More concerningly, both HRSA and J&J have an even more limited ability to identify (and no means to prevent) duplicate discounts in the Medicaid managed care context—which is the primary drug coverage mechanism for Medicaid beneficiaries—even though duplicate discounting in this context may be even more widespread.[15] In 2019, when the 340B program was less than half its current size, it was estimated that industry-wide Medicaid/340B duplicate discounts amounted to as much as $1.5 billion annually.[16] This duplicate discount risk persists despite the 340B statute expressly obligating the Secretary of HHS to "develop[]…more detailed guidance describing methodologies and options available to covered entities for billing covered outpatient drugs to State Medicaid agencies in a manner that avoids duplicate discounts…."[17]

Second, as discussed above, although the IRA states that a manufacturer is protected from providing access to the "MFP" for a selected drug to a 340B covered entity when the 340B ceiling price is lower than

[12] H.R. Rep. 102-384, pt. II, at 10–12 (1992).
[13] 42 U.S.C. § 256b(a)(5)(A).
[14] U.S. Gov't Accountability Off., GAO-21-107, *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, at 14 (Dec. 14, 2020), https://www.gao.gov/assets/gao-21-107.pdf.
[15] *Id.*
[16] Kalderos, Making Health Policy Work for Patients (2021), https://f.hubspotusercontent40.net/hubfs/7227094/2021%20Annual%20Report/Annual_report_2021.pdf.
[17] 42 U.S.C. § 256b(d)(2)(B)(iii).

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the "MFP",[18] no mechanism exists that would permit a manufacturer to verify whether the same unit of drug is subject to both 340B and "MFP" discounts. The magnitude of duplicate discount risk resulting from the absence of a deduplication mechanism is significant. As of April 2026, pharmacies have classified "fewer than 0.5 percent of "MFP" claims" as 340B through either CMS or Beacon MFP mechanisms. An analysis of Medicare Part D PDE data suggests 10% to 12% of "MFP" claims should be identified as 340B. This translates to "fewer than 5 percent of 340B claims [being] self-identified as such by pharmacies."[19] J&J's experience is similar. In early March 2026, J&J observed that fewer than 0.4% of "MFP" claims for its selected drugs were being self-identified as 340B. This dramatically poor rate improved to only 0.5% in April 2026 after J&J sent a communication to all MTF-registered dispensing entities reminding them of their obligation to submit accurate claims and providing instructions for self-identifying 340B-eligible "MFP" claims in Beacon MFP.

Additionally, based on one early report, in the first 30 days after the "MFP" went into effect, only 60% of "MFP" claims were properly processed.[20] Of the 40% of claims processed incorrectly, the report showed that "30% of total claims experienced duplicate payments, in which manufacturers paid both "MFP" and 340B pricing on the same transaction. The average dollar value per duplicate payment was $398…."[21] These error rates translate into substantial and avoidable financial exposure for manufacturers and highlight the need for more reliable, real-time mechanisms to ensure that only one statutory discount applies to a given claim.

J&J faces significant challenges in identifying duplicate discounts under the 340B Program. The third-party data sources available to J&J provide only retrospective transactional information, which does not allow J&J to prevent duplicate discounts at the point of sale. Compounding this problem, there is no universal data source that reliably identifies the 340B status of an individual claim. Most covered entities currently do not provide claims-level data to J&J. And, even where such data is available, it is often incomplete, inaccurate, or obsolete, making it difficult to reconcile with other rebate and utilization data. These challenges are further compounded by the "MFP's" timing requirements, under which J&J must provide access to the "MFP" on a selected drug dispense within 14 days.

When J&J is able to identify an improper 340B duplicate discount, the process for recouping those amounts is burdensome, inefficient, and often unsuccessful. State Medicaid agencies frequently direct us to seek repayment from the covered entity, rather than refunding the associated Medicaid rebate. The covered entity, on the other hand, often directs us to the state Medicaid agency. As a result, because CMS does not require states to implement clear Medicaid managed care guidelines addressing use of 340B drugs,[22] and because HRSA does not require covered entities to address identified duplicate discounts in Medicaid managed care and work with manufacturers to repay them,[23] recoupment of these duplicates, if identified, is often unsuccessful.

[18] Social Security Act § 1193(d)(1).
[19] BRG, Update on Effectuation of the Maximum Fair Price in 2026 and Outlook for 2027, at 2 (Apr. 2026), https://media.thinkbrg.com/wp-content/uploads/2026/04/03101442/Effectuation-of-the-Maximum-Fair-Price-in-2026-and-Outlook-to-2027.pdf.
[20] 340B Report, 40% of Claims Miss the Mark (Mar. 5, 2026), https://340breport.com/40-of-claims-miss-the-mark-sponcon-rxparadigm/.
[21] *Id.*
[22] U.S. Gov't Accountability Off., GAO-20-212, *340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement*, at 28 (Jan. 27, 2020), https://www.gao.gov/products/gao-20-212.
[23] *Id.* at 26.

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b. The Current 340B Program Structure Undermines Manufacturers' Ability to Prevent Diversion.

The 340B statute prohibits the resale or transfer of drugs at the 340B ceiling price to any person who is not an eligible patient of the purchasing covered entity, a practice commonly referred to as "diversion." HRSA's 1996 guidance defines a patient as having (i) an established relationship with the covered entity, including that the covered entity maintains the individual's healthcare records; (ii) the health care professional is either employed, contracted, or has another arrangement with the covered entity (*e.g.*, referral for consultation) such that responsibility for the care provided remains with the covered entity; and (iii) for grantee covered entities, the care provided is consistent with the scope of services for which the covered entity receives grant funding.[24] HRSA's 1996 guidance does not consider an individual "a 'patient' of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting."[25]

The 340B Program has experienced significant diversion concerns, as repeatedly confirmed by HRSA's audit findings.[26] In particular, as a result of replenishment systems adopted by covered entities, 340B eligibility is now determined long after the product dispense. Replenishment systems work in one of two ways. First, under product replenishment, a pharmacy initially purchases a drug from a wholesaler at a commercial price, places it in neutral inventory, and then dispenses the product to patrons of the pharmacy. The covered entity or its third-party administrator ("TPA") later will determine—weeks or even months after the dispense—that the patient was (according to them) a patient of the covered entity. The pharmacy then receives a replacement unit purchased by the covered entity at the 340B price and the manufacturer pays a chargeback to make the distributor whole. Second, under what is called "credit-based" replenishment, the process is essentially the same, except that, instead of receiving a new unit of the product to replace the unit dispensed to a 340B patient, the wholesaler performs a series of financial transactions that are not transparent to the manufacturer to effectuate 340B pricing without the physical distribution of drugs. While these models differ by wholesaler, they often result in (i) the pharmacy receiving a credit to its wholesale acquisition cost ("WAC") account on an invoice for drugs it previously purchased, and (ii) the covered entity being invoiced for those previously purchased drugs at the 340B price with a chargeback issued to the manufacturer.

Under either approach, the records associated with the drug dispense or administration to the (purported) covered entity patient do not identify 340B eligibility. Rather, the eligibility determination is made only after the covered entity or its TPA acts—weeks or even months following the dispense or administration. The chargeback invoice to the manufacturer requiring the 340B discount is disconnected from the dispense/administration records, therefore creating a lack of visibility into the patient eligibility assessment. And, although manufacturers are allowed to audit covered entities to assess compliance with the statutory duplicate discounting and diversion prohibitions, that process has proven ineffective for the reasons explained above and, in any event, does not allow manufacturers to audit contract pharmacies or TPAs, where much of the evidence concerning patient eligibility is housed.

Under this current opaque system that covered entities have created, most diversion can run rampant with virtually no visibility or means of detection. However, using the limited 340B claims data J&J has received from certain hospitals participating in its contract pharmacy policy, for the most recent three-year period, J&J identified more than 10,200 duplicate 340B claims submitted by distinct covered

[24] 61 Fed. Reg. 55156, 55157–58 (Oct. 24, 1996).
[25] 61 Fed. Reg. at 55158.
[26] HRSA, Program Integrity: FY25 Audit Results (last updated Mar. 30, 2026), https://www.hrsa.gov/opa/program-integrity/fy-25-audit-results.

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entities (*i.e.*, where multiple covered entities claimed 340B pricing on the same drug dispense/administration). Despite guidance stating that only one covered entity is permitted to receive 340B pricing on a single drug dispense or administration,[27] J&J's limited data clearly shows that covered entities' use of overbroad patient definitions and expansive contract pharmacy networks are causing unlawful diversion – on a likely much larger scale – that a rebate model would identify and prevent.

More broadly, in the GAO report referenced above, GAO found that HRSA made 546 findings related to diversion, meaning over 40% of HRSA's audits found that covered entities were dispensing 340B drugs to non-patients.[28] J&J does not have the data necessary to combat all instances of diversion, which manufacturers can only collect from covered entities. Indeed, J&J has been prevented from obtaining such data,[29] including from covered entities, even where J&J has reasonable cause to suspect 340B noncompliance and has secured HRSA approval to conduct an audit.[30] A rebate model can mitigate this serious problem.

III. A Rebate Model Will Improve Program Integrity.

A rebate model offers a practical and effective framework for strengthening program integrity and improving compliance within the 340B Program. By requiring standardized reporting of pharmacy claims, medical claims, and purchase data, a rebate model would enhance transparency, enable timely validation of 340B eligibility, and support more effective oversight. This approach represents the most viable means of delivering the real-time data necessary to prevent noncompliance while preserving program functionality. Consistent with these objectives, J&J supports manufacturer-required reporting mechanisms that are essential to demonstrating and operationalizing a rebate model in practice.

Below we respond to the following questions that HRSA sets forth in the RFI: Question 1, Costs to Covered Entities; Question 3, Rebate Denials; Question 5, Manufacturer Efforts to Avoid Duplicate Discounting; Question 6, Required Reporting; and Question 7, 340B Program Integrity and other Potential Benefits of a Rebate Pilot.

a. HRSA Should Not Limit the Types of Covered Entities that Participate in the Rebate Model.

The RFI requests that covered entities "[i]dentify any organization-specific factors that could impact your organization's ability to participate in a potential 340B Rebate Model Pilot Program (e.g., rural, small business, community health center)."[31] HRSA should not limit a rebate model pilot to certain covered entity types. J&J assumes the purpose of a pilot would be to "test" the feasibility of rebates with a limited set of drugs. Excluding certain covered entities from a pilot would frustrate this purpose by depriving HRSA and stakeholders of the ability to assess the viability of rebate models across the 340B program.

Additionally, implementing a rebate model for only a subset of covered entities, and allowing non-participating covered entities to continue purchasing all 340B drugs at up-front discounts, would create considerable operational complexity across the pharmaceutical supply chain and introduce new 340B

[27] 340B Prime Vendor Program. (September 30, 2020). FAQ ID: 1599. 340B Patient Definition. Available at: https://www.340bpvp.com/search#tab=faq&cf-p_faq_category_hierarchy=Policy/Implementation.Patient%20Definition.
[28] U.S. Gov't Accountability Off., GAO-21-107, *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, at 14 (Dec. 14, 2020), https://www.gao.gov/assets/gao-21-107.pdf.
[29] *Pharm. Rsch. & Mfrs. of Am. v. McCuskey et al.*, No. 25-1054, --- F.4th ----, 2026 WL 898259, at *11 (4th Cir. Mar. 31, 2026) (stating that if manufacturers are prohibited from obtaining claims data from covered entities, they lack the ability to identify potential diversion).
[30] *See, e.g., Or. Health & Sci. Univ. v. Engels*, No. 24-cv-2184, 2025 WL 1707630 (D.D.C. Jun. 17, 2025).
[31] 91 Fed. Reg. at 7289.

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compliance risks. While it is difficult to identify the universe of 340B compliance risks that could flow from a bifurcated rebate model approach, such risks include, for example: (i) a single health system may own facilities designated as different covered entity types, which provides the opportunity for the covered entity to circumvent rebate model application, and (ii) pharmacies may dispense 340B drugs for both participating and non-participating covered entities, creating even greater inventory management complexity that increases the risk of 340B statutory violations.

Furthermore, excluding certain covered entity types from a pilot would leave manufacturers with no reliable access to 340B claims data to deduplicate 340B/"MFP" and 340B/Medicaid discounts for these entity types. This would require implementation of one or more alternatives to allow manufacturers to access 340B claims information; however, those alternatives would be less effective than a rebate model (see Section III.c.iii. below), and simultaneous use of these alternatives alongside a rebate model would create considerable complexity and burden for all stakeholders. In August 2024, J&J sought to implement a limited scope rebate model that included only DSH covered entities, partly in anticipation of the need to deduplicate 340B and "MFP" discounts for all covered entities beginning January 1, 2026. Following hospital litigation challenging and ultimately thwarting the Pilot, there is no longer time to implement a rebate model in such a stepwise fashion. Since 340B and "MFP" discounts must be deduplicated across all covered entities, a rebate model pilot should apply to all covered entities.

Finally, the 340B statute does not expressly define "rural," which has allowed large urban hospitals to qualify as rural hospitals (*e.g.*, Cleveland Clinic, Northwestern Memorial Hospital).[32] Uniform application of the rebate model pilot across covered entity types will enable HRSA to comprehensively assess the benefits and burdens of a rebate model, and thus will result in better-informed findings at the end of the pilot.

b. Manufacturers Should Be Permitted to Deny Ineligible Rebate Claims Under Specified Circumstances (RFI Question 3).

