Citrus
HEALTH NETWORK, INC.
FEDERALLY QUALIFIED HEALTH CENTER
4175 WEST 20TH AVENUE • HIALEAH, FL 33012-5875

April 27, 2026

Chantelle Britton, Director
Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
Rockville, Maryland 20857
Submitted via paperwork@hrsa.gov

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

Dear Director Britton:

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

Citrus is a Federally Qualified Health Center serving approximately 30,000 patients in South Florida. The 340B program is foundational to CHC's ability to serve the most vulnerable members of our community. However, the proposed shift of responsibility from manufacturers to safety-net providers directly serving patients through a rebate model threatens to destabilize CHC pharmacy operations nationwide. Based on national assessments from the National Association of Community Health Centers (NACHC) and our own internal assessments, the hours and dollars spent complying with a rebate program are staggering.

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

There is no necessity of the proposed information collection for the proper performance of the agency's functions. The health center, our contracted vendors and payors have already developed policies and procedures to avoid duplicate discounts. HRSA should be able to automatically collect this from each provider's software (FSI for us). The claims data is already there. It is only a matter of getting the provider's permission to share it. That would take all the work burden from CHCs.

By requiring CHCs to purchase medications at full price and wait for rebates, this model would cause significant financial turmoil and directly affect our ability to serve the 30,000 patients who

By requiring CHCs to purchase medications at full price and wait for rebates, this model would cause significant financial turmoil and directly affect our ability to serve the 30,000 patients who rely on us. We operate on razor-thin margins, and these additional costs are not an option for many entities. Similar to navigating manufacturers' existing contract pharmacy restrictions, CHCs will need to invest in IT infrastructure upgrades and hire or reassign staff to manage new complexities, including varying data submission requirements and timelines, payment reconciliations, and dispute processes for denied rebates. We will face an increased administrative burden in monitoring rebate claims and payments.

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

Workforce Impact:

- **Staffing Impact**: Citrus anticipates needing **at least three (3) additional Full-Time Equivalent (FTEs)** to account for the increase in operational, administrative, and compliance burden created by a rebate model.
- **Number of Hours:** Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, Citrus will face an increased administrative burden to monitor rebate claims and payments. **Approximately ten hours** will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: Citrus anticipates an unknown additional expense for external vendors, including consultants, legal counsel, program coordination, third-party administrators (TPAs), electronic medical records (EMRs), pharmacy software, and reconciliation services.

Pharmacy Software & Third-Party Administration Changes

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

- **One-Time Implementation Costs:** We anticipate high upfront costs to adapt our pharmacy software, pay for custom dashboard modifications, and design new internal workflows. We estimate at least $10,000 will be required simply to reach the baseline of compliance before a single rebate is ever received.
- **Total Cost:** For our CHC, which serves approximately 30,000 patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at $150,000 annually.

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

The In-House Pharmacy: The Burden of IT Integration

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

- **System Interoperability:** Unlike contract pharmacies that use TPAs, in-house pharmacies must directly integrate their Electronic Health Record (EHR) and Pharmacy Management System (PMS) with a complex new rebate infrastructure.
- **One-Time Integration Costs:** We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools. We estimate $50,000 in costs.
- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend **at least 10** hours per pharmacy per week manually pulling "Purchase Files" and "Price Files" to verify that every rebate check matches the statutory 340B price.

Clinic Administered Drugs: The Burden of New Systems Required

Clinic-administered drug (CAD) operations and record-keeping in CHCs are designed cost-effectively to reflect the nuances of CHC billing. Implementing a rebate model for CADs would also require new software, system integration, and staff training. NACHC estimates these costs would range from $30,000 to $50,000 annually and could be much higher, depending on the software.[2]

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

I. Patient Impact

Citrus has significant concerns about the impact a 340B Rebate Model Pilot would have on our most vulnerable patients' access to life-saving medications. The majority of drugs selected for the MDPNP for 2026 and 2027, and included in the proposed rebate model, manage chronic conditions prevalent in primary care settings. CHCs serve a patient population with a higher burden of chronic conditions compared to private practices, with studies showing a significantly higher prevalence of illnesses like diabetes, hypertension, and obesity.[3] This patient population relies on affordable medications to manage these long-term conditions.

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[2] Internal NACHC survey data

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

The impact on insulin access is also alarming and directly conflicts with federal requirements. With over 3 million Americans relying on CHCs for essential diabetes care,[4] insulin affordability is a matter of life and death. Furthermore, Executive Order #14273 conditions future Section 330(e) funds on CHCs providing low-income patients with access to discounted insulin. No current operational method exists to provide discounted medications in a rebate model. In the proposed model, the wholesaler price file would reflect the full Wholesale Acquisition Cost (WAC) rather than the discounted 340B price, making the price unattainable for patients and precluding CHCs from fulfilling their legal obligation to offer the required discount at the point of care.

II. Financial Challenges

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

- **Purchasing Drugs at the WAC Price Upfront:** Under the proposed model, CHCs would be required to purchase drugs at the WAC. CHCs will have to wait to receive their rebate payment *after* providing medications to their patients, forcing difficult decisions about how to allocate limited financial resources, including cutting essential services and reducing operating hours. We are particularly worried that the need to purchase drugs at full WAC will cause cash flow issues and potentially lead CHCs to exceed credit limits with wholesalers, halting their ability to order medications until payments are submitted.
- **Sliding Fee Scale:** A rebate model creates substantial uncertainty about CHCs' ability to apply sliding-fee discounts at the point of sale. By statute and regulation, CHCs are required to offer sliding fee discounts for all required and additional health services within the HRSA-approved scope of project.[5] In line with their mission, CHCs offer flat or sliding-scale discounts on prescription drugs to make them more affordable for low-income individuals.[6] A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size. Citrus uses a sliding fee scale model, where most indigent patients only pay 340B cost plus a minimum dispensing fee. This would be erased when we cannot determine the 340B cost up front.

Conclusion

Citrus strongly urges HRSA to exempt CHCs from any 340B Rebate Model Pilot Program. Alternatively, HRSA should be able to automatically collect this from each provider's software (FSI for us). The claims data is already there. It is only a matter of getting the provider's permission to share it. That would take all the work burden from us. The Proposed 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,

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[4] 2025 UDA Data, HRSA (hrsa.gov)

[5] HRSA FAQ

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

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

Citrus appreciates the opportunity to respond to this ICR on the 340B Rebate Model Pilot Program, and we look forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please contact Armando Merino, Pharmacy Director at email: AMerino@citrushealth.com.

Sincerely,

Mario Jardon, L.C.S.W.
President & C.E.O.

OCONEE VALLEY
HEALTHCARE

April 24, 2025

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

Re: Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation (OMB No. 0906-NEW)
Submitted via paperwork@hrsa.gov

Dear Director Britton:

On behalf of **Oconee Valley Healthcare, Inc.**, a federally qualified health center serving **surrounding areas of Greensboro, Georgia. A community with high poverty and very low household incomes creating barriers to affording basic healthcare.** We appreciate the opportunity to provide comments regarding the proposed information collection requirements associated with the 340B Rebate Model Pilot Program. Given the significant administrative, financial, and operational burden this model would impose, we respectfully request that Community Health Centers (CHCs) be exempted from participation in the pilot program.

The 340B Program is foundational to our ability to serve vulnerable populations and stretch scarce federal resources. At **Oconee Valley Healthcare**, we dispense approximately **70,000 prescriptions annually** across **32 pharmacy locations**. The program generates approximately **$4.6 million annually**, which is reinvested into essential patient services including **free medication delivery, dental services, behavioral health programs, care coordination, medication access programs, and many other critical clinical services**. A shift to a rebate model fundamentally disrupts this structure by transferring financial and operational responsibility from manufacturers to safety-net providers.

Under the proposed model, we would be required to purchase medications at full Wholesale Acquisition Cost (WAC) and wait for rebates, creating immediate and material cash flow strain. We estimate an increase in monthly inventory spend of approximately **$400k**, requiring additional working capital of **$1.6 million** to sustain operations. For organizations like ours operating on thin margins and serving **16,000 patients**, this creates significant financial instability and may force reductions in services, staffing, or medication access. The risk of delayed or denied rebates further compounds this issue and introduces uncertainty into an already complex system.

Operationally, the rebate model introduces a parallel claims lifecycle that does not exist today. We would be required to identify eligible claims post-dispense, submit claims-level data across multiple manufacturer platforms, track rebate payments, reconcile discrepancies, and manage disputes. Based on our current operations, we estimate the need for **3 additional FTEs**, approximately **50 hours per week** dedicated to rebate tracking and reconciliation, and an increase of **$350k annually** in administrative costs. We also anticipate **$250k in vendor-related expenses**, including third-party administrators, consultants, legal support, EMR and pharmacy system upgrades, and reconciliation tools.

The burden extends across all aspects of our pharmacy and clinical operations. In-house pharmacy systems will require significant customization to integrate with rebate platforms, including API development, pricing validation tools, and ongoing manual verification processes. Across our contract pharmacy network of **4 partners**, we will need to monitor

claims and rebate activity across multiple external systems, significantly increasing coordination complexity and administrative overhead. There is also a real risk that contract pharmacies may opt out of participation due to increased financial and operational burden, further limiting patient access.

Clinic-administered drugs present an additional layer of complexity, as many are not captured in traditional claims data due to bundled payment structures. This would require new systems, workflows, and manual processes to convert existing documentation into rebate-eligible formats. We estimate this will require **900 hours and approximately $150k annually** to support, driven by system integration, training, and manual data conversion.

These challenges are compounded by existing manufacturer restrictions, which have already significantly increased administrative costs and operational strain. National assessments, including those conducted by the National Association of Community Health Centers (NACHC), demonstrate that the financial and administrative burden associated with rebate-style models is substantial and unsustainable. Tools such as NACHC's Operational & Administrative Cost Calculator further confirm that CHCs would face significant increases in staffing, IT infrastructure, and ongoing operational costs under a rebate model.

Most importantly, the proposed model will directly impact patient access. CHCs serve populations with disproportionately high rates of chronic conditions such as diabetes, hypertension, and obesity. Many of the drugs included in the proposed model treat these conditions, making affordability critical. The inability to access upfront 340B pricing creates a scenario where medications must be purchased at full WAC, making it operationally impossible to provide discounted pricing at the point of care. This directly conflicts with federal requirements, including obligations tied to Section 330 funding and sliding fee scale programs, which require CHCs to provide affordable access to medications based on patient income. **Oconee Valley Healthcare currently provides medication discounts through our in-house pharmacy and 340B contract pharmacy, and this model would severely disrupt our ability to continue doing so.**

A rebate model represents a fundamental departure from the intent of the 340B Program. It introduces unnecessary administrative burden, creates financial instability, and places patient access at risk. Covered entities like ours depend on the immediacy and predictability of upfront discounts to operate effectively and provide essential services.

Conclusion

For these reasons, **Oconee Valley Healthcare** strongly urges HRSA to exempt CHCs from the 340B Rebate Model Pilot Program. The proposed model will create significant operational and financial challenges while undermining the very purpose of the 340B Program. We believe this approach will disproportionately harm safety-net providers and the patients they serve.

We appreciate the opportunity to provide comments and welcome continued engagement on this critical issue. If you have any questions, please contact **Carri Thomas, Chief Operating Officer at cthomas@ovhealth.org**.

Respectfully,

Carri Thomas
Chief Operating Officer
Oconee Valley Healthcare, Inc.
cthomas@ovhealth.org
(706) 453-1201

April 23, 2026

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

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

Submitted via paperwork@hrsa.gov

Dear Director Britton:

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

MCR Health is a leading not-for-profit healthcare system that provides high quality, compassionate care to families throughout Florida.

MCR operates 27 healthcare centers and 13 pharmacies, providing a wide range of services including family practice, internal medicine, pediatrics, OB/GYN, behavioral health, vision, dental, podiatry, cardiology, general surgery and many other medical services. Our mission is to provide all patients including the underserved and uninsured access to quality primary care and preventative health education regardless of race, sex, disability, or economic status.

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

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

By requiring CHCs to purchase medications at full price and wait for rebates, this model would cause significant financial turmoil and directly affect our ability to serve the **106,563** patients who rely on us. We operate on razor-thin margins, and these additional costs are not an option for many entities. Similar to navigating manufacturers' existing contract pharmacy restrictions, CHCs will need to invest in IT infrastructure upgrades and hire or reassign staff to manage new complexities, including varying data

infrastructure upgrades and hire or reassign staff to manage new complexities, including varying data submission requirements and timelines, payment reconciliations, and dispute processes for denied rebates. We will face an increased administrative burden in monitoring rebate claims and payments.

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

Workforce Impact:

- **Staffing Impact**: MCR Health anticipates needing one additional FTEs to account for the increase in operational, administrative, and compliance burden created by a rebate model.
- **Number of Hours:** Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, MCR Health will face an increased administrative burden to monitor rebate claims and payments. On a weekly basis 12 hours will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: MCR Health anticipates an additional $30,000 for external vendors, including consultants, legal counsel, program coordination, third-party administrators (TPAs), electronic medical records (EMRs), pharmacy software, and reconciliation services.

Pharmacy Software & Third-Party Administration Changes

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

- **One-Time Implementation Costs:** We anticipate high upfront costs to adapt our pharmacy software, pay for custom dashboard modifications, and design new internal workflows. **$50,000** will be required simply to reach the baseline of compliance before a single rebate is ever received.
- **Ongoing Operational Fees**: Beyond implementation, our TPA and software vendors will likely charge ongoing service fees $15,000 to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Cost:** For our CHC, which serves 106,563 patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at **$170,000** annually.

The In-House Pharmacy: The Burden of IT Integration

MCR Health operates 13 pharmacies. The rebate model is not a simple accounting change; it is a significant technological disruption. To remain compliant, in-house pharmacy systems will require costly customization to provide real-time, accurate information at the pharmacy counter.

- **System Interoperability:** Unlike contract pharmacies that use TPAs, in-house pharmacies must directly integrate their Electronic Health Record (EHR) and Pharmacy Management System (PMS) with a complex new rebate infrastructure.

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

- **One-Time Integration Costs:** We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools.
- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend unnecessary hours per week manually pulling "Purchase Files" and "Price Files" to verify that every rebate check matches the statutory 340B price.

The Contract Pharmacy: The Burden of Network Coordination

The rebate model introduces a new complexity that threatens the existence of contractual arrangements. My CHC currently partners with 206 pharmacies to increase access to affordable medications.

- **TPA Reliance and Fees:** Navigating manufacturers' varying requirements across multiple contract pharmacies requires high-level TPA intervention. We anticipate that our TPAs will pass on the costs of developing rebate-tracking modules to us through increased per-claim fees.
- **Verification Latency:** The rebate model creates a reconciliation gap. Our staff must monitor claims across 206 different pharmacy locations to ensure rebates are paid correctly.
- **Risk of Pharmacy Exodus:** The model shifts financial risk to the pharmacy, potentially causing contract partners to opt out of the 340B program entirely rather than manage the administrative headache. In Manatee, Sarasota, and Desoto counties, this would leave patients with no affordable medication options. Over 17 percent of the U.S. population already lives in a pharmacy desert.[2]

Clinic Administered Drugs: The Burden of New Systems Required

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

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

II. Patient Impact

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

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

[3] Internal NACHC survey data

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

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

III. Financial Challenges

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

- **Purchasing Drugs at the WAC Price Upfront:** Under the proposed model, CHCs would be required to purchase drugs at the WAC. CHCs will have to wait to receive their rebate payment *after* providing medications to their patients, forcing difficult decisions about how to allocate limited financial resources, including cutting essential services and reducing operating hours. We are particularly worried that the need to purchase drugs at full WAC will cause cash flow issues and potentially lead CHCs to exceed credit limits with wholesalers, halting their ability to order medications until payments are submitted.
- **Sliding Fee Scale:** A rebate model creates substantial uncertainty about CHCs' ability to apply sliding-fee discounts at the point of sale. By statute and regulation, CHCs are required to offer sliding fee discounts for all required and additional health services within the HRSA-approved scope of project.[6] In line with their mission, CHCs offer flat or sliding-scale discounts on prescription drugs to make them more affordable for low-income individuals.[7] A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size. 31% of our entity owned pharmacy activity is generated by uninsured patients who receive a significant portion of the savings from the 340B drug discount program.

Conclusion

MCR Health strongly urges HRSA to exempt CHCs from any 340B Rebate Model Pilot Program. A 340B rebate program represents a departure from the original intent of the 340B program—to allow safety-net providers to "stretch scarce Federal resources" and provide more comprehensive care. A rebate model would create significant cash flow challenges, forcing 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

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

340B discount, making it operationally impossible to provide the sliding fee scale and steeply discounted medications required by law. MCR Health believes that a 340B rebate pilot would cause disproportionate harm to patients served by CHCs and other safety net providers.

MCR Health appreciates the opportunity to respond to this ICR on the 340B Rebate Model Pilot Program, and we look forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please contact Randy Heiser, Vice President Pharmacy at rheiser@mcr.health.

