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

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

Dear Administrator Engels:

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

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

The RFI poses 30 questions and encourages commenters to include supporting facts, research, and evidence in their responses. Meadville Medical Center has done its best to provide detailed answers in the limited time available to us. For purposes of estimating costs, we have assumed that any future Rebate Program will include the 10 drugs that HRSA previously approved for its original Program and those that have been approved under the Medicare Drug Price Negotiation Program (MDPNP) for 2027, per HRSA's February 25, 2026 Information Collection Request. With the addition of the 2027 drugs, our cost estimates have increased over the estimates we had calculated for the 2026 drugs alone. After all, more drugs and more drug companies mean *more* claims to submit, *more* rebates to track and reconcile, *more* money that we will need to float to drug companies while we await our statutory discount, *more* likely disputes over delays and denials, and therefore *less* money that MMC can spend on patient care and comprehensive health care services.

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

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

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

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

Incremental Costs:

- Additional staff expense year one: $43,257
- Additional staff expense year two: $105,048
- Additional staff expense year three: $132,674
- **Cumulative three-year total of additional staff expense**: $280,980

- Child site accumulator addition within third party administrator: $3,600/year
- Software to track and monitor both 340B and MFP rebates: $30,000/year
- Software to monitor drug pricing and payments: $150,000/year

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

Also, Meadville Medical Center was required to build additional clean-site accumulators within our third-party administrator system, which results in an ongoing monthly fee. MMC also obtained a quote for software necessary to assist with tracking and monitoring rebate activity.

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

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

One-time Startup Costs:

- Additional FTE(s) salary wages and benefits: $97,500
- Information systems interface modification: $245
- Staff education and training: $5,756

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

- Year one variance in initial drug spend: $2,808,315
- Year two variance in initial drug spend: $6,121,842
- Year three variance in initial drug spend: $8,395,565
- **Cumulative three-year total variance in drug spend:** $17,325,722

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

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

By 2027 (Year Two), the total estimated time required to manage Rebate Model claims is **2,913 hours annually**, which exceeds the standard 2,080 annual hours for one full-time equivalent (FTE) employee. By 2028, the estimated administrative time increases further to 3,680 hours annually.

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

To meet the demands of the proposed model, MMC would need to hire one additional FTE by 2027 and at least another half FTE by 2028, resulting in an anticipated annual staffing cost of approximately $97,500.

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

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

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

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

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

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

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

Presently, data is transmitted from MMC's electronic medical records system to our third-party administrators. 340B eligibility is determined based on MMC's internal policies and procedures, which align with the 340B Program requirements outlined in the Federal Register and guidance provided by HRSA. MMC's auditors routinely download 340B-eligible claims from our TPAs to conduct monthly compliance audits. During these reviews, auditors verify that the provider, service location, financial class, and drug meet

eligibility requirements in accordance with the established policies and program guidelines. These claim downloads are maintained in Excel files and stored in a shared folder for documentation and reference.

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

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

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

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

Payment Timing and Potential Cash Flow Impacts. Unlike the existing upfront discount mechanism, any rebate mechanism will force MMC to effectively provide drug

companies interest-free loans as we await the discounts that we are owed under the 340B statute. Even if drug companies paid within a 10-day period as required under the prior iteration of the Rebate Program, that delayed discount will have meaningful impact on our institution and the patients we serve.

MMC is currently operating under a thin operating margin, and this unexpected increase in supply costs would further strain our health system's cash flow. Specifically, purchasing the IRA high-cost medications selected for the Rebate Model Pilot Program at wholesale acquisition cost (WAC) could increase our small sole community hospital's annual drug spend by more than $8 million by 2028. This projected variance to our cash flow is estimated to reduce MMC's days cash on hand by approximately 4.63 days by 2028. Such a reduction could place MMC at risk of violating strict bond covenants.

This diversion of already limited financial resources would further reduce the funds our covered entity relies upon to care for our low-income rural population which directly conflicts with the intent of the 340B Program. It is also important to consider that presently Medicare- and in some cases commercial payers- currently reimburse drugs at 106% of the average sales price. Under the IRA model, the selected drugs will now be reimbursed at 106% of the newly negotiated, lower price. As a result, MMC anticipates a significant reduction in pharmacy reimbursement, creating an additional negative impact on our cash flow.

Decrease in Reimbursement:

- Year one decrease in reimbursement: $(253,204)
- Year two decrease in reimbursement: $(1,121,640)
- Year three decrease in reimbursement: $(3,386,240)
- **Cumulative three-year decrease in reimbursement:** $(4,761,085)

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

Given these circumstances, additional transparency is needed regarding the average time manufacturers take to issue 340B rebates. HRSA should consider whether

manufacturers should be subject to penalties for untimely rebate payments outside of the proposed 10-day window, such as requiring manufacturers to pay daily interest to covered entities for delayed rebates.

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

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

Meadville Medical Center utilizes its 340B savings to stretch scarce Federal resources, consistent with the intent of the program for safety-net hospitals such as ours. These savings help subsidize essential patient programs including population health management, mental health counseling, drug and alcohol treatment services, and oncology care. As 340B savings decline, costs increase, and reimbursement continues to decrease, MMC will need to carefully evaluate whether it can sustain these services for our low-income rural patient population.

This situation could have significant consequences for our service area, particularly as demand for these critical services continues to grow year over year. If MMC were forced to reduce or eliminate any of these programs, patients in our community would be required to travel between 45 and 120 miles to access comparable care.

Given these concerns, has HRSA considered excluding sole community hospitals, rural referral centers and critical access hospitals from participation in the 340B Rebate Model? Small rural covered entities such as MMC already face persistent staffing shortages and have been significantly impacted by the declining Medicaid enrollment. Across the country, many rural hospitals are being absorbed by larger health systems that subsequently reduce or eliminate essential services.

In addition, rural covered entities have experienced substantial reductions in 340B savings due to increasingly restrictive manufacturer contract pharmacy policies. MMC alone has lost approximately $5.7 million annually as a result of these policies. Further reductions in 340B savings through the proposed rebate model could place additional strain on rural hospitals that are already operating under significant financial pressure.

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

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

Problems with the Beacon IT Platform. Under HRSA's original Rebate Program, the approved drug companies were planning to use Second Sight Solutions' Beacon IT platform to operate the Program. In the few weeks we had to prepare for the start of that Program, we encountered serious problems with Beacon.

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

The second set of issues are in relation to tracking claims to understand the reason for the denial. For example, the Rx number is not ingested by Beacon from the MTF

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

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

Likewise, we support the AHA's position that there are viable, lawful, and less burdensome alternatives that could achieve the same potential benefits as a rebate mechanism. In particular, we urge HRSA to adopt a third-party clearinghouse, rather than a rebate mechanism, to advance 340B/MDPNP deduplication, program integrity, and any other potential benefits. At a minimum, HRSA must provide a reasoned explanation for why the third-party clearinghouse is neither viable nor less costly than a rebate mechanism.

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

Summary. Meadville Medical Center is a small sole community hospital that relies on 340B savings to subsidize programs such as population health management, drug and alcohol rehabilitation, mental health counseling, and oncology care. MMC also provides more than $4 million annually in charity care to our low-income patient population. If our supply and staffing costs increase as anticipated due to the proposed rebate model, MMC may be forced to cut back on some these essential services. To more easily visualize the

overall financial impact the proposed 340B Rebate Model could have on Meadville Medical Center, the below illustration summarizes what our comments hoped to convey.

	2026	2027	2028	Cumulative Total
Additional Drug Spend	$ 2,808,315	$ 6,121,842	$ 8,395,565	$ 17,325,722
Incremental Staffing Costs	43,257	105,048	132,674	280,980
Decline in Reimbursement	253,204	1,121,640	3,386,240	4,761,085
IT Infrastructure	183,845	183,600	183,600	551,045
Staff Education / Webinars	5,756	-	-	5,756
Additional FTEs [based on number of claims]	-	97,500	100,425	197,925
Overall Impact:	**$ 3,294,377**	**$ 7,629,630**	**$ 12,198,504**	**$ 23,122,513**
% Increase over current 340B expenses:	*121%*	*149%*	*178%*	
Decrease to days cash on hand	*1.25*	*2.89*	*4.63*	

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

If, however, HRSA chooses to move forward with this ill-conceived effort, it must allow MMC and other covered entities to comment on the specifics of its new program. While we have endeavored to provide the most detailed information possible, we are doing so without precise knowledge of which drugs will be included in a Rebate Program and many other critical details (*e.g.*, data required, possible grounds for denial of rebates, dispute resolution processes, other guardrails). A failure to permit additional comments on the specific features of the program will be, in effect, a wholesale failure to consider important aspects of the problem.

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

Sincerely,

Ellie J. Amory
Director of Financial Reporting / 340B Administrator
Meadville Medical Center
751 Liberty Street
Meadville, Pennsylvania 16335

TITUSVILLE AREA HOSPITAL

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

April 2, 2026

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

Dear Administrator Engels:

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

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

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

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

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

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

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One-time Startup Costs:

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

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

- Year one variance in initial drug spend: $2,311,394
- Year two variance in initial drug spend: $4,721,710
- Year three variance in initial drug spend: $5,186,806
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Additionally, there are cost of good impacts that will occur with each drug removed from the 340B contract model and placed onto the IRA rebate model on wholesale purchase agreements between covered entities and wholesalers. Commonly, one such modifier that affects overall cost of good discounts offered by the drug wholesalers to the covered entities in their contracts is the percentage of purchases made on contract. Our wholesaler agreement considered purchasing on the Apexus 340B contracts as meeting this requirement of purchasing an item on contract. When the drugs are removed from the Apexus 340B contract, and there is no longer a contract on that drug purchase, this decreases the spend on contracted items per our agreement. This ultimately results in an impact on the overall cost of any goods purchased through the wholesaler, regardless of an item's individual contracted status.

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

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

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

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

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

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

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

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

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

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

Decrease in Reimbursement:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Sincerely,

Holli Wolfe
Vice President Operations
Titusville Area Hospital
406 West Oak Street
Titusville, Pennsylvania 16354

From: Angela Gubbels
To: HRSA Paperwork
Cc: Lisa Voorhees
Subject: [EXTERNAL] 340B REBATE MODEL PILOT PROGRAM, HHS DOCKET NO. HRSA-2026-03042
Date: Tuesday, April 7, 2026 12:59:28 PM

The Honorable Thomas J. Engels
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services 5
600 Fishers Lane
Rockville, MD 20852

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

Dear Administrator Engels:

On behalf of Syracuse Area Health in Syracuse, Nebraska, we appreciate the opportunity to comment on the Department of Health and Human Services' (HHS) "Request for Information: 340B Rebate Model Pilot Program." Among other issues, the RFI asks whether HRSA should implement a rebate model under the 340B Program in place of the longstanding upfront discount model that has functioned effectively for decades. The answer is no.

As detailed below, a rebate mechanism would impose substantial administrative, operational, and financial burdens on Syracuse Area Health—burdens that far outweigh any potential benefits. HRSA's own cost estimates underscore the magnitude of these impacts. More fundamentally, the premise that HRSA must balance the interests of covered entities and drug manufacturers when selecting a discount mechanism is incorrect. HRSA's statutory obligation is to prioritize the needs of covered entities so they can "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Preserving the upfront discount model, which Syracuse Area Health has relied upon for years, is the most effective way to fulfill that purpose.

The RFI poses 30 questions and encourages commenters to provide supporting facts, research, and evidence. Syracuse Area Health has responded as comprehensively as possible within the limited time available. For cost-estimation purposes, we assumed that any future Rebate Program would include the 10 drugs previously approved for HRSA's original program, as well as the drugs selected under the Medicare Drug Price Negotiation Program (MDPNP) for 2027, consistent with HRSA's February 25, 2026 Information Collection Request. The addition of the 2027 drugs significantly increases the expected administrative and financial burden. More drugs and more manufacturers mean more claims to submit, more rebates to track and reconcile, more funds advanced to manufacturers while awaiting statutory discounts, more disputes over delays or denials, and ultimately fewer resources available for patient care and community health services.

Administrative Costs Under a Potential 340B Rebate Program

A rebate model would require Syracuse Area Health to incur substantial new administrative

expenses. When we elected to participate in the 340B Program, we anticipated reasonable administrative costs and structured our staffing, operations, and compliance systems around an upfront discount model. Transitioning to a rebate mechanism would require significant new resources and impose burdens far beyond what we planned for as a 340B hospital—and far beyond what we experience today.

Staffing Impacts

Syracuse Area Health does not currently have the personnel necessary to manage the demands of a rebate-based program. Implementing such a model would require additional staffing and training, diverting resources from patient care.

Systems and Infrastructure

Our technological systems and operational infrastructure were designed around upfront discounts. A shift to a rebate model would necessitate costly system modifications, new workflows, and expanded data-management capabilities.

Data Collection Requirements

During the prior iteration of the Rebate Program, both HRSA and drug manufacturers asserted that a rebate model would not impose new data burdens because hospitals already provide the necessary information through 340B ESP. That assertion is **incorrect**. A rebate mechanism would require additional data collection, validation, and submission processes that do not exist today.

Payment Timing and Cash-Flow Impacts

Unlike the upfront discount model, a rebate mechanism would require Syracuse Area Health to advance funds to drug manufacturers and wait for reimbursement. Even if manufacturers paid rebates within the previously proposed 10-day window, the delay would create meaningful cash-flow challenges and reduce the resources available for patient services.

Adverse Impacts on Patient Care

These cumulative costs and burdens would diminish Syracuse Area Health's ability to use 340B savings to support patient care and community health programs. The result would be tangible harm to the patients and communities we serve.

Reliance Interests

The RFI asks whether covered entities have reasonable reliance interests in continuing to receive 340B ceiling prices through upfront discounts. Respectfully, this framing is flawed. The mere existence of statutory authority to use rebates does not imply that HRSA may or should exercise that authority, particularly when the agency has consistently used upfront discounts since the program's inception. Syracuse Area Health reasonably relied on this longstanding practice when designing operations, staffing, contractual relationships, and financial planning. A fundamental shift to a rebate model would disrupt these settled reliance interests without any demonstrated problem in the current system and at enormous cost to covered entities.

Problems With the Beacon IT Platform

During the brief preparation period for HRSA's original Rebate Program, we encountered significant issues with the Beacon IT platform selected by participating manufacturers. These problems further illustrate the operational risks and inefficiencies inherent in a rebate‑based approach.

Efforts to Avoid 340B/MDPNP Duplicate Discounts

HRSA has already acknowledged that drug manufacturers have other viable options to prevent duplicate discounts under the 340B and MDPNP programs. Given the substantial burdens a rebate mechanism would impose on Syracuse Area Health, HRSA should rely on those alternatives. Any other approach would improperly elevate the interests of drug manufacturers over those of covered entities, their patients, and the communities they serve.

We also support the American Hospital Association's position that a third‑party clearinghouse offers a lawful, effective, and far less burdensome alternative to a rebate model. At a minimum, HRSA must provide a reasoned explanation if it determines that a clearinghouse is not viable or is more costly than a rebate mechanism.

Conclusion

For all of these reasons, Syracuse Area Health respectfully submits that the costs of any Rebate Program would far outweigh any anticipated benefits. HRSA should abandon the rebate concept entirely and instead adopt a neutral, third‑party clearinghouse.

If HRSA nonetheless chooses to move forward with this proposal, it must allow Syracuse Area Health and other covered entities to comment on the specific features of the program. While we have provided detailed information to the best of our ability, we do so without clarity on critical elements such as the list of included drugs, required data elements, grounds for rebate denials, dispute‑resolution processes, and other essential guardrails. Failing to solicit additional comments on these specifics would amount to a failure to consider important aspects of the issue.

We appreciate your consideration of these comments and look forward to continued engagement with HRSA on this matter, which has significant implications for the millions of patients who rely on the 340B Program. Please contact me with any questions.

Sincerely,

Lisa Voorhees, CEO

Syracuse Area Health
Syracuse, Nebraska

April 20, 2026
Chantelle Britton
Director
Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
Rockville, Maryland 20857

Re: *Information Collection Request Title:* 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-XXXX.

On behalf of Santa Cruz Community Health Centers (SCCH), a proud Federally Qualified Health Center (FQHC) and participant in the 340B Drug Pricing Program, I appreciate the opportunity to comment on the proposed 340B Rebate Model Pilot Program.

SCCH serves a diverse patient population across Santa Cruz County, providing comprehensive care to individuals and families regardless of their ability to pay. In 2025 alone, we delivered approximately 100,000 visits to 13,500 patients, many of whom face significant barriers to accessing affordable health care. The 340B Program is essential to our mission, enabling us to stretch limited resources and ensure our patients receive the medications and services they need.

Based on our experience, we do not support the implementation of a rebate-based payment model under the 340B Program. The current upfront discount structure is vital for predictable pricing and manageable administrative processes. Transitioning to a rebate-based approach would impose new costs, risks, and operational burdens on covered entities like ours, without clear benefits for patient care or program efficiency.

Our primary concerns include:

- **Increased Administrative Burden and Cost:** Managing the 340B Program is already complex. A rebate model would significantly increase staffing, IT, compliance, and vendor expenses, diverting resources from direct patient care.
- **Cash Flow Risk:** Requiring covered entities to pay full price upfront and await manufacturer reimbursement would create financial instability and threaten timely access to medications for our patients.
- **Rebate Denials and Disputes:** Our experience with other rebate programs highlights the risk of payment delays, denials, and lengthy appeals, all of which strain limited resources.

- **Expanded Data Collection and Reporting:** Additional claims-level data requirements would overburden our systems and raise privacy and compliance concerns, with little demonstrated benefit to program operations.
- **Program Integrity:** While we support robust oversight, we do not believe a rebate-based model is necessary to ensure program integrity or prevent duplicate discounts. Existing requirements already demand significant compliance efforts from covered entities.

We respectfully urge HRSA to maintain the current upfront discount model. Any future changes to the 340B Program should prioritize minimizing administrative burden, preserving financial stability, and supporting the ability of safety-net providers to serve vulnerable populations.

Thank you for considering our perspective. Please feel free to contact me at aaguirre@schealthcenters.org if you need additional information or real-world examples from our experience.

Sincerely,

Anita Aguirre, MPH
CEO
Santa Cruz Community Health Centers
Santa Cruz, California

April 17, 2026

Samantha Miller
Director of Division of Oversight, Reporting, and Regulatory Compliance
Office of Planning Analysis and Evaluation
Health Resources and Services Administration
5600 Fishers Lane, Room 13N82
Rockville, MD 20857

Submitted electronically via paperwork@hrsa.gov

Dear Director Miller:

RE: Neighborhood Health Comments in Response to: "340B Rebate Model Pilot Program Application, Implementation, and Evaluation" Information Collection Request Federal Register Notice

United Neighborhood Health Services, Inc. (dba Neighborhood Health) appreciates the opportunity to submit comments to the Health Resources and Services Administration (HRSA) in response to the above-referenced information collection request (ICR) Federal Register Notice ("FRN") dated February 26, 2026. The purpose of this comment is to express our alarm that HRSA is proposing a rebate model in the ICR that is unnecessary and so highly burdensome. In the FRN and in its previous Rebate Model Pilot Program ICR, HRSA drastically underestimates the burden of such a collection, and fails to consider less burdensome alternatives that would enhance the collected information.

As demonstrated by the data and information we provide below, we are deeply concerned about the tremendous administrative and financial burdens a rebate model would place on our patients, our organization, and other covered entities. We respectfully urge HRSA to refrain from implementing a Rebate Model Pilot and instead collaborate with the Centers for Medicare & Medicaid Services (CMS) to develop an alternative approach that prevents manufacturers from providing a covered entity access to both the 340B ceiling price and a maximum fair price (MFP) rebate on the same drug claim.

The proposed 340B rebate model introduces significant financial, operational, and patient access risks that are not resolved by "prompt pay" assurances. Requiring covered entities to purchase drugs at full cost and await rebates shifts working capital burden to safety-net providers, creating ongoing cash flow exposure and financial volatility. The model also imposes substantial new administrative requirements, including claim-level tracking, reconciliation across manufacturers, denial management, and new IT infrastructure, all of which divert limited resources away from patient care. For Ryan White and HIV providers, these changes threaten the stability of programs that rely on 340B savings to fund comprehensive, integrated care. Disruptions to contract pharmacy arrangements and increased operational complexity risk limiting medication access, delaying treatment, and undermining adherence and viral suppression outcomes. Additionally, the rebate model does not address root causes of program integrity concerns, such as payer-side data limitations, and instead adds duplicative

reporting burdens to entities that are already among the most highly regulated in healthcare. Critically, weakening the current 340B structure will not eliminate program value but will redirect it away from mission-driven providers to intermediaries, including pharmacy benefit managers, that have no statutory obligation to serve vulnerable populations. The cumulative effect is reduced access, increased administrative cost, and misalignment with the program's intent.

Neighborhood Health is a federally qualified health center and Ryan White–funded provider delivering comprehensive, integrated care to medically underserved populations, including individuals living with HIV. As a 340B covered entity, Neighborhood Health operates under extensive federal oversight, including HRSA program requirements tied to its Scope of Project, Uniform Data System reporting, and independent financial audits under Uniform Guidance (45 CFR Part 75). The organization maintains strict compliance with all 340B requirements, including prevention of diversion and duplicate discounts. 340B savings are essential to Neighborhood Health's care model and are reinvested directly into patient services. These funds support access to affordable medications, same-day treatment initiation, integrated behavioral health, case management, transportation assistance, and other wraparound services that improve health outcomes and reduce barriers to care. Neighborhood Health serves a high-need patient population, many of whom rely on these services as their primary access point to care. The organization's use of 340B resources is tightly aligned with its mission to expand access, improve outcomes, and sustain comprehensive care for vulnerable communities.

HRSA's Rebate Model Pilot Program Proposal is Unnecessary and Untenable

Financial Impact of Increased Drug Acquisition Costs

A Rebate Model Pilot will increase covered entities' drug acquisition costs because we will lose the upfront 340B price reductions and subceiling discounts that we receive at the time of purchase. We will be forced to pay wholesale acquisition cost for drugs at the point of sale and face the uncertainty of obtaining a rebate in the future. This process places a cash flow strain on our already under-resourced organization and threatens our ability to provide patients with upfront discounts on their medications at the point of sale.

Implementation and Administrative Burden

For the last 30 years, covered entities and their vendors partners have developed sophisticated technologies and workflows to manage the complexities of 340B compliance and operations. These carefully crafted systems are built on the premise that entities receive 340B ceiling prices as upfront discounts. Converting 340B into a rebate program completely upends these systems, poses substantial implementation and managements costs, and does nothing to improve 340B compliance or operations. Covered entities will have to make significant upfront and ongoing financial investments in technology, staff, and redesigning workflows to accommodate a rebate program. Worst of all, these investments will diminish covered entities' ability to care for their patients.

Some RWCs are also federally qualified health centers (FQHCs) and participate in 340B as FQHCs. The administrative burden of a rebate model would be even worse for RWCs that are enrolled in 340B as FQHCs and have subgrantees. HRSA currently assigns an FQHC and its subgrantees the same 340B ID, forcing the FQHC and its subgrantees to act as one entity when

uploading data to manufacturer platforms. If HRSA were to advance its rebate model, FQHCs and their subgrantees would face an onerous process to discern which purchases, dispenses, and rebate payments belong to which 340B ID holder.

HRSA's Burden Estimation Drastically Underestimates the Effort to Implement the Rebate Model

A Rebate Model Pilot Program, by its very nature, will significantly increase our organization's drug acquisition costs because we will lose the upfront 340B price reductions and subceiling discounts that we currently receive at the time of purchase. We will have to pay wholesale acquisition cost for drugs at the point of sale, with the hope of obtaining a rebate in the future. This process places a huge cash flow strain on our already under-resourced organization. HRSA has not accounted for this additional cost. Nor has the agency accounted for additional upfront costs to implement a Rebate Model Pilot Program like additional staffing or purchasing of additional equipment to implement the model.

HRSA failed to appreciate the disruptive nature of the rebate model estimating that each covered entity would spend an average of 260 hours per year on complying with Rebate Model Pilot Program requirements. In the FRN, HRSA justifies its low burden estimate for the Rebate Model Pilot Program by stating that the covered entity data:

> will be comparable to data already being collected and maintained by covered entities through existing third-party vendor relationships or data that is already being provided to manufacturers with respect to certain contract pharmacy policies, in-house pharmacy claims requests, and data elements provided for claims with drugs dispensed under the Medicare Drug Price Negotiation Program.

HRSA's assumption that the data will be comparable to information that covered entities already collect is inaccurate and results in HRSA's low burden estimate. To help HRSA adequately evaluate the Rebate Model Pilot Program costs, we have presented our estimate of the impact that the Rebate Model Pilot Program would have on our organization below.

Annual Covered Entity Burden for Rebate Processing:

	Number of Claims/Year	Time Estimate per Claim
Time Spent Reporting Rebate Claims	50,000	.25

HRSA Failed to Consider More Efficient Rebate Model Alternatives

Listing all Viable Alternatives

HRSA has proposed various Rebate Model Pilot Program iterations since July 2025 to prevent 340B-Medicare Part D inflation rebate duplicate discounts. Despite public comments describing the burdensome nature of the rebate model, HRSA has failed to consider any more efficient rebate model alternatives such as: implementing a neutral clearinghouse, prospective maximum fair pricing, or use of a modifier to delineate 340B claims.

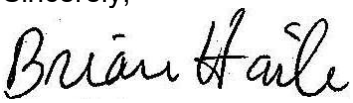
Neutral Clearinghouse as an Alternative

Instead of proceeding with a rebate model, we ask that HRSA instead work with CMS to develop a neutral clearinghouse run by the federal government or a government contractor, to which covered entities, third-party administrators, and/or contract pharmacies retrospectively submit 340B claims data to prevent 340B-MFP duplicate discounts. A 340B clearinghouse model represents the ideal solution for all stakeholders - covered entities, contract pharmacies, manufacturers, and the government -- by providing an efficient and coordinated framework that streamlines and enhances compliance, data exchange, and program integrity.

The clearinghouse would remove 340B claims from Medicare drug claims and share the non-340B claims with manufacturers for MFP rebate payments. Since manufacturers would only pay rebates on non-340B claims, duplicate discounts would be prevented. This approach is not without precedent. CMS already plans to test 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-Medicaid rebate duplicate discounts.

We appreciate HRSA’s consideration of our comments. For further information, please contact me at 615-227-3000.

Sincerely,



Brian Haile, JD, MPP, MA
Patient & Chief Executive Officer

HEARTLAND
COMMUNITY HEALTH CENTER

April 17, 2026

Chantelle Britton
Director
Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
Rockville, Maryland 20857

RE: Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042)

Dear Director Britton:

On behalf of **Heartland Community Health Center,** I would like to thank the Health Resources and Services Administration (HRSA) for extending the comment deadline to April 20, 2026. This extension has been vital in enabling our organization to conduct a deep-dive analysis of the operational and financial risks to CHCs posed by the proposed rebate model. The 340B program is foundational to CHC's ability to serve the most vulnerable members of our community. However, the proposed shift of responsibility from manufacturers to safety-net providers directly serving patients through a rebate model threatens to destabilize CHC pharmacy operations nationwide. Based on national assessments from NACHC, we know that CHCs are facing staggering impacts:

- **Financial Losses: Heartland Community Health Center** anticipates an average loss of **$801,378,22** from entity-owned pharmacy operations and **4%** for contract pharmacy arrangements due to the administrative hurdles of manual reconciliation.
- **Projected Cost Increases:** CHCs anticipate significant increases in operational costs. National data shows that a single mid-sized CHC expects to incur over $3 million in additional costs **annually** to manage the pilot.
    - **Rural Health Center Breakdown:** For rural CHCs, these costs are even more devastating. Rural centers invest nearly **one-quarter (25%)** of their 340B savings in rural-specific infrastructure, such as mobile clinics and telehealth.

I. We Strongly Urge HRSA To Exempt CHCs from the 340B Rebate Model Pilot Program.

The proposed 340B Rebate Model Pilot Program is a direct threat to CHCs' core mission and a significant departure from the original purpose of the 340B Drug Pricing Program. For over three decades, the 340B program has enabled CHCs to purchase outpatient medications at significantly reduced prices, enabling them to provide affordable and sometimes free medications to millions of low-income and uninsured patients. As congressional intent made clear, the program was created to help safety-net providers "stretch scarce Federal resources as far as possible." The proposed rebate model undermines this by placing an immense financial burden on CHCs.

By requiring CHCs to purchase medications at full price and wait for rebates, this model would cause significant financial turmoil and directly affect CHCs' ability to serve the 52 million patients who rely on us. **For Heartland Community Health Center in particular, this could lead to:**

- **Decreased ability to continue to provide over 20,000 prescriptions at a 340B sliding fee scale discount saving patients over $6.7 million.**
- **Require an estimated increase in annual costs of over $1.8 million and the addition of at least 2 FTE to manage the increased complexity and significant administrative burden of a 340B rebate model.**
- **Decrease our ability to provide robust wrap around services to our patients that connect them to life saving resources or increase needed behavioral health services through expansion of providers and dedicated space to provide those services.**

We strongly urge HRSA to exempt CHCs from any rebate model to protect the financial stability of safety-net providers and ensure continued access to care for the most vulnerable patients.

II. Patient Impact

Most importantly, a 340B rebate model poses a direct and serious threat to medication access for the vulnerable patients that CHCs serve. For uninsured and underinsured patients who rely on the affordability that the 340B program provides, this model could render critical medications financially out of reach. Patients may be forced to make tough decisions in transitioning to other medications, due to cost or lack of availability, as a direct result of a 340B rebate pilot program. These forced therapeutic interchanges introduce real clinical risk, including medication nonadherence, treatment delays, and adverse outcomes, particularly for patients managing multiple chronic conditions who have limited alternatives and no other pharmacies close by. When the rebate model was last proposed, CHCs were actively preparing their patients for these disruptions through in-pharmacy educational materials and prescription bag stuffers, a signal that the operational and human impact of this change is both imminent and significant. For patients who have spent years achieving stability on a given medication regimen, the prospect of disruption is a threat to their health, safety, and trust in the health care system.

We have significant concerns about the impact a 340B Rebate Model Pilot would have on our most vulnerable patients' access to life-saving medications. The majority of drugs selected for the MDPNP for 2026 and 2027, and included in the proposed rebate model, are used to manage chronic conditions prevalent in primary care settings, meaning CHC patients will be disproportionately affected. CHCs serve a patient population with a **higher burden of chronic conditions** compared to private practices, with studies showing a significantly higher prevalence of illnesses like diabetes, hypertension, and obesity.[1] This patient population relies on affordable medications to manage these long-term conditions.

We are deeply concerned that implementing a rebate model would cause CHC patients to lose access to essential, life-sustaining therapies. For instance, **direct oral anticoagulants (DOACs)** such as Xarelto® and Eliquis® are vital for patients with deep vein thrombosis, pulmonary

[1] Richard P, Ku L, Dor A, Tan E, Shin P, Rosenbaum S. Cost savings associated with the use of community health centers. J Ambul Care Manage. 2012 Jan-Mar;35(1):50-9. doi: 10.1097/JAC.0b013e31823d27b6. PMID: 22156955.

embolism, and atrial fibrillation. For many of our patients, there are minimal – and often less safe – alternatives. This is not an optional therapy but a critical tool for survival, as one study showed that discontinuing these drugs leads to a statistically significant increase in the risk of stroke, heart attack, and death.[2]

Similarly, the impact on patients requiring **SGLT2 inhibitors**, such as Farxiga® and Jardiance®, would be severe. These drugs are a mainstay of primary care for conditions like Type 2 Diabetes, chronic kidney disease, and heart failure, all of which are highly prevalent among our patients. Research has found that even a 30-day withdrawal of these inhibitors increases the annualized risk of cardiovascular death or heart failure hospitalization.[3] By making these drugs unaffordable, the rebate model would effectively deny our patients access to the most effective therapies for managing their chronic illnesses, leading to a predictable increase in preventable hospitalizations.

The United States is in the midst of an alarming mental health crisis. Nearly one in four (23.4%) Americans live with a mental illness.[4] Starting in 2027, the MDPNP will include some behavioral health drugs. Vraylar ® is an atypical antipsychotic; atypical antipsychotics are the mainstay of treatment for Schizophrenia. A rebate model could create regulatory barriers for CHCs seeking to provide this drug to uninsured and underinsured patients. Additionally, the 2027 list includes Austedo®, a drug used to treat Tardive Dyskinesia, a common side effect of antipsychotics. Studies have shown that 73% of patients treated with Austedo® achieved treatment success, resulting in improved quality of life.[5] Impairing access to these drugs could result in exacerbation of the mental health crisis.

The impact on **insulin access** is particularly alarming and directly conflicts with federal requirements. With over 3 million Americans relying on CHCs for essential diabetes care,[6] affordability of insulin is a matter of life and death. Furthermore, **Executive Order #14273 conditions future Section 330(e) funds on CHCs providing low-income patients with access to discounted insulin**. There is currently no operational method to provide these discounted medications in a retrospective rebate model. In the proposed model, the wholesaler price file would reflect the full WAC rather than the discounted 340B price. This makes the price unattainable for the patient and **precludes CHCs from fulfilling their legal obligation to offer the required discount at the point of care**.

Imposing a rebate model on CHCs would only weaken the safety-net providers that 52 million Americans rely on for health care. CHCs are required to provide sliding fee discounts to patients with incomes at or below 200% of the federal poverty guidelines. The same patients who need

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[2] Cools F, et al. Risks associated with discontinuation of oral anticoagulation in newly diagnosed patients with atrial fibrillation: Results from the GARFIELD-AF Registry. J Thromb Haemost. 2021 Sep;19(9):2322-2334. doi: 10.1111/jth.15415. Epub 2021 Jul 23. PMID: 34060704; PMCID: PMC8390436.

[3] Packer, M., et al. (2024). Blinded Withdrawal of Long-Term Randomized Treatment with Empagliflozin or Placebo in Patients with Heart Failure. Circulation. https://www.ahajournals.org/doi/pdf/10.1161/circulationaha.123.065748

[4] Substance Abuse and Mental Health Services Administration. (2025). Key substance uses and mental health indicators in the United States: Results from the 2024 National Survey on Drug Use and Health (HHS Publication No. PEP25-07-007, NSDUH Series H-60). Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. https://www.samhsa.gov/data/data-we-collect/nsduh-national-surveydrug-use-and-health/national-releases

[5] Hauser RA, et al. Long-Term Deutetrabenazine Treatment for Tardive Dyskinesia Is Associated With Sustained Benefits and Safety: A 3-Year, Open-Label Extension Study. Front Neurol. 2022 Feb 23;13:773999. doi: 10.3389/fneur.2022.773999. PMID: 35280262; PMCID: PMC8906841.

[6] 2025 UDA Data, HRSA (hrsa.gov)

access to discounted medical services also depend on CHCs to provide affordable medications. Without the up-front 340B discount, the drugs included in the pilot would become operationally impossible. **This model would create a new and significant barrier, rather than a solution, for our most vulnerable patients, especially those who are uninsured and have limited options for affordable care.**

Beyond the direct impact on individual patients, the rebate model threatens the broader infrastructure that makes affordable, comprehensive care possible at CHCs. The administrative burden of navigating the new rebate structure, including onboarding staff, conducting provider and patient education, and implementing new protocols, diverts limited staff resources away from direct patient care, disrupts established pharmacy workflows, and risks delays in reimbursement that undermine medication continuity. Every hour that a pharmacist spends reconciling rebate claims is an hour not spent on medication counseling. Every dollar spent on compliance and administration is a dollar that is no longer available for wraparound services and the full spectrum of care that make a meaningful difference in patients' lives. This diversion of time and resources is not a minor inconvenience; it is a structural undermining of the care model that CHCs depend on to serve their communities. If implemented without meaningful safeguards, this model will force CHCs to make impossible choices: cutting programs, limiting operating hours, and fundamentally compromising the mission of a program designed to expand access to care for those who need it most.

III. Administrative Complexities and Financial Challenges for CHCs

The proposed 340B Rebate Model Pilot Program is not only a financial threat to CHCs but also a duplicative and unnecessary administrative burden. To address manufacturers' "concerns" about duplicate discounts, the Pilot Program would force CHCs to divert even more scarce resources away from patient care. CHCs have already absorbed high administrative and technology costs over the past five and a half years to comply with manufacturers' existing contract pharmacy restrictions by submitting data to 340B ESP. Rather than serving as a solution, the pilot program would be a new barrier, further limiting the availability of affordable medications for patients with chronic conditions.

HRSA should exempt CHCs from the 340B Rebate Model Pilot because they will incur additional workforce and IT costs to comply with multiple manufacturer rebate requirements. A recent NACHC assessment illustrates that CHCs will incur additional workforce and IT costs to maintain compliance with multiple manufacturer rebate requirements, increasing the burden associated with this rebate pilot program. Similar to navigating manufacturers' existing contract pharmacy restrictions, CHCs will need to invest in IT infrastructure upgrades and hire or reassign staff to manage new complexities, including varying data submission requirements and timelines, payment reconciliations, and dispute processes for denied rebates. Depending on the volume of prescriptions a pharmacy fills for the selected drugs, CHCs will face an increased administrative burden in monitoring rebate claims and payments. We urge HRSA to consider the high up-front and ongoing costs of compliance with a potential 340B Rebate Model, which will ultimately impact the most underserved patients nationwide.

A. Detailed Administrative/Operational Impact

340B Rebate Model Operational & Administrative Cost Calculator Description

To support CHCs in assessing the **financial and operational impact** of current manufacturer restrictions and an anticipated rebate model, NACHC worked with their consultant, FQHC 340B Compliance, to create an **Operational & Administrative Cost Calculator.** The tool aggregates program savings, UDS financial data, staffing, external consulting costs, dispensing/capture activity, and clinic-administered drug tracking models to support operational cost forecasting.
CHCs have already experienced steep increases in operational costs given the multitude of manufacturer restrictions, which have now been extended to clinic-administered drugs and entity-owned pharmacies. A refund model will require a significant increase in already-strained operational capabilities.

- **Sliding Fee Discount**: **Heartland Community Health Center** provided **$10,586,801** in sliding fee discounts, provided through discounted medications and medical services. We anticipate that our ability to offer sliding fee discounts will decrease significantly under a rebate model.
- **Staffing Impact**: **Heartland Community Health Center** anticipates needing **2** additional FTEs to account for the increase in regulatory, operational, administrative, and compliance burden created by a rebate model.
- **External Vendor Costs**: Given increased complexity, **Heartland Community Health Center** anticipates an increase of **$4000** to costs for external support vendors. These vendors may include 340B consultants, legal counsel, program coordination, third-party administrators, electronic medical records, pharmacy software, and reconciliation services.

Below is specific data on the administrative costs that CHCs anticipate, based on thorough planning, review of current business practices, and the costs of implementing new systems and processes.

Workforce Impact

- 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.[7] **Heartland Community Health Center estimates needing to add 2 FTE to meet the increased workload demands associated with 340B rebate claims resulting in an estimated cost increase of $126,885.20. We have already had to increase our workforce by 1 FTE just to support the Maximum Fair Price (MFP) rebate program due to the complexity of the system. These are some of the administrative burdens that have been added just from the current MFP rebate program:**
    - **In order to determine the status of a claim and whether the MFP rebate was effectuated correctly we need to access four different data management systems. All four systems have different data and there is considerable lag time for claim status updates between systems. When a good faith inquiry (GFI) is needed to dispute a lack of rebate payment a fifth system is required unilaterally by the manufacturer. As part of the GFI the manufacturer requires claims data not**

[7] Internal NACHC assessment (99 responses).

related to MFP or Medicare claims to be submitted in order for a rebate to be processed even though they have access to our purchasing data and can see that WAC purchases have been made for the drug that is part of the GFI. If a 340B rebate model was allowed to be implemented, based on previous manufacturer plans, we would likely need to incorporate a sixth system into an already arduous, time consuming, and complex process.

- **Claims tracking due to rebate denials and inaccuracy in manufacturer effectuation of the MFP rebate can be a lengthy process. We have claims we have not received the required rebate from January 2026 due to the drawn out GFI process and lag time as the claims move back and forth from the Medicare Transaction Facilitator (MTF) and the manufacturers preferred rebate vendor, Beacon.**
- **When support is needed to facilitate GFIs and claims evaluation, Beacon, the manufacturer's chosen vendor is often not able to provide support in a timely manner or has the capability to assist with claim errors occurring in the Beacon platform. This requires additional staff time to continually follow-up with Beacon support staff when identified issues are not resolved in a timely manner and there is a lack of communication on next steps or updates received from Beacon.**

- Additionally, several CHCs estimate the cost to hire additional staff to be between $30,000 to $200,000 annually.[8] One midwestern CHC, serving approximately 12,000 unique patients last year, anticipates annual costs exceeding $3 million, including upfront costs for purchasing drugs in this pilot program, increased labor costs, carrying costs, and potential losses on discounted or expired drugs without rebate recovery. CHCs operate on razor-thin margins, and these additional costs are not an option for many entities. **If all MFP drugs in 2026 and 2027 were part of a 340B rebate model pilot program Heartland Community Health Center anticipates an increase in annual costs of over $1.8 million. This anticipated cost increase is due to the following:**
  - **Increase in the upfront cost of purchasing and keeping these 340B rebate drugs in stock. This increase in overall acquisition cost will decrease the amount of inventory the health center is able to keep on hand which could disrupt timely access for patients to these life-saving medications.**
  - **Increased carrying costs associated with purchasing these 340B rebate drugs at WAC and being reimbursed at a lower rate (i.e., MFP price or a self-pay sliding fee discount price). In order for the health center to continue to provide these medications to patients with a 340B sliding fee scale discount to ensure affordability the health center must carry the WAC cost of the drug until a rebate is received from the manufacturer. On average it has taken 19 days for the health center to receive MFP rebates that did not require a GFI and an average of 60 days when a GFI was required. If HRSA allows a 340B rebate program to be implemented our health center may no longer be capable of affording the financial burden of these carrying costs.**
  - **Increased labor costs in our pharmacy due to the increased complexity of the 340B program. Our current pharmacy management software would require several specialized workflows to facilitate implementing a 340B rebate model while still maintaining compliance with Medicaid fee for service billing and providing a**

[8] Ibid.

sliding fee scale discount to our patients. Many of these workflows would require our pharmacy management software vendor to spend time and financial resources on 340B rebate model integrations, which is a process we do not have any control over as a covered entity. Regardless of the updates provided by the software vendor, this added level of complexity will require at least 1 additional FTE to assist front line pharmacy staff with new manual processes required along with integrations to facilitate this 340B rebate pilot.

- **Financial losses resulting from the health center not receiving a 340B rebate on a drug purchased at WAC. This could occur for drugs purchased that end up expiring prior to being dispensed or due to manufacturer denied rebates. Manufacturers are currently only effectuating the MFP price correctly on 25% of our health centers' claims and require you to navigate numerous procedural requirements to dispute a lack of rebate with no required timetable from CMS to complete a GFI process. A 340B rebate model would also deny the health center the wholesaler discounts available to us in our contracts further driving up the acquisition cost of 340B rebate drugs.**

- Depending on the volume of prescriptions a pharmacy fills for the MFP 2026 and 2027 selected drugs, CHCs will face an increased administrative burden in terms of monitoring rebate claims and payments. **Heartland Community Health Center anticipates at least 20 hours per week** will be required to report 340B rebate claims to a third-party platform, assuming all adhere to the nine drug manufacturers' plans The lack of standardization and likely varying requirements across manufacturers will force CHCs to use multiple internal systems to manage and report the same data, thereby increasing costs and operational burdens. **Heartland Community Health Center urges HRSA to require uniformity among eligible manufacturers to mitigate potential administrative and financial burdens associated with receiving timely and appropriate 340B rebates.**

Pharmacy Software & Third-Party Administration Changes

Navigating this pilot requires more than just staff; it requires significant changes to pharmacy software and Third-Party Administrator (TPA) workflows. We encourage HRSA to consider the increased compliance burdens when manufacturers have the flexibility to require varying data submission standards and elements. Additionally, if manufacturers are allowed to select different software platforms, as they currently do with contract pharmacy policies, the administrative burden on CHCs would increase substantially.

- **One-Time Implementation Costs:** We anticipate high upfront costs to adapt our pharmacy software, pay for custom dashboard modifications, and design new internal workflows.
- **Ongoing Operational Fees**: Beyond implementation, our TPA and software vendors will likely charge ongoing service fees to maintain these complex rebate-tracking features. These are permanent, recurring costs that diminish our 340B savings.

The In-House Pharmacy: The Burden of Deep IT Integration

For CHCs that operate their own pharmacies, the rebate model is not a simple accounting change; it is a significant technological disruption. To remain compliant, in-house pharmacy systems will require costly customization to provide real-time, accurate information at the pharmacy counter.

- **System Interoperability:** Unlike contract pharmacies that use Third-Party Administrators (TPAs), in-house pharmacies must directly integrate their Electronic Health Record (EHR) and Pharmacy Management System (PMS) with a complex new rebate infrastructure.
    - **In order to stay compliant with Kansas Medicaid Fee-For-Service 340B billing requirements we need our pharmacy management software vendor to implement an integration that would allow for the 340B price to be accessible for billing. This is currently an integration that is not operational and it is unknown if or when it would be available to us. Without this integration an arduous and time consuming manual process would need to be developed to ensure that 340B pricing is updated quarterly and compliance is maintained. If the 340B rebate pilot was expanded to all drugs, which could be over 20,000 unique entries, a manual process for price updates would be unmanageable and impossible to maintain.**
    - **Our pharmacy would be required to operate a complex inventory management process to assist in handling inventory purchased prior to the rebate model with an up-front 340B discount.**
    - **Kansas pharmacies are required by law to provide comprehensive pharmacy services, and maintaining an appropriate on hand inventory ensures compliance with that regulation. As a result, pharmacies typically purchase inventory in advance of a prescription to ensure patients have timely access to their medications. This creates challenges with managing a rebate model because each invoiced drug does not align 1:1 with an exact prescription. Rebate models do not align with real time pharmacy services or direct patient care as they are not able to adapt to the immediate needs of the patient causing the pharmacy to shoulder increased administrative burden and financial loss to continue to provide high quality patient care. The 340B program needs to remain an up-front discount and a neutral clearinghouse model should be used to prevent duplicate discounts on the back end.**
    - **Due to the uncertainty of rebate effectuation potential rebate payments are not able to be accounted for in our pharmacy management software's financial reporting. This will require our finance department to create and maintain additional 340B rebate financial reporting again, adding unnecessary administrative burden.**
- **One-Time Integration Costs:** We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools.
- **Ongoing Resource Diversion:** Staff who currently manage pharmacy billing and pharmacy operations will be forced to spend **at least 20 hours** per week manually pulling "Purchase Files" and "Price Files" to verify that every rebate check matches the statutory 340B price.

The Contract Pharmacy: The Burden of Network Coordination

For CHC contract pharmacy partners, the rebate model introduces a new complexity that threatens the very existence of these arrangements. My CHC currently partners with **15** pharmacies to increase access to affordable medications.

- **TPA Reliance and Fees:** Navigating manufacturers' varying requirements across multiple contract pharmacies requires high-level TPA intervention. We anticipate that our TPAs will pass on the costs of developing rebate-tracking modules to us through increased per-claim fees.

- **Verification Latency:** The rebate model creates a reconciliation gap. Our staff must monitor claims across **15** different pharmacy locations to ensure rebates are paid correctly.
- **Risk of Pharmacy Exodus:** Because this model shifts the financial risk to the pharmacy, we fear our contract partners will opt out of the 340B program entirely rather than manage the administrative headache. Over 17 percent of the U.S. population lives in a pharmacy desert already,[9] and the closings of pharmacies have only exacerbated this, with nearly 30 percent of pharmacies that had been open from 2010 to 2021 closing by 2021.[10]

Clinic Administered Drugs: The Burden of New Systems Required

Clinic-administered drug (CAD) operations and record-keeping in CHCs are designed in a cost-effective manner that reflects the nuances of CHC billing.

- **Bundled Payments:** The majority of clinic-administered drugs are bundled into the prospective payment system (PPS) billing when administered to patients by CHCs. Because PPS visits are paid at a flat rate, the medications administered in CHCs are often not included on claims billed to payers.
- **Simplified Records:** Because CHCs maintain limited inventories of CADs and they are typically not separately billed on claims, it is still common for administration and inventory logs to be maintained on paper, with text documentation in patient visit notes describing what was administered. While the CHCs maintain perpetual inventories and complete administrative records, the fact that the records are often paper imposes the added burden of converting them to electronic data before submitting for rebate. Very few CHC records include electronic medication administration records (eMARs), which are common in hospital electronic medical records (EMRs). Where eMARs are available, they incur an additional cost and often require CHC to pay for a standalone software system.

- **Minimal Risk of Duplicate Discounts:** CHCs primarily bill under Medicare Part A, which is not statutorily included in the Medicare Drug Price Negotiation Program (MDPNP). Maximum Fair Prices (MFP) are only applicable to Medicare Part D claims in 2026 & 2027 and then expand to include Medicare Part B claims in 2028. Regarding Medicaid, each state already has mechanisms in place to address duplicate discounts.

B. Financial Challenges

Under the proposed 340B Rebate Model Pilot, CHCs 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 CHCs' ability to purchase drugs, as the uncertainty of waiting for a manufacturer to approve a rebate would constrain cash flow. CHCs will have to wait to receive their rebate payment ***after*** providing medications to their patients. This change will force CHCs to make difficult decisions about how to allocate their limited financial resources, including cutting essential health services, reducing operating hours, or discontinuing services that support patients' health outcomes.

[9] Vulnerability Index Approach to Identify Pharmacy Deserts and Keystone Pharmacies | Pharmacy and Clinical Pharmacology | JAMA Network Open | JAMA Network

[10] https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2024.00192?journalCode=hlthaff

The proposed 340B Rebate Model Pilot would directly impact CHCs' ability to offer patients steeply discounted medications at the point of sale by requiring them to purchase at full WAC pricing upfront. CHCs' pharmacies, as well as entity-owned and contract pharmacies, will not have access to the 340B price when the patient needs medication. This will create a very unpredictable process for determining the level of discount and pricing for a patient's medication, as the 340B price will no longer be reflected in the pharmacy software from the wholesaler's price catalog, since initial purchase prices will be at WAC. The rebate model creates confusion about its impact on a CHC's ability to offer sliding-fee discounts at the point of purchase.

A rebate model also creates substantial uncertainty about CHCs' ability to apply sliding-fee discounts at the point of sale. By statute and regulation, CHCs are required to offer sliding fee discounts for all required and additional health services within the HRSA-approved scope of the project.[11] In line with their mission, CHCs offer flat or sliding-scale discounts on prescription drugs to make them more affordable for low-income individuals.[12] A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size. **In 2025 Heartland Community Health Center had 1690 patients that relied on up front 340B sliding fee scale discounts to afford their prescriptions. Our pharmacy filled 20,079 prescriptions using the 340B sliding fee scale discount resulting in over $6.7 million in savings for our patients. The 340B rebate model threatens our ability to provide these upfront 340B sliding fee scale discounts if we are unable to maintain the increased financial burdens of purchasing these medications at WAC and waiting to receive a rebate.**

CHCs rely on wholesaler price files to determine acquisition costs and calculate patient discounts in real time. Pharmacy Software systems are not designed to incorporate manually added price files, particularly into a single inventory category. Current pharmacy systems continuously overwrite manually entered 340B prices with every wholesaler price load. Under a rebate model, the wholesaler price file reflects WAC rather than the 340B ceiling price, eliminating the operational ability to determine an accurate discounted patient price at the pharmacy counter. **This disconnect forces CHCs to estimate discounts without knowing whether or when a rebate will be paid, exposing them to financial loss if a rebate is denied or delayed and undermining federally required sliding fee discount obligations.**

CHCs are particularly worried that the need to purchase drugs at full WAC will cause cash flow issues and potentially lead them to exceed their credit limits with wholesalers, halting their ability to order medications until payments are submitted. While rebates are expected to arrive within 10 days from completed data submissions, the previously proposed rebate pilot allowed covered entities up to 45 days to submit data, meaning the potential time from dispense to rebate can extend to 55 days. The financial impact is further compounded when CHCs have entity-owned pharmacies with physical inventories and must stock their shelves with purchases at WAC. Retail pharmacies typically turn their inventory 10-12 times a year (roughly every 30 days).[13] Assuming a best-case scenario of 15 days to the average 30 days for inventory to turn, CHC

[11] HRSA FAQ

[12] Such discounts are subject to potential legal and contractual restrictions. https://bphc.hrsa.gov/compliance/compliance-manual/chapter9#footnote10

[13] https://enlivenhealth.co/blog/year-end-business-health-check-key-metrics-every-pharmacy-owner-should-review

pharmacies with physical inventory could be waiting 70-85 days from purchase to rebate under a 45-day data submission cadence. Anecdotal reports from CHC pharmacies suggest a planned cadence of 2-week data submissions for entity-owned pharmacy data. Pharmacies with physical inventory submitting data every 14 days would anticipate a purchase-to-rebate payment time frame of 40 to 55 days.

There may be other delays in receiving the full rebate, such as denials, which could create financial strain on CHCs. We appreciate HRSA's requirement for a 10-day timeframe for rebate payments; however, we have concerns about the lack of details regarding enforcement if manufacturers fail to meet this requirement. Based on experience with manufacturer denials related to the current MFP to 340B de-duplication processes, once an entity has contested a denied rebate and the issue is resolved so the CHC can receive the rebate, manufacturers and their vendors have failed to pay the rebate within the MFP standard of 14 days from when the status is corrected. We are concerned that in a 340B rebate pilot, manufacturers and their vendor(s) will continue to provide corrected contested rebates for an undefined and unlimited time. Complicatedly, the rebate amount may not match the initial discount offered to the patient, creating unpredictable financial losses. CHCs must estimate the rebate amount and may undercharge or overcharge patients due to confusion. Furthermore, if the rebate is denied, the CHC takes a net loss on the transaction. **We respectfully request that, if a rebate pilot is implemented, manufacturers be required to pay rebates within 10 days of both initial and corrected determinations.**

Lack of access to upfront 340B discounts, along with the high IT/infrastructure costs, will disproportionately impact CHCs and trickle down to patients. It is important to note that many CHCs are currently under financial strain. Nearly half of CHCs operate with fewer than 90 days of cash on hand, and one in four reports approximately negative five percent (-5%) operating margins. Below, you will find specific data demonstrating the significant increase in financial costs CHCs will incur under a 340B Rebate Model.

340B Rebate Drug Cost Impact Calculator Description

To support CHCs in assessing the financial impact of purchasing drugs at the full WAC price, NACHC worked with their consultant, FQHC 340B Compliance, to create another calculator for all CHCs. Financial data and projections are based on a 340B Rebate Drug Cost Impact Calculator, which utilizes CHC-specific purchasing data, 340B[14] and WAC pricing data for the first quarter of 2026 (Q1 2026), and the CMS list of MDPNP selected drugs by NDC.[15] For individual MDPNP Price Applicability Years, the calculator evaluates:

- **Increase Upfront Annual Drug Spend**: WAC – 340B for 2025 purchases by NDC & volume, reflected in Q1 2026. WAC and 340B prices applied for the overall annual program volume to determine the annual increase in initial drug spend.
- **Cash Flow Impact**: WAC – 340B for 2025 purchases by NDC & volume, reflected in Q1 2026 WAC and 340B prices to give overall annual program increase in initial spend reflected at intervals of 30, 45, 60, & 90 days. Represents potential WAC purchase to 340B rebate payment cycles. Inventory models, frequency of data submission, and manual processes for

[14] https://340bpricing.hrsa.gov/
[15] https://www.cms.gov/files/zip/selected-drug-list-negotiated-prices-also-known-maximum-fair-prices-statutezip.zip

referral claim capture can all influence Covered Entities' (CEs) intervals between purchasing a drug at WAC and receiving the Manufacturer Rebate to 340B Ceiling Price.

- **Rebate-Related Opportunity Costs**: Based on percentages of loss of prompt pay, purchase volume, and subceiling discounts and anticipated rebate denials as a portion of annual WAC spend (described above).
- **Increase Upfront Drug Spend** WAC – 340B for 2025 purchases by NDC & volume, reflected in Q1 2026, calculated by NDC, then aggregated at the MDPNP selected drug, manufacturer, and MDPNP Price Applicability Year levels.
- **WAC Purchase to 340B Rebate Payment "Wait" Period:** CHCs must wait to receive a rebate payment after purchasing and dispensing medication to the patient. This delay forces difficult decisions about allocating limited financial resources.

Based on our organization's data, we estimate it would cost **$1,591,167.02** to purchase these MFP 2026 and 2027 drugs under the proposed rebate model. Currently, our organization spends **$217,954,43** to purchase these same drugs at the 340B ceiling price. This represents a **630%** increase in upfront capital required for procurement.