In Question 3, HRSA asks stakeholders to consider whether a rebate model should contain specific guardrails that govern rebate denials and, if applicable, to describe what should be required to deny a rebate claim.[33] Manufacturers should be permitted to deny ineligible rebate claims for specified reasons. In that circumstance, manufacturers should provide supporting documentation that includes the rationale for the denial. Potential reasons for denials could include:

- **Ineligible National Drug Code ("NDC")**: The NDC is not part of the rebate model pilot program or the NDC expired more than a year before the date of dispense.
- **Ineligible date of dispense**: Claims with a date of dispense prior to the beginning of the rebate model pilot should not be eligible for a rebate, with the exception of a limited number of unreplenished 340B dispenses or administrations occurring prior to the pilot initiation.
- **Invalid user**: A user attempts to submit rebate data for a covered entity for which it is not an authorized representative.
- **Invalid data types**: Data submitted for a given field do not match the data format expected for that field (*e.g.*, an NDC is present within a date field).

[32] HRSA, Office of Pharmacy Affairs, 340B OPAIS, *Search Covered Entities*, https://340bopais.hrsa.gov/SearchCe (last visited Apr. 9, 2026).
[33] 91 Fed. Reg. at 7290.

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- **Invalid data values**: Prescriber or pharmacy National Provider Identifier ("NPI") does not align with accepted structure for an NPI; the prescriber NPI is not an active, individual healthcare provider; or the pharmacy NPI is not an active, organizational healthcare provider. Additionally, for NDCs that are only eligible for dispense through a limited distribution network ("LDN"), a rebate may be denied if it reflects dispense by a pharmacy NPI that is outside of the LDN.

- **Missing data**: One or more HRSA-required fields is not populated.

- **No Active HRSA Registration**: Location of dispense or administration is not actively registered with HRSA and active as of the date of dispense.

- **Duplicative rebate**: The same claim cannot be submitted more than once for a 340B rebate, either by the same covered entity or multiple covered entities.

- **Late submission**: A claim generally cannot be submitted for a 340B rebate after a certain period of time has passed since the date of dispense or administration. The 2025 Pilot utilized 45 days, and J&J provided for case-by-case exceptions due to covered entity operational extenuating circumstances.

- **No WAC purchase**: HRSA should require that covered entities only request 340B rebates for units they purchased at the WAC price. A rebate may be denied if there is no evidence of a WAC purchase.

- **Pricing not available (orphan drug)**: Offering the 340B price to certain covered entity types on orphan drugs is voluntary for manufacturers. A rebate may be denied in instances where the manufacturer does not offer this voluntary pricing.

- **Pricing not available (contract pharmacy)**: Only certain contract pharmacies may be eligible for a 340B rebate according to the manufacturer's contract pharmacy policy.

- **Aberrant quantity**: Claims with dispensed or administered units that exceed a certain threshold for reasonable volume may be denied. This check is designed to catch instances where a user inadvertently keys in an incorrect unit value or uses an incorrect unit conversion rate. If not denied, these instances could result in a rebate payment that is excessive for the volume of drug actually dispensed or administered.

To deny a rebate claim, manufacturers should establish fully transparent validation guidelines so that covered entities can validate their own claims prior to submission, thereby curtailing the need for denials. Compliance with HRSA's design specifications for manufacturer validations should limit the need for HRSA involvement in denied claims. The Beacon platform, operated by Second Sight Solutions, LLC ("Second Sight Solutions"), would provide robust support services to help covered entity users understand denial codes and to correct any incomplete or inaccurate data. When a denial does occur, the rebate model platform would communicate the specific reason for the denial and would allow covered entities to resubmit corrected claims, which J&J would not treat as duplicate submissions.

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c. The Rebate Model Should Require Pharmacy Claims, Medical Claims, and Purchase Data Elements (RFI Question 5).

Question 5 asks manufacturers to identify required data elements to detect potential duplicate discounts across the 340B Program and CMS payment programs.[34] To operate an effective rebate model, J&J believes three categories of data are necessary: pharmacy claims data, medical claims data, and purchase data. J&J agreed with HRSA's decision to include both pharmacy and medical claims data in the Pilot and urges HRSA to include that data in a future pilot program and add purchase data.

i. Pharmacy and Medical Claims Data Are Critical to a Rebate Model.

Although "MFP" effectuation is currently limited to pharmacy claims for IPAY 2026 and 2027 selected drugs, certain selected drugs still may be administered in the medical benefit portion of a patient's insurance. For example, approximately 10% of STELARA purchases are provider-administered. Similarly, XARELTO may be administered in an outpatient setting (*e.g.*, emergency department, in connection with outpatient surgery). J&J thus requires medical claims data for the associated reimbursement for these products when dispensed in these settings.

For this reason, J&J urges HRSA to include medical claims data elements, in addition to pharmacy claims data elements, in a future rebate model pilot. The table in Appendix 1 contains commercially standard information regarding drug administration that covered entities routinely collect and report to payors for reimbursement of medical claims, along with the corollaries between those data elements and pharmacy claims data elements.[35] These data are also retained in covered entities' auditable 340B records and are subject to production and review in HRSA- and manufacturer-conducted 340B audits, and thus should be readily available to submit to a rebate platform. J&J encourages HRSA to include these data elements in the rebate model.

ii. Purchase Data Would Contribute to Increased 340B Program Integrity.

Accurate 340B rebate processing also requires access to certain purchase data elements to confirm that rebate requests correspond to units the covered entity actually purchased at WAC, and then to calculate the appropriate rebate amount.

Purchase data could be validated, in part, by cross-referencing it with "867" product shipment transaction data exchanged between manufacturers and wholesalers. To reduce burden and protect covered entity confidentiality, J&J proposes to collect only data needed to identify relevant shipment transactions and to determine rebate amounts. Although J&J routinely receives 867 data from wholesalers describing shipments to purchasers,[36] that data alone is often insufficient to assess rebate eligibility.[37] For example, 867 data does not indicate whether units purchased at WAC are intended for 340B use and does not always identify the ship-to or bill-to customer. In addition, although J&J contracts for certain identifying information (*e.g.*, name, DEA, HIN, or 340B ID, and address) for ship-to and bill-to entities, some retail

[34] 91 Fed. Reg. at 7290.
[35] In the ICR, HRSA states, "OPA expects that data submitted by covered entities to manufacturers will be comparable to data already being collected and maintained by covered entities through existing third-party vendor relationships or data that is already being provided to manufacturers with respect to certain contract pharmacy policies, in-house pharmacy claims requests, and data elements provided for claims with drugs dispensed under the Medicare Drug Price Negotiation Program. Therefore, the burden associated with a potential 340B Rebate Model Pilot Program data requests may not be significant." 91 Fed. Reg. at 9633.
[36] Because units eligible under the rebate model are sold by J&J at WAC, wholesalers do not transmit chargeback data to J&J identifying a 340B covered entity as the purchaser of a given medication.
[37] Relevant data may be delayed or unavailable to J&J. In those circumstances, J&J must rely on purchase data submitted by covered entities to process rebates within the required timeframe.

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pharmacy chains restrict wholesalers from sharing these data or 867 data altogether. As a result, 867 data alone will not allow J&J to determine which covered entity purchased particular units for 340B use or to align shipment and claims data without additional confirmation.

Purchase data fills these gaps. First, it will confirm that the covered entity itself purchased the units for which rebates are claimed. This verification is particularly important in complex arrangements involving multiple entities, such as contract pharmacies. Second, purchase data will enable J&J to confirm that the drug was acquired at WAC.[38] Third, purchase data helps ensure that rebate claims correspond with units acquired at a commercial price rather than at the 340B price. Without this visibility, rebates could be requested for units purchased at the 340B price before the rebate model's effective date, particularly at the outset.

Appendix 2 includes the purchase data elements that J&J believes reflect standard, commercially available purchase information that covered entities can readily obtain from wholesalers as part of accounts payable and invoice management processes, including through electronic invoice access and bulk download tools.[39] As with claims data, it is appropriate to request the limited "standard information" necessary to confirm that rebates correspond to actual WAC purchases,[40] supporting efficient and reliable administration of the rebate model.

iii. A Rebate Model Is the Most Effective and Viable Approach for Providing Needed Real-Time Data and Preventing Noncompliance with the 340B Program.

In Question 5(e), HRSA references "the potential for the 340B Rebate Model Pilot Program to be an additional or alternative source" for "data elements…necessary for a manufacturer to identify potential duplicate discounts under 340B and CMS payment programs."[41] As described below, alternative approaches to a rebate model would pose operational challenges, would meet with significant covered entity opposition, and/or would result in delayed access to meaningful claims data (and a continued lack of real-time transparency). By contrast, the rebate model provides a structured and reliable framework for obtaining validated claims data in shorter timeframes.

Manufacturer Claims Collection. Some manufacturers have tried to offset the deficit created by the delay in implementation of a rebate model pilot by adopting policies that require covered entities to submit limited, commercially standard 340B claims data for all transactions (whether contract pharmacy or in-house pharmacy) as a condition of manufacturers' 340B pricing offers permitted under federal law. Although this approach may increase the volume of claims data available to manufacturers, it is likely less effective than a rebate model. Covered entity stakeholders have objected to providing claims data, and even where claims data is provided, known and ongoing challenges with the accuracy, completeness, and timeliness of the data could render that data less effective as compared to timely and validated claims data afforded by a rebate model. Finally, as with a clearinghouse addressed below, this approach relies on covered entities submitting 340B claims information on a lagged basis without a direct connection to the 340B discount extended on the units associated with each claim. Without the ability to link a request for 340B pricing to validated claims data in real time under a rebate model, manufacturers must identify and

[38] J&J would not request information regarding any additional discounts covered entities may negotiate with wholesalers, which we understand to be confidential.
[39] *See, e.g.*, McKesson, *Pharmacy Accounts Payable Management System*, https://www.mckesson.com/pharmacy-technology/pharmaceutical-ordering/pharmacy-accounts-payable/ (last visited Apr. 9, 2026).
[40] *See, e.g.*, *Novartis Pharm. Corp. v. Johnson*, 102 F.4th 452, 463 (D.C. Cir. May 21, 2024); 59 Fed. Reg. 25,109, 25,112 (May 13, 1994).
[41] 91 Fed. Reg. at 7290.

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address noncompliance retrospectively on a covered entity-by-covered entity basis subject to the inefficiencies and pitfalls described in Sections I and II of this letter.

Neutral Clearinghouse. Under a clearinghouse model, a centralized third-party repository would receive covered entity-reported 340B transaction data (and potentially attempt to reconcile that information against CMS data sources). However, this model is fundamentally dependent on covered entities or their TPAs self-identifying 340B claims—perhaps using a modifier—after the drug is dispensed or administered and without any independent mechanism to incentivize timeliness, accuracy, or completeness. As with the current system, therefore, unless HHS were to undertake robust oversight and enforcement to ensure covered entity compliance with clearinghouse reporting requirements, manufacturers would continue to lack the ability to validate reported claims or assess whether duplicate discounts have occurred.

Critically, a neutral clearinghouse cannot work properly unless it can substantiate the self-reported claims volume using 340B purchase data. CMS's ongoing efforts to establish a clearinghouse for Part D inflation rebates, which will be optional and is not expected to commence operations until fall 2026 at the earliest underscores the challenges with a narrow-scope clearinghouse option.[42] Past experience with the MDPNP also reaffirms that voluntary self-identification of 340B claims does not yield sufficient participation or reliability. As of April 2026, pharmacies have classified "fewer than 0.5 percent of MFP claims" as 340B through either CMS or Beacon "MFP" platform mechanisms, which is markedly less than Medicare Part D PDE data suggests should be occurring (potentially 10% to 12% of "MFP" claims).[43]

d. J&J Supports Manufacturer-Required Reporting to Demonstrate Rebate Model Operation (RFI Question 6 & ICR).

In Question 6 of the RFI, HRSA requests stakeholder feedback on how the rebate model should be monitored for compliance, including the specific data elements manufacturers should report, the frequency of such reporting, and the scope and cadence of HRSA reporting, including public disclosures.[44] In the ICR, HRSA proposes that "manufacturers will be required to submit data to the 340B Prime Vendor monthly to evaluate program integrity and to provide greater transparency in the 340B program."[45]

We note that the 340B Prime Vendor, Apexus, currently is the subject of a congressional investigation regarding its business practices related to the 340B Program, including potential conflicts of interest and alleged misaligned financial incentives.[46] Apexus also is a wholly-owned subsidiary of Vizient, which is the largest group purchasing organization in the United States and is owned by hospitals.[47] Vizient's clients include many covered entities. As a result, Apexus may not be an appropriate entity to manage the collection and evaluation of sensitive data related to a rebate model, and it may be more appropriate for manufacturers to report data elements directly to HRSA. J&J agrees with comments

[42] 90 Fed. Reg. 49266, 49741, 49754 (Nov. 5, 2025).
[43] BRG, Update on Effectuation of the Maximum Fair Price in 2026 and Outlook for 2027, at 2 (Apr. 2026), https://media.thinkbrg.com/wp-content/uploads/2026/04/03101442/Effectuation-of-the-Maximum-Fair-Price-in-2026-and-Outlook-to-2027.pdf ("To date, fewer than 0.5 percent of MFP claims have been self-identified as 340B by the pharmacy . . . . By comparison, analysis of Medicare Part D Prescription Drug Event (PDE) data suggests that between 10 and 12 percent of claims for 2026 selected drugs are subject to 340B pricing. In other words, fewer than 5 percent of 340B claims are self-identified as such by pharmacies.").
[44] 91 Fed. Reg. at 7290.
[45] 91 Fed. Reg. at 9632–33.
[46] Senate Health, Education, Labor & Pensions Committee, *Chair Cassidy Continues Investigation into 340B Drug Program, Seeks Information from 340B Prime Vendor* (Feb. 2, 2026), https://www.help.senate.gov/rep/newsroom/press/chair-cassidy-continues-investigation-into-340b-drug-program-seeks-information-from-340b-prime-vendor-1.
[47] Gabler, E. *How a Company Makes Millions Off a Hospital Program Meant to Help the Poor*, New York Times (Jan. 15, 2025), available at: https://www.nytimes.com/2025/01/15/us/340b-apexus-drugs-middleman.html.