Sincerely,

Dr Melvin Price
President and CEO
MCR Health

COMMUNITY HEALTH CENTER
Of The New River Valley

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April 24, 2026

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

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

Submitted via paperwork@hrsa.gov

Dear Director Britton:

On behalf of **Free Clinic of the New River Valley, Inc, DBA Community Health Center of the New River Valley,** a Federally Qualified Health Center located in the Commonwealth of Virginia, I would like to thank the Health Resources and Services Administration (HRSA) for providing the opportunity to **share our estimated burden with HRSA on compliance with the 340B rebate model pilot program. Given the severe administrative, financial, and operational burden a rebate model would place on CHCs, Free Clinic of the New River Valley, Inc, DBA Community Health Center of the New River Valley again requests that CHCs be exempted from the pilot program.**

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

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

By requiring CHCs to purchase medications at full price and wait for rebates, this model would cause significant financial turmoil and directly affect our ability to serve the **6,692** patients who rely on us. We operate on razor-thin margins, and these additional costs are not an option for many entities. Similar to navigating manufacturers' existing contract pharmacy restrictions, CHCs will need to invest in IT infrastructure upgrades and hire or reassign staff to manage new complexities, including varying data submission requirements and timelines, payment reconciliations, and dispute processes for denied rebates. We will face an increased administrative burden in monitoring rebate claims and payments.

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

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

for clinic-administered drugs and entity-owned pharmacies. A rebate model will require a significant increase in already-strained operational capabilities.

Workforce Impact:

- **External Vendor Costs**: **Free Clinic of the New River Valley, Inc, DBA Community Health Center of the New River Valley** anticipates an additional **$12,000 per year** for external vendors, including consultants, legal counsel, program coordination, third-party administrators (TPAs), electronic medical records (EMRs), pharmacy software, and reconciliation services.

The In-House Pharmacy: The Burden of IT Integration

Free Clinic of the New River Valley, Inc, DBA Community Health Center of the New River Valley plans to open an in-house pharmacy in the next year. The rebate model is not a simple accounting change; it is a significant technological disruption. To remain compliant, in-house pharmacy systems will require costly customization to provide real-time, accurate information at the pharmacy counter.

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

The Contract Pharmacy: The Burden of Network Coordination

The rebate model introduces a new complexity that threatens the existence of contractual arrangements. My CHC currently partners with 11 pharmacies to increase access to affordable medications.

- **TPA Reliance and Fees:** Navigating manufacturers' varying requirements across multiple contract pharmacies requires high-level TPA intervention. We anticipate that our TPAs will pass on the costs of developing rebate-tracking modules to us through increased per-claim fees.
- **Verification Latency:** The rebate model creates a reconciliation gap. Our staff must monitor claims across **11** different pharmacy locations to ensure rebates are paid correctly.
- **Risk of Pharmacy Exodus:** The model shifts financial risk to the pharmacy, potentially causing contract partners to opt out of the 340B program entirely rather than manage the administrative headache. In the New River Valley this would leave patients with no affordable medication options. Over 17 percent of the U.S. population already lives in a pharmacy desert.[2]

Clinic Administered Drugs: The Burden of New Systems Required

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

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

II. Patient Impact

Free Clinic of the New River Valley, Inc, DBA Community Health Center of the New River Valley has significant concerns about the impact a 340B Rebate Model Pilot would have on our most vulnerable patients' access to life-saving medications. The majority of drugs selected for the MDPNP for 2026 and 2027, and included in the proposed rebate model, manage chronic conditions prevalent in primary care settings. CHCs serve a patient population with a higher burden of chronic conditions compared to private practices, with studies showing a significantly higher prevalence of illnesses like

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

[3] Internal NACHC survey data

diabetes, hypertension, and obesity.[4] This patient population relies on affordable medications to manage these long-term conditions.

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

III. Financial Challenges

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

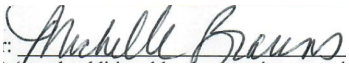
- **Purchasing Drugs at the WAC Price Upfront:** Under the proposed model, CHCs would be required to purchase drugs at the WAC. CHCs will have to wait to receive their rebate payment *after* providing medications to their patients, forcing difficult decisions about how to allocate limited financial resources,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

Conclusion

Free Clinic of the New River Valley, Inc, DBA Community Health Center of the New River Valley 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. **Free Clinic of the New River Valley, Inc, DBA Community Health Center of the New River Valley** believes that a 340B rebate pilot would cause disproportionate harm to patients served by CHCs and other safety net providers.

Free Clinic of the New River Valley, Inc, DBA Community Health Center of the New River Valley appreciates the opportunity to respond to this ICR on the 340B Rebate Model Pilot Program, and we look forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please contact **Albert Brogan, our Chief Financial Officer at 540-525-0623.**

Sincerely,



Michelle Brauns CEO
Free Clinic of the New River Valley, Inc, DBA Community Health Center of the New River Valley

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

MCKINNEY MEDICAL CENTER, INC.

April 24, 2025

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

Re: Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation (OMB No. 0906-NEW)
Submitted via paperwork@hrsa.gov

Dear Director Britton:

On behalf of **McKinney Medical Center, Inc.**, a federally qualified health center serving **[surrounding areas of Waycross, Georgia. A high poverty community where more than one-third of residents and nearly half of all children live below the poverty line. Low household incomes and high uninsured rates severely limit access to routine and preventive care.]** We appreciate the opportunity to provide comments regarding the proposed information collection requirements associated with the 340B Rebate Model Pilot Program. Given the significant administrative, financial, and operational burden this model would impose, we respectfully request that Community Health Centers (CHCs) be exempted from participation in the pilot program.

The 340B Program is foundational to our ability to serve vulnerable populations and stretch scarce federal resources. At **McKinney Medical Center**, we dispense approximately **2,500 prescriptions annually** across **16 pharmacy locations**. The program generates approximately **$700,000 annually**, which is reinvested into essential patient services including **free medication delivery, dental services, behavioral health programs, care coordination, medication access programs, and many other critical clinical services**. A shift to a rebate model fundamentally disrupts this structure by transferring financial and operational responsibility from manufacturers to safety-net providers.

Under the proposed model, we would be required to purchase medications at full Wholesale Acquisition Cost (WAC) and wait for rebates, creating immediate and material cash flow strain. We estimate an increase in monthly inventory spend of approximately **$35k**, requiring additional working capital of **$140k** to sustain operations. For organizations like ours operating on thin margins and serving **8,000 patients**, this creates significant financial instability and may force reductions in services, staffing, or medication access. The risk of delayed or denied rebates further compounds this issue and introduces uncertainty into an already complex system.

Operationally, the rebate model introduces a parallel claims lifecycle that does not exist today. We would be required to identify eligible claims post-dispense, submit claims-level data across multiple manufacturer platforms, track rebate payments, reconcile discrepancies, and manage disputes. Based on our current operations, we estimate the need for **1 additional FTEs**, approximately **15 hours per week** dedicated to rebate tracking and reconciliation, and an increase of **$90k annually** in administrative costs. We also anticipate **$75k in vendor-related expenses**, including third-party administrators, consultants, legal support, EMR and pharmacy system upgrades, and reconciliation tools.

The burden extends across all aspects of our pharmacy and clinical operations. In-house pharmacy systems will require significant customization to integrate with rebate platforms, including API development, pricing validation tools, and ongoing manual verification processes. Across our contract pharmacy network of **3 partners**, we will need to monitor claims and rebate activity across multiple external systems, significantly increasing coordination complexity and administrative overhead. There is also a real risk that contract pharmacies may opt out of participation due to increased financial and operational burden, further limiting patient access.

Clinic-administered drugs present an additional layer of complexity, as many are not captured in traditional claims data due to bundled payment structures. This would require new systems, workflows, and manual processes to convert existing documentation into rebate-eligible formats. We estimate this will require **300 hours and approximately $55k annually** to support, driven by system integration, training, and manual data conversion.

These challenges are compounded by existing manufacturer restrictions, which have already significantly increased administrative costs and operational strain. National assessments, including those conducted by the National Association of Community Health Centers (NACHC), demonstrate that the financial and administrative burden associated with rebate-style models is substantial and unsustainable. Tools such as NACHC's Operational & Administrative Cost Calculator further confirm that CHCs would face significant increases in staffing, IT infrastructure, and ongoing operational costs under a rebate model.

Most importantly, the proposed model will directly impact patient access. CHCs serve populations with disproportionately high rates of chronic conditions such as diabetes, hypertension, and obesity. Many of the drugs included in the proposed model treat these conditions, making affordability critical. The inability to access upfront 340B pricing creates a scenario where medications must be purchased at full WAC, making it operationally impossible to provide discounted pricing at the point of care. This directly conflicts with federal requirements, including obligations tied to Section 330 funding and sliding fee scale programs, which require CHCs to provide affordable access to medications based on patient income. **McKinney Medical Center currently provides medication discounts through our 340B contract pharmacy, and this model would severely disrupt our ability to continue doing so.**

A rebate model represents a fundamental departure from the intent of the 340B Program. It introduces unnecessary administrative burden, creates financial instability, and places patient access at risk. Covered entities like ours depend on the immediacy and predictability of upfront discounts to operate effectively and provide essential services.

Conclusion

For these reasons, **McKinney Medical Center** strongly urges HRSA to exempt CHCs from the 340B Rebate Model Pilot Program. The proposed model will create significant operational and financial challenges while undermining the very purpose of the 340B Program. We believe this approach will disproportionately harm safety-net providers and the patients they serve.

We appreciate the opportunity to provide comments and welcome continued engagement on this critical issue. If you have any questions, please contact **Ola Smith-Carter, Chief Executive Officer at osmith@mckinneyhealth.com**.

Sincerely,

Ola Smith-Carter
Chief Executive Officer
McKinney Medical Center, Inc.
osmith@mckinneyhealth.com
(912) 287-0301 x108

Submitted via paperwork@hrsa.gov

April 27, 2026

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

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

Dear Director Britton,

On behalf of OCHIN, thank you for the opportunity to comment on HRSA's proposed Information Collection Request (ICR) for the potential 340B Rebate Model Pilot Program. We commend the Administration's commitment to reducing regulatory burden, increasing government efficiency, and ensuring that federal programs deliver real value to American patients and providers. It is in that spirit that we respectfully urge HRSA to carefully reconsider the assumptions underlying this ICR and the operational consequences a rebate-based model would impose on rural and low-resourced covered entities.

OCHIN: Shared Infrastructure Built for Trust, Affordability, and Scale

OCHIN is a nonprofit shared health IT organization supporting more than 300 independent providers, including federally qualified health centers (FQHCs) and critical access hospitals (CAHs), across 44 states. We support nearly 44,000 clinicians delivering care in rural, tribal, and historically underserved communities. Through a shared Epic electronic health record platform, we integrate quality reporting and 340B compliance infrastructure at scale. We speak from direct operational experience: even with centralized shared services, the demands of this ICR would place unsustainable burden on the independent, community-based providers we serve.

Reducing Burden Means Reducing All Burden, Including This One

This Administration has made reducing unnecessary regulatory and administrative burden a centerpiece of its domestic agenda. We strongly support that goal. The proposed rebate model, however, moves in the opposite direction. HRSA estimates 3.7 million annual burden hours based on roughly five hours per submission, 52 times per year. That estimate does not reflect what providers actually experience.

Rural and low-resourced providers are already managing compounding compliance demands including federal reporting requirements, cybersecurity obligations, HIPAA and interoperability rules, and a growing number of non-standardized, manufacturer-specific data submission requirements. These obligations accumulate. They are not managed by specialists; they fall to clinical and operational staff who are already stretched thin. Adding another layer of fragmented, manufacturer-driven data collection does not reduce burden, it adds to it.

The ICR also fails to account for:

- **Data fragmentation and manual reconciliation.** Manufacturer portals and reporting rules vary widely and are not interoperable. Reconciliation is manual, time-consuming, and error-prone.
- **Cybersecurity and data governance risk.** Transmitting sensitive, claims-level patient data to multiple pharmaceutical manufacturers, without clear federal standards governing data access, use, retention, or security, creates serious and unquantified exposure for providers and patients alike.
- **Implementation and change management.** Staff training, workflow redesign, legal review, and vendor and TPA contract amendments represent real upfront costs not reflected in the burden estimate.
- **Recurring error resolution.** Claims rejections, duplicate rebate disputes, and data validation failures require ongoing, unpredictable staff time that compounds over the course of a year.
- **No specialized staff.** Most rural providers do not employ pharmacy data analysts, reimbursement specialists, or cybersecurity professionals. These responsibilities are absorbed by already overextended staff.

A Rebate Model Undermines Rural Access and Stability

The Administration has consistently prioritized protecting rural America and ensuring that communities outside major metropolitan areas have access to affordable, high-quality care. The 340B program is a critical tool in that effort. For rural providers, 340B savings are not supplemental revenue. They are operational revenue that keeps pharmacy counters open, funds primary care services, and supports the thin financial margins on which rural hospitals and health centers operate.

A rebate model fundamentally disrupts this dynamic. It requires providers to purchase drugs at full market price upfront and then wait, through a reconciliation and dispute process that is neither fast nor predictable, to recover the discount they are statutorily entitled to receive. Most rural and low-resourced providers do not have the cash reserves or access to financing needed to bridge that gap. The result is not efficiency. It is service reduction, pharmacy closures, and diminished access in the communities this Administration has committed to serve.

Furthermore, the ICR suggests that automation and third-party platforms can reduce burden. In practice, automation only delivers efficiency when data standards and submission rules are uniform across all manufacturers. Without that uniformity, covered entities face a proliferation of systems, formats, and requirements, which adds complexity rather than reducing it.

RECOMMENDATIONS

We respectfully offer the following recommendations, consistent with the Administration's goals of efficiency, deregulation, and protecting rural communities:

- **Do not implement a mandatory rebate model.** The upfront financial and administrative costs fall disproportionately on FQHCs, CAHs, and community-based ambulatory providers that depend on 340B savings as essential operating revenue. A mandatory model would undermine rural access and contradict the Administration's commitment to reducing burden on providers.
- **Recalculate the full and accurate burden.** The ICR must account for cybersecurity, data governance, system changes, staff training, reconciliation, dispute management, and cash-flow risk—not solely

the time required to submit data. An accurate estimate is essential to sound regulatory decision-making.

- **Establish a neutral national clearinghouse.** Rather than a fragmented rebate model, HRSA should designate a single, neutral national clearinghouse to manage 340B data and support duplicate discount prevention. This approach is more efficient, preserves upfront discounts, eliminates duplicative manufacturer-driven processes, limits unnecessary patient data exposure, and improves program integrity in a way that a rebate model cannot.
- **Set clear, enforceable guardrails.** If any rebate mechanism is pursued, manufacturers must bear the administrative and financial responsibility for the model they advocate. Payment timelines must be standardized and prompt. Data submissions must be limited to information already generated through routine dispensing and billing instead of new, bespoke reporting created at manufacturer request.

The 340B program works because it delivers affordable medications to vulnerable patients through providers who have earned trust in their communities. OCHIN urges HRSA to pause covered entity data collection under any rebate model until the full burden is accurately measured, meaningfully reduced, and consistent with this Administration's commitment to cutting red tape, not adding it. We deeply appreciate HRSA's engagement and welcome continued dialogue. Please contact Jennifer Stoll at **stollj@ochin.org** to discuss how OCHIN can support the agency's work.

Sincerely,

Jennifer Stoll
Chief External Affairs Officer

April 27, 2025

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

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

Submitted via paperwork@hrsa.gov

Dear Director Britton:

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

NEW HORIZON HEALTH CENTER is a nonprofit, federally qualified health center (FQHC) based in Brownsville, Texas, serving medically underserved populations throughout the Rio Grande Valley for over 40 years. As a HRSA-funded health center and 340B covered entity, the center provides comprehensive healthcare services, including primary and preventive care, pediatrics, women's health, behavioral health, dental, vision, and pharmacy services.

The organization delivers care regardless of patients' ability to pay and utilizes a sliding fee discount program in accordance with federal requirements. Through its participation in the 340B Drug Pricing Program, New Horizon Health Center supports access to affordable medications and reinvests program savings to expand services, enhance care delivery, and improve health outcomes for vulnerable populations.

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

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

By requiring CHCs to purchase medications at full price and wait for rebates, this model would cause significant financial turmoil and directly affect our ability to serve the **15,615** patients who rely on us. We operate on razor-thin margins, and these additional costs are not an option for many entities. Similar to navigating manufacturers' existing contract pharmacy restrictions, CHCs will need to invest in IT infrastructure upgrades and hire or reassign staff to manage new complexities, including varying data submission requirements and timelines, payment reconciliations, and dispute processes for denied rebates. We will face an increased administrative burden in monitoring rebate claims and payments.

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

Workforce Impact:

- **Staffing Impact**: **NEW HORIZON HEALTH CENTER** anticipates needing **2.0** additional FTEs to account for the increase in operational, administrative, and compliance burden created by a rebate model.
- **Number of Hours:** Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, **NEW HORIZON HEALTH CENTER** will face an increased administrative burden to monitor rebate claims and payments. **10 HOURS PER WEEK** will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: **NEW HORIZON HEALTH CENTER** anticipates an additional **$35,000** for external vendors, including consultants, legal counsel, program coordination, third-party administrators (TPAs), electronic medical records (EMRs), pharmacy software, and reconciliation services.

Pharmacy Software & Third-Party Administration Changes

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

- **One-Time Implementation Costs:** We anticipate high upfront costs to adapt our pharmacy software, pay for custom dashboard modifications, and design new internal workflows.