This increase in costs will have a devastating impact on our organization's ability to maintain an adequate supply of the drugs included in the HRSA 340B Rebate Model Pilot. As previously discussed, our CHC is navigating a difficult financial environment that cannot sustain purchasing drugs at WAC. To cover the upfront cost of purchasing drugs and operationalizing the rebate, **Heartland Community Health Center** anticipates needing to reduce:

- **Essential Clinical Services:** To offset the upfront cost of drugs, we would be forced to scale back low-revenue-generating but essential services, such as **increasing community access to behavioral health providers. Many of our patients are currently accessing therapy services for only $10 utilizing our sliding fee scale discount.**
- **Workforce & Staffing:** 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 **a full-time Community Health Worker directly increasing wait times for linking patients with necessary resources. Some of the resources are community health workers currently assist patients with are:**
    - **Access to food.**
    - **Transportation to health care appointments.**
    - **Navigating insurance eligibility, grant funding, and local funding sources to assist patients in affording healthcare costs associated with acute and chronic health conditions.**
    - **Connecting underserved patients in our community to needed dental, primary care, and behavioral health services at our health center through outreach.**
    - **Assisting families access needed early childhood development resources.**
- **Patient Financial Assistance:** 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 **5537** uninsured patients from rationing their insulin or heart medication.

C. Wholesaler Implications

Another concern is that purchasing drugs at full WAC will potentially lead the organizations to exceed wholesaler credit limits, halting their ability to order medications until payments are submitted. For example, some CHCs have suggested that paying 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.

Heartland Community Health Center 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.

Another complication is that the rebate amount may not match the initial discount offered to the patient, as mentioned above, creating unpredictable financial losses. CHCs must estimate the rebate amount and could potentially undercharge or overcharge patients due to confusion. The shift to WAC pricing disrupts the fundamental mechanics of our pharmacy procurement.

- **Wholesaler Credit Limits:** Purchasing drugs at full WAC will potentially lead organizations to exceed wholesaler credit limits, halting our ability to order medications until payments are submitted. At present, many CHCs are forced to pay invoices before their due dates to remain within their credit limits. Given that CHCs typically operate with extremely limited financial margins, they are often perceived as having higher credit risks, making increases to credit limits difficult or impractical.
- **Discounts:** CHCs often receive prompt pay, purchase volume, and sub-ceiling discounts on their drug purchases. Forcing a WAC-upfront model threatens our ability to meet these terms, potentially resulting in the loss of these essential discounts. Due to contractual confidentiality requirements, CHCs are unable to disclose their exact prompt-pay discount. However, **Heartland Community Health Center** estimates its 2027 Annual Rebate Opportunity Cost to be approximately **$737,935.62.** This cost aggregates the estimated financial impact of rebate denials and loss of purchase discounts.
- **Heartland Community Health Center** estimates that purchasing the MFP 2026 and 2027 selected drugs at WAC instead of 340B ceiling prices will increase our upfront monthly drug spend by **$114,434.38.**

Every dollar we pay upfront at WAC is a dollar that remains "frozen" in the manufacturer's reconciliation system. While we wait for rebates, we lose the liquidity necessary to respond to immediate public health crises or facility emergencies. To navigate the rebate model, our organization would be forced to **utilize limited financial reserves.** This is not a sustainable solution; **If our financial reserves are tied up with the carrying costs of the 340B rebate program we are unable to adapt to the needs of our community. A 2026 needs assessment conducted in our community indicated an aging population without access to specialized care and enhanced services delivered by internal medicine providers. To address those gaps in available healthcare we need the financial resources to fund the workforce and infrastructure to expand our services to include internal medicine.** Forcing CHCs into debt to

maintain their drug supply creates an environment of clinical instability. In our region, where patients have no choice but to rely on **Heartland Community Health Center**, the risk of our credit limit being reached or our reserves being depleted is a direct threat to the community's safety net. If we are forced into financial limbo, the "trickle-down" effect is immediate: longer wait times, reduced service availability, and a weakened ability to provide the steeply discounted medications that our 52 million patients across the country depend on.

a. Financial Impact of Rebate Denials and Delays

Heartland Community Health Center urges HRSA to recognize that without rigorous, non-discretionary safeguards, the rebate model is not a "pricing mechanism" but a significant financial liability. The current framework allows manufacturers to act as the sole arbiter of a CHC's statutory savings, creating an uncertain environment that results in direct financial harm. The framework proposed in the previously proposed 340B Rebate Pilot allowed manufacturers to deny rebate claims based on vague or ambiguous reasons, such as "duplicate rebate" or "MFP deduplication," without providing the data or documentation CHCs need to understand or contest those decisions.[16] The use of a vague "other" category for denial reasons only added to the confusion, leaving CHCs guessing compliance requirements that they are never clearly told exist. These unpredictable denials often rely on flawed assumptions or automated processes that fail to account for routine pharmacy operations.

If a rebate is denied, the CHC takes a net loss on the transaction, having already paid the full WAC price to the wholesaler and provided the drug to the patient at a steep discount. Given our current volume of the MFP 2026 and 2027 selected drugs, even a conservative **15%** denial rate would result in a net annual loss of **$ 205,981.89.** This is a sum our CHC cannot absorb, as it represents a direct extraction of resources from our safety net budget. Any reduction in financial resources will directly affect our ability to fulfill the CHC mission of serving all patients, regardless of their ability to pay.

While the RFI suggests a 10-day timeframe for rebate payments, the lack of enforcement details and the complexity of reconciliation create a high risk of financial loss. Any delay beyond the 10-day window creates an immediate cash flow crisis. CHCs are particularly worried that the need to purchase drugs at full WAC will cause them to exceed their credit limits with wholesalers, halting their ability to order medications until payments are submitted. There is currently no mechanism to penalize manufacturers for late payments or to ensure that CHCs are made whole for the interest lost while capital is "frozen" in the rebate system.

The financial harm is compounded by the fact that the 340B price is no longer reflected in the wholesaler's price catalog or the pharmacy software at the time of purchase. This forces CHCs to "estimate" rebate amounts, creating unpredictable financial losses and the potential to undercharge or overcharge patients. Additionally, the lack of real-time 340B pricing presents challenges for compliance with 340B actual acquisition cost (AAC) billing in fee-for-service Medicaid. This may lead to increased Medicaid costs and potential state-level claw-backs, creating a second layer of

[16] Application Process for the 340B Rebate Model Pilot Program, 2025-14619 (90 FR 36163) https://www.federalregister.gov/documents/2025/08/01/2025-14619/340b-program-notice-application-process-for-the-340b-rebate-model-pilot-program

financial liability for the CHC. Without a standardized, transparent, and neutral dispute resolution process, the 340B Rebate Model Pilot functions as an interest-free loan from safety-net providers to multi-billion-dollar manufacturers. These unpredictable denials and delays create serious cash flow issues for CHCs operating on thin margins, which depend on timely reimbursement to sustain services for medically underserved populations.

IV. Reconciliation and Rebate Denials Operational Challenges

Operational Guardrails and Enforcement Framework

Taken together, the administrative burden, cash-flow exposure, reconciliation complexity, and denial risk associated with a rebate model fundamentally conflict with CHCs' operational realities. Without robust guardrails, neutral infrastructure, and enforceable manufacturer accountability, a rebate model would undermine, not strengthen, the integrity of the 340B Program and threaten patient access to essential medications.

If HRSA proceeds with a rebate-based pricing model, the program must include clear, enforceable operational guardrails to prevent the systematic shifting of financial and administrative risk to covered entities. A rebate model that relies on retrospective payment and manufacturer discretion without firm controls will inevitably result in delayed reimbursement, inconsistent determinations, and increased denials, placing safety-net providers in untenable financial positions.

We request that the process for rebate denials align with current statutory, regulatory, and guidance processes. Rebate requests should be presumed valid unless a manufacturer can demonstrate, with claim-level documentation, a specific and permissible basis for denial tied directly to statutory requirements. Within the current MFP models used by manufacturers and their vendor Beacon Channel Management, CHCs are given very limited transparency into the process, and denials are often based on vague reasons tied to arbitrary, unpublished standards created by manufacturers. If the manufacturer of their vendor cannot demonstrate denials aligning with the statutory requirements to prevent duplication of 340B discounts on prescriptions in the Medicaid Drug Rebate Program (MDRP) or MDPNP, rebates must be paid, and the manufacturers must revert to the processes described in HRSA 1996 Manufacturer Audit Guidelines, including conducting good faith inquiries and OPA-approved audits.[17]

The previously proposed rebate construct and the one currently used by manufacturers for MFP de-duplication incentivize rebate denials by imposing a significant, ongoing burden of chasing denied rebates. The onus of battling for every rebate questioned by manufacturers will increase costs for CHCs and likely lead many covered entities to forgo the appropriate statutory 340B discounts due to insufficient personnel to perform the function and general process fatigue. All this added strain on CHCs would create a barrier to patient care delivery and fails to align with the 340B program's intent "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[18]

Rebate payment timing requirements must apply to both initial and corrected determinations. Experience with existing manufacturer-run MFP de-duplication processes

[17] Manufacturer Audit Guidelines https://www.hrsa.gov/sites/default/files/hrsa/opa/dispute-resolution-process-12-12-96.pdf
[18] 340B House Report – Legislative History. H.R. REP. 102-384(II).

demonstrates that, even when a covered entity successfully contests a denial, payment is often delayed for indeterminate periods. If HRSA adopts a 10-day payment requirement, that requirement must run from both the initial determination and any subsequent corrected determination to prevent manufacturers from using dispute processes as a delay mechanism.

The 340B statute explicitly provides for sanctions for noncompliance, including liability for underpayment of drugs. It also outlines a formal dispute resolution process with HRSA to address grievances. **We are concerned that the pilot program fails to provide such protections, leaving CHCs without recourse if rebates are improperly denied or delayed.** Without clear protections, the pilot program risks becoming a mechanism that benefits manufacturers at the expense of the safety-net providers it was created to support. We respectfully request that OPA provide a detailed plan to ensure rebates are paid, given the thin financial margins CHCs operate on and the detrimental impact of ongoing delayed payments has on patient care.

Additionally, the Administrative Dispute Resolution (ADR) cannot serve as the primary mechanism for routine rebate disputes; we request that HRSA establish a separate dispute resolution pathway. Current ADR timelines are reported to take up to a year from the time of a review panel assignment. Given the time to complete the review and up to 180 days to return a determination,[19] CHCs could be waiting up to 2 years for their issues to be resolved. Given the sheer volume of prescriptions and clinic-administered drugs slated to flow through the rebate program, the current ADR process does not provide a viable solution to address covered entities' rebate disputes with manufacturers. HRSA must establish a separate, expedited dispute pathway for rebate denials, with defined timelines, escalation protocols, and agency oversight.

HRSA must clearly articulate the **resources, authorities, and enforcement mechanisms** it will use to ensure manufacturer compliance, including corrective action requirements and potential sanctions for repeated late payments or improper denials. **Additionally, we recommend that OPA establish a stakeholder advisory panel to ensure that the feedback and concerns of covered entities are formally and consistently addressed.** This panel should include pharmacists with the necessary subject-matter expertise to understand the complexities of pharmacy software, billing, and data components. Without explicit enforcement, a rebate pilot risks becoming a system of manufacturer self-policing, contrary to HRSA's statutory responsibility to administer and oversee the 340B Program.

A. Operational and Enforcement Guardrails

HRSA must require that any rebate model operate under uniform national standards that limit manufacturer discretion, hold manufacturers accountable, and protect covered entities from financial harm. These guardrails should include:

- A presumption that rebate claims are valid unless the manufacturer demonstrates otherwise under statutorily sanctioned duplication of discount prevention (i.e., 340B with MDRP or MDPNP);
- Standardized, publicly defined denial categories with claim-level documentation;

[19] Administrative Dispute Resolution Regulation, https://www.govinfo.gov/content/pkg/FR-2024-04-19/pdf/2024-08262.pdf

- Firm payment timelines that apply to both initial and corrected determinations; and
- A clear enforcement framework, including consequences for repeated late payments or improper denials by manufacturers.

B. Enforcement Requirements

- **Resources:** HRSA should identify the internal resources and systems it will use to actively monitor manufacturer compliance, including the ability to track payment timeliness, denial rates by category, and dispute outcomes. Covered entities should not be required to police manufacturers' behavior through repeated appeals to manufacturers or the administrative dispute resolution process.
- **Dispute Resolution:** There must be a formal procedure for when a CHC's data (e.g., from their pharmacy software or 340B accumulators) does not align with the manufacturer's accumulation logic. Based on experience with data submissions to 340B ESP, the manufacturers, through their vendor, are starting with initial purchase data and calculating accumulations based on future dispensations, factoring in unpublished "reasonable use" timeframes. Virtual inventories operate on eligible 340B dispensations that must reach full package size before purchases are made. Because the logic used by manufacturers and covered entities differs, they can misalign even when the entity is fully compliant with the 340B program requirements. Currently, when this misalignment occurs, manufacturers block an entity's ability to purchase at 340B prices until the entity meets the manufacturer's unpublished standards.

C. Burden of Proof on Manufacturers

Manufacturers must bear the burden of establishing that a rebate is not owed. Any approach that requires covered entities to demonstrate compliance beyond existing statutory requirements, particularly where manufacturers control the unpublished algorithms, creates an imbalance not sanctioned by the 340B or IRA statutes and ultimately undermines program integrity.

D. Rebate Determinations Must Align with Statutory Patient Definition

Any rebate model must preserve the statutory allocation of responsibility for patient eligibility determinations. The 340B statute assigns patient definition and eligibility determinations to covered entities.[20] Systems or methodologies that effectively transfer this determination to manufacturers, whether through retrospective algorithms, proxy indicators, or undisclosed purchase-history logic, exceed statutory authority and introduce non-transparent conditions on access to 340B pricing. HRSA should explicitly prohibit rebate denial methodologies that rely on manufacturer-defined patient eligibility standards or undisclosed validation criteria.

Transparency Measures

Fully Transparent Manufacturer Decision Processes

We appreciate HRSA's commitment to transparency in the 340B Program. Since 2020, manufacturers have imposed several self-declared "340B transparency measures" as pricing

[20] Section 340B of the Public Health Service Act, https://www.hrsa.gov/sites/default/files/hrsa/rural-health/phs-act-section-340b.pdf

conditions on covered entities. Unfortunately, while this has increased manufacturers' visibility, it has significantly reduced transparency for CHCs. Under the current manufacturer conditions imposed through 340B ESP and the handling of 340B claims for MDPNP, which are in the confidential portion of the manufacturer's effectuation plan, CHCs are subject to an unpublished standard as a condition of 340B pricing, with very limited portions of the determination process shared with CHCs.

One example is within MFP effectuation: the manufacturer's vendor, Second Sight Solutions, has published a list of pricing codes[21] to be utilized "to understand the validations performed following the successful transmission of MFP claims data to Beacon MFP." Three of the MFP determination methodologies in the table below highlight this issue. For the "recent 340B purchase" and "aggregate 340B purchase history of the Dispensing Entity" scenarios, neither manufacturers nor Beacon has provided clarity on how these are defined or calculated. This leaves CHCs without a mechanism to validate manufacturers' determinations. **We request that all determination processes, eligibility calculations, and any other items involved in the determination process be published in detail for all covered entities.**

Code	Description	Type	Definition
P1	340B Claim Indicator	Pricing	Claim included a 340B modifier.
P2	340B Claim	Pricing	Claim submitted by the entity as 340B.
P3	340B Pharmacy	Pricing	Claim from a pharmacy with evidence of recent 340B purchase.
P4	340B Prescriber	Pricing	Prescription written by a 340B prescriber and dispensed by a pharmacy with evidence of recent 340B purchase.
P5	Contract Price	Pricing	Basis price is a Contract Price.
P5	Contract Price	Pricing	Basis price is a Contract Price.
P7	Non SDRA MFR Reprice	Pricing	Value other than WAC used to determine MFP refund amount.
P8	Entity Identified 340B	Pricing	Claim manually identified as 340B in Beacon by Dispensing Entity.
P9	340B Pharmacy Allocation	Pricing	Claim identified as 340B according to the aggregate 340B purchase history of the Dispensing Entity.

V. Limit the 340B Rebate Model Pilot to Retail Pharmacy Claims Only

If HRSA moves ahead with a rebate model, we request that the 340B rebate model pilot be limited to retail pharmacy claims only. Limiting the pilot to retail pharmacy claims is not merely a matter of operational convenience; it is essential to prevent unnecessary disruption in areas where no current duplicate discount risk exists. Extending a rebate model to clinic-administered drugs (CADs), where CHCs' claims are adjudicated under PPS and not at the drug level, and Medicare negotiated prices do not apply until future years, would impose extraordinary administrative burdens without advancing the stated deduplication goals of the pilot. As HRSA has already stated, there are mechanisms in place to prevent Medicaid duplicate discounts.[22] Therefore, a measured, retail-only approach is the minimum safeguard for an untested model.

[21] https://mfp.support.beaconchannelmanagement.com/en/articles/13335320-validation-codes-and-pricing-codes-glossary
[22] https://public-inspection.federalregister.gov/2025-14619.pdf?1753965918

CHCs generally operate under the PPS and do not bill CADs as discrete, line-item drug claims. Instead, the cost of these drugs is embedded within encounter-based reimbursement. As a result, CHCs do not maintain electronic, claim-level billing records for CADs that could be readily repurposed for rebate submission or reconciliation. Implementing a rebate-based framework for CADs would require the creation of entirely new data capture, reporting, and reconciliation workflows, rather than incremental modifications to existing systems.

In addition, auditable records for CADs are frequently maintained in paper logs or other non-standard internal documentation, rather than in structured electronic data fields. These record-keeping practices are designed to support internal controls and HRSA audit requirements, not retrospective rebate processing. A rebate model that requires structured electronic submission to a rebate platform would compel CHCs to convert paper-based records into discrete electronic datasets and maintain parallel documentation systems solely for rebate compliance. This would substantially increase administrative burden and compliance risk without improving program integrity.

Implementing a rebate model for CADs would also require new software, system integration, and staff training. NACHC estimates these costs would range from $30,000 to $50,000 annually and could be much higher, depending on the software.[23] CHCs would need to deploy tracking functionality either within their electronic medical record systems or through standalone software, incur ongoing licensing and maintenance costs, and redesign clinical and administrative workflows. These costs would be additive and ongoing, not one time, and would be incurred even though CADs are not currently billed to Medicare Parts B or D. Furthermore, Medicare Part B negotiated pricing provisions applicable to certain drugs do not take effect until 2028, underscoring the lack of near-term applicability.

Because CADs furnished by CHCs are not billed as discrete Medicare drug claims, there is no current Medicare duplicate discount risk associated with these drugs that would justify imposing a rebate-based reporting and reconciliation framework at this time. To the extent the policy objective relates to the implementation of Medicare drug pricing reforms under the IRA, CADs furnished by CHCs do not currently raise those concerns.

Moreover, where manufacturers have concerns about diversion or compliance for CADs, existing statutory mechanisms already include HRSA audits and the ADR process. These tools are specifically designed to address compliance concerns within the 340B Program. Layering a rebate model on top of these established statutory mechanisms—particularly in a context where no discrete billing or near-term Medicare interaction exists—would be duplicative and unnecessary.

For these reasons, HRSA should explicitly exclude CADs from any 340B rebate model pilot. At a minimum, such drugs should remain excluded unless and until they are billed as discrete claims by CHCs and a demonstrated duplicate discount risk exists that cannot be addressed through existing statutory mechanisms. Including CADs in a rebate pilot at this stage would impose disproportionate administrative costs, software expenses, and compliance risks on CHCs without corresponding benefits to program integrity or federal oversight.

[23] Internal NACHC survey data

VI. Existing CHC Compliance Actions

CHCs already operate under a comprehensive regulatory framework established through the Health Center Program and the 340B statute to make medications affordable for patients. In alignment with Section 330 of the Public Health Service Act, they utilize a sliding fee discount that adjusts costs based on a patient's income and household size, ensuring that no one is denied services due to an inability to pay. CHCs must also establish systems for eligibility determination and offer full discounts to individuals at or below 100% of the Federal Poverty Level (FPL). These services would not be possible without the savings generated from the 340B program.

CHCs pride themselves on maintaining compliance with both the Health Center Program requirements and the 340B program, and they adhere to rigorous oversight and compliance processes. Not only do they participate in regular Operational Site Visits (OSVs) to verify Health Center Program compliance, but they also follow strict 340B compliance protocols, including internal audits, training, and external oversight. This demonstrates a proven ability to manage 340B with integrity and accountability. In addition to implementing internal best practices, such as regular audits and staff training, CHCs participating in the 340B program are required to report 340B-related information annually through the Uniform Data System (UDS). This includes data on 340B-purchased drugs, associated costs and revenues, and detailed information about the patients served by the program. These reporting requirements provide a clear and consistent picture of how 340B savings are utilized to expand access and improve patient outcomes, consistently demonstrating CHCs' exemplary stewardship of the program.

Given the compliance infrastructure and strict statutory requirements already in place for CHCs, implementing a rebate model would cause disproportionate harm to CHCs and the patients they serve. The administrative, financial, and operational burdens from such a model would threaten the stability of the safety-net providers that the 340B program was designed to support. CHCs are not the source of misuse in the 340B program; rather, they are national models of compliance.

CHCs are required to provide sliding fee discounts to patients at or below 200% of the federal poverty level. Currently, CHCs routinely provide discounts to uninsured and underinsured patients, but a rebate model would make this operationally impossible because they rely on wholesale price files to determine the acquisition cost of the drug to calculate a discounted price. In a rebate model, the price file lists the WAC price, making the price unattainable for the patient. If CHCs are included in this pilot, it will be extremely difficult to offer the included medications at a discount. For these reasons, **we encourage HRSA to exempt all CHCs from this pilot program.**

VII. The 340B Rebate Model's Incompatibility with Deduplication Efforts

A. Medicare Inflation Reduction Act (IRA) Deduplication

While we understand that manufacturers' investment in a mechanism to deduplicate Medicare IRA maximum fair price (MFP) and the 340B price from the same unit of drug, we are deeply concerned that the previously proposed approach for addressing IRA deduplication—a 340B rebate model—would create significant administrative, financial, and operational burdens for CHCs. A 340B rebate model is not only unnecessary to achieve the goal of deduplication, but

also the option that would place the greatest burden on CHCs. Any change in government policy should seek to accomplish the government's goals in the least burdensome way with the least negative impact on stakeholders,[24] and a 340B rebate model is not that.

Several less burdensome alternatives are available for HHS' consideration. As further discussed below, CMS could implement Medicare-only claims data submission to a government vendor or neutral clearinghouse without also requiring an upfront purchase of 340B-priced drugs at WAC prices (i.e., a rebate) or without the requirement to submit commercial claims data, a process CMS is already exploring for purposes of Medicare IRA rebate deduplication through the 340B claims repository finalized as a voluntary model in the CY 2026 Medicare Physician Fee Schedule.[25] This intention was made clear in the CY 2026 Physician Fee Schedule Final Rule: CMS proposed that it would address the possibility of mandatory reporting of data elements to the 340B repository by covered entities in future rulemaking. CMS noted that many covered entities are providers and suppliers regulated by CMS under Title XVIII of the Act, including hospitals receiving DSH payments, CAHs, and FQHCs. CMS noted that it was actively considering options for mandatory reporting to the 340B repository in the near future and recommended that covered entities take advantage of the testing period to prepare for future policy development related to 340B repository reporting.[26]

If both a 340B rebate model and a 340B claims repository are made mandatory, CHCs will be subject to two new administrative burdens that accomplish nearly identical goals: identifying 340B claims for purposes of the IRA. Many alternative options exist for deduplicating 340B and MFP, and whichever deduplication mechanism is ultimately selected should be the least burdensome that accomplishes the deduplication goal. The 340B Legislative History demonstrates the 340B Statue was written with this intention stating, even going so far as to call out that what will work for an AIDS Drug Assistance Programs (ADAPs) – the manufacturer cited example of 340B rebates being workable common practice— may not be appropriate for CHCs: "The Committee bill does not specify whether "covered entities" would receive these favorable prices through a point-of-purchase discount, through a manufacturer rebate, or through some other mechanism. A mechanism that is appropriate to one type of "covered entity," such as CHCs, may not be appropriate to another type, such as State AIDS drug purchasing programs. The Committee expects that the Secretary of HHS, in developing these agreements, will use the mechanism that is the most effective and most efficient from the standpoint of each type of "covered entity."[27] The negative implications of a 340B rebate model are well documented, fail to align with legislative intent, and do not meet the "least burdensome" requirement.

A 340B rebate model not only contradicts principles of good governance but would also directly contradict congressional intent for the 340B Program and the IRA. When enacting the 340B statute, Congress intended for the administration to select **the most effective and efficient mechanism for each type of covered entity, but a 340B rebate model is the least effective**

[24] 5 U.S.C. §§ 500–596; Food & Drug Admin., Least Burdensome Provisions: Concept and Principles (n.d.), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/least-burdensome-provisions-concept-and-principles (last visited Mar. 13, 2026); H.R. REP. 102-384(II)).

[25] Medicare and Medicaid Programs; Calendar Year 2026 Payment Policies Under the Physician Fee Schedule, 90 Fed. Reg. 49,266 (2025).

[26] CY 2026 PFS, Final Rule, https://www.govinfo.gov/content/pkg/FR-2025-11-05/pdf/2025-19787.pdf

[27] H.R. REP. 102-384(II)

and least efficient mechanism for CHCs. We respectfully submit that mandating CHCs, the nation's primary care safety-net backbone, to pay upfront WAC pricing simply because a manufacturer is entitled to make the lower of two discounted price points available, 340B and MFP, is extra-statutory and appears to be punitive. Implementing a 340B rebate model, therefore, contradicts the intent of Congress when enacting 340B. A 340B rebate model also fails to align with the IRA's intent. Under the IRA, the manufacturer must provide the lower of the two prices—340B or MFP—to a covered entity. Under a 340B rebate model, however, a manufacturer can deny a 340B rebate whenever an MFP applies, even when the 340B ceiling price is lower than the MFP. By failing to address that a covered entity has a legal right to the lower of the two prices, a 340B rebate model ignores the protections Congress specifically included in enacting the IRA and imposes a punitive condition on the safety-net provider that it purchase the drug at the highest market price.

Moreover, we believe that any government-mandated rebate model for 340B-priced drugs that serves to deduplicate MFP from 340B pricing is inconsistent with HRSA's stated authority. The 340B statute – not the IRA – cursorily mentions the term "rebate" in a parenthetical in the first paragraph. Specifically, the 340B statute states that the "Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (*taking into account any rebate* or discount, as *provided by the Secretary*)."[28] That clause, however, cannot be read in a vacuum. From this clause, HHS has contended that it may authorize manufacturer 340B rebate models. However, HRSA's authority over the 340B statute, including its alleged ability to implement a 340B rebate model, is confined by the 340B statute's bounds. And such bounds do not include protections against or prevention of duplicate discounting of Medicare claims where 340B pricing and MFP are at issue. Rather, the 340B statute limits the bounds of HRSA's authority, including its alleged rebate authorization authority, to the limitations of the 340B statute, which only provides protections against Medicaid fee-for-service ("FFS") duplicate discounts. Accordingly, HRSA's rebate authority under the 340B statute cannot be extended to deduplication of MFP and 340B drug claims. Such an extension would be an *ultra vires* application of HRSA's alleged rebate authority.

Likewise, the IRA does not include language that permits HRSA to authorize drugmakers to charge prices above the 340B statutory ceiling price. That statute merely states that a drugmaker must make available the lower of two discounted prices – MFP and 340B. It cannot be construed as spontaneously modifying the 340B statute's plain text prohibiting a manufacturer from charging above the 340B ceiling price – "the maximum price that covered entities may permissibly be required to pay for the drug."[29] The only rebate mechanism HHS has contended is available to it is found under Section 340B, and, as stated above, Section 340B does not pertain to Medicare claims. Accordingly, HRSA's alleged rebate authority cannot be used as a deduplication tool under the IRA, and drugmakers are not permitted under the IRA or 340B statutes to charge upfront WAC prices for 340B drugs under at least the IRA because the IRA does not contain a 340B rebate pricing mechanism. For these reasons, a 340B rebate model would be an unworkable and burdensome mechanism for addressing 340B-MFP deduplication.

B. Medicaid Duplicate Discounts

[28] 42 U.S.C. § 256b(a)(1)
[29] *Id.*

The 340B rebate pilot is not a legal mechanism for addressing Medicaid FFS duplicate discounts. As stated above, the 340B statute – not the IRA – cursorily mentions the term "rebate" in a parenthetical in the first paragraph of that statute. Specifically, it states that the "Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (*taking into account any rebate* or discount, as *provided by the Secretary*)."[30] That clause cannot be read in a vacuum. HRSA's authority over the 340B statute, including its alleged ability to implement a 340B rebate model, is limited by the 340B and Medicaid Drug Rebate Program ("MDRP") statutes' bounds.

The 340B statute only protects drugmakers from *Medicaid* duplicate discounts. The 340B statute's clause addressing the obligation to prevent duplicate discounts applies only to such discounts under Medicaid FFS plans. That provision states that a covered entity – *not HHS and not a drug manufacturer* – shall prevent 340B duplicate discounts in the first instance. Specifically, that provision states that a "covered entity[, not HHS or a drugmaker,] shall not request payment under" the Medicaid FFS program for a 340B-priced drug.[31] Accordingly, only the covered entity may elect whether to bill a 340B drug to Medicaid and how it satisfies its obligation to prevent Medicaid FFS duplicate discounts under the plain language of the 340B statute. The state Medicaid agency may set the state-based requirements for 340B claim identification.[32] HRSA and drugmakers may only *audit* such Medicaid claims *after* such covered entity election has been made – meaning their authority to deduplicate such claims only vests *after* the 340B drug has already been billed to the Medicaid state plan.[33]

Specifically, the 340B statute's audit provision states that a "covered entity shall permit the Secretary and the manufacturer . . . *to audit* . . . *the records* of the entity that directly pertain to the entity's compliance with the" duplicate discount prohibition. Such records must first be generated, and thus such audit authority may reasonably be interpreted as vesting only *after* the covered entity has exercised its statutory discretion to prevent Medicaid FFS duplicate discounts and has billed a 340B drug claim to a state Medicaid FFS plan.[34] However, the 340B statute grants neither HHS nor drugmakers authority to prevent duplicate discounts in the first instance or to requisition related 340B claims data to prevent such discounts before a covered entity elects to bill the claim under applicable state requirements. Congress knew how to furnish such discretion to drugmakers but explicitly chose to grant it to safety-net providers.

Nevertheless, the 340B rebate model proposes to illegally usurp the covered entity's statutory responsibility regarding its prevention of Medicaid FFS duplicate discounts. It

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[30] 42 U.S.C. § 256b(a)(1)

[31] Indeed, the 340B statute states that the covered entity may choose "options" for billing 340B drugs to Medicaid. Specifically, it states that the HHS may "develop[][more detailed guidance describing methodologies and *options available* to covered entities for billing covered outpatient drugs to State Medicaid agencies in a manner that avoids duplicate discounts pursuant to subsection (a)(5)(A)." 42 U.S.C. 256b(d)(2)(B)(iii). And the Secretary of HHS may institute a system to ensure that the covered entity does what the statute says it's obligated to do – prevent duplicate discounts. *Id.*

[32] 42 U.S.C. § 1396r-8(a)(5)(C)(ii) ("Each such single State agency shall provide a means by which a covered entity shall indicate on any drug reimbursement claims form (or format, where electronic claims management is used) that a unit of the drug that is the subject of the form is subject to an agreement under section 256b of this title, and not submit to any manufacturer a claim for a rebate payment under subsection (b) with respect to such a drug.")

[33] 42 U.S.C. § 256b(a)(5)(C).

[34] 42 U.S.C. § 256b(a)(5)(C).

would illegally transfer that discretion to drugmakers by allowing them to require significantly high upfront pricing and the submission of claims data so that they, not the covered entity, may elect whether a drug is 340B or not, or whether such drug is subject to a Medicaid rebate. This proposed mechanism clearly violates the plain language of the duplicate discount prohibition. And a cursory mention of the term "rebate" in a parenthetical of the statute's first paragraph does not supplant that plain language.[35] Accordingly, the application of a 340B rebate model is illegal under the 340B statute because it shifts the discretion to choose to bill 340B drugs to, and the obligation to prevent duplicate discounts under, Medicaid FFS plans away from the covered entity and gives drugmakers first oversight of such claims. That policy cannot be supported by the text of the 340B statute, the Medicaid Drug Rebate Statute, or their legislative records.

The 340B rebate pilot disrupts CHCs' ability to comply with state Medicaid billing requirements. CHCs are also concerned that the proposed rebate pilot will impose significant legal risks and operational burdens on their requirement to appropriately bill 340B drugs to Medicaid plans. Those 340B billing rules require the CHC to determine whether a drug is a 340B drug or a non-340B drug prior to submitting the drug claim with the appropriate billing requirements. However, these billing requirements are virtually impossible to comply with under the rebate pilot because the CHC does not know that a drug is 340B eligible until after the manufacturer has paid the rebate.

Specifically, CHCs are required to identify and appropriately charge for 340B drugs when billing Medicaid plans. Those 340B billing requirements vary depending on whether the drug is billed: (1) to Medicaid FFS; or (2) to a Medicaid managed care plan or organization ("MCO"). The billing requirements vary further depending on whether the drugs are billed under a pharmacy benefit or a medical benefit for each plan type. These requirements create a complex web of billing and reimbursement policies for Medicaid FFS plans, which vary even within a single state. For instance, in California, a CHC cannot bill Medicaid until the rebate is processed. If a claim is submitted pre-rebate at the WAC, this could result in overpayment, requiring it to be reversed and resubmitted.[36] This demonstrates the infeasibility of a rebate model for many CHCs in states with similar Medicaid billing policies.

For Medicaid FFS retail pharmacy claims, federal regulations require states to implement policies where reimbursement is based on the actual acquisition cost (AAC) of a drug, including a separate methodology for 340B drugs compared to non-340B drugs.[37] Additionally, states have implemented AAC-based reimbursement for Medicaid FFS medical claims, and some Medicaid MCOs implement AAC-based reimbursement under the terms of their contracts with CHCs for drugs covered under the retail pharmacy and/or medical benefit. When 340B-based AAC is implicated, the CHC is typically required to submit the claim with certain data elements at the point of billing the claim, or the point-of-sale. These required elements are typically the Submission Clarification Code (SCC) 20, which identifies the claim as 340B, and a basis for cost determination code (BOC) 08, which provides the 340B-based AAC for Medicaid to use in determining the reimbursement amount for that claim.

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[35] *See* 42 U.S.C § 256b(a)(5)(A).
[36] https://medi-calrx.dhcs.ca.gov/cms/medicalrx/static-assets/documents/provider/2025/12_A_Claim_Submission_Requirements_340B_Rebate_Model_Pilot_Drugs.pdf
[37] C.F.R. § 447.518(a).

A 340B rebate pilot would create significant confusion and legal impossibility for covered entities because it would revoke the covered entity's ability to determine when a 340B drug is used. Specifically, the rebate pilot removes the covered entity's discretion to determine whether a drug is 340B at the point of billing a claim to a Medicaid plan. This is because the 340B rebate model illegally transfers that discretion to drugmakers by authorizing them to determine when a rebate should be paid. And thus, both state Medicaid agencies and CHCs are left confounded about how to intelligibly submit claims data for WAC-priced drugs that may or may not be subject to a 340B rebate at the drugmaker's future discretion.

Under a 340B rebate model, a drug is not a 340B drug until a manufacturer pays a rebate on the drug, which is long after the claim has been submitted for Medicaid reimbursement. Additionally, the 340B ceiling price is no longer an effective proxy for 340B-based AAC because additional costs are incurred at the initial purchase at the higher WAC price and through added administrative costs. Under the previous 340B rebate model pilot, HRSA directed covered entities to contact individual state Medicaid agencies for 340B rebate model claim submission policies. Some states provided guidance on how they expected covered entities to bill, but not all did. Even for those states that did provide guidance, such guidance became subject to serious legal challenge and confusion. Of the states that responded, most Medicaid departments would have required covered entities to submit the 340B ceiling price when billing Medicaid if the covered entity believed it would receive a 340B rebate under the drugmaker's discretion. But if the drug isn't subject to a rebate in the future, the initial 340B ceiling price claim may have been false. This creates operational, financial, and legal impediments for CHCs.

Operationally, CHCs rely on wholesaler price files when submitting a drug's AAC with a Medicaid claim. In a 340B rebate model, the wholesaler price file would provide the WAC, which is the price at which the CHC must purchase the drug. Thus, the 340B price would not be made available through the wholesaler for drugs subject to the 340B rebate model. Pharmacy billing software does not allow the use of an external price file, which would force CHCs to manually insert the 340B AAC for each Medicaid claim, an operationally infeasible endeavor. Adding to the operational burden is the variation between state policies. CHCs that treat patients from different states may have to tailor operations to comply with each state's Medicaid policy. Submitting an erroneous Medicaid claim exposes the CHC to significant civil and criminal liability under the False Claims Act. Accordingly, HHS has not only usurped the CHC's authority to prevent duplicate discounts, but it also confers on drugmakers the ability to induce false claims. This is a serious, unjustified, and unprecedented misstep that threatens the stability of the entire 340B program and Medicaid Programs.

A 340B rebate model is unduly burdensome. HHS's designing of a rebate model does not require it to authorize drugmakers to charge the nation's CHCs one of *the highest possible prices* to acquire a drug in the first instance. For example, a rebate model could be implemented through upfront discounts and retrospective credits or debits, a neutral clearinghouse, or a government-led clearinghouse repository.[38] Some of these ideas are explored later in this letter. This way, the manufacturer's rebate liability is adjusted, rather than the local CHC.

[38] Ctrs. for Medicare & Medicaid Servs., *IPAY 2028 Final Guidance*, https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf.

Multiple states have expressed concerns that a 340B rebate model would effectively change all drugs dispensed or administered by covered entities from 340B-based AAC to WAC-based AAC, thereby increasing costs for state Medicaid agencies. This is because federal regulations define AAC as "the agency's determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific manufacturers."[39] The definition indicates that Medicaid departments may determine that AAC should be based on the wholesaler pricing files, which would be WAC-based pricing under a 340B rebate model.

In submitting comments regarding HRSA's previous 340B rebate model, two states expressed serious concerns about how a 340B rebate model would negatively impact the state for this reason. Specifically, the Pennsylvania Department of Human Services stated, "[i]f the AAC for drugs in the Pilot Program is the covered entity's cost before the 340B rebate, then Medicaid FFS will no longer benefit from the 340B discount and Medicaid's cost for these drugs will increase."[40] The Oregon Health Authority commented, "[i]f Oregon's FFS Medicaid program continues to reimburse covered entities at the 340B ceiling price, we will fail to meet the entity's initial cost and will contribute to cash flow problems and financial instability for the impacted safety net providers."[41]

Furthermore, the 340B rebate model would create legal impossibilities under Medicaid managed care for covered entities, state Medicaid agencies, and Medicaid managed care organizations. The Medicaid statute authorizes only the covered entity to select a 340B drug and bill it to a Medicaid managed care plan. Specifically, 42 U.S.C. § 1396r-8(j)(1) states that a drug purchased by a covered entity under the 340B Program is no longer subject to a rebate payment under Medicaid managed care plans. Put differently, that statute grants to the covered entity, not HHS or a drugmaker, the authority to choose to use 340B drugs for Medicaid managed care beneficiaries. By mandating upfront WAC pricing and authorizing drugmakers to choose when to pay a 340B rebate, the discretion is illegally usurped in violation of federal law.

Moreover, state Medicaid agencies are required by federal law to implement systems to remove 340B drug utilization data from their rebate invoices charged to drugmakers under Medicaid managed care arrangements. Specifically, 42 C.F.R. 438.3(s)(3) states that states must contract with Medicaid managed care organizations to require that they, not drugmakers or HHS, "establish procedures to exclude utilization data for covered outpatient drugs that are subject to discounts under the 340B drug pricing program from the reports" submitted to manufacturers for Medicaid rebate payments. Although their policies vary, most states require Medicaid managed care organizations to require covered entities to identify 340B drugs when billing for such claims. As with Medicaid FFS plans, neither the state Medicaid agency nor the CHC may comply with this federal requirement under the proposed 340B rebate model because the discretion regarding how and/or when to identify 340B drug claims under Medicaid managed care arrangements is seized from them and given to drugmakers. This is not only an irresponsible policy; it is also quite a

[39] 42 C.F.R. § 447.502

[40] [14]: Comment on Agency Information Collection Activities; Proposed Collection; 340B Drug Pricing Program, Docket No. HRSA-2025-0001-0095, https://www.regulations.gov/comment/HRSA-2025-0001-0095.

[41] Comment on Agency Information Collection Activities; Proposed Collection; 340B Drug Pricing Program, Docket No. HRSA-2025-0001-0980, https://www.regulations.gov/comment/HRSA-2025-0001-0980.

dangerous policy, as it creates a serious impediment to submitting claims that may or may not be later deemed to be false based on a third-party drugmaker's decision.

Even if CHCs could operationalize a manual claims submission process, either the CHC, the state, or both would be financially burdened by a 340B rebate model. First, 340B-based AAC must account for added actual costs. A 340B rebate model effectively raises the 340B price of a drug above the 340B ceiling price, and such costs must be included in billing state Medicaid plans. This is because the CHC would have to float WAC pricing for each drug and incur additional administrative costs related to claiming a rebate, which are factored into the true "actual acquisition cost" of a 340B-rebated drug. Second, the CHC may be forced to over-identify claims as 340B because, though a CHC may accurately identify a claim as 340B-eligible, a manufacturer may still refuse the rebate, meaning a CHC would have identified the drug as 340B for Medicaid purposes, received a lower 340B-based reimbursement, but would not receive the benefit of the 340B price on the claim because a manufacturer unilaterally denied the rebate. This scenario is particularly harmful to CHCs that are required to extend sliding fee discounts to patients at the point of sale before rebate payment. And it raises serious federal questions relating to whether a federal grantee may be required to overpay for drugs.[42] It is also harmful to CHCs because wholesalers might not allow the CHC to reprocess a denied rebate at a non-WAC, non-340B price. And, as stated, this raises potential False Claims Act considerations because the CHC submitted a Medicaid claim as 340B when the claim ultimately was not 340B based on the manufacturer's subsequent discretionary denial of the 340B rebate.

Accordingly, the proposed 340B rebate pilot is unworkable because it creates significant operational and financial uncertainties, creates legal billing compliance impossibilities, and raises potential False Claims Act implications when submitting Medicaid claims for reimbursement for drugs identified as 340B-eligible by the covered entity that are ultimately denied a 340B rebate by drugmakers. HRSA's authorization of this illegal framework would violate the Administrative Procedure Act and is clearly inconsistent with federal statutes that grant the CHC alone the authority to prevent Medicaid FFS duplicate discounts in the first instance.

*i. **Adopting a Revised Medicaid Duplicate Discount Prevention Database***

We strongly recommend that HRSA adopt a publicly available database of Medicaid plan identification information. This database could be called the Medicaid Plan Billing Information Database (MPBID). The MBPID could be created by requiring manufacturers, state Medicaid agencies, and/or Medicaid managed care organizations to submit plan billing information used to identify Medicaid plans. This plan identification information includes the Medicaid plan's unique Bank Identification Number (BIN), Processing Control Number (PCN), and Group Number (GRP) to identify those FFS and managed care plans under which a manufacturer may pay a rebate under the MDRP. This information should be published on 340B OPAIS or some other public federal website. This critical recommendation is buttressed by existing requirements that Medicaid plans, including Medicaid managed care plans, use unique BIN and PCN numbers to separate the Medicaid business lines from commercial business lines for pharmacy billing.[43]

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[42] *See, e.g.,* 31 U.S.C. 3729 (making it illegal to overcharge a federal grantee).

[43] 42 C.F.R. § 438.3(s)(7) The MCO, PIHP, or PAHP must assign and exclusively use a unique Medicaid-specific Bank Identification Number (BIN) and Processor Control Number (PCN) combination, and group number identifiers for all Medicaid managed care enrollee identification cards for pharmacy benefits. https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-438/subpart-A/section-438.3

While we appreciate the insinuation that manufacturer processes in the 340B rebate pilot will ensure the prevention of 340B and MDRP duplicate discounts, as stated above, the statutory obligation for the compliance measure falls to the covered entities:

> *"A **covered entity shall not request** payment under title XIX of the Social Security Act for medical assistance described in section 1905(a)(12) of such Act with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under section 1927 of such Act."*[44]

After more than 33 years, CHCs request that HRSA put in place systematic mechanisms to support covered entities' compliance with the duplicate discount prohibition by implementing the Medicaid Plan Billing Information Database. To date, the mechanisms in place support HRSA and manufacturer processes for validating and auditing compliance. Systems like the Medicaid Exclusion File fail to provide CHCs and other 340B entities with a mechanism to ensure covered entities comply with the expectation that they will not request payment. The Medicaid Plan Billing Information Database would provide all covered entities with access to accurate Medicaid billing information (including BIN/PCN/GRP).

C. TRICARE Duplicate Discounts

The 340B rebate pilot would make it difficult to comply with TRICARE expectations because providers will not know whether a drug is 340B until a rebate is paid. The TRICARE Pharmacy Benefits Program, as codified in federal regulations, interacts with the 340B Drug Pricing Program in a manner designed to prevent overlapping federal discounts. The key regulatory provision is found at 32 C.F.R. § 199.21, which governs the TRICARE Pharmacy Benefits Program. This regulation incorporates the concept of a "covered drug" as defined under 38 U.S.C. § 8126, which serves as the statutory basis for the Federal Ceiling Price (FCP) program applicable to drugs purchased by certain federal agencies, including those under the TRICARE Program.

The TRICARE regulation explicitly excludes from the definition of a "covered drug" any drug that is dispensed by a pharmacy under the 340B program. If a prescription is purchased under the 340B Program, it is not considered a "covered drug" for purposes of TRICARE's retail network pricing and TRICARE's manufacturer rebate obligations.[45] The effect of this exclusion is to prevent the same prescription from being subject to both the 340B discount and the TRICARE FCP-based pricing, as effectuated through manufacturer rebate requirements. The regulatory structure thus creates a clear separation between the two programs, ensuring that the TRICARE rebate does not apply to a 340B discounted drug. Consistent with the statutory exclusion, TRICARE PBM agreements may obligate participants to identify 340B drugs to prevent the assessment or payment of TRICARE rebates on 340B discounted drugs.

Under the 340B rebate pilot, pharmacies would learn of a drug's 340B status only after a manufacturer pays a 340B rebate. Despite a covered entity identifying a claim as 340B-eligible, a

[44] 42 U.S.C. § 256b(a)(5)(A)(emphasis added).
[45] 32 C.F.R. § 199.21(q)(2)(iii)(E)

manufacturer may reject the 340B rebate request, meaning that a drug identified as 340B by the pharmacy may not be 340B after a manufacturer unilaterally implements rebate policies and denies rebate requests, even if such policy requirements can be found nowhere in state or federal law. The 340B rebate model would therefore impair a covered entity's ability to comply with contractual terms in TRICARE agreements and is likely to lead to many circumstances where the covered entity not only does not get the benefit of the 340B discount, but TRICARE also does not get the benefit of a TRICARE rebate because a manufacturer rejects a 340B rebate request and the covered entity has no mechanism to notify TRICARE of the rebate denial. Ultimately, this will divert resources from both safety-net providers and the health care program for uniformed service members, retirees, and their families.

D. Commercial Duplicate Discounts

The requirement for CHCs to provide valuable 340B commercial claims data to pharmaceutical manufacturers cannot be included under the rebate pilot or any federally authorized program. The purpose of the 340B Program is to enable covered entities to stretch scarce federal resources in order to offset the costs of providing care to uninsured and underinsured patients.[46] The statute's design reflects Congress's intent to ensure non-discriminatory access to discounted drugs, not to insulate manufacturers from commercial pricing dynamics. Allowing manufacturers to recapture value through regulatory mechanisms that Congress declined to authorize undermines the 340B program's purpose and contradicts its statutory structure.

Commercial claims data is extraordinarily valuable proprietary information to CHCs.[47] Studies conducted by IQVIA and others demonstrate that pharmaceutical manufacturers and PBMs routinely pay significant sums to obtain access to such data.[48] This regulatory action represents the first time in recorded history that the federal government has authorized pharmaceutical manufacturers, through subregulatory guidance, to transfer this valuable property away from covered entities and into manufacturers' possession without compensation or a valid public use.

That data will be used by drugmakers to reduce their rebate payment liabilities to commercial PBMs under contracts between the two private parties. Those contracts are privately negotiated so that drugmakers can obtain better formulary placement for their products and exclude cheaper drug alternatives.[49] They are negotiated with market discounts, including 340B discounts, already factored into their high drug list prices.[50] Drug industry data vendors have reported that such data

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[46] Genesis Health Care, Inc. v. Becerra, No. 4:19-cv-01531-RBH, slip op. (D.S.C. Nov. 3, 2023).

[47] Kalderos, *Sightlines Issue No. 3, Double, double, toil and trouble with commercial contracts,* www.Kalderos.com (Oct. 2023), Issue No. 3. (stating that commercial claims data is worth billions of dollars).

[48] Kalderos, *Sightlines Issue No. 3, Double, double, toil and trouble with commercial contracts,* www.Kalderos.com (Oct. 2023), Issue No. 3. (stating that "5% of commercial rebates paid by manufacturers are likely duplicates with the 340B Drug Pricing Program — meaning a total of roughly $6 billion annually.")

[49] Kalderos, *Sightlines Issue No. 3, Double, double, toil and trouble with commercial contracts,* www.Kalderos.com (Oct. 2023), Issue No. 3. (widely used drug industry data vendor and analytics services provider, Kalderos, identifying that commercial 340B claims data is worth "at least . . . $6 billion annually" in 2022.)

[50] Kalderos, *Sightlines Issue No. 3, Double, double, toil and trouble with commercial contracts,* www.Kalderos.com (Oct. 2023), Issue No. 3. (stating that "5% of commercial rebates paid by manufacturers are likely duplicates with the 340B Drug Pricing Program — meaning a total of roughly $6 billion annually.").

is highly valuable to manufacturers.[51] Further, manufacturers or PBMs have been and would continue to use such data to harm covered entities if covered entities are forced to provide it. This is because manufacturers will use commercial claims data to dispute rebate obligations to commercial PBMs, and those PBMs will then, in turn, discriminate against 340B claims and 340B providers to make up for the lost profit. These PBMs use the data to impose onerous claims identification requirements against covered entities, reduce reimbursement on identified 340B drug claims, restrict networks to exclude CHCs and their pharmacies, restrict patient choice of CHCs and their pharmacies, or all the above. These are widespread practices that fundamentally undermine the core purpose of the 340B Program, which is to permit safety-net providers to generate savings on commercial 340B claims to offset the vast uncompensated and undercompensated services they furnish to our country's most vulnerable patient populations.[52] Indeed, over 30 states have passed laws to prevent this manufacturer-payer gamesmanship that seeks to usurp the 340B benefit.[53]

We believe that Congress did not intend to protect manufacturers or PBMs from their own commercial contracts. Federal law contains no prohibition on commercial duplicate discounts, and Congress expressly chose not to create one. When Congress enacted the 340B statute, it included explicit protection for manufacturers against Medicaid duplicate discounts but declined to extend that protection to commercial claims. Congress's omission of any comparable protection in the commercial market is therefore meaningful and dispositive. Respectfully, HHS may not unilaterally mandate the transfer of such valuable property outside the bounds of any applicable federal or state law.

We contend that HRSA lacks statutory authority to require the submission of commercial claims data. HRSA's authorization of mandatory commercial claims data submission under the rebate pilot exceeds the agency's statutory authority.[54] The 340B statute authorizes HRSA to administer ceiling pricing requirements; it does not authorize the agency to compel covered entities to surrender valuable proprietary data as a condition of accessing pricing to which they are statutorily entitled. As the District of D.C. explained, "Congress therefore constrained the Secretary's ability to adopt regulations that have the force of law. This denial of general rulemaking authority supports the conclusion that Congress did not mean for the Secretary to create extra-statutory hurdles to 340B participation."[55] Even if the statute were silent on this issue, silence cannot serve as a basis for imposing affirmative obligations on regulated parties. As the Third Circuit has made clear, "obligations cannot spring from silence."[56] By conditioning access

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[51] Kalderos, *Sightlines Issue No. 3, Double, double, toil and trouble with commercial contracts,* www.Kalderos.com (Oct. 2023), Issue No. 3. (rebate data is worth billions).

[52] *See*, *e.g., Genesis Health Care, Inc. v. Becerra*, 701 F. Supp. 3d 312, 330 (D.S.C. 2023) (stating that "the goal of the 340B statute . . . is to make 'covered entities' profitable in the face of the prescription drug price increases that followed the Medicaid Drug Rebate Program and that continue to this day.").

[53] 340B Report, *Legislative Map: Contract Pharmacy Protection Bills*, https://340breport.com/legislative-map/contract-pharmacy-protection-bill/; 340B Report,*Legislative Map: Laws Passed That Prohibit PBM Underpayment*, https://340breport.com/legislative-map/laws-passed-that-prohibit-pbm-underpayment/.

[54] Pharmaceutical Research & Manufacturers of America v. U.S. Department of Health & Human Services, No. 1:14-cv-01685 (RC) (D.D.C. Oct. 9, 2014).

[55] Albany Med Health System v. Health Resources & Services Administration, No. 23-cv-03252 (APM), slip op. (D.D.C. Mar. 3, 2026).

[56] Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs., 58 F.4th 696 (3d Cir. 2023).

to 340B pricing on the transfer of commercial claims data, HRSA has created a requirement wholly untethered to the statutory text.

In addition, the requirement is arbitrary, capricious, and not in accordance with applicable law, in violation of the federal Administrative Procedure Act.[57] There is no commercial duplicate discount prohibition for HRSA to enforce, and the agency has failed to articulate a reasoned explanation for how mandating commercial claims data, for the first time in the 340B statute's history, advances the statutory purpose of the 340B Program to enable safety-net providers, including CHCs, to stretch their resources to provide more comprehensive services to more patients.

We harbor significant concerns that the 340B rebate model's requirement that CHCs furnish valuable commercial claims data to drugmakers in exchange for drug price discounts raises the potential for fraud and abuse. Requiring covered entities to provide valuable data in exchange for preferential pricing not authorized by statute may implicate the federal Anti-Kickback Statute and analogous state laws.[58] The 340B rebate pilot requires CHCs to provide valuable commercial claims data to manufacturers in exchange for discounted pricing on items (drugs) that may be billed to federal health care programs such as Medicaid or Medicare. This raises fraud and abuse risks and potential violations of the False Claims Act. HRSA cannot lawfully authorize a program that places covered entities at risk of violating federal fraud and abuse laws.

For these reasons, the requirement that CHCs provide commercial claims data to pharmaceutical manufacturers in exchange for discounted pricing cannot be included under the rebate pilot or any federally authorized program. HRSA's action exceeds statutory authority, violates the APA, raises serious constitutional concerns, and directly undermines the purpose of the 340B statute.

VIII. Alternative Approach: Upfront 340B-Priced Payments to CHCs

We respectfully assert that the 340B Rebate Pilot program must be replaced with a program that facilitates upfront 340B-priced drug payments from CHCs. This is because, under the plain language of the 340B statute, it is illegal to transfer discretion to the manufacturer about CHC patient eligibility. By requiring a CHC to purchase a drug at WAC and allowing a manufacturer to determine whether to pay a 340B rebate based on the data it receives, including data relating to whether a person is a patient of the CHC, the 340B Rebate Pilot shifts the authority to ascertain a patient away from the CHC-provider to a non-provider – the drugmaker.

Specifically, the 340B statute grants the covered entity discretion to determine which of its patients are covered. Importantly, the statute allows HRSA and drugmakers to audit only *after* such a determination has been made. Indeed, the only provision that mentions the term "patient" in the 340B statute prohibits the covered entity – not HHS nor the manufacturer – from reselling or transferring 340B drugs to nonpatients.[59] This is commonly referenced as the "diversion prohibition." Thus, the statute exclusively grants the covered entity the authority to determine

[57] 5 U.S.C. § 706(2)(A) (federal courts must set aside agency actions found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law").
[58] 42 U.S.C. 1320a-7b (making it illegal to pay remuneration in exchange for items or services billable to federal health care programs.)
[59] 42 U.S.C. § 256b(a)(5)(B)

which of its patients are eligible for 340B drugs and requires the covered entity to furnish 340B drugs only to those persons. It is reasonable for covered entities that employ or contract with health care professionals because, after all, the health professional is responsible for establishing the patient relationship. Drugmakers do not establish patient relationships.

Notwithstanding the clear language of the diversion prohibition, the 340B Rebate Pilot transfers that explicit statutory discretion to drugmakers by allowing them to require upfront pricing and to consider data elements before deciding whether to pay a 340B rebate. Simply put, the 340B Rebate Pilot will determine whether a person is a patient of a covered entity, prior to any audit, and in clear contravention of the plain text of the diversion prohibition. We respectfully contend that the term "rebate" in the first paragraph of the 340B statute only relates to AIDS Drug Assistance Programs, which are mere payment systems for covering drugs and do not involve the establishment of patient relationships. Specifically, AIDS Drug Assistance Programs are statutorily obligated to pay for drugs *after* the drug has been prescribed. However, AIDS Drug Assistance Programs do not establish patient relationships because they are not health care providers that employ or contract with health care professionals to do so. Rather, they act as payers to assist with paying for drugs, among other things. Hence, a rebate model is appropriate for them. Indeed, HRSA's longstanding guidance defining eligible 340B patients explicitly excludes "individual[s] *registered* in a State operated or funded AIDS drug purchasing assistance program [from the requirements of] 'patient' of the covered entity for purposes of this definition if so registered as eligible by the State program."[60]And the legislative history of the 340B statute supports the position that rebate models, while appropriate for ADAPs, may not be appropriate for CHCs.[61]

IX. Establishing a National, Neutral Claims Clearinghouse

We recommend OPA use a Neutral Claims Clearinghouse (NCC), which would produce more accurate deduplication at a tiny fraction of the cost and administrative burden of a rebate model. As described above, a 340B rebate pilot would impose significant cash flow demands and administrative burdens on covered entities (CEs). Fortunately, the primary goal of the rebate pilot – "to address 340B and Maximum Fair Price (MFP) deduplication" - can be achieved quickly, without overturning the fundamental structure of the program, and at a fraction of the cost and administrative burden of the rebate model, through the creation of a 340B Neutral Claims Clearinghouse (NCC).