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submitted by PhRMA and BIO that HRSA and other government agencies (*e.g.*, HHS-OIG and certain functions within CMS) should evaluate the pilot.

Regardless, J&J agrees that manufacturers should report data elements aligned with the pilot for the duration of the rebate model. J&J proposes that these data elements should include:

- Claim Submission Date
- 340B ID
- NDC-11 Purchased
- Quantity
- Unit WAC Price
- Unit 340B Ceiling Price
- Unit "MFP" Price
- Rebate Amount
- Rebate Date Paid
- Rejection Reason (if applicable)

In addition, manufacturers should be required to provide aggregated data regarding the operation of the rebate model, including:

- Aggregated sales by covered entity type as defined in 42 U.S.C. § 256b(a)(4)
- Average days from claim submission to rebate payment for all rebates paid
- Number of rebates paid after 10 calendar days
- Number of rebates denied with denial reasons
- Number of selected drug claims with "MFP" refunds that are duplicative of 340B pricing provided through the rebate model pilot program

Further, HRSA could consider publishing the manufacturer-reported aggregated data. If it does so, HRSA should aggregate data across manufacturers so that it does not inadvertently report proprietary and sensitive data of an individual manufacturer.

e. A Rebate Model Would Materially Improve Compliance Associated with the 340B Program (RFI Question 7).

Question 7 asks commenters whether a rebate model pilot would affect 340B Program integrity, reduce duplicate discounts and diversion, and increase pricing transparency. It also seeks recommendations on how to improve data collection and reporting and asks stakeholders to describe other potential benefits, as well as to weigh these benefits against potential costs.

A rebate model will significantly enhance program transparency, which will help prevent duplicate discounts and other forms of noncompliance. Stakeholders need transparency into the 340B Program, which is the second largest federal drug pricing program. Compared to other federal drug pricing programs of a similar scale (*e.g.*, Medicaid, Medicare), there is a lack of publicly available data necessary to evaluate program integrity and effectiveness. For example, CMS and state Medicaid agencies have access to complete Medicare and Medicaid claims data, enabling robust oversight and analysis. No comparable claims-level data exists for the 340B Program—not for the entities funding the discounts (manufacturers) nor for the agency charged with overseeing the program (HRSA).

Participation in the 340B Program is a bargained-for exchange pursuant to the Spending Clause of the United States Constitution. Manufacturers like J&J agree to charge no more than the 340B price to eligible purchasers, subject to the limitations set out in the duplicate discount prohibition, the diversion prohibition, and the theoretical protection afforded by the right to audit, in exchange for coverage and

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payment for their drugs under Medicaid and Medicare Part B.[48] Notably, the 340B program was intended to restore access to voluntary discounts that certain drug manufacturers had offered certain safety net providers prior to enactment of the Medicaid Drug Rebate Program in 1990.[49] As noted above, therefore, the purpose and structure of the 340B program were narrow, and the diversion and duplicate discounting provisions are essential parts of the Spending Clause bargain, designed by Congress to moor the program to its intended scope. More transparency through a rebate model is consistent with this intent and will help to restore the 340B program to its original purpose, by enabling better and real-time enforcement of the duplicate discount and diversion prohibitions. Transparency also will enable HRSA to better monitor and enforce program integrity requirements.

Duplicate Discounts. The rebate model will provide more complete and timely information, enabling HRSA to gain a comprehensive view of the 340B Program and how it operates across various covered entity categories. Claim-level data fields create an auditable trail that would allow J&J to assess whether a discount has already been provided on the same drug unit (*e.g.*, "MFP", Medicaid). By creating a mechanism for manufacturers to receive 340B claims data before providing the 340B price, the rebate model provides real-time insight into specific claims that resulted in payment of a 340B discount and thus facilitates timely, accurate, and efficient deduplication of "MFP" and Medicaid rebates.

In contrast to the current replenishment model, this approach promotes greater and more timely transparency. In addition, by providing real-time access to claims data that can avoid duplicate discounts, disputes between manufacturers and covered entities would be reduced. Ultimately, this conserves stakeholder resources, including those of the government.

Diversion. The rebate model also reduces opportunities for diversion, in that it would allow manufacturers to use real-time information to verify that the 340B price is provided only on eligible claims. Unlike a replenishment model—under which covered entities rely on a neutral inventory that commingles 340B and non-340B drugs—a rebate model ensures that the same drug for which a covered entity requests a 340B rebate is the drug actually dispensed or administered to the patient. Therefore, it materially reduces the risk of diversion by directly linking the 340B rebate to a specific dispensed or administered drug. By standardizing claim-level validation across covered entity types, a rebate model strengthens diversion controls and reduces risks arising from differing inventory tracking practices. Additionally, by requiring submission of standardized data for each drug dispense or administration, manufacturers can identify instances where a rebate is requested by more than one covered entity and ensure only one rebate is paid, consistent with the diversion prohibition and HRSA guidance.

Further, the rebate model would provide data that validates that the pharmacy that dispensed the unit is eligible for the program (*i.e.*, listed as active in Office of Pharmacy Affairs Information System ("OPAIS")), reducing the risk of diversion. Access to real-time claims and purchase data would permit J&J to identify any instances in which the dispense or administration occurred in advance of the purchase date. The rebate model provides an alternative to ADR to address certain types of diversion—while conserving government resources.

Manufacturer Audits. A rebate model would reduce the need for inefficient and expensive audits by providing manufacturers with claims data in real-time. By verifying claims before providing the 340B price, the rebate model would mitigate the opacity resulting from prevalent use of replenishment models and also reduce the need for manufacturer audits overall. J&J would be able to identify program integrity concerns earlier and more precisely, creating more thorough and detailed reasonable cause and audit work

[48] *See Pharm. Rsch. & Mfrs. of Am. v. McCuskey et al.*, No. 25-1054, --- F.4th ----, 2026 WL 898259 (4th Cir. Mar. 31, 2026) (finding West Virginia's contract pharmacy law likely preempted by the 340B statute).
[49] H.R. Rep. 102-384, pt. II, at 10–12 (1992).

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plans. Accordingly, HRSA's review also would be more thorough and efficient, utilizing less agency time and allowing HRSA to better direct its own covered entity audits.

IRA "MFP" Compliance. A rebate model is the most effective known means for identifying 340B-eligible Medicare "MFP" claims in real-time, which in turn allows a manufacturer to meet the IRA's nonduplication requirement within CMS's 14-day "prompt 'MFP' payment window."

IV. The 340B Rebate Model Would Not Impose Undue Burdens on Covered Entities.

Despite assertions to the contrary, transitioning to a rebate model would not introduce significant new financial or operational burdens for covered entities. Rather, manufacturers would bear the costs associated with administering a rebate model platform and providing implementation resources in the form of live and recorded education sessions, data reporting templates, and TPA integrations. In addition, a rebate model would provide a shortened timeline for delivery of 340B pricing and would rely on commercially standard data collection supported by robust privacy and security protections. Below, we discuss RFI questions related to covered entity impact: Question 1, Costs to Covered Entities; Question 2, Payment Timing and Potential Cash Flow Impacts for Covered Entities; and Question 4, Data Collection by Covered Entities.

a. Covered Entities Currently Pay Costs to Support Existing 340B Program Operations and a 340B Rebate Model Would Not Create Significant New Financial Burdens (RFI Question 1(a)).

Question 1(a) seeks information on 340B-related costs paid by covered entities under the existing 340B Program. Covered entities have utilized TPAs and other vendors to handle the administrative requirements of the 340B Program for many years, including to determine ways to extract more value from the 340B Program.[50] For a fee, TPAs offer services to covered entities including compliance, auditing, inventory management and split-billing, program optimization and revenue capture, and patient access.[51] TPAs also have begun to offer services that would assist covered entities in implementing rebate model processes.[52] Notably, many of the TPA rebate model-specific functions do not vary significantly from the support they presently offer.

A 2025 congressional report provided insight on certain TPA fees. The report found that fees charged by Wellpartner, LLC, a CVS Health subsidiary, had more than doubled over four years, rising from $147 million in 2019 to $382 million in 2023 for "services . . . includ[ing], but not limited to 340B eligibility determination, technology support and compliance."[53] The report also found that Sun River Health, a Federally Qualified Health Center covered entity, spent "5.9 percent of its total 340B revenue of 2019, 9.3 percent in 2020, nine percent in 2021, and 8.7 percent in 2022" on TPA services.[54]

Separately, the Minnesota Department of Health released a 340B Covered Entity Report in February 2026,[55] which found that, in 2024, covered entities in the state reported having 340B "operational

[50] Sayeh Nikpay et al., Health Affairs Scholar, *Growing Administrative Complexity in the 340B Program and the Rise of Third-Party Administrators* (Nov. 2023), https://academic.oup.com/healthaffairsscholar/article/1/5/qxad052/7320443?login=false.
[51] *Id.*
[52] *See, e.g.,* Verity Solutions, *Your 340B Rebate Model Pilot and MFP Checklist: How to Prepare for Launch* (Dec. 19, 2025), https://verity-solutions.com/your-340b-rebate-model-pilot-and-mfp-checklist/.
[53] Senate Comm. on Health Educ. Lab. & Pensions, *Congress Must Act to Bring Needed Reforms to the 340B Drug Pricing Program* (Apr. 2025), https://www.help.senate.gov/imo/media/doc/final_340b_majority_staff_reportpdf.pdf.
[54] *Id*.
[55] Minn. Dep't of Health, *340B Covered Entity Report* (Feb. 27, 2026), https://www.health.state.mn.us/data/340b/docs/2025report.pdf.

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costs [of] approximately $165 million." About $137 million of this amount (83%) was paid to contract pharmacies and other external vendors "representing nearly 10% of total statewide gross 340B revenue." This means that "[f]or every $100 of gross 340B revenue generated, Covered Entities collectively paid approximately $10 to [these] *external* organizations."[56] The remaining approximately $28 million (17%) of these operational costs were for covered entities' "internal costs for administering their 340B programs," including staffing and technology.

These reports make clear that, under the current discount model, covered entities derive significant financial benefit from the 340B Program and are spending significant shares of their 340B revenues on vendors to grow those revenues further. These growth-driven arrangements often come at the expense of program integrity. The Minnesota report also highlights the comparatively small share of operational costs that covered entities devote to internal functions that would cover 340B Program compliance. Given the size, scope, and complexity of covered entities' 340B programs and the program integrity challenges they present, any incremental covered entity costs associated with implementing a rebate model would be outweighed by the model's transparency and compliance benefits. Further, as the D.C. Circuit recognized in *Novartis Pharms. Corp. v. Johnson*,[57] it is reasonable that covered entities would be required to expend a small amount of resources to maintain compliance.[58]

Regarding the provision of medical claims data, to the extent a covered entity has not already implemented a 340B-specific reporting system for this data, we expect that a covered entity would be able to leverage technology they already use to electronically exchange this data with payors (including government programs), 340B TPAs/consultants, and certain manufacturers. As data elements needed for rebate processing overlap with those collected through 340B ESP and the data request list used in HRSA covered entity audits, covered entities should already have access to such data and, in most cases, have already reported data to manufacturers using 340B ESP, a platform that is similar to Beacon's rebate model platform. Recently, J&J has observed that certain covered entities have begun submitting their medical claims data for J&J's provider-administered drugs to 340B ESP as a result of claims data policies recently instituted by other manufacturers. J&J has also received medical claims data as part of its "good faith inquiry" process for "MFP"/340B deduplication. Submission of medical claims data in response to new manufacturer policies demonstrates that covered entities possess the data required under a rebate model and can share it with a rebate model platform vendor with minimal effort and cost. It is worth emphasizing that any costs incurred in creating a new data reporting stream would be a one-time expense—not an ongoing burden for covered entities.

b. Manufacturers Pay Costs Associated with the Operation of a Rebate Model and 340B Compliance Generally—They Should Not Be Expected to Reimburse Covered Entities' Costs (RFI Question 1(b)).

Question 1(b) suggests that HRSA is considering whether a rebate model could be "structured so as to offset these administrative and operational costs" and requests information as to "how [that could] be achieved and how [] such an offset be accurately quantified."[59]

J&J incurs significant costs to maintain 340B compliance—costs that continue to increase as program complexity grows and which are in addition to the $7.4 billion in 340B discounts that J&J paid to

[56] *Id*.
[57] 102 F.4th 452 (D.C. Cir. 2024).
[58] BRG, 340B Program at a Glance: 2025, https://media.thinkbrg.com/wp-content/uploads/2025/02/19075246/340B-Program-at-a-Glance-2025_F.pdf (2025).
[59] 91 Fed. Reg. at 7289.