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

$20,000 will be required simply to reach the baseline of compliance before a single rebate is ever received.

- **Ongoing Operational Fees**: Beyond implementation, our TPA and software vendors will likely charge ongoing service fees **$22,000** to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Cost:** For our CHC, which serves **15,615** patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at **$42,000** annually.

The In-House Pharmacy: The Burden of IT Integration

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

- **System Interoperability:** Unlike contract pharmacies that use TPAs, in-house pharmacies must directly integrate their Electronic Health Record (EHR) and Pharmacy Management System (PMS) with a complex new rebate infrastructure. Furthermore, we would have to re-program our PMS to reflect the current wholesale acquisition cost (WAC) catalog pricing for the selected MFP drugs when processing prescriptions for our uninsured patients AND simultaneously reflect our actual acquisition cost (AAC) catalog pricing for billing third-party insurance plans and Texas Medicaid Fee-For-Service (FFS).
- **One-Time Integration Costs:** We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools. The one-time integration cost is likely to be around **$30,000.**
- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend **8** hours per week manually pulling "Purchase Files" and "Price Files" to verify that every rebate check matches the statutory 340B price.

The Contract Pharmacy: The Burden of Network Coordination

The rebate model introduces a new complexity that threatens the existence of contractual arrangements. My CHC currently partners with 83 pharmacies to increase access to affordable medications.

- **TPA Reliance and Fees:** Navigating manufacturers' varying requirements across multiple contract pharmacies requires high-level TPA intervention. We anticipate that our TPAs will pass on the costs of developing rebate-tracking modules to us through increased per-claim fees.
- **Verification Latency:** The rebate model creates a reconciliation gap. Our staff must monitor claims across **83** different pharmacy locations to ensure rebates are paid correctly.
- **Risk of Pharmacy Exodus:** The model shifts financial risk to the pharmacy, potentially causing contract partners to opt out of the 340B program entirely rather than manage the administrative headache. In **Brownsville, TX and surrounding areas in Cameron County,** this would leave patients with no affordable medication options. Over 17 percent of the U.S. population already lives in a pharmacy desert.[2]

Clinic Administered Drugs: The Burden of New Systems Required

Clinic-administered drug (CAD) operations and record-keeping in CHCs are designed cost-effectively to reflect the nuances of CHC billing. Implementing a rebate model for CADs would

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

also require new software, system integration, and staff training. NACHC estimates these costs would range from $30,000 to $50,000 annually and could be much higher, depending on the software.[3] **NEW HORIZON HEALTH CENTER** estimates it will take **20 hours a week to successfully upload CAD claims and $20,000 to implement a new EHR module** for eClinicalWorks, the electronic medical record system at New Horizon Health Center.

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

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

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

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Conclusion

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

NEW HORIZON HEALTH CENTER appreciates the opportunity to respond to this ICR on the 340B Rebate Model Pilot Program, and we look forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please contact me at jwallace@newhorizonhc.org

Sincerely,

Jason K. Wallace

Jason K. Wallace, CEO
New Horizon Health Center

[6] HRSA FAQ

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

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BELLEVUE MEDICAL & DENTAL CLINIC
1050 140th Ave NE
Bellevue, WA 98005
425.373.3000

ICHS AT SOUND AUBURN
4238 Auburn Wy N
Auburn, WA 98002
253.444.0106

ICHS PRIMARY CARE CLINIC AT ACRS
3639 Martin Luther King Jr Wy S
Seattle, WA 98144
206.788.3700

RON CHEW HEALTHY AGING & WELLNESS CENTER
939 Golf Dr S
Seattle, WA 98144
206.462.7100

ICHS LEGACY HOUSE
803 S Lane St
Seattle, WA 98104
206.292.5184

ICHS MEAL PROGRAM AT BUSH ASIA CENTER
409 Maynard Ave S, Plaza 6
Seattle, WA 98104
206.521.4129

SEATTLE WORLD SCHOOL TEEN HEALTH CENTER
1700 E Union St
Seattle, WA 98122
206.332.7160

HIGHLAND HEALTH CENTER
15027 Bel-Red Rd
Bellevue, WA 98007
425.373.3135

MOBILE MEDICAL CLINIC
206.788.3700

MOBILE DENTAL CLINIC
206.533.2614

April 27, 2026

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

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

Submitted via paperwork@hrsa.gov

Dear Director Britton:

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

ICHS is a Community Health Center in King County, Washington. We served 36,283 unique patients in 2025 living across the greater Puget Sound region. The overwhelming majority of our patients – 81 percent – are low-income, and over half are on Medicaid or are dually eligible for Medicare and Medicaid. We serve patients regardless of insurance or ability to pay.

We request that HRSA exempt CHCs from the 340B Rebate Model Pilot Program due to significant financial and administrative burdens.

Requiring CHCs to purchase medications at full price and wait for rebates would cause significant financial turmoil and directly affect our ability to serve the 36,283 patients who rely on ICHS. We operate on razor-thin margins, and these additional costs are not an option for many entities. Nationally, CHCs operate

with an average margin below -4 percent.[1] 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: varying data submission requirements and timelines, payment reconciliations, and dispute processes for denied rebates, among others.

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

Workforce, Pharmacy Software, and Third-Party Administration Impacts

ICHS anticipates needing at least two additional full-time equivalent (FTE) staff to account for the increase in operational, administrative, and compliance burden created by a rebate model. Navigating this pilot requires both additional staff and changes to workflow and software. HRSA should consider the increased compliance burdens when manufacturers have the flexibility to require varying data submission standards and elements.

Additionally, if manufacturers can select different software platforms, as for current contract pharmacy policies, CHC administrative burdens would increase substantially. We anticipate high upfront costs to adapt our pharmacy software, pay for custom dashboard modifications, and design new internal workflows. ICHS estimates it will cost appropriately $325,000 upfront simply to reach the baseline of compliance before a single rebate is ever received. ICHS, which serves over 36,000 patients, estimates that the total projected increase in administrative expenses – including stand-up and implementation of new IT and pharmacy systems, staff resources, and carrying costs – will be nearly $720,000.

In-House Pharmacy and the Burden of IT Integration

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

Unlike contract pharmacies that use TPAs, in-house pharmacies must directly integrate their Electronic Health Record (EHR) and Pharmacy Management System (PMS) with a complex new rebate infrastructure. ICHS' difficulties are compounded because our EHR is purchased through

[1] https://www.nachc.org/community-health-centers-grew-in-2024-but-patient-access-faces-a-tipping-point/

another health care network. We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools. Staff who currently manage clinical pharmacy services will be forced to spend additional time each week manually pulling "Purchase Files" and "Price Files" to verify that every rebate check matches the statutory 340B price.

Contract Pharmacy and the Burden of Network Coordination

The rebate model introduces new complexity that threatens the existence of contractual arrangements. ICHS currently partners with seven pharmacies to increase access to affordable medications. Navigating manufacturers' varying requirements across multiple contract pharmacies requires high-level TPA intervention. We anticipate that our TPAs will pass on the costs of developing rebate-tracking modules to us through increased per-claim fees.

The rebate model creates a reconciliation gap. Our staff must monitor claims across three different pharmacy locations to ensure rebates are paid correctly. Additionally, the model shifts financial risk to the pharmacy, potentially causing contract partners to opt out of the 340B program entirely rather than manage the administrative headache. In King County and the greater Puget Sound region, this would leave patients with no affordable medication options. Over 17 percent of the US population already lives in a pharmacy desert.[2] This is acutely felt in Washington, where up to 1.2 million people live in areas with minimal access to pharmacies.[3] Our Bellevue Medical and Dental Clinic does not have an in-house pharmacy and relies almost entirely on contract pharmacies to fill our patients' prescriptions.

Clinic-Administered Drugs and the Burden of New Required Systems

Clinic-administered drug (CAD) operations and record-keeping in CHCs are designed cost-effectively to reflect the nuances of CHC billing. Implementing a rebate model for CADs would also require new software, system integration, and staff training. NACHC estimates these costs would range from $30,000 to $50,000 annually and could be much higher. ICHS estimates that implementing new CAD systems would cost $262,000. We cannot yet calculate annual fees associated with this change, as we do not know what the owner of our EHR module will charge us.

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

[2] Vulnerability Index Approach to Identify Pharmacy Deserts and Keystone Pharmacies | Pharmacy and Clinical Pharmacology | JAMA Network Open | JAMA Network
[3] https://www.seattletimes.com/business/the-loss-of-bartell-drugs-weighs-heavy-on-a-city-rich-with-assets/

submitting for rebate. Very few CHC records include electronic medication administration records (eMARs), which are common in hospital EMRs. Where eMARs are available, they incur an additional cost and often require CHCs to pay for a standalone software system.

Impacts to Patients' Access to Life-Saving Medications

ICHS has significant concerns about the impact the 340B rebate pilot will 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 rebate model, manage chronic conditions prevalent in primary care settings. CHCs serve a patient population with a higher burden of chronic conditions compared to private practices, with studies showing a significantly higher prevalence of illnesses like diabetes, hypertension, and obesity. This patient population relies on affordable medications to manage these long-term conditions.[4] We anticipate that some of the SGLT2 inhibitors, which treat Type 2 diabetes, chronic kidney disease, and heart failure, will require anywhere from an 11,683 percent to an 18,023 percent net spending increase.

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

The lack of access to upfront 340B discounts, along with the high IT infrastructure costs, will disproportionately impact CHCs and be felt by patients. Many CHCs are currently under financial strain, with nearly half operating with less than 90 days of cash on hand. This rebate model creates significant financial challenges. Under the proposed model, CHCs would be required to purchase drugs at the WAC. CHCs will have to wait to receive their rebate payment *after* providing medications to their patients, forcing difficult decisions about how to allocate limited financial resources, including cutting essential services and reducing operating hours.

We are particularly worried that the need to purchase drugs at full WAC will cause cash flow issues and potentially lead CHCs to exceed credit limits with wholesalers, halting their ability to order medications until payments are submitted. ICHS estimates that purchasing the ten selected drugs at WAC instead of 340B ceiling prices will increase our 2027 average upfront monthly drug spend by $584,996.

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

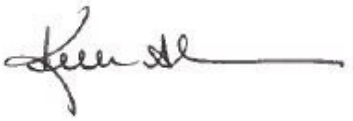
A rebate model also creates substantial uncertainty about CHCs' ability to apply sliding fee discounts at the point of sale. By statute and regulation, CHCs are required to offer sliding fee discounts for all required and additional health services within their HRSA-approved scope of project. In line with their mission, CHCs offer flat or sliding scale discounts on prescription drugs to make them more affordable for low-income individuals. A CHC can adjust the cost of health care services, including medication, based on a patient's income and family size. ICHS provided $560,641 in sliding fee discounts in 2025, and we expect that need will increase in 2026 and beyond.

Conclusion

ICHS 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"[5] 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 create a new barrier for patients, especially uninsured patients, who depend on the upfront 340B discount, making it operationally impossible to provide the sliding fee scale and steeply discounted medications required by law. ICHS believes that a 340B rebate model would cause disproportionate harm to patients served by CHCs and other safety net providers.

ICHS appreciates the opportunity to respond to this ICR on the 340B Rebate Model Pilot Program. Please do not hesitate to contact us if you have any questions.

Sincerely,



Kelli Nomura, MBA, MHP
Chief Executive Officer
International Community Health Services

[5] https://www.hrsa.gov/opa

ZUFALL HEALTH COMMUNITY HEALTH CENTERS

Providing care in Bridgewater, Dover, Flemington, Franklin Township, Hackettstown, Morristown, Newton, Plainsboro, Somerville, and West Orange and on the Highlands Health Van and Delta Dental Mobile
zufallhealth.org

April 27, 2025

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

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

Submitted via paperwork@hrsa.gov

Dear Director Britton:

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

Zufall Health Center ("Zufall") is an award winning, nationally recognized 50l(c)(3) non-profit community health center driven by our mission to provide access to quality, affordable and culturally responsive health care to people and communities who experience barriers to care. Zufall provides primary health care, oral health, behavioral health, and support services at fifteen sites, including fixed sites, mobile sites, a retail pharmacy, and a school-based site. Our service area encompasses seven New Jersey counties (Essex, Hunterdon, Middlesex, Morris, Somerset, Sussex, and Warren).

Zufall's patients are among the most vulnerable members of our communities. In 2025, Zufall served 52,088 patients in 189,579 visits. Of all our patients, 87% live at or below 200% of the federal poverty level, 49% are uninsured, 34% are recipients of Medicaid, and 76% identify as Hispanic. Zufall receives funding from the Health Resources and Services Administration for designated special populations: migrant/seasonal farm workers, the homeless population, and public housing residents.

Emphasizing integrated and high-quality services, Zufall maintains recognition by the National Committee for Quality Assurance as a Patient Centered Medical Home and is accredited by The Joint Commission. Zufall is consistently in the top 10% of community health centers nationally based on our clinical quality.

The 340B program is foundational to CHC's ability to serve the most vulnerable members of our community. However, the proposed shift of responsibility from manufacturers to safety-net

providers directly serving patients through a rebate model threatens to destabilize CHC pharmacy operations nationwide. Based on national assessments from the National Association of Community Health Centers (NACHC) and our own internal assessments, the hours and dollars spent complying with a rebate program are staggering.

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

By requiring CHCs to purchase medications at full price and wait for rebates, this model would cause significant financial turmoil and directly affect our ability to serve the 52,088 patients who rely on us. We operate on razor-thin margins, and these additional costs are not an option for many entities. Similar to navigating manufacturers' existing contract pharmacy restrictions, CHCs will need to invest in IT infrastructure upgrades and hire or reassign staff to manage new complexities, including varying data submission requirements and timelines, payment reconciliations, and dispute processes for denied rebates. We will face an increased administrative burden in monitoring rebate claims and payments.

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

Workforce Impact:

- **Staffing Impact**: Zufall Health Center anticipates needing 1 additional FTEs to account for the increase in operational, administrative, and compliance burden created by a rebate model.
- **Number of Hours:** Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, Zufall Health Center will face an increased administrative burden to monitor rebate claims and payments. Forty hours per week will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: Zufall Health Center anticipates an additional **$30,050 annually** for external vendors, including consultants, legal counsel, program coordination, third-party administrators (TPAs), electronic medical records (EMRs), pharmacy software, and reconciliation services.
- **One-Time Implementation Costs:** We anticipate high upfront costs to adapt our pharmacy software, pay for custom dashboard modifications, and design new internal workflows. An additional $10,000 will be required simply to reach the baseline of compliance before a single rebate is ever received.
- **Ongoing Operational Fees**: Beyond implementation, our TPA and software vendors will likely charge ongoing service fees to maintain these rebate-tracking features. We will also need

[1] 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

to increase annual auditing fees by approximately $6,000. These permanent, recurring costs diminish our 340B savings.

- **Total Cost:** For our CHC, which serves 52,088 patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at $125,000 annually.

The In-House Pharmacy: The Burden of IT Integration

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

- **System Interoperability:** Unlike contract pharmacies that use Third-Party Administrators (TPAs), in-house pharmacies must directly integrate their Electronic Health Record (EHR) and Pharmacy Management System (PMS) with a complex new rebate infrastructure. These systems were not designed to communicate in real time for rebate validation, requiring the development of new data interfaces, manual workarounds, and cross-platform reconciliation processes to ensure compliance with manufacturer-specific requirements. This level of system fragmentation and manual validation introduces a high risk of discrepancies, delayed reimbursement, and audit exposure, further compounding financial and operational strain on the Covered Entity.
- **One-Time Integration Costs:** We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools.
- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend **40** hours per week manually pulling "Purchase Files" and "Price Files" to verify that every rebate check matches the statutory 340B price.

The Contract Pharmacy: The Burden of Network Coordination

The rebate model introduces a new complexity that threatens the existence of contractual arrangements. My CHC currently partners with **16** pharmacies to increase access to affordable medications.

- **TPA Reliance and Fees:** Navigating manufacturers' varying requirements across multiple contract pharmacies requires high-level TPA intervention. We anticipate that our TPAs will pass on the costs of developing rebate-tracking modules to us through increased per-claim fees.
- **Verification Latency:** The rebate model creates a reconciliation gap. Our staff must monitor claims across **16** different pharmacy locations to ensure rebates are paid correctly.
- **Risk of Pharmacy Exodus:** The model shifts financial risk to the pharmacy, potentially causing contract partners to opt out of the 340B program entirely rather than manage the administrative headache. In **Northern New Jersey** this would leave patients with no affordable medication options. Over 17 percent of the U.S. population already lives in a pharmacy desert.[2]

Clinic Administered Drugs: The Burden of New Systems Required

Clinic-administered drug (CAD) operations and record-keeping in CHCs are designed cost-effectively to reflect the nuances of CHC billing. Implementing a rebate model for CADs would

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

also require new software, system integration, and staff training. NACHC estimates these costs would range from $30,000 to $50,000 annually and could be much higher, depending on the software.[3]

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

II. Patient Impact

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

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

III. Financial Challenges

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

- **Purchasing Drugs at the WAC Price Upfront:** Under the proposed model, CHCs would be required to purchase drugs at the WAC. CHCs will have to wait to receive their rebate

[3] Internal NACHC survey data

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

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

payment *after* providing medications to their patients, forcing difficult decisions about how to allocate limited financial resources, including cutting essential services and reducing operating hours. We are particularly worried that the need to purchase drugs at full WAC will cause cash flow issues and potentially lead CHCs to exceed credit limits with wholesalers, halting their ability to order medications until payments are submitted.