A. Benefits of an NCC

Under an NCC, CEs would submit standardized claims data to a secure web platform for each MFP drug purchased under 340B and dispensed to a Medicare Part D patient. This data would be submitted within 45 days of the drug's administration or dispensation. The NCC would aggregate this data and transmit it to the Medicare Transaction Facilitator, which would use it to identify claims that are ineligible for a Medicare MFP rebate.

[60] Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55,156, 55,157 (Oct. 24, 1996) (emphasis added).]
[61] H.R. REP. 102-384, 16

This clearinghouse could be used to identify potential Medicaid-340B duplicate discounts; identify potential MFP-340B duplicate discounts under the IRA; share identified 340B units reimbursed by Medicare with CMS for exclusion from Part B and Part D inflation rebates; identify duplicate covered entity claims for 340B discounts on the same prescribed units of drugs (e.g., for patients of both entities); and to provide manufacturers access to a specified list of claims-level data elements for dispensing of their 340B drugs.

Compared to HRSA's proposed rebate model, the NCC approach would:

- **Avoid cash-flow and borrowing challenges** for CEs by preserving the upfront 340B discount.
- **Substantially reduce administrative burden on CEs** by significantly reducing the need for them to build and maintain complex rebate compliance systems, and the staff time needed to track and reconcile claims and to manage cashflow issues. A rebate model, on the other hand, would force CHCs to divert resources away from patient care to cover these costs.
- **Provide manufacturers with the necessary deduplication data within the same 45-day timeframe.**
- **Improve rebate accuracy**, reducing the time and effort manufacturers and CEs must spend correcting errors.
- **Preserve the longstanding upfront discount structure** that has defined the 340B program for more than three decades and is essential to most CHCs' participation in the program.
- **Protect patient access to affordable MFP drugs.** If a rebate model were implemented, the resulting cash-flow pressures could force many CHCs to sftop purchasing or dispensing MFP drugs altogether.

B. Expansion to Prevent Other Statutorily-Prohibited Duplicate Discounts

This letter previously discussed concerns about the practicality of implementing a rebate model and the logistical challenges it would pose for existing duplicate discount identification efforts. An NCC could easily be expanded to include the two other types of statutorily-prohibited discounts:

- **Medicaid Duplicate discounts in Medicaid.** State Medicaid programs currently rely on a patchwork of approaches to identify 340B drugs and avoid requesting manufacturer rebates on those claims. These approaches include claim modifiers, manual reconciliation processes, and state-specific clearinghouses. An NCC could provide a standardized national approach to preventing duplicate Medicaid discounts by collecting CEs' 340B claims data for Medicaid prescriptions and making it available to states. This approach would benefit all stakeholders:
    - **State Medicaid agencies** would no longer need to build, administer, or finance their own systems to identify 340B claims. Instead, they could rely on a single national data source.
    - **Covered entities** would face lower reporting burdens by submitting data to a single system rather than navigating separate state and Federal reporting requirements.
    - **Manufacturers** would benefit from a single, standardized system for preventing duplicate Medicaid discounts, replacing the current patchwork of 50 different state processes and data sets.

- **Medicare inflation rebates.** CMS also needs 340B claims data to exclude 340B drugs from Medicare inflation rebate assessments sent to manufacturers. CMS is currently developing a

"voluntary data repository" for this purpose and hopes to launch it this fall. Rather than creating another standalone system, CMS could collect this information through the NCC. Because participation in the NCC would be mandatory for covered entities, the resulting data would likely be completer and more accurate than data collected through the voluntary repository CMS is currently developing.

C. Importance of Neutrality

For an NCC to succeed, it must be widely viewed as neutral and trustworthy by all stakeholders. The 340B program has long been the subject of significant policy disputes among manufacturers, covered entities, and payers. Any national claims data infrastructure will only work if participants trust that it operates independently and does not favor one group of stakeholders over another. If the clearinghouse is perceived as aligned with a particular stakeholder interest, other stakeholders are unlikely to have confidence in the quality of the data it produces or how that data will be used.

The experience with the 340B ESP platform illustrates this concern. ESP was developed for and is financed by pharmaceutical manufacturers; its terms and conditions are widely viewed by CEs as favoring manufacturers' interests and the platform itself. As a result, many CEs do not view ESP as a neutral system and are reluctant to rely on it as a trusted intermediary for sensitive claims information. This example underscores why neutrality must be a foundational design principle for any national clearinghouse.

For these reasons, we recommend that the NCC be developed and administered either directly by the federal government or by an independent contractor selected by, and accountable to, the federal government. A governance structure rooted in federal oversight would provide transparency, independence, and stakeholder confidence, necessary for the NCC to function effectively and serve its intended purpose of preventing duplicate discounts without undermining the intent of the 340B program.

D. Types and Use of Data

Clear rules must also govern what data the NCC will collect, who may access it, and how it may be used. Key principles should include:

- **Data minimization:** CEs should submit only the data necessary to prevent the types of statutorily-prohibited duplicate discounts that the NCC is designed to address.
    - *Allowable data elements* should include National Drug Code (NDC), quantity dispensed, date of service, prescription number, dispensing pharmacy identifier (NPI), and covered entity identifier (340B ID).
    - *Prohibited data elements* should include patient-identifiable information, diagnosis codes, CPT codes, and other clinical data. Additionally, requests for purchasing data, as originally proposed by Johnson & Johnson in its initial rebate model[62] published August 23, 2024, should be prohibited. Manufacturers have already demonstrated ready access to purchasing data, so CHCs should not be burdened with providing it.

[62] https://beaconchannelmanagement.com/pages/resources (Johnson & Johnson Policy Documents)

- **Manufacturer access:** Manufacturers should not require access to this data because the information will be transmitted to the MTF and state Medicaid agencies for the purpose of preventing statutorily prohibited duplication of discounts.
- **Strict confidentiality:** Organizations receiving data from the NCC should be prohibited from sharing it with other entities.
- **Purpose limitations:** NCC data may only be used to determine whether a claim is eligible for other discounts or rebates. Data may not be used for other purposes, including, but not limited to, utilization management, reimbursement decisions, network participation determinations, or enforcement of restrictions not explicitly authorized by federal statute.
- **No access for PBMs or payers.** As previously mentioned, manufacturers can use claims data to dispute rebate obligations to commercial PBMs, and then PBMs will discriminate against 340B claims and 340B providers to make up for the lost profit.

E. Bipartisan Congressional Support

Because a neutral clearinghouse offers a cost-effective and low-burden way to prevent statutorily prohibited duplicate discounts, it has received significant bipartisan support in Congress. Examples include:

- **340B PROTECT 340B Act**: This bipartisan House bill, which received over 100 cosponsors in the 2021-22 session, aims to address Medicaid duplicate discount issues through the establishment of a neutral clearinghouse operated by a federal contractor.
- **SUSTAIN 340B Act**: The bipartisan "Group of Six" Senators released draft sections of this bill in early 2024. These sections included a neutral clearinghouse for claims data on both Medicaid and Medicare drugs.
- **340B ACCESS Act**: This bill advocates for an NCC that would encompass all claims, including those from commercial sources.

Given the major disruption the 340B rebate program is anticipated to have on CHCs, a system that forces CHCs to provide data that is already accurately and readily available to manufacturers is not only redundant but also adds additional administrative burdens on safety-net providers. It is imperative that HRSA require manufacturers to leverage existing resources to protect the stability of the safety-net providers that the 340B program was designed to support.

Conclusion

Heartland Community Health Center strongly urges HRSA to exempt CHCs from any 340B Rebate Model Pilot Program. A 340B rebate program represents a departure from the original intent of the 340B program—to allow safety-net providers to "stretch scarce Federal resources" and provide more comprehensive care. A rebate model would create significant cash flow challenges, forcing CHCs to make difficult decisions about staffing, services, and the range of drugs they can afford to stock. Additionally, CHCs would need to make significant investments in IT infrastructure and staff to comply with rebate requirements and track rebates. It would also create a new barrier for patients, especially uninsured patients, who depend on the up-front 340B discount, making it operationally impossible to provide the sliding fee scale and steeply discounted medications required by law. **Heartland Community Health Center** believes that a 340B rebate pilot would cause disproportionate harm to patients served by CHCs and other safety net providers.

Heartland Community Health Center appreciates the opportunity to respond to this Request for Information on the 340B Rebate Model Pilot, and we look forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please contact **Brittany Wessels at bwessels@heartlandhealth.org]**

Sincerely,

Julie Branstrom
Heartland Community Health Center

Mountain Family
HEALTH CENTERS

Our Family, Caring For Yours

TO: Mr. Thomas J. Engels
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services

Ms. Chantelle Britton
Director
Office of Pharmacy Affairs, Health Resources and Services Administration
U.S. Department of Health and Human Services

FROM: Mountain Family Health Centers
DATE: April 17, 2026

RE: Comments on HRSA's Information Collection Request: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB # 0906-NEW

Mountain Family Health Centers serves nearly 17,000 unique patients on the Western Slope of Colorado which includes Garfield, Eagle, and Pitkin Counties. Participation in the 340b program is critically important for both our patients and our financial sustainability. Last year, 45 percent of our patients were uninsured. We utilize the revenue from the 340b program to directly offset the cost of providing high quality services to our uninsured patients. We do not believe that a rebate model is an appropriate, efficient, or ethical manner to operate the 340B program, as it pulls CHCs' limited funding and staff time away from patients and towards management of the rebate model; a rebate model damages the integrity of the program and inhibits patient access to affordable prescription medications.

The Information Collection Request (ICR), OMB # 0906-NEW, published by the Health Resources and Services Administration (HRSA) represents a fundamentally flawed perspective of the burden, staff time, and resources that compliance with a rebate model would impose on covered entities, including CHCs. We would like to provide our CHC's perspective as to the actual cost of participating in a 340B rebate model on CHCs, to better inform HRSA's estimates and understanding. We maintain that a rebate model will be catastrophic to the health care safety net in Colorado, and across the country, and devastate low-income, vulnerable patients' access to affordable medications and integrated health care services. **We request that HRSA exempt all CHCs from any 340B rebate model, including the pilot program being explored in HHS Docket # HRSA-2026-03042.**

Data collected by CCHN from fifteen CHCs, which are representative in size and location of the 21 CHCs in Colorado, demonstrates the enormity of the burden, and the vast underestimation HRSA assumes, that a rebate model poses on these local, community-based providers. This burden includes substantial staffing impacts and administrative and operational changes to account for the data compilation and collation, data reporting, and tracking of the rebates

throughout the process. As defined in the ICR, burden, in this context, means "the time expended…to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems…for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information." The total annualized burden hours are estimated for CHCs to be an additional five hours to implement a 340B rebate model pilot program compared to current practices, with no additional estimates on new or reallocated staff or cost.

Of the fifteen CHCs that responded, 87% indicated it would require more staff time and dollars to manage the rebate model than their current pharmacy program. To sufficiently and adequately track the submission of the data and the receipt of rebates across in-house and contract pharmacies, those CHCs estimate spending, on average, nearly $100,000 annually in additional staff time and cost, ranging from roughly $10,000 for a small, rural CHC to upwards of $500,000 for a large, urban CHC.

Additionally, CHCs report that it would take an additional 1,962 hours on average per CHC, to compile, calculate, and collate the necessary data, submit the rebate data, reconcile the received rebate with the expected amount, contest any incorrectly denied rebates or follow-up on delayed rebates, and audit their 340B program. This estimated burden ranges from 130 more hours per year for a small CHCs up to more than 6,200 hours for larger CHCs. If one full-time equivalent (FTE) employee equates to 2,080 hours per year, CHCs estimate the new, additional burden in managing the rebate model to take on average 94% of an FTE. At the high end, one CHC estimates this could take 300% of an FTE (6,240 hours per year) and others estimate that this could take 200% of an FTE (4,160 hours per year). HRSA estimated that the additional burden from participating in the rebate model to take just 0.2% of an FTE (five hours per year).

On average, using 2025 drug purchasing as a proxy, CHCs would need to account for an average upfront cost increase of $11.6 million if the rebate model was expanded to all 340B drugs. According to data CCHN calculated in 2024, with a rebate model imposed on the ten drugs subject to the Medicare Fair Price negotiations, CHCs would need to account for an upfront cost increase exceeding 7,000%, which does not include any increased revenue or resources spent on hiring or reallocating and retraining staff, implementing new and upgraded technological systems, and dedicating time to tracking and accounting for rebates.

If the proposed rebate model were to go into effect, Mountain Family would be faced with additional administrative burden and financial strains that would put out risk our ability to care for over 7,000 uninsured patients. Mountain Family spent $515,000 on 340b medications in 2026. I the proposed rebate model requiring the upfront expense of the full retail drug costs were in place during the same time frame, this expense would have been $4.3 million, and 850 percent increase. This outlay of cash would represent 17 percent of our entire organizational budget. Navigating a rebate process would also place increased strain on our already limited staff capacity. We estimate that an additional 500 hours of dedicated administrative staff time would be needed within the proposed rebate model.

With any additional revenue or reserves tied up to account for this astronomical increase and no guarantee of a return on the investment, along with the need to pull funds from other areas of the clinic's operations – including staffing, services, and even clinic locations – to simply maintain compliance with a rebate model, the burden to account for this increase in staff time and cost, and the impact on CHC patients' access to care and medications, is mind-boggling. It is incomprehensible to impose a rebate model with this level of burden on local, nonprofit CHCs when 70% of CHCs in Colorado had negative or breakeven financial operating margins in 2024 and 2025 and it is anticipated a similar number of CHCs will face this financial challenge in 2026.

Thank you for considering our feedback on the true cost that managing and participating in a 340B rebate model pilot program would have on CHCs. This proposed program would not be a simple operating change or a cost rearrangement; it would lead to a drastic, catastrophic detriment in how CHCs operate pharmacy programs, fund staff, health care services, and programs, and support their patients. **We reiterate our request for HRSA to exempt all CHCs from this pilot program, and any 340B rebate model in the future.** If you have any questions, please reach out to dmoyer@mountainfamily.org

Dustin Moyer

CEO
Mountain Family Health Centers

neighborhood HEALTHCARE

April 17, 2026

Chantelle Britton
Director
Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
Rockville, Maryland 20857

RE: Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906-NEW

Submitted via paperwork@hrsa.gov

Dear Director Britton:

On behalf of Neighborhood Healthcare**,** I would like to thank the Health Resources and Services Administration (HRSA) for providing the opportunity to **share our estimated burden with HRSA on compliance with the 340B rebate model pilot program. Given the severe administrative, financial, and operational burden a rebate model would place on CHCs, Neighborhood Healthcare, again requests that CHCs be exempted from the pilot program.**

Neighborhood Healthcare has been providing health care services in San Diego County since 1969 and in Riverside County since 1996. Today, we operate 34 health centers among three geographic areas: Southwest Riverside County, North Inland (San Diego County), and East County (San Diego County). The organization provides comprehensive care to all its patients, including medical, dental, prenatal, mental health, podiatry, chiropractic, and acupuncture services.

The 340B program is foundational to CHC's ability to serve the most vulnerable members of our community. However, the proposed shift of responsibility from manufacturers to safety-net providers directly serving patients through a rebate model threatens to destabilize CHC pharmacy operations nationwide. Based on national assessments from the National Association of Community Health Centers (NACHC) and our own internal assessments, the hours and dollars spent complying with a rebate program are staggering.

I. We Request HRSA Exempt CHCs from the 340B Rebate Model Pilot Program Due to Significant Financial and Administrative Burden

By requiring CHCs to purchase medications at full price and wait for rebates, this model would cause significant financial turmoil and directly affect our ability to serve the **103,659** patients who rely on us. We operate on razor-thin margins, and these additional costs are not an option for many entities. Similar to navigating manufacturers' existing contract pharmacy restrictions, CHCs will need to invest in IT infrastructure upgrades and hire or reassign staff to manage new complexities, including varying data submission requirements and timelines, payment reconciliations, and dispute processes for denied rebates. We will face an increased administrative burden in monitoring rebate claims and payments.

To support CHCs in assessing the financial and operational impact of current manufacturer restrictions and an anticipated rebate model, NACHC worked with their consultant, FQHC 340B Compliance, to create an

Operational & Administrative Cost Calculator.[1] The tool aggregates program savings, UDS financial data, staffing, external consulting costs, dispensing/capture activity, and clinic-administered drug tracking models to support cost forecasting. CHCs have already experienced steep increases in operational costs given the multitude of manufacturer restrictions, including requirements for clinic-administered drugs and entity-owned pharmacies. A rebate model will require a significant increase in already-strained operational capabilities.

Workforce Impact:

- **Staffing Impact**: **Neighborhood Healthcare** anticipates needing **0.60** additional FTEs to account for the increase in operational, administrative, and compliance burden created by a rebate model.
- **Number of Hours:** Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, **Neighborhood Healthcare** will face an increased administrative burden to monitor rebate claims and payments 24 hours per week will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: **Neighborhood Healthcare** anticipates an additional **$24,500** for external vendors, including consultants, legal counsel, program coordination, third-party administrators (TPAs), electronic medical records (EMRs), pharmacy software, and reconciliation services.

Pharmacy Software & Third-Party Administration Changes

Navigating this pilot requires both staff and changes to workflow and software. HRSA should consider the increased compliance burdens when manufacturers have the flexibility to require varying data submission standards and elements. Additionally, if manufacturers can select different software platforms, like current contract pharmacy policies, CHC administrative burden would increase substantially.

- **One-Time Implementation Costs:** We anticipate high upfront costs to adapt our pharmacy software, pay for custom dashboard modifications, and design new internal workflows. **$16,990** will be required simply to reach the baseline of compliance before a single rebate is ever received.
- **Ongoing Operational Fees**: Beyond implementation, our TPA and software vendors will likely charge ongoing service fees of **$985 per month** to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Cost:** For our CHC, which serves **103,659** patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at **$11,400** annually.

The In-House Pharmacy: The Burden of IT Integration

Neighborhood Healthcare operates 1 in-house pharmacy. The rebate model is not a simple accounting change; it is a significant technological disruption. To remain compliant, in-house pharmacy systems will require costly customization to provide real-time, accurate information at the pharmacy counter.

- **System Interoperability:** Unlike contract pharmacies that use TPAs, in-house pharmacies must directly integrate their Electronic Health Record (EHR) and Pharmacy Management System (PMS) with a complex new rebate infrastructure.
- **One-Time Integration Costs:** We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools.

[1] https://www.nachc.org/policy-advocacy/policy-priorities/340b-drug-pricing-program/340b-rebate-model-pilot-program/

- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend **16 hours per week** manually pulling "Purchase Files" and "Price Files" to verify that every rebate check matches the statutory 340B price.

The Contract Pharmacy: The Burden of Network Coordination

The rebate model introduces a new complexity that threatens the existence of contractual arrangements. My CHC currently partners with **179** pharmacies to increase access to affordable medications.

- **TPA Reliance and Fees:** Navigating manufacturers' varying requirements across multiple contract pharmacies requires high-level TPA intervention. We anticipate that our TPAs will pass on the costs of developing rebate-tracking modules to us through increased per-claim fees.
- **Verification Latency:** The rebate model creates a reconciliation gap. Our staff must monitor claims across **179** different pharmacy locations to ensure rebates are paid correctly.
- **Risk of Pharmacy Exodus:** The model shifts financial risk to the pharmacy, potentially causing contract partners to opt out of the 340B program entirely rather than manage the administrative headache. In **San Diego and Riverside Counties,** this would leave patients with no affordable medication options. Over 17 percent of the U.S. population already lives in a pharmacy desert.[2]

Clinic Administered Drugs: The Burden of New Systems Required

Clinic-administered drug (CAD) operations and record-keeping in CHCs are designed cost-effectively to reflect the nuances of CHC billing. Implementing a rebate model for CADs would also require new software, system integration, and staff training. NACHC estimates these costs would range from $30,000 to $50,000 annually and could be much higher, depending on the software.[3] **Neighborhood Healthcare** estimates it will take 96 **hours and cost $30,000** to upload records related to CADs.

Most CADs are bundled into the prospective payment system (PPS) billing when administered to patients by CHCs. Because PPS visits are paid at a flat rate, the medications administered in CHCs are often not included on claims billed to payers. CHCs maintain limited inventories of CADs and typically do not separately bill on claims. Administration and inventory logs are commonly maintained on paper, with text documentation in patient visit notes describing what was administered. While CHCs maintain perpetual inventories and complete administrative records, paper records impose an additional burden of converting them to electronic data before submitting for rebate. Very few CHC records include electronic medication administration records (eMARs), which are common in hospital EMRs. Where eMARs are available, they incur an additional cost and often require CHCs to pay for a standalone software system.

II. Patient Impact

Neighborhood Healthcare has significant concerns about the impact a 340B Rebate Model Pilot would have on our most vulnerable patients' access to life-saving medications. The majority of drugs selected for the MDPNP for 2026 and 2027, and included in the proposed rebate model, manage chronic conditions prevalent in primary care settings. CHCs serve a patient population with a higher burden of chronic conditions compared to private practices, with studies showing a significantly higher prevalence of illnesses like diabetes, hypertension, and obesity.[4] This patient population relies on affordable medications to manage these long-term conditions.

[2] Vulnerability Index Approach to Identify Pharmacy Deserts and Keystone Pharmacies | Pharmacy and Clinical Pharmacology | JAMA Network Open | JAMA Network

[3] Internal NACHC survey data

[4] Richard P, Ku L, Dor A, Tan E, Shin P, Rosenbaum S. Cost savings associated with the use of community health centers. J Ambul Care Manage. 2012 Jan-Mar;35(1):50-9. doi: 10.1097/JAC.0b013e31823d27b6. PMID: 22156955.

The impact on insulin access is also alarming and directly conflicts with federal requirements. With over 3 million Americans relying on CHCs for essential diabetes care,[5] insulin affordability is a matter of life and death. Furthermore, Executive Order #14273 conditions future Section 330(e) funds on CHCs providing low-income patients with access to discounted insulin. No current operational method exists to provide discounted medications in a rebate model. In the proposed model, the wholesaler price file would reflect the full Wholesale Acquisition Cost (WAC) rather than the discounted 340B price, making the price unattainable for patients and precluding CHCs from fulfilling their legal obligation to offer the required discount at the point of care.

III. Financial Challenges

Lack of access to upfront 340B discounts, along with the high IT/infrastructure costs, will disproportionately impact CHCs and trickle down to patients. Many CHCs are currently under financial strain, with nearly half operating with fewer than 90 days of cash on hand, and one in four reporting negative five percent operating margins. This rebate model creates significant financial challenges, including:

- **Purchasing Drugs at the WAC Price Upfront:** Under the proposed model, CHCs would be required to purchase drugs at the WAC. CHCs will have to wait to receive their rebate payment *after* providing medications to their patients, forcing difficult decisions about how to allocate limited financial resources, including cutting essential services and reducing operating hours. We are particularly worried that the need to purchase drugs at full WAC will cause cash flow issues and potentially lead CHCs to exceed credit limits with wholesalers, halting their ability to order medications until payments are submitted.
- **Sliding Fee Scale:** A rebate model creates substantial uncertainty about CHCs' ability to apply sliding-fee discounts at the point of sale. By statute and regulation, CHCs are required to offer sliding fee discounts for all required and additional health services within the HRSA-approved scope of project.[6] In line with their mission, CHCs offer flat or sliding-scale discounts on prescription drugs to make them more affordable for low-income individuals.[7] A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size. **. Neighborhood Healthcare provides our low-income patients with access to affordable medications that would have otherwise been extremely expensive at retail cost. Insulins normally costing $200 - $1,000 retail would only cost uninsured patients $50-$100 under 340B.**

Conclusion

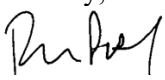
Neighborhood Healthcare strongly urges HRSA to exempt CHCs from any 340B Rebate Model Pilot Program. A 340B rebate program represents a departure from the original intent of the 340B program—to allow safety-net providers to "stretch scarce Federal resources" and provide more comprehensive care. A rebate model would create significant cash flow challenges, forcing CHCs to make difficult decisions about staffing, services, and the range of drugs they can afford to stock. Additionally, CHCs would need to make significant investments in IT infrastructure and staff to comply with rebate requirements and track rebates. It would also create a new barrier for patients, especially uninsured patients, who depend on the up-front 340B discount, making it operationally impossible to provide the sliding fee scale and steeply discounted

[5] 2025 UDA Data, HRSA (hrsa.gov)
[6] HRSA FAQ
[7] Such discounts are subject to potential legal and contractual restrictions. https://bphc.hrsa.gov/compliance/compliance-manual/chapter9#footnote10

medications required by law. **Neighborhood Healthcare** believes that a 340B rebate pilot would cause disproportionate harm to patients served by CHCs and other safety net providers.

Neighborhood Healthcare appreciates the opportunity to respond to this ICR on the 340B Rebate Model Pilot Program, and we look forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please contact **Julie Nguyen, Senior Director of Financial Analytics & 340B at Julie.Nguyen@nhcare,org.**

Sincerely,



Rakesh Patel, MD, MBA, FACHE, CPE
Chief Executive Officer
Neighborhood Healthcare

CHANGE, Inc.
Community Action Agency & Community Health Center
Administrative Office: 3158 West Street ■ Weirton, WV 26062
304.797.7733 ■ www.changeinc.org

April 17, 2026

Chantelle Britton
Director
Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
Rockville, Maryland 20857

RE: Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042)

Dear Director Britton:

On behalf of CHANGE, Inc., I would like to thank the Health Resources and Services Administration (HRSA) for extending the comment deadline to April 20, 2026. This extension has been vital in enabling our organization to conduct a deep-dive analysis of the operational and financial risks to CHCs posed by the proposed rebate model. The 340B program is foundational to CHC's ability to serve the most vulnerable members of our community. However, the proposed shift of responsibility from manufacturers to safety-net providers directly serving patients through a rebate model threatens to destabilize CHC pharmacy operations nationwide. Based on national assessments from NACHC, we know that CHCs are facing staggering impacts:

- **Financial Losses:** CHANGE, Inc. anticipates a financial impact from rebate denials and loss of purchase discounts of $525,865.
- **Projected Cost Increases:** CHCs anticipate significant increases in operational costs. National data shows that a single mid-sized CHC expects to incur over $3 million in additional costs **annually** to manage the pilot.
    - **Rural Health Center Breakdown:** For rural CHCs, these costs are even more devastating. Rural centers invest nearly **one-quarter (25%)** of their 340B savings in rural-specific infrastructure, such as mobile clinics and telehealth.

I. We Strongly Urge HRSA To Exempt CHCs from the 340B Rebate Model Pilot Program.

The proposed 340B Rebate Model Pilot Program is a direct threat to CHCs' core mission and a significant departure from the original purpose of the 340B Drug Pricing Program. For over three decades, the 340B program has enabled CHCs to purchase outpatient medications at significantly reduced prices, enabling them to provide affordable and sometimes free medications to millions

of low-income and uninsured patients. As congressional intent made clear, the program was created to help safety-net providers "stretch scarce Federal resources as far as possible." The proposed rebate model undermines this by placing an immense financial burden on CHCs.

By requiring CHCs to purchase medications at full price and wait for rebates, this model would cause significant financial turmoil and directly affect CHCs' ability to serve the 52 million patients who rely on us. **For CHANGE, Inc. in particular, this means it will impact:**

- Over 70,170 340B transactions and almost 18,450 patients
- Services supported by 340B Revenue, including patient transportation, Chronic Care Management and medical and prescription discounts for low-income households

We strongly urge HRSA to exempt CHCs from any rebate model to protect the financial stability of safety-net providers and ensure continued access to care for the most vulnerable patients.

II. Patient Impact

Most importantly, a 340B rebate model poses a direct and serious threat to medication access for the vulnerable patients that CHCs serve. For uninsured and underinsured patients who rely on the affordability that the 340B program provides, this model could render critical medications financially out of reach. Patients may be forced to make tough decisions in transitioning to other medications, due to cost or lack of availability, as a direct result of a 340B rebate pilot program. These forced therapeutic interchanges introduce real clinical risk, including medication nonadherence, treatment delays, and adverse outcomes, particularly for patients managing multiple chronic conditions who have limited alternatives and no other pharmacies close by. When the rebate model was last proposed, CHCs were actively preparing their patients for these disruptions, a signal that the operational and human impact of this change is both imminent and significant. For patients who have spent years achieving stability on a given medication regimen, the prospect of disruption is a threat to their health, safety, and trust in the health care system.

We have significant concerns about the impact a 340B Rebate Model Pilot would have on our most vulnerable patients' access to life-saving medications. The majority of drugs selected for the MDPNP for 2026 and 2027, and included in the proposed rebate model, are used to manage chronic conditions prevalent in primary care settings, meaning CHC patients will be disproportionately affected. CHCs serve a patient population with a **higher burden of chronic conditions** compared to private practices, with studies showing a significantly higher prevalence of illnesses like diabetes, hypertension, and obesity.[1] This patient population relies on affordable medications to manage these long-term conditions.

We are deeply concerned that implementing a rebate model would cause CHC patients to lose access to essential, life-sustaining therapies. For instance, **direct oral anticoagulants (DOACs)** such as Xarelto® and Eliquis® are vital for patients with deep vein thrombosis, pulmonary embolism, and atrial fibrillation. For many of our patients, there are minimal – and often less safe – alternatives. This is not an optional therapy but a critical tool for survival, as one study showed

[1] Richard P, Ku L, Dor A, Tan E, Shin P, Rosenbaum S. Cost savings associated with the use of community health centers. J Ambul Care Manage. 2012 Jan-Mar;35(1):50-9. doi: 10.1097/JAC.0b013e31823d27b6. PMID: 22156955.

that discontinuing these drugs leads to a statistically significant increase in the risk of stroke, heart attack, and death.[2]

Similarly, the impact on patients requiring **SGLT2 inhibitors**, such as Farxiga® and Jardiance®, would be severe. These drugs are a mainstay of primary care for conditions like Type 2 Diabetes, chronic kidney disease, and heart failure, all of which are highly prevalent among our patients. Research has found that even a 30-day withdrawal of these inhibitors increases the annualized risk of cardiovascular death or heart failure hospitalization.[3] By making these drugs unaffordable, the rebate model would effectively deny our patients access to the most effective therapies for managing their chronic illnesses, leading to a predictable increase in preventable hospitalizations.

The United States is in the midst of an alarming mental health crisis. Nearly one in four (23.4%) Americans live with a mental illness.[4] Starting in 2027, the MDPNP will include some behavioral health drugs. Vraylar ® is an atypical antipsychotic; atypical antipsychotics are the mainstay of treatment for Schizophrenia. A rebate model could create regulatory barriers for CHCs seeking to provide this drug to uninsured and underinsured patients. Additionally, the 2027 list includes Austedo®, a drug used to treat Tardive Dyskinesia, a common side effect of antipsychotics. Studies have shown that 73% of patients treated with Austedo® achieved treatment success, resulting in improved quality of life.[5] Impairing access to these drugs could result in exacerbation of the mental health crisis.

The impact on **insulin access** is particularly alarming and directly conflicts with federal requirements. With over 3 million Americans relying on CHCs for essential diabetes care,[6] affordability of insulin is a matter of life and death. Furthermore, **Executive Order #14273 conditions future Section 330(e) funds on CHCs providing low-income patients with access to discounted insulin**. There is currently no operational method to provide these discounted medications in a retrospective rebate model. In the proposed model, the wholesaler price file would reflect the full WAC rather than the discounted 340B price. This makes the price unattainable for the patient and **precludes CHCs from fulfilling their legal obligation to offer the required discount at the point of care**.

Imposing a rebate model on CHCs would only weaken the safety-net providers that 52 million Americans rely on for health care. CHCs are required to provide sliding fee discounts to patients with incomes at or below 200% of the federal poverty guidelines. The same patients who need access to discounted medical services also depend on CHCs to provide affordable medications. Without the up-front 340B discount, the drugs included in the pilot would become operationally

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[2] Cools F, et al. Risks associated with discontinuation of oral anticoagulation in newly diagnosed patients with atrial fibrillation: Results from the GARFIELD-AF Registry. J Thromb Haemost. 2021 Sep;19(9):2322-2334. doi: 10.1111/jth.15415. Epub 2021 Jul 23. PMID: 34060704; PMCID: PMC8390436.

[3] Packer, M., et al. (2024). Blinded Withdrawal of Long-Term Randomized Treatment with Empagliflozin or Placebo in Patients with Heart Failure. Circulation. https://www.ahajournals.org/doi/pdf/10.1161/circulationaha.123.065748

[4] Substance Abuse and Mental Health Services Administration. (2025). Key substance use and mental health indicators in the United States: Results from the 2024 National Survey on Drug Use and Health (HHS Publication No. PEP25-07-007, NSDUH Series H-60). Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. https://www.samhsa.gov/data/data-we-collect/nsduh-national-surveydrug-use-and-health/national-releases

[5] Hauser RA, et al. Long-Term Deutetrabenazine Treatment for Tardive Dyskinesia Is Associated With Sustained Benefits and Safety: A 3-Year, Open-Label Extension Study. Front Neurol. 2022 Feb 23;13:773999. doi: 10.3389/fneur.2022.773999. PMID: 35280262; PMCID: PMC8906841.

[6] 2025 UDA Data, HRSA (hrsa.gov)

impossible. **This model would create a new and significant barrier, rather than a solution, for our most vulnerable patients, especially those who are uninsured and have limited options for affordable care.**

Beyond the direct impact on individual patients, the rebate model threatens the broader infrastructure that makes affordable, comprehensive care possible at CHCs. The administrative burden of navigating the new rebate structure, including onboarding staff, conducting provider and patient education, and implementing new protocols, diverts limited staff resources away from direct patient care, disrupts established pharmacy workflows, and risks delays in reimbursement that undermine medication continuity. Every hour that a pharmacist spends reconciling rebate claims is an hour not spent on medication counseling. Every dollar spent on compliance and administration is a dollar that is no longer available for wraparound services and the full spectrum of care that make a meaningful difference in patients' lives. This diversion of time and resources is not a minor inconvenience; it is a structural undermining of the care model that CHCs depend on to serve their communities. If implemented without meaningful safeguards, this model will force CHCs to make impossible choices: cutting programs, limiting operating hours, and fundamentally compromising the mission of a program designed to expand access to care for those who need it most.

III. Administrative Complexities and Financial Challenges for CHCs

The proposed 340B Rebate Model Pilot Program is not only a financial threat to CHCs but also a duplicative and unnecessary administrative burden. To address manufacturers' "concerns" about duplicate discounts, the Pilot Program would force CHCs to divert even more scarce resources away from patient care. CHCs have already absorbed high administrative and technology costs over the past five and a half years to comply with manufacturers' existing contract pharmacy restrictions by submitting data to 340B ESP. Rather than serving as a solution, the pilot program would be a new barrier, further limiting the availability of affordable medications for patients with chronic conditions.

HRSA should exempt CHCs from the 340B Rebate Model Pilot because they will incur additional workforce and IT costs to comply with multiple manufacturer rebate requirements. A recent NACHC assessment illustrates that CHCs will incur additional workforce and IT costs to maintain compliance with multiple manufacturer rebate requirements, increasing the burden associated with this rebate pilot program. Similar to navigating manufacturers' existing contract pharmacy restrictions, CHCs will need to invest in IT infrastructure upgrades and hire or reassign staff to manage new complexities, including varying data submission requirements and timelines, payment reconciliations, and dispute processes for denied rebates. Depending on the volume of prescriptions a pharmacy fills for the selected drugs, CHCs will face an increased administrative burden in monitoring rebate claims and payments. We urge HRSA to consider the high up-front and ongoing costs of compliance with a potential 340B Rebate Model, which will ultimately impact the most underserved patients nationwide.

A. Detailed Administrative/Operational Impact

<u>340B Rebate Model Operational & Administrative Cost Calculator Description</u>

To support CHCs in assessing the **financial and operational impact** of current manufacturer restrictions and an anticipated rebate model, NACHC worked with their consultant, FQHC 340B Compliance, to create an **Operational & Administrative Cost Calculator.** The tool aggregates program savings, UDS financial data, staffing, external consulting costs, dispensing/capture activity, and clinic-administered drug tracking models to support operational cost forecasting.
CHCs have already experienced steep increases in operational costs given the multitude of manufacturer restrictions, which have now been extended to clinic-administered drugs and entity-owned pharmacies. A refund model will require a significant increase in already-strained operational capabilities.

- **Sliding Fee Discount**: CHANGE, Inc. provided over $5.9 million in sliding fee discounts, provided through discounted medications and medical services. We anticipate that our ability to offer sliding fee discounts will decrease significantly under a rebate model.
- **Staffing Impact**: CHANGE, Inc. anticipates needing additional staff to account for the increase in regulatory, operational, administrative, and compliance burden created by a rebate model.
- **External Vendor Costs**: Given increased complexity, CHANGE, Inc. would require over $70,000 for costs for external support vendors. These vendors may include 340B consultants, legal counsel, program coordination, third-party administrators, electronic medical records, pharmacy software, and reconciliation services.

Below is specific data on the administrative costs that CHCs anticipate, based on thorough planning, review of current business practices, and the costs of implementing new systems and processes.

Workforce Impact

- 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.[7]
- Additionally, several CHCs estimate the cost to hire additional staff to be between $30,000 to $200,000 annually.[8] One midwestern CHC, serving approximately 12,000 unique patients last year, anticipates annual costs exceeding $3 million, including upfront costs for purchasing drugs in this pilot program, increased labor costs, carrying costs, and potential losses on discounted or expired drugs without rebate recovery. CHCs operate on razor-thin margins, and these additional costs are not an option for many entities.
- Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, CHCs will face an increased administrative burden in terms of monitoring rebate claims and payments. CHANGE, Inc. will require an additional 5 hours per month to report 340B rebate claims to a third-party platform, assuming all adhere to the nine drug manufacturers' plans The lack of standardization and likely varying requirements across manufacturers will force CHCs to use multiple internal systems to manage and report the same data, thereby increasing costs and operational burdens. **CHANGE, Inc. urges HRSA to require uniformity among eligible manufacturers to mitigate potential administrative and financial burdens associated with receiving timely and appropriate 340B rebates.**

[7] Internal NACHC assessment (99 responses).
[8] Ibid.

Pharmacy Software & Third-Party Administration Changes

Navigating this pilot requires more than just staff; it requires significant changes to pharmacy software and Third-Party Administrator (TPA) workflows. We encourage HRSA to consider the increased compliance burdens when manufacturers have the flexibility to require varying data submission standards and elements. Additionally, if manufacturers are allowed to select different software platforms, as they currently do with contract pharmacy policies, the administrative burden on CHCs would increase substantially.

- **One-Time Implementation Costs:** We anticipate high upfront costs to adapt our pharmacy software, pay for custom dashboard modifications, and design new internal workflows.
- **Ongoing Operational Fees**: Beyond implementation, our TPA and software vendors will likely charge ongoing service fees to maintain these complex rebate-tracking features. These are permanent, recurring costs that diminish our 340B savings.
- **Total Cost:** For our CHC, which serves 18,450 patients, the total projected increase in expenses—including labor, IT, and carrying costs—is estimated at $10,000 annually.

The In-House Pharmacy: The Burden of Deep IT Integration

For CHCs that operate their own pharmacies, the rebate model is not a simple accounting change; it is a significant technological disruption. To remain compliant, in-house pharmacy systems will require costly customization to provide real-time, accurate information at the pharmacy counter.

- **System Interoperability:** Unlike contract pharmacies that use Third-Party Administrators (TPAs), in-house pharmacies must directly integrate their Electronic Health Record (EHR) and Pharmacy Management System (PMS) with a complex new rebate infrastructure. This capability requires funding to reconfigure the system, create the needed reports, and labor to enter and verify the information.
- **One-Time Integration Costs:** We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools. CHANGE, Inc. estimates a one time integration cost for its Pharmacy software system of $20,000.
- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend 5 hours per week manually pulling “Purchase Files” and “Price Files” to verify that every rebate check matches the statutory 340B price.

The Contract Pharmacy: The Burden of Network Coordination

For CHC contract pharmacy partners, the rebate model introduces a new complexity that threatens the very existence of these arrangements. My CHC currently partners with 11 independent and 16 chain and specialty pharmacies to increase access to affordable medications.

- **TPA Reliance and Fees:** Navigating manufacturers’ varying requirements across multiple contract pharmacies requires high-level TPA intervention. We anticipate that our TPAs will pass on the costs of developing rebate-tracking modules to us through increased per-claim fees.
- **Verification Latency:** The rebate model creates a reconciliation gap. Our staff must monitor claims across 27 different pharmacy locations to ensure rebates are paid correctly.
- **Risk of Pharmacy Exodus:** Because this model shifts the financial risk to the pharmacy, we fear our contract partners will opt out of the 340B program entirely rather than manage the

administrative headache. In our region, this would leave patients in the Ohio Valley with no affordable medication options. Over 17 percent of the U.S. population lives in a pharmacy desert already,[9] and the closings of pharmacies have only exacerbated this, with nearly 30 percent of pharmacies that had been open from 2010 to 2021 closing by 2021.[10] Our region saw three independent and two chain pharmacies close in the past two years.

Clinic Administered Drugs: The Burden of New Systems Required

Clinic-administered drug (CAD) operations and record-keeping in CHCs are designed in a cost-effective manner that reflects the nuances of CHC billing.

- **Bundled Payments:** The majority of clinic-administered drugs are bundled into the prospective payment system (PPS) billing when administered to patients by CHCs. Because PPS visits are paid at a flat rate, the medications administered in CHCs are often not included on claims billed to payers.
- **Simplified Records:** Because CHCs maintain limited inventories of CADs and they are typically not separately billed on claims, it is still common for administration and inventory logs to be maintained on paper, with text documentation in patient visit notes describing what was administered. While the CHCs maintain perpetual inventories and complete administrative records, the fact that the records are often paper imposes the added burden of converting them to electronic data before submitting for rebate. Very few CHC records include electronic medication administration records (eMARs), which are common in hospital electronic medical records (EMRs). Where eMARs are available, they incur an additional cost and often require CHC to pay for a standalone software system.

- **Minimal Risk of Duplicate Discounts:** CHCs primarily bill under Medicare Part A, which is not statutorily included in the Medicare Drug Price Negotiation Program (MDPNP). Maximum Fair Prices (MFP) are only applicable to Medicare Part D claims in 2026 & 2027 and then expand to include Medicare Part B claims in 2028. Regarding Medicaid, each state already has mechanisms in place to address duplicate discounts.

B. Financial Challenges

Under the proposed 340B Rebate Model Pilot, CHCs 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 CHCs' ability to purchase drugs, as the uncertainty of waiting for a manufacturer to approve a rebate would constrain cash flow. CHCs will have to wait to receive their rebate payment ***after*** providing medications to their patients. This change will force CHCs to make difficult decisions about how to allocate their limited financial resources, including cutting essential health services, reducing operating hours, or discontinuing services that support patients' health outcomes.

The proposed 340B Rebate Model Pilot would directly impact CHCs' ability to offer patients steeply discounted medications at the point of sale by requiring them to purchase at full WAC pricing upfront. CHCs' pharmacies, as well as entity-owned and contract pharmacies,

[9] Vulnerability Index Approach to Identify Pharmacy Deserts and Keystone Pharmacies | Pharmacy and Clinical Pharmacology | JAMA Network Open | JAMA Network

[10] https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2024.00192?journalCode=hlthaff

will not have access to the 340B price when the patient needs medication. This will create a very unpredictable process for determining the level of discount and pricing for a patient's medication, as the 340B price will no longer be reflected in the pharmacy software from the wholesaler's price catalog, since initial purchase prices will be at WAC. The rebate model creates confusion about its impact on a CHC's ability to offer sliding-fee discounts at the point of purchase.

A rebate model also creates substantial uncertainty about CHCs' ability to apply sliding-fee discounts at the point of sale. By statute and regulation, CHCs are required to offer sliding fee discounts for all required and additional health services within the HRSA-approved scope of the project.[11] In line with their mission, CHCs offer flat or sliding-scale discounts on prescription drugs to make them more affordable for low-income individuals.[12] A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size. CHANGE, Inc. offers medication costs savings to patients under 200% of the Federal Poverty Level based off the actual acquisition cost and a small administrative fee to cover supplies, passing up to 80% of the discount received to patients.

CHCs rely on wholesaler price files to determine acquisition costs and calculate patient discounts in real time. Pharmacy Software systems are not designed to incorporate manually added price files, particularly into a single inventory category. Current pharmacy systems continuously overwrite manually entered 340B prices with every wholesaler price load. Under a rebate model, the wholesaler price file reflects WAC rather than the 340B ceiling price, eliminating the operational ability to determine an accurate discounted patient price at the pharmacy counter. **This disconnect forces CHCs to estimate discounts without knowing whether or when a rebate will be paid, exposing them to financial loss if a rebate is denied or delayed and undermining federally required sliding fee discount obligations.**

CHCs are particularly worried that the need to purchase drugs at full WAC will cause cash flow issues and potentially lead them to exceed their credit limits with wholesalers, halting their ability to order medications until payments are submitted. While rebates are expected to arrive within 10 days from completed data submissions, the previously proposed rebate pilot allowed covered entities up to 45 days to submit data, meaning the potential time from dispense to rebate can extend to 55 days. The financial impact is further compounded when CHCs have entity-owned pharmacies with physical inventories and must stock their shelves with purchases at WAC. Retail pharmacies typically turn their inventory 10-12 times a year (roughly every 30 days).[13] Assuming a best-case scenario of 15 days to the average 30 days for inventory to turn, CHC pharmacies with physical inventory could be waiting 70-85 days from purchase to rebate under a 45-day data submission cadence. Anecdotal reports from CHC pharmacies suggest a planned cadence of 2-week data submissions for entity-owned pharmacy data. Pharmacies with physical inventory submitting data every 14 days would anticipate a purchase-to-rebate payment time frame of 40 to 55 days.

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[11] HRSA FAQ

[12] Such discounts are subject to potential legal and contractual restrictions. https://bphc.hrsa.gov/compliance/compliance-manual/chapter9#footnote10

[13] https://enlivenhealth.co/blog/year-end-business-health-check-key-metrics-every-pharmacy-owner-should-review

There may be other delays in receiving the full rebate, such as denials, which could create financial strain on CHCs. We appreciate HRSA's requirement for a 10-day timeframe for rebate payments; however, we have concerns about the lack of details regarding enforcement if manufacturers fail to meet this requirement. Based on experience with manufacturer denials related to the current MFP to 340B de-duplication processes, once an entity has contested a denied rebate and the issue is resolved so the CHC can receive the rebate, manufacturers and their vendors have failed to pay the rebate within the MFP standard of 14 days from when the status is corrected. We are concerned that in a 340B rebate pilot, manufacturers and their vendor(s) will continue to provide corrected contested rebates for an undefined and unlimited time. Complicatedly, the rebate amount may not match the initial discount offered to the patient, creating unpredictable financial losses. CHCs must estimate the rebate amount and may undercharge or overcharge patients due to confusion. Furthermore, if the rebate is denied, the CHC takes a net loss on the transaction. **We respectfully request that, if a rebate pilot is implemented, manufacturers be required to pay rebates within 10 days of both initial and corrected determinations.**

Lack of access to upfront 340B discounts, along with the high IT/infrastructure costs, will disproportionately impact CHCs and trickle down to patients. It is important to note that many CHCs are currently under financial strain. Nearly half of CHCs operate with fewer than 90 days of cash on hand, and one in four reports approximately negative five percent (-5%) operating margins. Below, you will find specific data demonstrating the significant increase in financial costs CHCs will incur under a 340B Rebate Model.

340B Rebate Drug Cost Impact Calculator Description

To support CHCs in assessing the financial impact of purchasing drugs at the full WAC price, NACHC worked with their consultant, FQHC 340B Compliance, to create another calculator for all CHCs. Financial data and projections are based on a 340B Rebate Drug Cost Impact Calculator, which utilizes CHC-specific purchasing data, 340B[14] and WAC pricing data for the first quarter of 2026 (Q1 2026), and the CMS list of MDPNP selected drugs by NDC.[15] For individual MDPNP Price Applicability Years, the calculator evaluates:

- **Increase Upfront Annual Drug Spend**: WAC – 340B for 2025 purchases by NDC & volume, reflected in Q1 2026. WAC and 340B prices applied for the overall annual program volume to determine the annual increase in initial drug spend.
- **Cash Flow Impact**: WAC – 340B for 2025 purchases by NDC & volume, reflected in Q1 2026 WAC and 340B prices to give overall annual program increase in initial spend reflected at intervals of 30, 45, 60, & 90 days. Represents potential WAC purchase to 340B rebate payment cycles. Inventory models, frequency of data submission, and manual processes for referral claim capture can all influence Covered Entities' (CEs) intervals between purchasing a drug at WAC and receiving the Manufacturer Rebate to 340B Ceiling Price.
- **Rebate-Related Opportunity Costs**: Based on percentages of loss of prompt pay, purchase volume, and subceiling discounts and anticipated rebate denials as a portion of annual WAC spend (described above).

[14] https://340bpricing.hrsa.gov/
[15] https://www.cms.gov/files/zip/selected-drug-list-negotiated-prices-also-known-maximum-fair-prices-statutezip.zip

- **Increase Upfront Drug Spend** WAC – 340B for 2025 purchases by NDC & volume, reflected in Q1 2026, calculated by NDC, then aggregated at the MDPNP selected drug, manufacturer, and MDPNP Price Applicability Year levels.
- **WAC Purchase to 340B Rebate Payment "Wait" Period:** CHCs must wait to receive a rebate payment after purchasing and dispensing medication to the patient. This delay forces difficult decisions about allocating limited financial resources.

Based on our organization's data, we estimate it would cost $7.8 million to purchase these 10 drugs under the proposed rebate model. Currently, our organization spends $3.8 million to purchase these same drugs at the 340B ceiling price. This represents a 105% increase in upfront capital required for procurement.

This increase in costs will have a devastating impact on our organization's ability to maintain an adequate supply of the drugs included in the HRSA 340B Rebate Model Pilot. As previously discussed, our CHC is navigating a difficult financial environment that cannot sustain purchasing drugs at WAC. To cover the upfront cost of purchasing drugs and operationalizing the rebate, **CHANGE, Inc.** anticipates needing to reduce:

- **Essential Clinical Services:** To offset the upfront cost of drugs, we would be forced to scale back non-revenue-generating but essential services, such as School Based Health Center locations and services, Mobile Health services, Patient Transportation, Chronic Care Management and Diabetes Education.
- **Workforce & Staffing:** The administrative burden of this pilot requires us to divert funds away from clinical staff. We will lose the ability to fund School Based Health Center providers, directly increasing missed work and school for families needing medical or behavioral health services; Care Team members that provide care gap services worsening patients' chronic conditions; and Drivers to transport patients to needed health appointments decreasing patients' consistency of care.
- **Patient Financial Assistance:** 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 over 850 uninsured and 15,200 low-income patients from rationing their insulin or heart medication.

C. Wholesaler Implications

Another concern is that purchasing drugs at full WAC will potentially lead the organizations to exceed wholesaler credit limits, halting their ability to order medications until payments are submitted. For example, some CHCs have suggested that paying 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.

CHANGE, Inc. 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.

Another complication is that the rebate amount may not match the initial discount offered to the patient, as mentioned above, creating unpredictable financial losses. CHCs must estimate the rebate amount and could potentially undercharge or overcharge patients due to confusion. The shift to WAC pricing disrupts the fundamental mechanics of our pharmacy procurement.

- **Wholesaler Credit Limits:** Purchasing drugs at full WAC will potentially lead organizations to exceed wholesaler credit limits, halting our ability to order medications until payments are submitted. At present, many CHCs are forced to pay invoices before their due dates to remain within their credit limits. Given that CHCs typically operate with extremely limited financial margins, they are often perceived as having higher credit risks, making increases to credit limits difficult or impractical.
- **Discounts:** CHCs often receive prompt pay, purchase volume, and sub-ceiling discounts on their drug purchases. Forcing a WAC-upfront model threatens our ability to meet these terms, potentially resulting in the loss of these essential discounts. Due to contractual confidentiality requirements, CHCs are unable to disclose their exact prompt-pay discount. However, CHANGE, Inc. estimates its 2027 Annual Rebate Opportunity Cost to be approximately $525,860. This cost aggregates the estimated financial impact of rebate denials and loss of purchase discounts.
- CHANGE, Inc. estimates that purchasing the 10 selected drugs at WAC instead of 340B ceiling prices will increase our upfront monthly drug spend by $155,000. That amount will increase to $315,000 by 2028.

Every dollar we pay upfront at WAC is a dollar that remains "frozen" in the manufacturer's reconciliation system. While we wait for rebates, we lose the liquidity necessary to respond to immediate public health crises or facility emergencies. To navigate the rebate model, our organization would be forced to take out a line of credit and utilize limited financial reserves. This is not a sustainable solution; the interest costs alone are estimated to be $30,000 annually—funds that are currently dedicated to enabling services, chronic care management and school based and patient care. Forcing CHCs into debt to maintain their drug supply creates an environment of clinical instability. In our region, where patients have no choice but to rely on CHANGE, Inc., the risk of our credit limit being reached or our reserves being depleted is a direct threat to the community's safety net. If we are forced into financial limbo, the "trickle-down" effect is immediate: longer wait times, reduced service availability, and a weakened ability to provide the steeply discounted medications that our 52 million patients across the country depend on.

a. Financial Impact of Rebate Denials and Delays

CHANGE, Inc. urges HRSA to recognize that without rigorous, non-discretionary safeguards, the rebate model is not a "pricing mechanism" but a significant financial liability. The current framework allows manufacturers to act as the sole arbiter of a CHC's statutory savings, creating an uncertain environment that results in direct financial harm. The framework proposed in the previously proposed 340B Rebate Pilot allowed manufacturers to deny rebate claims based on vague or ambiguous reasons, such as "duplicate rebate" or "MFP deduplication," without

providing the data or documentation CHCs need to understand or contest those decisions.[16] The use of a vague "other" category for denial reasons only added to the confusion, leaving CHCs guessing compliance requirements that they are never clearly told exist. These unpredictable denials often rely on flawed assumptions or automated processes that fail to account for routine pharmacy operations.

If a rebate is denied, the CHC takes a net loss on the transaction, having already paid the full WAC price to the wholesaler and provided the drug to the patient at a steep discount. Given our current volume of the 10 selected drugs, even a conservative 10% denial rate would result in a net annual loss of $400,000. This is a sum our CHC cannot absorb, as it represents a direct extraction of resources from our safety net budget. Any reduction in financial resources will directly affect our ability to fulfill the CHC mission of serving all patients, regardless of their ability to pay.

While the RFI suggests a 10-day timeframe for rebate payments, the lack of enforcement details and the complexity of reconciliation create a high risk of financial loss. Any delay beyond the 10-day window creates an immediate cash flow crisis. CHCs are particularly worried that the need to purchase drugs at full WAC will cause them to exceed their credit limits with wholesalers, halting their ability to order medications until payments are submitted. There is currently no mechanism to penalize manufacturers for late payments or to ensure that CHCs are made whole for the interest lost while capital is "frozen" in the rebate system.

The financial harm is compounded by the fact that the 340B price is no longer reflected in the wholesaler's price catalog or the pharmacy software at the time of purchase. This forces CHCs to "estimate" rebate amounts, creating unpredictable financial losses and the potential to undercharge or overcharge patients. Additionally, the lack of real-time 340B pricing presents challenges for compliance with 340B actual acquisition cost (AAC) billing in fee-for-service Medicaid. This may lead to increased Medicaid costs and potential state-level claw-backs, creating a second layer of financial liability for the CHC. Without a standardized, transparent, and neutral dispute resolution process, the 340B Rebate Model Pilot functions as an interest-free loan from safety-net providers to multi-billion-dollar manufacturers. These unpredictable denials and delays create serious cash flow issues for CHCs operating on thin margins, which depend on timely reimbursement to sustain services for medically underserved populations.

IV. Reconciliation and Rebate Denials Operational Challenges

Operational Guardrails and Enforcement Framework

Taken together, the administrative burden, cash-flow exposure, reconciliation complexity, and denial risk associated with a rebate model fundamentally conflict with CHCs' operational realities. Without robust guardrails, neutral infrastructure, and enforceable manufacturer accountability, a rebate model would undermine, not strengthen, the integrity of the 340B Program and threaten patient access to essential medications.

[16] Application Process for the 340B Rebate Model Pilot Program, 2025-14619 (90 FR 36163) https://www.federalregister.gov/documents/2025/08/01/2025-14619/340b-program-notice-application-process-for-the-340b-rebate-model-pilot-program

If HRSA proceeds with a rebate-based pricing model, the program must include clear, enforceable operational guardrails to prevent the systematic shifting of financial and administrative risk to covered entities. A rebate model that relies on retrospective payment and manufacturer discretion without firm controls will inevitably result in delayed reimbursement, inconsistent determinations, and increased denials, placing safety-net providers in untenable financial positions.