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covered entities in 2024.[60] In 2025, for example, J&J paid millions of dollars in primary 340B compliance costs, such as:

- $14 million to external vendors and systems to manage data intake, validation, and policy enforcement (including "MFP" deduplication solutions);
- $5 million for complex data reconciliation across claims, chargebacks, rebates, and government pricing; and
- $5 million for audit and monitoring requirements, including internal controls and external reviews.

In sum, J&J's estimated annual 340B compliance costs approximate upwards of $24 million, before taking into account internal and external 340B legal expenses. These expenses are non-discretionary, recurring, and scale with operational complexity.

J&J would fund the operation of its rebate model and provide covered entities no-cost access to an electronic rebate platform and certain implementation resources described below. Any requirement that J&J would then need to offset covered entities' 340B operational and compliance costs on top of this would impermissibly extend manufacturers' obligations beyond the statutory requirement to "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price."[61] Further, there is no precedent for requiring manufacturers—or any other party—to offset covered entities' 340B operational and compliance costs, and asking covered entities to catalog their costs, submit them to manufacturers, and then require manufacturers to validate and pay those costs would create further audit questions and logistical challenges.

In anticipation of the Pilot, the Beacon platform, to which J&J would provide covered entities and their contractors no-cost access, offered trainings and assistance to help covered entities and vendors prepare for launch. Beacon conducted 21 live webinars in November and December 2025 in anticipation of a January 1, 2026 Pilot launch.[62] To further help covered entities, Beacon offers a software development kit ("SDK") which is a secure and direct data integration that allows automated 340B rebate data submissions and status updates, thereby alleviating covered entity costs and personnel efforts. According to Second Sight Solutions, there are currently over 50 organizations (10 of which are large health systems) set up on the Beacon SDK. Covered entities thus have the technological and administrative ability to support a rebate model, and many have already undertaken significant preparation to begin operating under one.

c. A Rebate Model Provides for a Shortened Payment Timeline for 340B Pricing (RFI Questions 1 and 2).

In part, Question 1 seeks information regarding whether implementation of a rebate model requires meaningful changes to covered entities' resources (*e.g.*, staffing, systems), as well as whether such a model would have any impact on patient access to drugs.[63] Question 2 seeks information related to the impact of a payment schedule under a rebate model "(*e.g.*, within ten calendar days of submission of a complete claim)" and any effect that would have on covered entities.[64]

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[60] Johnson & Johnson Center for U.S. Healthcare Policy Research, Issue Brief: The 340B Program: Missing the Mark for Patients (2025), https://policyresearch.jnj.com/the-340b-program/.
[61] 42 U.S.C. § 256b(a)(1).
[62] Second Sight Solutions, LLC, Beacon Support Center, https://support.beaconchannelmanagement.com/en/articles/9519227-beacon-support-calendar (last visited Apr. 9, 2026).
[63] 91 Fed. Reg. at 7289.
[64] 91 Fed. Reg. at 7289–90.

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Covered entity payment terms under a rebate model are as good or better than existing payment terms in the 340B Program.[65] In today's 340B Program, covered entities voluntarily participate in replenishment models that they created (at their own expense and without HRSA pre-approval), described above in Section II.b. The rebate model would operate at the unit level, as compared to a package level. Thus, covered entities will not need to wait until accumulation to a full package to receive the 340B price as they do under the replenishment model. IQVIA recently reported that any impact of a rebate model on covered entities' cash flow should be "small and unlikely to be a barrier to its use by covered entities."[66] The study found that interest costs as a percent of WAC for a rebate model were consistent with, or less than, interest costs incurred under prevailing inventory models.[67]

Further, a 10-day payment timeframe benefits covered entities compared to that of the "MFP" payment period, which the MTF reports takes approximately 21 days (or more) from dispense to payment.[68]

The Beacon platform includes standard functionality that permits a covered entity to reconcile its 340B-eligible rebate claims to 340B rebate payments received. We agree that manufacturers should be held to making timely rebate payments, which should be done in a manner consistent with the statutory "shall offer" requirement.

Importantly, J&J's rebate model efforts would not affect patient access to J&J drugs. Patients generally are identified as 340B-eligible only after a drug has been dispensed. The 340B discount rarely is passed on to the patient at the point of sale, and patients are typically not aware of their 340B eligibility. A covered entity's decision not to acquire a drug at the 340B ceiling price does not affect a patient's ability to access the medication. The patient's cost sharing obligation—set by their insurance—is exactly the same as it would have been, irrespective of the patient's choice of hospital or pharmacy provider.

d. The Rebate Model Provides Commercially Standard Data Collection with Robust Privacy and Security Protections (RFI Question 4).

Question 4 requests information regarding covered entity and rebate model data collection practices, as well as recommendations for establishing guardrails to address privacy and security concerns.[69]

Data Collection. The rebate model would collect standard pharmacy and medical claims data elements that covered entities maintain in the ordinary course of business and provide to other stakeholders. As described in Sections III.c.i. and IV.a. above, these fields substantially overlap with data elements that covered entities maintain in their auditable records and produce in the context of audits, collect and report to payors for reimbursement, and provide to manufacturers under various contract pharmacy, in-house pharmacy, and 340B/"MFP" deduplication processes.

Data Privacy and Confidentiality. J&J treats privacy and security with the utmost seriousness. The Beacon platform has robust guardrails in place to manage any privacy or security concerns and applies

[65] *See* SmartSourceRx, *Credit and Payment Details*, https://www.smartsourcerx.com/credit-and-payment-details (last visited Apr. 9, 2026).
[66] Chuan Sun et al., IQVIA, *How Will a Rebate Model Impact Cash Flow in the 340B Drug Pricing Program?*, at 1, 13 (2025), https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2025/iqvia-cash-flow-impact-in-340b-white-paper-2025.pdf.
[67] Chuan Sun et al, IQVIA, *How Will a Rebate Model Impact Cash Flow in the 340B Drug Pricing Program?*, at 1, 13 (2025), https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2025/iqvia-cash-flow-impact-in-340b-white-paper-2025.pdf.
[68] BRG, Update on Effectuation of the Maximum Fair Price in 2026 and Outlook for 2027, at 1 (Apr. 2026), https://media.thinkbrg.com/wp-content/uploads/2026/04/03101442/Effectuation-of-the-Maximum-Fair-Price-in-2026-and-Outlook-to-2027.pdf (citing data transmitted from the MTF to the Beacon MFP platform).
[69] 91 Fed. Reg. at 7290.

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its terms uniformly to ensure consistent program administration. Second Sight Solutions' platforms are subject to an independent expert determination under the HIPAA de-identification standard at 45 C.F.R. § 164.514(b)(1) and to third-party information security audits.[70]

We note that Second Sight Solutions works directly with 340B Covered Entities to address conflicts with applicable law.[71] To date, more than 10,000 340B Covered Entities have registered on the Beacon platform and accepted its terms and privacy policy.[72]

* * *

J&J appreciates HRSA's attention to the issues raised in this letter and welcomes further discussion to support a rebate model. Please do not hesitate to contact us with any questions or if additional information would be helpful.

Sincerely,

Lauren Paluzzi

Lauren Paluzzi
Senior Director, 340B & Emerging Government
Program Strategy & Operations

[70] Beacon Channel Management, Beacon Trust Center, https://cm.beaconchannelmanagement.com/pages/trust-center; 340B ESP, Frequently Asked Questions, https://help.340besp.com/en/articles/8808065-frequently-asked-questions-faqs#h_b553637062.
[71] Information provided by Second Sight Solutions.
[72] Information provided by Second Sight Solutions.

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Appendix 1

Pharmacy Claim and Medical Claim Data Elements

Pharmacy Claim Data Element	Medical Claim Data Elements	Description	Required / Optional	HRSA DRL	340B ESP	Included in 2025 Pilot[73]
Date of Service	Date of Service	Date the prescription was filled at the pharmacy or the drug was administered to the patient	Required	Date on which the drug was furnished, administered, or dispensed	Date of Service	Yes
Date Prescribed	N/A	Date the healthcare provider wrote the prescription	Required	Date the drug order or prescription was written	Date Prescribed	Yes
Rx Number	Claim Number	The native (unmodified) prescription number for the prescription as generated by the pharmacy (pharmacy claims), or the claim number as assigned by the healthcare provider (medical claims)	Required	Patient ID number	Rx Number	Yes
Fill Number	N/A	The code indicating whether the prescription is an original or a refill. For example, a value of 0 indicates that the prescription is the original dispense, whereas the value of 1 indicates the prescription has been refilled once.	Required	N/A	Fill Number	Yes
11-Digit National Drug Code (NDC)	11-Digit National Drug Code (NDC)	NDC-11 of the product that was purchased by the Covered Entity	Required	NDC	NDC	Yes
Quantity Dispensed	Quantity	Number of units dispensed to the patient (pharmacy claims), or total	Required	Quantity Issued	Quantity	Yes

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

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Pharmacy Claim Data Element	Medical Claim Data Elements	Description	Required / Optional	HRSA DRL	340B ESP	Included in 2025 Pilot[73]
		quantity being submitted on medical claim (units billed) (medical claims)				
Prescriber ID	Rendering Physician ID	NPI of the prescriber who wrote the prescription (pharmacy claims) or who administered the medication to the patient (medical claims)	Required	Ordering provider	Prescriber ID	Yes
Service Provider ID	Service Provider ID	NPI of the pharmacy that filled the prescription (pharmacy claims) or a pharmacy or facility where the patient received the medication administration (medical claims)	Required	Location	Service Provider ID	Yes
340B ID	340B ID	The HRSA assigned parent 340B ID of the entity that designated the prescription as 340B (pharmacy claims) or purchased the drug (medical claims)	Required	Type of account through which the drug was purchased, purchase account, and the associated 340B ID	Contracted Entity ID	Yes
Rx Bank Identification Number ("BIN") / Rx Processor Control Number ("PCN")	Health Plan ID / Health Plan Name	Bank identification number of the primary payer on the claim and processor control number assigned by the entity processing payment (pharmacy claims); name and identifier code of patient's primary health insurance plan (medical claims)	Required / Required	N/A	Payer BIN / Payer PCN	Yes
N/A	Claim line number	The line number of the claim	Required	N/A	Claim Line Number	Yes

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Pharmacy Claim Data Element	Medical Claim Data Elements	Description	Required / Optional	HRSA DRL	340B ESP	Included in 2025 Pilot[73]
N/A	Unit of measure	The unit of measure for the quantity submitted on medical claim. Either HCPCS code or UOM is required. If HCPCS code is not included, UOM is required, and it should be consistent with NCPDP units.	Required	N/A	Unit of Measure	Yes
N/A	HCPCS Code	The five character HCPCS code for separately payable medications	Optional	N/A	HCPCS Code	Yes
N/A	HCPCS Modifiers (up to 4)	Modifier code associated with a separately payable medication with its own five character HCPCS code	Optional	N/A	HCPCS Code Modifier	Yes

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Appendix 2

Purchase Data Elements

Purchase Data Element	Description	Required / Optional	HRSA DRL
Wholesaler Name	Name of the wholesaler that processed the invoice and shipped the purchased drug. Where 867 transaction data is blocked entirely for a transaction, this data element allows J&J to identify the relevant wholesaler and work directly with that entity, when necessary, to identify the relevant transaction and validate the rebate claim, which may reduce follow up inquiries with the covered entity.	Required	Wholesaler name
Wholesaler Account Number	Wholesaler assigned account number used to place the order. This data element allows J&J effectively to resolve any discrepancies between information submitted by the covered entity and data received from the wholesaler. Purchase Account Number enables J&J to work directly with the wholesaler to identify the relevant transaction and validate the rebate claim. While not strictly required, this data point is strongly recommended to reduce the likelihood of follow up inquiries and streamline the rebate validation process for covered entities. This data element is not provided in 867 transaction data.	Optional	Account number
Invoice Date	Wholesaler-assigned invoice number for the purchase order. The platform uses Invoice Date to identify the relevant transaction to support verification that the purchase qualifies for a 340B rebate. Because invoice numbers are not necessarily unique across different wholesalers or transactions, the platform requires a combination of Invoice Number, Invoice Date, and NDC-11 to accurately match the covered entity's purchase data to J&J's corresponding 867 data describing the shipment transaction. This multi-field approach ensures reliable identification of WAC purchases while compensating for gaps in standard transaction data. In addition, the platform relies on the Invoice Date paired with the reported NDC-11 to determine the applicable WAC for the unit at the time of purchase, ensuring that the rebate amount is calculated based on the correct pricing in effect on the transaction date.	Required	Invoice date
Invoice Number	Wholesaler-assigned invoice number for the purchase order. The platform uses Invoice Number to identify the relevant transaction to support verification that the	Required	Invoice number