- **Sliding Fee Scale:** A rebate model creates substantial uncertainty about CHCs' ability to apply sliding-fee discounts at the point of sale. By statute and regulation, CHCs are required to offer sliding fee discounts for all required and additional health services within the HRSA-approved scope of project.[6] In line with their mission, CHCs offer flat or sliding-scale discounts on prescription drugs to make them more affordable for low-income individuals.[7]A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size. Zufall Health Center adheres to all applicable statutory and regulatory requirements related to sliding fee discounts, ensuring medications are provided at reduced, income-based pricing at the point of sale for eligible patients. In addition, we offer free medication delivery services, further reducing barriers to access for individuals who may face transportation or socioeconomic challenges.

Conclusion

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

Zufall Health Center appreciates the opportunity to respond to this ICR on the 340B Rebate Model Pilot Program, and we look forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please contact please contact me at fpalm@zufallhealth.org or by phone at 973-985-8120.

Sincerely,

Frances L. Palm, MPA
President & CEO

[6] HRSA FAQ

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

EAST CENTRAL MISSISSIPPI HEALTH CARE, INC.
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April 27, 2026

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

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

Submitted via paperwork@hrsa.gov

Dear Director Britton:

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

In addition to the costs we will incur from adding staff and software, we anticipate our net spend for drugs to increase by 8,040% and our upfront inventory spend by 53,586%. This is will have a significant impact on our cash flow.

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

internal assessments, the hours and dollars spent complying with a rebate program are staggering.

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

By requiring CHCs to purchase medications at full price and wait for rebates, this model would cause significant financial turmoil and directly affect our ability to serve the **9,617** patients who rely on us. We operate on razor-thin margins, and these additional costs are not an option for many entities. Similar to navigating manufacturers' existing contract pharmacy restrictions, CHCs will need to invest in IT infrastructure upgrades and hire or reassign staff to manage new complexities, including varying data submission requirements and timelines, payment reconciliations, and dispute processes for denied rebates. We will face an increased administrative burden in monitoring rebate claims and payments.

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

Workforce Impact:

- **Staffing Impact: ECMHCI** anticipates needing **two** additional FTEs to account for the increase in operational, administrative, and compliance burden created by a rebate model.
- **Number of Hours:** Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, **ECMHCI** will face an increased administrative burden to monitor rebate claims and payments. **Approximately 40 hours** will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs: ECMHCI** anticipates an additional **$100,000** for external vendors, including consultants, legal counsel, program coordination, third-party

administrators (TPAs), electronic medical records (EMRs), pharmacy software, and reconciliation services.

Pharmacy Software & Third-Party Administration Changes

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

- **One-Time Implementation Costs:** We anticipate high upfront costs to adapt our pharmacy software, pay for custom dashboard modifications, and design new internal workflows. **ESTIMATED ONE-TIME COST of $50,000** will be required simply to reach the baseline of compliance before a single rebate is ever received.
- **Ongoing Operational Fees**: Beyond implementation, our TPA and software vendors will likely charge ongoing service fees **of approximately $50,000** to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Cost:** For our CHC, which serves **9,617** patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at **$150,000** annually.

The Contract Pharmacy: The Burden of Network Coordination

The rebate model introduces a new complexity that threatens the existence of contractual arrangements. My CHC currently partners with **10** pharmacies to increase access to affordable medications.

- **TPA Reliance and Fees:** Navigating manufacturers' varying requirements across multiple contract pharmacies requires high-level TPA intervention. We anticipate that our TPAs will pass on the costs of developing rebate-tracking modules to us through increased per-claim fees.
- **Verification Latency:** The rebate model creates a reconciliation gap. Our staff must monitor claims across **10** different pharmacy locations to ensure rebates are paid correctly.
- **Risk of Pharmacy Exodus:** The model shifts financial risk to the pharmacy, potentially causing contract partners to opt out of the 340B program entirely rather than manage the administrative headache. In East Central Mississippi, this would leave patients with no affordable medication options. Over 17 percent of the U.S. population already lives in a pharmacy desert.[2]

Clinic Administered Drugs: The Burden of New Systems Required

Clinic-administered drug (CAD) operations and record-keeping in CHCs are designed cost-effectively to reflect the nuances of CHC billing. Implementing a rebate model for CADs would also require new software, system integration, and staff training. NACHC estimates these costs would range from $30,000 to $50,000 annually and could be much higher, depending on the software.[3] **ECMHCI** estimates it will take 40**hours and cost $40,000** to upload records related to CADs

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

II. Patient Impact

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

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

340B price, making the price unattainable for patients and precluding CHCs from fulfilling their legal obligation to offer the required discount at the point of care.

III. Financial Challenges

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

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

Conclusion

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

ECMHCI appreciates the opportunity to respond to this ICR on the 340B Rebate Model Pilot Program, and we look forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please contact me at jbishop@ecmhci.com

Sincerely,

Jill Bishop, Executive Director
East Central Mississippi Health Care Inc.

GREATER PORTLAND HEALTH

CARING FOR THE WHOLE COMMUNITY

April 27, 2025

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

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

Submitted via paperwork@hrsa.gov

Dear Director Britton:

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

Greater Portland Health's mission is to provide high quality patient-centered healthcare that is accessible, affordable, and contributes to a healthier community. We currently serve over 17,000 active patients. Our services include but are not limited to medical, behavioral health, recuperative care, oral health, substance use treatment, chronic and infectious disease management, optometry, and psychiatric services.

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

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

By requiring CHCs to purchase medications at full price and wait for rebates, this model would cause significant financial turmoil and directly affect our ability to serve the 13,427 patients who rely on us. Many CHC's operate on razor-thin margins, and these additional costs are not an option for many entities. Similar to navigating manufacturers' existing contract pharmacy restrictions, CHCs will need to invest in IT infrastructure upgrades and hire or reassign staff to manage new complexities, including varying data submission requirements and timelines, payment reconciliations, and dispute processes for denied rebates. We will face an increased administrative burden in monitoring rebate claims and payments.

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

Workforce Impact:

- **Staffing Impact**: Portland Community Health Center anticipates needing 0.80 additional FTEs to account for the increase in operational, administrative, and compliance burden created by a rebate model.
- **Number of Hours:** Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, Portland Community Health Center will face an increased administrative burden to monitor rebate claims and payments. 832 hours annually will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: Portland Community Health Center anticipates an additional $24,000 to $30,000 for external vendors, including consultants, legal counsel, program coordination, third-party administrators (TPAs), electronic medical records (EMRs), pharmacy software, and reconciliation services.

The Contract Pharmacy: The Burden of Network Coordination

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

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

Portland Community Health Center has significant concerns about the impact a 340B Rebate Model Pilot would have on our most vulnerable patients' access to life-saving medications. The majority of drugs selected for the MDPNP for 2026 and 2027, and included in the proposed rebate model, manage chronic conditions prevalent in primary care settings. CHCs serve a patient population with a

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

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

higher burden of chronic conditions compared to private practices, with studies showing a significantly higher prevalence of illnesses like diabetes, hypertension, and obesity.[3] This patient population relies on affordable medications to manage these long-term conditions.

The impact on insulin access is also alarming and directly conflicts with federal requirements. With over 3 million Americans relying on CHCs for essential diabetes care,[4] insulin affordability is a matter of life and death. Furthermore, Executive Order #14273 conditions future Section 330(e) funds on CHCs providing low-income patients with access to discounted insulin. No current operational method exists to provide discounted medications in a rebate model. In the proposed model, the wholesaler price file would reflect the full Wholesale Acquisition Cost (WAC) rather than the discounted 340B price, making the price unattainable for patients and precluding CHCs from fulfilling their legal obligation to offer the required discount at the point of care.

II. Financial Challenges

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

- **Purchasing Drugs at the WAC Price Upfront:** Under the proposed model, CHCs would be required to purchase drugs at the WAC. CHCs will have to wait to receive their rebate payment *after* providing medications to their patients, forcing difficult decisions about how to allocate limited financial resources, including cutting essential services and reducing operating hours. We are particularly worried that the need to purchase drugs at full WAC will cause cash flow issues and potentially lead CHCs to exceed credit limits with wholesalers, halting their ability to order medications until payments are submitted.
- **Sliding Fee Scale:** A rebate model creates substantial uncertainty about CHCs' ability to apply sliding-fee discounts at the point of sale. By statute and regulation, CHCs are required to offer sliding fee discounts for all required and additional health services within the HRSA-approved scope of project.[5] In line with their mission, CHCs offer flat or sliding-scale discounts on prescription drugs to make them more affordable for low-income individuals.[6]

Portland Community Health Center asks that 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. Portland Community Health Center appreciates the opportunity to respond to this ICR on

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[3] Richard P, Ku L, Dor A, Tan E, Shin P, Rosenbaum S. Cost savings associated with the use of community health centers. J Ambul Care Manage. 2012 Jan-Mar;35(1):50-9. doi: 10.1097/JAC.0b013e31823d27b6. PMID: 22156955.
[4] 2025 UDA Data, HRSA (hrsa.gov)
[5] HRSA FAQ
[6] Such discounts are subject to potential legal and contractual restrictions. https://bphc.hrsa.gov/compliance/compliance-manual/chapter9#footnote10

the 340B Rebate Model Pilot Program, and we look forward to continuing to engage with HRSA on this prominent issue.

Sincerely,

Ann Tucker

Ann Tucker, CEO
Portland Community Health Center

April 27, 2025

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

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

Submitted via paperwork@hrsa.gov

Dear Director Britton:

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

For more than 50 years LCH has served the communities of southern Chester County and officially became a Federally Qualified Health Center (FQHC) in 2012. Today, LCH offers a wide range of health services across three locations to more than 8,700 patients, many of whom are uninsured or underinsured. LCH prides itself on providing accessible and expert care to all our patients regardless of their ability to pay.

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

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

By requiring CHCs to purchase medications at full price and wait for rebates, this model would cause significant financial turmoil and directly affect our ability to serve the **8,700** patients who rely on us. We operate on razor-thin margins, and these additional costs are not an option for many entities. Similar to navigating manufacturers' existing contract pharmacy restrictions, CHCs will need to invest in IT infrastructure upgrades and hire or reassign staff to manage new complexities,

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

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

Workforce Impact:

- **Staffing Impact**: LCH anticipates needing **2.5** additional FTEs to account for the increase in operational, administrative, and compliance burden created by a rebate model.
- **Number of Hours:** Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, LCH will face an increased administrative burden to monitor rebate claims and payments. **40 hours per week** will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: LCH anticipates an additional $50,000 to $100,000 for external vendors, including consultants, legal counsel, program coordination, third-party administrators (TPAs), electronic medical records (EMRs), pharmacy software, and reconciliation services.

Pharmacy Software & Third-Party Administration Changes

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

- **One-Time Implementation Costs:** We anticipate high upfront costs to adapt our pharmacy software, pay for custom dashboard modifications, and design new internal workflows. An initial $50,000 will be required simply to reach the baseline of compliance before a single rebate is ever received.
- **Ongoing Operational Fees**: Beyond implementation, our TPA and software vendors will likely charge ongoing service fees to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Cost:** For our CHC, which serves 8,700 patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at 10% annually.

The In-House Pharmacy: The Burden of IT Integration

LCH operates one entity-owned in-house pharmacy. The rebate model is not a simple accounting change; it is a significant technological disruption. To remain compliant, in-house

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

pharmacy systems will require costly customization to provide real-time, accurate information at the pharmacy counter.

- **System Interoperability:** Unlike contract pharmacies that use TPAs, in-house pharmacies must directly integrate their Electronic Health Record (EHR) and Pharmacy Management System (PMS) with a complex new rebate infrastructure.
- **One-Time Integration Costs:** We anticipate high upfront costs of at least $50,000 to pay software vendors for custom API builds and "Price File" reconciliation tools.
- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend 15 hours per week manually pulling "Purchase Files" and "Price Files" to verify that every rebate check matches the statutory 340B price.

The Contract Pharmacy: The Burden of Network Coordination

The rebate model introduces a new complexity that threatens the existence of contractual arrangements. My CHC currently partners with 5 pharmacies to increase access to affordable medications.

- **TPA Reliance and Fees:** Navigating manufacturers' varying requirements across multiple contract pharmacies requires high-level TPA intervention. We anticipate that our TPAs will pass on the costs of developing rebate-tracking modules to us through increased per-claim fees.
- **Verification Latency:** The rebate model creates a reconciliation gap. Our staff must monitor claims across 5 different pharmacy locations to ensure rebates are paid correctly.
- **Risk of Pharmacy Exodus:** The model shifts financial risk to the pharmacy, potentially causing contract partners to opt out of the 340B program entirely rather than manage the administrative headache. In Chester County, Pennsylvania**,** this would leave patients with no affordable medication options. Over 17 percent of the U.S. population already lives in a pharmacy desert.[2]

Clinic Administered Drugs: The Burden of New Systems Required

Clinic-administered drug (CAD) operations and record-keeping in CHCs are designed cost-effectively to reflect the nuances of CHC billing. Implementing a rebate model for CADs would also require new software, system integration, and staff training. NACHC estimates these costs would range from $30,000 to $50,000 annually and could be much higher, depending on the software.[3] LCH estimates it will take 10 hours per week to upload records related to CADs alone.

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

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

[3] Internal NACHC survey data

II. Patient Impact

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

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

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- **Purchasing Drugs at the WAC Price Upfront:** Under the proposed model, CHCs would be required to purchase drugs at the WAC. CHCs will have to wait to receive their rebate payment *after* providing medications to their patients, forcing difficult decisions about how to allocate limited financial resources, including cutting essential services and reducing operating hours. We are particularly worried that the need to purchase drugs at full WAC will cause cash flow issues and potentially lead CHCs to exceed credit limits with wholesalers, halting their ability to order medications until payments are submitted.
- **Sliding Fee Scale:** A rebate model creates substantial uncertainty about CHCs' ability to apply sliding-fee discounts at the point of sale. By statute and regulation, CHCs are required to offer sliding fee discounts for all required and additional health services within the HRSA-approved scope of project.[6] In line with their mission, CHCs offer flat or sliding-scale discounts on prescription drugs to make them more affordable for low-income individuals.[7] A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size. LCH's ability to provide medications at deeply discounted rates under our sliding fee scale will be compromised. If the cash is not in our

[4] Richard P, Ku L, Dor A, Tan E, Shin P, Rosenbaum S. Cost savings associated with the use of community health centers. J Ambul Care Manage. 2012 Jan-Mar;35(1):50-9. doi: 10.1097/JAC.0b013e31823d27b6. PMID: 22156955.
[5] 2025 UDA Data, HRSA (hrsa.gov)
[6] HRSA FAQ
[7] Such discounts are subject to potential legal and contractual restrictions. https://bphc.hrsa.gov/compliance/compliance-manual/chapter9#footnote10

accounts because it is being held by a manufacturer waiting for a rebate, we cannot provide the "bridge support" that prevents our 3,914 uninsured patients from rationing their medications needed for diabetes or heart conditions.

Conclusion

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

LCH appreciates the opportunity to respond to this ICR on the 340B Rebate Model Pilot Program, and we look forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please do not hesitate to contact me at rgannon@lchservices.org or 610-444-7550.

Sincerely,

Ronan Gannon

Ronan W. Gannon
CEO

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

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

FROM: Clinica Family Health and Wellness
DATE: April 27, 2026

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

Clinica Family Health & Wellness is a nonprofit Federally Qualified Health Center (FQHC) serving Adams, Boulder, Broomfield, and Gilpin counties in Colorado. We serve approximately 50,000 individuals annually, half of whom live at or below the federal poverty level, 31% are uninsured, and 55% rely on Medicaid or Medicare. In 2025, our participation in the 340B Drug Discount Program enabled 17,681 patients to directly access significant prescription savings.

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

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

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

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

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

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

At Clinica Family Health and Wellness, the rebate model will impose a significant administrative burden. Not only will the model require us to pay a higher cost on drugs while receiving less 340B savings, it will require us to invest in staff, technology, and vendor support to manage.

We anticipate needing to hire at least 1.0 FTE to submit and track the rebates to reconciliation as we anticipate this will take 40+ staff hours per week to manage. While the data submission itself will require extra time, the true burden comes in tracking the outcome of the submissions to reconciliation. Staff will be required to investigate every claim submitted, matching different data sources across multiple platforms, and then working with manufacturers when reconciliation issues or denials occur. Our experience with support from manufacturers in identifying why a claim was denied thus far, has been either non-existent or frequently unresolved with little explanation as to why. The staff support required is also very specialized. We need someone who understands 340B, finance and accounting, and is very skilled with information technology and data manipulation. This skill set will likely not be found in one single person, thus requiring frequent meetings and coordination to keep all parties involved up to date on different elements in all the steps required.

New technology will also be needed to support the rebate reconciliation process. At Clinica, we have at least six different software systems that will need to be used to gather and reconcile data. Pulling and organizing data from all the different platforms and software will be incredibly time-consuming, particularly as none of these systems were built to support a rebate model. The processes will be very manual, require significant training, and likely to result in human error that results in loss of 340B savings. This will be especially challenging when denials occur as the vendors engaged in the rebate model currently are not neutral. There is no incentive to support covered entities resolve issues.