We request that the process for rebate denials align with current statutory, regulatory, and guidance processes. Rebate requests should be presumed valid unless a manufacturer can demonstrate, with claim-level documentation, a specific and permissible basis for denial tied directly to statutory requirements. Within the current MFP models used by manufacturers and their vendor Beacon Channel Management, CHCs are given very limited transparency into the process, and denials are often based on vague reasons tied to arbitrary, unpublished standards created by manufacturers. If the manufacturer of their vendor cannot demonstrate denials aligning with the statutory requirements to prevent duplication of 340B discounts on prescriptions in the Medicaid Drug Rebate Program (MDRP) or MDPNP, rebates must be paid, and the manufacturers must revert to the processes described in HRSA 1996 Manufacturer Audit Guidelines, including conducting good faith inquiries and OPA-approved audits.[17]

The previously proposed rebate construct and the one currently used by manufacturers for MFP de-duplication incentivize rebate denials by imposing a significant, ongoing burden of chasing denied rebates. The onus of battling for every rebate questioned by manufacturers will increase costs for CHCs and likely lead many covered entities to forgo the appropriate statutory 340B discounts due to insufficient personnel to perform the function and general process fatigue. All this added strain on CHCs would create a barrier to patient care delivery and fails to align with the 340B program's intent "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[18]

Rebate payment timing requirements must apply to both initial and corrected determinations. Experience with existing manufacturer-run MFP de-duplication processes demonstrates that, even when a covered entity successfully contests a denial, payment is often delayed for indeterminate periods. If HRSA adopts a 10-day payment requirement, that requirement must run from both the initial determination and any subsequent corrected determination to prevent manufacturers from using dispute processes as a delay mechanism.

The 340B statute explicitly provides for sanctions for noncompliance, including liability for underpayment of drugs. It also outlines a formal dispute resolution process with HRSA to address grievances. **We are concerned that the pilot program fails to provide such protections, leaving CHCs without recourse if rebates are improperly denied or delayed.** Without clear protections, the pilot program risks becoming a mechanism that benefits manufacturers at the expense of the safety-net providers it was created to support. We respectfully request that OPA provide a detailed plan to ensure rebates are paid, given the thin financial margins CHCs operate on and the detrimental impact of ongoing delayed payments has on patient care.

[17] Manufacturer Audit Guidelines https://www.hrsa.gov/sites/default/files/hrsa/opa/dispute-resolution-process-12-12-96.pdf
[18] 340B House Report – Legislative History. H.R. REP. 102-384(II).

Additionally, the Administrative Dispute Resolution (ADR) cannot serve as the primary mechanism for routine rebate disputes; we request that HRSA establish a separate dispute resolution pathway. Current ADR timelines are reported to take up to a year from the time of a review panel assignment. Given the time to complete the review and up to 180 days to return a determination,[19] CHCs could be waiting up to 2 years for their issues to be resolved. Given the sheer volume of prescriptions and clinic-administered drugs slated to flow through the rebate program, the current ADR process does not provide a viable solution to address covered entities' rebate disputes with manufacturers. HRSA must establish a separate, expedited dispute pathway for rebate denials, with defined timelines, escalation protocols, and agency oversight.

HRSA must clearly articulate the **resources, authorities, and enforcement mechanisms** it will use to ensure manufacturer compliance, including corrective action requirements and potential sanctions for repeated late payments or improper denials. **Additionally, we recommend that OPA establish a stakeholder advisory panel to ensure that the feedback and concerns of covered entities are formally and consistently addressed.** This panel should include pharmacists with the necessary subject-matter expertise to understand the complexities of pharmacy software, billing, and data components. Without explicit enforcement, a rebate pilot risks becoming a system of manufacturer self-policing, contrary to HRSA's statutory responsibility to administer and oversee the 340B Program.

A. Operational and Enforcement Guardrails

HRSA must require that any rebate model operate under uniform national standards that limit manufacturer discretion, hold manufacturers accountable, and protect covered entities from financial harm. These guardrails should include:

- A presumption that rebate claims are valid unless the manufacturer demonstrates otherwise under statutorily sanctioned duplication of discount prevention (i.e., 340B with MDRP or MDPNP);
- Standardized, publicly defined denial categories with claim-level documentation;
- Firm payment timelines that apply to both initial and corrected determinations; and
- A clear enforcement framework, including consequences for repeated late payments or improper denials by manufacturers.

B. Enforcement Requirements

- **Resources:** HRSA should identify the internal resources and systems it will use to actively monitor manufacturer compliance, including the ability to track payment timeliness, denial rates by category, and dispute outcomes. Covered entities should not be required to police manufacturers' behavior through repeated appeals to manufacturers or the administrative dispute resolution process.
- **Dispute Resolution:** There must be a formal procedure for when a CHC's data (e.g., from their pharmacy software or 340B accumulators) does not align with the manufacturer's accumulation logic. Based on experience with data submissions to 340B ESP, the

[19] Administrative Dispute Resolution Regulation, https://www.govinfo.gov/content/pkg/FR-2024-04-19/pdf/2024-08262.pdf

manufacturers, through their vendor, are starting with initial purchase data and calculating accumulations based on future dispensations, factoring in unpublished "reasonable use" timeframes. Virtual inventories operate on eligible 340B dispensations that must reach full package size before purchases are made. Because the logic used by manufacturers and covered entities differs, they can misalign even when the entity is fully compliant with the 340B program requirements. Currently, when this misalignment occurs, manufacturers block an entity's ability to purchase at 340B prices until the entity meets the manufacturer's unpublished standards.

C. Burden of Proof on Manufacturers

Manufacturers must bear the burden of establishing that a rebate is not owed. Any approach that requires covered entities to demonstrate compliance beyond existing statutory requirements, particularly where manufacturers control the unpublished algorithms, creates an imbalance not sanctioned by the 340B or IRA statutes and ultimately undermines program integrity.

D. Rebate Determinations Must Align with Statutory Patient Definition

Any rebate model must preserve the statutory allocation of responsibility for patient eligibility determinations. The 340B statute assigns patient definition and eligibility determinations to covered entities.[20] Systems or methodologies that effectively transfer this determination to manufacturers, whether through retrospective algorithms, proxy indicators, or undisclosed purchase-history logic, exceed statutory authority and introduce non-transparent conditions on access to 340B pricing. HRSA should explicitly prohibit rebate denial methodologies that rely on manufacturer-defined patient eligibility standards or undisclosed validation criteria.

Transparency Measures

Fully Transparent Manufacturer Decision Processes

We appreciate HRSA's commitment to transparency in the 340B Program. Since 2020, manufacturers have imposed several self-declared "340B transparency measures" as pricing conditions on covered entities. Unfortunately, while this has increased manufacturers' visibility, it has significantly reduced transparency for CHCs. Under the current manufacturer conditions imposed through 340B ESP and the handling of 340B claims for MDPNP, which are in the confidential portion of the manufacturer's effectuation plan, CHCs are subject to an unpublished standard as a condition of 340B pricing, with very limited portions of the determination process shared with CHCs.

One example is within MFP effectuation: the manufacturer's vendor, Second Sight Solutions, has published a list of pricing codes[21] to be utilized "to understand the validations performed following the successful transmission of MFP claims data to Beacon MFP." Three of the MFP determination methodologies in the table below highlight this issue. For the "recent 340B purchase" and "aggregate 340B purchase history of the Dispensing Entity" scenarios, neither manufacturers nor Beacon has provided clarity on how these are defined or calculated. This leaves CHCs without a

[20] Section 340B of the Public Health Service Act, https://www.hrsa.gov/sites/default/files/hrsa/rural-health/phs-act-section-340b.pdf

[21] https://mfp.support.beaconchannelmanagement.com/en/articles/13335320-validation-codes-and-pricing-codes-glossary

mechanism to validate manufacturers' determinations. **We request that all determination processes, eligibility calculations, and any other items involved in the determination process be published in detail for all covered entities.**

Code	Description	Type	Definition
P1	340B Claim Indicator	Pricing	Claim included a 340B modifier.
P2	340B Claim	Pricing	Claim submitted by the entity as 340B.
P3	340B Pharmacy	Pricing	Claim from a pharmacy with evidence of recent 340B purchase.
P4	340B Prescriber	Pricing	Prescription written by a 340B prescriber and dispensed by a pharmacy with evidence of recent 340B purchase.
P5	Contract Price	Pricing	Basis price is a Contract Price.
P5	Contract Price	Pricing	Basis price is a Contract Price.
P7	Non SDRA MFR Reprice	Pricing	Value other than WAC used to determine MFP refund amount.
P8	Entity Identified 340B	Pricing	Claim manually identified as 340B in Beacon by Dispensing Entity.
P9	340B Pharmacy Allocation	Pricing	Claim identified as 340B according to the aggregate 340B purchase history of the Dispensing Entity.

V. Limit the 340B Rebate Model Pilot to Retail Pharmacy Claims Only

If HRSA moves ahead with a rebate model, we request that the 340B rebate model pilot be limited to retail pharmacy claims only. Limiting the pilot to retail pharmacy claims is not merely a matter of operational convenience; it is essential to prevent unnecessary disruption in areas where no current duplicate discount risk exists. Extending a rebate model to clinic-administered drugs (CADs), where CHCs' claims are adjudicated under PPS and not at the drug level, and Medicare negotiated prices do not apply until future years, would impose extraordinary administrative burdens without advancing the stated deduplication goals of the pilot. As HRSA has already stated, there are mechanisms in place to prevent Medicaid duplicate discounts.[22] Therefore, a measured, retail-only approach is the minimum safeguard for an untested model.

CHCs generally operate under the PPS and do not bill CADs as discrete, line-item drug claims. Instead, the cost of these drugs is embedded within encounter-based reimbursement. As a result, CHCs do not maintain electronic, claim-level billing records for CADs that could be readily repurposed for rebate submission or reconciliation. Implementing a rebate-based framework for CADs would require the creation of entirely new data capture, reporting, and reconciliation workflows, rather than incremental modifications to existing systems.

In addition, auditable records for CADs are frequently maintained in paper logs or other non-standard internal documentation, rather than in structured electronic data fields. These record-keeping practices are designed to support internal controls and HRSA audit requirements, not retrospective rebate processing. A rebate model that requires structured electronic submission to a rebate platform would compel CHCs to convert paper-based records into discrete electronic datasets and maintain parallel documentation systems solely for rebate compliance. This would substantially increase administrative burden and compliance risk without improving program integrity.

[22] https://public-inspection.federalregister.gov/2025-14619.pdf?1753965918

Implementing a rebate model for CADs would also require new software, system integration, and staff training. NACHC estimates these costs would range from $30,000 to $50,000 annually and could be much higher, depending on the software.[23] CHANGE, Inc. would need to update its medication management systems, which would require over $18,000 in equipment and $40,000 in annual fees. CHCs would need to deploy tracking functionality either within their electronic medical record systems or through standalone software, incur ongoing licensing and maintenance costs, and redesign clinical and administrative workflows. These costs would be additive and ongoing, not one time, and would be incurred even though CADs are not currently billed to Medicare Parts B or D. Furthermore, Medicare Part B negotiated pricing provisions applicable to certain drugs do not take effect until 2028, underscoring the lack of near-term applicability.

Because CADs furnished by CHCs are not billed as discrete Medicare drug claims, there is no current Medicare duplicate discount risk associated with these drugs that would justify imposing a rebate-based reporting and reconciliation framework at this time. To the extent the policy objective relates to the implementation of Medicare drug pricing reforms under the IRA, CADs furnished by CHCs do not currently raise those concerns.

Moreover, where manufacturers have concerns about diversion or compliance for CADs, existing statutory mechanisms already include HRSA audits and the ADR process. These tools are specifically designed to address compliance concerns within the 340B Program. Layering a rebate model on top of these established statutory mechanisms—particularly in a context where no discrete billing or near-term Medicare interaction exists—would be duplicative and unnecessary.

For these reasons, HRSA should explicitly exclude CADs from any 340B rebate model pilot. At a minimum, such drugs should remain excluded unless and until they are billed as discrete claims by CHCs and a demonstrated duplicate discount risk exists that cannot be addressed through existing statutory mechanisms. Including CADs in a rebate pilot at this stage would impose disproportionate administrative costs, software expenses, and compliance risks on CHCs without corresponding benefits to program integrity or federal oversight.

VI. Existing CHC Compliance Actions

CHCs already operate under a comprehensive regulatory framework established through the Health Center Program and the 340B statute to make medications affordable for patients. In alignment with Section 330 of the Public Health Service Act, they utilize a sliding fee discount that adjusts costs based on a patient's income and household size, ensuring that no one is denied services due to an inability to pay. CHCs must also establish systems for eligibility determination and offer full discounts to individuals at or below 100% of the Federal Poverty Level (FPL). These services would not be possible without the savings generated from the 340B program.

CHCs pride themselves on maintaining compliance with both the Health Center Program requirements and the 340B program, and they adhere to rigorous oversight and compliance processes. Not only do they participate in regular Operational Site Visits (OSVs) to verify Health Center Program compliance, but they also follow strict 340B compliance protocols, including

[23] Internal NACHC survey data

internal audits, training, and external oversight. This demonstrates a proven ability to manage 340B with integrity and accountability. In addition to implementing internal best practices, such as regular audits and staff training, CHCs participating in the 340B program are required to report 340B-related information annually through the Uniform Data System (UDS). This includes data on 340B-purchased drugs, associated costs and revenues, and detailed information about the patients served by the program. These reporting requirements provide a clear and consistent picture of how 340B savings are utilized to expand access and improve patient outcomes, consistently demonstrating CHCs' exemplary stewardship of the program.

Given the compliance infrastructure and strict statutory requirements already in place for CHCs, implementing a rebate model would cause disproportionate harm to CHCs and the patients they serve. The administrative, financial, and operational burdens from such a model would threaten the stability of the safety-net providers that the 340B program was designed to support. CHCs are not the source of misuse in the 340B program; rather, they are national models of compliance.

CHCs are required to provide sliding fee discounts to patients at or below 200% of the federal poverty level. Currently, CHCs routinely provide discounts to uninsured and underinsured patients, but a rebate model would make this operationally impossible because they rely on wholesale price files to determine the acquisition cost of the drug to calculate a discounted price. In a rebate model, the price file lists the WAC price, making the price unattainable for the patient. If CHCs are included in this pilot, it will be extremely difficult to offer the included medications at a discount. For these reasons, **we encourage HRSA to exempt all CHCs from this pilot program.**

VII. The 340B Rebate Model's Incompatibility with Deduplication Efforts

A. Medicare Inflation Reduction Act (IRA) Deduplication

While we understand that manufacturers' investment in a mechanism to deduplicate Medicare IRA maximum fair price (MFP) and the 340B price from the same unit of drug, we are deeply concerned that the previously proposed approach for addressing IRA deduplication—a 340B rebate model—would create significant administrative, financial, and operational burdens for CHCs. A 340B rebate model is not only unnecessary to achieve the goal of deduplication, but also the option that would place the greatest burden on CHCs. Any change in government policy should seek to accomplish the government's goals in the least burdensome way with the least negative impact on stakeholders,[24] and a 340B rebate model is not that.

Several less burdensome alternatives are available for HHS' consideration. As further discussed below, CMS could implement Medicare-only claims data submission to a government vendor or neutral clearinghouse without also requiring an upfront purchase of 340B-priced drugs at WAC prices (i.e., a rebate) or without the requirement to submit commercial claims data, a process CMS is already exploring for purposes of Medicare IRA rebate deduplication through the 340B claims repository finalized as a voluntary model in the CY 2026 Medicare Physician Fee

[24] 5 U.S.C. §§ 500–596; Food & Drug Admin., Least Burdensome Provisions: Concept and Principles (n.d.), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/least-burdensome-provisions-concept-and-principles (last visited Mar. 13, 2026); H.R. REP. 102-384(II)).

Schedule.[25] This intention was made clear in the CY 2026 Physician Fee Schedule Final Rule: CMS proposed that it would address the possibility of mandatory reporting of data elements to the 340B repository by covered entities in future rulemaking. CMS noted that many covered entities are providers and suppliers regulated by CMS under Title XVIII of the Act, including hospitals receiving DSH payments, CAHs, and FQHCs. CMS noted that it was actively considering options for mandatory reporting to the 340B repository in the near future and recommended that covered entities take advantage of the testing period to prepare for future policy development related to 340B repository reporting.[26]

If both a 340B rebate model and a 340B claims repository are made mandatory, CHCs will be subject to two new administrative burdens that accomplish nearly identical goals: identifying 340B claims for purposes of the IRA. Many alternative options exist for deduplicating 340B and MFP, and whichever deduplication mechanism is ultimately selected should be the least burdensome that accomplishes the deduplication goal. The 340B Legislative History demonstrates the 340B Statue was written with this intention stating, even going so far as to call out that what will work for an AIDS Drug Assistance Programs (ADAPs) – the manufacturer cited example of 340B rebates being workable common practice— may not be appropriate for CHCs: "The Committee bill does not specify whether "covered entities" would receive these favorable prices through a point-of-purchase discount, through a manufacturer rebate, or through some other mechanism. A mechanism that is appropriate to one type of "covered entity," such as CHCs, may not be appropriate to another type, such as State AIDS drug purchasing programs. The Committee expects that the Secretary of HHS, in developing these agreements, will use the mechanism that is the most effective and most efficient from the standpoint of each type of "covered entity."[27] The negative implications of a 340B rebate model are well documented, fail to align with legislative intent, and do not meet the "least burdensome" requirement.

A 340B rebate model not only contradicts principles of good governance but would also directly contradict congressional intent for the 340B Program and the IRA. When enacting the 340B statute, Congress intended for the administration to select **the most effective and efficient mechanism for each type of covered entity, but a 340B rebate model is the least effective and least efficient mechanism for** CHCs. We respectfully submit that mandating CHCs, the nation's primary care safety-net backbone, to pay upfront WAC pricing simply because a manufacturer is entitled to make the lower of two discounted price points available, 340B and MFP, is extra-statutory and appears to be punitive. Implementing a 340B rebate model, therefore, contradicts the intent of Congress when enacting 340B. A 340B rebate model also fails to align with the IRA's intent. Under the IRA, the manufacturer must provide the lower of the two prices—340B or MFP—to a covered entity. Under a 340B rebate model, however, a manufacturer can deny a 340B rebate whenever an MFP applies, even when the 340B ceiling price is lower than the MFP. By failing to address that a covered entity has a legal right to the lower of the two prices, a 340B rebate model ignores the protections Congress specifically included in enacting the IRA and imposes a punitive condition on the safety-net provider that it purchase the drug at the highest market price.

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[25] Medicare and Medicaid Programs; Calendar Year 2026 Payment Policies Under the Physician Fee Schedule, 90 Fed. Reg. 49,266 (2025).

[26] CY 2026 PFS, Final Rule, https://www.govinfo.gov/content/pkg/FR-2025-11-05/pdf/2025-19787.pdf

[27] H.R. REP. 102-384(II)

Moreover, we believe that any government-mandated rebate model for 340B-priced drugs that serves to deduplicate MFP from 340B pricing is inconsistent with HRSA's stated authority. The 340B statute – not the IRA – cursorily mentions the term "rebate" in a parenthetical in the first paragraph. Specifically, the 340B statute states that the "Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (*taking into account any rebate* or discount, as *provided by the Secretary*)."[28] That clause, however, cannot be read in a vacuum. From this clause, HHS has contended that it may authorize manufacturer 340B rebate models. However, HRSA's authority over the 340B statute, including its alleged ability to implement a 340B rebate model, is confined by the 340B statute's bounds. And such bounds do not include protections against or prevention of duplicate discounting of Medicare claims where 340B pricing and MFP are at issue. Rather, the 340B statute limits the bounds of HRSA's authority, including its alleged rebate authorization authority, to the limitations of the 340B statute, which only provides protections against Medicaid fee-for-service ("FFS") duplicate discounts. Accordingly, HRSA's rebate authority under the 340B statute cannot be extended to deduplication of MFP and 340B drug claims. Such an extension would be an *ultra vires* application of HRSA's alleged rebate authority.

Likewise, the IRA does not include language that permits HRSA to authorize drugmakers to charge prices above the 340B statutory ceiling price. That statute merely states that a drugmaker must make available the lower of two discounted prices – MFP and 340B. It cannot be construed as spontaneously modifying the 340B statute's plain text prohibiting a manufacturer from charging above the 340B ceiling price – "the maximum price that covered entities may permissibly be required to pay for the drug."[29] The only rebate mechanism HHS has contended is available to it is found under Section 340B, and, as stated above, Section 340B does not pertain to Medicare claims. Accordingly, HRSA's alleged rebate authority cannot be used as a deduplication tool under the IRA, and drugmakers are not permitted under the IRA or 340B statutes to charge upfront WAC prices for 340B drugs under at least the IRA because the IRA does not contain a 340B rebate pricing mechanism. For these reasons, a 340B rebate model would be an unworkable and burdensome mechanism for addressing 340B-MFP deduplication.

B. Medicaid Duplicate Discounts

The 340B rebate pilot is not a legal mechanism for addressing Medicaid FFS duplicate discounts. As stated above, the 340B statute – not the IRA – cursorily mentions the term "rebate" in a parenthetical in the first paragraph of that statute. Specifically, it states that the "Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (*taking into account any rebate* or discount, as *provided by the Secretary*)."[30] That clause cannot be read in a vacuum. HRSA's authority over the 340B statute, including its alleged ability to implement a 340B rebate model, is limited by the 340B and Medicaid Drug Rebate Program ("MDRP") statutes' bounds.

[28] 42 U.S.C. § 256b(a)(1)
[29] *Id.*
[30] 42 U.S.C. § 256b(a)(1)

The 340B statute only protects drugmakers from *Medicaid* duplicate discounts. The 340B statute's clause addressing the obligation to prevent duplicate discounts applies only to such discounts under Medicaid FFS plans. That provision states that a covered entity – *not HHS and not a drug manufacturer* – shall prevent 340B duplicate discounts in the first instance. Specifically, that provision states that a "covered entity[, not HHS or a drugmaker,] shall not request payment under" the Medicaid FFS program for a 340B-priced drug.[31] Accordingly, only the covered entity may elect whether to bill a 340B drug to Medicaid and how it satisfies its obligation to prevent Medicaid FFS duplicate discounts under the plain language of the 340B statute. The state Medicaid agency may set the state-based requirements for 340B claim identification.[32] HRSA and drugmakers may only *audit* such Medicaid claims *after* such covered entity election has been made – meaning their authority to deduplicate such claims only vests *after* the 340B drug has already been billed to the Medicaid state plan.[33]

Specifically, the 340B statute's audit provision states that a "covered entity shall permit the Secretary and the manufacturer . . . *to audit* . . . *the records* of the entity that directly pertain to the entity's compliance with the" duplicate discount prohibition. Such records must first be generated, and thus such audit authority may reasonably be interpreted as vesting only *after* the covered entity has exercised its statutory discretion to prevent Medicaid FFS duplicate discounts and has billed a 340B drug claim to a state Medicaid FFS plan.[34] However, the 340B statute grants neither HHS nor drugmakers authority to prevent duplicate discounts in the first instance or to requisition related 340B claims data to prevent such discounts before a covered entity elects to bill the claim under applicable state requirements. Congress knew how to furnish such discretion to drugmakers but explicitly chose to grant it to safety-net providers.

Nevertheless, the 340B rebate model proposes to illegally usurp the covered entity's statutory responsibility regarding its prevention of Medicaid FFS duplicate discounts. It would illegally transfer that discretion to drugmakers by allowing them to require significantly high upfront pricing and the submission of claims data so that they, not the covered entity, may elect whether a drug is 340B or not, or whether such drug is subject to a Medicaid rebate. This proposed mechanism clearly violates the plain language of the duplicate discount prohibition. And a cursory mention of the term "rebate" in a parenthetical of the statute's first paragraph does not supplant that plain language.[35] Accordingly, the application of a 340B rebate model is illegal under the 340B statute because it shifts the discretion to choose to bill 340B drugs to, and the obligation to prevent duplicate discounts under, Medicaid FFS plans away from the covered entity and gives drugmakers first oversight of such claims. That policy cannot be supported by the text of the 340B statute, the Medicaid Drug Rebate Statute, or their legislative records.

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[31] Indeed, the 340B statute states that the covered entity may choose "options" for billing 340B drugs to Medicaid. Specifically, it states that the HHS may "develop[][more detailed guidance describing methodologies and *options available* to covered entities for billing covered outpatient drugs to State Medicaid agencies in a manner that avoids duplicate discounts pursuant to subsection (a)(5)(A)." 42 U.S.C. 256b(d)(2)(B)(iii). And the Secretary of HHS may institute a system to ensure that the covered entity does what the statute says it's obligated to do – prevent duplicate discounts. *Id.*

[32] 42 U.S.C. § 1396r-8(a)(5)(C)(ii) ("Each such single State agency shall provide a means by which a covered entity shall indicate on any drug reimbursement claims form (or format, where electronic claims management is used) that a unit of the drug that is the subject of the form is subject to an agreement under section 256b of this title, and not submit to any manufacturer a claim for a rebate payment under subsection (b) with respect to such a drug.")

[33] 42 U.S.C. § 256b(a)(5)(C).

[34] 42 U.S.C. § 256b(a)(5)(C).

[35] *See* 42 U.S.C § 256b(a)(5)(A).

The 340B rebate pilot disrupts CHCs' ability to comply with state Medicaid billing requirements. CHCs are also concerned that the proposed rebate pilot will impose significant legal risks and operational burdens on their requirement to appropriately bill 340B drugs to Medicaid plans. Those 340B billing rules require the CHC to determine whether a drug is a 340B drug or a non-340B drug prior to submitting the drug claim with the appropriate billing requirements. However, these billing requirements are virtually impossible to comply with under the rebate pilot because the CHC does not know that a drug is 340B eligible until after the manufacturer has paid the rebate.

Specifically, CHCs are required to identify and appropriately charge for 340B drugs when billing Medicaid plans. Those 340B billing requirements vary depending on whether the drug is billed: (1) to Medicaid FFS; or (2) to a Medicaid managed care plan or organization ("MCO"). The billing requirements vary further depending on whether the drugs are billed under a pharmacy benefit or a medical benefit for each plan type. These requirements create a complex web of billing and reimbursement policies for Medicaid FFS plans, which vary even within a single state. For instance, in West Virginia, a CHC bills Medicaid the 340B AAC, which will not be know at the time of purchase, and not verified until the rebate is received.

For Medicaid FFS retail pharmacy claims, federal regulations require states to implement policies where reimbursement is based on the actual acquisition cost (AAC) of a drug, including a separate methodology for 340B drugs compared to non-340B drugs.[36] Additionally, states have implemented AAC-based reimbursement for Medicaid FFS medical claims, and some Medicaid MCOs implement AAC-based reimbursement under the terms of their contracts with CHCs for drugs covered under the retail pharmacy and/or medical benefit. When 340B-based AAC is implicated, the CHC is typically required to submit the claim with certain data elements at the point of billing the claim, or the point-of-sale. These required elements are typically the Submission Clarification Code (SCC) 20, which identifies the claim as 340B, and a basis for cost determination code (BOC) 08, which provides the 340B-based AAC for Medicaid to use in determining the reimbursement amount for that claim.

A 340B rebate pilot would create significant confusion and legal impossibility for covered entities because it would revoke the covered entity's ability to determine when a 340B drug is used. Specifically, the rebate pilot removes the covered entity's discretion to determine whether a drug is 340B at the point of billing a claim to a Medicaid plan. This is because the 340B rebate model illegally transfers that discretion to drugmakers by authorizing them to determine when a rebate should be paid. And thus, both state Medicaid agencies and CHCs are left confounded about how to intelligibly submit claims data for WAC-priced drugs that may or may not be subject to a 340B rebate at the drugmaker's future discretion.

Under a 340B rebate model, a drug is not a 340B drug until a manufacturer pays a rebate on the drug, which is long after the claim has been submitted for Medicaid reimbursement. Additionally, the 340B ceiling price is no longer an effective proxy for 340B-based AAC because additional costs are incurred at the initial purchase at the higher WAC price and through added administrative costs. Under the previous 340B rebate model pilot, HRSA directed covered entities to contact

[36] C.F.R. § 447.518(a).

individual state Medicaid agencies for 340B rebate model claim submission policies. Some states provided guidance on how they expected covered entities to bill, but not all did. Even for those states that did provide guidance, such guidance became subject to serious legal challenge and confusion. Of the states that responded, most Medicaid departments would have required covered entities to submit the 340B ceiling price when billing Medicaid if the covered entity believed it would receive a 340B rebate under the drugmaker's discretion. But if the drug isn't subject to a rebate in the future, the initial 340B ceiling price claim may have been false. This creates operational, financial, and legal impediments for CHCs.

Operationally, CHCs rely on wholesaler price files when submitting a drug's AAC with a Medicaid claim. In a 340B rebate model, the wholesaler price file would provide the WAC, which is the price at which the CHC must purchase the drug. Thus, the 340B price would not be made available through the wholesaler for drugs subject to the 340B rebate model. Pharmacy billing software does not allow the use of an external price file, which would force CHCs to manually insert the 340B AAC for each Medicaid claim, an operationally infeasible endeavor. Adding to the operational burden is the variation between state policies. CHCs that treat patients from different states may have to tailor operations to comply with each state's Medicaid policy. Submitting an erroneous Medicaid claim exposes the CHC to significant civil and criminal liability under the False Claims Act. Accordingly, HHS has not only usurped the CHC's authority to prevent duplicate discounts, but it also confers on drugmakers the ability to induce false claims. This is a serious, unjustified, and unprecedented misstep that threatens the stability of the entire 340B program and Medicaid Programs.

A 340B rebate model is unduly burdensome. HHS's designing of a rebate model does not require it to authorize drugmakers to charge the nation's CHCs one of *the highest possible prices* to acquire a drug in the first instance. For example, a rebate model could be implemented through upfront discounts and retrospective credits or debits, a neutral clearinghouse, or a government-led clearinghouse repository.[37] Some of these ideas are explored later in this letter. This way, the manufacturer's rebate liability is adjusted, rather than the local CHC.

Multiple states have expressed concerns that a 340B rebate model would effectively change all drugs dispensed or administered by covered entities from 340B-based AAC to WAC-based AAC, thereby increasing costs for state Medicaid agencies. This is because federal regulations define AAC as "the agency's determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific manufacturers."[38] The definition indicates that Medicaid departments may determine that AAC should be based on the wholesaler pricing files, which would be WAC-based pricing under a 340B rebate model.

In submitting comments regarding HRSA's previous 340B rebate model, two states expressed serious concerns about how a 340B rebate model would negatively impact the state for this reason. Specifically, the Pennsylvania Department of Human Services stated, "[i]f the AAC for drugs in the Pilot Program is the covered entity's cost before the 340B rebate, then Medicaid FFS will no

[37] Ctrs. for Medicare & Medicaid Servs., *IPAY 2028 Final Guidance*, https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf.
[38] 42 C.F.R. § 447.502

longer benefit from the 340B discount and Medicaid's cost for these drugs will increase."[39] The Oregon Health Authority commented, "[i]f Oregon's FFS Medicaid program continues to reimburse covered entities at the 340B ceiling price, we will fail to meet the entity's initial cost and will contribute to cash flow problems and financial instability for the impacted safety net providers."[40]

Furthermore, the 340B rebate model would create legal impossibilities under Medicaid managed care for covered entities, state Medicaid agencies, and Medicaid managed care organizations. The Medicaid statute authorizes only the covered entity to select a 340B drug and bill it to a Medicaid managed care plan. Specifically, 42 U.S.C. § 1396r-8(j)(1) states that a drug purchased by a covered entity under the 340B Program is no longer subject to a rebate payment under Medicaid managed care plans. Put differently, that statute grants to the covered entity, not HHS or a drugmaker, the authority to choose to use 340B drugs for Medicaid managed care beneficiaries. By mandating upfront WAC pricing and authorizing drugmakers to choose when to pay a 340B rebate, the discretion is illegally usurped in violation of federal law.

Moreover, state Medicaid agencies are required by federal law to implement systems to remove 340B drug utilization data from their rebate invoices charged to drugmakers under Medicaid managed care arrangements. Specifically, 42 C.F.R. 438.3(s)(3) states that states must contract with Medicaid managed care organizations to require that they, not drugmakers or HHS, "establish procedures to exclude utilization data for covered outpatient drugs that are subject to discounts under the 340B drug pricing program from the reports" submitted to manufacturers for Medicaid rebate payments. Although their policies vary, most states require Medicaid managed care organizations to require covered entities to identify 340B drugs when billing for such claims. As with Medicaid FFS plans, neither the state Medicaid agency nor the CHC may comply with this federal requirement under the proposed 340B rebate model because the discretion regarding how and/or when to identify 340B drug claims under Medicaid managed care arrangements is seized from them and given to drugmakers. This is not only an irresponsible policy; it is also quite a dangerous policy, as it creates a serious impediment to submitting claims that may or may not be later deemed to be false based on a third-party drugmaker's decision.

Even if CHCs could operationalize a manual claims submission process, either the CHC, the state, or both would be financially burdened by a 340B rebate model. First, 340B-based AAC must account for added actual costs. A 340B rebate model effectively raises the 340B price of a drug above the 340B ceiling price, and such costs must be included in billing state Medicaid plans. This is because the CHC would have to float WAC pricing for each drug and incur additional administrative costs related to claiming a rebate, which are factored into the true "actual acquisition cost" of a 340B-rebated drug. Second, the CHC may be forced to over-identify claims as 340B because, though a CHC may accurately identify a claim as 340B-eligible, a manufacturer may still refuse the rebate, meaning a CHC would have identified the drug as 340B for Medicaid purposes, received a lower 340B-based reimbursement, but would not receive the benefit of the 340B price on the claim because a manufacturer unilaterally denied the rebate. This scenario is particularly

[39] [14]: Comment on Agency Information Collection Activities; Proposed Collection; 340B Drug Pricing Program, Docket No. HRSA-2025-0001-0095, https://www.regulations.gov/comment/HRSA-2025-0001-0095.

[40] Comment on Agency Information Collection Activities; Proposed Collection; 340B Drug Pricing Program, Docket No. HRSA-2025-0001-0980, https://www.regulations.gov/comment/HRSA-2025-0001-0980.

harmful to CHCs that are required to extend sliding fee discounts to patients at the point of sale before rebate payment. And it raises serious federal questions relating to whether a federal grantee may be required to overpay for drugs.[41] It is also harmful to CHCs because wholesalers might not allow the CHC to reprocess a denied rebate at a non-WAC, non-340B price. And, as stated, this raises potential False Claims Act considerations because the CHC submitted a Medicaid claim as 340B when the claim ultimately was not 340B based on the manufacturer's subsequent discretionary denial of the 340B rebate.

Accordingly, the proposed 340B rebate pilot is unworkable because it creates significant operational and financial uncertainties, creates legal billing compliance impossibilities, and raises potential False Claims Act implications when submitting Medicaid claims for reimbursement for drugs identified as 340B-eligible by the covered entity that are ultimately denied a 340B rebate by drugmakers. HRSA's authorization of this illegal framework would violate the Administrative Procedure Act and is clearly inconsistent with federal statutes that grant the CHC alone the authority to prevent Medicaid FFS duplicate discounts in the first instance.

i. ***Adopting a Revised Medicaid Duplicate Discount Prevention Database***

We strongly recommend that HRSA adopt a publicly available database of Medicaid plan identification information. This database could be called the Medicaid Plan Billing Information Database (MPBID). The MBPID could be created by requiring manufacturers, state Medicaid agencies, and/or Medicaid managed care organizations to submit plan billing information used to identify Medicaid plans. This plan identification information includes the Medicaid plan's unique Bank Identification Number (BIN), Processing Control Number (PCN), and Group Number (GRP) to identify those FFS and managed care plans under which a manufacturer may pay a rebate under the MDRP. This information should be published on 340B OPAIS or some other public federal website. This critical recommendation is buttressed by existing requirements that Medicaid plans, including Medicaid managed care plans, use unique BIN and PCN numbers to separate the Medicaid business lines from commercial business lines for pharmacy billing.[42]

While we appreciate the insinuation that manufacturer processes in the 340B rebate pilot will ensure the prevention of 340B and MDRP duplicate discounts, as stated above, the statutory obligation for the compliance measure falls to the covered entities:

> *"A* ***covered entity shall not request*** *payment under title XIX of the Social Security Act for medical assistance described in section 1905(a)(12) of such Act with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under section 1927 of such Act."*[43]

After more than 33 years, CHCs request that HRSA put in place systematic mechanisms to support covered entities' compliance with the duplicate discount prohibition by implementing the Medicaid Plan Billing Information Database. To date, the mechanisms in place support HRSA and

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[41] *See, e.g.,* 31 U.S.C. 3729 (making it illegal to overcharge a federal grantee).

[42] 42 C.F.R. § 438.3(s)(7) The MCO, PIHP, or PAHP must assign and exclusively use a unique Medicaid-specific Bank Identification Number (BIN) and Processor Control Number (PCN) combination, and group number identifiers for all Medicaid managed care enrollee identification cards for pharmacy benefits. https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-438/subpart-A/section-438.3

[43] 42 U.S.C. § 256b(a)(5)(A)(emphasis added).

manufacturer processes for validating and auditing compliance. Systems like the Medicaid Exclusion File fail to provide CHCs and other 340B entities with a mechanism to ensure covered entities comply with the expectation that they will not request payment. The Medicaid Plan Billing Information Database would provide all covered entities with access to accurate Medicaid billing information (including BIN/PCN/GRP).

C. TRICARE Duplicate Discounts

The 340B rebate pilot would make it difficult to comply with TRICARE expectations because providers will not know whether a drug is 340B until a rebate is paid. The TRICARE Pharmacy Benefits Program, as codified in federal regulations, interacts with the 340B Drug Pricing Program in a manner designed to prevent overlapping federal discounts. The key regulatory provision is found at 32 C.F.R. § 199.21, which governs the TRICARE Pharmacy Benefits Program. This regulation incorporates the concept of a "covered drug" as defined under 38 U.S.C. § 8126, which serves as the statutory basis for the Federal Ceiling Price (FCP) program applicable to drugs purchased by certain federal agencies, including those under the TRICARE Program.

The TRICARE regulation explicitly excludes from the definition of a "covered drug" any drug that is dispensed by a pharmacy under the 340B program. If a prescription is purchased under the 340B Program, it is not considered a "covered drug" for purposes of TRICARE's retail network pricing and TRICARE's manufacturer rebate obligations.[44] The effect of this exclusion is to prevent the same prescription from being subject to both the 340B discount and the TRICARE FCP-based pricing, as effectuated through manufacturer rebate requirements. The regulatory structure thus creates a clear separation between the two programs, ensuring that the TRICARE rebate does not apply to a 340B discounted drug. Consistent with the statutory exclusion, TRICARE PBM agreements may obligate participants to identify 340B drugs to prevent the assessment or payment of TRICARE rebates on 340B discounted drugs.

Under the 340B rebate pilot, pharmacies would learn of a drug's 340B status only after a manufacturer pays a 340B rebate. Despite a covered entity identifying a claim as 340B-eligible, a manufacturer may reject the 340B rebate request, meaning that a drug identified as 340B by the pharmacy may not be 340B after a manufacturer unilaterally implements rebate policies and denies rebate requests, even if such policy requirements can be found nowhere in state or federal law. The 340B rebate model would therefore impair a covered entity's ability to comply with contractual terms in TRICARE agreements and is likely to lead to many circumstances where the covered entity not only does not get the benefit of the 340B discount, but TRICARE also does not get the benefit of a TRICARE rebate because a manufacturer rejects a 340B rebate request and the covered entity has no mechanism to notify TRICARE of the rebate denial. Ultimately, this will divert resources from both safety-net providers and the health care program for uniformed service members, retirees, and their families.

D. Commercial Duplicate Discounts

[44] 32 C.F.R. § 199.21(q)(2)(iii)(E)

The requirement for CHCs to provide valuable 340B commercial claims data to pharmaceutical manufacturers cannot be included under the rebate pilot or any federally authorized program. The purpose of the 340B Program is to enable covered entities to stretch scarce federal resources in order to offset the costs of providing care to uninsured and underinsured patients.[45] The statute's design reflects Congress's intent to ensure non-discriminatory access to discounted drugs, not to insulate manufacturers from commercial pricing dynamics. Allowing manufacturers to recapture value through regulatory mechanisms that Congress declined to authorize undermines the 340B program's purpose and contradicts its statutory structure.

Commercial claims data is extraordinarily valuable proprietary information to CHCs.[46] Studies conducted by IQVIA and others demonstrate that pharmaceutical manufacturers and PBMs routinely pay significant sums to obtain access to such data.[47] This regulatory action represents the first time in recorded history that the federal government has authorized pharmaceutical manufacturers, through subregulatory guidance, to transfer this valuable property away from covered entities and into manufacturers' possession without compensation or a valid public use.

That data will be used by drugmakers to reduce their rebate payment liabilities to commercial PBMs under contracts between the two private parties. Those contracts are privately negotiated so that drugmakers can obtain better formulary placement for their products and exclude cheaper drug alternatives.[48] They are negotiated with market discounts, including 340B discounts, already factored into their high drug list prices.[49] Drug industry data vendors have reported that such data is highly valuable to manufacturers.[50] Further, manufacturers or PBMs have been and would continue to use such data to harm covered entities if covered entities are forced to provide it. This is because manufacturers will use commercial claims data to dispute rebate obligations to commercial PBMs, and those PBMs will then, in turn, discriminate against 340B claims and 340B providers to make up for the lost profit. These PBMs use the data to impose onerous claims identification requirements against covered entities, reduce reimbursement on identified 340B drug claims, restrict networks to exclude CHCs and their pharmacies, restrict patient choice of CHCs and their pharmacies, or all the above. These are widespread practices that fundamentally undermine the core purpose of the 340B Program, which is to permit safety-net providers to generate savings on commercial 340B claims to offset the vast uncompensated and undercompensated services they furnish to our country's most vulnerable patient populations.[51]

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[45] Genesis Health Care, Inc. v. Becerra, No. 4:19-cv-01531-RBH, slip op. (D.S.C. Nov. 3, 2023).

[46] Kalderos, *Sightlines Issue No. 3, Double, double, toil and trouble with commercial contracts,* www.Kalderos.com (Oct. 2023), Issue No. 3. (stating that commercial claims data is worth billions of dollars).

[47] Kalderos, *Sightlines Issue No. 3, Double, double, toil and trouble with commercial contracts,* www.Kalderos.com (Oct. 2023), Issue No. 3. (stating that "5% of commercial rebates paid by manufacturers are likely duplicates with the 340B Drug Pricing Program — meaning a total of roughly $6 billion annually.")

[48] Kalderos, *Sightlines Issue No. 3, Double, double, toil and trouble with commercial contracts,* www.Kalderos.com (Oct. 2023), Issue No. 3. (widely used drug industry data vendor and analytics services provider, Kalderos, identifying that commercial 340B claims data is worth "at least . . . $6 billion annually" in 2022.)

[49] Kalderos, *Sightlines Issue No. 3, Double, double, toil and trouble with commercial contracts,* www.Kalderos.com (Oct. 2023), Issue No. 3. (stating that "5% of commercial rebates paid by manufacturers are likely duplicates with the 340B Drug Pricing Program — meaning a total of roughly $6 billion annually.").

[50] Kalderos, *Sightlines Issue No. 3, Double, double, toil and trouble with commercial contracts,* www.Kalderos.com (Oct. 2023), Issue No. 3. (rebate data is worth billions).

[51] *See*, *e.g., Genesis Health Care, Inc. v. Becerra*, 701 F. Supp. 3d 312, 330 (D.S.C. 2023) (stating that "the goal of the 340B statute . . . is to make 'covered entities' profitable in the face of the prescription drug price increases that followed the Medicaid Drug Rebate Program and that continue to this day.").

Indeed, over 30 states have passed laws to prevent this manufacturer-payer gamesmanship that seeks to usurp the 340B benefit.[52]

We believe that Congress did not intend to protect manufacturers or PBMs from their own commercial contracts. Federal law contains no prohibition on commercial duplicate discounts, and Congress expressly chose not to create one. When Congress enacted the 340B statute, it included explicit protection for manufacturers against Medicaid duplicate discounts but declined to extend that protection to commercial claims. Congress's omission of any comparable protection in the commercial market is therefore meaningful and dispositive. Respectfully, HHS may not unilaterally mandate the transfer of such valuable property outside the bounds of any applicable federal or state law.

We contend that HRSA lacks statutory authority to require the submission of commercial claims data. HRSA's authorization of mandatory commercial claims data submission under the rebate pilot exceeds the agency's statutory authority.[53] The 340B statute authorizes HRSA to administer ceiling pricing requirements; it does not authorize the agency to compel covered entities to surrender valuable proprietary data as a condition of accessing pricing to which they are statutorily entitled. As the District of D.C. explained, "Congress therefore constrained the Secretary's ability to adopt regulations that have the force of law. This denial of general rulemaking authority supports the conclusion that Congress did not mean for the Secretary to create extra-statutory hurdles to 340B participation."[54] Even if the statute were silent on this issue, silence cannot serve as a basis for imposing affirmative obligations on regulated parties. As the Third Circuit has made clear, "obligations cannot spring from silence."[55] By conditioning access to 340B pricing on the transfer of commercial claims data, HRSA has created a requirement wholly untethered to the statutory text.

In addition, the requirement is arbitrary, capricious, and not in accordance with applicable law, in violation of the federal Administrative Procedure Act.[56] There is no commercial duplicate discount prohibition for HRSA to enforce, and the agency has failed to articulate a reasoned explanation for how mandating commercial claims data, for the first time in the 340B statute's history, advances the statutory purpose of the 340B Program to enable safety-net providers, including CHCs, to stretch their resources to provide more comprehensive services to more patients.

We harbor significant concerns that the 340B rebate model's requirement that CHCs furnish valuable commercial claims data to drugmakers in exchange for drug price discounts raises the potential for fraud and abuse. Requiring covered entities to provide valuable data in exchange for preferential pricing not authorized by statute may implicate the federal

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[52] 340B Report, *Legislative Map: Contract Pharmacy Protection Bills*, https://340breport.com/legislative-map/contract-pharmacy-protection-bill/; 340B Report,*Legislative Map: Laws Passed That Prohibit PBM Underpayment*, https://340breport.com/legislative-map/laws-passed-that-prohibit-pbm-underpayment/.

[53] Pharmaceutical Research & Manufacturers of America v. U.S. Department of Health & Human Services, No. 1:14-cv-01685 (RC) (D.D.C. Oct. 9, 2014).

[54] Albany Med Health System v. Health Resources & Services Administration, No. 23-cv-03252 (APM), slip op. (D.D.C. Mar. 3, 2026).

[55] Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs., 58 F.4th 696 (3d Cir. 2023).

[56] 5 U.S.C. § 706(2)(A) (federal courts must set aside agency actions found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law").

Anti-Kickback Statute and analogous state laws.[57] The 340B rebate pilot requires CHCs to provide valuable commercial claims data to manufacturers in exchange for discounted pricing on items (drugs) that may be billed to federal health care programs such as Medicaid or Medicare. This raises fraud and abuse risks and potential violations of the False Claims Act. HRSA cannot lawfully authorize a program that places covered entities at risk of violating federal fraud and abuse laws.

For these reasons, the requirement that CHCs provide commercial claims data to pharmaceutical manufacturers in exchange for discounted pricing cannot be included under the rebate pilot or any federally authorized program. HRSA's action exceeds statutory authority, violates the APA, raises serious constitutional concerns, and directly undermines the purpose of the 340B statute.

VIII. Alternative Approach: Upfront 340B-Priced Payments to CHCs

We respectfully assert that the 340B Rebate Pilot program must be replaced with a program that facilitates upfront 340B-priced drug payments from CHCs. This is because, under the plain language of the 340B statute, it is illegal to transfer discretion to the manufacturer about CHC patient eligibility. By requiring a CHC to purchase a drug at WAC and allowing a manufacturer to determine whether to pay a 340B rebate based on the data it receives, including data relating to whether a person is a patient of the CHC, the 340B Rebate Pilot shifts the authority to ascertain a patient away from the CHC-provider to a non-provider – the drugmaker.

Specifically, the 340B statute grants the covered entity discretion to determine which of its patients are covered. Importantly, the statute allows HRSA and drugmakers to audit only *after* such a determination has been made. Indeed, the only provision that mentions the term "patient" in the 340B statute prohibits the covered entity – not HHS nor the manufacturer – from reselling or transferring 340B drugs to nonpatients.[58] This is commonly referenced as the "diversion prohibition." Thus, the statute exclusively grants the covered entity the authority to determine which of its patients are eligible for 340B drugs and requires the covered entity to furnish 340B drugs only to those persons. It is reasonable for covered entities that employ or contract with health care professionals because, after all, the health professional is responsible for establishing the patient relationship. Drugmakers do not establish patient relationships.

Notwithstanding the clear language of the diversion prohibition, the 340B Rebate Pilot transfers that explicit statutory discretion to drugmakers by allowing them to require upfront pricing and to consider data elements before deciding whether to pay a 340B rebate. Simply put, the 340B Rebate Pilot will determine whether a person is a patient of a covered entity, prior to any audit, and in clear contravention of the plain text of the diversion prohibition. We respectfully contend that the term "rebate" in the first paragraph of the 340B statute only relates to AIDS Drug Assistance Programs, which are mere payment systems for covering drugs and do not involve the establishment of patient relationships. Specifically, AIDS Drug Assistance Programs are statutorily obligated to pay for drugs *after* the drug has been prescribed. However, AIDS Drug Assistance Programs do not establish patient relationships because they are not health care

[57] 42 U.S.C. 1320a-7b (making it illegal to pay remuneration in exchange for items or services billable to federal health care programs.)
[58] 42 U.S.C. § 256b(a)(5)(B)

providers that employ or contract with health care professionals to do so. Rather, they act as payers to assist with paying for drugs, among other things. Hence, a rebate model is appropriate for them. Indeed, HRSA's longstanding guidance defining eligible 340B patients explicitly excludes "individual[s] *registered* in a State operated or funded AIDS drug purchasing assistance program [from the requirements of] 'patient' of the covered entity for purposes of this definition if so registered as eligible by the State program."[59]And the legislative history of the 340B statute supports the position that rebate models, while appropriate for ADAPs, may not be appropriate for CHCs.[60]

IX. Establishing a National, Neutral Claims Clearinghouse

We recommend OPA use a Neutral Claims Clearinghouse (NCC), which would produce more accurate deduplication at a tiny fraction of the cost and administrative burden of a rebate model. As described above, a 340B rebate pilot would impose significant cash flow demands and administrative burdens on covered entities (CEs). Fortunately, the primary goal of the rebate pilot – "to address 340B and Maximum Fair Price (MFP) deduplication" - can be achieved quickly, without overturning the fundamental structure of the program, and at a fraction of the cost and administrative burden of the rebate model, through the creation of a 340B Neutral Claims Clearinghouse (NCC).

A. Benefits of an NCC

Under an NCC, CEs would submit standardized claims data to a secure web platform for each MFP drug purchased under 340B and dispensed to a Medicare Part D patient. This data would be submitted within 45 days of the drug's administration or dispensation. The NCC would aggregate this data and transmit it to the Medicare Transaction Facilitator, which would use it to identify claims that are ineligible for a Medicare MFP rebate.

This clearinghouse could be used to identify potential Medicaid-340B duplicate discounts; identify potential MFP-340B duplicate discounts under the IRA; share identified 340B units reimbursed by Medicare with CMS for exclusion from Part B and Part D inflation rebates; identify duplicate covered entity claims for 340B discounts on the same prescribed units of drugs (e.g., for patients of both entities); and to provide manufacturers access to a specified list of claims-level data elements for dispensing of their 340B drugs.

Compared to HRSA's proposed rebate model, the NCC approach would:

- **Avoid cash-flow and borrowing challenges** for CEs by preserving the upfront 340B discount.
- **Substantially reduce administrative burden on CEs** by significantly reducing the need for them to build and maintain complex rebate compliance systems, and the staff time needed to track and reconcile claims and to manage cashflow issues. A rebate model, on the other hand, would force CHCs to divert resources away from patient care to cover these costs.
- **Provide manufacturers with the necessary deduplication data within the same 45-day timeframe.**

[59] Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55,156, 55,157 (Oct. 24, 1996) (emphasis added).]
[60] H.R. REP. 102-384, 16

- **Improve rebate accuracy**, reducing the time and effort manufacturers and CEs must spend correcting errors.
- **Preserve the longstanding upfront discount structure** that has defined the 340B program for more than three decades and is essential to most CHCs' participation in the program.
- **Protect patient access to affordable MFP drugs.** If a rebate model were implemented, the resulting cash-flow pressures could force many CHCs to stop purchasing or dispensing MFP drugs altogether.

B. Expansion to Prevent Other Statutorily-Prohibited Duplicate Discounts

This letter previously discussed concerns about the practicality of implementing a rebate model and the logistical challenges it would pose for existing duplicate discount identification efforts. An NCC could easily be expanded to include the two other types of statutorily-prohibited discounts:

- **Medicaid Duplicate discounts in Medicaid.** State Medicaid programs currently rely on a patchwork of approaches to identify 340B drugs and avoid requesting manufacturer rebates on those claims. These approaches include claim modifiers, manual reconciliation processes, and state-specific clearinghouses. An NCC could provide a standardized national approach to preventing duplicate Medicaid discounts by collecting CEs' 340B claims data for Medicaid prescriptions and making it available to states. This approach would benefit all stakeholders:
    - **State Medicaid agencies** would no longer need to build, administer, or finance their own systems to identify 340B claims. Instead, they could rely on a single national data source.
    - **Covered entities** would face lower reporting burdens by submitting data to a single system rather than navigating separate state and Federal reporting requirements.
    - **Manufacturers** would benefit from a single, standardized system for preventing duplicate Medicaid discounts, replacing the current patchwork of 50 different state processes and data sets.

- **Medicare inflation rebates.** CMS also needs 340B claims data to exclude 340B drugs from Medicare inflation rebate assessments sent to manufacturers. CMS is currently developing a "voluntary data repository" for this purpose and hopes to launch it this fall. Rather than creating another standalone system, CMS could collect this information through the NCC. Because participation in the NCC would be mandatory for covered entities, the resulting data would likely be completer and more accurate than data collected through the voluntary repository CMS is currently developing.

C. Importance of Neutrality

For an NCC to succeed, it must be widely viewed as neutral and trustworthy by all stakeholders. The 340B program has long been the subject of significant policy disputes among manufacturers, covered entities, and payers. Any national claims data infrastructure will only work if participants trust that it operates independently and does not favor one group of stakeholders over another. If the clearinghouse is perceived as aligned with a particular stakeholder interest, other stakeholders are unlikely to have confidence in the quality of the data it produces or how that data will be used.

The experience with the 340B ESP platform illustrates this concern. ESP was developed for and is financed by pharmaceutical manufacturers; its terms and conditions are widely viewed by CEs as favoring manufacturers' interests and the platform itself. As a result, many CEs do not view ESP as a neutral system and are reluctant to rely on it as a trusted intermediary for sensitive claims information. This example underscores why neutrality must be a foundational design principle for any national clearinghouse.

For these reasons, we recommend that the NCC be developed and administered either directly by the federal government or by an independent contractor selected by, and accountable to, the federal government. A governance structure rooted in federal oversight would provide transparency, independence, and stakeholder confidence, necessary for the NCC to function effectively and serve its intended purpose of preventing duplicate discounts without undermining the intent of the 340B program.

D. Types and Use of Data

Clear rules must also govern what data the NCC will collect, who may access it, and how it may be used. Key principles should include:

- **Data minimization:** CEs should submit only the data necessary to prevent the types of statutorily-prohibited duplicate discounts that the NCC is designed to address.
    - *Allowable data elements* should include National Drug Code (NDC), quantity dispensed, date of service, prescription number, dispensing pharmacy identifier (NPI), and covered entity identifier (340B ID).
    - *Prohibited data elements* should include patient-identifiable information, diagnosis codes, CPT codes, and other clinical data. Additionally, requests for purchasing data, as originally proposed by Johnson & Johnson in its initial rebate model[61] published August 23, 2024, should be prohibited. Manufacturers have already demonstrated ready access to purchasing data, so CHCs should not be burdened with providing it.

- **Manufacturer access:** Manufacturers should not require access to this data because the information will be transmitted to the MTF and state Medicaid agencies for the purpose of preventing statutorily prohibited duplication of discounts.
- **Strict confidentiality:** Organizations receiving data from the NCC should be prohibited from sharing it with other entities.
- **Purpose limitations:** NCC data may only be used to determine whether a claim is eligible for other discounts or rebates. Data may not be used for other purposes, including, but not limited to, utilization management, reimbursement decisions, network participation determinations, or enforcement of restrictions not explicitly authorized by federal statute.
- **No access for PBMs or payers.** As previously mentioned, manufacturers can use claims data to dispute rebate obligations to commercial PBMs, and then PBMs will discriminate against 340B claims and 340B providers to make up for the lost profit.

