NATIONAL ASSOCIATION OF Community Health Centers

April 20, 2025

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:

For the past 55 years, the National Association of Community Health Centers (NACHC) has been the leading national, nonpartisan organization dedicated to supporting Community Health Centers (CHCs), also known as Federally Qualified Health Centers, as the Employer, Provider, and Partner of choice in all communities. Collectively, CHCs are the largest primary care network in the nation, serving as the medical home for 34 million patients[1] and employing 326,000 dedicated staff.

For 60 years, CHCs have provided high-quality, affordable, comprehensive care – including primary, preventive, dental, behavioral health, pharmacy, vision, and other essential health services at over 17,000 locations across rural and nonrural communities. This includes 1 in 3 rural residents and 1 in 2 in poverty. As our nation's largest primary care system, there is strong evidence, including from the Congressional Budget Office, that our work saves lives and also saves Medicaid and Medicare billions annually by reducing costly emergency, inpatient, and specialty care.[2] Research shows that every dollar invested in primary care yields a 13-to-1 return in overall health system savings.[3]

On behalf of NACHC, 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 the bedrock of their 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 with a rebate model threatens to destabilize CHC pharmacy operations nationwide. Based on national assessments done by NACHC, we know that CHCs are facing staggering impacts:

[1] Weitzman, 2025. https://www.mwhs1.com/wp-content/uploads/2025/08/The-Real-CHC-Patient-Base_080525_final.pdf
[2] Volerman A, Carlson B, Wan W, Murugesan M, Asfour N, Bolton J, Chin MH, Sripipatana A, Nocon RS. Utilization, quality, and spending for pediatric Medicaid enrollees with primary care in health centers vs non-health centers. BMC Pediatr. 2024 Feb 8;24(1):100. doi: 10.1186/s12887-024-04547-y. PMID: 38331758; PMCID: PMC10851548. https://pubmed.ncbi.nlm.nih.gov/38331758/
[3] https://www.oregon.gov/oha/HPA/dsi-pcpch/Documents/PCPCH-Program-Implementation-Report-Final-Sept-2016.pdf

- **Financial Losses:** Nationwide, CHCs report up to $4 million for implementation for entity-owned pharmacy operations and $5,000 to $720,000 for contract pharmacy arrangements due to the administrative hurdles of manual reconciliation.
- **Projected Cost Increases:** CHCs anticipate their operational costs will increase significantly. National data show that a single mid-sized CHC expects to incur over $3 million in additional costs **annually** to manage the pilot.[4]
    - **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. From a NACHC survey, nearly 75 percent of rural health centers spent at least five percent of their 340B savings on mobile clinics, with nearly eight percent spending 20 percent or more. Rural health centers also reported utilizing 340B savings for mental health services, nutrition programs, and capital investment.

I. NACHC Strongly Urges 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 34 million patients who rely on us. NACHC data indicates that without discounted or free medications, a substantial portion of CHC patients—up to 3 million or more—would lose access to essential treatments.[5] These patients often have chronic conditions like diabetes, heart disease, and behavioral health needs. They depend on the essential drugs included in the rebate pilot more than patients with any other conditions.

A change of this nature will have an immediate and direct impact on patients at the pharmacy counter. It would limit the range and volume of drugs CHCs can afford to stock, directly contradicting the program's goal of increasing access to affordable medications. Since 90% of CHC patients are at or below 200% of the federal poverty level, they rely on discounted medications from their local CHC.[6] To navigate this model, CHCs are being forced into precarious financial positions. Recent surveys indicate that over 50% of CHCs anticipate depleting their limited financial reserves, while 27% anticipate needing to take out lines of credit or loans just to cover the upfront "float" costs of drugs. Survey findings indicate that CHCs estimate financial losses ranging from four thousand to four million dollars annually, depending on the organization's pharmacy structure, size, and patient volume.[7] These projections reflect both delayed

[4] NACHC Internal Survey on Rebate Model Burden (2025).
[5] https://www.hcadvocacy.org/wp-content/uploads/2023/02/NACHC-340B-Report-Summary-June-2022.pdf
[6] Ibid.
[7] PCA Survey.

reimbursement structures and increased administrative burden associated with the anticipated rebate reconciliation processes.