Knowing the challenges of data submission and reconciliation, our organization may need to consider engaging an additional vendor, at an additional cost, to help keep track of all the moving parts. This extra cost directly takes funding away from our ability to stretch scarce federal resources to help more patients.

Ultimately the rebate model creates more bureaucracy and decreases already limited funding used to support covered entities, like Clinica, from helping patients. The administrative burden associated with the proposed rebate model is not only costly, but also incredibly inefficient, especially as different manufacturers have liberty to dictate different requirements. This makes an already challenging process take even more time as different reports with different data elements may be required.

With any additional revenue or reserves tied up to account for this astronomical increase and no guarantee of a return on the investment, along with the need to pull funds from other areas of the clinic's operations – including staffing, services, and even clinic locations – to simply maintain compliance with a rebate model, the burden to account for this increase in staff time and cost, and the impact on CHC patients' access to care and medications, is mind-boggling. It is incomprehensible to impose a rebate model with this level of burden on local, nonprofit CHCs

when 70% of CHCs in Colorado had negative or breakeven financial operating margins in 2024 and 2025 and it is anticipated a similar number of CHCs will face this financial challenge in 2026.

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

Sincerely,

Simon Smith
Chief Executive Officer
Clinica Family Health and Wellness

FAMILY Health

BUILDING HEALTHY LIVES TOGETHER

April 27, 2026

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

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

Submitted via paperwork@hrsa.gov

Dear Director Britton:

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

Here in our small farming community in Ohio, Family Health Services of Darke County has proudly served patients for more than 50 years. We provide integrated medical, dental, behavioral health, 340B pharmacy, clinical pharmacy, dietitian services, a Medication Assisted Treatment (MAT) program, Patient Assistance, optometry, and care coordination to 27,963 patients through 115,126 visits annually, reaching 65 ZIP codes across 11 counties. Our patients include 1,297 veterans, along with thousands of uninsured and underinsured individuals. Our mission—to provide quality, cost-effective healthcare and promote wellness for all people in our community—relies on the continued strength of the 340B Program, allowing us to stretch scarce federal resources as far as possible.

The 340B program is foundational to CHC's ability to serve the most vulnerable members of our community. However, the proposed shift of responsibility from manufacturers to safety-net providers directly serving patients through a rebate model threatens to destabilize CHC pharmacy operations nationwide. Based on national assessments from the National Association of

Community Health Centers (NACHC) and our own internal assessments, the hours and dollars spent complying with a rebate program are staggering.

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

By requiring CHCs to purchase medications at full price and wait for rebates, this model would cause significant financial turmoil and directly affect our ability to serve the **27,963** patients who rely on us. We operate on razor-thin margins, and these additional costs are not an option for many entities. **At Family Health we are currently projecting a negative net income of ($800,000) for 2026 due to the Inflation Reduction Act's Medicare Fair Pricing, which reduced our net income ($1.2M). This does not include any new manufacturer restrictions in 2026. We simply cannot bend anymore or we'll break!** Similar to navigating manufacturers' existing contract pharmacy restrictions, CHCs will need to invest in IT infrastructure upgrades and hire or reassign staff to manage new complexities, including varying data submission requirements and timelines, payment reconciliations, and dispute processes for denied rebates. We will face an increased administrative burden in monitoring rebate claims and payments.

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

Workforce Impact:

- **Staffing Impact**: Family Health anticipates needing **1.5** additional FTEs to account for the increase in operational, administrative, and compliance burden created by a rebate model.
- **Number of Hours:** Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, Family Health will face an increased administrative burden to monitor rebate claims and payments. We estimate this to be around **60 hours per week** that will be required to report 340B rebate claims to a third-party platform and reconcile the rebates to the original claims.
- **External Vendor Costs**: Family Health anticipates an additional **$330,000 in 2026** for external vendors, including consultants, legal counsel, program coordination, third-party administrators (TPAs), electronic medical records (EMRs), pharmacy software, and reconciliation services. We anticipate **$370,000 in 2027 and $440,000 in 2028** with the increase in IRA drugs each year.

Pharmacy Software & Third-Party Administration Changes

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

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

- **One-Time Implementation Costs:** We anticipate high upfront costs to adapt our pharmacy software, pay for custom dashboard modifications, and design new internal workflows. **$17,000** will be required simply to reach the baseline of compliance before a single rebate is ever received.
- **Ongoing Operational Fees**: Beyond implementation, our TPA and software vendors will likely charge ongoing service fees **$12,000** to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Cost:** For our CHC, which serves 27,963 patients and generated approximately 122,000 340B transactions in 2025, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at **$29,000** annually.

The In-House Pharmacy: The Burden of IT Integration

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

- **System Interoperability:** Unlike contract pharmacies that use TPAs, in-house pharmacies must directly integrate their Electronic Health Record (EHR) and Pharmacy Management System (PMS) with a complex new rebate infrastructure. Family Health Pharmacy uses PioneerRx, a platform common among independent pharmacies. We are already encountering a significant operational gap as policy requirements—such as 340B pass-through pricing or capped insulin and EpiPen costs—move faster than vendor software capabilities or vendor willingness to reprioritize enhancements for a small number of affected clients. The broader issue is that Wholesale Acquisition Cost (WAC) does not accurately reflect true acquisition cost once rebates, chargebacks, and 340B pricing are considered. Without systems that can reconcile those layers, any requirement to charge "actual cost plus a dispensing fee" becomes extremely difficult to implement and document for compliance.
- **One-Time Integration Costs:** Family Health anticipates substantial one-time expenses for custom API development, pricing file integrations, and reconciliation tools, with projected costs of approximately $30,000.
- **Ongoing Resource Strain:** Staff who currently manage daily pharmacy operations—including filling more than 100,000 prescriptions annually—would be diverted to manual administrative work. We estimate 40 or more staff hours each week would be needed to pull purchase files, compare pricing files, and verify claim-by-claim that rebate payments match the required 340B pricing. This burden would fall on both pharmacy staff and administrative/finance teams.

The Contract Pharmacy: The Burden of Network Coordination

The rebate model introduces a new complexity that threatens the existence of contractual arrangements. My CHC currently partners with **90** pharmacies to increase access to affordable medications.

- **TPA Reliance and Fees:** Navigating manufacturers' varying requirements across multiple contract pharmacies requires high-level TPA intervention. We anticipate that our TPAs will pass on the costs of developing rebate-tracking modules to us through increased per-claim fees.
- **Verification Latency:** The rebate model creates a reconciliation gap. Our staff must monitor claims across **90** different pharmacy locations to ensure rebates are paid correctly.
- **Risk of Pharmacy Exodus:** The model shifts financial risk to the pharmacy, potentially causing contract partners to opt out of the 340B program entirely rather than manage the administrative headache. In Darke County**,** this would leave patients with no affordable medication options. Over 17 percent of the U.S. population already lives in a pharmacy desert.[2] 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. A small independent chain in the neighboring area of Darke County recently closed all five of its locations after 108 years of business.

Clinic Administered Drugs: The Burden of New Systems Required

Clinic-administered drug (CAD) operations and record-keeping in CHCs are designed cost-effectively to reflect the nuances of CHC billing. Implementing a rebate model for CADs would also require new software, system integration, and staff training. NACHC estimates these costs would range from $30,000 to $50,000 annually and could be much higher, depending on the software.[3] Family Health estimates it will take **5 hours per week and cost $24,000 annually** to upload records related to CADs. Family Health must still track each dose purchased on the 340B program for compliance. We use the Cardinal IMS system costing $2,000 per month as well as providing documentation in patient visit notes describing what was administered.

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

II. Patient Impact

Family Health Services of Darke County, Inc. has significant concerns about the impact a 340B Rebate Model Pilot would have on our most vulnerable patients' access to life-saving medications. The majority of drugs selected for the MDPNP for 2026 and 2027, and included in the proposed rebate model, manage chronic conditions prevalent in primary care settings. CHCs serve a patient population with a higher burden of chronic conditions compared to private practices, with studies showing a significantly higher prevalence of illnesses like diabetes,

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

[3] Internal NACHC survey data

hypertension, and obesity.[4] This patient population relies on affordable medications to manage these long-term conditions.

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

III. Financial Challenges

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

- **Purchasing Drugs at the WAC Price Upfront:** Under the proposed model, CHCs would be required to purchase drugs at the WAC. CHCs will have to wait to receive their rebate payment *after* providing medications to their patients, forcing difficult decisions about how to allocate limited financial resources, including cutting essential services and reducing operating hours. We are particularly worried that the need to purchase drugs at full WAC will cause cash flow issues and potentially lead CHCs to exceed credit limits with wholesalers, halting their ability to order medications until payments are submitted. **Family Health Services of Darke County, Inc. estimates a cash flow disruption of $1,000,000 in 2026, $1,300,000 in 2027, and $2,000,000 in 2028.**
- **Sliding Fee Scale:** A rebate model creates substantial uncertainty about CHCs' ability to apply sliding-fee discounts at the point of sale. By statute and regulation, CHCs are required to offer sliding fee discounts for all required and additional health services within the HRSA-approved scope of project.[6] In line with their mission, CHCs offer flat or sliding-scale discounts on prescription drugs to make them more affordable for low-income individuals.[7] A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size. **Many CHCs calculate their sliding-fee discounts to their patients based off of the cost of the drug in the system plus a small dispensing fee. Because the "cost" in the pharmacy system will reflect wholesale price (thanks to the rebate system), it will make it impossible to give a discount to the patient based on the 340B price. This will cause the patient's cost to inflate, making it impossible to pass along the 340B discount to our patients at the time of dispense.**

[4] Richard P, Ku L, Dor A, Tan E, Shin P, Rosenbaum S. Cost savings associated with the use of community health centers. J Ambul Care Manage. 2012 Jan-Mar;35(1):50-9. doi: 10.1097/JAC.0b013e31823d27b6. PMID: 22156955.
[5] 2025 UDA Data, HRSA (hrsa.gov)
[6] HRSA FAQ
[7] Such discounts are subject to potential legal and contractual restrictions. https://bphc.hrsa.gov/compliance/compliance-manual/chapter9#footnote10

Conclusion

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

Family Health Services of Darke County, Inc. appreciates the opportunity to respond to this ICR on the 340B Rebate Model Pilot Program, and we look forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please contact myself or **Kalie Riffle at kriffle@familyhealthservices.org.**

Sincerely,

Jared Pollick, CEO
Family Health Services of Darke County, Inc.
jpollick@familyhealthservices.org

April 27, 2026

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

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

Submitted via paperwork@hrsa.gov

Dear Director Britton:

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

Noble Community Clinics is a nonprofit network of Federally Qualified Health Centers formed through the recent integration of Lakeshore Community Health Care and Noble Community Clinics. The organization provides comprehensive, affordable care, including medical, dental, and behavioral health, and pharmacy services, regardless of ability to pay, while advancing health equity and expanding access to care across east-central and central Wisconsin.

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

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

By requiring CHCs to purchase medications at full price and wait for rebates, this model would cause significant financial turmoil and directly affect our ability to serve the **nearly 40,000 patients** who rely on us. We operate on razor-thin margins, and these additional costs are not an option for many entities. Similar to navigating manufacturers' existing contract pharmacy restrictions, CHCs will need to invest in IT infrastructure upgrades and hire or reassign staff to manage new complexities, including varying data

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

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

Workforce Impact:

- **Staffing Impact**: Noble Community Clinics **anticipates needing 40 staff hours/week (approx. $175,000 annually) to administer a rebate program, or one additional FTEs** to account for the increase in operational, administrative, and compliance burden created by a rebate model.
- **Number of Hours:** Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, Noble Community Clinics will face an increased administrative burden to monitor rebate claims and payments. **It is anticipated 95 – 140 hours annually** will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: CHCs anticipate significant increases in operational costs. **National data shows that a single mid-sized CHC expects to incur over $3 million in additional costs annually** for external vendors, including consultants, legal counsel, program coordination, third-party administrators (TPAs), electronic medical records (EMRs), pharmacy software, and reconciliation services.

Pharmacy Software & Third-Party Administration Changes

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

- **Ongoing Operational Fees**: Beyond implementation, our TPA and software vendors will likely charge ongoing service fees between $30,000 to $50,000 annually to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Cost:** For our CHC, which serves **nearly 40,000 patients,** the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at **$1,785,400 annually**.

The In-House Pharmacy: The Burden of IT Integration

Noble Community Clinics operates 2 Onsite Pharmacies, 2 Onsite Remote Dispensing Site, 1 contract pharmacy. The rebate model is not a simple accounting change; it is a significant technological disruption. To remain compliant, in-house pharmacy systems will require costly customization to provide real-time, accurate information at the pharmacy counter.

- **System Interoperability:** Unlike contract pharmacies that use TPAs, in-house pharmacies must directly integrate their Electronic Health Record (EHR) and Pharmacy Management System (PMS) with a complex new rebate infrastructure. Our in-house pharmacy operates on OCHIN Epic Willow and does

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

not utilize a TPA. Willow is optimized for dispensing and billing, not manufacturer rebate workflows, and currently lacks native functionality to identify rebate-eligible claims, carve out uninsured prescriptions, transmit required rebate data elements, manage reversals, or perform manufacturer-specific reconciliation.

- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend 40 hours per week manually pulling "Purchase Files" and "Price Files" to verify that every rebate check matches the statutory 340B price.

The Contract Pharmacy: The Burden of Network Coordination

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

- **TPA Reliance and Fees:** Navigating manufacturers' varying requirements across multiple contract pharmacies requires high-level TPA intervention. We anticipate that our TPAs will pass on the costs of developing rebate-tracking modules to us through increased per-claim fees.
- **Verification Latency:** The rebate model creates a reconciliation gap. Our staff must monitor claims across 4, soon to be 5, different pharmacy locations to ensure rebates are paid correctly.
- **Risk of Pharmacy Exodus:** The model shifts financial risk to the pharmacy, potentially causing contract partners to opt out of the 340B program entirely rather than manage the administrative headache. In 15+ Counties in east-central and central Wisconsin this would leave patients with no affordable medication options. Over 17 percent of the U.S. population already lives in a pharmacy desert.[2]

II. Patient Impact

Noble Community Clinics has significant concerns about the impact a 340B Rebate Model Pilot would have on our most vulnerable patients' access to life-saving medications. The majority of drugs selected for the MDPNP for 2026 and 2027, and included in the proposed rebate model, manage chronic conditions prevalent in primary care settings. CHCs serve a patient population with a higher burden of chronic conditions compared to private practices, with studies showing a significantly higher prevalence of illnesses like diabetes, hypertension, and obesity.[3] This patient population relies on affordable medications to manage these long-term conditions.

The impact on insulin access is also alarming and directly conflicts with federal requirements. With over 3 million Americans relying on CHCs for essential diabetes care,[4] insulin affordability is a matter of life and death. Furthermore, Executive Order #14273 conditions future Section 330(e) funds on CHCs providing low-income patients with access to discounted insulin. No current operational method exists to provide discounted medications in a rebate model. In the proposed model, the wholesaler price file would reflect the full Wholesale Acquisition Cost (WAC) rather than the discounted 340B price, making the price unattainable for patients and precluding CHCs from fulfilling their legal obligation to offer the required discount at the point of care.

III. Financial Challenges

Lack of access to upfront 340B discounts, along with the high IT/infrastructure costs, will disproportionately impact CHCs and trickle down to patients. Many CHCs are currently under financial

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

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

[4] 2025 UDA Data, HRSA (hrsa.gov)

strain, with nearly half operating with fewer than 90 days of cash on hand, and one in four reporting negative five percent operating margins. This rebate model creates significant financial challenges, including:

- **Purchasing Drugs at the WAC Price Upfront:** Under the proposed model, CHCs would be required to purchase drugs at the WAC. CHCs will have to wait to receive their rebate payment *after* providing medications to their patients, forcing difficult decisions about how to allocate limited financial resources, including cutting essential services and reducing operating hours. We are particularly worried that the need to purchase drugs at full WAC will cause cash flow issues and potentially lead CHCs to exceed credit limits with wholesalers, halting their ability to order medications until payments are submitted.
- **Sliding Fee Scale:** A rebate model creates substantial uncertainty about CHCs' ability to apply sliding-fee discounts at the point of sale. By statute and regulation, CHCs are required to offer sliding fee discounts for all required and additional health services within the HRSA-approved scope of project.[5] In line with their mission, CHCs offer flat or sliding-scale discounts on prescription drugs to make them more affordable for low-income individuals.[6] A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size. **Noble Community Clinics uses a sliding fee discount scale and has a nominal fee in addition to the drug cost that is stratified based on the Federal Poverty Level of the patient. In addition, we subscribe to a charitable formulary which allows us to dispense those medications to patients at no cost. We also match the price of local large retail chain discount club lists.**

Conclusion

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

Noble Community Clinics appreciates the opportunity to respond to this ICR on the 340B Rebate Model Pilot Program, and we look forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please contact **If you have any questions, please contact Kristin Stearns at Kristin.Stearns@nobleclinics.org**

Sincerely,

Kristin Blanchard Stearns

Kristin Stearns
President
Noble Community Clinics

[5] HRSA FAQ

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

Franciscan ALLIANCE

April 27, 2026

Thomas J. Engels
Administrator
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD

CORPORATE OFFICE
PH: 574 256 3935

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RE: Information Collection Request Title: 340B Rebate Model Pilot Program Application, Information, and Evaluation, OMB No. 0906-NEW

Dear Administrator Engels:

Franciscan Alliance, Inc. ("Franciscan") respectfully submits these comments in response to HRSA's Information Collection Request (ICR) (91 FR, 9632) about the role of *340B covered entities* in providing data to request a rebate in connection with a potential 340B Rebate Model Pilot Program. Franciscan strongly opposes any shift to a rebate-based model and urges HRSA to maintain the upfront discount structure that has governed 340B for more than 30 years. We understand that HRSA is considering developing a rebate model to effectuate 340B ceiling prices for 25 drugs—10 subject to Medicare Part D negotiated prices in 2026 and 15 beginning in 2027. Our hospitals have relied on receiving 340B pricing through upfront discounts. For decades, the program has operated successfully on this basis—not post-sale rebates—and only recently has HRSA suggested a change.