E. Bipartisan Congressional Support

[61] https://beaconchannelmanagement.com/pages/resources (Johnson & Johnson Policy Documents)

Because a neutral clearinghouse offers a cost-effective and low-burden way to prevent statutorily prohibited duplicate discounts, it has received significant bipartisan support in Congress. Examples include:

- **340B PROTECT 340B Act**: This bipartisan House bill, which received over 100 cosponsors in the 2021-22 session, aims to address Medicaid duplicate discount issues through the establishment of a neutral clearinghouse operated by a federal contractor.
- **SUSTAIN 340B Act**: The bipartisan "Group of Six" Senators released draft sections of this bill in early 2024. These sections included a neutral clearinghouse for claims data on both Medicaid and Medicare drugs.
- **340B ACCESS Act**: This bill advocates for an NCC that would encompass all claims, including those from commercial sources.

Given the major disruption the 340B rebate program is anticipated to have on CHCs, a system that forces CHCs to provide data that is already accurately and readily available to manufacturers is not only redundant but also adds additional administrative burdens on safety-net providers. It is imperative that HRSA require manufacturers to leverage existing resources to protect the stability of the safety-net providers that the 340B program was designed to support.

Conclusion

CHANGE, Inc. **strongly urges HRSA to exempt CHCs from any 340B Rebate Model Pilot Program**. A 340B rebate program represents a departure from the original intent of the 340B program—to allow safety-net providers to "stretch scarce Federal resources" and provide more comprehensive care. A rebate model would create significant cash flow challenges, forcing CHCs to make difficult decisions about staffing, services, and the range of drugs they can afford to stock. Additionally, CHCs would need to make significant investments in IT infrastructure and staff to comply with rebate requirements and track rebates. It would also create a new barrier for patients, especially uninsured patients, who depend on the up-front 340B discount, making it operationally impossible to provide the sliding fee scale and steeply discounted medications required by law. CHANGE, Inc. believes that a 340B rebate pilot would cause disproportionate harm to patients served by CHCs and other safety net providers.

CHANGE, Inc. appreciates the opportunity to respond to this Request for Information on the 340B Rebate Model Pilot, and we look forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please contact us at **lmowry@changeinc.org.**

Sincerely,

Lisa Mowry

CEO
CHANGE, Inc.
Community Action & Community Health Center

April 17, 2026

Chantelle Britton
Director
Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
Rockville, Maryland 20857

RE: Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906-NEW

Submitted via paperwork@hrsa.gov

Dear Director Britton:

On behalf of Philadelphia FIGHT**,** I would like to thank the Health Resources and Services Administration (HRSA) for providing the opportunity to **share our estimated burden with HRSA on compliance with the 340B rebate model pilot program. Given the severe administrative, financial, and operational burden a rebate model would place on CHCs, Philadelphia FIGHT again requests that CHCs be exempted from the pilot program.**

The 340B program is foundational to CHC's ability to serve the most vulnerable members of our community. However, the proposed shift of responsibility from manufacturers to safety-net providers directly serving patients through a rebate model threatens to destabilize CHC pharmacy operations nationwide. Based on national assessments from the National Association of Community Health Centers (NACHC) and our own internal assessments, the hours and dollars spent complying with a rebate program are staggering.

I. We Request HRSA Exempt CHCs from the 340B Rebate Model Pilot Program Due to Significant Financial and Administrative Burden

By requiring CHCs to purchase medications at full price and wait for rebates, this model would cause significant financial turmoil and directly affect our ability to serve the nearly 8,000 unduplicated patients who rely on us. We operate on razor-thin margins, and these additional costs are not an option for many entities. Like navigating manufacturers' existing contract pharmacy restrictions, CHCs will need to invest in IT infrastructure upgrades and hire or reassign staff to manage new complexities, including varying data submission requirements and timelines, payment reconciliations, and dispute processes for denied rebates. We will face an increased administrative burden in monitoring rebate claims and payments.

To support CHCs in assessing the financial and operational impact of current manufacturer restrictions and an anticipated rebate model, NACHC worked with their consultant, FQHC 340B Compliance, to create an Operational & Administrative Cost Calculator.[1] The tool aggregates program savings, UDS financial data, staffing, external consulting costs, dispensing/capture activity, and clinic-administered drug tracking models to support cost forecasting. CHCs have already experienced steep increases in operational costs given the multitude of manufacturer restrictions, including requirements for clinic-administered drugs and entity-owned pharmacies. A rebate model will require a significant increase in already-strained operational capabilities.

Workforce Impact:

- **Staffing Impact**: Philadelphia FIGHT anticipates needing .75 additional FTEs to account for the increase in operational, administrative, and compliance burden created by a rebate model.
- **Number of Hours:** Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, Philadelphia FIGHT will face an increased administrative burden to monitor rebate claims and payments. Thirty (30) weekly hours will be required to report 340B rebate claims to a third-party platform, along with troubleshooting any data issues, addressing purported validation errors and following up on anticipated denials.
- **External Vendor Costs**: Philadelphia FIGHT anticipates an additional $570,000 for external vendors, including consultants, legal counsel, program coordination, third-party administrators (TPAs), electronic medical records (EMRs), pharmacy software, and reconciliation services.

Pharmacy Software & Third-Party Administration Changes

Navigating this pilot requires both staff and changes to workflow and software. HRSA should consider the increased compliance burdens when manufacturers have the flexibility to require varying data submission standards and elements. Additionally, if manufacturers can select different software platforms, like current contract pharmacy policies, CHC administrative burden would increase substantially.

- **One-Time Implementation Costs:** We anticipate high upfront costs to adapt our pharmacy software, pay for custom dashboard modifications, and design new internal workflows. $12,000 will be required simply to reach the baseline of compliance before a single rebate is ever received.
- **Ongoing Operational Fees**: Beyond implementation, our TPA and software vendors will likely charge ongoing service fees of 1% gross sales to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Cost:** For our CHC, which serves nearly 8,000 patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at $95,000 annually.

The Contract Pharmacy: The Burden of Network Coordination

The rebate model introduces a new complexity that threatens the existence of contractual arrangements. My CHC currently partners with 146 pharmacies to increase access to affordable medications.

[1] https://www.nachc.org/policy-advocacy/policy-priorities/340b-drug-pricing-program/340b-rebate-model-pilot-program/

- **TPA Reliance and Fees:** Navigating manufacturers' varying requirements across multiple contract pharmacies requires high-level TPA intervention. We anticipate that our TPAs will pass on the costs of developing rebate-tracking modules to us through increased per-claim fees.
- **Verification Latency:** The rebate model creates a reconciliation gap. Our staff must monitor claims across 146 different pharmacy locations to ensure rebates are paid correctly.
- **Risk of Pharmacy Exodus:** The model shifts financial risk to the pharmacy, potentially causing contract partners to opt out of the 340B program entirely rather than manage the administrative headache. In Philadelphia County**,** this would leave patients with no affordable medication options. Over 17 percent of the U.S. population already lives in a pharmacy desert.[2]

Clinic Administered Drugs: The Burden of New Systems Required

Clinic-administered drug (CAD) operations and record-keeping in CHCs are designed cost-effectively to reflect the nuances of CHC billing. Implementing a rebate model for CADs would also require new software, system integration, and staff training. NACHC estimates these costs would range from $30,000 to $50,000 annually and could be much higher, depending on the software.[3]

Most CADs are bundled into the prospective payment system (PPS) billing when administered to patients by CHCs. Because PPS visits are paid at a flat rate, the medications administered in CHCs are often not included on claims billed to payers. CHCs maintain limited inventories of CADs and typically do not separately bill on claims. Administration and inventory logs are commonly maintained on paper, with text documentation in patient visit notes describing what was administered. While CHCs maintain perpetual inventories and complete administrative records, paper records impose an additional burden of converting them to electronic data before submitting for rebate. Very few CHC records include electronic medication administration records (eMARs), which are common in hospital EMRs. Where eMARs are available, they incur an additional cost and often require CHCs to pay for a standalone software system.

II. Patient Impact

Philadelphia FIGHT has significant concerns about the impact a 340B Rebate Model Pilot would have on our most vulnerable patients' access to life-saving medications. The majority of drugs selected for the MDPNP for 2026 and 2027, and included in the proposed rebate model, manage chronic conditions prevalent in primary care settings. CHCs serve a patient population with a higher burden of chronic conditions compared to private practices, with studies showing a significantly higher prevalence of illnesses like diabetes, hypertension, and obesity.[4] This patient population relies on affordable medications to manage these long-term conditions.

The impact on insulin access is also alarming and directly conflicts with federal requirements. With over 3 million Americans relying on CHCs for essential diabetes care,[5] insulin affordability is a matter of life and death. Furthermore, Executive Order #14273 conditions future Section 330(e) funds on CHCs providing low-income patients with access to discounted insulin. No current

[2] Vulnerability Index Approach to Identify Pharmacy Deserts and Keystone Pharmacies | Pharmacy and Clinical Pharmacology | JAMA Network Open | JAMA Network

[3] Internal NACHC survey data

[4] Richard P, Ku L, Dor A, Tan E, Shin P, Rosenbaum S. Cost savings associated with the use of community health centers. J Ambul Care Manage. 2012 Jan-Mar;35(1):50-9. doi: 10.1097/JAC.0b013e31823d27b6. PMID: 22156955.

[5] 2025 UDA Data, HRSA (hrsa.gov)

operational method exists to provide discounted medications in a rebate model. In the proposed model, the wholesaler price file would reflect the full Wholesale Acquisition Cost (WAC) rather than the discounted 340B price, making the price unattainable for patients and precluding CHCs from fulfilling their legal obligation to offer the required discount at the point of care.

III. Financial Challenges

Lack of access to upfront 340B discounts, along with the high IT/infrastructure costs, will disproportionately impact CHCs and trickle down to patients. Many CHCs are currently under financial strain, with nearly half operating with fewer than 90 days of cash on hand, and one in four reporting negative five percent operating margins. This rebate model creates significant financial challenges, including:

- **Purchasing Drugs at the WAC Price Upfront:** Under the proposed model, CHCs would be required to purchase drugs at the WAC. CHCs will have to wait to receive their rebate payment *after* providing medications to their patients, forcing difficult decisions about how to allocate limited financial resources, including cutting essential services and reducing operating hours. We are particularly worried that the need to purchase drugs at full WAC will cause cash flow issues and potentially lead CHCs to exceed credit limits with wholesalers, halting their ability to order medications until payments are submitted.
- **Sliding Fee Scale:** A rebate model creates substantial uncertainty about CHCs' ability to apply sliding-fee discounts at the point of sale. By statute and regulation, CHCs are required to offer sliding fee discounts for all required and additional health services within the HRSA-approved scope of project.[6] In line with their mission, CHCs offer flat or sliding-scale discounts on prescription drugs to make them more affordable for low-income individuals.[7] A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size. Philadelphia FIGHT currently offers sliding fee discounts that range from $0-$25 based on a patient's ability to pay, as well as providing 340B drugs at cost and in many cases waiving this cost based on need. We also leverage the 340B discounts to provide additional specialty and supportive services that would otherwise be unavailable to our patients.

Conclusion

Philadelphia FIGHT strongly urges HRSA to exempt CHCs from any 340B Rebate Model Pilot Program. A 340B rebate program represents a departure from the original intent of the 340B program—to allow safety-net providers to "stretch scarce Federal resources" and provide more comprehensive care. A rebate model would create significant cash flow challenges, forcing CHCs to make difficult decisions about staffing, services, and the range of drugs they can afford to stock. Additionally, CHCs would need to make significant investments in IT infrastructure and staff to comply with rebate requirements and track rebates. It would also create a new barrier for patients, especially uninsured patients, who depend on the up-front 340B discount, making it operationally impossible to provide the sliding fee scale and steeply discounted medications required by law. Philadelphia FIGHT believes that a 340B rebate pilot would cause disproportionate harm to patients served by CHCs and other safety net providers.

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[6] HRSA FAQ

[7] Such discounts are subject to potential legal and contractual restrictions. https://bphc.hrsa.gov/compliance/compliance-manual/chapter9#footnote10

Philadelphia FIGHT appreciates the opportunity to respond to this ICR on the 340B Rebate Model Pilot Program, and we look forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please contact **Greg Landistratis at glandistratis@fight.org.**

Respectfully,

Jose A. Benitez

Jose A Benitez, MSW, FCPP
Chief Executive Officer

TO: Mr. Thomas J. Engels
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services

Ms. Chantelle Britton
Director
Office of Pharmacy Affairs, Health Resources and Services Administration
U.S. Department of Health and Human Services

FROM: Elevated Community Health
DATE: April 17, 2026

RE: Comments on HRSA's Information Collection Request: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB # 0906-NEW

Elevated Community Health is a federally qualified health center serving Summit, Lake, Park, and surrounding counties in rural Colorado. We provide integrated medical, dental, and behavioral health services, along with an onsite pharmacy, to more than 10,000 patients annually, many of whom are low-income or face barriers to care such as housing instability, limited access to providers, and transportation challenges.

As a 340B covered entity, Elevated Community Health participates in the federal 340B Drug Discount Program to stretch scarce federal resources and expand access to care. Savings generated through the program are reinvested directly into patient services, including pharmacy operations, care coordination, and integrated service delivery.

Our 340B program is tightly managed to ensure compliance with all federal requirements, including patient eligibility, prevention of diversion, and avoidance of duplicate discounts. Medications purchased through 340B are limited to eligible outpatients receiving care from our providers, ensuring the program directly supports the patients we serve

For our organization and the communities we serve, the 340B program is not supplemental. It is foundational to maintaining access to affordable medications and sustaining the comprehensive, integrated care model that defines community health centers.

We do not believe that a rebate model is an appropriate, efficient, or ethical manner to operate the 340B program, as it pulls CHCs' limited funding and staff time away from patients and towards management of the rebate model; a rebate model damages the integrity of the program and inhibits patient access to affordable prescription medications.

The Information Collection Request (ICR), OMB # 0906-NEW, published by the Health Resources and Services Administration (HRSA) represents a fundamentally flawed perspective of the burden, staff time, and resources that compliance with a rebate model would impose on covered entities, including CHCs. We would like to provide our CHC's perspective as to the actual cost of participating in a 340B rebate model on CHCs, to better inform HRSA's estimates and understanding. We maintain that a rebate model will be catastrophic to the health care safety net in Colorado, and across the country, and devastate low-income, vulnerable patients' access to affordable medications and integrated health care services. **We request that HRSA exempt all CHCs from any 340B rebate model, including the pilot program being explored in HHS Docket # HRSA-2026-03042.**

Data collected by CCHN from fifteen CHCs, which are representative in size and location of the 21 CHCs in Colorado, demonstrates the enormity of the burden, and the vast underestimation HRSA assumes, that a rebate model poses on these local, community-based providers. This burden includes substantial staffing impacts and administrative and operational changes to account for the data compilation and collation, data reporting, and tracking of the rebates throughout the process. As defined in the ICR, burden, in this context, means "the time expended…to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems…for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information." The total annualized burden hours are estimated for CHCs to be an additional five hours to implement a 340B rebate model pilot program compared to current practices, with no additional estimates on new or reallocated staff or cost.

Of the fifteen CHCs that responded, 87% indicated it would require more staff time and dollars to manage the rebate model than their current pharmacy program. To sufficiently and adequately track the submission of the data and the receipt of rebates across in-house and contract pharmacies, those CHCs estimate spending, on average, nearly $100,000 annually in additional staff time and cost, ranging from roughly $10,000 for a small, rural CHC to upwards of $500,000 for a large, urban CHC.

Additionally, CHCs report that it would take an additional 1,962 hours on average per CHC, to compile, calculate, and collate the necessary data, submit the rebate data, reconcile the received rebate with the expected amount, contest any incorrectly denied rebates or follow-up on delayed rebates, and audit their 340B program. This estimated burden ranges from 130 more hours per year for a small CHCs up to more than 6,200 hours for larger CHCs. If one full-time equivalent (FTE) employee equates to 2,080 hours per year, CHCs estimate the new, additional burden in managing the rebate model to take on average 94% of an FTE. At the high end, one CHC estimates this could take 300% of an FTE (6,240 hours per year) and others estimate that this could take 200% of an FTE (4,160 hours per year). HRSA estimated that the additional burden from participating in the rebate model to take just 0.2% of an FTE (five hours per year).

On average, using 2025 drug purchasing as a proxy, CHCs would need to account for an average upfront cost increase of $11.6 million if the rebate model was expanded to all 340B drugs. According to data CCHN calculated in 2024, with a rebate model imposed on the ten drugs subject to the Medicare Fair Price negotiations, CHCs would need to account for an upfront cost increase exceeding 7,000%, which does not include any increased revenue or resources spent on hiring or reallocating and retraining staff, implementing new and upgraded technological systems, and dedicating time to tracking and accounting for rebates.

A 340B rebate model would introduce significant administrative and financial strain on Elevated Community Health, particularly as a rural health center operating with limited margins. Under a rebate structure, we would be required to purchase medications at full price upfront and wait for reimbursement, creating immediate cash flow challenges and increasing financial risk.

Operationally, this model would require new infrastructure to track, reconcile, and manage rebate submissions across payers, prescriptions, and dispensing points. This adds complexity to an already highly regulated program and increases the likelihood of errors, delays, and compliance risk. For an organization of our size, this would require additional staffing, system investments, and ongoing administrative oversight that are not currently necessary under the existing model.

The shift to a rebate model also undermines the intent of the 340B program. Instead of allowing covered entities to realize savings at the point of purchase and reinvest those resources into patient care, it delays and potentially reduces access to those funds. This creates uncertainty in budgeting and limits our ability to make timely investments in services, staffing, and patient support programs.

Ultimately, the administrative burden and financial instability introduced by a rebate model would divert resources away from patient care and compromise our ability to serve rural, underserved populations effectively.

With any additional revenue or reserves tied up to account for this astronomical increase and no guarantee of a return on the investment, along with the need to pull funds from other areas of the clinic's operations – including staffing, services, and even clinic locations – to simply maintain compliance with a rebate model, the burden to account for this increase in staff time and cost, and the impact on CHC patients' access to care and medications, is mind-boggling. It is incomprehensible to impose a rebate model with this level of burden on local, nonprofit CHCs when 70% of CHCs in Colorado had negative or breakeven financial operating margins in 2024 and 2025 and it is anticipated a similar number of CHCs will face this financial challenge in 2026.

Thank you for considering our feedback on the true cost that managing and participating in a 340B rebate model pilot program would have on CHCs. This proposed program would not be a simple operating change or a cost rearrangement; it would lead to a drastic, catastrophic detriment in how CHCs operate pharmacy programs, fund staff, health care services, and programs, and support their patients. **We reiterate our request for HRSA to exempt all CHCs from this pilot program, and any 340B rebate model in the future.** If you have any questions, please reach out to jcogdill@elevatedch.org.

Sincerely,

Josh Cogdill, CEO

Phone: 970-668-4040 | Fax: 970-668-6699 | Email: info@elevatedch.org

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Ghazala Q. Sharieff, MD
Corporate Executive Vice President
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Scripps Health

4555 Executive Drive, HQ 504
San Diego, CA 92121
858-678-6611

April 17, 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, HHS Docket No. HRSA-2026-03042

Dear Administrator Engels:

On behalf of Scripps Health, we appreciate the opportunity to comment on the Department of Health and Human Services (HHS) Request for Information: 340B Rebate Model Pilot Program.

The RFI asks whether the Health Resources and Services Administration (HRSA) should implement a rebate model under the 340B Program in place of the upfront discount mechanism that has governed the program for decades. It should not add to the existing burden on hospitals.

A rebate mechanism would impose substantial administrative, operational, technological, privacy, and cash-flow burdens on Scripps Health while diminishing the value of the 340B Program for the patients and communities we serve. HRSA's estimates appear to understate those burdens. More fundamentally, the 340B Program's purpose is to enable covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. The longstanding upfront discount model advances that purpose. Replacing it with a rebate structure would do the opposite.

For purposes of estimating the likely burden, Scripps Health assumes that any rebate model could include the drugs previously approved for the original HRSA rebate initiative together with the drugs approved under the Medicare Drug Price Negotiation Program for 2027, for a total of approximately 25 drugs. As the number of included drugs grows, so do the burdens:

more claims to identify and submit, more data to compile and validate, more rebate payments to track and reconcile, more denials and disputes to challenge, and more money that covered entities must front to manufacturers while awaiting the statutory discount. Each of those burdens diverts resources away from patient care.

I. Administrative and Operational Burdens

Scripps Health participates in the 340B Program based on the longstanding upfront discount model. Our staffing, workflows, oversight processes, vendor relationships, and financial planning were built around that structure. A move to a rebate mechanism would require substantial new investment and create burdens well beyond what Scripps Health anticipated or budgeted for when participating in the 340B Program.

At a minimum, Scripps Health would need an additional full-time 340B Analyst to support rebate operations. That position would be responsible for preparing and submitting data for rebate drugs, tracking rebate submissions and payments, validating and auditing the receipt of rebates, and working with the 340B ESP™ (Eligibility and Submissions Portal) to resolve rebates not received within the applicable timeframe. If needed, Scripps can provide an estimate of salary and benefits for this additional position.

That new FTE would not eliminate the broader operational burden. A rebate model would also require substantial time from existing 340B personnel for implementation, workflow redesign, reconciliation, oversight, denial management, and coordination with outside parties. Those demands do not exist under the current upfront discount framework.

The risk of rebate denials is particularly concerning. Without strong guardrails, denials could result both in the loss of 340B savings and in substantial administrative burdens associated with challenging denials, researching discrepancies, and potentially rebilling or reversing claims. The denial process itself would consume considerable staff time and create ongoing uncertainty.

Scripps Health would also incur additional costs associated with:

- IT resources needed to build reports and extract submission data;
- potential engagement of an additional third-party administrator (TPA) to support tracking and reconciliation of rebates;
- added charges from Elevate, our vendor that collects and processes rebate payments; and
- increased accounts receivable effort to locate and follow up on unpaid or delayed rebate amounts.

Our current mixed-use TPA, Sentry, has quoted a one-time implementation fee of $10,000 and an annual fee of $30,000 to support rebate-related activity. Those costs are incremental and would be in addition to internal staffing, IT support, and any fees charged by other vendors.

These new resources would be needed for functions including:

- claims processing;
- data submission;
- reconciliation and rebate follow-up;
- audit support; and
- denial review and challenges.

The rebate model would also create significant complications for Medicaid billing, particularly with respect to the requirement to bill at 340B AAC. During the initial rebate pilot discussions, the California Department of Health Care Services (DHCS) was planning to require covered entities to hold claims until the 340B rebate was received. That would require IT reconfiguration of our billing systems and could force Scripps Health to provide services without timely payment.

On the retail pharmacy side, holding claims is not feasible. It would require either dispensing product to patients without any assurance of future payment or initially billing claims at WAC and then rebilling at 340B once the rebate is received, creating still more administrative burden. Although DHCS is now considering allowing pharmacies to bill 340B claims at the 340B ceiling price before rebates are received, that alternative remains problematic. If a rebate is later denied, the pharmacy would need either to rebill the claim at WAC or absorb the reimbursement loss.

II. Staffing Impact

Scripps Health does not currently have staffing levels designed to support a rebate-based 340B framework. Implementation would require both additional personnel and reallocation of existing staff time across 340B operations, pharmacy, finance, accounts receivable, and IT.

As noted above, we expect to need at least one additional full-time 340B Analyst to support rebate program administration. Existing staff would also need to devote significant time to implementation, file preparation, report maintenance, reconciliation, denial review, communications with vendors and manufacturers, and audit support.

For that reason, HRSA's estimate of only five additional hours per week for a rebate model involving approximately 25 drugs is not realistic. That estimate does not reflect the operational complexity of preparing and validating submissions, manually reviewing data, tracking payment status, validating payment accuracy, appealing denials, coordinating among vendors, and maintaining records sufficient for compliance and audit purposes. For a large health system, those activities would require ongoing and material staff effort.

III. Systems and Infrastructure

The rebate model would require substantial changes to Scripps Health's current systems and infrastructure.

Our IT team would need to develop a new report to support submission of rebate data. At least

initially, the process would be manual: Scripps Health would need to run the report manually and upload claims data into Beacon unless and until an automated interface could be designed, tested, and implemented. Building automated data sharing with another vendor would be extensive and time-consuming.

The rebate model would also require significant changes to drug pricing workflows within our electronic health record. For rebate drugs, the 340B price would no longer come from our wholesaler price catalogs. Instead, our IT team would need to:

- block wholesaler catalog pricing for the affected NDCs; and
- manually upload a separate price file containing the 340B ceiling price provided by Beacon.

This process would need to be repeated every time there is a change in 340B pricing. Moreover, the only practical way to validate the 340B prices in that file would be to manually check each NDC in the OPAIS database, which would be extremely time-consuming given the potentially large number of NDCs involved.

Current 340B reporting and auditing already require Scripps Health to pull information from multiple sources, including:

- our EHR;
- two TPAs; and
- our wholesaler.

A rebate model would add still more sources, including:

- Beacon;
- Medicare Transaction Facilitator (MTF);
- Elevate; and
- potentially an additional TPA.

This would materially increase the complexity of reconciliation, reporting, and audit readiness.

A rebate model would also impair our ability to report 340B savings accurately. Under the current model, savings are known at the time of purchase or dispense. Under a rebate approach, we would not know at that point whether a rebate will be paid, delayed, partially paid, or denied. We do not know whether our TPAs would be able to report the information needed to track 340B savings accurately under that structure. The result would be continuous backtracking and adjustment.

IV. Data Collection, Reporting, and Privacy Concerns

Scripps Health currently collects and maintains the data necessary to administer its 340B Program under the existing framework. Those processes support compliance, inventory management, and current program operations. They were not designed for a manufacturer-

specific rebate claims system.

A rebate program would materially change our data collection and reporting obligations. It would require us to extract and reconcile data from multiple internal and external systems and manually assemble submission files in ways that are not part of our current 340B processes.

It also raises significant privacy concerns. The data elements required for pharmacy rebate claims would transmit protected health information through the switch to manufacturers. That is not information currently visible to them. Likewise, Scripps Health does not currently provide medical claim field data to manufacturers. Under a rebate model, we would need to build a new report to extract the necessary medical claims data and manually upload it.

This is not comparable to current payer billing. Claims submitted to payers are designed to obtain reimbursement for covered services. A rebate model would instead require post-sale submission of additional pharmacy and medical claims data to manufacturers or their platforms to establish entitlement to statutory pricing after purchase at a higher acquisition cost.

The resulting burden would include:

- identifying additional required data elements;
- extracting data from multiple sources;
- manually preparing and uploading files;
- validating data completeness and accuracy;
- maintaining supporting documentation for disputes and audits; and
- managing privacy and security obligations associated with transmitting PHI to new entities.

These are significant new burdens, not merely extensions of current operations.

V. Payment Timing and Cash-Flow Impact

The existing upfront discount model allows Scripps Health to purchase covered drugs at the 340B price at the point of sale. A rebate model would reverse that process and require Scripps Health to purchase affected drugs at WAC and await later reimbursement from manufacturers. In practical terms, that would force covered entities to extend manufacturers an interest-free loan.

For Scripps Health, implementation of a rebate model for the first 25 drugs would mean potentially floating approximately $14 million annually to manufacturers. That estimate was calculated as the sum of WAC minus the 340B price, multiplied by expected annual units for each of the 25 drugs. In other words, Scripps Health would be advancing roughly $14 million per year representing statutory 340B savings while waiting for rebate payment—and that assumes the rebates are not denied. This cost would also be expected to increase annually as the number of drugs included in the program grows.

Nor would a nominal 10-day payment window solve the problem. Claims will not necessarily be submitted immediately after dispense or administration. Depending on the operational workflow required to prepare, validate, and submit data, the float period could approach two months before

rebate payment is received. The true burden therefore extends well beyond the stated payment period.

Payment timing would not change for our primary wholesaler. Scripps Health would still have to pay for product under existing wholesaler terms, but under a rebate model we would no longer receive the statutory discount at the point of purchase. The result is a substantial working-capital burden that does not exist under the current framework.

The Medicaid billing issues described above would compound these concerns. If claims must be held until rebates are received, Scripps Health may be furnishing services and dispensing medications without timely reimbursement. If claims are billed at 340B pricing before rebate receipt and the rebate is later denied, the claim may need to be rebilled at WAC or the loss absorbed.

VI. Impact on 340B Savings and Patient Care

These additional costs and burdens would reduce the practical value of the 340B Program for Scripps Health. Dollars spent on an additional 340B Analyst, IT development, vendor support, TPA implementation and maintenance, accounts receivable follow-up, denial management, audit support, rebilling activity, and the working-capital burden of floating millions of dollars in drug costs are dollars unavailable for patient care and community benefit.

The rebate model would therefore do more than change the timing of discounts. It would redirect scarce resources away from the very services the 340B Program is intended to support.

VII. Reliance Interests

The RFI asks whether covered entities have reliance interests in continuing to receive 340B ceiling prices through upfront discounts and whether those interests are reasonable given the Secretary's statutory authority to provide for "rebate or discount." They are.

The existence of statutory authority to adopt either mechanism does not mean covered entities should have expected the government to abandon a decades-long, uniform operational model without compelling justification. Scripps Health reasonably relied on the longstanding upfront discount structure in designing its staffing, purchasing processes, financial planning, vendor relationships, EHR pricing workflows, and compliance and reporting operations.

A shift to a rebate model would disrupt those settled arrangements and require substantial changes in staffing, systems, contracting, and administration, all without any demonstrated need to replace the existing framework.

VIII. Problems with the Beacon IT Platform

If HRSA considers using Beacon or any similar third-party platform in connection with a rebate model, it should proceed with caution.

As noted above, the proposed process would require Scripps Health to manually run reports and

upload claims data into Beacon unless and until a much more extensive automated interface could be developed. In addition, when Scripps Health sought clarification from Beacon regarding required data fields, we did not receive clear answers, which created the impression that the platform itself did not have definitive guidance on the submission requirements. That lack of clarity is especially problematic where rebate payment may turn on whether a submission is deemed complete.

Scripps Health also identified serious concerns with Beacon's contractual terms.

First, **Section 6(c)** limits Beacon's liability to **$1,000**. That might be less concerning if Beacon's indemnification obligations were expressly carved out from the cap, but they are not. As a result, the indemnification provision in **Section 7(b)** offers limited practical protection unless Scripps Health could establish gross negligence or willful misconduct. If a security breach on Beacon's end resulted in a disclosure of our data and Beacon's conduct were merely negligent, Beacon could likely avoid meaningful liability while Scripps Health remained exposed. By contrast, Scripps Health's liability to Beacon is not similarly capped.

Second, **Section 10** applies Illinois law and requires litigation in Illinois. It also requires users to waive any right to participate in a class action or otherwise proceed jointly with other plaintiffs. Those provisions materially restrict the practical ability of covered entities to seek recourse.

Third, **Section 11(f)** allows Beacon to amend its terms and conditions at any time by posting revised terms on its website, without direct notice. Continued use of the platform is deemed acceptance. That is not a reasonable arrangement for covered entities participating in a highly regulated federal program and handling sensitive data.

Additional concerns include:

- **Section 4(d)**, which allows Beacon to identify alleged noncompliance and require correction within **five days**, an unreasonably short cure period;
- **Section 9(c)**, which appears to omit important provisions that should survive termination, including indemnification; and
- **Section 11(d)**, which requires confidentiality but omits a standard exception for disclosures compelled by law, subpoena, or legal process.

Beacon's contract is offered on a take-it-or-leave-it basis. There is no opportunity to negotiate these terms. Any platform used in a rebate model should be required to provide stable and transparent submission requirements, reasonable contractual protections, meaningful liability for privacy and security failures, clear standards for denials, effective dispute resolution, and strong customer support. HRSA should not move forward with any platform that does not provide these safeguards.

IX. 340B/MDPNP Duplicate Discount Issues

Scripps Health agrees that duplicate discount concerns should be addressed in a lawful and workable manner. But a 340B rebate model is not the right solution.

Scripps Health has experienced issues with 340B/MDPNP deduplication since January 1, 2026. Those issues demonstrate that the operational challenges are real, but they do not support layering a separate 340B rebate mechanism on top of the Medicare Maximum Fair Price framework. Adding an additional 340B rebate to fix MFP rebate duplication is not the answer.

A second rebate process would not eliminate the underlying complexity. It would add another layer of data submission, tracking, reconciliation, denial management, repayment risk, and financial exposure, while still requiring covered entities to purchase drugs at higher upfront cost and wait for funds they are already statutorily owed.

In our experience, the existing deduplication issues are already difficult to administer. Superimposing a separate 340B rebate structure would make the process more complex, more costly, and more susceptible to errors and disputes. Rather than shifting the burden of solving these issues onto covered entities, HRSA should pursue less burdensome alternatives, including a neutral third-party clearinghouse or another standardized mechanism that addresses deduplication without undermining the fundamental structure and value of the 340B Program.

If HRSA rejects that approach, it should provide a reasoned explanation for why a clearinghouse or similar alternative is not viable or less burdensome than a rebate mechanism.

Conclusion

For all of these reasons, Scripps Health respectfully submits that the costs and burdens of any 340B Rebate Model Pilot Program outweigh any expected benefits. HRSA should therefore abandon the rebate concept and instead pursue a neutral, third-party clearinghouse or another less burdensome approach.

If HRSA nevertheless proceeds, it should provide covered entities with a meaningful opportunity to comment on the specific features of any proposed program. At present, key details remain unknown, including the drugs included, required data fields, completeness standards, payment mechanics, permissible grounds for denial, dispute resolution procedures, platform requirements, and privacy and security guardrails. Without those details, covered entities cannot fully assess the program's impact or provide complete comment.

We appreciate your consideration of these comments and welcome the opportunity to engage further on this important issue.

Sincerely,

Ghazala Q Sharieff, M.D.
Corporate Executive Vice President
Chief Medical and Operations Officer, Acute Care
Scripps Health

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

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

Dear Administrator Engels:

On behalf of National Jewish Health (NJH) in Denver, Colorado, we appreciate the opportunity to comment on the Department of Health and Human Services' Request for Information regarding the proposed 340B Rebate Model Pilot Program.

National Jewish Health is a small specialty hospital focused on the treatment of respiratory, cardiovascular, rheumatologic, autoimmune, and immunologic diseases. We serve patients from across the country, many of whom have complex, chronic conditions. Our care is primarily delivered in the outpatient setting, with the goal of preventing hospitalizations whenever possible. We treat all patients regardless of payer mix and operate on extremely thin margins, without the benefit of significant cash reserves. Many of our programs rely on uncompensated support from nurses, social workers, and care managers—services that are rarely reimbursed in outpatient care.

The 340B program is critical to sustaining these services. The proposed shift from an upfront discount model to a rebate model would fundamentally undermine our ability to operate and care for patients.

We have based our analysis on direct experience with existing rebate processes, including those associated with the Medicare Drug Price Negotiation Program. Based on this experience, we can state clearly: the rebate model does not function effectively today at small scale and would be unworkable if expanded across the 340B program. This proposal would not merely add complexity—it would overwhelm pharmacy operations, divert clinical resources, and materially impair patient care.

The current rebate infrastructure is fragmented, manual, and inefficient. Staff must navigate multiple disconnected systems (e.g., MTF, Beacon, ESP) to track a single claim. Even within today's limited rebate environment, we routinely encounter conflicting claim data that must be manually corrected. While providers like NJH maintain complete patient insurance information and have implemented safeguards to prevent duplicate discounts, manufacturers lack reliable mechanisms to accurately identify 340B claims.

As a result, every claim must be manually reviewed to ensure proper classification. Errors are common in both directions—manufacturers issue rebates on ineligible claims and fail to issue rebates on eligible ones. NJH is then required to identify and reverse incorrect payments. While manufacturers can quickly recoup funds, providers are forced into lengthy Good Faith Inquiry (GFI) processes that often take two to three months or longer and may not result in resolution.

In a sample of 36 prescriptions, 6 were incorrectly rebated despite being 340B-eligible, while other eligible claims remained misclassified and unresolved. This is not a system that can be optimized; it is a system that does not function reliably.

Rebate timelines further compound these issues. Rebates are never issued within 10 days; claims are not even eligible for evaluation for at least that long, and resolution frequently takes months. Disputes are frequent, repetitive, and often reset or disappear without explanation. In our small sample, staff spent more than 20 hours resolving issues, approximately one hour for every two prescriptions.

Scaling this across our operations illustrates the magnitude of the burden. NJH processed more than 6,750 prescriptions for the 25 drugs identified for the program through 2027. With refills, this equates to approximately 22,000 transactions annually requiring rebate adjudication (excluding Medicaid and unaffiliated pharmacies). At current efficiency levels, this would require approximately 11,000 staff hours annually—equivalent to five full-time employees. Even assuming substantial process improvements, we estimate a minimum of three full-time staff dedicated solely to rebate management.

These are not administrative roles; they require pharmacists and other healthcare professionals, diverting them from direct patient care to perform manual, repetitive reconciliation work. In addition, at least one full-time accounting resource would be required to reconcile invoices, payments, and rebate activity.

National Jewish Health operates on margins below 2 percent. The incremental staffing and system costs associated with a rebate model are estimated at no less than $824,045 annually, excluding financing costs related to delayed cash flow. In many years, this would eliminate our entire operating margin. These costs cannot be absorbed without negatively impacting patient care.

NJH takes its compliance responsibilities seriously and has implemented rigorous safeguards to prevent duplicate discounts, including:

- Use of Submission Clarification Codes (420-DK and 423-DN) to identify 340B claims with Colorado Medicaid

- Third-party administrator validation of every prescription prior to 340B accumulation
- A closed-door pharmacy model, limiting dispensing to NJH patients and employees
- Monthly audits of all 340B activity, with immediate investigation and correction of discrepancies

The proposed rebate model disregards these safeguards and replaces them with an error-prone, externally driven process.

In addition, the rebate model would significantly strain cash flow. NJH would be required to purchase drugs at full price while waiting months for reimbursement. At the same time, we already experience payment delays from payers ranging from 45 to 180 days and provide care to patients whose coverage does not meet the cost of care. Pharmaceutical distributor invoices must often be paid within 15 days to avoid penalties.

Even under a limited implementation involving only 25 drugs, we would likely need to draw on lines of credit to cover routine expenses. For providers operating on thin margins in an already inefficient system, absorbing additional cash flow delays is not feasible. Shifting financial burden from manufacturers and insurers—entities with significantly greater margins and liquidity—to safety-net providers is inequitable and unsustainable.

For these reasons, we strongly urge HRSA to reject a rebate-based approach and maintain the current upfront discount structure, which has provided stability and predictability for more than 30 years.

If changes are deemed necessary, we recommend an alternative approach in which providers continue to purchase drugs at discounted prices but reconcile and remit payments for ineligible claims within a defined timeframe (e.g., 10 days). While not without challenges, this approach would better align cash flow and reduce operational risk without jeopardizing the financial viability of providers like NJH.

Thank you for your consideration of our comments.

Sincerely,

Christine Forkner

Executive Vice President of Corporate Affairs & Chief Financial Officer

National Jewish Health

SUNSET HEALTH

April 17, 2025

Chantelle Britton
Director
Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
Rockville, Maryland 20857

RE: Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906-NEW

Submitted via paperwork@hrsa.gov

Dear Director Britton:

On behalf of **Sunset Community Health Center,** I would like to thank the Health Resources and Services Administration (HRSA) for providing the opportunity to **share our estimated burden with HRSA on compliance with the 340B rebate model pilot program. Given the severe administrative, financial, and operational burden a rebate model would place on CHCs, Sunset Community Health Center again requests that CHCs be exempted from the pilot program.**

Sunset Community Health Center is a non-profit, Federally Qualified Health Center (FQHC) located in Yuma, Arizona. As a FQHC, Sunset Community Health Center is community-driven and provides high-quality, comprehensive primary and preventive care to all people, regardless of their ability to pay. Sunset Community Health Center continues to serve as a critical resource within the rural healthcare safety net.

The 340B program is foundational to CHC's ability to serve the most vulnerable members of our community. However, the proposed shift of responsibility from manufacturers to safety-net providers directly serving patients through a rebate model threatens to destabilize CHC pharmacy operations nationwide. Based on national assessments from the National Association of Community Health Centers (NACHC) and our own internal assessments, the hours and dollars spent complying with a rebate program are staggering.

I. We Request HRSA Exempt CHCs from the 340B Rebate Model Pilot Program Due to Significant Financial and Administrative Burden

By requiring CHCs to purchase medications at full price and wait for rebates, this model would cause significant financial turmoil and directly affect our ability to serve the **28,229** patients who rely on us. We operate on razor-thin margins, and these additional costs are not an option for many entities. Similar to navigating manufacturers' existing contract pharmacy restrictions, CHCs will need to invest in IT infrastructure upgrades and hire or reassign staff to manage new complexities,

including varying data submission requirements and timelines, payment reconciliations, and dispute processes for denied rebates. We will face an increased administrative burden in monitoring rebate claims and payments.

To support CHCs in assessing the financial and operational impact of current manufacturer restrictions and an anticipated rebate model, NACHC worked with their consultant, FQHC 340B Compliance, to create an Operational & Administrative Cost Calculator.[1] The tool aggregates program savings, UDS financial data, staffing, external consulting costs, dispensing/capture activity, and clinic-administered drug tracking models to support cost forecasting. CHCs have already experienced steep increases in operational costs given the multitude of manufacturer restrictions, including requirements for clinic-administered drugs and entity-owned pharmacies. A rebate model will require a significant increase in already-strained operational capabilities.

Workforce Impact:

- **Staffing Impact**: **Sunset Community Health Center** anticipates needing an additional **0.5 FTE** to account for the increase in operational, administrative, and compliance burden created by a rebate model.
- **Number of Hours:** Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, **Sunset Community Health Center** will face an increased administrative burden to monitor rebate claims and payments. It is estimated that **20 hours a week** will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: **Sunset Community Health Center** anticipates an additional **$5,000** for external vendors, including consultants, legal counsel, program coordination, third-party administrators (TPAs), electronic medical records (EMRs), pharmacy software, and reconciliation services.

Pharmacy Software & Third-Party Administration Changes

Navigating this pilot requires both staff and changes to workflow and software. HRSA should consider the increased compliance burdens when manufacturers have the flexibility to require varying data submission standards and elements. Additionally, if manufacturers can select different software platforms, like current contract pharmacy policies, CHC administrative burden would increase substantially.

- **One-Time Implementation Costs:** We anticipate high upfront costs to adapt our pharmacy software, pay for custom dashboard modifications, and design new internal workflows. **Approximately $30,000** will be required simply to reach the baseline of compliance before a single rebate is ever received.
- **Ongoing Operational Fees**: Beyond implementation, our TPA and software vendors will likely charge ongoing service fees to maintain these complex rebate-tracking features. These are permanent, recurring costs that diminish our 340B savings.
- **Total Cost:** For our CHC, which serves 28,229 patients, the total projected increase in expenses—including labor, IT, and carrying costs—is estimated at $10,000 annually.

The In-House Pharmacy: The Burden of IT Integration

[1] https://www.nachc.org/policy-advocacy/policy-priorities/340b-drug-pricing-program/340b-rebate-model-pilot-program/

Sunset Community Health Center operates a total of 4 in-house pharmacies. The rebate model is not a simple accounting change; it is a significant technological disruption. To remain compliant, in-house pharmacy systems will require costly customization to provide real-time, accurate information at the pharmacy counter.

- **System Interoperability:** Unlike contract pharmacies that use TPAs, in-house pharmacies must directly integrate their Electronic Health Record (EHR) and Pharmacy Management System (PMS) with a complex new rebate infrastructure. **The feasibility of pharmacy management systems to be able to accommodate a rebate model is challenging as they are less customizable. The systems receive pricing reports directly from the wholesaler. This would update all of our drug costs to WAC pricing, impacting our Medicaid billing process and Sliding Fee Scale Program, as that is based on acquisition cost.**
- **One-Time Integration Costs:** We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools.
- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend **20** hours per week manually pulling "Purchase Files" and "Price Files" to verify that every rebate check matches the statutory 340B price.

The Contract Pharmacy: The Burden of Network Coordination

The rebate model introduces a new complexity that threatens the existence of contractual arrangements. My CHC currently partners with 66 pharmacies to increase access to affordable medications.

- **TPA Reliance and Fees:** Navigating manufacturers' varying requirements across multiple contract pharmacies requires high-level TPA intervention. We anticipate that our TPAs will pass on the costs of developing rebate-tracking modules to us through increased per-claim fees.
- **Verification Latency:** The rebate model creates a reconciliation gap. Our staff must monitor claims across **sixty-six** different pharmacy locations to ensure rebates are paid correctly.
- **Risk of Pharmacy Exodus:** The model shifts financial risk to the pharmacy, potentially causing contract partners to opt out of the 340B program entirely rather than manage the administrative headache. In **Yuma County,** this would leave patients with no affordable medication options. Over 17 percent of the U.S. population already lives in a pharmacy desert.[2]

Clinic Administered Drugs: The Burden of New Systems Required

Clinic-administered drug (CAD) operations and record-keeping in CHCs are designed cost-effectively to reflect the nuances of CHC billing. Implementing a rebate model for CADs would also require new software, system integration, and staff training. NACHC estimates these costs would range from $30,000 to $50,000 annually and could be much higher, depending on the software.[3]

Most CADs are bundled into the prospective payment system (PPS) billing when administered to patients by CHCs. Because PPS visits are paid at a flat rate, the medications administered in CHCs are often not included on claims billed to payers. CHCs maintain limited inventories of CADs and typically do not separately bill on claims. Administration and inventory logs are commonly maintained on paper, with text documentation in patient visit notes describing what was

[2] Vulnerability Index Approach to Identify Pharmacy Deserts and Keystone Pharmacies | Pharmacy and Clinical Pharmacology | JAMA Network Open | JAMA Network

[3] Internal NACHC survey data

administered. While CHCs maintain perpetual inventories and complete administrative records, paper records impose an additional burden of converting them to electronic data before submitting for rebate. Very few CHC records include electronic medication administration records (eMARs), which are common in hospital EMRs. Where eMARs are available, they incur an additional cost and often require CHCs to pay for a standalone software system.

II. Patient Impact

Sunset Community Health Center has significant concerns about the impact a 340B Rebate Model Pilot would have on our most vulnerable patients' access to life-saving medications. The majority of drugs selected for the MDPNP for 2026 and 2027, and included in the proposed rebate model, manage chronic conditions prevalent in primary care settings. CHCs serve a patient population with a higher burden of chronic conditions compared to private practices, with studies showing a significantly higher prevalence of illnesses like diabetes, hypertension, and obesity.[4] This patient population relies on affordable medications to manage these long-term conditions.

The impact on insulin access is also alarming and directly conflicts with federal requirements. With over 3 million Americans relying on CHCs for essential diabetes care,[5] insulin affordability is a matter of life and death. Furthermore, Executive Order #14273 conditions future Section 330(e) funds on CHCs providing low-income patients with access to discounted insulin. No current operational method exists to provide discounted medications in a rebate model. In the proposed model, the wholesaler price file would reflect the full Wholesale Acquisition Cost (WAC) rather than the discounted 340B price, making the price unattainable for patients and precluding CHCs from fulfilling their legal obligation to offer the required discount at the point of care.

III. Financial Challenges

Lack of access to upfront 340B discounts, along with the high IT/infrastructure costs, will disproportionately impact CHCs and trickle down to patients. Many CHCs are currently under financial strain, with nearly half operating with fewer than 90 days of cash on hand, and one in four reporting negative five percent operating margins. This rebate model creates significant financial challenges, including:

- **Purchasing Drugs at the WAC Price Upfront:** Under the proposed model, CHCs would be required to purchase drugs at the WAC. CHCs will have to wait to receive their rebate payment *after* providing medications to their patients, forcing difficult decisions about how to allocate limited financial resources, including cutting essential services and reducing operating hours. We are particularly worried that the need to purchase drugs at full WAC will cause cash flow issues and potentially lead CHCs to exceed credit limits with wholesalers, halting their ability to order medications until payments are submitted.
- **Sliding Fee Scale:** A rebate model creates substantial uncertainty about CHCs' ability to apply sliding-fee discounts at the point of sale. By statute and regulation, CHCs are required to offer sliding fee discounts for all required and additional health services within the HRSA-approved scope of project.[6] In line with their mission, CHCs offer flat or sliding-

[4] Richard P, Ku L, Dor A, Tan E, Shin P, Rosenbaum S. Cost savings associated with the use of community health centers. J Ambul Care Manage. 2012 Jan-Mar;35(1):50-9. doi: 10.1097/JAC.0b013e31823d27b6. PMID: 22156955.
[5] 2025 UDA Data, HRSA (hrsa.gov)
[6] HRSA FAQ

scale discounts on prescription drugs to make them more affordable for low-income individuals.[7] A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size. Sunset Community Health Center makes drugs affordable for patients by offering a sliding fee scale program that is income based. This program alleviates the financial burden that many of our patient population faces.

Conclusion

Sunset Community Health Center strongly urges HRSA to exempt CHCs from any 340B Rebate Model Pilot Program. A 340B rebate program represents a departure from the original intent of the 340B program—to allow safety-net providers to "stretch scarce Federal resources" and provide more comprehensive care. A rebate model would create significant cash flow challenges, forcing CHCs to make difficult decisions about staffing, services, and the range of drugs they can afford to stock. Additionally, CHCs would need to make significant investments in IT infrastructure and staff to comply with rebate requirements and track rebates. It would also create a new barrier for patients, especially uninsured patients, who depend on the up-front 340B discount, making it operationally impossible to provide the sliding fee scale and steeply discounted medications required by law. **Sunset Community Health Center** believes that a 340B rebate pilot would cause disproportionate harm to patients served by CHCs and other safety net providers.

Sunset Community Health Center appreciates the opportunity to respond to this ICR on the 340B Rebate Model Pilot Program, and we look forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please contact Jacey Sims, PharmD at jasims@mysunsethealth.org.

Sincerely,

Jonathan Leonard, MPA
Chief Executive Officer
Sunset Community Health Center

[7] Such discounts are subject to potential legal and contractual restrictions. https://bphc.hrsa.gov/compliance/compliance-manual/chapter9#footnote10

Bucksport Regional
Health Center

April 17, 2026

Chantelle Britton
Director
Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
Rockville, Maryland 20857

RE: Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042)

Dear Director Britton:

On behalf of Bucksport Regional Health Center, I would like to thank the Health Resources and Services Administration (HRSA) for extending the comment deadline to April 20, 2026. This extension has been vital in enabling our organization to conduct a deep-dive analysis of the operational and financial risks to CHCs posed by the proposed rebate model. The 340B program is foundational to CHC's ability to serve the most vulnerable members of our community. However, the proposed shift of responsibility from manufacturers to safety-net providers directly serving patients through a rebate model threatens to destabilize CHC pharmacy operations nationwide. Based on national assessments from NACHC, we know that CHCs are facing staggering impacts:

- **Financial Losses:** Bucksport Regional Health Center anticipates a loss of **$782,094** from entity-owned pharmacy operations and contract pharmacy arrangements due to the administrative hurdles of manual reconciliation and implementation of the 340B rebate model.
- **Projected Cost Increases:** CHCs anticipate significant increases in operational costs. National data shows that a single mid-sized CHC expects to incur over $3 million in additional costs **annually** to manage the pilot.
    - **Rural Health Center Breakdown:** For rural CHCs, these costs are even more devastating. Rural centers invest nearly **one-quarter (25%)** of their 340B savings in rural-specific infrastructure, such as mobile clinics and telehealth.

- BRHC is a federally qualified health center that has been serving the Hancock, Penobscot and Waldo County Maine for 52 years. We serve 9,000 residents with 2 primary sites and 5 school-based health services. We provide primary care, behavioral health, dental, laboratory, x-ray and pharmacy services through our organization.

The Health Center uses 340B savings solely to **stretch federal resources**, allowing us to **maintain and expand access to comprehensive, high-quality care for underserved patients**, consistent with HRSA guidance. The Program enables us to serve uninsured and underinsured individuals, reduce financial barriers to medications, and support clinical services that would otherwise be financially unsustainable.

I. We Strongly Urge HRSA To Exempt CHCs from the 340B Rebate Model Pilot Program.

The proposed 340B Rebate Model Pilot Program is a direct threat to CHCs' core mission and a significant departure from the original purpose of the 340B Drug Pricing Program. For over three decades, the 340B program has enabled CHCs to purchase outpatient medications at significantly reduced prices, enabling them to provide affordable and sometimes free medications to millions of low-income and uninsured patients. As congressional intent made clear, the program was created to help safety-net providers "stretch scarce Federal resources as far as possible." The proposed rebate model undermines this by placing an immense financial burden on CHCs.

By requiring CHCs to purchase medications at full price and wait for rebates, this model would cause significant financial turmoil and directly affect CHCs' ability to serve the 52 million patients who rely on us. **For Bucksport Regional Health Center in particular, this means it will impact:**

- **8753 patients**
- **Current admin costs for our 340B program**
- **How do you use your 340B revenue specifically?** Savings generated through the 340B Program are reinvested to directly benefit Health Center patients, including but not limited to:
- Sliding fee discounts for care and medications
- Expansion of clinical services (medical, behavioral health, dental, and preventive care) including a health educator
- Support for care coordination, pharmacy services, and chronic disease management,
- Outreach services for vulnerable populations paying for our community health worker, food gleaning program, food pantry program, and clothes closet for those in need. We also use the funds to upgrade of exam room tables and cabinets in our Bucksport clinic.

We strongly urge HRSA to exempt CHCs from any rebate model to protect the financial stability of safety-net providers and ensure continued access to care for the most vulnerable patients.

II. Patient Impact

Most importantly, a 340B rebate model poses a direct and serious threat to medication access for the vulnerable patients that CHCs serve. For uninsured and underinsured patients who rely on the affordability that the 340B program provides, this model could render critical medications financially out of reach. Patients may be forced to make tough decisions in transitioning to other medications, due to cost or lack of availability, as a direct result of a 340B rebate pilot program. These forced therapeutic interchanges introduce real clinical risk, including medication nonadherence, treatment delays, and adverse outcomes, particularly for patients managing multiple chronic conditions who have limited alternatives and no other pharmacies close by.

We have significant concerns about the impact a 340B Rebate Model Pilot would have on our most vulnerable patients' access to life-saving medications. The majority of drugs selected for the MDPNP for 2026 and 2027, and included in the proposed rebate model, are used to manage chronic conditions prevalent in primary care settings, meaning CHC patients will be disproportionately affected. CHCs serve a patient population with a **higher burden of chronic conditions** compared to private practices, with studies showing a significantly higher prevalence of illnesses like diabetes, hypertension, and obesity.[1] This patient population relies on affordable medications to manage these long-term conditions.

We are deeply concerned that implementing a rebate model would cause CHC patients to lose access to essential, life-sustaining therapies. For instance, **direct oral anticoagulants (DOACs)** such as Xarelto® and Eliquis® are vital for patients with deep vein thrombosis, pulmonary embolism, and atrial fibrillation. For many of our patients, there are minimal – and often less safe – alternatives. This is not an optional therapy but a critical tool for survival, as one study showed that discontinuing these drugs leads to a statistically significant increase in the risk of stroke, heart attack, and death.[2]

Similarly, the impact on patients requiring **SGLT2 inhibitors**, such as Farxiga® and Jardiance®, would be severe. These drugs are a mainstay of primary care for conditions like Type 2 Diabetes, chronic kidney disease, and heart failure, all of which are highly prevalent among our patients. Research has found that even a 30-day withdrawal of these inhibitors increases the annualized risk of cardiovascular death or heart failure hospitalization.[3] By making these drugs unaffordable, the rebate model would effectively deny our patients access to the most effective therapies for managing their chronic illnesses, leading to a predictable increase in preventable hospitalizations.

The United States is in the midst of an alarming mental health crisis. Nearly one in four (23.4%) Americans live with a mental illness.[4] Starting in 2027, the MDPNP will include some behavioral

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[1] Richard P, Ku L, Dor A, Tan E, Shin P, Rosenbaum S. Cost savings associated with the use of community health centers. J Ambul Care Manage. 2012 Jan-Mar;35(1):50-9. doi: 10.1097/JAC.0b013e31823d27b6. PMID: 22156955.

[2] Cools F, et al. Risks associated with discontinuation of oral anticoagulation in newly diagnosed patients with atrial fibrillation: Results from the GARFIELD-AF Registry. J Thromb Haemost. 2021 Sep;19(9):2322-2334. doi: 10.1111/jth.15415. Epub 2021 Jul 23. PMID: 34060704; PMCID: PMC8390436.

[3] Packer, M., et al. (2024). Blinded Withdrawal of Long-Term Randomized Treatment with Empagliflozin or Placebo in Patients with Heart Failure. Circulation. https://www.ahajournals.org/doi/pdf/10.1161/circulationaha.123.065748

[4] Substance Abuse and Mental Health Services Administration. (2025). Key substance use and mental health indicators in the United States: Results from the 2024 National Survey on Drug Use and Health (HHS Publication No. PEP25-07-007, NSDUH

health drugs. Vraylar ® is an atypical antipsychotic; atypical antipsychotics are the mainstay of treatment for Schizophrenia. A rebate model could create regulatory barriers for CHCs seeking to provide this drug to uninsured and underinsured patients. Additionally, the 2027 list includes Austedo®, a drug used to treat Tardive Dyskinesia, a common side effect of antipsychotics. Studies have shown that 73% of patients treated with Austedo® achieved treatment success, resulting in improved quality of life.[5] Impairing access to these drugs could result in exacerbation of the mental health crisis.