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	purchase qualifies for a 340B rebate. Because invoice numbers are not necessarily unique across different wholesalers or transactions, the platform requires a combination of Invoice Number, Invoice Date, and NDC-11 to accurately match the covered entity's purchase data to J&J's corresponding 867 data describing the shipment transaction. This multi-field approach ensures reliable identification of WAC purchases while compensating for gaps in standard transaction data.		
Ship-To Pharmacy NPI	The NPI of the pharmacy that received the physical shipment of the drug from the wholesaler. This data element is used to validate that the pharmacy receiving the shipment is appropriately associated with the covered entity registered as active in OPAIS, ensuring that rebate claims are paid on 340Beligible transactions. Because shipment data is frequently blocked in 867 transaction data or may not precisely match the relevant ship to location, the data source cannot be reliably used on its own for validation—making direct collection of the ShipTo Pharmacy NPI essential for rebate processing.	Required	Ordering location
11-Digit NDC	Identifier of the drug purchased by the covered entity. The platform uses NDC-11 to identify the relevant transaction to support verification that the purchase qualifies for a 340B rebate. Because invoice numbers are not necessarily unique across different wholesalers or transactions, the platform requires a combination of Invoice Number, Invoice Date, and NDC-11 to accurately match the covered entity's purchase data to J&J's corresponding 867 data describing the shipment transaction. This multi-field approach ensures reliable identification of WAC purchases while compensating for gaps in standard transaction data. In addition, the platform relies on the NDC-11 paired with the reported Invoice Date to determine the applicable WAC for the unit at the time of purchase, ensuring that the rebate amount is calculated based on the correct pricing in effect on the transaction date.	Required	Drug NDC
Package Units	Number of packages of the product ordered. This data element is used to validate that the quantity of units for which 340B rebates are claimed matches (or does not exceed) the quantity of validated units purchased by the covered entity, thereby helping to ensure that 340B rebates are issued only for drugs purchased by the covered entity. Additionally, Package Units is used to calculate the total rebate amount owed, based on the number of validated units.	Required	Quantity ordered

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340B ID	HRSA-assigned identifier of the 340B covered entity that purchased the drug. This data element is used to validate that the purchasing entity is a 340B covered entity registered as active in the HRSA OPAIS database, ensuring that rebate claims are tied to eligible 340B covered entities. It also enables the platform to link purchase records with rebate claims submitted by the covered entity. This field does not exist in J&J's corresponding 867 data, making direct collection of the 340B ID essential for rebate processing.	Required	

Mountain Park Health Center

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MOUNTAIN PARK HEALTH CENTER

July 15, 2026

Chantelle Britton
Director
Office of Pharmacy Affairs
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, Maryland 20857
Submitted via email to *paperwork@hrsa.gov*

RE: Agency Information Collection Activities: Proposed Collection: Public Comment Request (30-Day Notice); Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906-NEW (FR Doc. 2026-11989, 91 Fed. Reg. 35989, June 15, 2026)

Dear Director Britton:

Each year, more than 100,000 members of the community receive high-quality primary health care at one of Mountain Park's 11 clinics located in underserved areas across metropolitan Phoenix. Mountain Park serves patients from all walks of life through all stages of life. Mountain Park was the first Joint Commission accredited Federally Qualified Health Center in Arizona, achieving ambulatory health accreditation in 1999 and Primary Care Medical Home accreditation in 2014. Primary care services provided directly at Mountain Park include medical care for adults; pediatric care for infants, children, and adolescents; obstetrical and gynecological care for women; and integrated behavioral health care for all patients. Mountain Park also provides dental services at three clinics, and full-service pharmacies at two clinics. Other professional services provided on-site include nutrition and dietitian services, and a wide array of enabling services that support primary care, including eligibility assistance as well as language and translation programs. The organization is committed to meeting each patient's physical and mental health care needs, including prevention, wellness, acute care, and chronic care services. Sliding fees discounts cover all services provided at Mountain Park. As a Patient Centered Medical Home, Mountain Park actively supports the patient's ability and desire to learn to manage their own care. Each patient has a designated care team which includes the patient at the center, a primary care provider (PCP), non-provider personnel (e.g., medical assistants and case managers), and same day access to integrated behavioral health providers and registered dietitians. Same day access to a clinical pharmacist is also part of the patients' care teams. These teams provide health care services and self-management support, arrange for needed resources, and provide care coordination or other services.

The 340B program is foundational to CHCs' ability to serve the most vulnerable members of our community. However, the proposed shift of responsibility from manufacturers to safety-net providers directly serving patients through a rebate model threatens to destabilize CHC pharmacy operations nationwide. Based on information from CHCs, the hours and dollars spent complying with a rebate program would be significant. Our focus in this letter is on the practical utility, accuracy of the burden estimate, and minimization of burden of the proposed collection, consistent with 44 U.S.C. 3506(c)(2)(A). **Mountain Park Health Center** appreciates the opportunity to comment on this Information Collection Request (ICR).

I. Summary of Mountain Park Health Center Recommendations

1. Mountain Park strongly urges HRSA to exempt CHCs from any 340B Rebate Model Pilot Program since the additional compliance burden would be overwhelming for safety-net providers operating on

an average margin of negative two percent, with one quarter of CHCs operating below negative five percent.

2. **Mountain Park**calculates the annual burden of complying with the Pilot Program to be between 2,321-3,900 hours per year, or $306,368 - $514,961 per year.
3. **Mountain Park** recommends HRSA requires a single uniform set of data fields, formats, and submission timelines across all manufacturers, and prohibits manufacturers from requesting additional data fields from covered entities, unless first approved by HRSA.
4. **Mountain Park** recommends that covered entities be permitted to submit data through a single neutral-party platform, ensuring consistent processes and eliminating duplicative system interactions.
5. **Mountain Park** requests that HRSA make all approved manufacturer plans and manufacturer-reported data publicly available in their entirety on OPA's website.
6. **Mountain Park** recommends HRSA's burden analysis account for covered entities already reporting duplicative data necessary in a 340B rebate pilot program to the existing CMS Medicare Part D 340B Data Repository.

II. HRSA Has Materially Underestimated the Burden on Community Health Centers to Submit Claims Data to Manufacturers

The ICR estimates an average of **5 hours per response** for covered entities reporting claims data to a third-party platform, applied across 15,249 covered entities, filing 52 responses each (792,948 total responses; 3,964,740 total burden hours, costing $523,345,680 annually).[1] HRSA's burden logic[2] assumes that each CHC will complete a 5 hour, data reporting cycle, weekly for the entire covered entity. The Office of Pharmacy Affairs Information System (OPAIS) reflects that there are 1,452 active CHCs and CHC Look-Alikes (CHC-LAs), with 13,805 active grantee sites, as of June 29th, 2026.[3] Utilizing HRSA's burden logic calculations, this equates to 377,520 burden hours at a cost of $49,832,640.

Mountain Park respectfully requests that HRSA address the inconsistencies in the methods used to estimate the burden of the proposed 340B rebate pilot on CHCs. HRSA has asked covered entities to comment on the "burden in the context of this information collection means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested." This comment request does not appear to include time spent reconciling submissions and tracking rebate status, and addressing errors, denials, or follow-up requests, which CHCs expect to be the most burdensome steps. Additionally, the methodology does not consider the burden of new financial tasks the rebate model would impose on CHCS, such as applying for new lines of credit or changing payment management with wholesalers.

The Task-Based Methodology HRSA Used Supports a Higher Estimate

According to the ICR, HRSA developed its burden estimate by applying a "task-based methodology that considers the discrete activities required to complete a reporting cycle, including:

1. Identifying and extracting eligible claims data;
2. Formatting and validating data to meet manufacturer specifications;
3. Submitting the data;
4. Reconciling submissions and tracking rebate status; and

[1] 340B Rebate Model Pilot Program ICR, Table 1, FR Doc. 2026-11989, 91 Fed. Reg. 35989 (June 15, 2026), https://www.federalregister.gov/d/2026-11989.
[2] Supporting Statement A - OPA - 340B Rebate Model Pilot - 0906-NEW https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=202606-0906-001
[3] https://340bopais.hrsa.gov/SearchCe

5. Addressing errors, denials, or follow-up requests."[4]

Working within HRSA's five-element methodology, the cumulative per-response time for a CHC greatly exceeds five hours. HRSA's covered entity-level assumption does not accurately reflect how CHCs participate in the 340B Program. In contrast to hospital covered entities whose child sites obtain their 340B-eligibility from the hospital itself, each CHC location is individually 340B eligible and operates as a "parent" site for purposes of purchasing and data reporting. Accordingly, CHCs must separately register contract pharmacies under grantee sites on OPAIS by obtaining separate HINs for each 340B ID (reflecting individual pharmacy relationships), aligning wholesaler accounts to the associated site 340B IDs to ensure the purchases are properly aligned to a specific site, making the necessary designations in the manufacturer chosen platform, submitting utilization data for each designated site (which entails manipulating TPA reports, since most systems do not accommodate this nuance of CHC reporting), reconciling submission data, and troubleshooting any discrepancies. This is all at the individual site or 340B ID level.

Recommendations to Reduce 340B Rebate Model Burden

The burden of a 340B rebate model is driven primarily by fragmentation in data standards, submission pathways, and platform requirements by drug manufacturers, forcing covered entities to duplicate data mapping, submission, and reconciliation efforts across systems. **To address this burden at its source, Mountain Park recommends HRSA require a single uniform set of data fields, formats, and submission timelines across all manufacturers, and prohibit unapproved additional data requests.** In the absence of standardization, these parallel workflows significantly expand the administrative workload beyond HRSA's assumptions.[5] **Mountain Park further recommends covered entities be permitted to submit data through a single neutral-party platform, ensuring consistent processes and eliminating duplicative system interactions.**

We have outlined several of these burdens in more detail below:

- **Rebate processes mirror existing data submissions to manufacturers.** HRSA is correct that many CHCs are already submitting the majority of the requested data elements (except for BIN & PCN) regularly through the 340B ESP platform. At present, Teva is the only manufacturer included in the proposed rebate pilot that does not request data from CHCs for contract pharmacies. Furthermore, six of the manufacturers also require entity-level claims as a condition of sale to covered entity sites and pharmacies listed as 340B-eligible on OPAIS. **Mountain Park** respectfully disagrees that program transparency will improve since identical data is already being submitted through 340B ESP. The proposed rebate pilot would replicate existing processes, while significantly increasing the burden on covered entities through an exponential increase in the volume, complexity, and financial risk, with little evidence it will improve 340B Program operations.
- **Lack of standardization across manufacturer platforms.** Today, covered entities already submit manufacturer-restriction claims data through Second Sight Solutions' 340B ESP and Truzo (Kalderos / Model N) platforms. Under the anticipated rebate model, there is potential for manufacturer participants to use multiple, non-interoperable platforms with different data specifications. The result: covered entities may need to identify, format, validate, submit, reconcile, and pursue denials for the selected-drug claims across multiple manufacturer platforms, each with its own registration, data specifications, file layouts, and workflows. Variation across manufacturer platforms will require multiple logins, repeated mapping, and duplicate submission of the same underlying claim data. Presently, Truzo's platform is highly manual, requiring individual, customized submissions tailored to each participating manufacturer rather than a single standardized file. Potentially maintaining claims data in parallel across multiple manufacturer IT platforms (e.g., 340B ESP, Beacon, and Truzo), and tracking rebate status and denials separately in each, multiplies the CHCs burden.

[4] Internal NACHC survey data
[5] Supporting Statement A - OPA - 340B Rebate Model Pilot - 0906-NEW

- **TPA automation is not a consistently viable solution.** A significant volume of CHC 340B activity, including clinic-administered drugs and entity-owned pharmacies, occurs outside the TPA workflow that HRSA has assumed is standard. For many CHCs, there is no existing automated TPA "extract-and-submit" pipeline for these claims. Therefore, identification, formatting, and submission for these areas will be predominantly manual. Many existing TPAs' automated data upload processes are designed for hospitals, uploading all data through the parent-site 340B ID. For CHCs utilizing TPAs for entity-owned or contract pharmacies, this means their TPAs' automated data submission processes are not designed for the CHCs grantee site specific data upload needs. If the CHC did use the TPA's hospital-centric automated data upload process, it would create submission errors. On average, CHCs, even with TPAs, must upload data manually to the manufacturer IT platforms. The few TPAs with CHC-specific data upload processes charge CHCs extra for this, reducing 340B savings that could otherwise be used to expand services, increase access to affordable medications, and improve patient care. Many CHCs operate across contract pharmacies, entity-owned pharmacies, and Clinic Administered Drugs (CADs) workflows, and those activities do not reside in a single data stream that can be exported once and sent to manufacturer IT platforms.[6]
- **Clinic-administered drugs (CAD) and paper records.** The majority of CADs are bundled into the CHCs' Prospective Payment System and are not separately billed. For many CHCs, administration logs are maintained on paper or in visit notes rather than in discrete reportable fields within electronic medication administration records (eMAR). Converting these records into the claims-level electronic data elements required for rebate submission is a manual process that imposes additional burden not captured by HRSA's "automated-extract" assumptions.
- **Reconciliation and denial management.** Tasks (4) and (5) of HRSA's methodology[7] are recurring and resource intensive. A time study of current CHC submission processes, conducted by NACHC's 340B Technical Advisors, FQHC 340B Compliance, found that, even at maximum efficiency, an experienced individual requires at least 20 minutes to investigate and resolve a denial or erroneous claim.[8] Because no empirical study currently exists for the proposed 340B rebate model, NACHC estimated reasonable range of claim classification error and claim denial rates using available proxy measures. Improper payment rates reported across CMS programs provide a reasonable lower-bound benchmark for claims requiring staff investigation, appeals, or reconciliation, while reported implementation experience from the Beacon Maximum Fair Price (MFP) rebate program provides an upper-bound benchmark during the launch of a new national rebate infrastructure.
    - **Together, these data suggest claim classification rates provide a reasonable range from approximately 10% to 40% while claim denial rates could range from approximately 5% to 20%.**[9] Additional evidence from Medicare Advantage further demonstrates the administrative burden associated with claim denials.[10] The study found approximately 17% of prior authorization denials meeting Medicare coverage rules were ultimately overturned upon appeal, illustrating that claim denials frequently require extensive provider review, documentation, and follow-up before payment is received. Even assuming a minimum claim classification error rate of 10% and a claim denial rate of 5%, both of which require CHC staff investigation, the estimated burden for claim error and denial is associated with claim investigation ranges from 4 hours for smaller CHCs to more than 50 hours weekly for larger

[6] 340B Rebate Model Pilot Program ICR, 91 Fed. Reg. 35989 (June 15, 2026), https://www.federalregister.gov/d/2026-11989.
[7] This includes reconciling submissions, tracking rebate status, and addressing errors, denials, or follow-up requests
[8] Time estimates to complete each task were based on time studies of gathering, formatting and uploading claims to 340B ESP to reconcile and remediate issues in 340B ESP and Beacon MFP. Highly skilled staff that perform these tasks for nearly 100 community health centers on an ongoing basis conducted timed trials across health centers ranging in size and complexity (patient size, payer mix, number of pharmacies (entity owned vs contract pharmacy), number of Third Party Administrators, presence of CAD and method, and rural vs urban). These time per tasks are an average.
[9] https://340breport.com/denied-disputed-delayed-sponcon-rxparadigm/
[10] Medicare Advantage Denies 17 Percent Of Initial Claims; Most Denials Are Reversed, But Provider Payouts Dip 7 Percent | Health Affairs

CHCs. Although Beacon MFP's performance is expected to improve as the program matures, the timeframe for resolving technical, operational, and system integration challenges remains uncertain. Accordingly, the estimates range provide a reasonable basis for estimating the administrative burden CHCs can expect during implementation of the 340B rebate model.