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

Who Franciscan Is and How It Uses 340B Savings

Franciscan Alliance, Inc. is a mission-driven, Catholic, not-for-profit health system serving Indiana communities for over 150 years. Franciscan has served local communities operating 11 hospitals in Indiana and employing over 18,000 individuals and practitioners. Over seventy percent of Franciscan's patients are Medicare or Medicaid beneficiaries, or self-pay, with reimbursement substantially below the cost of care. In fact, in 2024, Franciscan provided approximately $912 million in community benefits and unreimbursed Medicare and Medicaid costs, with uncompensated care of $749 million and charitable assistance of $131.6 million.

Franciscan hospitals eligible to participate in the 340B Program include Franciscan Health Lafayette and Franciscan Health Michigan City (340B Disproportionate Share Hospitals); Franciscan Health Indianapolis and Franciscan Health Dyer (340B Rural Referral Centers); and Franciscan Health Rensselaer (340B Critical Access Hospital). Franciscan relies on its 2025 340B savings of approximately $88 million to sustain essential, loss-generating services for low-income, rural, and medically underserved populations. Franciscan uses 340B savings for basic purposes, like paying our nurses, doctors, and other providers. 340B savings support a broad range of essential services and community programs for Indiana's most vulnerable populations. Specifically, Franciscan has used its 340B savings to: (1) offset costs of caring for uninsured and underinsured patients; (2) sustain its Critical Access Hospital and rural health clinics; (3) support one of two Bone Marrow Transplant Programs in Indiana, and programs providing outpatient infusion for cancer, rheumatology, and other non-oncology indications; (4) support pharmacist-managed anticoagulation clinics; (5) provide free indigent care and sexual assault clinics; (6) offer community outreach programs including free immunizations, breast health screenings, cancer screenings, various lab screening tests, health fairs, education, and support groups; (7) offer transition of care and medication-to-bedside programs to bridge the gap from hospital to the community; (8) operate healthy living centers for diabetes management, medical education, and other chronic disease state management. These examples highlight Franciscan's longstanding commitment to providing care for Indiana's most vulnerable populations and underscore the critical importance of 340B remaining an upfront discount at the time of purchase in supporting each hospital's charitable mission.

The ICR expressly invites comment on (1) the necessity and utility of the proposed information collection; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

(1) Necessity and Utility of the Proposed Information Collection

Franciscan believes the 340B Rebate Model Pilot Program, if implemented, will negatively impact Franciscan's programs and divert resources away from improving the health of our communities to 340B administrative tasks. Franciscan respectfully requests HRSA remove consideration of a rebate-based model to effectuate the 340B ceiling price. Franciscan recommends HRSA implement a clearinghouse of 340B prescription and medical claims using the minimum necessary data elements maintained by a neutral party. This clearinghouse could provide the necessary information to the Medicare Transaction Facilitator (MTF) to ensure deduplication under the Medicare Drug Price Negotiation Program (MDPNP) and to other related parties to ensure deduplication of Medicaid rebates. Franciscan agrees a solution is needed related to deduplication of Medicaid rebates or Medicare Maximum Fair Price (MFP) refunds. Franciscan wishes to make clear that we support data transparency strategies designed to address those goals. However, a 340B rebate model is simply not needed to achieve those goals.

We could not have anticipated HRSA would abruptly consider replacing a longstanding and effective discount system with a rebate approach that would increase costs and administrative burdens for the very providers that Congress intended to benefit from 340B. Our 340B program—including our process for managing 340B and non-340B drug inventory, the data we share with our third-party vendors, and the resources we have available to support patient care— is built around upfront discounts. Moving to a rebate model would disrupt well-established reliance interests grounded in decades of consistent implementation of 340B through upfront discounts. Respectfully, HRSA's assumption that a rebate model—even one designed with safeguards—could cause only a "minimal impact" on 340B covered entities is incorrect.

(2) Accuracy of Estimated Burden

HRSA's current estimates are 52 submissions per year; 5 hours per submission; totaling 260 hours annually. Franciscan's per entity estimates are 156 to 250 submissions per year; 5 hours per submission; 5 hours per week for reconciliation and issues; totaling 1,040 to 1,510 hours annually per entity driven by frequency of submission, volume of claims, and non-reconciled transactions.

Franciscan's five 340B hospitals would be required to front to drug manufacturers approximately $15 million based on our actual 2025 purchases of the 2026 and 2027 Medicare Drug Price Negotiation Program (MDPNP) drugs. Franciscan estimates additional expense of $2.5 million per year due to (1) loss of cost-minus drug wholesaler

discounts when purchasing at WAC prices and (2) drug manufacturer rebate denials for unclear reasons. Franciscan estimates a $2.4 million negative impact to 60-day cash on hand based on projected average increase in inventory costs for the 25 drugs. This impact disrupts decades of business practices built around 340B upfront discounts.

HRSA's ICR statements,"OPA expects the data submitted by covered entities to manufacturers will be comparable to data already being collected and maintained by covered entities through existing third-party vendor relationships or data that is already being provided to manufacturers with respect to certain contract pharmacy policies, in-house pharmacy claims requests, and data elements provided for claims with drugs dispensed under the Medicare Drug Price Negotiation Program. Therefore, the burden associated with a potential 340B Rebate Model Pilot Program data requests may not be significant." are respectfully and simply not true. First, the initial 340B Rebate Model Pilot Program did require different data than what is provided to existing third-party vendors. Second, Franciscan no longer provides data to manufacturers with respect to manufacturer contract pharmacy policies. Franciscan completed a large project in 2024-2025 to transition from contract pharmacies to 340B covered entity-owned retail pharmacies for most of its 340B-eligible prescription volume. Franciscan did this to STOP sharing claims with manufacturers under 30+ different manufacturer contract pharmacy policy terms that were repeatedly changed with almost no notice.

Our past experience with manufacturer data submission platforms (e.g., 340B ESP) has been rife with costly challenges, such as addressing errors, inconsistencies, and opaque requirements, with access to 340B pricing often delayed or denied despite compliance with the manufacturers' policies. We must dedicate staff just to address these issues. With rebates applying across all hospital settings—not just contract pharmacies—the administrative burden and financial risk would increase greatly. Franciscan planned to hire 3 additional full-time employees for HRSA's withdrawn rebate pilot with a primary responsibility of completing necessary tasks to comply with a 340B Rebate Program with the goal of obtaining all rebates owed to Franciscan as quickly as possible. *The new expense for the 3 additional full-time employees would be approximately $312,500 per year.* Part of the new employees' responsibilities would be data preparation, data submission, payment reconciliation between the MDPNP refunds and 340B rebates, and maintaining 340B pricing access on the impacted drugs.

- Data Preparation and Submission: The employees will access the three (3) third-party administrator applications used by Franciscan to prepare the data for submission at least three times per week. Within the applications, multiple data extracts would be processed and combined. Franciscan would target a more frequent submission

than the minimum required to decrease the impact on cash flow. From Franciscan's experience submitting only prescription claims data to 340B ESP, Franciscan reviewed all data submissions to ensure only the minimum necessary fields and transactions were shared. It is common pharmacy business practice for multiple insurance adjudications to be required before the final payment transaction. Franciscan reviews the data submissions to remove non-final transactions insignificant to 340B. In addition, the data submissions required manual review to capture reversal transactions for prescriptions not picked up by patients that cross data submission periods. If the reversal happens within the same reporting period, Franciscan would not include the transaction in the data submission as it strives to only share the minimum necessary data.

- Medical Claims Challenges: The withdrawn 340B Rebate Pilot Program required medical claims data in addition to pharmacy claims data, even though the stated purpose of ensuring MDPNP deduplication is only applicable to pharmacy claims data in 2026 and 2027. Franciscan does not provide the requested medical claim data fields to other parties, like our 340B third-party administrator applications. Franciscan had prioritized preparation to submit pharmacy claims because of experience with 340B ESP data submissions. Franciscan was not prepared to submit medical claims data by 1/1/26 and was going to purchase impacted drugs in the hospital setting at a non-340B, sometimes the highest cost WAC price. The required Medical Claims fields were unclear. The manufacturer's chosen vendor, Beacon, had acknowledged in webinars and communications that some of the fields were inconsistently identified in practice. There were error-prone issues for drugs dosed more than once per day during a hospital observation stay. Two approaches would have been required to address drugs with HCPCS codes and drugs without HCPCS codes. There were concerns about the time it takes to ICD-10 code a patient's hospital visit and issue a bill. *On average, Franciscan's outpatient-only visits with drugs take 8 days to bill with less than 1% falling outside of a 45-day window to bill. Billing delays take an average of 10 days to resolve. Therefore, many of our medical claims are final in 8 to 45 days.* This would cause the rebate payment to Franciscan to be well after the drug's administration.

- Manufacturer 340B Policy Variation: From Franciscan's experience in preparing for the withdrawn 340B Rebate Pilot Program, the initial eight HRSA-approved manufacturer rebate policies included variations that would cause Franciscan to incur additional expense to understand, manage, and reconcile the differences. The differences included how unreplenished accumulations prior to

1/1/26 would be managed. It is standard practice in the 340B inventory replenishment model to accumulate until a full package size is reached. 340B covered entities should not be penalized and lose accumulation based on drug utilization rates. The manufacturer policies would have led to irresponsible drug purchasing or loss of 340B accumulations based on past 340B-eligible drug dispenses or administrations. Another variation was that data upload specifications were similar, but not consistent. There was a variation on whether manufacturers would continue to require 340B ESP submissions in addition to Beacon, essentially doubling the work.

- Payment Reconciliation: Franciscan was concerned about the administrative burden of reconciling 340B rebate payments. Based on experience with manufacturers' contract pharmacy restriction policies, involved parties wanted to blame others when transactions could not be reconciled. There was a lack of transparency. Covered entities could not obtain clear answers regarding 340B pricing when it was removed. With a Rebate Program, Franciscan expects there will not be clear answers when a rebate is denied. Manufacturer actions have shown that they are comfortable making unilateral decisions about who is a 340B patient, including adding more requirements than the HRSA patient guidance. The withdrawn Rebate Program included receiving multiple payments from multiple manufacturers on multiple timelines, requiring reconciliation.

- Program Integrity: A 340B Rebate Program would introduce more internal and external audits for Franciscan in our efforts to always value program integrity via self-monitoring.

- Other Operational Impacts: A 340B Rebate Program would require manual updates to the weekly drug price files Franciscan loads in its electronic health record. The Rebate Program will cause the 340B price file to commonly include WAC prices. This will have to be modified manually, involving multiple price files per week per location.

A rebate model would impose onerous administrative requirements and costs on covered entities, diverting critical resources from patient care—outcomes that conflict with the program's statutory intent. *HRSA's continued consideration of a rebate approach for 340B is deeply concerning and even more so that HRSA is considering putting forth a broader rebate model than the one in HRSA's withdrawn rebate pilot notice.* We nonetheless appreciate the opportunity to provide input through

this ICR to document the significant costs and harm a rebate model would create for our hospital and the patients we serve.

(3) Ways to Enhance the Quality, Utility, and Clarity of the Information to be Collected

HRSA should continue the 340B program as an up-front discount program at the time of purchase. Franciscan agrees a data collection process is needed to improve the implementation of the MDPNP to deduplicate 340B and Medicare discounts. Covered entities should not be sending medical and prescription claims data to manufacturers or their chosen vendor. The manufacturers' chosen vendor is setting non-negotiable terms on how the data can be used. Covered entities should be sending 340B eligibility determinations to a neutral party that interacts with the MTF for deduplication. A similar neutral clearinghouse could be used to prevent Medicaid rebate and 340B duplicate discounts.

(4) Use of Automated Collection Techniques

Franciscan supports the use of automated collection techniques if a neutral clearinghouse was used to collect 340B-eligibility determination. The 340B-eligibility determination should be combined with one to three other fields necessary to relate the 340B-eligiblity to the prescription or medical claim. Franciscan would be supportive of scheduling a daily or weekly extract that could be automatically moved to an electronic location for a neutral party to acquire and process. Covered entities would need the ability to send multiple files due to multiple third-party applications. The neutral application would need to process negative entries.

Conclusion

Introducing rebates into the broader 340B Program would be a monumental decision with enormous impacts on Franciscan and the communities we serve. Notably, a rebate model is entirely unnecessary to achieve MDPNP or Medicaid deduplication and is therefore suspect on its face, absent robust treatment and attention to the voluminous concerns noted above. We hope that HRSA will seriously consider and meaningfully address the questions presented in this letter, take into account the information provided by other stakeholders, and reach a solution that protects vulnerable patients. Without due care, our healthcare safety net—and the lives that rely on it—are at risk.

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

If, however, HRSA chooses to move forward with this deeply concerning effort, it must allow Franciscan and other covered entities to comment on the specifics of its new program. While we have endeavored to provide the most detailed information possible, we are doing so without precise knowledge of which drugs will be included in a Rebate Program and many other critical details (*e.g.*, data required, possible grounds for denial of rebates, dispute resolution processes, other guardrails). Providing an opportunity for additional comment on program specifics would help ensure that HRSA has a complete and informed record addressing the significant operational and legal issues raised by a rebate model.

We thank you again for the opportunity to respond to the ICR. We would appreciate any opportunity to discuss our comments further.

Respectfully submitted,

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University Health

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April 27, 2026

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

Electronically submitted via paperwork@hrsa.gov

Re: Information Collection Request: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-XXXX (91 FR 9632)

Dear Administrator Engels:

On behalf of Bexar County Hospital District, San Antonio, TX, dba University Health, we appreciate the opportunity to comment on the Department of Health and Human Services' (HHS) "Information Collection Request: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation."

University Health is the safety-net county hospital system for Bexar County, Texas. Approximately 75% of our patients are covered by government-sponsored insurance or are uninsured. Our mission is to care for anyone and everyone, regardless of ability to pay, while reducing barriers to care and improving community health outcomes. The 340B Drug Pricing Program is essential to University Health's financial stability and to our ability to deliver charity care, sliding-scale drug access, and comprehensive safety-net services. Because of our payer mix and role as a safety-net provider, University Health is uniquely exposed to financial, operational, and patient access harms associated with a rebate-based model.

As explained below, *any* rebate mechanism will impose substantial costs and operational burdens on University Health that far outweigh any benefits that might come from it. The Health Resources and Services Administration (HRSA) own cost assumptions appear materially understated. More fundamentally, HRSA's desire to test a rebate model is seemingly based on the incorrect premise that it must balance the interests of 340B hospitals and drug companies when choosing a discount mechanism. In practice, HRSA must prioritize the need of covered entities to enable them to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Preserving the upfront discount mechanism, which University Health has relied on for years, is the best way to fulfill that purpose of the 340B program.

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In accordance with the Paperwork Reduction Act (PRA), HRSA requests comment on: (1) whether the proposed information collection is necessary for the proper performance of the agency's functions, including whether the information has practical utility; (2) the accuracy of HRSA's estimate of the burden of the proposed collection; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology.

University Health's comments are set forth below.

Necessity and Practical Utility of the Proposed Collection.

University Health supports HRSA's objectives regarding program integrity, including preventing duplicate discounts, such as those involving the 340B and Medicare Drug Price Negotiation Program (MDPNP) deduplication. However, the proposed data collection appears primarily intended to implement a rebate-based pricing system that involves purchasing medications at the wholesale acquisition cost (WAC), submitting claim-level rebate requests, and subsequent reconciliation and dispute resolution, rather than facilitate oversight of the current upfront-discount 340B model.

Consequently, the necessity and practical utility of this collection depend on the underlying policy decision to adopt a rebate-based framework. University Health respectfully recommends that HRSA refrain from adopting a rebate model, as we believe the proposed data collection is unnecessary for the effective administration of HRSA's functions within the 340B Program, which has historically operated through upfront discounts. Should HRSA decide to proceed despite these concerns, the collection should be strictly limited to the essential information needed to verify eligibility and prevent duplicate discounts, while avoiding the requirement of redundant data elements already maintained by covered entities to ensure audit readiness under existing 340B compliance procedures.

Accuracy of HRSA's Burden Estimate.