The impact on **insulin access** is particularly alarming and directly conflicts with federal requirements. With over 3 million Americans relying on CHCs for essential diabetes care,[6] affordability of insulin is a matter of life and death. Furthermore, **Executive Order #14273 conditions future Section 330(e) funds on CHCs providing low-income patients with access to discounted insulin**. There is currently no operational method to provide these discounted medications in a retrospective rebate model. In the proposed model, the wholesaler price file would reflect the full WAC rather than the discounted 340B price. This makes the price unattainable for the patient and **precludes CHCs from fulfilling their legal obligation to offer the required discount at the point of care**.

Imposing a rebate model on CHCs would only weaken the safety-net providers that 52 million Americans rely on for health care. CHCs are required to provide sliding fee discounts to patients with incomes at or below 200% of the federal poverty guidelines. The same patients who need access to discounted medical services also depend on CHCs to provide affordable medications. Without the up-front 340B discount, the drugs included in the pilot would become operationally impossible. **This model would create a new and significant barrier, rather than a solution, for our most vulnerable patients, especially those who are uninsured and have limited options for affordable care.**

III. Administrative Complexities and Financial Challenges for CHCs

The proposed 340B Rebate Model Pilot Program is not only a financial threat to CHCs but also a duplicative and unnecessary administrative burden. HRSA should exempt CHCs from the 340B Rebate Model Pilot because they will incur additional workforce and IT costs to comply with multiple manufacturer rebate requirements. A recent NACHC assessment illustrates that CHCs will incur additional workforce and IT costs to maintain compliance with multiple manufacturer rebate requirements, increasing the burden associated with this rebate pilot program. Similar to navigating manufacturers' existing contract pharmacy restrictions, CHCs will need to invest in IT infrastructure upgrades and hire or reassign staff to manage new complexities, including varying data submission requirements and timelines, payment reconciliations, and dispute processes for denied rebates. Depending on the volume of prescriptions a pharmacy fills for the selected drugs, CHCs will face an increased administrative burden in monitoring rebate claims and payments.

Series H-60). Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. https://www.samhsa.gov/data/data-we-collect/nsduh-national-survey-drug-use-and-health/national-releases

[5] Hauser RA, et al. Long-Term Deutetrabenazine Treatment for Tardive Dyskinesia Is Associated With Sustained Benefits and Safety: A 3-Year, Open-Label Extension Study. Front Neurol. 2022 Feb 23;13:773999. doi: 10.3389/fneur.2022.773999. PMID: 35280262; PMCID: PMC8906841.

[6] 2025 UDA Data, HRSA (hrsa.gov)

340B Rebate Model Operational & Administrative Cost Calculator Description

To support CHCs in assessing the **financial and operational impact** of current manufacturer restrictions and an anticipated rebate model, NACHC worked with their consultant, FQHC 340B Compliance, to create an **Operational & Administrative Cost Calculator.** The tool aggregates program savings, UDS financial data, staffing, external consulting costs, dispensing/capture activity, and clinic-administered drug tracking models to support operational cost forecasting.
CHCs have already experienced steep increases in operational costs given the multitude of manufacturer restrictions, which have now been extended to clinic-administered drugs and entity-owned pharmacies. A refund model will require a significant increase in already-strained operational capabilities.

- **Sliding Fee Discount**: Bucksport Regional Health Center provided $50,505 in 2025 sliding fee discounts, provided through discounted medications and medical services. We anticipate that our ability to offer sliding fee discounts will decrease significantly under a rebate model.
- **Staffing Impact**: **BUCKSPORT REGIONAL HEALTH CENTER** anticipates needing **2.25** additional FTEs to account for the increase in regulatory, operational, administrative, and compliance burden created by a rebate model.
- **External Vendor Costs**: Given increased complexity, **BUCKSPORT REGIONAL HEALTH CENTER** anticipates an increase of **$95,446** to costs for external support vendors. These vendors may include 340B consultants, legal counsel, program coordination, third-party administrators, electronic medical records, pharmacy software, and reconciliation services.

Workforce Impact

Below is specific data on the administrative costs that CHCs anticipate, based on thorough planning, review of current business practices, and the costs of implementing new systems and processes.

- 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.[7] **BRHC estimates that we would need to add 1 FTE 340B Compliance Staff, .75 Finance Staff and .5 pharmacy staff as a result of the rebate model.**
- Additionally, several CHCs estimate the cost to hire additional staff to be between $30,000 to $200,000 annually.[8] One midwestern CHC, serving approximately 12,000 unique patients last year, anticipates annual costs exceeding $3 million, including upfront costs for purchasing drugs in this pilot program, increased labor costs, carrying costs, and potential losses on discounted or expired drugs without rebate recovery. CHCs operate on razor-thin margins, and these additional costs are not an option for many entities. **The estimated costs to employ these extra staff are $307,580 annually.**
- Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, CHCs will face an increased administrative burden in terms of monitoring rebate claims and payments. **ESTIMATED HOURS TO REPORT CLAIMS of 10 hours weekly** will be required to report 340B rebate claims to a third-party platform, assuming all adhere to the nine drug manufacturers' plans. The lack of standardization and likely varying requirements across

[7] Internal NACHC assessment (99 responses).
[8] Ibid.

manufacturers will force CHCs to use multiple internal systems to manage and report the same data, thereby increasing costs and operational burdens. **Bucksport Regional Health Center urges HRSA to require uniformity among eligible manufacturers to mitigate potential administrative and financial burdens associated with receiving timely and appropriate 340B rebates.**

Pharmacy Software & Third-Party Administration Changes

Navigating this pilot requires more than just staff; it requires significant changes to pharmacy software and Third-Party Administrator (TPA) workflows. We encourage HRSA to consider the increased compliance burdens when manufacturers have the flexibility to require varying data submission standards and elements. Additionally, if manufacturers are allowed to select different software platforms, as they currently do with contract pharmacy policies, the administrative burden on CHCs would increase substantially.

- **One-Time Implementation Costs:** We anticipate high upfront costs to adapt our pharmacy software, pay for custom dashboard modifications, and design new internal workflows. An estimated $50,000 will be required simply to reach the baseline of compliance before a single rebate is ever received.
- **Ongoing Operational Fees**: Beyond implementation, our TPA and software vendors will likely charge ongoing service fees to maintain these complex rebate-tracking features. These are permanent, recurring costs that diminish our 340B savings.
- **Total Cost:** For our CHC, which serves 8,753 patients, the total projected increase in expenses—including labor, IT, and carrying costs—is estimated at $35,384 annually.

The In-House Pharmacy: The Burden of Deep IT Integration

For CHCs that operate their own pharmacies, the rebate model is not a simple accounting change; it is a significant technological disruption. To remain compliant, in-house pharmacy systems will require costly customization to provide real-time, accurate information at the pharmacy counter.

- **System Interoperability:** Unlike contract pharmacies that use Third-Party Administrators (TPAs), in-house pharmacies must directly integrate their Electronic Health Record (EHR) and Pharmacy Management System (PMS) with a complex new rebate infrastructure. BRHC hires an pharmacy vendor to manage our program and anticipate an increase in administrative costs if the rebate program is implemented for community health centers.
- **One-Time Integration Costs:** We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools. **We estimate this cost at $75,000.**
- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services and/or additional staff that will need to be hired will be forced to spend at a minimum **ten (10)** hours per week manually pulling "Purchase Files" and "Price Files" to verify that every rebate check matches the statutory 340B price.

The Contract Pharmacy: The Burden of Network Coordination

For CHC contract pharmacy partners, the rebate model introduces a new complexity that threatens the very existence of these arrangements. My CHC currently partners with seventeen (17) pharmacies to increase access to affordable medications.

- **TPA Reliance and Fees:** Navigating manufacturers' varying requirements across multiple contract pharmacies requires high-level TPA intervention. We anticipate that our TPAs will pass on the costs of developing rebate-tracking modules to us through increased per-claim fees.

- **Verification Latency:** The rebate model creates a reconciliation gap. Our staff must monitor claims across seventeen (17) different pharmacy locations to ensure rebates are paid correctly.
- **Risk of Pharmacy Exodus:** Because this model shifts the financial risk to the pharmacy, we fear our contract partners will opt out of the 340B program entirely rather than manage the administrative headache. In our region, this would leave patients in **rural Hancock, Penobscot and Waldo County, Maine and the surrounding area** with no affordable medication options. Over 17 percent of the U.S. population lives in a pharmacy desert already,[9] and the closings of pharmacies have only exacerbated this, with nearly 30 percent of pharmacies that had been open from 2010 to 2021 closing by 2021.[10]

Clinic Administered Drugs: The Burden of New Systems Required

Clinic-administered drug (CAD) operations and record-keeping in CHCs are designed in a cost-effective manner that reflects the nuances of CHC billing. Implementing a rebate model for CADs would also require new software, system integration, and staff training. NACHC estimates these costs would range from $30,000 to $50,000 annually and could be much higher, depending on the software.[11]

- **Bundled Payments:** The majority of clinic-administered drugs are bundled into the prospective payment system (PPS) billing when administered to patients by CHCs. Because PPS visits are paid at a flat rate, the medications administered in CHCs are often not included on claims billed to payers.
- **Simplified Records:** Because CHCs maintain limited inventories of CADs and they are typically not separately billed on claims, it is still common for administration and inventory logs to be maintained on paper, with text documentation in patient visit notes describing what was administered. While the CHCs maintain perpetual inventories and complete administrative records, the fact that the records are often paper imposes the added burden of converting them to electronic data before submitting for rebate. Very few CHC records include electronic medication administration records (eMARs), which are common in hospital electronic medical records (EMRs). Where eMARs are available, they incur an additional cost and often require CHC to pay for a standalone software system.
- **Minimal Risk of Duplicate Discounts:** CHCs primarily bill under Medicare Part A, which is not statutorily included in the Medicare Drug Price Negotiation Program (MDPNP). Maximum Fair Prices (MFP) are only applicable to Medicare Part D claims in 2026 & 2027 and then expand to include Medicare Part B claims in 2028. Regarding Medicaid, each state already has mechanisms in place to address duplicate discounts.
- **HRSA should explicitly exclude CADs from any 340B rebate model pilot.** At a minimum, such drugs should remain excluded unless and until they are billed as discrete claims by CHCs and a demonstrated duplicate discount risk exists that cannot be addressed through existing statutory mechanisms. Including CADs in a rebate pilot at this stage would impose disproportionate administrative costs, software expenses, and compliance risks on CHCs without corresponding benefits to program integrity or federal oversight.

A. Financial Challenges

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[9] Vulnerability Index Approach to Identify Pharmacy Deserts and Keystone Pharmacies | Pharmacy and Clinical Pharmacology | JAMA Network Open | JAMA Network

[10] https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2024.00192?journalCode=hlthaff

[11] Internal NACHC survey data

Under the proposed 340B Rebate Model Pilot, CHCs 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 CHCs' ability to purchase drugs, as the uncertainty of waiting for a manufacturer to approve a rebate would constrain cash flow. CHCs will have to wait to receive their rebate payment ***after*** providing medications to their patients. This change will force CHCs to make difficult decisions about how to allocate their limited financial resources, including cutting essential health services, reducing operating hours, or discontinuing services that support patients' health outcomes.

The proposed 340B Rebate Model Pilot would directly impact CHCs' ability to offer patients steeply discounted medications at the point of sale by requiring them to purchase at full WAC pricing upfront. CHCs' pharmacies, as well as entity-owned and contract pharmacies, will not have access to the 340B price when the patient needs medication. This will create a very unpredictable process for determining the level of discount and pricing for a patient's medication, as the 340B price will no longer be reflected in the pharmacy software from the wholesaler's price catalog, since initial purchase prices will be at WAC. The rebate model creates confusion about its impact on a CHC's ability to offer sliding-fee discounts at the point of purchase.

A rebate model also creates substantial uncertainty about CHCs' ability to apply sliding-fee discounts at the point of sale. By statute and regulation, CHCs are required to offer sliding fee discounts for all required and additional health services within the HRSA-approved scope of the project.[12] In line with their mission, CHCs offer flat or sliding-scale discounts on prescription drugs to make them more affordable for low-income individuals.[13] A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size. In addition to sliding fee discounts for income eligible patients, we offer comparison shopping and coupons to our patients at our in-house pharmacy.

CHCs are particularly worried that the need to purchase drugs at full WAC will cause cash flow issues and potentially lead them to exceed their credit limits with wholesalers, halting their ability to order medications until payments are submitted. While rebates are expected to arrive within 10 days from completed data submissions, the previously proposed rebate pilot allowed covered entities up to 45 days to submit data, meaning the potential time from dispense to rebate can extend to 55 days. The financial impact is further compounded when CHCs have entity-owned pharmacies with physical inventories and must stock their shelves with purchases at WAC. Retail pharmacies typically turn their inventory 10-12 times a year (roughly every 30 days).[14] Assuming a best-case scenario of 15 days to the average 30 days for inventory to turn, CHC pharmacies with physical inventory could be waiting 70-85 days from purchase to rebate under a 45-day data submission cadence. Anecdotal reports from CHC pharmacies suggest a planned cadence of 2-week data submissions for entity-owned pharmacy data. Pharmacies with physical

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[12] HRSA FAQ

[13] Such discounts are subject to potential legal and contractual restrictions. https://bphc.hrsa.gov/compliance/compliance-manual/chapter9#footnote10

[14] https://enlivenhealth.co/blog/year-end-business-health-check-key-metrics-every-pharmacy-owner-should-review

inventory submitting data every 14 days would anticipate a purchase-to-rebate payment time frame of 40 to 55 days.

There may be other delays in receiving the full rebate, such as denials, which could create financial strain on CHCs. We appreciate HRSA's requirement for a 10-day timeframe for rebate payments; however, we have concerns about the lack of details regarding enforcement if manufacturers fail to meet this requirement. Based on experience with manufacturer denials related to the current MFP to 340B de-duplication processes, once an entity has contested a denied rebate and the issue is resolved so the CHC can receive the rebate, manufacturers and their vendors have failed to pay the rebate within the MFP standard of 14 days from when the status is corrected. We are concerned that in a 340B rebate pilot, manufacturers and their vendor(s) will continue to provide corrected contested rebates for an undefined and unlimited time. Complicatedly, the rebate amount may not match the initial discount offered to the patient, creating unpredictable financial losses. CHCs must estimate the rebate amount and may undercharge or overcharge patients due to confusion. Furthermore, if the rebate is denied, the CHC takes a net loss on the transaction. **We respectfully request that, if a rebate pilot is implemented, manufacturers be required to pay rebates within 10 days of both initial and corrected determinations.**

Lack of access to upfront 340B discounts, along with the high IT/infrastructure costs, will disproportionately impact CHCs and trickle down to patients. It is important to note that many CHCs are currently under financial strain. Nearly half of CHCs operate with fewer than 90 days of cash on hand, and one in four reports approximately negative five percent (-5%) operating margins. Below, you will find specific data demonstrating the significant increase in financial costs CHCs will incur under a 340B Rebate Model.

340B Rebate Drug Cost Impact Calculator Description

To support CHCs in assessing the financial impact of purchasing drugs at the full WAC price, NACHC worked with its consultant, FQHC 340B Compliance, to create another calculator for all CHCs. Financial data and projections are based on a 340B Rebate Drug Cost Impact Calculator, which utilizes CHC-specific purchasing data, 340B[15] and WAC pricing data for the first quarter of 2026 (Q1 2026), and the CMS list of MDPNP selected drugs by NDC.[16] For individual MDPNP Price Applicability Years, the calculator evaluates:

- **Increase Upfront Annual Drug Spend**: WAC – 340B for 2025 purchases by NDC & volume, reflected in Q1 2026. WAC and 340B prices applied for the overall annual program volume to determine the annual increase in initial drug spend.
- **Cash Flow Impact**: WAC – 340B for 2025 purchases by NDC & volume, reflected in Q1 2026 WAC and 340B prices to give overall annual program increase in initial spend reflected at intervals of 30, 45, 60, & 90 days. Represents potential WAC purchase to 340B rebate payment cycles. Inventory models, frequency of data submission, and manual processes for referral claim capture can all influence Covered Entities' (CEs) intervals between purchasing a drug at WAC and receiving the Manufacturer Rebate to 340B Ceiling Price.

[15] https://340bpricing.hrsa.gov/

[16] https://www.cms.gov/files/zip/selected-drug-list-negotiated-prices-also-known-maximum-fair-prices-statutezip.zip

- **Rebate-Related Opportunity Costs**: Based on percentages of loss of prompt pay, purchase volume, and subceiling discounts and anticipated rebate denials as a portion of annual WAC spend (described above).
- **Increase Upfront Drug Spend** WAC – 340B for 2025 purchases by NDC & volume, reflected in Q1 2026, calculated by NDC, then aggregated at the MDPNP selected drug, manufacturer, and MDPNP Price Applicability Year levels.
- **WAC Purchase to 340B Rebate Payment "Wait" Period:** CHCs must wait to receive a rebate payment after purchasing and dispensing medication to the patient. This delay forces difficult decisions about allocating limited financial resources.

Based on our organization's data, we estimate it would cost **$777,685** to purchase these 10 drugs under the proposed rebate model. Currently, our organization spends **$120,841** to purchase these same drugs at the 340B ceiling price. This represents a **644%** increase in upfront capital required for procurement.

This increase in costs will have a devastating impact on our organization's ability to maintain an adequate supply of the drugs included in the HRSA 340B Rebate Model Pilot. As previously discussed, our CHC is navigating a difficult financial environment that cannot sustain purchasing drugs at WAC. To cover the upfront cost of purchasing drugs and operationalizing the rebate, **BUCKSPORT REGIONAL HEALTH CENTER** anticipates needing to reduce:

Essential Clinical Services: To offset the upfront cost of drugs, we would be forced to scale back non-revenue-generating but essential services, such as access on Saturday by closing our walk-in care program, behavioral health services and primary care services on the weekend.
Operating Hours: We anticipate needing to reduce our clinic hours by 8 per week, specifically impacting our Saturday clinic hours in Bucksport eliminating walk-in, primary care and behavioral health services on the weekend.
Workforce & Staffing: 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 Community Health Workers and our Health Educator's Position.
Patient Financial Assistance: 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 383 uninsured patients from rationing their insulin or heart medication.

B. Wholesaler Implications

Another concern is that purchasing drugs at full WAC will potentially lead the organizations to exceed wholesaler credit limits, halting their ability to order medications until payments are submitted. For example, some CHCs have suggested that paying 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.

BUCKSPORT REGIONAL HEALTH CENTER 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.

- **Wholesaler Credit Limits:** Purchasing drugs at full WAC will potentially lead organizations to exceed wholesaler credit limits, halting our ability to order medications until payments are submitted. At present, many CHCs are forced to pay invoices before their due dates to remain within their credit limits. Given that CHCs typically operate with extremely limited financial margins, they are often perceived as having higher credit risks, making increases to credit limits difficult or impractical.
- **Discounts:** CHCs often receive prompt pay, purchase volume, and sub-ceiling discounts on their drug purchases. Forcing a WAC-upfront model threatens our ability to meet these terms, potentially resulting in the loss of these essential discounts. Due to contractual confidentiality requirements, CHCs are unable to disclose their exact prompt-pay discount. However, **BUCKSPORT REGIONAL HEALTH CENTER]** estimates its 2027 Annual Rebate Opportunity Cost to be approximately **$118,645.** This cost aggregates the estimated financial impact of rebate denials and loss of purchase discounts.
- **BUCKSPORT REGIONAL HEALTH CENTER** estimates that purchasing the 10 selected drugs at WAC instead of 340B ceiling prices will increase our upfront monthly drug spend by **$ 64,807**.

Every dollar we pay upfront at WAC is a dollar that remains "frozen" in the manufacturer's reconciliation system. While we wait for rebates, we lose the liquidity necessary to respond to immediate public health crises or facility emergencies. To navigate the rebate model, our organization would be forced to take out a line of credit. This is not a sustainable solution; the interest costs alone are estimated to be $46,039 annually—funds that are currently dedicated to support our sliding fee program, support activities to support the under and uninsured such as our community health worker, food gleaning program, food pantry program, and clothes closet for those in need. We also use the funds to pay for a part-time health educator, and an upgrade of exam room tables and cabinets in our Bucksport clinic.

Forcing CHCs into debt to maintain their drug supply creates an environment of clinical instability. In our region, where patients have no choice but to rely on Bucksport Regional Health Center, the risk of our credit limit being reached or our reserves being depleted is a direct threat to the community's safety net. If we are forced into financial limbo, the "trickle-down" effect is immediate: longer wait times, reduced service availability, and a weakened ability to provide the steeply discounted medications that our 34 million patients across the country depend on.

a. Financial Impact of Rebate Denials and Delays

BUCKSPORT REGIONAL HEALTH CENTER urges HRSA to recognize that without rigorous, non-discretionary safeguards, the rebate model is not a "pricing mechanism" but a significant financial liability. The current framework allows manufacturers to act as the sole arbiter of CHC's statutory savings, creating an uncertain environment that results in direct financial harm. The framework proposed in the previously proposed 340B Rebate Pilot allowed manufacturers to deny rebate claims based on vague or ambiguous reasons, such as "duplicate rebate" or "MFP

deduplication," without providing the data or documentation CHCs need to understand or contest those decisions.[17]

If a rebate is denied, the CHC takes a net loss on the transaction, having already paid the full WAC price to the wholesaler and provided the drug to the patient at a steep discount. Given our current volume of the 10 selected drugs, even a conservative 15% denial rate would result in a net annual loss of $118,645. This is a sum our CHC cannot absorb, as it represents a direct extraction of resources from our safety net budget. Any reduction in financial resources will directly affect our ability to fulfill the CHC mission of serving all patients, regardless of their ability to pay.

The financial harm is compounded by the fact that the 340B price is no longer reflected in the wholesaler's price catalog or the pharmacy software at the time of purchase. This forces CHCs to "estimate" rebate amounts, creating unpredictable financial losses and the potential to undercharge or overcharge patients. Additionally, the lack of real-time 340B pricing presents challenges for compliance with 340B actual acquisition cost (AAC) billing in fee-for-service Medicaid. This may lead to increased Medicaid costs and potential state-level claw-backs, creating a second layer of financial liability for the CHC. Without a standardized, transparent, and neutral dispute resolution process, the 340B Rebate Model Pilot functions as an interest-free loan from safety-net providers to multi-billion-dollar manufacturers. These unpredictable denials and delays create serious cash flow issues for CHCs operating on thin margins, which depend on timely reimbursement to sustain services for medically underserved populations.

IV. Reconciliation and Rebate Denials Operational Challenges

If HRSA proceeds with a rebate-based pricing model, the program must include clear, enforceable operational guardrails to prevent the systematic shifting of financial and administrative risk to covered entities. **HRSA must require that any rebate model operate under uniform national standards that limit manufacturer discretion, hold manufacturers accountable, and protect covered entities from financial harm.** Recommendations around guardrails include:

- A presumption that rebate claims are valid unless the manufacturer demonstrates otherwise under statutorily sanctioned duplication of discount prevention (i.e., 340B with MDRP or MDPNP);
- Standardized, publicly defined denial categories with claim-level documentation;
- Rebate payment timing requirements must apply to both initial and corrected determinations. If HRSA adopts a 10-day payment requirement, that requirement must run from both the initial determination and any subsequent corrected determination to prevent manufacturers from using dispute processes as a delay mechanism;
- A clear enforcement framework, including consequences for repeated late payments or improper denials by manufacturers;
- Manufacturers must bear the burden of establishing that a rebate is not owed;
- Rebate determinations must align with statutory patient definition: HRSA should explicitly prohibit rebate denial methodologies that rely on manufacturer-defined patient eligibility standards or undisclosed validation criteria.

[17] Application Process for the 340B Rebate Model Pilot Program, 2025-14619 (90 FR 36163) https://www.federalregister.gov/documents/2025/08/01/2025-14619/340b-program-notice-application-process-for-the-340b-rebate-model-pilot-program

- OPA should establish a stakeholder advisory panel to ensure that the feedback and concerns of covered entities are formally and consistently addressed. This panel should include pharmacists with the necessary subject-matter expertise to understand the complexities of pharmacy software, billing, and data components.

V. Existing CHC Compliance Actions

CHCs already operate under a comprehensive regulatory framework established through the Health Center Program and the 340B statute to make medications affordable for patients.

- In alignment with Section 330 of the Public Health Service Act, they utilize a sliding fee discount that adjusts costs based on a patient's income and household size, ensuring that no one is denied services due to an inability to pay.
- CHCs also establish systems for eligibility determination and offer full discounts to individuals at or below 100% of the Federal Poverty Level (FPL). These services would not be possible without the savings generated from the 340B program.
- CHCs participate in regular Operational Site Visits (OSVs) to verify Health Center Program compliance, and also follow strict 340B compliance protocols, including internal audits, training, and external oversight.
- CHCs participating in the 340B program are required to report 340B-related information annually through the Uniform Data System (UDS). This includes data on 340B-purchased drugs, associated costs and revenues, and detailed information about the patients served by the program.

Given the compliance infrastructure and strict statutory requirements already in place for CHCs, implementing a rebate model would cause disproportionate harm to CHCs and the patients they serve. The administrative, financial, and operational burdens from such a model would threaten the stability of the safety-net providers that the 340B program was designed to support. CHCs are not the source of misuse in the 340B program; rather, they are national models of compliance.

VI. Establishing a National, Neutral Claims Clearinghouse

We recommend OPA use a Neutral Claims Clearinghouse, which would produce more accurate deduplication at a tiny fraction of the cost and administrative burden of a rebate model. Compared to HRSA's proposed rebate model, the NCC approach would:

- **Avoid cash-flow and borrowing challenges** for CEs by preserving the upfront 340B discount.
- **Substantially reduce administrative burden on CEs** by significantly reducing the need for them to build and maintain complex rebate compliance systems, and the staff time needed to track and reconcile claims and to manage cashflow issues.
- **Provide manufacturers with the necessary deduplication data within the same 45-day timeframe.**
- **Improve rebate accuracy**, reducing the time and effort manufacturers and CEs must spend correcting errors.
- **Preserve the longstanding upfront discount structure** that has defined the 340B program for more than three decades and is essential to most CHCs' participation in the program.

- **Protect patient access to affordable MFP drugs.** If a rebate model were implemented, the resulting cash-flow pressures could force many CHCs to stop purchasing or dispensing MFP drugs altogether.
- **Identify Medicaid Duplicate discounts in Medicaid.** An NCC could provide a standardized national approach to preventing duplicate Medicaid discounts by collecting CEs' 340B claims data for Medicaid prescriptions and making it available to states.

Given the major disruption the 340B rebate program is anticipated to have on CHCs, a system that forces CHCs to provide data that is already accurately and readily available to manufacturers is not only redundant but also adds additional administrative burdens on safety-net providers. It is imperative that HRSA require manufacturers to leverage existing resources to protect the stability of the safety-net providers that the 340B program was designed to support.

Conclusion

BUCKSPORT REGIONAL HEALTH CENTER strongly urges HRSA to exempt CHCs from any 340B Rebate Model Pilot Program. A 340B rebate program represents a departure from the original intent of the 340B program—to allow safety-net providers to "stretch scarce Federal resources" and provide more comprehensive care. A rebate model would create significant cash flow challenges, forcing CHCs to make difficult decisions about staffing, services, and the range of drugs they can afford to stock. Additionally, CHCs would need to make significant investments in IT infrastructure and staff to comply with rebate requirements and track rebates. It would also create a new barrier for patients, especially uninsured patients, who depend on the up-front 340B discount, making it operationally impossible to provide the sliding fee scale and steeply discounted medications required by law. BUCKSPORT REGIONAL HEALTH CENTER believes that a 340B rebate pilot would cause disproportionate harm to patients served by CHCs and other safety net providers.

BUCKSPORT REGIONAL HEALTH CENTER appreciates the opportunity to respond to this Request for Information on the 340B Rebate Model Pilot, and we look forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please contact me at ccarew@brhcme.org.

Sincerely,

CAROL CAREW, RN, BSN, MBA
Chief Executive Officer
BUCKSPORT REGIONAL HEALTH CENTER

SALINA FAMILY
HEALTHCARE CENTER

Medical 785-825-7251
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April 20, 2026

Maria G. Button
Director, Executive Secretariat
Health Resources and Services Administration
5600 Fishers Lane
Rockville, Maryland 20857

Re: Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906-NEW
Submitted via paperwork@hrsa.gov

Dear Director Button:

On behalf of Salina Health Education Foundation dba Salina Family Healthcare Center (SFHC), thank you for the opportunity to comment on HRSA's proposed Information Collection Request (ICR) associated with the 340B Rebate Model Pilot Program. SFHC previously submitted comments in November 2025 regarding the initial ICR and appreciates the opportunity to provide updated feedback based on additional operational analysis and real-world experience evaluating the proposed rebate model.

SFHC is a Federally Qualified Health Center (FQHC) located in central Kansas that serves patients from Saline County and the four surrounding counties. In 2025, SFHC cared for 12,205 patients, with 55.1% living at or below 200% of the Federal Poverty Level, 17.9% uninsured, and 29.4% enrolled in Medicaid. The 340B Program is essential to our ability to provide affordable medications at the point of care and sustain patient services. In 2025 alone, SFHC generated approximately $8.5 million in savings for patients by using 340B pricing and related discount programs compared to the uninsured cash price.

Estimated Burden Hours and Labor Categories

SFHC believes the burden estimates presented in the proposed ICR materially understate the actual administrative burden that a rebate-based 340B model would impose on FQHCs.

Based on the "Total Estimated Annualized Burden Hours" table included in the Federal Register notice, HRSA appears to assume that covered entities will submit claims data 52 times per year, with an average burden of five hours per submission. This results in an implied burden of approximately 260 hours per year per covered entity, or roughly five hours per week, regardless of prescription volume, number of manufacturers, or dispensing channels.

According to SFHC's analysis, this assumption is not realistic. Based on our prescription volume, current 340B compliance workflows, and experience with manufacturer-driven data submission, monitoring,

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and dispute resolution, we estimate that administering a rebate-based model would require a minimum of 20 hours per week—four times HRSA's estimated burden. Rebate administration would not function as a discrete weekly reporting task, but rather as a continuous, transaction-level operational workload.

At SFHC, rebate-related activities would be performed by experienced pharmacy compliance and financial staff, not entry-level administrative personnel. Based on current staffing obligations and labor costs, SFHC estimates the need to add at least one additional full-time equivalent (FTE) position dedicated to rebate administration, reconciliation, monitoring, and dispute management, at an estimated annual cost of approximately $77,000.

These activities would include, at a minimum:

- Identification of rebate-eligible prescriptions across entity-owned and contract pharmacy arrangements
- Submission of rebate data to manufacturer-designated third-party platforms
- Ongoing monitoring of rebate payment status
- Reconciliation of rebate payments to pharmacy purchases and dispensations
- Investigation, documentation, and follow-up of denied or partially paid rebate claims
- Maintenance and retention of auditable records to support compliance and potential manufacturer or agency review

Critically, these labor demands are in addition to—rather than a replacement for—existing 340B compliance activities. Patient discounts must still be provided at the point of care, eligibility rules enforced, and full auditable records maintained regardless of whether a rebate is ultimately paid.

In practical terms, HRSA's burden estimate treats rebate administration as a limited weekly reporting activity. However, SFHC's analysis demonstrates that it would function as a persistent operational responsibility equivalent to at least 0.5 FTE—and more realistically one full-time position—for the duration of any rebate-based pilot.

Frequency of Reporting, Reconciliation, and Recordkeeping

The ICR burden tables appear to assume a limited reporting frequency and a streamlined reconciliation process. SFHC's analysis indicates that rebate reporting and reconciliation would be continuous, with activity driven by prescription volume and manufacturer policies rather than reporting intervals alone.

Each prescription subject to a rebate model creates a downstream compliance obligation requiring tracking, verification, and reconciliation. Disputed or unpaid rebates would require repeated follow-up, documentation, and appeals, compounding the burden over time. The cumulative effect is a persistent recordkeeping and audit-support workload that extends well beyond the discrete submission events reflected in the ICR estimates.

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Systems and Data Collection Burden

The proposed ICR does not sufficiently account for the systems and data-integration burden associated with a rebate-based model. Existing pharmacy management systems and wholesaler pricing files are designed for upfront 340B pricing and do not natively support retrospective rebate workflows.

Implementation would require custom workarounds, external vendor support, or system modifications to:

- Discount the price of prescriptions based on the 340B price for:
  - Health center financially qualified patients
  - Medicaid FFS prescriptions
  - Presidential Executive Order-associated prescriptions for insulin and injectable epinephrine
- Capture and store rebate-specific data elements
- Track rebate status across manufacturers
- Reconcile purchases, dispensing events, and payments over time

These requirements create both one-time and recurring burden that is not reflected in the ICR's proposed estimates.

Conclusion

Based on updated modeling and operational analysis, SFHC believes the proposed ICR significantly understates the true administrative, staffing, data-collection, and recordkeeping burden associated with a rebate-based 340B model. These burdens are not theoretical and would divert substantial resources away from patient care and safety-net services.

SFHC respectfully urges HRSA to revise its burden estimates to reflect the ongoing, transaction-level nature of rebate administration and to exempt FQHCs from participation in any rebate-based 340B pilot.

Thank you for the opportunity to submit these comments. Please feel free to contact me at dpihl@salinahealth.org or (785) 825-7251 x240 with any questions.

Respectfully submitted,

Derek R. Pihl, PharmD
Chief Pharmacy Officer
Salina Family Healthcare Center

RiverStone Health

Connecting you to a better life

April 17, 2025
Chantelle Britton
Director
Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
Rockville, Maryland 20857

RE:
Request for Information HRSA-2026-03042

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

Submitted via regulations.gov comments portal and paperwork@hrsa.gov

Dear Director Britton:

On behalf of Yellowstone City County Health Department dba RiverStone Health (RiverStone Health), I would like to thank the Health Resources and Services Administration (HRSA) for providing the opportunity to share our estimated burden with HRSA on compliance with the 340B rebate model pilot program. **Given the severe administrative, financial, and operational burden a rebate model would place on CHCs, RiverStone Health strongly urges HRSA to exempt CHCs from the pilot program.**

RiverStone Health is a multi-jurisdictional health district serving Yellowstone and Carbon Counties, Montana. RiverStone Health operates a full-scope federally qualified health center (including a Healthcare for the Homeless program), home health and hospice services, the Yellowstone City County Health Department, the Montana Family Medicine Residency Program, and an AHEC/AETC training program. RiverStone Health also operates an entity owned and 340B contract pharmacy network filling approx. 52,000 prescriptions per year. Approx. 37,000 of the prescriptions filled each year are 340B eligible.

The 340B program is foundational to RiverStone's ability to serve the most vulnerable members of our community. However, the proposed shift of responsibility from manufacturers to safety-net providers directly serving patients through a rebate model threatens to destabilize RiverStone Health's pharmacy operations. Based on our internal assessment, the hours and dollars spent complying with a rebate program are staggering.

I. **We Request HRSA Exempt CHCs from the 340B Rebate Model Pilot Program Due to Significant Financial and Administrative Burden**.

II. **Including CHCs in the rebate model pilot is a disproportionate response to 340B entities that are, by-and-large, excellent stewards of the program.**

III. **RiverStone Health has had an exemplary track record of compliance with 340B program and individual drug manufacturer requirements. In the history of RiverStone Health's participation in the 340B program, we have never had an adverse 340B audit finding, we have had no instances of duplicate discounts occurring, we provide 100% of 340B savings to uninsured patients at the point of sale, and we reinvest 100% of our 340B revenue into providing enhanced access and services for our patients.**

By requiring CHCs to purchase medications at full price and wait for rebates, this model would cause significant financial turmoil and directly affect our ability to serve the approx. 14,000 patients who rely on us. RiverStone Health operates on small margins and **our estimates indicate that our upfront cash outlay for purchasing the 340B medications subject to the rebate pilot would go from approx. $18,000 to $1.3Million annually.** This represents **a 7,000% increase in our up-front cash outlay.** Up front expense increases of this magnitude will significantly impact our ability to ensure 340B savings are passed along to our patients. In addition to navigating manufacturers' existing contract pharmacy restrictions, RiverStone will need to hire additional staff to manage new complexities, including varying data submission requirements and timelines, payment reconciliations, and dispute processes for denied rebates. We will face an increased administrative burden in monitoring rebate claims and payments. **Based on historical data, just a 5% manufacturer rebate denial rate would result in the loss or delay of approx. $65,000 annually.**

RiverStone Health has already experienced increases in operational costs given the multitude of manufacturer restrictions, including requirements for clinic-administered drugs and entity-owned pharmacies. A rebate model will require a significant increase in already-strained operational capabilities.

Workforce Impact:

- **Staffing Impact**: RiverStone Health anticipates needing 1.0 additional FTE at a cost of approx. $75,000/annually to account for the increase in operational, administrative, and compliance burden created by a rebate model.
- **Number of Hours:** RiverStone Health will face an increased administrative burden to monitor rebate claims and payments. **We estimate 10 hours weekly** will be required to report 340B rebate claims to all of the different third-party platform, payment reconciliations, and manage the dispute process in the event of denied rebates.

Pharmacy Software & Third-Party Administration Changes

Navigating this pilot requires both staff and changes to workflow and software. HRSA should consider the increased compliance burdens when manufacturers have the flexibility to require varying data submission standards and elements. Additionally, if manufacturers can select different software platforms, like current contract pharmacy policies and as was the case when

this pilot was going to be originally implemented, CHC administrative burden would increase substantially.

- **Ongoing Operational Fees**: Beyond implementation, our TPA and software vendors will likely charge ongoing service fees to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings. To date, our software vendor and our TPA have been unable to provide RiverStone Health with estimates of cost increases they anticipate as a result of rebate pilot implementation. Our TPA has been unable to explain to us how they will facilitate the rebate model with our contract pharmacies providing contract pharmacy network uncertainty.

The In-House Pharmacy: The Burden of IT Integration

RiverStone Health operates an entity owned pharmacy and has contractual arrangements with several pharmacies in our service area. The rebate model is not a simple accounting change; it is a significant technological disruption. To remain compliant, in-house pharmacy systems will require costly customization to provide real-time, accurate information at the pharmacy counter.

- **System Interoperability:** Unlike contract pharmacies that use TPAs, in-house pharmacies must directly integrate their Electronic Health Record (EHR) and Pharmacy Management System (PMS) with a complex new rebate infrastructure. RiverStone Health currently configures our PMS so that the price we pay for 340B medications is the amount entered into the PMS to charge the patient. In order to continue providing medications to patients at the discounted **estimated** 340B rate after implementation of the rebate model, complex and time consuming processes to estimate how much the 340B rebate will be and manually deduct that from the price of medications will need to be implemented in order to continue to pass those savings onto patients and reconcile the discount provided to the patient with the actual 340B rebate received.
- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend 10 hours per week manually pulling "Purchase Files" and "Price Files" to verify that every rebate check matches the statutory 340B price.

The Contract Pharmacy: The Burden of Network Coordination

The rebate model introduces a new complexity that threatens the existence of contractual arrangements. RiverStone Health currently partners with 12 pharmacies to increase access to affordable medications.

- **TPA Reliance and Fees:** Navigating manufacturers' varying requirements across multiple contract pharmacies requires high-level TPA intervention. We anticipate that our TPAs will pass on the costs of developing rebate-tracking modules to us through increased per-claim fees.
- **Verification Latency:** The rebate model creates a reconciliation gap. Our staff must monitor claims across 13 different pharmacy locations to ensure rebates are paid correctly.
- **Risk of Pharmacy Exodus:** The model shifts financial risk to the pharmacy, potentially causing contract partners to opt out of the 340B program entirely rather than manage the administrative headache. In Yellowstone and Carbon Counties, RiverStone

Health's service area, this would leave patients with no affordable medication options. Over 17 percent of the U.S. population already lives in a pharmacy desert.

II. Patient Impact

RiverStone Health has significant concerns about the impact a 340B Rebate Model Pilot would have on our most vulnerable patients' access to life-saving medications. The majority of drugs selected for the MDPNP for 2026 and 2027, and included in the proposed rebate model, manage chronic conditions prevalent in primary care settings. CHCs serve a patient population with a higher burden of chronic conditions compared to private practices, with studies showing a significantly higher prevalence of illnesses like diabetes, hypertension, and obesity. RiverStone Health is no exception to this. RiverStone Health service users rely on affordable medications to manage these long-term conditions.

The impact on insulin access is also alarming and directly conflicts with federal requirements. With over 3 million Americans relying on CHCs for essential diabetes care, insulin affordability is a matter of life and death. Furthermore, Executive Order #14273 conditions future Section 330(e) funds on CHCs providing low-income patients with access to discounted insulin. No current operational method exists to provide discounted medications in a rebate model. In the proposed model, the wholesaler price file would reflect the full Wholesale Acquisition Cost (WAC) rather than the discounted 340B price, making the price unattainable for patients and precluding CHCs from fulfilling their legal obligation to offer the required discount at the point of care.

RiverStone Health invests 100% of our 340B savings into expanded services for our CHC patients. Erosion of this funding source will have significant impacts on our ability to continue to provide enhanced services such as restorative dental care, nutrition counseling, chronic disease care management, and resource navigation services.

III. Financial Challenges

Lack of access to upfront 340B discounts, along with increased administrative costs, will disproportionately impact CHCs and trickle down to patients. **As stated above, moving to a rebate model for the qualifying medications will result in RiverStone Health's initial cash outlay going from approx. $18,000 to $1.3Million annually. With that impact to our cash flow, even minor delays in rebate reimbursements will have significant impacts on our ability to continue supporting the expanded services currently financed through 340B savings.** Many CHCs are currently under financial strain, with nearly half operating with fewer than 90 days of cash on hand, and one in four reporting negative five percent operating margins. This rebate model creates significant financial challenges, including:

- **Purchasing Drugs at the WAC Price Upfront:** Under the proposed model, CHCs would be required to purchase drugs at the WAC. CHCs will have to wait to receive their rebate payment *after* providing medications to their patients, forcing difficult decisions about how to allocate limited financial resources, including cutting essential services and reducing operating hours. We are particularly worried that the need to purchase drugs at

full WAC will cause cash flow issues and potentially lead CHCs to exceed credit limits with wholesalers, halting their ability to order medications until payments are submitted.

- **Sliding Fee Scale:** A rebate model creates substantial uncertainty about RiverStone Health's ability to apply sliding-fee discounts at the point of sale. **Historically, RiverStone Health has passed 100% of 340B savings on to uninsured patients at point of sale.** By statute and regulation, CHCs are required to offer sliding fee discounts for all required and additional health services within the HRSA-approved scope of project. In line with their mission, CHCs offer flat or sliding-scale discounts on prescription drugs to make them more affordable for low-income individuals. A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size.

Conclusion

RiverStone Health strongly urges HRSA to exempt CHCs from any 340B Rebate Model Pilot Program. A 340B rebate program represents a departure from the original intent of the 340B program—to allow safety-net providers to "stretch scarce Federal resources" and provide more comprehensive care. A rebate model would create significant cash flow challenges, forcing RiverStone Health to make difficult decisions about staffing, services, and the range of drugs we can afford to stock. Additionally, RiverStone Health would need to make significant investments in staff to comply with rebate requirements and track rebates. It would also create a new barrier for patients, especially uninsured patients, who depend on the up-front 340B discount, making it operationally impossible to provide the sliding fee scale and steeply discounted medications required by law. RiverStone Health believes that a 340B rebate pilot would cause disproportionate harm to patients served by CHCs and other safety net providers.

RiverStone Health appreciates the opportunity to respond to this ICR on the 340B Rebate Model Pilot Program, and we look forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please contact Jonathon Forte, CEO, at jon.for@riverstonehealth.org or Eric Owen, COO, at eric.owe@riverstonehealth.org.

Sincerely,

Jonathan P. Forte
Chief Executive Officer
City-County Health Officer

LRMC
LITTLE RIVER MEDICAL CENTER

April 20, 2025

Chantelle Britton
Director
Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
Rockville, Maryland 20857

RE: Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906-NEW

Submitted via paperwork@hrsa.gov

Dear Director Britton:

On behalf of Little River Medical Center (LRMC), I would like to thank the Health Resources and Services Administration (HRSA) for providing the opportunity to **share our estimated burden with HRSA on compliance with the 340B rebate model pilot program. Given the severe administrative, financial, and operational burden a rebate model would place on CHCs, LRMC again requests that CHCs be exempted from the pilot program.**

Since its founding in 1978, LRMC has delivered comprehensive preventative health care services to residents of Horry County, South Carolina, and Brunswick County, North Carolina. LRMC currently operates seven brick-and-mortar locations and maintains a fleet of four mobile units, providing a wide range of services including medical, dental, behavioral health, pharmacy, and additional support offerings. In 2025, LRMC served a total of 34,339 patients, with more than 89% of those patients living at or below 200% of the Federal Poverty Guideline. Since 1992, LRMC has actively participated in the 340B Discount Drug Program, enabling qualifying patients to access discounted pharmaceuticals at each eligible 340B site, across its now five owned and operated pharmacy locations, as well as through contract pharmacy partners.

The 340B program is foundational to CHC's ability to serve the most vulnerable members of our community. However, the proposed shift of responsibility from manufacturers to safety-net providers directly serving patients through a rebate model threatens to destabilize CHC pharmacy operations nationwide. Based on national assessments from the National Association of Community Health Centers (NACHC) and our own internal assessments, the hours and dollars spent complying with a rebate program are staggering.

I. We Request HRSA Exempt CHCs from the 340B Rebate Model Pilot Program Due to Significant Financial and Administrative Burden

By requiring CHCs to purchase medications at full price and wait for rebates, this model would cause significant financial turmoil and directly affect our ability to serve the **34,339** patients who rely on us. We operate on razor-thin margins, and these additional costs are not an option for many

entities. Like navigating manufacturers' existing contract pharmacy restrictions, CHCs will need to invest in IT infrastructure upgrades and hire or reassign staff to manage new complexities, including varying data submission requirements and timelines, payment reconciliations, and dispute processes for denied rebates. We will face an increased administrative burden in monitoring rebate claims and payments.

To support CHCs in assessing the financial and operational impact of current manufacturer restrictions and an anticipated rebate model, NACHC worked with their consultant, FQHC 340B Compliance, to create an Operational & Administrative Cost Calculator.[1] The tool aggregates program savings, UDS financial data, staffing, external consulting costs, dispensing/capture activity, and clinic-administered drug tracking models to support cost forecasting. CHCs have already experienced steep increases in operational costs given the multitude of manufacturer restrictions, including requirements for clinic-administered drugs and entity-owned pharmacies. A rebate model will require a significant increase in already-strained operational capabilities.

Workforce Impact:

- **Staffing Impact**: LRMC anticipates needing 1.5 – 2 additional FTEs to account for the increase in operational, administrative, and compliance burden created by a rebate model.
- **Number of Hours:** Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, LRMC will face an increased administrative burden to monitor rebate claims and payments. Twelve to fourteen hours per week will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: LRMC anticipates an additional $45,000 in the months immediately after enactment of any 340B Rebate program for external vendors, including consultants, legal counsel, program coordination, third-party administrators (TPAs), electronic medical records (EMRs), pharmacy software, and reconciliation services.

Pharmacy Software & Third-Party Administration Changes

Navigating this pilot requires both staff and changes to workflow and software. HRSA should consider the increased compliance burdens when manufacturers have the flexibility to require varying data submission standards and elements. Additionally, if manufacturers can select different software platforms, like current contract pharmacy policies, CHC administrative burden would increase substantially.

- **One-Time Implementation Costs:** We anticipate high upfront costs to adapt our pharmacy software, pay for custom dashboard modifications, and design new internal workflows. $6,000 – $10,000 will be required simply to reach the baseline of compliance before a single rebate is ever received.
- **Ongoing Operational Fees**: Beyond implementation, our TPA and software vendors will charge ongoing service fees which cannot be accurately predicted to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Cost:** For our CHC, which serves 34,339 patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at $194,000 - $218,000 annually.

[1] https://www.nachc.org/policy-advocacy/policy-priorities/340b-drug-pricing-program/340b-rebate-model-pilot-program/

The In-House Pharmacy: The Burden of IT Integration

LRMC operates five pharmacies. The rebate model is not a simple accounting change; it is a significant technological disruption. To remain compliant, in-house pharmacy systems will require costly customization to provide real-time, accurate information at the pharmacy counter.

- **System Interoperability:** Unlike contract pharmacies that use TPAs, in-house pharmacies must directly integrate their Electronic Health Record (EHR) and Pharmacy Management System (PMS) with a complex new rebate infrastructure. LRMCs current EHR and PMS do not communicate with one another. For cross communication between systems – it will need to be determined if a connection of what is needed is even possible. If significant pieces that each system share cannot be integrated, there is risk for a significant increase in manual based processes to satisfy the rebate program requirements.
- **One-Time Integration Costs:** We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools. For example, our PMS currently charges $200.00 per hour for developer time. To allow for the proper pricing of 340B prescriptions – especially for uninsured, sliding fee eligible patients - we will need our PMS system to build a new architecture so that the 340B cost of drugs is within the PMS moving forward for any drugs on a rebate program. Depending on how long such architectural work would take, in both the HER and PMS it is quite evident that these costs could be substantial when coupled together.
- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend four to eight hours per week manually pulling "Purchase Files" and "Price Files" to verify that every rebate check matches the statutory 340B price.

The Contract Pharmacy: The Burden of Network Coordination

The rebate model introduces a new complexity that threatens the existence of contractual arrangements. My CHC currently partners with eighty-nine pharmacies to increase access to affordable medications.

- **TPA Reliance and Fees:** Navigating manufacturers' varying requirements across multiple contract pharmacies requires high-level TPA intervention. We anticipate that our TPAs will pass on the costs of developing rebate-tracking modules to us through increased per-claim fees.
- **Verification Latency:** The rebate model creates a reconciliation gap. Our staff must monitor claims across eighty-nine different pharmacy locations to ensure rebates are paid correctly.
- **Risk of Pharmacy Exodus:** The model shifts financial risk to the pharmacy, potentially causing contract partners to opt out of the 340B program entirely rather than manage the administrative headache. In our service area, this could leave patients no affordable medication options if they cannot access a pharmacy owned and operated by LRMC. Horry and Brunswick counties cover 2,305 square miles – Horry County alone is the largest county in South Carolina. This action could further fuel pharmacy deserts. Currently, over 17 percent of the U.S. population lives in a pharmacy desert.[2]

Clinic Administered Drugs: The Burden of New Systems Required

Clinic-administered drug (CAD) operations and record-keeping in CHCs are designed cost-effectively to reflect the nuances of CHC billing. Implementing a rebate model for CADs would also require new software, system integration, and staff training. NACHC estimates these costs

[2] Vulnerability Index Approach to Identify Pharmacy Deserts and Keystone Pharmacies | Pharmacy and Clinical Pharmacology | JAMA Network Open | JAMA Network

would range from $30,000 to $50,000 annually and could be much higher, depending on the software.[3] LRMC estimates that it would take four to eight hours weekly to manage the use of CADs that could be included in any 340B rebate program. To meet new requirements LRMC would be forced to set aside $25,000 to $40,000 dollars for a one-time implementation cost for a module to be added onto its EHR related to CADs plus any ongoing maintenance fees, if applicable, for such a module.

Most CADs are bundled into the prospective payment system (PPS) billing when administered to patients by CHCs. Because PPS visits are paid at a flat rate, the medications administered in CHCs are often not included on claims billed to payers. CHCs maintain limited inventories of CADs and typically do not separately bill on claims. Administration and inventory logs are commonly maintained on paper, with text documentation in patient visit notes describing what was administered. While CHCs maintain perpetual inventories and complete administrative records, paper records impose an additional burden of converting them to electronic data before submitting for rebate. Very few CHC records include electronic medication administration records (eMARs), which are common in hospital EMRs. Where eMARs are available, they incur an additional cost and often require CHCs to pay for a standalone software system.

II. Patient Impact

LRMC has significant concerns about the impact a 340B Rebate Model Pilot would have on our most vulnerable patients' access to life-saving medications. The majority of drugs selected for the MDPNP for 2026 and 2027, and included in the proposed rebate model, manage chronic conditions prevalent in primary care settings. CHCs serve a patient population with a higher burden of chronic conditions compared to private practices, with studies showing a significantly higher prevalence of illnesses like diabetes, hypertension, and obesity.[4] This patient population relies on affordable medications to manage these long-term conditions.

The impact on insulin access is also alarming and directly conflicts with federal requirements. With over 3 million Americans relying on CHCs for essential diabetes care,[5] insulin affordability is a matter of life and death. Furthermore, Executive Order #14273 conditions future Section 330(e) funds on CHCs providing low-income patients with access to discounted insulin. No current operational method exists to provide discounted medications in a rebate model. In the proposed model, the wholesaler price file would reflect the full Wholesale Acquisition Cost (WAC) rather than the discounted 340B price, making the price unattainable for patients and precluding CHCs from fulfilling their legal obligation to offer the required discount at the point of care.

III. Financial Challenges

Lack of access to upfront 340B discounts, along with the high IT/infrastructure costs, will disproportionately impact CHCs and trickle down to patients. Many CHCs are currently under financial strain, with nearly half operating with fewer than 90 days of cash on hand, and one in four reporting negative five percent operating margins. This rebate model creates significant financial challenges, including:

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[3] Internal NACHC survey data

[4] Richard P, Ku L, Dor A, Tan E, Shin P, Rosenbaum S. Cost savings associated with the use of community health centers. J Ambul Care Manage. 2012 Jan-Mar;35(1):50-9. doi: 10.1097/JAC.0b013e31823d27b6. PMID: 22156955.

[5] 2025 UDA Data, HRSA (hrsa.gov)

- **Purchasing Drugs at the WAC Price Upfront:** Under the proposed model, CHCs would be required to purchase drugs at the WAC. CHCs will have to wait to receive their rebate payment *after* providing medications to their patients, forcing tough decisions about how to allocate limited financial resources, including cutting essential services and reducing operating hours. We are particularly worried that the need to purchase drugs at full WAC will cause cash flow issues and potentially lead CHCs to exceed credit limits with wholesalers, halting their ability to order medications until payments are submitted.
- **Sliding Fee Scale:** A rebate model creates substantial uncertainty about CHCs' ability to apply sliding-fee discounts at the point of sale. By statute and regulation, CHCs are required to offer sliding fee discounts for all required and additional health services within the HRSA-approved scope of project.[6] In line with their mission, CHCs offer flat or sliding-scale discounts on prescription drugs to make them more affordable for low-income individuals.[7] A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size. LRMC currently provides a formulary of free and deeply discounted pharmaceuticals to all 340B eligible patients. In addition to this benefit, LRMC offers a sliding-fee discount of charges when 340B drug is dispensed to 340B eligible patients who are at or below 200% of the Federal Poverty Guideline. For pharmaceuticals purchased at the 340B price that are not on the free or deeply discounted formularies, the 340B cost of drug plus a professional dispensing fee is charged to a sliding-fee eligible patient. 340B eligible patients who are in the nominal fee sliding-fee category are charged the lowest professional dispensing fee for a prescription and the professional dispensing fee for a prescription increases as patients move closer to 200% of the Federal Poverty Guideline. If pharmaceuticals included in the 340B Rebate Model Pilot Program are purchased at WAC - with a rebate ***possibly*** being paid later if the prescription claim is deemed to be 340B eligible upon data review - LRMC does not feel that it will be able to maintain the outlined pricing structures in place for 340B eligible patients who may or may not be sliding-fee eligible. This determination is due to the risk of LRMC not ***possibly*** being paid a rebate for a 340B eligible claims submission that was submitted as there would be zero to a very low percentage chance of LRMC being successful in collecting the difference in the WAC and 340B drug cost from the 340B eligible patient after any prescription adjudication and purchase of the prescription has taken place. The attempt to explain this cumbersome process is the complete antithesis of how any pharmacy was expected to operate for the past thirty plus years since the origination of the 340B Program.

Conclusion

LRMC strongly urges HRSA to exempt CHCs from any 340B Rebate Model Pilot Program. A 340B rebate program represents a departure from the original intent of the 340B program—to allow safety-net providers to "stretch scarce Federal resources" and provide more comprehensive care. A rebate model would create significant cash flow challenges, forcing CHCs to make complex decisions about staffing, services, and the range of drugs they can afford to stock. Additionally, CHCs would need to make significant investments in IT infrastructure and staff to

[6] HRSA FAQ

[7] Such discounts are subject to potential legal and contractual restrictions. https://bphc.hrsa.gov/compliance/compliance-manual/chapter9#footnote10

comply with rebate requirements and track rebates. It would also create a new barrier for patients, especially uninsured patients, who depend on the up-front 340B discount, making it operationally impossible to provide the sliding fee scale and steeply discounted medications required by law. LRMC believes that a 340B rebate pilot would cause disproportionate harm to patients served by CHCs and other safety net providers.

LRMC appreciates the opportunity to respond to this ICR on the 340B Rebate Model Pilot Program, and we look forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please contact Kris Chiplinski, Chief Pharmacy Officer, kchiplinski@lrmcenter.com.