Additionally, the evolving operational landscape for CHCs further compounds these challenges. CHCs are concurrently navigating workforce shortages across clinical and pharmacy staff, increased demand for behavioral health, chronic disease management, and enabling services, and persistent reimbursement constraints across Medicaid, Medicare, and other payers. At the same time, CHCs are absorbing rising operational expenses, including labor costs, IT or technology infrastructure investments necessary to maintain compliance with the ever-changing federal and state program requirements. These pressures are further intensified by ongoing coverage instability among patient populations, administrative burden associated with payer prior authorization and billing requirements, and variability in state-level Medicaid policies. Within this constrained and resource-limited environment, CHCs have limited financial flexibility to absorb additional risk or upfront capital requirements. **A 340B rebate model creates a radical shift in financial risk from manufacturers to CHCs, requiring significant liquidity and administrative capacity that many CHCs are not structurally positioned to sustain without compromising service delivery.**

Nationwide, more than half of CHCs (55.5%) currently own and operate a pharmacy within their organization, offering immediate access to medications and other pharmacy services during a patient's visit.[8] Not only could this shift reduce formulary options and limit pharmacy hours for patients, but it could also eliminate entity-owned, in-house pharmacy services altogether, effectively undermining critical access points for medically underserved communities.[9] Collectively, the proposed rebate model introduces significant financial instability into an already constrained operating environment, with direct implications for patient access, continuity of care, and CHC financial and operational capacity. **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.

[8] https://www.nachc.org/wp-content/uploads/2026/01/Pharmacy-Survey_Expanding-Access_V2.pdf
[9] PCA Survey

NACHC 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, 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.[10] This patient population relies on affordable medications to manage these long-term conditions.

NACHC is 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.[11]

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.[12] 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.[13] 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 uninsured patients. Additionally, the 2027 list includes Austedo®, a drug used to treat Tardive Dyskensia, 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.[14] Impairing access to these drugs could result in exacerbation of the mental health crisis.

---

[10] 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.

[11] 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.

[12] 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

[13] 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

[14] 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.

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,[15] 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 Wholesale Acquisition Cost (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 34 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.**

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 no longer available for wraparound services and the full spectrum of care that makes 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.

[15] 2025 UDA Data, HRSA (hrsa.gov)

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. NACHC urges 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 our 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. CHCs will submit data to demonstrate that the cost to comply with a 340B Rebate Model would lead to a significant increase in administrative costs, not incremental, as HRSA suggests.

- **Sliding Fee Discount**: We have heard from CHCs that increased costs will lead to changes in their sliding fee scales. For instance, large health center in Georgia estimated that these increased costs will cause them to eliminate and reduce services as well as increase the nominal sliding fee charges for medications and indigent care, since their 330 grant only subsidizes only 25% of their uninsured patients.
- **External Vendor Costs**: Given increased complexity, many CHCs anticipate increased costs for external support vendors. Some CHCs have received quotes for hundreds of thousands of dollars for these vendors, and others have already decided they do not have the resources to add another vendor but are concerned about their ability to utilize current capacity to meet the additional burden. 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.[16] For instance, one mid-sized CHC in Alaska stated that the administration time involved in setting up new IT processes to establish data feeds, run financial reports, and decipher Beacon claims will result in at least one FTE employee at $120,000 and another $100,000 for investment in IT systems. For another large health center in Alabama, the estimated logistics will require an additional one to two FTE if the program grows to manage the reconciliation and continued burden.
- Additionally, several CHCs estimate the cost to hire additional staff to be between $30,000 to $200,000 annually.[17] 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. Thirty-nine percent of CHCs estimate it will take their staff more than 20 hours to report 340B rebate claims to a third-party platform, assuming all adhere to the nine drug manufacturers' plans; another 38% estimate between 15 to 20 hours, and 23% believe it will take 5 to 10 hours to meet reporting requirements with this pilot program.[18] 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. **NACHC 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. NACHC encourages 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:** CHCs anticipate high upfront costs to adapt their pharmacy software, pay for custom dashboard modifications, and design new internal workflows, all of which will be required simply to reach the baseline of compliance before a single rebate is ever received.
- **Ongoing Operational Fees**: Beyond implementation, CHC TPAs 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.

[16] Internal NACHC assessment (99 responses).
[17] Ibid.
[18] Internal NACHC assessment (out of 101 responses).

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. The rebate model shifts significant IT, staffing, and operational burden onto CHCs with in-house pharmacies, diverting limited resources away from patient care and core service delivery. To remain compliant, our in-house pharmacy systems will require costly customization to provide real-time, accurate information at the pharmacy counter.