Critically, our experience indicates that HRSA's estimate of approximately 5 additional hours per week to manage rebate-related activities is a significant underestimation of the time, labor, and costs that would be incurred by covered entities under a rebate-based model. Internal analysis at our facility demonstrates that the time commitment is substantially higher. In advance of HRSA's previously proposed rebate program, University Health devoted approximately 165 hours across pharmacy, information technology (IT), analytics, finance, and senior leadership during the 60-day

preparation window (estimated internal labor costs of approximately $19,000), prior to implementation of any ongoing operational requirements.

For ongoing operations, HRSA's estimate of approximately 5 additional hours per week to manage rebate-related activities is inconsistent with University Health's operational analysis. The estimated burden reflects claim-level processing across multiple steps, including validation, submission, reconciliation, and exception handling. Total effort is driven by overall claim volume, number of participating drugs, number of covered entity sites, and the need for coordination across pharmacy, finance, and IT functions. For example, across our 8 entity-owned pharmacies, 2 hospitals, 181 child sites, and 66 contract pharmacies, for the 10 drugs that HRSA previously approved for its original Program and those that have been approved under the Medicare Drug Price Negotiation Program (MDPNP) for 2027, University Health estimates:

- Manual claims submission alone would require approximately 1-2 additional hours per week.
- Claim reconciliation across the lifecycle would require approximately 133 additional hours per week, excluding dispute resolution, audit preparation, compliance oversight, and coordination with manufacturers and third-party administrators (TPAs).

Staffing impacts also exceed what would be implied by HRSA's estimates, and University Health does not currently have the staff needed to comply with a Rebate Program. These activities represent new operational requirements that do not exist under the current upfront discount model, where pricing is applied at the point of purchase without claim-level submission, reconciliation, and dispute resolution. University Health anticipates that implementing a 340B rebate model would require adding dedicated staff to manage the wide range of new, labor-intensive responsibilities highlighted above that do not exist under the current program structure. These responsibilities are largely manual due to the lack of comprehensive, integrated software solutions to support rebate processing. As a result, the administrative burden is not only increased but also operationally inefficient and highly resource intensive. University Health anticipates that initial implementation would require at least:

- 0.5-1.0 additional administrative full-time equivalent (FTE), representing an estimated cost of $250,000 annually.
- 3 additional operational FTEs, representing an estimated cost of $144,000 annually.
- If expanded to all 340B-eligible medications, University Health estimates staffing needs could exceed 20 additional full-time employees to submit and reconcile hundreds of thousands of claims monthly, at an estimated annual cost of over $960,000.

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Finally, HRSA's burden estimate should explicitly account for significant systems-integration work and higher vendor costs. University Health estimates that health system vendor-related expenses could increase from about $185,000 annually to as much as $500,000 annually, when including implementation fees, system upgrades, consulting fees, and expanded service needs.

In total, the administrative and staffing impact of a 340B rebate model is substantial, ongoing, and operationally disruptive. It introduces a level of manual workload and financial risk that necessitates significant personnel expansion and diverts critical resources from patient care. We respectfully urge HRSA to reassess its assumptions about administrative burden and fully account for the real-world staffing implications such a model would impose on covered entities.

Enhancing the Quality, Utility, and Clarity of the Information to Be Collected.

If HRSA proceeds despite these concerns, several improvements are critical. To enhance data quality, reduce ambiguity, and improve the practical utility of any information collected, HRSA should, at a minimum:

- Specify with precision the minimum data elements required and identify the authoritative source(s) for each element (e.g., dispensing record, adjudicated claim, invoice), recognizing that rebate submissions depend on fully adjudicated and validated claims.
- Clearly explain how each data element directly contributes to program integrity without adding unnecessary reporting requirements.
- Standardize submission formats, frequency, and validation rules, and require uniform data specifications across participating manufacturers, to avoid disparate manufacturer-specific requirements that increase manual workload and error risk.
- Require transparent and standardized manufacturer responses (including clear denial and underpayment reason codes), timelines for review and payment, and a standardized dispute-resolution process that supports efficient error correction without repeated resubmissions.
- Align any submission deadlines with real-world claims adjudication timelines. University Health notes that a 45-day window measured from the dispensing date may expire before many claims are finalized, increasing the likelihood of missed deadlines and unrecoverable losses.
- Provide covered entities an additional opportunity to comment on specific, operative program requirements (including participating drugs, required data elements, denial criteria, dispute-resolution processes, and other guardrails) prior to implementation, because the feasibility and burden of compliance cannot be evaluated accurately in the absence of those details.

However, the core inefficiencies of a rebate model would persist despite these improvements.

Use of Automated Collection Techniques and Information Technology to Minimize Burden.

If HRSA proceeds, burden minimization should be an explicit design requirement. While automation can mitigate some burden, it cannot offset the structural inefficiencies introduced by a rebate model. As described in these comments, a rebate-based model would convert what are currently largely automated 340B compliance processes into a transaction-based process requiring continuous tracking, validation, submission, reconciliation, and potential resubmission.

To minimize burden, HRSA should:

- Implement a neutral third-party clearinghouse for deduplication and standardized data exchange, rather than requiring covered entities to submit to and reconcile with numerous manufacturers separately.
- Require a single standardized submission pathway with uniform edits, acknowledgments, and response codes, rather than manufacturer-specific portals and data specifications.
- Ensure that any IT platform used to support the collection incorporates transparent security controls, appropriate privacy safeguards, and contracting terms compatible with public-entity legal constraints. University Health's review of the Beacon platform participation agreement in the prior iteration identified significant governance, privacy/security, data licensing, and indemnification concerns. Any platform selected must resolve these issues to avoid creating barriers to participation and to mitigate compliance and cybersecurity risk.

The proposed rebate model and the associated information collection would impose substantial operational, administrative, and financial burdens on safety-net providers like University Health while offering little to no programmatic benefit. A rebate model risks disrupting access to discounted drugs, diverting resources away from patient care, and undermining the core mission of the 340B program. We strongly urge HRSA to maintain the current upfront discount structure and withdraw from the proposed rebate model and associated information collection requirements.

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

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

We appreciate the opportunity to provide input on this request and the consideration of these comments. The issues outlined above have meaningful operational and patient care implications for covered entities participating in the 340B program.

CommWell Health

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April 27, 2026

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

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

Submitted via paperwork@hrsa.gov

Dear Director Britton:

On behalf of Tri-County Community Health Council, Inc. d/b/a CommWell Health, I would like to thank the Health Resources and Services Administration (HRSA) for providing the opportunity to share our estimated burden with HRSA on compliance with the 340B rebate model pilot program. Given the severe administrative, financial, and operational burden a rebate model would place on Community Health Centers (CHCs), CommWell Health again requests that CHCs be exempted from the pilot program.

CommWell Health is a Community Health Center headquartered in southeastern North Carolina, providing accessible, affordable, and high-quality outpatient care to low-income, uninsured, and medically underserved residents across Sampson, Johnston, Pender, Bladen, and Brunswick counties. Founded in 1976 and celebrating 50 years of service in 2026, CommWell Health operates 13 campuses and two mobile units and will open a new comprehensive medical, dental, and behavioral health site in Coats, Harnett County later this year. CommWell Health serves nearly 27,000 patients annually and provides integrated medical, dental, behavioral health, pediatrics, OB/GYN, HIV/AIDS care, Medication for Opioid Use Disorder treatment, mobile mammography, in-house and mail-order pharmacy services, and enabling services including WIC, nutrition counseling, transportation assistance, care coordination, centralized scheduling, specialist referrals, and financial counseling.

The 340B program is foundational to CHCs' ability to serve the most vulnerable members of our community. However, the proposed shift of responsibility from manufacturers to safety-net providers directly serving patients through a rebate model threatens to

destabilize CHC pharmacy operations nationwide. Based on national assessments from the National Association of Community Health Centers (NACHC) and our own internal assessments, the hours and dollars spent complying with a rebate program are staggering.

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

By requiring CHCs to purchase medications at full price and wait for rebates, this model would cause significant financial turmoil and directly affect our ability to serve the nearly 27,000 patients who rely on us. We operate on razor-thin margins, and these additional costs are not an option for many entities. Similar to navigating manufacturers' existing contract pharmacy restrictions, CHCs will need to invest in IT infrastructure upgrades and hire or reassign staff to manage new complexities, including varying data submission requirements and timelines, payment reconciliations, and dispute processes for denied rebates. We will face an increased administrative burden in monitoring rebate claims and payments.

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

Workforce Impact

- **Staffing Impact:** CommWell Health anticipates needing 1.0 additional FTE to account for the increase in operational, administrative, and compliance burden created by a rebate model.
- **Annual Administrative Compliance Burden:** CommWell Health estimates annual compliance-related labor and support costs associated with one additional FTE and supporting infrastructure to be approximately $225,000–$250,000.
- **Number of Hours:** Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, CommWell Health will face increased administrative burden in monitoring rebate claims and payments. Based on current internal assessment, CommWell Health estimates a minimum of 10 hours per week for rebate claim preparation and submission, with an additional 20 hours per week potentially required for reconciliation activities, including review of Purchase Files, Price Files, rebate payments received, and dispute follow-up related to denied claims. Given anticipated denial activity, this burden may be understated.
- **External Vendor Costs:** CommWell Health anticipates additional costs for external vendors, including consultants, legal counsel, program coordination, EMR/pharmacy software support, and reconciliation services. While precise recurring vendor costs cannot yet be fully quantified due to uncertainty surrounding

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

manufacturer-specific requirements, CommWell Health expects these costs would be additive to the administrative burden described above.

Pharmacy Software & Third-Party Administration Changes

Navigating this pilot requires more than staff; it requires significant changes to pharmacy software and workflow. HRSA should consider the increased compliance burdens when manufacturers have 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:** CommWell Health anticipates high upfront costs to adapt pharmacy software, pay for custom dashboard modifications, and design new internal workflows before a single rebate is ever received. Based on preliminary internal estimates, one-time implementation costs could range from $10,000 to $15,000, exclusive of potential future manufacturer-specific system requirements.
- **Ongoing Operational Fees:** Beyond implementation, software vendors may impose ongoing service fees to maintain rebate-tracking features. Because manufacturer requirements and associated vendor pricing remain undefined, these recurring costs cannot yet be reliably quantified, which itself underscores uncertainty and burden inherent in the model.
- **Total Cost:** For our CHC, expenses for labor, IT, and carrying costs will increase substantially, in addition to the significant gross upfront capital requirements described elsewhere in this letter.

The In-House Pharmacy: The Burden of IT Integration

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

- **System Interoperability:** CommWell Health would need to integrate Epic and PioneerRx with a complex new rebate infrastructure.
- **One-Time Integration Costs:** CommWell Health estimates upfront integration costs associated with custom API builds and Price File reconciliation tools could range from **$10,000 to $15,000**, recognizing these estimates may increase depending on final manufacturer requirements.
- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services anticipate spending approximately **20 hours per week** manually validating Purchase Files and Price Files and pursuing claim discrepancies and rebate denials.

The Contract Pharmacy: The Burden of Network Coordination

CommWell Health does not currently utilize contract pharmacy arrangements. However, we believe it is important to retain comment on this component of the proposed rebate model because the burdens associated with contract pharmacy administration further illustrate the broader operational complexity the model would impose across covered entities.

The rebate model introduces a new complexity that threatens the viability of contractual arrangements used by many Community Health Centers to increase access to affordable medications, particularly in rural and medically underserved communities.

While CommWell Health does not currently partner with contract pharmacies and therefore cannot provide organization-specific quantitative estimates related to contract pharmacy claims volume, per-claim fees, or network-specific reconciliation burden, we offer the following observations consistent with concerns raised nationally:

- TPA Reliance and Fees: Navigating manufacturers' varying requirements across multiple contract pharmacies would likely require high-level third-party administrator intervention. We are concerned that TPAs may pass on the costs of developing rebate-tracking modules through increased per-claim fees or other administrative charges to covered entities.

- Verification Latency: The rebate model creates a reconciliation gap in which covered entities may be required to monitor claims across multiple pharmacy locations to ensure rebates are paid correctly. Even though CommWell Health does not currently operate in this environment, this burden has implications for overall program integrity and administrative feasibility.

- Risk of Pharmacy Exodus: The model shifts financial risk to pharmacy partners, potentially causing contract pharmacies to opt out of 340B participation rather than absorb added administrative complexity. In rural regions, this could leave patients with fewer affordable medication access points, particularly in communities already vulnerable to pharmacy deserts. Over 17 percent of the U.S. population already lives in a pharmacy desert.[2]

Importantly, CommWell Health's comments throughout this letter reflect the burden imposed even in a comparatively streamlined entity-owned pharmacy model without contract pharmacy complexity. If a rebate model creates significant administrative and financial disruption under these circumstances, the burden is likely even greater for CHCs operating multiple contract pharmacy relationships.

Clinic Administered Drugs (CADs): The Burden of New Systems Required

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

CommWell Health estimates approximately 20 staff hours per reporting cycle could be required to convert, validate, and upload records associated with clinic-administered drugs should such reporting be required under a rebate model.

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

[3] Internal NACHC survey data

Most CADs are bundled into the prospective payment system when administered to patients. Because PPS visits are paid at a flat rate, the medications administered are often not separately included on claims billed to payers.

Administration and inventory logs are commonly maintained on paper, with text documentation in patient visit notes. While CHCs maintain perpetual inventories and complete records, paper records impose the added burden of converting them to electronic data before submitting for rebate. Very few CHCs maintain electronic Medication Administration Records (eMARs), and where available they often require standalone systems.

CommWell Health continues to support exclusion of CADs from any rebate model pilot.

II. Patient Impact

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

We are deeply concerned that implementing a rebate model could cause CHC patients to lose access to essential therapies. For example, direct oral anticoagulants (DOACs) such as Eliquis® and Xarelto® are vital for patients with deep vein thrombosis, pulmonary embolism, and atrial fibrillation. For many patients, there are minimal—and often less safe—alternatives. Forced therapeutic interchanges or interruptions in access introduce real clinical risk, including medication nonadherence, treatment delays, and adverse outcomes — one study found that discontinuing these drugs leads to a statistically significant increase in the risk of stroke, heart attack, and death.[5]

Similarly, the impact on patients requiring SGLT2 inhibitors such as Farxiga® and Jardiance® would be severe. These drugs are a mainstay of primary care treatment for Type 2 diabetes, chronic kidney disease, and heart failure, all of which are highly prevalent among CHC patients. Research has found that even a 30-day withdrawal of these inhibitors increases the annualized risk of cardiovascular death or heart failure hospitalization.[6] By making these therapies unaffordable or operationally inaccessible, the rebate model could contribute to preventable hospitalizations and worsening outcomes.

The United States is also in the midst of a mental health crisis, and the inclusion of behavioral health drugs in future negotiated drug lists raises additional concerns for

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

[5] 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.

[6] 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

continuity of treatment among vulnerable populations who already face substantial barriers to care.

The impact on insulin access is also alarming and directly conflicts with federal requirements. With over 3 million Americans relying on CHCs for essential diabetes care[7], insulin affordability is a matter of life and death. Furthermore, Executive Order #14273 conditions future Section 330(e) funds on CHCs providing low-income patients with access to discounted insulin. No current operational method exists to provide discounted medications in a rebate model. In the proposed model, the wholesaler price file would reflect the full Wholesale Acquisition Cost (WAC) rather than the discounted 340B price, making the price unattainable for patients and precluding CHCs from fulfilling their legal obligation to offer the required discount at the point of care.

Imposing a rebate model on CHCs would only weaken the safety-net providers millions rely on for health care. 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 could become operationally difficult to sustain in the same way they are today. This model would create a new barrier, rather than a solution, for the patients least able to absorb it.

III. Financial Challenges

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

- **Purchasing Drugs at the WAC Price Upfront**
  Based on our organization's purchasing data, the rebate model would require approximately **$5.6 million** in gross annual upfront capital required for procurement before rebate recovery, compared with approximately $104,000 at 340B ceiling pricing. This represents a **5,300% increase** in upfront capital required for procurement before rebate recovery.
    - Approximately **$13.5 million increase** in upfront drug spend over three years.
    - Approximately $750,000 in estimated annual rebate-related opportunity costs, including potential loss of prompt pay, purchase-volume discounts, sub-ceiling discounts, and denial-related exposure.
    - Approximately $560,000 in potential annual denial-related exposure assuming a 10 percent denial rate.

  We are particularly concerned the need to purchase drugs at full WAC could cause cash flow issues and potentially lead CHCs to exceed credit limits with wholesalers, affecting the ability to order medications.

- **Sliding Fee Scale**
  A rebate model creates substantial uncertainty about CHCs' ability to apply sliding-fee discounts at the point of sale. By statute and regulation, CHCs are required to offer sliding fee discounts for required and additional health services within the

[7] 2025 UDA Data, HRSA (hrsa.gov)

HRSA-approved scope of project.[8] In line with their mission, CHCs offer flat or sliding-scale discounts on prescription drugs to make them more affordable for low-income individuals.[9] A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size.

