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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

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[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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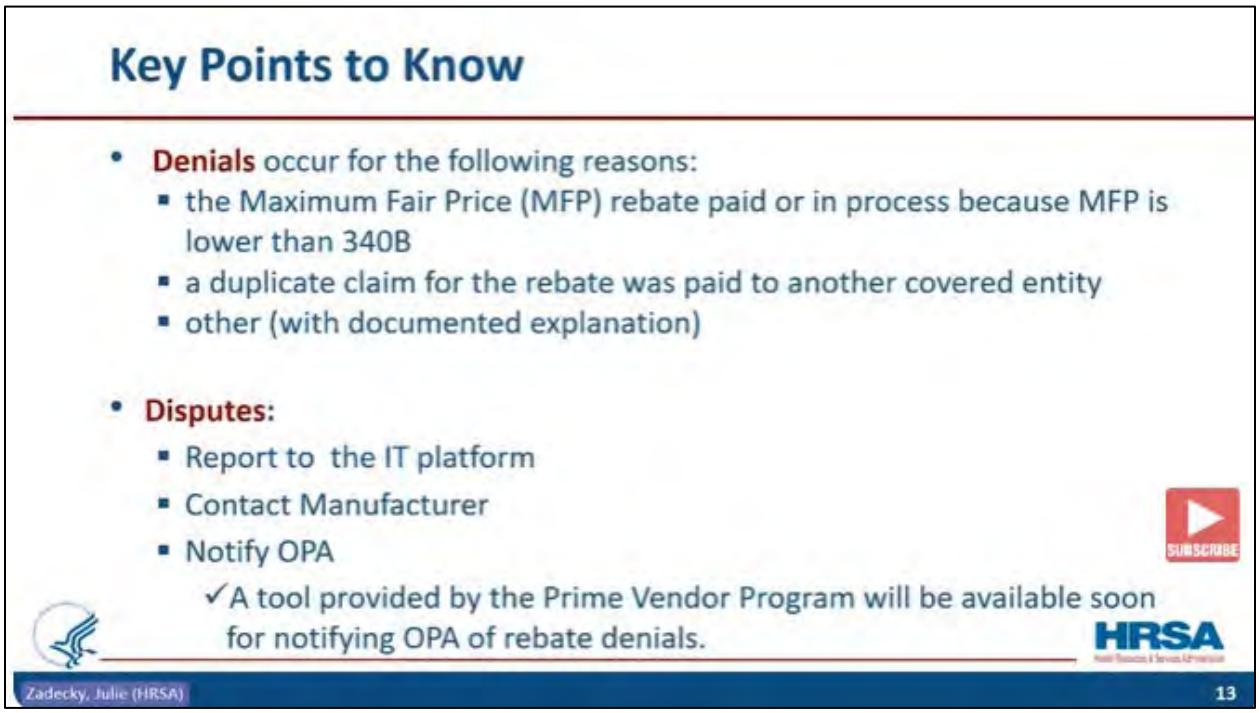
2026-03042) (Apr. 17), https://www.regulations.gov/comment/HRSA-2026-0001-1720 ("From our UVM Health pharmacies' experience of the first year of the MDPNP, companies like Amgen, Boehringer Ingelheim, and Johnson & Johnson have denied refund claims, asserting, without evidence, that drugs were dispensed 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.
>
> ….
>
> 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

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[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*., *not* 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.").