- **System Interoperability Challenges:** Unlike contract pharmacies that use Third-Party Administrators (TPAs), CHC with in-house pharmacies must directly integrate their Electronic Health Record (EHR) and Pharmacy Management System (PMS) with a complex new rebate infrastructure. This creates new technical dependencies and increases the risk of workflow disruptions at the pharmacy counter.
- **High Upfront Integration Costs:** NACHC anticipates CHC would face significant upfront costs to modify existing systems, including building custom APIs and implementing "Price File" reconciliation tools to meet rebate model data submissions and claims validation requirements.
- **Ongoing Administrative Burden and Cost:** Reporting requirements alone are expected to be resource intensive. Thirty-nine percent of CHCs estimate it will take their staff more than 20 hours to report 340B rebate claims to a third-party platform, assuming all adhere to the nine drug manufacturers' plans; another 38% estimate between 15 to 20 hours, and 23% believe it will take 5 to 10 hours to meet reporting requirements with this rebate model.[19] Additionally, several CHCs estimate the cost to hire additional staff to be between $30,000 to $200,000 annually.[20]

The Contract Pharmacy: The Burden of Network Coordination

Nationwide, **more than 65% of CHCs utilize a contract pharmacy** to expand medication access, maintain affordability, and meet patients where they are.[21] For contract pharmacy partners, the rebate model introduces a new complexity that threatens the very existence of these partnerships.

- **TPA Reliance and Fees:** Navigating manufacturers' varying requirements across multiple contract pharmacies requires high-level TPA intervention. CHCs anticipate that 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. CHC staff will have to monitor claims in their entity owned pharmacies, if applicable, and work with their different contract pharmacy locations to ensure rebates are paid correctly.
- **Risk of Pharmacy Exodus:** Because this model shifts the financial risk to the pharmacy, many CHCs fear their contract partners will opt out of the 340B program entirely rather than manage the administrative headache. This would leave patients in our area with no affordable medication options. Over 17 percent of the U.S. population lives in a pharmacy desert

[19] Internal NACHC assessment (out of 101 responses).
[20] Internal NACHC assessment (99 responses).
[21] https://www. nachc.org/wp-content/uploads/2026/01/Pharmacy-Survey_Expanding-Access_V2.pdf

already,[22] 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.[23]

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 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 (eMAR) common to electronic medical records (EMR) seen at hospitals. Where eMARs are available, they are at an added cost and often require CHC to pay for a standalone software system.
- **Minimal Risk for Duplication of 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. With respect to 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, 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

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

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

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.[24] In line with their mission, CHCs offer flat or sliding-scale discounts on prescription drugs to make them more affordable for low-income individuals.[25] A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size.

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 will continuously overwrite the manually added 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).[26] 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.

There may be other delays in receiving the full rebate, such as denials, which could create financial strain on CHCs. NACHC appreciates 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.

[24] HRSA FAQ
[25] Such discounts are subject to potential legal and contractual restrictions. https://bphc.hrsa.gov/compliance/compliance-manual/chapter9#footnote10
[26] https://enlivenhealth.co/blog/year-end-business-health-check-key-metrics-every-pharmacy-owner-should-review

NACHC is 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. **NACHC respectfully requests that, if a rebate pilot is implemented, manufacturers are 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, with the median cash-on-hand at around 100 days and one-quarter reporting operating margins of -4%.[27] 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 our 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[28] and WAC pricing data for the first quarter of 2026 (Q1 2026), and the CMS list of MDPNP selected drugs by NDC.[29] 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 sub-ceiling 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 providing medication to the patient. This delay forces difficult decisions about allocating limited financial resources.

[27] Forvis presentation, 2025 NACHC CHI Conference, "3 Key Governance Conversations for Financial Health and Mission Sustainability"
[28] https://340bpricing.hrsa.gov/
[29] https://www.cms.gov/files/zip/selected-drug-list-negotiated-prices-also-known-maximum-fair-prices-statutezip.zip

Based on data collected by NACHC, nearly 30 percent of CHCs surveyed estimated it would cost over $1,000,000 in increased acquisition costs annually to purchase these 10 drugs under the proposed rebate model. This increase in costs will have a devastating impact on a CHC's ability to maintain an adequate supply of the drugs included in the HRSA 340B Rebate Model Pilot. As previously discussed, many CHCs are navigating a difficult financial environment that cannot sustain purchasing drugs at WAC. To cover the upfront cost of purchasing drugs and operationalizing the rebate, CHCs would need to reduce or eliminate certain clinical services and care delivery workflows. For example:

- **Medication affordability programs and pharmacy services, including clinical pharmacist staffing and medication therapy management (MTM), represent one of the most heavily supported uses of 340B savings.** Survey data show that approximately 60% of CHCs allocate at least 20% of their 340B savings to these functions, with a substantial subset dedicating 30% or more.[30] Reductions in 340B savings would therefore directly limit patients' ability to obtain and adhere to prescribed medications, resulting in increased rates of treatment interruption, disease progression, and avoidable hospitalizations.
- **Enabling services, such as community health workers, patient education, outreach and enrollment, and transportation assistance, are similarly dependent on 340B reinvestment.** Approximately 65% of CHCs report allocating 20% or more of their savings to these services.[31] The loss of these supports would significantly impair patients' ability to access care, attend appointments, and navigate complex treatment plans, particularly for individuals with chronic conditions and limited financial resources.
- **Behavioral health services, including both mental health and substance use disorder (SUD) care, are heavily supported through 340B-generated revenue, with roughly two-thirds of CHCs allocating at least 20% of savings to these services and many reporting allocations of 25–40%.[32]** A reduction in 340B savings would likely result in decreased availability of integrated behavioral health services, leading to longer wait times, reduced treatment continuity, and increased risk of acute behavioral health crises.
- **Mobile health services, such as mobile clinics and street medicine programs, also rely heavily on 340B.** More than 70% of CHCs dedicate at least 20% of their 340B savings to these outreach models.[33] The loss of funding would directly reduce access points for patients in rural and other medically underserved areas, resulting in delayed diagnostics, untreated conditions, and an increased reliance on emergency care.

C. Wholesaler Implications

As previously mentioned, 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. At present, many

[30] PCA Survey, March 2026.
[31] Ibid.
[32] Ibid.
[33] Ibid.

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. 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.
NACHC asserts that taking out a loan or an extended line of credit to fund drug procurement is a high-risk strategy that places many CHCs in a state of "financial limbo." This approach fundamentally defeats the purpose of the 340B program—to "stretch" scare 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.

Every dollar paid upfront at WAC is a dollar that remains "frozen" in the manufacturer's reconciliation system. While they await rebates, they lose the liquidity necessary to respond to immediate public health crises or facility emergencies. To navigate the rebate model, a CHC could be forced to either take out a line of credit or utilize limited financial reserves, neither of which are long-term, sustainable solutions. Forcing CHCs into debt to maintain their drug supply creates an environment of clinical instability. In many areas of the country, patients only have their local CHC to access care; the risk of the CHC's credit limit being reached or reserves being depleted is a direct threat to the community's safety net.

a. Financial Impact of Rebate Denials and Delays

NACHC 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.[34] 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.

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-

[34] 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

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 the operational realities of CHCs. 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.

NACHC requests that the process utilized for rebate denials must 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.[35]

[35] Manufacturer Audit Guidelines https://www.hrsa.gov/sites/default/files/hrsa/opa/dispute-resolution-process-12-12-96.pdf

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."[36]

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 of time. 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. **NACHC is 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. NACHC respectfully requests 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 HRSA create a different pathway for dispute resolution. 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,[37] 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, NACHC recommends 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

[36] 340B House Report – Legislative History. H.R. REP. 102-384(II).
[37] Administrative Dispute Resolution Regulation, https://www.govinfo.gov/content/pkg/FR-2024-04-19/pdf/2024-08262.pdf

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 and hold them accountable while protecting 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 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 is different, they have the potential to misalign even when the entity is fully compliant with 340B program requirements. Currently, when this misalignment happens, manufacturers block entities' 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.[38] 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 of this is within MFP effectuation, the manufacturer's vendor, Second Sight Solutions, has published a list of pricing codes[39] 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. **NACHC requests 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.

[38] Section 340B of the Public Health Service Act, https://www.hrsa.gov/sites/default/files/hrsa/rural-health/phs-act-section-340b.pdf
[39] https://mfp.support.beaconchannelmanagement.com/en/articles/13335320-validation-codes-and-pricing-codes-glossary

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

NACHC requests 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.[40] 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.

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.[41] 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 Part 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.

[40] https://public-inspection.federalregister.gov/2025-14619.pdf?1753965918
[41] Internal NACHC survey data

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 Inflation Reduction Act, 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, adhering 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, **NACHC encourages 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,[42] 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.[43] 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.[44]

---

[42] 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)).