Sincerely,

Pamela Davis, President and CEO
Little River Medical Center

March 31, 2026

Chantelle Britton
Director
Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
Rockville, Maryland 20857

RE: Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042)

Dear Director Britton:

On behalf of CareSouth Carolina, Inc., I would like to thank the Health Resources and Services Administration (HRSA) for extending the comment deadline to April 20, 2026. This extension has been vital in enabling our organization to conduct a deep-dive analysis of the operational and financial risks to CHCs posed by the proposed rebate model. The 340B program is foundational to CHC's ability to serve the most vulnerable members of our community. However, the proposed shift of responsibility from manufacturers to safety-net providers directly serving patients through a rebate model threatens to destabilize CHC pharmacy operations nationwide. Based on national assessments from NACHC, we know that CHCs are facing staggering impacts:

- **Financial Losses:** Nationwide, CHCs report an average loss of **$1,000,000 to $5,000,000** from entity-owned pharmacy operations and **a 75% reduction in savings** for contract pharmacy arrangements due to the administrative hurdles of manual reconciliation.
- **Projected Cost Increases:** CHCs anticipate significant increases in operational costs. National data shows that a single mid-sized CHC expects to incur over $3 million in additional costs **annually** to manage the pilot.
    - **Rural Health Center Breakdown:** For rural CHCs, these costs are even more devastating. Rural centers invest nearly **one-quarter (25%)** of their 340B savings in rural-specific infrastructure, such as mobile clinics and telehealth.

CareSouth Carolina is a private, non-profit community health center delivering patient-centered health and life services in the Pee Dee region of South Carolina. CareSouth Carolina operates centers in Bennettsville, Bishopville, Cheraw, Chesterfield, Dillon, Hartsville, Lake View, Latta, McColl and Society Hill. Services provided by CareSouth Carolina include family practice, internal medicine, pediatrics, women services, OB/GYN, HIV/AIDS primary care, dental, chiropractic services, pharmacy, geriatrics, social services, clinical counseling, laboratory, 4D ultrasound, X-Ray, migrant services and veterans' choice provider.

I. We Strongly Urge HRSA To Exempt CHCs from the 340B Rebate Model Pilot Program.

The proposed 340B Rebate Model Pilot Program is a direct threat to CHCs' core mission and a significant departure from the original purpose of the 340B Drug Pricing Program. For over three decades, the 340B program has enabled CHCs to purchase outpatient medications at significantly reduced prices, enabling them to provide affordable and sometimes free medications to millions of low-income and uninsured patients. As congressional intent made clear, the program was created to help safety-net providers "stretch scarce Federal resources as far as possible." The proposed rebate model undermines this by placing an immense financial burden on CHCs.

By requiring CHCs to purchase medications at full price and wait for rebates, this model would cause significant financial turmoil and directly affect CHCs' ability to serve the 52 million patients who rely on us. **For CareSouth Carolina, Inc. in particular, this means it will impact:**

- **315,107 340B prescriptions and 38,116 patients served by CareSouth Carolina**
- **$250,000 in administrative costs for our 340B program**
- **Our 340B pharmacy revenue services many disciplines within our organization. Those services include pharmacy services, pediatric and adult dental services, family support services, vision care, chiropractic care, behavioral health services, IV infusion services, podiatry services, adult and pediatric family care services, and MAT services.**

We strongly urge HRSA to exempt CHCs from any rebate model to protect the financial stability of safety-net providers and ensure continued access to care for the most vulnerable patients.

II. Patient Impact

Most importantly, a 340B rebate model poses a direct and serious threat to medication access for the vulnerable patients that CHCs serve. For uninsured and underinsured patients who rely on the affordability that the 340B program provides, this model could render critical medications financially out of reach. Patients may be forced to make tough decisions in transitioning to other medications, due to cost or lack of availability, as a direct result of a 340B rebate pilot program. These forced therapeutic interchanges introduce real clinical risk, including medication nonadherence, treatment delays, and adverse outcomes, particularly for patients managing multiple chronic conditions who have limited alternatives and no other pharmacies close by.

We have significant concerns about the impact a 340B Rebate Model Pilot would have on our most vulnerable patients' access to life-saving medications. The majority of drugs selected for the MDPNP for 2026 and 2027, and included in the proposed rebate model, are used to manage chronic conditions prevalent in primary care settings, meaning CHC patients will be disproportionately affected. CHCs serve a patient population with a **higher burden of chronic conditions** compared to private practices, with studies showing a significantly higher prevalence of illnesses like diabetes, hypertension, and obesity.[1] This patient population relies on affordable medications to manage these long-term conditions.

[1] Richard P, Ku L, Dor A, Tan E, Shin P, Rosenbaum S. Cost savings associated with the use of community health centers. J Ambul Care Manage. 2012 Jan-Mar;35(1):50-9. doi: 10.1097/JAC.0b013e31823d27b6. PMID: 22156955.

We are deeply concerned that implementing a rebate model would cause CHC patients to lose access to essential, life-sustaining therapies. For instance, **direct oral anticoagulants (DOACs)** such as Xarelto® and Eliquis® are vital for patients with deep vein thrombosis, pulmonary embolism, and atrial fibrillation. For many of our patients, there are minimal – and often less safe – alternatives. This is not an optional therapy but a critical tool for survival, as one study showed that discontinuing these drugs leads to a statistically significant increase in the risk of stroke, heart attack, and death.[2]

Similarly, the impact on patients requiring **SGLT2 inhibitors**, such as Farxiga® and Jardiance®, would be severe. These drugs are a mainstay of primary care for conditions like Type 2 Diabetes, chronic kidney disease, and heart failure, all of which are highly prevalent among our patients. Research has found that even a 30-day withdrawal of these inhibitors increases the annualized risk of cardiovascular death or heart failure hospitalization.[3] By making these drugs unaffordable, the rebate model would effectively deny our patients access to the most effective therapies for managing their chronic illnesses, leading to a predictable increase in preventable hospitalizations.

The United States is in the midst of an alarming mental health crisis. Nearly one in four (23.4%) Americans live with a mental illness.[4] Starting in 2027, the MDPNP will include some behavioral health drugs. Vraylar ® is an atypical antipsychotic; atypical antipsychotics are the mainstay of treatment for Schizophrenia. A rebate model could create regulatory barriers for CHCs seeking to provide this drug to uninsured and underinsured patients. Additionally, the 2027 list includes Austedo®, a drug used to treat Tardive Dyskinesia, a common side effect of antipsychotics. Studies have shown that 73% of patients treated with Austedo® achieved treatment success, resulting in improved quality of life.[5] Impairing access to these drugs could result in exacerbation of the mental health crisis.

The impact on **insulin access** is particularly alarming and directly conflicts with federal requirements. With over 3 million Americans relying on CHCs for essential diabetes care,[6] affordability of insulin is a matter of life and death. Furthermore, **Executive Order #14273 conditions future Section 330(e) funds on CHCs providing low-income patients with access to discounted insulin**. There is currently no operational method to provide these discounted medications in a retrospective rebate model. In the proposed model, the wholesaler price file would reflect the full WAC rather than the discounted 340B price. This makes the price unattainable for the patient and **precludes CHCs from fulfilling their legal obligation to offer the required discount at the point of care**.

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[2] Cools F, et al. Risks associated with discontinuation of oral anticoagulation in newly diagnosed patients with atrial fibrillation: Results from the GARFIELD-AF Registry. J Thromb Haemost. 2021 Sep;19(9):2322-2334. doi: 10.1111/jth.15415. Epub 2021 Jul 23. PMID: 34060704; PMCID: PMC8390436.

[3] Packer, M., et al. (2024). Blinded Withdrawal of Long-Term Randomized Treatment with Empagliflozin or Placebo in Patients with Heart Failure. Circulation. https://www.ahajournals.org/doi/pdf/10.1161/circulationaha.123.065748

[4] Substance Abuse and Mental Health Services Administration. (2025). Key substance use and mental health indicators in the United States: Results from the 2024 National Survey on Drug Use and Health (HHS Publication No. PEP25-07-007, NSDUH Series H-60). Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. https://www.samhsa.gov/data/data-we-collect/nsduh-national-surveydrug-use-and-health/national-releases

[5] Hauser RA, et al. Long-Term Deutetrabenazine Treatment for Tardive Dyskinesia Is Associated With Sustained Benefits and Safety: A 3-Year, Open-Label Extension Study. Front Neurol. 2022 Feb 23;13:773999. doi: 10.3389/fneur.2022.773999. PMID: 35280262; PMCID: PMC8906841.

[6] 2025 UDA Data, HRSA (hrsa.gov)

Imposing a rebate model on CHCs would only weaken the safety-net providers that 52 million Americans rely on for health care. CHCs are required to provide sliding fee discounts to patients with incomes at or below 200% of the federal poverty guidelines. The same patients who need access to discounted medical services also depend on CHCs to provide affordable medications. Without the up-front 340B discount, the drugs included in the pilot would become operationally impossible. **This model would create a new and significant barrier, rather than a solution, for our most vulnerable patients, especially those who are uninsured and have limited options for affordable care.**

III. Administrative Complexities and Financial Challenges for CHCs

The proposed 340B Rebate Model Pilot Program is not only a financial threat to CHCs but also a duplicative and unnecessary administrative burden. HRSA should exempt CHCs from the 340B Rebate Model Pilot because they will incur additional workforce and IT costs to comply with multiple manufacturer rebate requirements. A recent NACHC assessment illustrates that CHCs will incur additional workforce and IT costs to maintain compliance with multiple manufacturer rebate requirements, increasing the burden associated with this rebate pilot program. Similar to navigating manufacturers' existing contract pharmacy restrictions, CHCs will need to invest in IT infrastructure upgrades and hire or reassign staff to manage new complexities, including varying data submission requirements and timelines, payment reconciliations, and dispute processes for denied rebates. Depending on the volume of prescriptions a pharmacy fills for the selected drugs, CHCs will face an increased administrative burden in monitoring rebate claims and payments.

340B Rebate Model Operational & Administrative Cost Calculator Description

To support CHCs in assessing the **financial and operational impact** of current manufacturer restrictions and an anticipated rebate model, NACHC worked with their consultant, FQHC 340B Compliance, to create an **Operational & Administrative Cost Calculator.** The tool aggregates program savings, UDS financial data, staffing, external consulting costs, dispensing/capture activity, and clinic-administered drug tracking models to support operational cost forecasting.

CHCs have already experienced steep increases in operational costs given the multitude of manufacturer restrictions, which have now been extended to clinic-administered drugs and entity-owned pharmacies. A refund model will require a significant increase in already-strained operational capabilities.

- **Sliding Fee Discount**: **CareSouth Carolina, Inc.** provided **$435,000** in sliding fee discounts, provided through discounted medications and medical services. We anticipate that our ability to offer sliding fee discounts will decrease significantly under a rebate model.
- **Staffing Impact**: **CareSouth Carolia, Inc.** anticipates needing 2 to 3 additional FTEs to account for the increase in regulatory, operational, administrative, and compliance burden created by a rebate model.
- **External Vendor Costs**: Given increased complexity, **CareSouth Carolina, Inc.** anticipates an increase of **$300,000** in additional costs for external support vendors. These vendors may include 340B consultants, legal counsel, program coordination, third-party administrators, electronic medical records, pharmacy software, and reconciliation services.

Workforce Impact

Below is specific data on the administrative costs that CHCs anticipate, based on thorough planning, review of current business practices, and the costs of implementing new systems and processes.

- 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.[7] **CareSouth Carolina, Inc. estimates needing to hire 2 FTE's to meet the additional reporting needs required from the 340B rebate model.**
- Additionally, several CHCs estimate the cost to hire additional staff to be between $30,000 to $200,000 annually.[8] One midwestern CHC, serving approximately 12,000 unique patients last year, anticipates annual costs exceeding $3 million, including upfront costs for purchasing drugs in this pilot program, increased labor costs, carrying costs, and potential losses on discounted or expired drugs without rebate recovery. CHCs operate on razor-thin margins, and these additional costs are not an option for many entities. **CareSouth Carolina Inc. anticipates its annual cost to hire additional staff to be between $150,000 to $250,000.**
- Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, CHCs will face an increased administrative burden in terms of monitoring rebate claims and payments. **CareSouth Carolina Inc. estimates 15-20 hours** will be required to report 340B rebate claims to a third-party platform, assuming all adhere to the nine drug manufacturers' plans. The lack of standardization and likely varying requirements across manufacturers will force CHCs to use multiple internal systems to manage and report the same data, thereby increasing costs and operational burdens. **CareSouth Carolina, Inc. urges HRSA to require uniformity among eligible manufacturers to mitigate potential administrative and financial burdens associated with receiving timely and appropriate 340B rebates.**

Pharmacy Software & Third-Party Administration Changes

Navigating this pilot requires more than just staff; it requires significant changes to pharmacy software and Third-Party Administrator (TPA) workflows. We encourage HRSA to consider the increased compliance burdens when manufacturers have the flexibility to require varying data submission standards and elements. Additionally, if manufacturers are allowed to select different software platforms, as they currently do with contract pharmacy policies, the administrative burden on CHCs would increase substantially.

- **One-Time Implementation Costs:** We anticipate high upfront costs to adapt our pharmacy software, pay for custom dashboard modifications, and design new internal workflows. CareSouth Carolina Inc. estimates spending a one-time cost of $75,000 will be required simply to reach the baseline of compliance before a single rebate is ever received.
- **Ongoing Operational Fees**: Beyond implementation, our TPA and software vendors will likely charge ongoing service fees to maintain these complex rebate-tracking features. These are permanent, recurring costs that diminish our 340B savings.
- **Total Cost:** For our CHC, which serves 38,116 patients, the total projected increase in expenses—including labor, IT, and carrying costs—is estimated at $350,000 annually.

The In-House Pharmacy: The Burden of Deep IT Integration

[7] Internal NACHC assessment (99 responses).
[8] Ibid.

For CHCs that operate their own pharmacies, the rebate model is not a simple accounting change; it is a significant technological disruption. To remain compliant, in-house pharmacy systems will require costly customization to provide real-time, accurate information at the pharmacy counter.

- **System Interoperability:** Unlike contract pharmacies that use Third-Party Administrators (TPAs), in-house pharmacies must directly integrate their Electronic Health Record (EHR) and Pharmacy Management System (PMS) with a complex new rebate infrastructure. With Pioneer, we would need to ensure real-time or near-real-time data exchange between the EHR and Pioneer Rx. This includes patient demographics, encounter data, provider credentials, and location-specific details (e.g., eligible clinic sites). Accurate linkage is critical for determining 340B eligibility at the prescription level. Pioneer would need to be able to evaluate each prescription against 340B qualification criteria. These criteria would include mapping prescriber NPI's to eligible providers, associating prescriptions with qualifying encounters, tracking service dates versus dispense dates, and looking at carve-in/carve-out rules for insurance plans such as Medicaid. Without a TPA, Pioneer RX must export structured claims data to a third-party rebate processor like NCPDP. You would also have to look at accumulator and inventory management that might include custom reporting, split billing logic if mixed inventories are used, or enhanced auditing. Data extraction and reporting would need to be extremely robust and need to be able to produce audit-ready record reporting, reconciliation of rebate payments, and the ability to monitor savings and program performance. Since there is no TPA, the pharmacy must internally manage claim mismatches or rejected rebate submissions, data validation errors between the electronic health record and Pioneer RX and manually review queues for eligibility exceptions. Lastly, integrations must support traceability and be able to provide documentation of eligibility determination, lead to historical claim-level audit trails, and provide easy retrieval of encounter-to-dispense linkage for HRSA audits.
- **One-Time Integration Costs:** We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools. **$150,000 to $300,000 for**
- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend **15-25** hours per week manually pulling "Purchase Files" and "Price Files" to verify that every rebate check matches the statutory 340B price.

<u>The Contract Pharmacy: The Burden of Network Coordination</u>

For CHC contract pharmacy partners, the rebate model introduces a new complexity that threatens the very existence of these arrangements. My CHC currently partners with 16 pharmacies to increase access to affordable medications.

- **TPA Reliance and Fees:** Navigating manufacturers' varying requirements across multiple contract pharmacies requires high-level TPA intervention. We anticipate that our TPAs will pass on the costs of developing rebate-tracking modules to us through increased per-claim fees.
- **Verification Latency:** The rebate model creates a reconciliation gap. Our staff must monitor claims across **16** different pharmacy locations to ensure rebates are paid correctly.
- **Risk of Pharmacy Exodus:** Because this model shifts the financial risk to the pharmacy, we fear our contract partners will opt out of the 340B program entirely rather than manage the administrative headache. In our region, this would leave patients in **Darlington, Marlboro, Lee, Dillon, and Chesterfield Counties** with no affordable medication options. Over 17

percent of the U.S. population lives in a pharmacy desert already,[9] and the closings of pharmacies have only exacerbated this, with nearly 30 percent of pharmacies that had been open from 2010 to 2021 closing by 2021.[10]

Clinic Administered Drugs: The Burden of New Systems Required

Clinic-administered drug (CAD) operations and record-keeping in CHCs are designed in a cost-effective manner that reflects the nuances of CHC billing. Implementing a rebate model for CADs would also require new software, system integration, and staff training. NACHC estimates these costs would range from $30,000 to $50,000 annually and could be much higher, depending on the software.[11]

- **Bundled Payments:** The majority of clinic-administered drugs are bundled into the prospective payment system (PPS) billing when administered to patients by CHCs. Because PPS visits are paid at a flat rate, the medications administered in CHCs are often not included on claims billed to payers.
- **Simplified Records:** Because CHCs maintain limited inventories of CADs and they are typically not separately billed on claims, it is still common for administration and inventory logs to be maintained on paper, with text documentation in patient visit notes describing what was administered. While the CHCs maintain perpetual inventories and complete administrative records, the fact that the records are often paper imposes the added burden of converting them to electronic data before submitting for rebate. Very few CHC records include electronic medication administration records (eMARs), which are common in hospital electronic medical records (EMRs). Where eMARs are available, they incur an additional cost and often require CHC to pay for a standalone software system.
- **Minimal Risk of Duplicate Discounts:** CHCs primarily bill under Medicare Part A, which is not statutorily included in the Medicare Drug Price Negotiation Program (MDPNP). Maximum Fair Prices (MFP) are only applicable to Medicare Part D claims in 2026 & 2027 and then expand to include Medicare Part B claims in 2028. Regarding Medicaid, each state already has mechanisms in place to address duplicate discounts.
- **HRSA should explicitly exclude CADs from any 340B rebate model pilot.** At a minimum, such drugs should remain excluded unless and until they are billed as discrete claims by CHCs and a demonstrated duplicate discount risk exists that cannot be addressed through existing statutory mechanisms. Including CADs in a rebate pilot at this stage would impose disproportionate administrative costs, software expenses, and compliance risks on CHCs without corresponding benefits to program integrity or federal oversight.

A. Financial Challenges

Under the proposed 340B Rebate Model Pilot, CHCs 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 CHCs' ability to purchase drugs, as the uncertainty of waiting for a manufacturer to approve a rebate would constrain cash flow. CHCs will have to wait to receive their rebate payment ***after*** providing medications to their patients. This change will

[9] Vulnerability Index Approach to Identify Pharmacy Deserts and Keystone Pharmacies | Pharmacy and Clinical Pharmacology | JAMA Network Open | JAMA Network

[10] https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2024.00192?journalCode=hlthaff

[11] Internal NACHC survey data

force CHCs to make difficult decisions about how to allocate their limited financial resources, including cutting essential health services, reducing operating hours, or discontinuing services that support patients' health outcomes.

The proposed 340B Rebate Model Pilot would directly impact CHCs' ability to offer patients steeply discounted medications at the point of sale by requiring them to purchase at full WAC pricing upfront. CHCs' pharmacies, as well as entity-owned and contract pharmacies, will not have access to the 340B price when the patient needs medication. This will create a very unpredictable process for determining the level of discount and pricing for a patient's medication, as the 340B price will no longer be reflected in the pharmacy software from the wholesaler's price catalog, since initial purchase prices will be at WAC. The rebate model creates confusion about its impact on a CHC's ability to offer sliding-fee discounts at the point of purchase.

A rebate model also creates substantial uncertainty about CHCs' ability to apply sliding-fee discounts at the point of sale. By statute and regulation, CHCs are required to offer sliding fee discounts for all required and additional health services within the HRSA-approved scope of the project.[12] In line with their mission, CHCs offer flat or sliding-scale discounts on prescription drugs to make them more affordable for low-income individuals.[13] A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size. At CareSouth Carolina Inc., we offer sliding fee discounts to patients by discounting the service fee or dispensing fee. The resulting discounted dispensing fee results in a nominal charge. The discount will be used on the slide category associated with their medical visit. We also offer a value priced drug list to patients, charging them $4 to $10 based on the medication and quantity prescribed.

CHCs are particularly worried that the need to purchase drugs at full WAC will cause cash flow issues and potentially lead them to exceed their credit limits with wholesalers, halting their ability to order medications until payments are submitted. While rebates are expected to arrive within 10 days from completed data submissions, the previously proposed rebate pilot allowed covered entities up to 45 days to submit data, meaning the potential time from dispense to rebate can extend to 55 days. The financial impact is further compounded when CHCs have entity-owned pharmacies with physical inventories and must stock their shelves with purchases at WAC. Retail pharmacies typically turn their inventory 10-12 times a year (roughly every 30 days).[14] Assuming a best-case scenario of 15 days to the average 30 days for inventory to turn, CHC pharmacies with physical inventory could be waiting 70-85 days from purchase to rebate under a 45-day data submission cadence. Anecdotal reports from CHC pharmacies suggest a planned cadence of 2-week data submissions for entity-owned pharmacy data. Pharmacies with physical inventory submitting data every 14 days would anticipate a purchase-to-rebate payment time frame of 40 to 55 days.

[12] HRSA FAQ

[13] Such discounts are subject to potential legal and contractual restrictions. https://bphc.hrsa.gov/compliance/compliance-manual/chapter9#footnote10

[14] https://enlivenhealth.co/blog/year-end-business-health-check-key-metrics-every-pharmacy-owner-should-review

There may be other delays in receiving the full rebate, such as denials, which could create financial strain on CHCs. We appreciate HRSA's requirement for a 10-day timeframe for rebate payments; however, we have concerns about the lack of details regarding enforcement if manufacturers fail to meet this requirement. Based on experience with manufacturer denials related to the current MFP to 340B de-duplication processes, once an entity has contested a denied rebate and the issue is resolved so the CHC can receive the rebate, manufacturers and their vendors have failed to pay the rebate within the MFP standard of 14 days from when the status is corrected. We are concerned that in a 340B rebate pilot, manufacturers and their vendor(s) will continue to provide corrected contested rebates for an undefined and unlimited time. Complicatedly, the rebate amount may not match the initial discount offered to the patient, creating unpredictable financial losses. CHCs must estimate the rebate amount and may undercharge or overcharge patients due to confusion. Furthermore, if the rebate is denied, the CHC takes a net loss on the transaction. **We respectfully request that, if a rebate pilot is implemented, manufacturers be required to pay rebates within 10 days of both initial and corrected determinations.**

Lack of access to upfront 340B discounts, along with the high IT/infrastructure costs, will disproportionately impact CHCs and trickle down to patients. It is important to note that many CHCs are currently under financial strain. Nearly half of CHCs operate with fewer than 90 days of cash on hand, and one in four reports approximately negative five percent (-5%) operating margins. Below, you will find specific data demonstrating the significant increase in financial costs CHCs will incur under a 340B Rebate Model.

340B Rebate Drug Cost Impact Calculator Description

To support CHCs in assessing the financial impact of purchasing drugs at the full WAC price, NACHC worked with its consultant, FQHC 340B Compliance, to create another calculator for all CHCs. Financial data and projections are based on a 340B Rebate Drug Cost Impact Calculator, which utilizes CHC-specific purchasing data, 340B[15] and WAC pricing data for the first quarter of 2026 (Q1 2026), and the CMS list of MDPNP selected drugs by NDC.[16] For individual MDPNP Price Applicability Years, the calculator evaluates:

- **Increase Upfront Annual Drug Spend**: WAC – 340B for 2025 purchases by NDC & volume, reflected in Q1 2026. WAC and 340B prices applied for the overall annual program volume to determine the annual increase in initial drug spend.
- **Cash Flow Impact**: WAC – 340B for 2025 purchases by NDC & volume, reflected in Q1 2026 WAC and 340B prices to give overall annual program increase in initial spend reflected at intervals of 30, 45, 60, & 90 days. Represents potential WAC purchase to 340B rebate payment cycles. Inventory models, frequency of data submission, and manual processes for referral claim capture can all influence Covered Entities' (CEs) intervals between purchasing a drug at WAC and receiving the Manufacturer Rebate to 340B Ceiling Price.
- **Rebate-Related Opportunity Costs**: Based on percentages of loss of prompt pay, purchase volume, and subceiling discounts and anticipated rebate denials as a portion of annual WAC spend (described above).

[15] https://340bpricing.hrsa.gov/
[16] https://www.cms.gov/files/zip/selected-drug-list-negotiated-prices-also-known-maximum-fair-prices-statutezip.zip

- **Increase Upfront Drug Spend** WAC – 340B for 2025 purchases by NDC & volume, reflected in Q1 2026, calculated by NDC, then aggregated at the MDPNP selected drug, manufacturer, and MDPNP Price Applicability Year levels.
- **WAC Purchase to 340B Rebate Payment "Wait" Period:** CHCs must wait to receive a rebate payment after purchasing and dispensing medication to the patient. This delay forces difficult decisions about allocating limited financial resources.

Based on our organization's data, we estimate it would cost **$15,000,000** to purchase these 10 drugs under the proposed rebate model. Currently, our organization spends **$2,300,000** to purchase these same drugs at the 340B ceiling price. This represents a **650%** increase in upfront capital required for procurement.

This increase in costs will have a devastating impact on our organization's ability to maintain an adequate supply of the drugs included in the HRSA 340B Rebate Model Pilot. As previously discussed, our CHC is navigating a difficult financial environment that cannot sustain purchasing drugs at WAC. To cover the upfront cost of purchasing drugs and operationalizing the rebate, **CareSouth Carolina, Inc.** anticipates needing to reduce:

- **Essential Clinical Services:** To offset the upfront cost of drugs, we would be forced to scale back non-revenue-generating but essential services, such as Chiropractic services, Community Health Worker services, dental services, MAT services, and behavioral health services.
- **Operating Hours:** We anticipate needing to reduce our clinic hours by **20 hours** per week, specifically impacting **our evening and weekend hours, which affect our working-class and agricultural patients can seek care without losing wages]**.
- **Workforce & Staffing:** 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 **a full-time Community Health Worker or a Behavioral Health Counselor**, directly increasing wait times for mental health appointments.
- **Patient Financial Assistance:** 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 **4,326** uninsured patients from rationing their insulin or heart medication.

B. Wholesaler Implications

Another concern is that purchasing drugs at full WAC will potentially lead the organizations to exceed wholesaler credit limits, halting their ability to order medications until payments are submitted. For example, some CHCs have suggested that paying 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.

CareSouth Carolina, Inc. 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.

- **Wholesaler Credit Limits:** Purchasing drugs at full WAC will potentially lead organizations to exceed wholesaler credit limits, halting our ability to order medications until payments are submitted. At present, many CHCs are forced to pay invoices before their due dates to remain within their credit limits. Given that CHCs typically operate with extremely limited financial margins, they are often perceived as having higher credit risks, making increases to credit limits difficult or impractical.
- **Discounts:** CHCs often receive prompt pay, purchase volume, and sub-ceiling discounts on their drug purchases. Forcing a WAC-upfront model threatens our ability to meet these terms, potentially resulting in the loss of these essential discounts. Due to contractual confidentiality requirements, CHCs are unable to disclose their exact prompt-pay discount. However, **CareSouth Carolina, Inc.** estimates its 2027 Annual Rebate Opportunity Cost to be approximately **$1,000,000.** This cost aggregates the estimated financial impact of rebate denials and loss of purchase discounts.
- CareSouth Carolina, Inc. estimates that purchasing the 10 selected drugs at WAC instead of 340B ceiling prices will increase our upfront monthly drug spend by **$13,000,000**.

Every dollar we pay upfront at WAC is a dollar that remains "frozen" in the manufacturer's reconciliation system. While we wait for rebates, we lose the liquidity necessary to respond to immediate public health crises or facility emergencies. To navigate the rebate model, our organization would be forced to **take out a line of credit / utilize limited financial reserves.** This is not a sustainable solution; the interest costs alone are estimated to be $1,500,000 annually—funds that are currently dedicated to our **IV Infusion program, Chiropractic program, Dental services, Podiatry services, behavioral health services, Community Health Care worker services, and hiring additional nurse practitioners**. Forcing CHCs into debt to maintain their drug supply creates an environment of clinical instability. In our region, where patients have no choice but to rely on **CareSouth Carolia, Inc.,** the risk of our credit limit being reached or our reserves being depleted is a direct threat to the community's safety net. If we are forced into financial limbo, the "trickle-down" effect is immediate: longer wait times, reduced service availability, and a weakened ability to provide the steeply discounted medications that our 34 million patients across the country depend on.

a. Financial Impact of Rebate Denials and Delays

CareSouth Carolina, Inc. urges HRSA to recognize that without rigorous, non-discretionary safeguards, the rebate model is not a "pricing mechanism" but a significant financial liability. The current framework allows manufacturers to act as the sole arbiter of a CHC's statutory savings, creating an uncertain environment that results in direct financial harm. The framework proposed in the previously proposed 340B Rebate Pilot allowed manufacturers to deny rebate claims based on vague or ambiguous reasons, such as "duplicate rebate" or "MFP deduplication," without providing the data or documentation CHCs need to understand or contest those decisions.[17]

[17] Application Process for the 340B Rebate Model Pilot Program, 2025-14619 (90 FR 36163) https://www.federalregister.gov/documents/2025/08/01/2025-14619/340b-program-notice-application-process-for-the-340b-rebate-model-pilot-program

If a rebate is denied, the CHC takes a net loss on the transaction, having already paid the full WAC price to the wholesaler and provided the drug to the patient at a steep discount. Given our current volume of the 10 selected drugs, even a conservative **5%** denial rate would result in a net annual loss of **$2,000,000.** This is a sum our CHC cannot absorb, as it represents a direct extraction of resources from our safety net budget. Any reduction in financial resources will directly affect our ability to fulfill the CHC mission of serving all patients, regardless of their ability to pay.

The financial harm is compounded by the fact that the 340B price is no longer reflected in the wholesaler's price catalog or the pharmacy software at the time of purchase. This forces CHCs to "estimate" rebate amounts, creating unpredictable financial losses and the potential to undercharge or overcharge patients. Additionally, the lack of real-time 340B pricing presents challenges for compliance with 340B actual acquisition cost (AAC) billing in fee-for-service Medicaid. This may lead to increased Medicaid costs and potential state-level claw-backs, creating a second layer of financial liability for the CHC. Without a standardized, transparent, and neutral dispute resolution process, the 340B Rebate Model Pilot functions as an interest-free loan from safety-net providers to multi-billion-dollar manufacturers. These unpredictable denials and delays create serious cash flow issues for CHCs operating on thin margins, which depend on timely reimbursement to sustain services for medically underserved populations.

IV. Reconciliation and Rebate Denials Operational Challenges

If HRSA proceeds with a rebate-based pricing model, the program must include clear, enforceable operational guardrails to prevent the systematic shifting of financial and administrative risk to covered entities. **HRSA must require that any rebate model operate under uniform national standards that limit manufacturer discretion, hold manufacturers accountable, and protect covered entities from financial harm.** Recommendations around guardrails include:

- A presumption that rebate claims are valid unless the manufacturer demonstrates otherwise under statutorily sanctioned duplication of discount prevention (i.e., 340B with MDRP or MDPNP);
- Standardized, publicly defined denial categories with claim-level documentation;
- Rebate payment timing requirements must apply to both initial and corrected determinations. If HRSA adopts a 10-day payment requirement, that requirement must run from both the initial determination and any subsequent corrected determination to prevent manufacturers from using dispute processes as a delay mechanism;
- A clear enforcement framework, including consequences for repeated late payments or improper denials by manufacturers;
- Manufacturers must bear the burden of establishing that a rebate is not owed;
- Rebate determinations must align with statutory patient definition: HRSA should explicitly prohibit rebate denial methodologies that rely on manufacturer-defined patient eligibility standards or undisclosed validation criteria.
- OPA should establish a stakeholder advisory panel to ensure that the feedback and concerns of covered entities are formally and consistently addressed. This panel should include pharmacists with the necessary subject-matter expertise to understand the complexities of pharmacy software, billing, and data components.

V. Existing CHC Compliance Actions

CHCs already operate under a comprehensive regulatory framework established through the Health Center Program and the 340B statute to make medications affordable for patients.

- In alignment with Section 330 of the Public Health Service Act, they utilize a sliding fee discount that adjusts costs based on a patient's income and household size, ensuring that no one is denied services due to an inability to pay.
- CHCs also establish systems for eligibility determination and offer full discounts to individuals at or below 100% of the Federal Poverty Level (FPL). These services would not be possible without the savings generated from the 340B program.
- CHCs participate in regular Operational Site Visits (OSVs) to verify Health Center Program compliance, and also follow strict 340B compliance protocols, including internal audits, training, and external oversight.
- CHCs participating in the 340B program are required to report 340B-related information annually through the Uniform Data System (UDS). This includes data on 340B-purchased drugs, associated costs and revenues, and detailed information about the patients served by the program.

Given the compliance infrastructure and strict statutory requirements already in place for CHCs, implementing a rebate model would cause disproportionate harm to CHCs and the patients they serve. The administrative, financial, and operational burdens from such a model would threaten the stability of the safety-net providers that the 340B program was designed to support. CHCs are not the source of misuse in the 340B program; rather, they are national models of compliance.

VI. Establishing a National, Neutral Claims Clearinghouse

We recommend OPA use a Neutral Claims Clearinghouse, which would produce more accurate deduplication at a tiny fraction of the cost and administrative burden of a rebate model. Compared to HRSA's proposed rebate model, the NCC approach would:

- **Avoid cash-flow and borrowing challenges** for CEs by preserving the upfront 340B discount.
- **Substantially reduce administrative burden on CEs** by significantly reducing the need for them to build and maintain complex rebate compliance systems, and the staff time needed to track and reconcile claims and to manage cashflow issues.
- **Provide manufacturers with the necessary deduplication data within the same 45-day timeframe.**
- **Improve rebate accuracy**, reducing the time and effort manufacturers and CEs must spend correcting errors.
- **Preserve the longstanding upfront discount structure** that has defined the 340B program for more than three decades and is essential to most CHCs' participation in the program.
- **Protect patient access to affordable MFP drugs.** If a rebate model were implemented, the resulting cash-flow pressures could force many CHCs to stop purchasing or dispensing MFP drugs altogether.
- **Identify Medicaid Duplicate discounts in Medicaid.** An NCC could provide a standardized national approach to preventing duplicate Medicaid discounts by collecting CEs' 340B claims data for Medicaid prescriptions and making it available to states.

Given the major disruption the 340B rebate program is anticipated to have on CHCs, a system that forces CHCs to provide data that is already accurately and readily available to manufacturers is not only redundant but also adds additional administrative burdens on safety-net providers. It is imperative that HRSA require manufacturers to leverage existing resources to protect the stability of the safety-net providers that the 340B program was designed to support.

Conclusion

CareSouth Carolina Inc. strongly urges HRSA to exempt CHCs from any 340B Rebate Model Pilot Program. A 340B rebate program represents a departure from the original intent of the 340B program—to allow safety-net providers to "stretch scarce Federal resources" and provide more comprehensive care. A rebate model would create significant cash flow challenges, forcing CHCs to make difficult decisions about staffing, services, and the range of drugs they can afford to stock. Additionally, CHCs would need to make significant investments in IT infrastructure and staff to comply with rebate requirements and track rebates. It would also create a new barrier for patients, especially uninsured patients, who depend on the up-front 340B discount, making it operationally impossible to provide the sliding fee scale and steeply discounted medications required by law. **CareSouth Carolina Inc.** believes that a 340B rebate pilot would cause disproportionate harm to patients served by CHCs and other safety net providers.

CareSouth Carolina Inc. appreciates the opportunity to respond to this Request for Information on the 340B Rebate Model Pilot, and we look forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please contact **[YOUR POLICY DIRECTOR'S/VP'S NAME AND EMAIL ADDRESS.]**

Sincerely,

Ann Lewis
CareSouth Carolina Inc.

Johnson & Johnson Health Care Systems Inc.
1000 US Highway 202 South
Raritan NJ 08869 United States

SUBMITTED VIA EMAIL (paperwork@hrsa.gov)

April 20, 2026

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

Re: Johnson & Johnson Health Care Systems Inc. Comments on Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906-NEW

Dear Administrator Engels:

I write on behalf of Johnson & Johnson Health Care Systems Inc. ("J&J") in response to the Health Resources & Services Administration ("HRSA") Request for Information: 340B Rebate Model Pilot Program (HHS Docket No. HRSA-2026-03042) (the "RFI")[1] and the accompanying Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation ("ICR").[2] J&J appreciates the opportunity to provide feedback regarding the RFI and ICR.

J&J has sought to work transparently and constructively with HRSA on implementation of a rebate model since July 2024. Most recently, in September 2025, J&J submitted comments in response to HRSA's announcement of the application process for the initial 340B Rebate Model Pilot Program ("Pilot"),[3] and HRSA approved J&J's application for initial price applicability year ("IPAY") 2026 drugs STELARA®[4] and XARELTO®. J&J planned to participate in the Pilot until HRSA terminated the program earlier this year pursuant to a court order. Although J&J maintains that the 340B statute authorizes manufacturers to implement rebate models without HRSA's prior approval, we nevertheless commend HRSA for re-starting the pilot process and seeking stakeholder input on a new 340B rebate model pilot program. HRSA's support for a rebate model offers a practical mechanism that allows manufacturers to more effectively deduplicate discounts and address ongoing 340B program integrity concerns. We welcome the opportunity to contribute to the success of a rebate model pilot program and support its expansion to all covered outpatient drugs and broader use for 340B Program compliance purposes.

Since 2024, J&J has corresponded extensively with HRSA regarding the use of a rebate model and J&J's attempts to conduct statutorily authorized audits of various covered entities due to documented concerns of potential diversion and duplicate discounting. Although HRSA approved our audit requests and associated work plans nearly two years ago, we continue to encounter substantial resistance from certain covered entities, causing those audits to remain incomplete and to result in extraordinary expense, despite the fact that covered entity compliance with HRSA-approved manufacturer audits is a condition of

[1] Request for Information: 340B Rebate Model Pilot Program, 91 Fed. Reg. 7287 (Feb. 17, 2026).
[2] Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906–NEW, 91 Fed. Reg. 9632 (Feb. 26, 2026).
[3] 90 Fed. Reg. 38165 (Aug. 7, 2025).
[4] We note that J&J's drug USKETINUMAB (unbranded STELARA) is a selected drug for IPAY 2026 and would also be included in a pilot covering IPAY 2026 selected drugs if J&J's rebate model plan were to be approved.

participation in the 340B Program.[5] Our experience with the audit process reinforces the need for a rebate model.

Below we have provided our comments in response to the RFI. **Section I** outlines J&J's advocacy efforts regarding a rebate model, frustrated pursuit of HRSA-approved covered entity audits, and initial participation in the Pilot. **Section II** describes the 340B Program's widespread issues with abuse, including duplicate discounting, diversion, the replenishment model, and covered entity audits. Sections III and IV respond to HRSA's questions raised in the RFI. **Section III** outlines how a rebate model would address program integrity concerns, including through real-time claim and program reporting. In conclusion, **Section IV** clarifies the limited impact a rebate model would have on covered entities.

I. J&J's Advocacy for a Rebate Model, Frustrated Audit Efforts, and Participation in HRSA's Initial Pilot.

Since 2024, J&J has advocated for a 340B rebate model that would support program integrity and facilitate deduplication of discounts under Section 340B and the Medicare Drug Price Negotiation Program ("MDPNP") created by the Inflation Reduction Act ("IRA").[6] J&J first proposed a rebate model for sales to Disproportionate Share Hospital ("DSH") covered entities of its two IRA-selected drugs (STELARA and XARELTO) in mid-2024, explaining that the deduplication procedure directed by the IRA presented serious logistical hurdles that a rebate model would best address.

J&J's advocacy for a rebate model proceeded alongside its efforts to conduct a series of HRSA-approved audits of covered entities. For nearly two years, however, J&J has faced fervent resistance from several covered entities, making clear that audits are not an adequate means to address longstanding program integrity concerns.

a. J&J's Pre-Pilot Advocacy for a 340B Rebate Model

J&J's interest in pursuing a 340B rebate model arose from concerning trends it observed in the volume of purchases of its products at 340B prices. Across its portfolio, purchases of J&J's drugs at 340B prices have increased at least twice as fast as its overall sales, and 340B purchases of certain of its products increased even faster. For example, from the second quarter of 2023 to the second quarter of 2024, 340B purchases of STELARA increased by 56%—about five times as fast as STELARA's overall sales. Likewise, 340B purchases of XARELTO increased by 33%—about eight times as fast as XARELTO's overall sales. These significant increases in 340B sales occurred even though the population of patients either uninsured or living in poverty—the patients who should be benefiting from 340B discounts—has actually declined by almost half, from 15.7% of the U.S. population in 2013 to 8.7% in 2021.[7] These aberrant purchasing patterns were a key factor that prompted J&J to pursue covered entity audits and to consider a rebate model.

J&J first met with HRSA to discuss 340B rebate models in mid-2024, explaining that under the current structure of the 340B Program, it has little to no visibility into the claims-level data necessary to validate 340B claims—in particular, whether covered entities are unlawfully causing duplicate discounts on 340B-priced drugs. Offering the 340B price through a rebate, J&J explained, would improve the integrity

[5] 42 U.S.C. § 256b(a)(5)(C).
[6] Pub. L. No. 117-169, 136 Stat. 1818 (2022).
[7] *See* Rory Martin et al., IQVIA, *Unintended Consequences: How the Affordable Care Act Helped Grow the 340B Program*, at 8 (Aug. 30, 2024), https://bit.ly/3XFDWh8.

of the 340B Program by helping to mitigate the risk of duplicate discounts, which HRSA's own audits demonstrate occur frequently year after year.[8]

J&J also described the challenges it faced in attempting to comply with its obligations under the IRA's MDPNP. Under the IRA, covered entities are entitled to the lesser of the 340B price or the maximum fair price ("MFP") for drugs selected for "negotiation" by CMS. For calendar year 2026, this includes two J&J products, STELARA and XARELTO. Because the IRA's nonduplication provision protects manufacturers from providing both the 340B ceiling price and the "MFP" on the same drug unit and requires manufacturers to make this determination within 14 days of the transaction, effectuating the "MFP" requires manufacturers to identify when 340B-priced drugs are dispensed to Medicare beneficiaries in real-time. However, CMS had not yet (and to date, still has not) developed a mechanism that would enable manufacturers to identify 340B-eligible "MFP" claims. Offering the 340B price through a rebate, J&J explained, would be the most effective means for J&J to fill the gap left by CMS, enabling J&J to identify Medicare claims in real-time and comply with the IRA's nonduplication requirement.

In light of these challenges, J&J informed HRSA that it was contemplating a shift to a rebate model. Under the model, DSH covered entities—which J&J's data showed were particularly prone to abuse—would acquire STELARA and XARELTO from wholesalers at commercial prices and then receive a rebate to realize the 340B ceiling price promptly after submitting commercially standard claims data, which could occur before payment is due under standard wholesaler terms. J&J stressed that the rebate model would utilize standard claims data that covered entities already collect in the normal course of business, retain for 340B compliance purposes, and submit to payers in the reimbursement process.

After further correspondence between J&J and HRSA, however, HRSA concluded that Section 340B grants HRSA authority to require its pre-approval before a manufacturer may adopt a rebate model and warned J&J that penalties for proceeding with an unapproved rebate model could include termination from the program. HRSA provided similar responses to other manufacturers that proposed their rebate models. Faced with the threat of termination, J&J paused its plan to implement a rebate model and brought litigation against HRSA. That case, along with other cases brought by other manufacturers, remains pending before the U.S. Court of Appeals for the District of Columbia Circuit.

b. J&J's Stymied Audits of Covered Entities

In parallel with its efforts to adopt a limited-scope rebate model, J&J sought and obtained HRSA's approval to conduct audits of a dozen covered entities. Instead of cooperating with the duly authorized audits—as the 340B statute required them to do[9]—many of the covered entities resisted, obfuscated, and delayed. Six of the covered entities filed suit against HRSA seeking to halt the audits altogether. All six suits were dismissed.[10]

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[8] *See* U.S. Gov't Accountability Off., GAO-21-107, *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, at 13–14 (Dec. 14, 2020), https://www.gao.gov/assets/gao-21-107.pdf (finding nearly 35% of HRSA's 2012-2019 audits resulted in a finding of duplicate discounting, and 44% resulted in a finding of diversion); *see also* HRSA, Program Integrity: FY22 Audit Results, https://www.hrsa.gov/opa/program-integrity/fy-22-audit-results (last updated Feb. 23, 2026) (finding duplicate discounts at nearly two dozen of the 199 covered entities HRSA audited in 2022); HRSA, Program Integrity: FY23 Audit Results, https://www.hrsa.gov/opa/program-integrity/fy-23-audit-results (last updated Mar. 30, 2026) (finding duplicate discounts at nearly two dozen of 176 entities audited in 2023); HRSA, Program Integrity: FY24 Audit Results, https://www.hrsa.gov/opa/program-integrity/fy-24-audit-results (last updated Mar. 30, 2026) (finding duplicate discounts at nearly two dozen of the 179 entities audited in 2024); HRSA, Program Integrity: FY25 Audit Results, https://www.hrsa.gov/opa/program-integrity/fy-25-audit-results (last updated Mar. 30, 2026) (finding duplicate discounts at nearly two dozen of the 115 entities with completed audits conducted in 2025).

[9] 42 U.S.C. § 256b(a)(5)(C).

[10] *Or. Health & Sci. Univ. v. Engels*, No. 24-cv-2184, 2025 WL 1707630 (D.D.C. Jun. 17, 2025).

Even now, *two years* after J&J began its good-faith outreach to covered entities and almost one year since the district court dismissed their lawsuits, some of the entities that brought suit continue to resist J&J's audits—despite multiple reminders from HRSA that they are required to comply as a condition of their 340B Program eligibility. These covered entities have developed a playbook to vitiate J&J's rights by dramatically increasing the costs and time required even to *initiate* an audit, let alone complete one and take any disputes to administrative dispute resolution ("ADR").

Moreover, even when audits can be effectively conducted, they serve a different purpose than rebate models. Audits are backward-looking and cannot ensure future compliance; they address only a narrow subset of historical claims; they can take months or, in our experience, years to complete; they can be conducted only for a handful of entities per year at most; and they do not require covered entities to address the full scope of identified noncompliance or revise the policies or procedures that led to any identified violations. As a result—and especially in light of covered entities' ability to resist them without apparent consequence—audits are a profoundly inefficient and ineffective tool for addressing program abuse and only serve to reinforce the need for a rebate model.

c. HRSA's 340B Rebate Model Pilot Program and J&J's IRA Compliance Without a Rebate Model

J&J appreciates HRSA's willingness to explore practical solutions to ensure greater program integrity and address challenges manufacturers face in implementing their overlapping statutory obligations. J&J was prepared to participate in the initial Pilot after HRSA approved its application and applauded HRSA for taking an important first step toward structured and transparent rebate models. J&J is pleased to share responses to the questions posed in HRSA's RFI, along with related information that J&J believes will be useful as HRSA considers the potential for another rebate model pilot.

Without a rebate model, J&J has been grappling with its limited ability to implement the deduplication provisions of the IRA since the "MFP" became effective on January 1, 2026. J&J has relatively little access to real-time data needed to deduplicate 340B and "MFP" discounts consistent with its obligations under the IRA. Without the claims data that a rebate model would make available for all "MFP" claims across all covered entities, J&J must rely on limited and imperfect data and analytics to reasonably identify units of STELARA or XARELTO dispensed to Medicare Part D beneficiaries that were eligible for 340B pricing. This is, in part, because J&J's current contract pharmacy policy applies only to hospital covered entities, many of which have opted out and submit no data to J&J. As of this time, a very limited subset of dispensing entities self-identify 340B-eligible "MFP" claims to J&J. To date, pharmacies have classified "fewer than 0.5 percent of "MFP" claims" as 340B, despite estimates suggesting 10% to 12% of "MFP" claims are 340B.[11] In the absence of a mechanism to identify all 340B-eligible "MFP" claims, J&J estimates that it faces increased risk of paying duplicate discounts on up to 40% to 50% of 340B-eligible "MFP" claims and estimates that it has already paid approximately $80 million in duplicate discounts on 340B-eligible "MFP" claims for STELARA and XARELTO since January 1, 2026.

[11] BRG, Update on Effectuation of the Maximum Fair Price in 2026 and Outlook for 2027, at 2 (Apr. 2026), https://media.thinkbrg.com/wp-content/uploads/2026/04/03101442/Effectuation-of-the-Maximum-Fair-Price-in-2026-and-Outlook-to-2027.pdf.

II. The 340B Program Suffers from Pervasive Program Integrity Abuse.

The 340B Program is rife with abuse and has increasingly operated beyond its narrow statutory purpose. The legislative history of the 340B statute confirms the program's intent: to "reduce pharmaceutical costs for safety-net medical providers and the indigent populations they serve."[12] Over time, however, the Program has expanded in scope and complexity without necessary guardrails or transparency. This expansion has contributed to persistent compliance concerns, including duplicate discounts between Medicaid and 340B, diversion of discounted drugs to ineligible individuals, and the inability to verify program integrity in a timely manner. This section discusses these concerns in more detail.

a. Duplicate Discounting is Widespread Under the 340B Program.

Covered entities may receive improper duplicate discounts in two ways. *First*, the 340B statute expressly prohibits a covered entity from obtaining a 340B discount on the same units of a covered outpatient drug that generate a Medicaid rebate.[13] Despite this prohibition and well documented risks of manufacturers paying duplicate discounts, manufacturers are significantly limited in their ability to access Medicaid and 340B claims data to prevent duplicate discounts. With respect to accessing 340B claims data, we note that J&J's 340B contract pharmacy policy currently applies only to hospital covered entities (*i.e.*, it excludes grantee covered entities) that opt to submit claims data to 340B ESP, and, even then, only to self-administered drugs that were billed through pharmacy claims. On the Medicaid side, only a subset of states currently provide J&J access to Medicaid claims data that allows for matching against 340B claims to identify potential duplicate claims. Notwithstanding these data limitations, J&J analyzed 340B claims that hospital covered entities submitted to the ESP platform for the most recent nearly three-year period and found more than 16,500 340B claims that were potentially duplicated with Medicaid rebate claims. This amounted to more than $22.4 million in potentially duplicated Medicaid rebate requests during the period. Given the data limitations described above, this estimate likely dramatically understates the true scope of J&J's potential Medicaid duplicate discount exposure.

More broadly, however, a 2020 report issued by the Government Accountability Office ("GAO") found that, in the 1,242 audits HRSA conducted from fiscal years 2012 through 2019, HRSA had identified 429 findings related to duplicate discounts.[14] In other words, nearly 35% of HRSA's audits found evidence of prohibited duplicate discounting. More concerningly, both HRSA and J&J have an even more limited ability to identify (and no means to prevent) duplicate discounts in the Medicaid managed care context—which is the primary drug coverage mechanism for Medicaid beneficiaries—even though duplicate discounting in this context may be even more widespread.[15] In 2019, when the 340B program was less than half its current size, it was estimated that industry-wide Medicaid/340B duplicate discounts amounted to as much as $1.5 billion annually.[16] This duplicate discount risk persists despite the 340B statute expressly obligating the Secretary of HHS to "develop[]…more detailed guidance describing methodologies and options available to covered entities for billing covered outpatient drugs to State Medicaid agencies in a manner that avoids duplicate discounts…."[17]

Second, as discussed above, although the IRA states that a manufacturer is protected from providing access to the "MFP" for a selected drug to a 340B covered entity when the 340B ceiling price is lower than

[12] H.R. Rep. 102-384, pt. II, at 10–12 (1992).
[13] 42 U.S.C. § 256b(a)(5)(A).
[14] U.S. Gov't Accountability Off., GAO-21-107, *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, at 14 (Dec. 14, 2020), https://www.gao.gov/assets/gao-21-107.pdf.
[15] *Id.*
[16] Kalderos, Making Health Policy Work for Patients (2021), https://f.hubspotusercontent40.net/hubfs/7227094/2021%20Annual%20Report/Annual_report_2021.pdf.
[17] 42 U.S.C. § 256b(d)(2)(B)(iii).

the "MFP",[18] no mechanism exists that would permit a manufacturer to verify whether the same unit of drug is subject to both 340B and "MFP" discounts. The magnitude of duplicate discount risk resulting from the absence of a deduplication mechanism is significant. As of April 2026, pharmacies have classified "fewer than 0.5 percent of "MFP" claims" as 340B through either CMS or Beacon MFP mechanisms. An analysis of Medicare Part D PDE data suggests 10% to 12% of "MFP" claims should be identified as 340B. This translates to "fewer than 5 percent of 340B claims [being] self-identified as such by pharmacies."[19] J&J's experience is similar. In early March 2026, J&J observed that fewer than 0.4% of "MFP" claims for its selected drugs were being self-identified as 340B. This dramatically poor rate improved to only 0.5% in April 2026 after J&J sent a communication to all MTF-registered dispensing entities reminding them of their obligation to submit accurate claims and providing instructions for self-identifying 340B-eligible "MFP" claims in Beacon MFP.

Additionally, based on one early report, in the first 30 days after the "MFP" went into effect, only 60% of "MFP" claims were properly processed.[20] Of the 40% of claims processed incorrectly, the report showed that "30% of total claims experienced duplicate payments, in which manufacturers paid both "MFP" and 340B pricing on the same transaction. The average dollar value per duplicate payment was $398…."[21] These error rates translate into substantial and avoidable financial exposure for manufacturers and highlight the need for more reliable, real-time mechanisms to ensure that only one statutory discount applies to a given claim.

J&J faces significant challenges in identifying duplicate discounts under the 340B Program. The third-party data sources available to J&J provide only retrospective transactional information, which does not allow J&J to prevent duplicate discounts at the point of sale. Compounding this problem, there is no universal data source that reliably identifies the 340B status of an individual claim. Most covered entities currently do not provide claims-level data to J&J. And, even where such data is available, it is often incomplete, inaccurate, or obsolete, making it difficult to reconcile with other rebate and utilization data. These challenges are further compounded by the "MFP's" timing requirements, under which J&J must provide access to the "MFP" on a selected drug dispense within 14 days.

When J&J is able to identify an improper 340B duplicate discount, the process for recouping those amounts is burdensome, inefficient, and often unsuccessful. State Medicaid agencies frequently direct us to seek repayment from the covered entity, rather than refunding the associated Medicaid rebate. The covered entity, on the other hand, often directs us to the state Medicaid agency. As a result, because CMS does not require states to implement clear Medicaid managed care guidelines addressing use of 340B drugs,[22] and because HRSA does not require covered entities to address identified duplicate discounts in Medicaid managed care and work with manufacturers to repay them,[23] recoupment of these duplicates, if identified, is often unsuccessful.

[18] Social Security Act § 1193(d)(1).
[19] BRG, Update on Effectuation of the Maximum Fair Price in 2026 and Outlook for 2027, at 2 (Apr. 2026), https://media.thinkbrg.com/wp-content/uploads/2026/04/03101442/Effectuation-of-the-Maximum-Fair-Price-in-2026-and-Outlook-to-2027.pdf.
[20] 340B Report, 40% of Claims Miss the Mark (Mar. 5, 2026), https://340breport.com/40-of-claims-miss-the-mark-sponcon-rxparadigm/.
[21] *Id.*
[22] U.S. Gov't Accountability Off., GAO-20-212, *340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement*, at 28 (Jan. 27, 2020), https://www.gao.gov/products/gao-20-212.
[23] *Id.* at 26.

b. The Current 340B Program Structure Undermines Manufacturers' Ability to Prevent Diversion.

The 340B statute prohibits the resale or transfer of drugs at the 340B ceiling price to any person who is not an eligible patient of the purchasing covered entity, a practice commonly referred to as "diversion." HRSA's 1996 guidance defines a patient as having (i) an established relationship with the covered entity, including that the covered entity maintains the individual's healthcare records; (ii) the health care professional is either employed, contracted, or has another arrangement with the covered entity (*e.g.*, referral for consultation) such that responsibility for the care provided remains with the covered entity; and (iii) for grantee covered entities, the care provided is consistent with the scope of services for which the covered entity receives grant funding.[24] HRSA's 1996 guidance does not consider an individual "a 'patient' of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting."[25]

The 340B Program has experienced significant diversion concerns, as repeatedly confirmed by HRSA's audit findings.[26] In particular, as a result of replenishment systems adopted by covered entities, 340B eligibility is now determined long after the product dispense. Replenishment systems work in one of two ways. First, under product replenishment, a pharmacy initially purchases a drug from a wholesaler at a commercial price, places it in neutral inventory, and then dispenses the product to patrons of the pharmacy. The covered entity or its third-party administrator ("TPA") later will determine—weeks or even months after the dispense—that the patient was (according to them) a patient of the covered entity. The pharmacy then receives a replacement unit purchased by the covered entity at the 340B price and the manufacturer pays a chargeback to make the distributor whole. Second, under what is called "credit-based" replenishment, the process is essentially the same, except that, instead of receiving a new unit of the product to replace the unit dispensed to a 340B patient, the wholesaler performs a series of financial transactions that are not transparent to the manufacturer to effectuate 340B pricing without the physical distribution of drugs. While these models differ by wholesaler, they often result in (i) the pharmacy receiving a credit to its wholesale acquisition cost ("WAC") account on an invoice for drugs it previously purchased, and (ii) the covered entity being invoiced for those previously purchased drugs at the 340B price with a chargeback issued to the manufacturer.