- **Medical-claims data elements differ from pharmacy fields.** Proposed medical claims data elements, including claim line number, claim number, health plan name, health plan ID, and health plan ID qualifier, are not standardized across health care systems and may not be available at the time of claim submission. Assembling and validating these distinct data field sets adds burden beyond a routine pharmacy extract.

In summary, each entity-owned pharmacy, TPA platform, and electronic health record will constitute a discrete data set that must flow through all five claim-cycle elements. HRSA estimates appear to envision one data upload per week; operational realities dictate that CHCs will have numerous disparate data sets to address each week. While TPAs do offer the potential to improve efficiency, they also drive added cost and are typically not utilized by CHCs for clinic-administered drugs or entity-owned pharmacies.

III. Mountain Park Burden Estimate

To assist HRSA in developing a more accurate, evidence-based, per-response estimate, individual covered entities' burden for providing requested data is provided below. The burden estimate components reflect time studies conducted of HRSA's five task-based activities and capture the entity-specific drivers, including number of impacted claims, number of TPAs, and claim types reported without a TPA, that materially affect burden.

HRSA Task Cycle Area	Platform	Time per Tasks (Min)[11]
1. Identify and extract eligible claims data	In-House	3.00
	CAD	3.00
	CAD Paper Log	5.00
	TPA	3.25
2. Format and validate data to meet manufacturer specifications	In-House	6.50
	CAD EHR Report	3.00
	CAD Paper Log	15.00
	Sites Specific Formatting	2.00
	TPA	2.00
3. Submit the data	Manufacturer Platform	5.00
4. Reconcile submissions & track rebate status	Manufacturer Platform	30.00
5. Addressing errors, denials, or follow-up requests	Manufacturer Platform	20.00

Time estimates to complete each task were based on time studies of gathering, formatting, and uploading claims to 340B ESP to reconcile and remediate issues in 340B ESP and Beacon MFP. Claim issues and denial rates were estimated at 10% and 5% respectively, based on a publication from Rx Paradigm reporting on error (40%) and denial (18%) rates, applying a 4-fold decrease to account for system improvements hoped to be gained over 2026.[12] **As mentioned on the previous page, taken together, these data suggest claim classification rates provide a reasonable range from approximately 10% to 40% while claim denial rates could range from approximately 5% to 20%.[13]**

[11] Time estimates to complete each task were based on time studies of gathering, formatting and uploading claims to 340B ESP to reconcile and remediate issues in 340B ESP and Beacon MFP. Highly skilled staff that perform these tasks for nearly 100 community health centers on an ongoing basis conducted timed trials across health centers ranging in size and complexity (patient size, payer mix, number of pharmacies (entity owned vs contract pharmacy), number of Third Party Administrators, presence of CAD and method, and rural vs urban). These time per tasks are an average.

[12] https://340breport.com/denied-disputed-delayed-sponcon-rxparadigm/

[13] https://340breport.com/denied-disputed-delayed-sponcon-rxparadigm/

To assist HRSA in developing a more accurate, evidence-based, per-response estimate, individual covered entities' burden for providing requested data is provided below. The burden estimate components reflect HRSA's five task-based activities and capture the entity-specific drivers, including number of impacted claims, number of TPAs, and claim types reported without a TPA, that materially affect burden.

Entity Profile and Burden Drivers

Burden Driver	Entity's Value
Covered entity type (e.g., CHC, CHC-LAL, CHC-638)	FQHC
Number of covered entity sites / registered 340B IDs	13
Number of unique patients served annually	100,000
Estimated Selected Drug Claims per Reporting Cycle	203
Estimated number of impacted claims per year (selected drugs)	10,535
Number of participating manufacturer IT platforms reported to	2
Number of distinct manufacturer data specifications / file formats	5
Number of third-party administrators (TPAs) used	3
Number of contract pharmacy locations	138
Number of entity-owned (in-house) pharmacies	2
Number of clinic-administered drug locations with discrete, reportable electronic data	18
Number of clinic-administered drug locations requiring manual data extraction (e.g. paper logs or medications documented in text fields)	18
Volume of other claims reported without a TPA (if applicable)	200/year
Records maintained on paper or non-eMAR systems requiring conversion (Y/N; volume)	18 reports across 13 sites

Time per Task-Based Activity (per Reporting Cycle)

Task-Based Activity (per HRSA methodology)	Est. Hours / Cycle (Low End)	Est. Hours / Cycle (High End)
1. Identifying and extracting eligible claims data	2.77	2.77
2. Formatting and validating data to meet manufacturer specifications	6.65	6.65
3. Submitting the data	3.58	3.58
4. Reconciling submissions and tracking rebate status	21.5	21.5
5. Addressing errors, denials, or follow-up requests	10.13	40.52
Subtotal: Estimated hours per response/cycle	44.63	75.02

Annualized Burden Calculation (cycle = week)

Calculation	Entity's Value (Low End)	Entity's Value (High End)
Estimated hours per response/cycle (per week)	44.63	75.02
Number of responses (Task Cycles) per year (HRSA used 52, assuming 1 per week)	2,236	2,236
Estimated ongoing annual burden hours (hours/cycle × responses/year)	2,320.97	3,901.22
Responsible staff roles (OPA assigned hourly rate of $132/hour for a pharmacist)	$306,367.60	$514,960.60

Mountain Park Health Center anticipates that the actual burden of participating in the proposed 340B Rebate Model Pilot Program will substantially exceed HRSA's estimate of five hours per weekly cycle. Mountain Park operates 13 registered 340B sites, serves approximately 100,000 patients annually, utilizes three separate TPAs, manages relationships with 138 contract pharmacy locations, operates two entity-owned pharmacies, and administers clinic-administered drugs across multiple locations. These operational realities create numerous distinct data streams that must be separately identified, validated, formatted, submitted, reconciled, and maintained throughout the rebate process.

Unlike hospitals that often report under a single parent 340B identifier, community health centers must maintain site-specific reporting and compliance activities at the individual 340B ID level. This requires separate alignment of pharmacy relationships, wholesaler accounts, utilization data, and manufacturer platform requirements for each eligible site. The need to manage these activities across multiple sites substantially increases administrative burden beyond HRSA's assumptions.

The anticipated lack of standardization among participating manufacturers is a major burden driver. Mountain Park expects to report through multiple manufacturer platforms with different file layouts, data specifications, validation requirements, submission procedures, and denial management processes. Requiring covered entities to repeatedly map and submit the same underlying claims data across multiple non-interoperable systems creates significant duplicative work, increases error risk, and requires ongoing staff training and oversight.

The assumption that TPAs can automate most reporting functions does not reflect Mountain Park's operational reality. A substantial portion of our 340B activity occurs through entity-owned pharmacies and clinic-administered drugs that do not flow through standard TPA reporting processes. Significant manual work is required to prepare, validate, and submit data for rebate requests. In addition, TPA vendors often charge additional fees for customized reporting functionality, further reducing scarce 340B resources.

Mountain Park also expects substantial burden associated with clinic-administered drugs. Many clinic-administered drugs are not maintained in discrete reportable fields and require manual extraction from clinical records, administration logs, visit documentation, or other sources. In some cases, paper-based documentation for reconciliation. These activities are labor intensive and are not adequately reflected in HRSA's burden estimate.

Reconciliation and denial management are expected to be among the most resource-intensive aspects of the pilot. Current experience with manufacturer restriction platforms and other rebate programs demonstrates that claims frequently require investigation, correction, supporting documentation, resubmission, and follow-up communication. Even under optimistic assumptions, claim classification errors and denials could require many hours of staff time each reporting cycle. Mountain Park

expects pharmacists, 340B program staff, pharmacy purchasers, revenue cycle personnel, finance staff, and information technology personnel to participate in denial resolution and rebate tracking activities, creating ongoing operational costs that extend far beyond simple data submission.
The pilot would also require significant staff training, development of new standard operating procedures, software configuration, validation testing, and ongoing monitoring to ensure compliance with changing manufacturer requirements. Additional information technology support would be necessary to maintain interfaces, troubleshoot data transmission issues, generate site-specific reports, and reconcile rebate payments. These implementation and maintenance costs are not fully captured in HRSA's burden calculations.
Finally, the proposed rebate model would duplicate many of the same claims-identification, extraction, formatting, validation, and reporting activities that covered entities are simultaneously being asked to develop for the CMS Medicare Part D 340B Data Repository. As a result, Mountain Park would be required to maintain parallel reporting workflows, separate validation processes, and multiple submission channels for substantially similar data. This duplication further increases administrative burden and diverts resources away from patient care.
Based on Mountain Park's operational structure and the burden drivers identified above, the estimated ongoing burden ranges from approximately 2,321 to 3,901 hours annually, with associated personnel costs ranging from approximately $306,000 to $515,000 per year. These estimates do not fully account for one-time implementation expenses, software modifications, staff training, additional IT support, consultant costs, cash-flow management activities, or the operational disruption associated with implementing an entirely new rebate infrastructure. Consequently, Mountain Park believes the actual burden imposed by the proposed 340B Rebate Model Pilot Program will be substantially greater than HRSA's estimate and would divert significant resources away from caring for vulnerable patients

IV. Burden Associated with the Manufacturer Collections Should Address Downstream Effects on Covered Entities

A. Manufacturer Plan Submissions (Estimated 8 Hours; 11 Respondents)

The ICR estimates 8 hours per manufacturer plan submission across 11 manufacturers, totaling 88 total burden hours.[14] **Mountain Park** does not opine on the time a manufacturer needs to draft a plan but emphasizes that the *content* of these plans directly determines covered-entity burden. **Mountain Park respectfully requests all approved manufacturer plans be publicly published in their entirety on OPA's website.** Published manufacturer plans should include complete descriptions of "dispense to rebate" calculation logics to be used by manufacturers' IT platform vendors, including any conditions such as reasonable use timeframes (e.g., rebate requests must be made within X days of a WAC purchase), to alleviate participation burden. This would also align with the 340B rebate pilot's stated intent to improve program transparency.

B. Manufacturer Monthly Purchase Reports (Estimated 2 Hours; 132 Responses)

The ICR estimates 2 hours per monthly purchase report, 12 reports per manufacturer across 11 manufacturers, totaling 264 total burden hours.[15] **Mountain Park supports robust manufacturer reporting to OPA and the 340B Prime Vendor as a program-integrity measure. We also recommend HRSA make manufacturer-reported performance data publicly available on OPA's website.** For transparency purposes, NACHC strongly suggests the following metrics be made publicly available, both by drug and by manufacturer:

- Average days from claim submission to rebate payment

[14] Id., Table 1, row 1 (Plan Submission: 11 respondents × 8 hours = 88 hours).
[15] Id., Table 1, row 2 (Monthly purchase reports: 11 respondents × 12 responses × 2 hours = 264 hours).

- Percentage of rebates paid after 10 days
- Percentage of rebates denied by denial reason
- Aggregate volume of rebates requested and rebates approved.

V. The Pilot Duplicates Reporting Already Being Requested Under the CMS Medicare Part D 340B Data Repository

HRSA's covered entity burden estimate fails to account for the substantial duplication of effort between the anticipated Rebate Model Pilot and the new Medicare Part D Claims Data 340B Repository (the "340B repository"). The Centers for Medicare and Medicaid Services (CMS) finalized the 340B repository in the Calendar Year 2026 Physician Fee Schedule final rule (90 Fed. Reg. 49266) as part of its implementation of the Medicare Part D Drug Inflation Rebate Program under the Inflation Reduction Act. CMS plans to make the repository available for submissions beginning October 1, 2026, which matches the general timeframe in which this Pilot is expected to operate. Both collections require covered entities to identify, extract, format, and transmit claims-level data on the very same 340B dispenses, yet they are being built as separate, parallel systems with different operators, specifications, and workflows. This is precisely the type of information collection burden that the Paperwork Reduction Act directs agencies to identify and avoid under 44 U.S.C. 3506(c)(3)(A) and 3506(c)(3)(B).