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

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

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."[45] 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 intent of the IRA itself. 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 goes against 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*)."[46] 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

[45] H.R. REP. 102-384(II)
[46] 42 U.S.C. § 256b(a)(1)

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 contain language permitting 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."[47] 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*)."[48] 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.[49] 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

[47] *Id.*
[48] 42 U.S.C. § 256b(a)(1)
[49] 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 its obligated to do – prevent duplicate discounts. *Id.*

identification.[50] 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.[51]

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 plans.[52] 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 safety-net providers that choice.

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.[53] 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, 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 they bill to 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

---

[50] 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.")

[51] 42 U.S.C. § 256b(a)(5)(C).

[52] 42 U.S.C. § 256b(a)(5)(C).

[53] *See* 42 U.S.C § 256b(a)(5)(A).

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.[54] 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.[55] 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 for each drug are incurred by an initial purchase at the higher WAC price and 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 every state provided guidance. 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.

[54] https://medi-calrx.dhcs.ca.gov/cms/medicalrx/static-assets/documents/provider/2025/12_A_Claim_Submission_Requirements_340B_Rebate_Model_Pilot_Drugs.pdf
[55] C.F.R. § 447.518(a).

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 price because that 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 CHC's 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.[56] 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."[57] 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."[58] 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."[59]

---

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

[57] 42 C.F.R. § 447.502

[58] [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.

[59] 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.

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 added administrative costs related to claiming a rebate that are factored into the true "actual acquisition cost" for 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, occurring prior to rebate payment. And it raises serious federal questions relating to whether a federal grantee may be required to overpay for drugs.[60] 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.

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

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 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.[61]

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."*[62]

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

---

[61] 42 C.F.R. § 438.3(s)(7) The MCO, PIHP, or PAHP must assign and exclusively use 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

[62] 42 U.S.C. § 256b(a)(5)(A)(emphasis added).

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.[63] 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

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.[64] 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.

[63] 32 C.F.R. § 199.21(q)(2)(iii)(E)

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

Commercial claims data is extraordinarily valuable proprietary information to CHCs.[65] Studies conducted by IQVIA and others demonstrate that pharmaceutical manufacturers and PBMs routinely pay significant sums to obtain access to such data.[66] 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.[67] They are negotiated with market discounts, including 340B discounts, already factored into their high drug list prices.[68] Drug industry data vendors have reported that such data is highly valuable to manufacturers.[69] 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 of 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.[70] Indeed, over 30 states have passed laws to prevent this manufacturer-payer gamesmanship that seeks to usurp the 340B benefit.[71]

NACHC believes 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

---

[65] 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).

[66] 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.")

[67] 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.)

[68] 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.").

[69] 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).

[70] *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.").

[71] 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/.

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.

NACHC contends 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.[72] 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."[73] 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."[74] 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.[75] 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.

NACHC harbors 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.[76] 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.

---

[72] 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).

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

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

[75] 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").

[76] 42 U.S.C. 1320a-7b (making it illegal to pay remuneration in exchange for items or services billable to federal health care programs.)

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 and not a manufacturer–from reselling or transferring 340B drugs to nonpatients.[77] 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 providers that employ or contract with health care professionals to establish such relationships. 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."[78]And the legislative

[77] 42 U.S.C. § 256b(a)(5)(B)
[78] 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).]

history of the 340B statute supports the position that rebate models, while appropriate for ADAPs, may not be appropriate for CHCs.[79]

IX. Establishing a National, Neutral Claims Clearinghouse

NACHC recommends 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 Inflation Reduction Act; 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 stop purchasing or dispensing MFP drugs altogether.

[79] H.R. REP. 102-384, 16

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 fifty 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[80] 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

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.

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

- **340B Access Act**: This Republican-sponsored bill advocates for a NCC that would encompass all claims, including those from commercial sources.

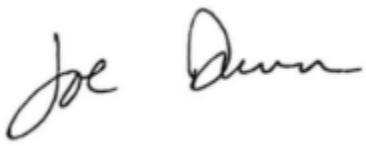
Given the major disruption the 340B rebate program is anticipated to have on CHCs, a system that forces CHCs to provide data that is already accurately and readily available to manufacturers is not only redundant but also adds additional administrative burdens on safety-net providers. It is imperative 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

NACHC 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. NACHC believes that a 340B rebate pilot would cause disproportionate harm to patients served by CHCs and other safety net providers.

NACHC 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 Elizabeth Linderbaum, Director of Regulatory Affairs, at elinderbaum@nachc.org

Sincerely,



Joe Dunn
Chief Policy Officer