Under either approach, the records associated with the drug dispense or administration to the (purported) covered entity patient do not identify 340B eligibility. Rather, the eligibility determination is made only after the covered entity or its TPA acts—weeks or even months following the dispense or administration. The chargeback invoice to the manufacturer requiring the 340B discount is disconnected from the dispense/administration records, therefore creating a lack of visibility into the patient eligibility assessment. And, although manufacturers are allowed to audit covered entities to assess compliance with the statutory duplicate discounting and diversion prohibitions, that process has proven ineffective for the reasons explained above and, in any event, does not allow manufacturers to audit contract pharmacies or TPAs, where much of the evidence concerning patient eligibility is housed.

Under this current opaque system that covered entities have created, most diversion can run rampant with virtually no visibility or means of detection. However, using the limited 340B claims data J&J has received from certain hospitals participating in its contract pharmacy policy, for the most recent three-year period, J&J identified more than 10,200 duplicate 340B claims submitted by distinct covered

[24] 61 Fed. Reg. 55156, 55157–58 (Oct. 24, 1996).
[25] 61 Fed. Reg. at 55158.
[26] HRSA, Program Integrity: FY25 Audit Results (last updated Mar. 30, 2026), https://www.hrsa.gov/opa/program-integrity/fy-25-audit-results.

entities (*i.e.*, where multiple covered entities claimed 340B pricing on the same drug dispense/administration). Despite guidance stating that only one covered entity is permitted to receive 340B pricing on a single drug dispense or administration,[27] J&J's limited data clearly shows that covered entities' use of overbroad patient definitions and expansive contract pharmacy networks are causing unlawful diversion – on a likely much larger scale – that a rebate model would identify and prevent.

More broadly, in the GAO report referenced above, GAO found that HRSA made 546 findings related to diversion, meaning over 40% of HRSA's audits found that covered entities were dispensing 340B drugs to non-patients.[28] J&J does not have the data necessary to combat all instances of diversion, which manufacturers can only collect from covered entities. Indeed, J&J has been prevented from obtaining such data,[29] including from covered entities, even where J&J has reasonable cause to suspect 340B noncompliance and has secured HRSA approval to conduct an audit.[30] A rebate model can mitigate this serious problem.

III. A Rebate Model Will Improve Program Integrity.

A rebate model offers a practical and effective framework for strengthening program integrity and improving compliance within the 340B Program. By requiring standardized reporting of pharmacy claims, medical claims, and purchase data, a rebate model would enhance transparency, enable timely validation of 340B eligibility, and support more effective oversight. This approach represents the most viable means of delivering the real-time data necessary to prevent noncompliance while preserving program functionality. Consistent with these objectives, J&J supports manufacturer-required reporting mechanisms that are essential to demonstrating and operationalizing a rebate model in practice.

Below we respond to the following questions that HRSA sets forth in the RFI: Question 1, Costs to Covered Entities; Question 3, Rebate Denials; Question 5, Manufacturer Efforts to Avoid Duplicate Discounting; Question 6, Required Reporting; and Question 7, 340B Program Integrity and other Potential Benefits of a Rebate Pilot.

a. HRSA Should Not Limit the Types of Covered Entities that Participate in the Rebate Model.

The RFI requests that covered entities "[i]dentify any organization-specific factors that could impact your organization's ability to participate in a potential 340B Rebate Model Pilot Program (e.g., rural, small business, community health center)."[31] HRSA should not limit a rebate model pilot to certain covered entity types. J&J assumes the purpose of a pilot would be to "test" the feasibility of rebates with a limited set of drugs. Excluding certain covered entities from a pilot would frustrate this purpose by depriving HRSA and stakeholders of the ability to assess the viability of rebate models across the 340B program.

Additionally, implementing a rebate model for only a subset of covered entities, and allowing non-participating covered entities to continue purchasing all 340B drugs at up-front discounts, would create considerable operational complexity across the pharmaceutical supply chain and introduce new 340B

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[27] 340B Prime Vendor Program. (September 30, 2020). FAQ ID: 1599. 340B Patient Definition. Available at: https://www.340bpvp.com/search#tab=faq&cf-p_faq_category_hierarchy=Policy/Implementation.Patient%20Definition.
[28] U.S. Gov't Accountability Off., GAO-21-107, *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, at 14 (Dec. 14, 2020), https://www.gao.gov/assets/gao-21-107.pdf.
[29] *Pharm. Rsch. & Mfrs. of Am. v. McCuskey et al.*, No. 25-1054, --- F.4th ----, 2026 WL 898259, at *11 (4th Cir. Mar. 31, 2026) (stating that if manufacturers are prohibited from obtaining claims data from covered entities, they lack the ability to identify potential diversion).
[30] *See, e.g., Or. Health & Sci. Univ. v. Engels*, No. 24-cv-2184, 2025 WL 1707630 (D.D.C. Jun. 17, 2025).
[31] 91 Fed. Reg. at 7289.

compliance risks. While it is difficult to identify the universe of 340B compliance risks that could flow from a bifurcated rebate model approach, such risks include, for example: (i) a single health system may own facilities designated as different covered entity types, which provides the opportunity for the covered entity to circumvent rebate model application, and (ii) pharmacies may dispense 340B drugs for both participating and non-participating covered entities, creating even greater inventory management complexity that increases the risk of 340B statutory violations.

Furthermore, excluding certain covered entity types from a pilot would leave manufacturers with no reliable access to 340B claims data to deduplicate 340B/"MFP" and 340B/Medicaid discounts for these entity types. This would require implementation of one or more alternatives to allow manufacturers to access 340B claims information; however, those alternatives would be less effective than a rebate model (see Section III.c.iii. below), and simultaneous use of these alternatives alongside a rebate model would create considerable complexity and burden for all stakeholders. In August 2024, J&J sought to implement a limited scope rebate model that included only DSH covered entities, partly in anticipation of the need to deduplicate 340B and "MFP" discounts for all covered entities beginning January 1, 2026. Following hospital litigation challenging and ultimately thwarting the Pilot, there is no longer time to implement a rebate model in such a stepwise fashion. Since 340B and "MFP" discounts must be deduplicated across all covered entities, a rebate model pilot should apply to all covered entities.

Finally, the 340B statute does not expressly define "rural," which has allowed large urban hospitals to qualify as rural hospitals (*e.g.*, Cleveland Clinic, Northwestern Memorial Hospital).[32] Uniform application of the rebate model pilot across covered entity types will enable HRSA to comprehensively assess the benefits and burdens of a rebate model, and thus will result in better-informed findings at the end of the pilot.

b. Manufacturers Should Be Permitted to Deny Ineligible Rebate Claims Under Specified Circumstances (RFI Question 3).

In Question 3, HRSA asks stakeholders to consider whether a rebate model should contain specific guardrails that govern rebate denials and, if applicable, to describe what should be required to deny a rebate claim.[33] Manufacturers should be permitted to deny ineligible rebate claims for specified reasons. In that circumstance, manufacturers should provide supporting documentation that includes the rationale for the denial. Potential reasons for denials could include:

- **Ineligible National Drug Code ("NDC")**: The NDC is not part of the rebate model pilot program or the NDC expired more than a year before the date of dispense.
- **Ineligible date of dispense**: Claims with a date of dispense prior to the beginning of the rebate model pilot should not be eligible for a rebate, with the exception of a limited number of unreplenished 340B dispenses or administrations occurring prior to the pilot initiation.
- **Invalid user**: A user attempts to submit rebate data for a covered entity for which it is not an authorized representative.
- **Invalid data types**: Data submitted for a given field do not match the data format expected for that field (*e.g.*, an NDC is present within a date field).

[32] HRSA, Office of Pharmacy Affairs, 340B OPAIS, *Search Covered Entities*, https://340bopais.hrsa.gov/SearchCe (last visited Apr. 9, 2026).
[33] 91 Fed. Reg. at 7290.

- **Invalid data values**: Prescriber or pharmacy National Provider Identifier ("NPI") does not align with accepted structure for an NPI; the prescriber NPI is not an active, individual healthcare provider; or the pharmacy NPI is not an active, organizational healthcare provider. Additionally, for NDCs that are only eligible for dispense through a limited distribution network ("LDN"), a rebate may be denied if it reflects dispense by a pharmacy NPI that is outside of the LDN.

- **Missing data**: One or more HRSA-required fields is not populated.

- **No Active HRSA Registration**: Location of dispense or administration is not actively registered with HRSA and active as of the date of dispense.

- **Duplicative rebate**: The same claim cannot be submitted more than once for a 340B rebate, either by the same covered entity or multiple covered entities.

- **Late submission**: A claim generally cannot be submitted for a 340B rebate after a certain period of time has passed since the date of dispense or administration. The 2025 Pilot utilized 45 days, and J&J provided for case-by-case exceptions due to covered entity operational extenuating circumstances.

- **No WAC purchase**: HRSA should require that covered entities only request 340B rebates for units they purchased at the WAC price. A rebate may be denied if there is no evidence of a WAC purchase.

- **Pricing not available (orphan drug)**: Offering the 340B price to certain covered entity types on orphan drugs is voluntary for manufacturers. A rebate may be denied in instances where the manufacturer does not offer this voluntary pricing.

- **Pricing not available (contract pharmacy)**: Only certain contract pharmacies may be eligible for a 340B rebate according to the manufacturer's contract pharmacy policy.

- **Aberrant quantity**: Claims with dispensed or administered units that exceed a certain threshold for reasonable volume may be denied. This check is designed to catch instances where a user inadvertently keys in an incorrect unit value or uses an incorrect unit conversion rate. If not denied, these instances could result in a rebate payment that is excessive for the volume of drug actually dispensed or administered.

To deny a rebate claim, manufacturers should establish fully transparent validation guidelines so that covered entities can validate their own claims prior to submission, thereby curtailing the need for denials. Compliance with HRSA's design specifications for manufacturer validations should limit the need for HRSA involvement in denied claims. The Beacon platform, operated by Second Sight Solutions, LLC ("Second Sight Solutions"), would provide robust support services to help covered entity users understand denial codes and to correct any incomplete or inaccurate data. When a denial does occur, the rebate model platform would communicate the specific reason for the denial and would allow covered entities to resubmit corrected claims, which J&J would not treat as duplicate submissions.

c. The Rebate Model Should Require Pharmacy Claims, Medical Claims, and Purchase Data Elements (RFI Question 5).

Question 5 asks manufacturers to identify required data elements to detect potential duplicate discounts across the 340B Program and CMS payment programs.[34] To operate an effective rebate model, J&J believes three categories of data are necessary: pharmacy claims data, medical claims data, and purchase data. J&J agreed with HRSA's decision to include both pharmacy and medical claims data in the Pilot and urges HRSA to include that data in a future pilot program and add purchase data.

i. Pharmacy and Medical Claims Data Are Critical to a Rebate Model.

Although "MFP" effectuation is currently limited to pharmacy claims for IPAY 2026 and 2027 selected drugs, certain selected drugs still may be administered in the medical benefit portion of a patient's insurance. For example, approximately 10% of STELARA purchases are provider-administered. Similarly, XARELTO may be administered in an outpatient setting (*e.g.*, emergency department, in connection with outpatient surgery). J&J thus requires medical claims data for the associated reimbursement for these products when dispensed in these settings.

For this reason, J&J urges HRSA to include medical claims data elements, in addition to pharmacy claims data elements, in a future rebate model pilot. The table in Appendix 1 contains commercially standard information regarding drug administration that covered entities routinely collect and report to payors for reimbursement of medical claims, along with the corollaries between those data elements and pharmacy claims data elements.[35] These data are also retained in covered entities' auditable 340B records and are subject to production and review in HRSA- and manufacturer-conducted 340B audits, and thus should be readily available to submit to a rebate platform. J&J encourages HRSA to include these data elements in the rebate model.

ii. Purchase Data Would Contribute to Increased 340B Program Integrity.

Accurate 340B rebate processing also requires access to certain purchase data elements to confirm that rebate requests correspond to units the covered entity actually purchased at WAC, and then to calculate the appropriate rebate amount.

Purchase data could be validated, in part, by cross-referencing it with "867" product shipment transaction data exchanged between manufacturers and wholesalers. To reduce burden and protect covered entity confidentiality, J&J proposes to collect only data needed to identify relevant shipment transactions and to determine rebate amounts. Although J&J routinely receives 867 data from wholesalers describing shipments to purchasers,[36] that data alone is often insufficient to assess rebate eligibility.[37] For example, 867 data does not indicate whether units purchased at WAC are intended for 340B use and does not always identify the ship-to or bill-to customer. In addition, although J&J contracts for certain identifying information (*e.g.*, name, DEA, HIN, or 340B ID, and address) for ship-to and bill-to entities, some retail

[34] 91 Fed. Reg. at 7290.
[35] In the ICR, HRSA states, "OPA expects that data submitted by covered entities to manufacturers will be comparable to data already being collected and maintained by covered entities through existing third-party vendor relationships or data that is already being provided to manufacturers with respect to certain contract pharmacy policies, in-house pharmacy claims requests, and data elements provided for claims with drugs dispensed under the Medicare Drug Price Negotiation Program. Therefore, the burden associated with a potential 340B Rebate Model Pilot Program data requests may not be significant." 91 Fed. Reg. at 9633.
[36] Because units eligible under the rebate model are sold by J&J at WAC, wholesalers do not transmit chargeback data to J&J identifying a 340B covered entity as the purchaser of a given medication.
[37] Relevant data may be delayed or unavailable to J&J. In those circumstances, J&J must rely on purchase data submitted by covered entities to process rebates within the required timeframe.

pharmacy chains restrict wholesalers from sharing these data or 867 data altogether. As a result, 867 data alone will not allow J&J to determine which covered entity purchased particular units for 340B use or to align shipment and claims data without additional confirmation.

Purchase data fills these gaps. First, it will confirm that the covered entity itself purchased the units for which rebates are claimed. This verification is particularly important in complex arrangements involving multiple entities, such as contract pharmacies. Second, purchase data will enable J&J to confirm that the drug was acquired at WAC.[38] Third, purchase data helps ensure that rebate claims correspond with units acquired at a commercial price rather than at the 340B price. Without this visibility, rebates could be requested for units purchased at the 340B price before the rebate model's effective date, particularly at the outset.

Appendix 2 includes the purchase data elements that J&J believes reflect standard, commercially available purchase information that covered entities can readily obtain from wholesalers as part of accounts payable and invoice management processes, including through electronic invoice access and bulk download tools.[39] As with claims data, it is appropriate to request the limited "standard information" necessary to confirm that rebates correspond to actual WAC purchases,[40] supporting efficient and reliable administration of the rebate model.

iii. A Rebate Model Is the Most Effective and Viable Approach for Providing Needed Real-Time Data and Preventing Noncompliance with the 340B Program.

In Question 5(e), HRSA references "the potential for the 340B Rebate Model Pilot Program to be an additional or alternative source" for "data elements…necessary for a manufacturer to identify potential duplicate discounts under 340B and CMS payment programs."[41] As described below, alternative approaches to a rebate model would pose operational challenges, would meet with significant covered entity opposition, and/or would result in delayed access to meaningful claims data (and a continued lack of real-time transparency). By contrast, the rebate model provides a structured and reliable framework for obtaining validated claims data in shorter timeframes.

Manufacturer Claims Collection. Some manufacturers have tried to offset the deficit created by the delay in implementation of a rebate model pilot by adopting policies that require covered entities to submit limited, commercially standard 340B claims data for all transactions (whether contract pharmacy or in-house pharmacy) as a condition of manufacturers' 340B pricing offers permitted under federal law. Although this approach may increase the volume of claims data available to manufacturers, it is likely less effective than a rebate model. Covered entity stakeholders have objected to providing claims data, and even where claims data is provided, known and ongoing challenges with the accuracy, completeness, and timeliness of the data could render that data less effective as compared to timely and validated claims data afforded by a rebate model. Finally, as with a clearinghouse addressed below, this approach relies on covered entities submitting 340B claims information on a lagged basis without a direct connection to the 340B discount extended on the units associated with each claim. Without the ability to link a request for 340B pricing to validated claims data in real time under a rebate model, manufacturers must identify and

[38] J&J would not request information regarding any additional discounts covered entities may negotiate with wholesalers, which we understand to be confidential.
[39] *See, e.g.*, McKesson, *Pharmacy Accounts Payable Management System*, https://www.mckesson.com/pharmacy-technology/pharmaceutical-ordering/pharmacy-accounts-payable/ (last visited Apr. 9, 2026).
[40] *See, e.g.*, *Novartis Pharm. Corp. v. Johnson*, 102 F.4th 452, 463 (D.C. Cir. May 21, 2024); 59 Fed. Reg. 25,109, 25,112 (May 13, 1994).
[41] 91 Fed. Reg. at 7290.

address noncompliance retrospectively on a covered entity-by-covered entity basis subject to the inefficiencies and pitfalls described in Sections I and II of this letter.

Neutral Clearinghouse. Under a clearinghouse model, a centralized third-party repository would receive covered entity-reported 340B transaction data (and potentially attempt to reconcile that information against CMS data sources). However, this model is fundamentally dependent on covered entities or their TPAs self-identifying 340B claims—perhaps using a modifier—after the drug is dispensed or administered and without any independent mechanism to incentivize timeliness, accuracy, or completeness. As with the current system, therefore, unless HHS were to undertake robust oversight and enforcement to ensure covered entity compliance with clearinghouse reporting requirements, manufacturers would continue to lack the ability to validate reported claims or assess whether duplicate discounts have occurred.

Critically, a neutral clearinghouse cannot work properly unless it can substantiate the self-reported claims volume using 340B purchase data. CMS's ongoing efforts to establish a clearinghouse for Part D inflation rebates, which will be optional and is not expected to commence operations until fall 2026 at the earliest underscores the challenges with a narrow-scope clearinghouse option.[42] Past experience with the MDPNP also reaffirms that voluntary self-identification of 340B claims does not yield sufficient participation or reliability. As of April 2026, pharmacies have classified "fewer than 0.5 percent of MFP claims" as 340B through either CMS or Beacon "MFP" platform mechanisms, which is markedly less than Medicare Part D PDE data suggests should be occurring (potentially 10% to 12% of "MFP" claims).[43]

d. J&J Supports Manufacturer-Required Reporting to Demonstrate Rebate Model Operation (RFI Question 6 & ICR).

In Question 6 of the RFI, HRSA requests stakeholder feedback on how the rebate model should be monitored for compliance, including the specific data elements manufacturers should report, the frequency of such reporting, and the scope and cadence of HRSA reporting, including public disclosures.[44] In the ICR, HRSA proposes that "manufacturers will be required to submit data to the 340B Prime Vendor monthly to evaluate program integrity and to provide greater transparency in the 340B program."[45]

We note that the 340B Prime Vendor, Apexus, currently is the subject of a congressional investigation regarding its business practices related to the 340B Program, including potential conflicts of interest and alleged misaligned financial incentives.[46] Apexus also is a wholly-owned subsidiary of Vizient, which is the largest group purchasing organization in the United States and is owned by hospitals.[47] Vizient's clients include many covered entities. As a result, Apexus may not be an appropriate entity to manage the collection and evaluation of sensitive data related to a rebate model, and it may be more appropriate for manufacturers to report data elements directly to HRSA. J&J agrees with comments

[42] 90 Fed. Reg. 49266, 49741, 49754 (Nov. 5, 2025).
[43] BRG, Update on Effectuation of the Maximum Fair Price in 2026 and Outlook for 2027, at 2 (Apr. 2026), https://media.thinkbrg.com/wp-content/uploads/2026/04/03101442/Effectuation-of-the-Maximum-Fair-Price-in-2026-and-Outlook-to-2027.pdf ("To date, fewer than 0.5 percent of MFP claims have been self-identified as 340B by the pharmacy . . . . By comparison, analysis of Medicare Part D Prescription Drug Event (PDE) data suggests that between 10 and 12 percent of claims for 2026 selected drugs are subject to 340B pricing. In other words, fewer than 5 percent of 340B claims are self-identified as such by pharmacies.").
[44] 91 Fed. Reg. at 7290.
[45] 91 Fed. Reg. at 9632–33.
[46] Senate Health, Education, Labor & Pensions Committee, *Chair Cassidy Continues Investigation into 340B Drug Program, Seeks Information from 340B Prime Vendor* (Feb. 2, 2026), https://www.help.senate.gov/rep/newsroom/press/chair-cassidy-continues-investigation-into-340b-drug-program-seeks-information-from-340b-prime-vendor-1.
[47] Gabler, E. *How a Company Makes Millions Off a Hospital Program Meant to Help the Poor*, New York Times (Jan. 15, 2025), available at: https://www.nytimes.com/2025/01/15/us/340b-apexus-drugs-middleman.html.

submitted by PhRMA and BIO that HRSA and other government agencies (*e.g.*, HHS-OIG and certain functions within CMS) should evaluate the pilot.

Regardless, J&J agrees that manufacturers should report data elements aligned with the pilot for the duration of the rebate model. J&J proposes that these data elements should include:

- Claim Submission Date
- 340B ID
- NDC-11 Purchased
- Quantity
- Unit WAC Price
- Unit 340B Ceiling Price
- Unit "MFP" Price
- Rebate Amount
- Rebate Date Paid
- Rejection Reason (if applicable)

In addition, manufacturers should be required to provide aggregated data regarding the operation of the rebate model, including:

- Aggregated sales by covered entity type as defined in 42 U.S.C. § 256b(a)(4)
- Average days from claim submission to rebate payment for all rebates paid
- Number of rebates paid after 10 calendar days
- Number of rebates denied with denial reasons
- Number of selected drug claims with "MFP" refunds that are duplicative of 340B pricing provided through the rebate model pilot program

Further, HRSA could consider publishing the manufacturer-reported aggregated data. If it does so, HRSA should aggregate data across manufacturers so that it does not inadvertently report proprietary and sensitive data of an individual manufacturer.

e. A Rebate Model Would Materially Improve Compliance Associated with the 340B Program (RFI Question 7).

Question 7 asks commenters whether a rebate model pilot would affect 340B Program integrity, reduce duplicate discounts and diversion, and increase pricing transparency. It also seeks recommendations on how to improve data collection and reporting and asks stakeholders to describe other potential benefits, as well as to weigh these benefits against potential costs.

A rebate model will significantly enhance program transparency, which will help prevent duplicate discounts and other forms of noncompliance. Stakeholders need transparency into the 340B Program, which is the second largest federal drug pricing program. Compared to other federal drug pricing programs of a similar scale (*e.g.*, Medicaid, Medicare), there is a lack of publicly available data necessary to evaluate program integrity and effectiveness. For example, CMS and state Medicaid agencies have access to complete Medicare and Medicaid claims data, enabling robust oversight and analysis. No comparable claims-level data exists for the 340B Program—not for the entities funding the discounts (manufacturers) nor for the agency charged with overseeing the program (HRSA).

Participation in the 340B Program is a bargained-for exchange pursuant to the Spending Clause of the United States Constitution. Manufacturers like J&J agree to charge no more than the 340B price to eligible purchasers, subject to the limitations set out in the duplicate discount prohibition, the diversion prohibition, and the theoretical protection afforded by the right to audit, in exchange for coverage and

payment for their drugs under Medicaid and Medicare Part B.[48] Notably, the 340B program was intended to restore access to voluntary discounts that certain drug manufacturers had offered certain safety net providers prior to enactment of the Medicaid Drug Rebate Program in 1990.[49] As noted above, therefore, the purpose and structure of the 340B program were narrow, and the diversion and duplicate discounting provisions are essential parts of the Spending Clause bargain, designed by Congress to moor the program to its intended scope. More transparency through a rebate model is consistent with this intent and will help to restore the 340B program to its original purpose, by enabling better and real-time enforcement of the duplicate discount and diversion prohibitions. Transparency also will enable HRSA to better monitor and enforce program integrity requirements.

Duplicate Discounts. The rebate model will provide more complete and timely information, enabling HRSA to gain a comprehensive view of the 340B Program and how it operates across various covered entity categories. Claim-level data fields create an auditable trail that would allow J&J to assess whether a discount has already been provided on the same drug unit (*e.g.*, "MFP", Medicaid). By creating a mechanism for manufacturers to receive 340B claims data before providing the 340B price, the rebate model provides real-time insight into specific claims that resulted in payment of a 340B discount and thus facilitates timely, accurate, and efficient deduplication of "MFP" and Medicaid rebates.

In contrast to the current replenishment model, this approach promotes greater and more timely transparency. In addition, by providing real-time access to claims data that can avoid duplicate discounts, disputes between manufacturers and covered entities would be reduced. Ultimately, this conserves stakeholder resources, including those of the government.

Diversion. The rebate model also reduces opportunities for diversion, in that it would allow manufacturers to use real-time information to verify that the 340B price is provided only on eligible claims. Unlike a replenishment model—under which covered entities rely on a neutral inventory that commingles 340B and non-340B drugs—a rebate model ensures that the same drug for which a covered entity requests a 340B rebate is the drug actually dispensed or administered to the patient. Therefore, it materially reduces the risk of diversion by directly linking the 340B rebate to a specific dispensed or administered drug. By standardizing claim-level validation across covered entity types, a rebate model strengthens diversion controls and reduces risks arising from differing inventory tracking practices. Additionally, by requiring submission of standardized data for each drug dispense or administration, manufacturers can identify instances where a rebate is requested by more than one covered entity and ensure only one rebate is paid, consistent with the diversion prohibition and HRSA guidance.

Further, the rebate model would provide data that validates that the pharmacy that dispensed the unit is eligible for the program (*i.e.*, listed as active in Office of Pharmacy Affairs Information System ("OPAIS")), reducing the risk of diversion. Access to real-time claims and purchase data would permit J&J to identify any instances in which the dispense or administration occurred in advance of the purchase date. The rebate model provides an alternative to ADR to address certain types of diversion—while conserving government resources.

Manufacturer Audits. A rebate model would reduce the need for inefficient and expensive audits by providing manufacturers with claims data in real-time. By verifying claims before providing the 340B price, the rebate model would mitigate the opacity resulting from prevalent use of replenishment models and also reduce the need for manufacturer audits overall. J&J would be able to identify program integrity concerns earlier and more precisely, creating more thorough and detailed reasonable cause and audit work

[48] *See Pharm. Rsch. & Mfrs. of Am. v. McCuskey et al.*, No. 25-1054, --- F.4th ----, 2026 WL 898259 (4th Cir. Mar. 31, 2026) (finding West Virginia's contract pharmacy law likely preempted by the 340B statute).
[49] H.R. Rep. 102-384, pt. II, at 10–12 (1992).

plans. Accordingly, HRSA's review also would be more thorough and efficient, utilizing less agency time and allowing HRSA to better direct its own covered entity audits.

IRA "MFP" Compliance. A rebate model is the most effective known means for identifying 340B-eligible Medicare "MFP" claims in real-time, which in turn allows a manufacturer to meet the IRA's nonduplication requirement within CMS's 14-day "prompt 'MFP' payment window."

IV. The 340B Rebate Model Would Not Impose Undue Burdens on Covered Entities.

Despite assertions to the contrary, transitioning to a rebate model would not introduce significant new financial or operational burdens for covered entities. Rather, manufacturers would bear the costs associated with administering a rebate model platform and providing implementation resources in the form of live and recorded education sessions, data reporting templates, and TPA integrations. In addition, a rebate model would provide a shortened timeline for delivery of 340B pricing and would rely on commercially standard data collection supported by robust privacy and security protections. Below, we discuss RFI questions related to covered entity impact: Question 1, Costs to Covered Entities; Question 2, Payment Timing and Potential Cash Flow Impacts for Covered Entities; and Question 4, Data Collection by Covered Entities.

a. Covered Entities Currently Pay Costs to Support Existing 340B Program Operations and a 340B Rebate Model Would Not Create Significant New Financial Burdens (RFI Question 1(a)).

Question 1(a) seeks information on 340B-related costs paid by covered entities under the existing 340B Program. Covered entities have utilized TPAs and other vendors to handle the administrative requirements of the 340B Program for many years, including to determine ways to extract more value from the 340B Program.[50] For a fee, TPAs offer services to covered entities including compliance, auditing, inventory management and split-billing, program optimization and revenue capture, and patient access.[51] TPAs also have begun to offer services that would assist covered entities in implementing rebate model processes.[52] Notably, many of the TPA rebate model-specific functions do not vary significantly from the support they presently offer.

A 2025 congressional report provided insight on certain TPA fees. The report found that fees charged by Wellpartner, LLC, a CVS Health subsidiary, had more than doubled over four years, rising from $147 million in 2019 to $382 million in 2023 for "services . . . includ[ing], but not limited to 340B eligibility determination, technology support and compliance."[53] The report also found that Sun River Health, a Federally Qualified Health Center covered entity, spent "5.9 percent of its total 340B revenue of 2019, 9.3 percent in 2020, nine percent in 2021, and 8.7 percent in 2022" on TPA services.[54]

Separately, the Minnesota Department of Health released a 340B Covered Entity Report in February 2026,[55] which found that, in 2024, covered entities in the state reported having 340B "operational

[50] Sayeh Nikpay et al., Health Affairs Scholar, *Growing Administrative Complexity in the 340B Program and the Rise of Third-Party Administrators* (Nov. 2023), https://academic.oup.com/healthaffairsscholar/article/1/5/qxad052/7320443?login=false.
[51] *Id.*
[52] *See, e.g.,* Verity Solutions, *Your 340B Rebate Model Pilot and MFP Checklist: How to Prepare for Launch* (Dec. 19, 2025), https://verity-solutions.com/your-340b-rebate-model-pilot-and-mfp-checklist/.
[53] Senate Comm. on Health Educ. Lab. & Pensions, *Congress Must Act to Bring Needed Reforms to the 340B Drug Pricing Program* (Apr. 2025), https://www.help.senate.gov/imo/media/doc/final_340b_majority_staff_reportpdf.pdf.
[54] *Id*.
[55] Minn. Dep't of Health, *340B Covered Entity Report* (Feb. 27, 2026), https://www.health.state.mn.us/data/340b/docs/2025report.pdf.

costs [of] approximately $165 million." About $137 million of this amount (83%) was paid to contract pharmacies and other external vendors "representing nearly 10% of total statewide gross 340B revenue." This means that "[f]or every $100 of gross 340B revenue generated, Covered Entities collectively paid approximately $10 to [these] *external* organizations."[56] The remaining approximately $28 million (17%) of these operational costs were for covered entities' "internal costs for administering their 340B programs," including staffing and technology.

These reports make clear that, under the current discount model, covered entities derive significant financial benefit from the 340B Program and are spending significant shares of their 340B revenues on vendors to grow those revenues further. These growth-driven arrangements often come at the expense of program integrity. The Minnesota report also highlights the comparatively small share of operational costs that covered entities devote to internal functions that would cover 340B Program compliance. Given the size, scope, and complexity of covered entities' 340B programs and the program integrity challenges they present, any incremental covered entity costs associated with implementing a rebate model would be outweighed by the model's transparency and compliance benefits. Further, as the D.C. Circuit recognized in *Novartis Pharms. Corp. v. Johnson*,[57] it is reasonable that covered entities would be required to expend a small amount of resources to maintain compliance.[58]

Regarding the provision of medical claims data, to the extent a covered entity has not already implemented a 340B-specific reporting system for this data, we expect that a covered entity would be able to leverage technology they already use to electronically exchange this data with payors (including government programs), 340B TPAs/consultants, and certain manufacturers. As data elements needed for rebate processing overlap with those collected through 340B ESP and the data request list used in HRSA covered entity audits, covered entities should already have access to such data and, in most cases, have already reported data to manufacturers using 340B ESP, a platform that is similar to Beacon's rebate model platform. Recently, J&J has observed that certain covered entities have begun submitting their medical claims data for J&J's provider-administered drugs to 340B ESP as a result of claims data policies recently instituted by other manufacturers. J&J has also received medical claims data as part of its "good faith inquiry" process for "MFP"/340B deduplication. Submission of medical claims data in response to new manufacturer policies demonstrates that covered entities possess the data required under a rebate model and can share it with a rebate model platform vendor with minimal effort and cost. It is worth emphasizing that any costs incurred in creating a new data reporting stream would be a one-time expense—not an ongoing burden for covered entities.

b. Manufacturers Pay Costs Associated with the Operation of a Rebate Model and 340B Compliance Generally—They Should Not Be Expected to Reimburse Covered Entities' Costs (RFI Question 1(b)).

Question 1(b) suggests that HRSA is considering whether a rebate model could be "structured so as to offset these administrative and operational costs" and requests information as to "how [that could] be achieved and how [] such an offset be accurately quantified."[59]

J&J incurs significant costs to maintain 340B compliance—costs that continue to increase as program complexity grows and which are in addition to the $7.4 billion in 340B discounts that J&J paid to

[56] *Id*.
[57] 102 F.4th 452 (D.C. Cir. 2024).
[58] BRG, 340B Program at a Glance: 2025, https://media.thinkbrg.com/wp-content/uploads/2025/02/19075246/340B-Program-at-a-Glance-2025_F.pdf (2025).
[59] 91 Fed. Reg. at 7289.

covered entities in 2024.[60] In 2025, for example, J&J paid millions of dollars in primary 340B compliance costs, such as:

- $14 million to external vendors and systems to manage data intake, validation, and policy enforcement (including "MFP" deduplication solutions);
- $5 million for complex data reconciliation across claims, chargebacks, rebates, and government pricing; and
- $5 million for audit and monitoring requirements, including internal controls and external reviews.

In sum, J&J's estimated annual 340B compliance costs approximate upwards of $24 million, before taking into account internal and external 340B legal expenses. These expenses are non-discretionary, recurring, and scale with operational complexity.

J&J would fund the operation of its rebate model and provide covered entities no-cost access to an electronic rebate platform and certain implementation resources described below. Any requirement that J&J would then need to offset covered entities' 340B operational and compliance costs on top of this would impermissibly extend manufacturers' obligations beyond the statutory requirement to "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price."[61] Further, there is no precedent for requiring manufacturers—or any other party—to offset covered entities' 340B operational and compliance costs, and asking covered entities to catalog their costs, submit them to manufacturers, and then require manufacturers to validate and pay those costs would create further audit questions and logistical challenges.

In anticipation of the Pilot, the Beacon platform, to which J&J would provide covered entities and their contractors no-cost access, offered trainings and assistance to help covered entities and vendors prepare for launch. Beacon conducted 21 live webinars in November and December 2025 in anticipation of a January 1, 2026 Pilot launch.[62] To further help covered entities, Beacon offers a software development kit ("SDK") which is a secure and direct data integration that allows automated 340B rebate data submissions and status updates, thereby alleviating covered entity costs and personnel efforts. According to Second Sight Solutions, there are currently over 50 organizations (10 of which are large health systems) set up on the Beacon SDK. Covered entities thus have the technological and administrative ability to support a rebate model, and many have already undertaken significant preparation to begin operating under one.

c. A Rebate Model Provides for a Shortened Payment Timeline for 340B Pricing (RFI Questions 1 and 2).

In part, Question 1 seeks information regarding whether implementation of a rebate model requires meaningful changes to covered entities' resources (*e.g.*, staffing, systems), as well as whether such a model would have any impact on patient access to drugs.[63] Question 2 seeks information related to the impact of a payment schedule under a rebate model "(*e.g.*, within ten calendar days of submission of a complete claim)" and any effect that would have on covered entities.[64]

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[60] Johnson & Johnson Center for U.S. Healthcare Policy Research, Issue Brief: The 340B Program: Missing the Mark for Patients (2025), https://policyresearch.jnj.com/the-340b-program/.
[61] 42 U.S.C. § 256b(a)(1).
[62] Second Sight Solutions, LLC, Beacon Support Center, https://support.beaconchannelmanagement.com/en/articles/9519227-beacon-support-calendar (last visited Apr. 9, 2026).
[63] 91 Fed. Reg. at 7289.
[64] 91 Fed. Reg. at 7289–90.

Covered entity payment terms under a rebate model are as good or better than existing payment terms in the 340B Program.[65] In today's 340B Program, covered entities voluntarily participate in replenishment models that they created (at their own expense and without HRSA pre-approval), described above in Section II.b. The rebate model would operate at the unit level, as compared to a package level. Thus, covered entities will not need to wait until accumulation to a full package to receive the 340B price as they do under the replenishment model. IQVIA recently reported that any impact of a rebate model on covered entities' cash flow should be "small and unlikely to be a barrier to its use by covered entities."[66] The study found that interest costs as a percent of WAC for a rebate model were consistent with, or less than, interest costs incurred under prevailing inventory models.[67]

Further, a 10-day payment timeframe benefits covered entities compared to that of the "MFP" payment period, which the MTF reports takes approximately 21 days (or more) from dispense to payment.[68]

The Beacon platform includes standard functionality that permits a covered entity to reconcile its 340B-eligible rebate claims to 340B rebate payments received. We agree that manufacturers should be held to making timely rebate payments, which should be done in a manner consistent with the statutory "shall offer" requirement.

Importantly, J&J's rebate model efforts would not affect patient access to J&J drugs. Patients generally are identified as 340B-eligible only after a drug has been dispensed. The 340B discount rarely is passed on to the patient at the point of sale, and patients are typically not aware of their 340B eligibility. A covered entity's decision not to acquire a drug at the 340B ceiling price does not affect a patient's ability to access the medication. The patient's cost sharing obligation—set by their insurance—is exactly the same as it would have been, irrespective of the patient's choice of hospital or pharmacy provider.

d. The Rebate Model Provides Commercially Standard Data Collection with Robust Privacy and Security Protections (RFI Question 4).

Question 4 requests information regarding covered entity and rebate model data collection practices, as well as recommendations for establishing guardrails to address privacy and security concerns.[69]

Data Collection. The rebate model would collect standard pharmacy and medical claims data elements that covered entities maintain in the ordinary course of business and provide to other stakeholders. As described in Sections III.c.i. and IV.a. above, these fields substantially overlap with data elements that covered entities maintain in their auditable records and produce in the context of audits, collect and report to payors for reimbursement, and provide to manufacturers under various contract pharmacy, in-house pharmacy, and 340B/"MFP" deduplication processes.

Data Privacy and Confidentiality. J&J treats privacy and security with the utmost seriousness. The Beacon platform has robust guardrails in place to manage any privacy or security concerns and applies

[65] *See* SmartSourceRx, *Credit and Payment Details*, https://www.smartsourcerx.com/credit-and-payment-details (last visited Apr. 9, 2026).
[66] Chuan Sun et al., IQVIA, *How Will a Rebate Model Impact Cash Flow in the 340B Drug Pricing Program?*, at 1, 13 (2025), https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2025/iqvia-cash-flow-impact-in-340b-white-paper-2025.pdf.
[67] Chuan Sun et al, IQVIA, *How Will a Rebate Model Impact Cash Flow in the 340B Drug Pricing Program?*, at 1, 13 (2025), https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2025/iqvia-cash-flow-impact-in-340b-white-paper-2025.pdf.
[68] BRG, Update on Effectuation of the Maximum Fair Price in 2026 and Outlook for 2027, at 1 (Apr. 2026), https://media.thinkbrg.com/wp-content/uploads/2026/04/03101442/Effectuation-of-the-Maximum-Fair-Price-in-2026-and-Outlook-to-2027.pdf (citing data transmitted from the MTF to the Beacon MFP platform).
[69] 91 Fed. Reg. at 7290.

its terms uniformly to ensure consistent program administration. Second Sight Solutions' platforms are subject to an independent expert determination under the HIPAA de-identification standard at 45 C.F.R. § 164.514(b)(1) and to third-party information security audits.[70]

We note that Second Sight Solutions works directly with 340B Covered Entities to address conflicts with applicable law.[71] To date, more than 10,000 340B Covered Entities have registered on the Beacon platform and accepted its terms and privacy policy.[72]

* * *

J&J appreciates HRSA's attention to the issues raised in this letter and welcomes further discussion to support a rebate model. Please do not hesitate to contact us with any questions or if additional information would be helpful.

Sincerely,

Lauren Paluzzi

Lauren Paluzzi
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[70] Beacon Channel Management, Beacon Trust Center, https://cm.beaconchannelmanagement.com/pages/trust-center; 340B ESP, Frequently Asked Questions, https://help.340besp.com/en/articles/8808065-frequently-asked-questions-faqs#h_b553637062.
[71] Information provided by Second Sight Solutions.
[72] Information provided by Second Sight Solutions.

Johnson & Johnson Health Care Systems Inc.
1000 US Highway 202 South
Raritan NJ 08869 United States

Appendix 1

Pharmacy Claim and Medical Claim Data Elements

Pharmacy Claim Data Element	Medical Claim Data Elements	Description	Required / Optional	HRSA DRL	340B ESP	Included in 2025 Pilot[73]
Date of Service	Date of Service	Date the prescription was filled at the pharmacy or the drug was administered to the patient	Required	Date on which the drug was furnished, administered, or dispensed	Date of Service	Yes
Date Prescribed	N/A	Date the healthcare provider wrote the prescription	Required	Date the drug order or prescription was written	Date Prescribed	Yes
Rx Number	Claim Number	The native (unmodified) prescription number for the prescription as generated by the pharmacy (pharmacy claims), or the claim number as assigned by the healthcare provider (medical claims)	Required	Patient ID number	Rx Number	Yes
Fill Number	N/A	The code indicating whether the prescription is an original or a refill. For example, a value of 0 indicates that the prescription is the original dispense, whereas the value of 1 indicates the prescription has been refilled once.	Required	N/A	Fill Number	Yes
11-Digit National Drug Code (NDC)	11-Digit National Drug Code (NDC)	NDC-11 of the product that was purchased by the Covered Entity	Required	NDC	NDC	Yes
Quantity Dispensed	Quantity	Number of units dispensed to the patient (pharmacy claims), or total	Required	Quantity Issued	Quantity	Yes

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

Pharmacy Claim Data Element	Medical Claim Data Elements	Description	Required / Optional	HRSA DRL	340B ESP	Included in 2025 Pilot[73]
		quantity being submitted on medical claim (units billed) (medical claims)				
Prescriber ID	Rendering Physician ID	NPI of the prescriber who wrote the prescription (pharmacy claims) or who administered the medication to the patient (medical claims)	Required	Ordering provider	Prescriber ID	Yes
Service Provider ID	Service Provider ID	NPI of the pharmacy that filled the prescription (pharmacy claims) or a pharmacy or facility where the patient received the medication administration (medical claims)	Required	Location	Service Provider ID	Yes
340B ID	340B ID	The HRSA assigned parent 340B ID of the entity that designated the prescription as 340B (pharmacy claims) or purchased the drug (medical claims)	Required	Type of account through which the drug was purchased, purchase account, and the associated 340B ID	Contracted Entity ID	Yes
Rx Bank Identification Number ("BIN") / Rx Processor Control Number ("PCN")	Health Plan ID / Health Plan Name	Bank identification number of the primary payer on the claim and processor control number assigned by the entity processing payment (pharmacy claims); name and identifier code of patient's primary health insurance plan (medical claims)	Required / Required	N/A	Payer BIN / Payer PCN	Yes
N/A	Claim line number	The line number of the claim	Required	N/A	Claim Line Number	Yes

Pharmacy Claim Data Element	Medical Claim Data Elements	Description	Required / Optional	HRSA DRL	340B ESP	Included in 2025 Pilot[73]
N/A	Unit of measure	The unit of measure for the quantity submitted on medical claim. Either HCPCS code or UOM is required. If HCPCS code is not included, UOM is required, and it should be consistent with NCPDP units.	Required	N/A	Unit of Measure	Yes
N/A	HCPCS Code	The five character HCPCS code for separately payable medications	Optional	N/A	HCPCS Code	Yes
N/A	HCPCS Modifiers (up to 4)	Modifier code associated with a separately payable medication with its own five character HCPCS code	Optional	N/A	HCPCS Code Modifier	Yes

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Appendix 2

Purchase Data Elements

Purchase Data Element	Description	Required / Optional	HRSA DRL
Wholesaler Name	Name of the wholesaler that processed the invoice and shipped the purchased drug. Where 867 transaction data is blocked entirely for a transaction, this data element allows J&J to identify the relevant wholesaler and work directly with that entity, when necessary, to identify the relevant transaction and validate the rebate claim, which may reduce follow up inquiries with the covered entity.	Required	Wholesaler name
Wholesaler Account Number	Wholesaler assigned account number used to place the order. This data element allows J&J effectively to resolve any discrepancies between information submitted by the covered entity and data received from the wholesaler. Purchase Account Number enables J&J to work directly with the wholesaler to identify the relevant transaction and validate the rebate claim. While not strictly required, this data point is strongly recommended to reduce the likelihood of follow up inquiries and streamline the rebate validation process for covered entities. This data element is not provided in 867 transaction data.	Optional	Account number
Invoice Date	Wholesaler-assigned invoice number for the purchase order. The platform uses Invoice Date to identify the relevant transaction to support verification that the purchase qualifies for a 340B rebate. Because invoice numbers are not necessarily unique across different wholesalers or transactions, the platform requires a combination of Invoice Number, Invoice Date, and NDC-11 to accurately match the covered entity's purchase data to J&J's corresponding 867 data describing the shipment transaction. This multi-field approach ensures reliable identification of WAC purchases while compensating for gaps in standard transaction data. In addition, the platform relies on the Invoice Date paired with the reported NDC-11 to determine the applicable WAC for the unit at the time of purchase, ensuring that the rebate amount is calculated based on the correct pricing in effect on the transaction date.	Required	Invoice date
Invoice Number	Wholesaler-assigned invoice number for the purchase order. The platform uses Invoice Number to identify the relevant transaction to support verification that the	Required	Invoice number

	purchase qualifies for a 340B rebate. Because invoice numbers are not necessarily unique across different wholesalers or transactions, the platform requires a combination of Invoice Number, Invoice Date, and NDC-11 to accurately match the covered entity's purchase data to J&J's corresponding 867 data describing the shipment transaction. This multi-field approach ensures reliable identification of WAC purchases while compensating for gaps in standard transaction data.		
Ship-To Pharmacy NPI	The NPI of the pharmacy that received the physical shipment of the drug from the wholesaler. This data element is used to validate that the pharmacy receiving the shipment is appropriately associated with the covered entity registered as active in OPAIS, ensuring that rebate claims are paid on 340Beligible transactions. Because shipment data is frequently blocked in 867 transaction data or may not precisely match the relevant ship to location, the data source cannot be reliably used on its own for validation—making direct collection of the ShipTo Pharmacy NPI essential for rebate processing.	Required	Ordering location
11-Digit NDC	Identifier of the drug purchased by the covered entity. The platform uses NDC-11 to identify the relevant transaction to support verification that the purchase qualifies for a 340B rebate. Because invoice numbers are not necessarily unique across different wholesalers or transactions, the platform requires a combination of Invoice Number, Invoice Date, and NDC-11 to accurately match the covered entity's purchase data to J&J's corresponding 867 data describing the shipment transaction. This multi-field approach ensures reliable identification of WAC purchases while compensating for gaps in standard transaction data. In addition, the platform relies on the NDC-11 paired with the reported Invoice Date to determine the applicable WAC for the unit at the time of purchase, ensuring that the rebate amount is calculated based on the correct pricing in effect on the transaction date.	Required	Drug NDC
Package Units	Number of packages of the product ordered. This data element is used to validate that the quantity of units for which 340B rebates are claimed matches (or does not exceed) the quantity of validated units purchased by the covered entity, thereby helping to ensure that 340B rebates are issued only for drugs purchased by the covered entity. Additionally, Package Units is used to calculate the total rebate amount owed, based on the number of validated units.	Required	Quantity ordered

340B ID	HRSA-assigned identifier of the 340B covered entity that purchased the drug. This data element is used to validate that the purchasing entity is a 340B covered entity registered as active in the HRSA OPAIS database, ensuring that rebate claims are tied to eligible 340B covered entities. It also enables the platform to link purchase records with rebate claims submitted by the covered entity. This field does not exist in J&J's corresponding 867 data, making direct collection of the 340B ID essential for rebate processing.	Required	

April 20, 2025

Chantelle Britton
Director
Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
Rockville, Maryland 20857

RE: Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906-NEW

Submitted via paperwork@hrsa.gov

Dear Director Britton:

On behalf of North Florida Medical Centers, Inc. (NFMC) I would like to thank the Health Resources and Services Administration (HRSA) for providing the opportunity to **share our estimated burden with HRSA on compliance with the 340B rebate model pilot program. Given the severe administrative, financial, and operational burden a rebate model would place on CHCs, North Florida Medical Centers, Inc. again requests that CHCs be exempted from the pilot program.**

NFMC, an FQHC originally incorporated in 1995, is the only nonprofit community health center that provides a full range of comprehensive medical, dental, and enabling services within the ten-county service area, located within the Florida Panhandle and Big Bend.

The 340B program is foundational to CHC's ability to serve the most vulnerable members of our community. However, the proposed shift of responsibility from manufacturers to safety-net providers directly serving patients through a rebate model threatens to destabilize CHC pharmacy operations nationwide. Based on national assessments from the National Association of Community Health Centers (NACHC) and our own internal assessments, the hours and dollars spent complying with a rebate program are staggering.

I. We Request HRSA Exempt CHCs from the 340B Rebate Model Pilot Program Due to Significant Financial and Administrative Burden

By requiring CHCs to purchase medications at full price and wait for rebates, this model would cause significant financial turmoil and directly affect our ability to serve the **20,000** patients who rely on us. We operate on razor-thin margins, and these additional costs are not an option for many entities. Similar to navigating manufacturers' existing contract pharmacy restrictions, CHCs will need to invest in IT infrastructure upgrades and hire or reassign staff to manage new complexities,

including varying data submission requirements and timelines, payment reconciliations, and dispute processes for denied rebates. We will face an increased administrative burden in monitoring rebate claims and payments.

To support CHCs in assessing the financial and operational impact of current manufacturer restrictions and an anticipated rebate model, NACHC worked with their consultant, FQHC 340B Compliance, to create an Operational & Administrative Cost Calculator.[1] The tool aggregates program savings, UDS financial data, staffing, external consulting costs, dispensing/capture activity, and clinic-administered drug tracking models to support cost forecasting. CHCs have already experienced steep increases in operational costs given the multitude of manufacturer restrictions, including requirements for clinic-administered drugs and entity-owned pharmacies. A rebate model will require a significant increase in already-strained operational capabilities.

Workforce Impact:

- **Staffing Impact**: North Florida Medical Centers, Inc. anticipates needing 5.0 additional FTEs to account for the increase in operational, administrative, and compliance burden created by a rebate model.
- **Number of Hours:** Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, North Florida Medical Centers, Inc. will face an increased administrative burden to monitor rebate claims and payments. Two hundred and fifty (250) hours will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: North Florida Medical Centers, Inc. anticipates an additional $7,500 for external vendors, including consultants, legal counsel, program coordination, third-party administrators (TPAs), electronic medical records (EMRs), pharmacy software, and reconciliation services.

Pharmacy Software & Third-Party Administration Changes

Navigating this pilot requires both staff and changes to workflow and software. HRSA should consider the increased compliance burdens when manufacturers have the flexibility to require varying data submission standards and elements. Additionally, if manufacturers can select different software platforms, like current contract pharmacy policies, CHC administrative burden would increase substantially.

- **One-Time Implementation Costs:** We anticipate high upfront costs to adapt our pharmacy software, pay for custom dashboard modifications, and design new internal workflows. Fifty thousand dollars ($50,000) will be required simply to reach the baseline of compliance before a single rebate is ever received.
- **Ongoing Operational Fees**: Beyond implementation, our TPA and software vendors will likely charge ongoing service fees of one thousand per month ($1,000/month) to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Cost:** For our CHC, which serves 20,000 patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at $396,000 annually.

[1] https://www.nachc.org/policy-advocacy/policy-priorities/340b-drug-pricing-program/340b-rebate-model-pilot-program/

The In-House Pharmacy: The Burden of IT Integration

North Florida Medical Centers, Inc. operates two entity owned pharmacy, utilizing the Pioneer pharmacy software. The rebate model is not a simple accounting change; it is a significant technological disruption. To remain compliant, in-house pharmacy systems will require costly customization to provide real-time, accurate information at the pharmacy counter.

- **System Interoperability:** Unlike contract pharmacies that use TPAs, in-house pharmacies must directly integrate their Electronic Health Record (EHR) and Pharmacy Management System (PMS) with a complex new rebate infrastructure.
- **One-Time Integration Costs:** We anticipate high upfront costs of $75,000 to pay software vendors for custom API builds and "Price File" reconciliation tools.
- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend ten (10) hours per week manually pulling "Purchase Files" and "Price Files" to verify that every rebate check matches the statutory 340B price.

The Contract Pharmacy: The Burden of Network Coordination

The rebate model introduces a new complexity that threatens the existence of contractual arrangements. My CHC currently partners with 14 pharmacies to increase access to affordable medications.

- **TPA Reliance and Fees:** Navigating manufacturers' varying requirements across multiple contract pharmacies requires high-level TPA intervention. We anticipate that our TPAs will pass on the costs of developing rebate-tracking modules to us through increased per-claim fees.
- **Verification Latency:** The rebate model creates a reconciliation gap. Our staff must monitor claims across 15 different pharmacy locations to ensure rebates are paid correctly.
- **Risk of Pharmacy Exodus:** The model shifts financial risk to the pharmacy, potentially causing contract partners to opt out of the 340B program entirely rather than manage the administrative headache. In our 5,000 square mile service area in the Panhandle and Big Bend Regions of Florida this would leave patients with no affordable medication options. Over 17 percent of the U.S. population already lives in a pharmacy desert.[2]

II. Patient Impact

North Florida Medical Centers, Inc. has significant concerns about the impact a 340B Rebate Model Pilot would have on our most vulnerable patients' access to life-saving medications. The majority of drugs selected for the MDPNP for 2026 and 2027, and included in the proposed rebate model, manage chronic conditions prevalent in primary care settings. CHCs serve a patient population with a higher burden of chronic conditions compared to private practices, with studies showing a significantly higher prevalence of illnesses like diabetes, hypertension, and obesity.[3] This patient population relies on affordable medications to manage these long-term conditions.

The impact on insulin access is also alarming and directly conflicts with federal requirements. With over 3 million Americans relying on CHCs for essential diabetes care,[4] insulin affordability is a matter of life and death. Furthermore, Executive Order #14273 conditions future Section 330(e) funds on CHCs providing low-income patients with access to discounted insulin. No current

[2] Vulnerability Index Approach to Identify Pharmacy Deserts and Keystone Pharmacies | Pharmacy and Clinical Pharmacology | JAMA Network Open | JAMA Network

[3] Richard P, Ku L, Dor A, Tan E, Shin P, Rosenbaum S. Cost savings associated with the use of community health centers. J Ambul Care Manage. 2012 Jan-Mar;35(1):50-9. doi: 10.1097/JAC.0b013e31823d27b6. PMID: 22156955.

[4] 2025 UDA Data, HRSA (hrsa.gov)

operational method exists to provide discounted medications in a rebate model. In the proposed model, the wholesaler price file would reflect the full Wholesale Acquisition Cost (WAC) rather than the discounted 340B price, making the price unattainable for patients and precluding CHCs from fulfilling their legal obligation to offer the required discount at the point of care.

III. Financial Challenges

Lack of access to upfront 340B discounts, along with the high IT/infrastructure costs, will disproportionately impact CHCs and trickle down to patients. Many CHCs are currently under financial strain, with nearly half operating with fewer than 90 days of cash on hand, and one in four reporting negative five percent operating margins. This rebate model creates significant financial challenges, including:

- **Purchasing Drugs at the WAC Price Upfront:** Under the proposed model, CHCs would be required to purchase drugs at the WAC. CHCs will have to wait to receive their rebate payment *after* providing medications to their patients, forcing difficult decisions about how to allocate limited financial resources, including cutting essential services and reducing operating hours. We are particularly worried that the need to purchase drugs at full WAC will cause cash flow issues and potentially lead CHCs to exceed credit limits with wholesalers, halting their ability to order medications until payments are submitted.

- **Sliding Fee Scale:** A rebate model creates substantial uncertainty about CHCs' ability to apply sliding-fee discounts at the point of sale. By statute and regulation, CHCs are required to offer sliding fee discounts for all required and additional health services within the HRSA-approved scope of project.[5] In line with their mission, CHCs offer flat or sliding-scale discounts on prescription drugs to make them more affordable for low-income individuals.[6] A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size.

Conclusion

North Florida Medical Centers, Inc. strongly urges HRSA to exempt CHCs from any 340B Rebate Model Pilot Program. A 340B rebate program represents a departure from the original intent of the 340B program—to allow safety-net providers to "stretch scarce Federal resources" and provide more comprehensive care. A rebate model would create significant cash flow challenges, forcing CHCs to make difficult decisions about staffing, services, and the range of drugs they can afford to stock. Additionally, CHCs would need to make significant investments in IT infrastructure and staff to comply with rebate requirements and track rebates. It would also create a new barrier for patients, especially uninsured patients, who depend on the up-front 340B discount, making it operationally impossible to provide the sliding fee scale and steeply discounted medications required by law. North Florida Medical Centers, Inc. believes that a 340B rebate pilot would cause disproportionate harm to patients served by CHCs and other safety net providers.

[5] HRSA FAQ

[6] Such discounts are subject to potential legal and contractual restrictions. https://bphc.hrsa.gov/compliance/compliance-manual/chapter9#footnote10

NFMC appreciates the opportunity to respond to this ICR on the 340B Rebate Model Pilot Program, and we look forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please contact Matt Mayo, mmayo@nfmc.org.

Sincerely,

Lane M. Lunn – CEO/President
North Florida Medical Centers, Inc.