The standardized data elements required for the 340B repository, including date of service, prescription number, fill number, dispensing pharmacy NPI and NDC-11, and the covered entity's 340B ID are all data elements that covered entities would also submit under the Pilot. Although repository participation is currently voluntary, CMS has actively encouraged broad participation, suggesting mandatory participation is likely in the near future. As a result, covered entities will likely be required to maintain two distinct claims data pipelines for the same underlying claims, each with distinct validation rules, submission processes, reconciliation activities, and record-retention requirements. **HRSA's burden analysis should expressly account for the fact that covered entities are simultaneously standing up the processes and systems needed for the 340B repository, and that the Pilot adds a second, non-interoperable reporting obligation on top of it.**

To mitigate these concerns, Mountain Park recommends that HRSA:

1. Exempt CHCs from the rebate model.
2. Expressly account for the duplicative burden of the 340B repository in its per response and annual burden estimates rather than treating the Pilot reporting as a standalone, first-time data exercise;
3. Coordinate with CMS so that the data elements, formats, and submission timelines for the Pilot align with the 340B repository to the greatest extent possible, ideally allowing a single, standardized covered entity submission to serve both purposes; and
4. Leverage the 340B repository as the source of truth for deduplication wherever feasible, rather than requiring covered entities to construct an additional, parallel reporting channel to each manufacturer's chosen platform.

VI. Conclusion

Mountain Park strongly urges HRSA to exempt CHCs from any 340B Rebate Model Pilot Program. As discussed in previous comment letters, a rebate model represents a substantial departure from the original intent of the 340B program; to allow safety-net providers to "stretch scarce Federal resources" and provide more comprehensive care. This pilot would create significant cash flow challenges, forcing CHCs to make difficult decisions about staffing, services, and the range of drugs they can afford to stock. Additionally, many CHCs would need to make significant investments in IT infrastructure and staff to

comply with rebate requirements and track rebates. It would also create a new barrier for patients, especially uninsured patients, who depend on the up-front 340B discount, making it operationally impossible to provide the sliding fee scale and steeply discounted medications required by law. **Mountain Park believes a 340B rebate pilot would cause disproportionate harm to the 52 million patients served by CHCs.**

Mountain Park appreciates the opportunity to respond to this ICR on the 340B Rebate Model Pilot Program and looks forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please contact Maegan Burris, Associate Director of Pharmacy, mburris@mphc-az.org

Sincerely,

Signed by:
John Swagert, MD
FE73935B505E459...

John Swagert, MD
Chief Executive Officer
Mountain Park Heath Center

Supplemental Supporting Data

HRSA Estimated Data Burden & Cost (All CEs)

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Covered Entities reporting claims data to third party platform	15,249	52	792,948	5	3964740
Total	15,260		793,091		**3,965,092**

Type of Respondent	Instrument	Total Estimated Burden Hours	Hourly Wage Rate	Total Respondent Costs
Pharmacist	**Covered Entities reporting claims data to third party platform**	**3,964,740**	**$132.00**	**$523,345,680**

HRSA Estimated CHC Data Burden & Cost

Health Center By CE reporting claims data to third party platform	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
CHC	1302	52	67,704	5	338,520
FQHC-LAL	150	52	7,800	5	39,000
Total	1,452		75,504	10	**377,520**

Type of Respondent	**Instrument**	**Total Estimated Burden Hours**	**Hourly Rate**	**Total Respondent Costs**
Pharmacist	Covered Entities reporting claims data to third party platform	377,520	$132.00	$49,832,640
Estimated Total		**3,965,356**		**$49,832,640**

Proposed Pilot Manufacturers Current Data Conditions for Sale at 340B Pricing

Manufacturer	**Drug**	**CHC Contract Pharmacy Data Requirements**	**CHC Entity Claims Data Requirements (Effective)**	**Platform**
AbbVie	Imbruvica, Linzess, Vraylar	Yes		340B ESP
Amgen	Enbrel, Otezla; Otezla XR	Yes	Yes (6/1/2026)	340B ESP
Astellas	Xtandi	Yes		340B ESP
AstraZeneca	Calquence, Farxiga	Yes	Yes (5/1/2026)	340B ESP
BI	Jardiance, Ofev, Tradjenta	Yes	Yes (7/6/2026)	340B ESP
BMS	Eliquis, Pomalyst	Yes	Yes (5/1/2026)	340B ESP
GSK	Breo Ellipta, Trelegy Ellipta	Yes	Yes (7/1/2026)	340B ESP
Merck	Janumet, Januvia	Yes		340B ESP
Novo Nordisk	Ozempic, Rybelsus, Wegovy	Yes	Yes (4/1/2026)	340B ESP
Pfizer	Ibrance	Yes		340B ESP
Teva	Austedo; Austedo Xr	Hospitals Only		340B ESP

Public Comments for IFR-202606-0906-001

Author Full Name : Maegan Burris **Received Date :** 07/15/2026 04:57 PM

Comments Received :

Please see attached letter for Mountain Park Health Center. Thank you for taking FQHC's comments for review.

Mercy Health System

JULY 13, 2026

VIA ELECTRONIC SUBMISSION TO
https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202606-0906-001

Ms. Samantha Miller
Health Resources and Services Administration
Information Collection Clearance Officer
5600 Fishers Lane, Room 13N82
Rockville, MD 20857

RE: Public Comment Response to HRSA's Request for Information Collection under OMB Number 0906-NEW

Dear Ms. Miller:

On behalf of MERCY HEALTH SYSTEM ("MERCY HOSPITAL COLUMBUS"), we respectfully submit this comment regarding the proposed collection of information described in *340B Rebate Model Pilot Program Application, Implementation, and Evaluation under OMB Number 0906-NEW* ("Proposed ICR").[1] We appreciate the opportunity to provide feedback during the 30-day comment period.

As a 340B Covered Entity, MERCY HOSPITAL COLUMBUS is particularly interested in ensuring that any future rebate model can be administered in a manner that is operationally feasible, appropriately tailored, and does not create unnecessary administrative burden for providers serving vulnerable patient populations. Considering that Covered Entities will ultimately be responsible for collecting, validating, submitting, and reconciling the information contemplated by the Proposed ICR, it is important that HRSA's burden estimates and reporting assumptions accurately reflect the realities of day-to-day program administration. The comments below reflect our concerns regarding (i) the lack of specificity surrounding required data elements, (ii) the continuing inconsistencies regarding future reporting obligations, and (iii) the significant administrative and technological burdens that may be imposed upon Covered Entities.

I. HRSA's Data Submission Requirements Are Not Only Ambiguous, They Are Contradictory.

One of the most significant challenges the Proposed ICR presents is that MERCY HOSPITAL COLUMBUS still does not know what information will ultimately be required under a future rebate model. Not only is HRSA's ambiguity contrary to the intent of the Paperwork Reduction

[1] *340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-NEW,* 91 Fed. Reg. 35989 (Jun. 26, 2026).

Act, but from an operational perspective, it is difficult for MERCY HOSPITAL COLUMBUS to evaluate staffing needs, technology requirements, vendor support needs, or reporting burden when the specific data elements have not yet been identified.

Notably, the Proposed ICR does not contain definitions that describe the specific data elements that MERCY HOSPITAL COLUMBUS would be required to submit, nor does it identify any standardized format or scope for such submissions. This lack of clarity is particularly problematic because HRSA has stated in the Proposed ICR that it has not approved nor reviewed any manufacturer rebate model proposals, and therefore cannot articulate what information would actually be required under a future rebate model.[2] The only confirmation Covered Entities have received from HRSA is that it will publish manufacturer plans in the Federal Register. Further, the Proposed ICR does not offer any general description of the type of data MERCY HOSPITAL COLUMBUS will be required to submit. Once again, the Proposed ICR states that the type and frequency of such submissions will be published in the Federal Register notice and that the data will be "comparable to data currently maintained through third-party vendors or previously provided to manufacturers under unrelated pharmacy or claims programs."[3] This expectation is entirely speculative and ambiguous.

This ambiguity is particularly concerning because it creates a fundamental inconsistency regarding the information MERCY HOSPITAL COLUMBUS may eventually be required to submit. HRSA repeatedly suggests that the necessary data elements are already generated and maintained by Covered Entities or their vendors, yet simultaneously acknowledges that it has not identified the specific data elements that will be required and that those requirements will be defined in a future Federal Register notice. If the required data elements are already standardized and commonly maintained, HRSA should be able to identify them now. Conversely, if HRSA cannot identify the data elements until after manufacturer proposals are received and evaluated, then there is no basis for concluding that such information is readily available or can be produced with minimal burden. This contradiction makes it difficult for MERCY HOSPITAL COLUMBUS to understand what we are being asked to prepare for and further underscores the lack of clarity surrounding the Proposed ICR.

HRSA's ambiguity and contradictory language is not entirely new. In the February 2026 ICR, Covered Entities raised similar objections regarding the inconsistencies between HRSA's claim that it would publish the standard data elements and that Covered Entities already maintained those data elements.[4] Since HRSA did not materially answer to these concerns in February, MERCY HOSPITAL COLUMBUS (and Covered Entities in general) remains in the same position it occupied in prior comment periods: to evaluate an information collection request without knowing what information will ultimately be collected or how such information will be used. Due to the above-mentioned ambiguities and inconsistencies, the Proposed ICR does not resolve the central uncertainty that has characterized each previous iteration of HRSA's rebate model information collection and instead perpetuates it.

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[2] *See* 91 Fed. Reg. at 35990.
[3] *Id.*
[4] *See 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-NEW,* 91 Fed. Reg. 9632, 9633.

This uncertainty is particularly challenging because health systems cannot build compliance processes overnight. New reporting requirements often require coordination among MERCY HOSPITAL COLUMBUS's own internal pharmacy department and its third party vendors. Without knowing what information will ultimately be collected, MERCY HOSPITAL COLUMBUS cannot meaningfully assess the resources necessary to comply nor comment on the Proposed ICR.

II. The Proposed ICR Is More Burdensome Than Necessary.

HRSA has not offered an accurate estimate of the average burden upon Covered Entities, nor has it demonstrated that it has selected the least burdensome means of collecting covered entities' information – because it cannot, for the reasons noted above. HRSA states that it employs a task-based methodology to estimate respondent burden and that its calculation accounts for "(1) identifying and extracting eligible claims data, (2) formatting and validating data to meet manufacturer specifications; (3) submitting the data; (4) reconciling submissions and tracking rebate status; and (5) addressing errors, denials, or follow-up requests."[5] Despite acknowledging the breadth of these operational functions, HRSA concludes that Covered Entities will only require approximately five hours per week to satisfy these obligations.[6]

That estimate is not—and again cannot be given the current lack of information—accompanied by sufficient explanation to permit meaningful public review. HRSA does not identify the assumptions that underlie its calculations, including the volume of expected claims transactions, the anticipated frequency of data submissions, the number of reconciliation events, the extent of staff involvement necessary to resolve disputes or denials, the processes for such disputes, or the costs associated with implementing and maintaining systems capable of complying with manufacturer reporting requirements.

To better inform HRSA and OMB regarding the actual burden associated with a rebate-based model, MERCY HOSPITAL COLUMBUS believes covered entities should be permitted to describe their real-world operational experience. Based on Mercy's current experience managing the complexities associated with the intersection of the Medicare Drug Price Negotiation Program and 340B duplicate discount prevention requirements, Mercy estimates that compliance with claims reporting, rebate administration, reconciliation, exception management, and dispute resolution activities would require a minimum of approximately 160 hours per week, or four full-time employees (4.0 FTEs).

Mercy has intentionally centralized its 340B operations team to create operational efficiencies, control administrative costs, and maintain a consistent level of expertise across all hospitals within the system. Even with a centralized operating model, the administrative burden associated with a rebate-based approach is significant. Without this structure, many smaller hospitals would

[5] 91 Fed. Reg. at 35990.
[6] *Id.*

face substantial challenges complying with reporting requirements and managing the financial and operational risks associated with the rebate model. A rebate model is not required to de-duplicate claims with the Maximum Fair Price (MFP) and our comments related to this should not be construed as a concession to that fact. Mercy opposes any rebate model and is concerned that this fundamental shift in how 340B has operated for over 30 years will negatively impact the expansion of services and community benefits this program has helped to support. Our patients and communities deserve better.

In particular, the requirement to purchase drugs at Wholesale Acquisition Cost (WAC) and wait for subsequent rebate payments creates a significant cash-flow burden. For many Critical Access Hospitals, Rural Referral Centers, and Sole Community Hospitals, the acquisition cost under a rebate model may exceed what those facilities would otherwise pay absent participation in the 340B Program. This shifts substantial financial risk to hospitals while requiring additional resources to monitor, validate, and recover expected rebates.

Focusing solely on the act of data submission materially understates the true administrative burden. The operational workload extends well beyond the initial transmission of claims data and includes ongoing claims validation, rebate tracking, reconciliation, investigation of discrepancies, management of denied or missing rebates, good-faith inquiries with manufacturers, dispute resolution, audit support, compliance oversight, and financial reporting activities.

Our experience demonstrates that the complexities associated with aligning 340B discounts and Medicare Maximum Fair Price (MFP) requirements are not eliminated under a rebate model. Rather, the rebate model introduces additional layers of administrative complexity and financial risk. Hospitals must establish processes to verify that rebates are received, ensure that rebate amounts are accurate, and identify instances where expected rebates are not paid.

Additionally, rebates are generally calculated at the unit level, while hospitals often must reconcile those rebates back to purchasing and dispensing records. This process is complex, time-consuming, and frequently delayed. Accurate reconciliation is essential to confirm that the hospital ultimately received the appropriate 340B price and to identify discrepancies requiring follow-up with manufacturers.

Based on Mercy's operational experience, we believe the administrative burden associated with rebate administration, reconciliation, monitoring, and dispute resolution has been significantly underestimated. The burden extends far beyond claims submission and requires dedicated personnel and ongoing operational support that should be fully reflected in HRSA's burden estimates and economic impact analysis.

III. The Proposed Rebate Model May Lead to Overcharges.

On a separate note, should MERCY HOSPITAL COLUMBUS be required to submit claims-data under a future rebate model, it may trigger overcharges under the 340B statute. Through manufacturer all-claims policies, Covered Entities are increasingly being required to provide extensive claims-level data as a condition of accessing 340B drugs. Under these arrangements, Covered Entities are required to submit more data than is necessary for platforms such as 340B ESP to match Covered Entities' claims with manufacturer's rebate data.[7] For example, CMS's Part D repository will only require Covered Entities to submit: (i) 340B ID, (ii) Date of Service, (iii) Prescription Number, (iv) Fill number, (v) NDC-11, (vi) Dispensing Pharmacy NPI, and (vii) Claim Record Indicator. If CMS has determined that it only needs these seven data elements to remove 340B claims from its Part D inflation rebate requests, it would be highly irregular for its sister agency to require Covered Entities to disclose more or different data to a private, for-profit data aggregator.

Any such requirement would raise immediate concerns under the 340B statute's prohibition against overcharges. While manufacturers may characterize these data-submission obligations as administrative requirements rather than part of the purchase price, the practical effect would be that MERCY HOSPITAL COLUMBUS could not obtain the full value of the 340B discount without providing valuable claims data and absorbing the significant costs associated with maintaining and submitting that information. MERCY HOSPITAL COLUMBUS also will not receive compensation for either the data itself or the resources required to support these activities. As a result, a future rebate model may effectively require MERCY HOSPITAL COLUMBUS to provide additional consideration beyond payment of the of the 340B ceiling price in order to access the 340B discount, which would result in an overcharge.

IV. Conclusion

MERCY HOSPITAL COLUMBUS appreciates HRSA's efforts to gather stakeholder feedback regarding reporting requirements for a future Rebate Model Pilot Program. As an organization committed to serving patients and maintaining compliance with the 340B Program, we support efforts to develop processes that are defined, operationally feasible, and tailored to the realities Covered Entities face.

At this time, however, we believe that additional information is needed regarding the data elements that may be required, the operational structure of the future rebate models, and the assumptions underlying HRSA's burden estimates. We respectfully encourage HRSA to revise the Proposed ICR and provide stakeholders with additional detail before seeking final approval from OMB.

[7] Bradley Malin, Expert's Assessment of Second Sight 340B ESP™ De-Identification Procedures for Medical Benefits Claims Data, 19 (2026).

Respectfully submitted,

Mike Loftus

Mike Loftus
ED-Pharmacy Integration & Performance

CC: Dr. John Mohart (Executive Vice President-Chief Operating Officer)
Mike Hubert (VP-Chief Corporate Affairs Officer)

St. Luke's Health System

St Luke's

July 15, 2026

VIA ELECTRONIC SUBMISSION TO
https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202606-0906-001

Ms. Samantha Miller
Health Resources and Services Administration
Information Collection Clearance Officer
5600 Fishers Lane, Room 13N82
Rockville, MD 20857

RE: Public Comment Response to HRSA's Request for Information Collection under OMB Number 0906-NEW

Dear Ms. Miller:

On behalf of St. Luke's Health System ("St. Luke's"), we respectfully submit this comment regarding the proposed information collection request described in *340B Rebate Model Pilot Program Application, Implementation, and Evaluation under OMB Number 0906-NEW* ("Proposed ICR").[1] St. Luke's is a community-led, Idaho-based, not-for-profit health system that includes six hospitals and a hemophilia treatment center enrolled as covered entities in the 340B Drug Pricing Program ("340B Program"). We appreciate the opportunity to provide feedback during the 30-day comment period.

In keeping with our not-for-profit mission, St. Luke's maintains an open-door policy under which we care for all patients regardless of their ability to pay. Thousands of patients with no or inadequate healthcare coverage receive free services at our hospitals and clinics each year. In fiscal year 2025, St. Luke's provided charity care at a total cost of over $36 million, and we provided services to patients covered by Medicare, Medicaid, and other government programs for which our unreimbursed costs exceeded $660 million. Our covered entities care for more Medicaid and charity patients than any other provider in our state, and 340B savings are essential to our ability to provide this care.

Given the critical role our covered entities play in Idaho's healthcare safety net, our covered entities have a vested interest in ensuring that any future 340B rebate model can be administered in a manner that is operationally feasible, appropriately tailored, and does not create unnecessary administrative burden for providers serving vulnerable patient populations. Considering that covered entities will ultimately be responsible for collecting, validating, submitting, and reconciling the information

[1] *340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-NEW,* 91 Fed. Reg. 35989 (Jun. 26, 2026).

contemplated by the Proposed ICR, it is important that HRSA's burden estimates and reporting assumptions accurately reflect the realities of day-to-day program administration. The comments below reflect our concerns regarding the lack of specificity surrounding required data elements and the significant administrative and technological burdens that may be imposed upon covered entities.

I. HRSA's Ambiguous Data Submission Requirements Preclude a Meaningful Covered Entity Response.

One of the most significant challenges the Proposed ICR presents is that covered entities still do not know what information will ultimately be required under a future rebate model. Not only is this ambiguity contrary to the intent of the Paperwork Reduction Act, but from an operational perspective, it is difficult for St. Luke's to evaluate staffing needs, technology requirements, vendor support needs, or reporting burden when the specific data elements have not yet been identified.

The Proposed ICR does not describe the specific data elements that covered entities would be required to submit, nor does it identify any standardized format or scope for such submissions. HRSA states in the Proposed ICR that it has not approved nor reviewed any manufacturer rebate model proposals, and therefore cannot articulate what information would actually be required under a future rebate model.[2] Instead, the Proposed ICR states that the type and frequency of such submissions will be published in the Federal Register notice and that the data will be "comparable to data currently maintained through third-party vendors or previously provided to manufacturers under unrelated pharmacy or claims programs."[3]

The Proposed ICR seems to presume that if covered entities maintain a certain type of data, it should be relatively easy for them to aggregate and produce similar types of data. This is a misguided presumption that belies the incredible complexity of healthcare operations in the United States, and could result in significant barriers and unanticipated burdens for covered entities. The recent CMS Outpatient Prospective Payment System Drug Acquisition Cost Survey ("ODACS") demonstrated the practical challenges posed by this kind of presumption; some of the survey reporting fields reflected fundamental misunderstandings about hospital drug procurement operations that precluded an accurate response.

The ODACS asked hospitals to report on the total units of non-340B outpatient drugs purchased during the survey period. While our robust 340B compliance program ensures that all 340B accumulations are for covered outpatient drugs administered or dispensed to eligible patients, we cannot easily segregate our non-340B drug purchasing data between outpatient and inpatient utilization. As we explained in the April 7, 2026, comment letter that we submitted to CMS:

[2] *See* 91 Fed. Reg. at 35990.
[3] *Id.*

> "340B participating DSH hospitals are prohibited from purchasing covered outpatient drugs 'through a group purchasing organization or other group purchasing arrangement,'[4] which is commonly referred to as the 'GPO prohibition.' . . . The result of the GPO prohibition is that our 340B participating DSH hospitals must acquire initial inventory at Wholesale Acquisition Cost (WAC) and also maintain separate accumulators to replenish inventory for i) inpatient drug utilization (which is not subject to the GPO prohibition), and ii) 340B eligible outpatient drug utilization. While this may seem like it would lend itself to Survey reporting, the Survey does not account for the fact that pharmacy split-billing software can only replenish 340B and GPO priced inventory when sufficient volumes exist to purchase full package quantities at either 340B or GPO pricing. When accumulated 340B and inpatient GPO utilization does not meet full package thresholds, these Hospitals must default to purchasing drugs at WAC, which is the most expensive option. Other purchases on WAC that cannot be categorized as inpatient or outpatient include uncaptured waste (some of which results from multi-dose vials that require disposal of the unused portion) and expired medications (some of which result from the hospital's need to be prepared for infrequent or emergent situations e.g. antidote stocking, post-exposure prophylaxis, crash carts, rapid sequence intubation, etc.). In short, our DSH WAC purchases cannot be tied exclusively to outpatient utilization."[5]

HRSA repeatedly suggests that the necessary data elements for any rebate model proposals are already generated and maintained by covered entities or their vendors. We provide the example above to illustrate the complexity of our drug procurement and related systems, and the danger of assuming that certain types of data will be readily available. If HRSA cannot identify the data elements until after manufacturer proposals are received and evaluated, we urge HRSA not to assume that such information is readily available or can be produced with minimal burden.

This uncertainty is particularly challenging because health systems cannot build compliance processes overnight. New reporting requirements often require coordination among our internal pharmacy department and third-party vendors. Without knowing what information will ultimately be collected, St. Luke's cannot meaningfully assess the resources necessary to comply nor substantively comment on the Proposed ICR.

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[4] 42 U.S.C. §256b(a)(4)(L)(iii)

[5] St. Luke's Health System, Letter to the Centers for Medicare & Medicaid Services regarding CMS Outpatient Prospective Payment System Drug Acquisition Cost Survey (Apr. 7, 2026) (submitted via email to OPPSdrugsurvey@cms.hhs.gov) (on file with CMS).

II. The Proposed ICR Is More Burdensome Than Necessary.

HRSA has not offered an accurate estimate of the average burden upon covered entities, nor has it demonstrated that it has selected the least burdensome means of collecting covered entities' information – because it cannot, for the reasons noted above. HRSA states that it employs a task-based methodology to estimate respondent burden and that its calculation accounts for "(1) identifying and extracting eligible claims data, (2) formatting and validating data to meet manufacturer specifications; (3) submitting the data; (4) reconciling submissions and tracking rebate status; and (5) addressing errors, denials, or follow-up requests."[6] Despite acknowledging the breadth of these operational functions, HRSA concludes that covered entities will only require approximately five hours per week to satisfy these obligations.[7]

That estimate is not—and again cannot be given the current lack of information—accompanied by sufficient explanation to permit meaningful public review. HRSA does not identify the assumptions that underlie its calculations, including the volume of expected claims transactions, the anticipated frequency of data submissions, the number of reconciliation events, the extent of staff involvement necessary to resolve disputes or denials, the processes for such disputes, or the costs associated with implementing and maintaining systems capable of complying with manufacturer reporting requirements. Without having this information and the specific data elements covered entities will be required to submit, we think it is unreasonable to assume that our data submission burden will be limited to five hours per week.

HRSA's burden estimate also fails to account for the likely need for covered entities to procure new vendor services to reconcile rebate payments. Under a rebate model, St. Luke's would need a reliable mechanism to independently confirm that each rebate payment is received, properly calculated, timely paid, and matched to the correct eligible 340B claim. Without such reconciliation, we would bear the risk of delayed, incomplete, or inaccurate rebate payments, while also absorbing the administrative burden of identifying and resolving discrepancies. St. Luke's current third-party administrator does not offer rebate payment reconciliation, and St. Luke's does not have the internal staffing, technology infrastructure, or system capabilities necessary to build and maintain such a tool. As a result, St. Luke's would likely need to engage an additional third-party vendor solely to verify that manufacturers pay the rebates owed.

Based on our experience using similar vendor-supported tools, we estimate that the cost of these services would likely exceed $120,000 annually. This estimate does not account for the additional internal staff time required to manage the vendor relationship, investigate discrepancies, validate payment data, follow up with manufacturers or platform vendors, and document compliance activity, which could easily average between 15 and 20 hours per week. This far exceeds the five hours per week estimated by HRSA. This significant recurring expense and ongoing burden would be imposed

[6] 91 Fed. Reg. at 35990.
[7] *Id.*

on our covered entities simply to ensure they receive the 340B pricing to which they are already entitled.

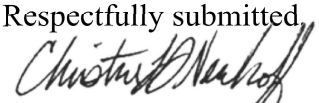
HRSA's burden estimate should account for these new vendor costs, the ongoing internal resources needed to support rebate reconciliation, and the financial risk covered entities would face if manufacturers delay, deny, or underpay rebate claims. We also respectfully request that HRSA consider mechanisms that would allocate the administrative burden and cash-flow risks associated with a rebate pilot to drug manufacturers, which are substantially better positioned than safety-net hospitals to absorb and manage these costs.

III. Conclusion

St. Luke's appreciates HRSA's efforts to gather stakeholder feedback regarding reporting requirements for a future Rebate Model Pilot Program. As an organization committed to 340B Program compliance and serving all of our patients regardless of their ability to pay, we support efforts to develop processes that are defined, operationally feasible, and tailored to the realities covered entities face. At this time, however, HRSA has not provided sufficient information regarding the required data elements, the operational structure of future rebate models, or the assumptions underlying HRSA's burden estimates to permit meaningful public comment.

Accordingly, we respectfully urge HRSA to revise the Proposed ICR to provide stakeholders with additional detail and a meaningful opportunity for public comment before seeking final approval from OMB.

Respectfully submitted,



Christine Neuhoff, JD, MBA
Senior Vice President and Chief Legal Officer
St. Luke's Health System