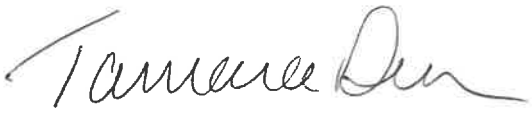
CommWell Health makes medications affordable through sliding-fee discounts with minimal dispensing fees. Through Express Discount Meds, prescription medications are sent directly to patients' homes, with shipping provided at no cost to all CommWell Health patients and supported through foundation resources. Since beginning free home delivery in 2022, we have seen the percentage of patients with poorly controlled diabetes decrease from 33% to 26% in 2025, and the percentage of patients with controlled hypertension increase from 59% to 75% in 2025. This service is particularly important in rural communities where transportation barriers and pharmacy access challenges can interrupt adherence. Programs like Express Discount Meds depend on an operational environment where resources flow toward patients rather than administrative overhead and manufacturer reconciliation cycles. A rebate model places that environment at risk.

Conclusion

CommWell Health strongly urges HRSA to exempt CHCs from any 340B Rebate Model Pilot Program. A rebate model 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, force difficult decisions about staffing and services, require substantial investments in compliance infrastructure, and create barriers for patients who depend on affordable medications. CommWell Health believes a 340B rebate pilot would cause disproportionate harm to patients served by CHCs and other safety-net providers.

CommWell Health appreciates the opportunity to respond to this ICR on the 340B Rebate Model Pilot Program. If you have questions, please contact Christopher Vann, Chief of Government Affairs and Development, CVann@commwellhealth.org.

Sincerely,



Tamara Dunn, MBA, RN
CEO
Tri-County Community Health Council, Inc.
d/b/a CommWell Health

[8] HRSA FAQ

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

Westside Family Healthcare
We treat you well.

April 27, 2026

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

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

Submitted via paperwork@hrsa.gov

Dear Director Britton:

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

As a Federally Qualified Health Center, **Westside serves 25,000 Delawareans each year**. We are on the front lines of caring for our neighbors most in need. **Westside relies on 340B savings to sustain essential service**s that would otherwise be financially out of reach for many of our patients. These savings directly offset the cost of uncompensated care for underinsured and uninsured individuals, ensuring that our most vulnerable community members receive high-quality, comprehensive care regardless of their ability to pay. **340B savings allow Westside to maintain critical services such as dental care, prenatal care, laboratory testing, and wraparound support** for uninsured patients. Additionally, **affordable 340B pricing facilitates medically necessary access to medications for uninsured and underinsured patients, including Medicare patients** who cannot afford supplemental prescription coverage. These are core components of whole-person primary care that are not fully reimbursed, yet they are indispensable to improving health outcomes and reducing long-term healthcare costs.

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

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

By requiring CHCs to purchase medications at full price and wait for rebates, this model would cause significant financial turmoil and directly affect our ability to serve the **25,000** patients who rely on us. We operate on razor-thin margins, and these additional costs are not an option for many entities. Similar to navigating manufacturers' existing contract pharmacy restrictions, CHCs will need to invest in IT infrastructure upgrades and hire or reassign staff to manage new complexities, including varying data submission requirements and timelines, payment reconciliations, and dispute processes for denied rebates. We will face an increased administrative burden in monitoring rebate claims and payments.

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

Workforce Impact:

- **Staffing Impact**: **Westside anticipates needing at least one additional FTE** to account for the increase in operational, administrative, and compliance burden created by a rebate model.
- **Increased Hours:** Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, Westside will face a significantly increased ongoing administrative burden to accurately monitor rebate claims and payments. Many additional hours will be required to regularly report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: **Westside anticipates an additional $50,000** for external vendors, including consultants, legal counsel, program coordination, third-party administrators (TPAs), electronic medical records (EMRs), pharmacy software, and reconciliation services.

Pharmacy Software & Third-Party Administration Changes

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

- **One-Time Implementation Costs:** We anticipate high upfront costs to adapt our pharmacy software, pay for custom dashboard modifications, and design new internal workflows. An estimated **$30,000** will be required simply to reach the baseline of compliance before a single rebate is ever received.
- **Ongoing Operational Fees**: Beyond implementation, our TPA and software vendors will likely charge ongoing service fees to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.

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

- **Total Cost:** For our CHC, which serves **25,000 patients**, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at **$150,000 and likely more** annually.

The In-House Pharmacy: The Burden of IT Integration

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

- **System Interoperability:** Unlike contract pharmacies that use TPAs, in-house pharmacies must directly integrate their Electronic Health Record (EHR) and Pharmacy Management System (PMS) with a complex new rebate infrastructure.
- **One-Time Integration Costs:** We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools.
- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend additional hours per week manually pulling "Purchase Files" and "Price Files" to verify that every rebate check matches the statutory 340B price.

The Contract Pharmacy: The Burden of Network Coordination

The rebate model introduces a new complexity that threatens the existence of contractual arrangements. My CHC currently partners with 7 major pharmacy organizations to increase access to affordable medications.

- **TPA Reliance and Fees:** Navigating manufacturers' varying requirements across multiple contract pharmacies requires high-level TPA intervention. We anticipate that our TPAs will pass on the costs of developing rebate-tracking modules to us through increased per-claim fees.
- **Verification Latency:** The rebate model creates a reconciliation gap. Our staff must monitor claims across over 100 different pharmacy locations to ensure rebates are paid correctly.
- **Risk of Pharmacy Exodus:** The model shifts financial risk to the pharmacy, potentially causing contract partners to opt out of the 340B program entirely rather than manage the administrative headache. In the State of Delaware**,** this would leave patients with no affordable medication options. Over 17 percent of the U.S. population already lives in a pharmacy desert.[2]

Clinic Administered Drugs: The Burden of New Systems Required

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

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

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

[3] Internal NACHC survey data

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

II. Patient Impact

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

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

III. Financial Challenges

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

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

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

scale discounts on prescription drugs to make them more affordable for low-income individuals.[7] A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size. **Our team at Westside spends countless hours each week navigating options to find medications that are affordable for our patients through our network of convenient contract pharmacy locations, which offer significant flat discounts.**

Conclusion

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

Westside appreciates the opportunity to respond to this ICR on the 340B Rebate Model Pilot Program, and we look forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please contact me at chris.fraser@westsidehealth.org.

Sincerely,

Chris Fraser, MBA, FACHE
Westside Family Healthcare

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

April 27, 2026

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

Re: ICR: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation

Dear Administrator Engels:

Second Sight Solutions, LLC ("Second Sight") appreciates the opportunity to respond to the Health Resources and Services Administration's (HRSA) Information Collection Request (ICR) published February 26, 2026, regarding a potential rebate model pilot program.[1]

Second Sight is a technology provider with a vision to promote transparency and integrity with healthcare innovators and industry partners. Second Sight provides technology services that identify and address 340B deduplication, including facilitating 340B and MFP data exchange among manufacturers and covered entities. Our team of industry-recognized experts combines deep policy knowledge with practical, technology-enabled solutions to deliver insight, innovation, and impact to manufacturers and integrate with and support their partners, including covered entities, third-party administrators (TPAs), and dispensing pharmacies. These comments reflect our operational experience and do not represent any individual client's position.

Since 2020, Second Sight has operated 340B ESP, a technology platform that supports pharmaceutical manufacturers' 340B channel management policies, including by allowing covered entities to submit 340B claims data.[2] Today, more than 30 manufacturers use the 340B ESP platform, and we have integrations with 33 TPAs. Since its inception, the platform has collected 340B claims data from more than 7,000 covered entities.

In 2024, Second Sight introduced a new technology platform, Beacon Rebate Model, that enables 340B covered entities to access 340B pricing through the submission of eligible purchase and claims data.[3] In 2025, HRSA announced a Rebate Model Pilot Program ("Rebate Model Pilot") available to nine manufacturers of "selected drugs" subject to the Maximum Fair Price (MFP) within the Medicare Drug Price Negotiation Program (MDPNP) for Initial Price Applicability Year (IPAY) 2026. In their HRSA-approved Rebate Model Pilot applications in October and

[1] Health Resources and Services Administration Information Collection Request: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, February 2025, available at: https://www.govinfo.gov/content/pkg/FR-2026-02-26/pdf/2026-03833.pdf.
[2] https://340besp.com/about.
[3] https://cm.beaconchannelmanagement.com/.

November 2025, all nine manufacturers indicated that they would use the Beacon Rebate Model platform to process 340B rebate requests as part of the pilot program. To date, 10,000 covered entities have registered on the platform, our organization has conducted 21 educational sessions for stakeholders which were attended by over 3,000 individuals, and 53 TPAs have successfully integrated with Beacon Rebate Model.

In 2026, Second Sight launched another technology platform, Beacon MFP, that facilitates the processing of MFP rebates on behalf of manufacturers and grants dispensing pharmacies real time visibility into MFP rebate status and access to good faith resolution tools.[4] Second Sight has partnered with CMS, drug manufacturers, and 62,000 dispensing pharmacies to successfully ingest and process more than 19 million rebates through the Beacon MFP platform since January 1, 2026. Additionally, Beacon MFP provides a good faith resolution center that facilitates resolution of MFP-related issues that arise between manufacturers and dispensing pharmacies; approximately 90% of these MFP issues also pertain to 340B.

HRSA is soliciting comments on the proposed data collection from covered entities to request rebates under a potential 340B Rebate Model Pilot Program, including the practical need for and usefulness of the collection, the reasonableness of the estimated reporting burden, and opportunities to improve the quality and clarity of the information, as well as on the design and operation of such a model. Second Sight is uniquely positioned to provide responsive data and insights, given our experience collecting 340B claims data from covered entities, facilitating de-duplication between 340B discounts and MFP rebates, and training the covered entity community in the use of the Beacon Rebate Model platform.

We respond to HRSA's Information Collection Request on the following targeted topics.

Necessity of Claims-Level Data Collection from Covered Entities

Collection of covered entity claims data is necessary to accomplish HRSA's stated goal of collecting manufacturer rebate reports to enhance 340B program integrity and compliance monitoring. Covered entities participating in a Rebate Model Pilot will need to submit a defined set of data elements that collectively facilitate validation of the rebate request and de-duplication with CMS payment programs (MDPNP, MDRP). These elements differ for pharmacy and medical claims. The data elements collected by the Beacon Rebate Model, as currently designed, are publicly available on the Beacon Rebate Model website.[5] These elements align with data already maintained by covered entities as part of standard claims processing workflows and for purposes of 340B program compliance and audit readiness.

One of HRSA's potential goals in implementing a Rebate Model Pilot is to resolve duplication between 340B and the MDPNP. For 2026 and 2027, the MDPNP applies only to Medicare Part D. Some advocates have stated that a Rebate Model Pilot can be limited in scope to only drugs

[4] https://mfp.beaconchannelmanagement.com/.

dispensed to Medicare Part D beneficiaries, or only to drugs used in retail pharmacy settings, while still allowing for this goal to be met. This assertion belies other potential goals of a Rebate Model Pilot, such as de-duplication with the MDRP, as well as significant operational and compliance concerns presented by a Rebate Model Pilot that is limited in this manner. If a Rebate Model Pilot were limited to one payer and/or one setting, the same covered entity would access the 340B price for the same drug through two different mechanisms: an up-front discount and a retrospective rebate. This bifurcated procurement process creates the risk that units purchased using an up-front 340B discount will be dispensed to patients who are within the scope of the Rebate Model Pilot. Whether intentionally or unintentionally, a covered entity could, as a result, submit a duplicative request for a 340B rebate when the underlying drug was already purchased at the 340B price. Manufacturers, receiving no claim-level data for the units purchased at the 340B price, would have no mechanism to identify these occurrences and prevent duplicate rebate payments. This would create yet a new type of 340B duplication: 340B chargeback – 340B rebate duplication.

In addition to claim-level data, the submission of standardized purchase data elements is important to operate a Rebate Model Pilot and prevent duplicate discounts. Specifically, purchase data elements enable manufacturers to validate that the drug for which a rebate is requested was purchased by the covered entity and to verify the purchase price. The submission of purchase data would also enable the calculation of different basis prices for 340B rebates, which could provide additional flexibility for 340B covered entities that retain access to discounted commercial prices such as a GPO price. While manufacturers receive sales data from their wholesaler partners, that data does not include the dispense level data elements needed to connect it to rebate requests, as claims level data is not available to the wholesaler.

Administrative Burden and Operational Considerations for Covered Entity Data Submission

HRSA defines burden to include the total time required to generate, maintain, retain, validate, and transmit requested information, including time for system development, training, and data processing.

Certain elements of burden described by HRSA, including reviewing instructions, establishing systems, and training personnel, are largely one-time or infrequent activities rather than recurring weekly costs. Covered entities participating in a Rebate Model Pilot would complete initial registration tasks to register with a manufacturer-supported platform such as Beacon Rebate Model. These tasks include providing information/documentation establishing that an individual is authorized to register a particular covered entity, as well as banking details for purposes of rebate payment. The timing for these tasks will vary by covered entity and may depend on the availability of relevant documentation. To date, over 10,000 340B covered entities have already registered with the Beacon Rebate Model platform and completed the one-time registration tasks. As a result, for many entities, the time associated with system setup, training, and initial familiarization should not be attributed to ongoing burden. Based on our work on behalf of manufacturers, we believe that the covered entities already registered with Beacon

Rebate Model account for the majority of 340B purchases of drugs subject to the MFP in IPAY 2026.

In addition to these one-time registration tasks, covered entities participating in a Rebate Model Pilot will need to regularly submit certain 340B utilization data. The required data fields and utilization data that entities would submit to Beacon Rebate Model are exactly the same as those submitted to 340B ESP. Thus, for the 7,000 covered entities that have already submitted data to 340B ESP, the incremental work necessary to submit data to Beacon Rebate Model is very limited.

For covered entities that have not previously utilized the 340B ESP platform, the process for submitting data is designed to be straightforward and user-friendly, even for new users. Based on our experience operating the platform, the upload, mapping, and validation steps typically require about 15 minutes per submission, excluding internal data preparation, with actual timing varying by covered entity. This metric is based on actual usage patterns tracked in the 340B ESP platform during 2025. Second Sight is also actively engaging with TPAs and other 340B vendors to support direct data submissions that significantly reduce or eliminate any potential burden of data compilation on the part of the 340B covered entity. As of spring 2026, 53 TPAs and vendors are fully provisioned and able to submit data directly to the Beacon Rebate Model.

We would add that HRSA requires covered entities to maintain "accurate records to ensure compliance," including "a list of all 340B drugs that were furnished, administered, or dispensed to patients," for purposes of audits conducted by HRSA.[6] Given this, we expect covered entities that already maintain HRSA-required documentation to experience only a modest incremental effort in preparing files for submission to Beacon. Indeed, covered entity advocacy groups have voiced prior support for a duplicate discount solution in which covered entities would regularly report 340B claims data, indicating that this is within the operational capabilities of covered entities.[7]

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[6] https://www.hrsa.gov/opa/program-integrity; Sample HRSA 340B Audit Data Request List (DRL) for Covered Entities, September 2025, available at: https://www.340bpvp.com/Documents/Public/340B%20Tools/sample-hrsa-340b-audit-data-request-for-covered-entities.pdf.

[6] American Hospital Association Comments to Medicare Drug Price Negotiation Program Draft Guidance, July 2024, available at: https://www.aha.org/lettercomment/2024-07-02-aha-submits-comments-cms-guidance-medicare-drug-price-negotiation-program ("Proposed Approach Ensuring Prospective Access to MFP and 340B Pricing… For a selected drug purchased at the 340B price, the 340B covered entity or its TPA would submit to the MTF a batch datafile that contains only necessary data elements for each 340B-eligible drug claim."); 340B Health Comments on Proposed Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request (OMB Control Number: 0938-New), December 27, 2024, available at: https://www.regulations.gov/comment/CMS-2024-0323-0015 ("we continue to urge CMS to permit covered entities (CEs) to choose to retrospectively submit 340B claims data to CMS' Medicare Transaction Facilitator (MTF)").

Additionally, with respect to HRSA's estimate of manufacturer burden for monthly purchase reports, the assumed 2-hour average per response should be viewed in the context of alternative approaches to duplicate discount prevention. In practice, the time required to generate and transmit standardized purchase reports is substantially lower than the administrative burden associated with resolving duplicate discounts through existing mechanisms, including the administrative dispute resolution (ADR) process, which often requires significantly greater time investment, coordination, and iterative documentation. Moreover, any manufacturer-developed alternative solution to duplicate discount prevention would require substantial upfront system design, stakeholder coordination, and ongoing maintenance, far exceeding the incremental effort associated with standardized monthly reporting under a rebate model. Importantly, the burden estimates also do not capture the significant amount of time currently expended by manufacturers and covered entities in identifying, investigating, and resolving duplicate discount discrepancies. A rebate model would substantially reduce these recurring reconciliation activities, thereby reducing total system-wide administrative burden beyond the reporting time reflected in the ICR.

Lastly, Second Sight remains receptive to covered entity feedback regarding the functionality of its platform, with the goal of minimizing the administrative costs of a Rebate Model Pilot. Second Sight also continues to remain supportive of automated collection techniques or other forms of technology to improve the collection process, including through collaboration with TPAs and covered entities. In late 2025, Second Sight convened a group of covered entity representatives for regular "insight forums" to discuss technical aspects of the Beacon Rebate Model platform. Second Sight continues to regularly meet with TPAs and consultant groups to educate them on the Beacon platforms, solicit feedback, and identify improvements.

Recommended Approach to Data Quality, Standardization, and Usability

To enhance the quality, utility, and clarity of the proposed information collection, HRSA could consider standardized data definitions and submission formats for both claim-level and purchase data across both pharmacy and medical claims. Uniformity in data requirements across manufacturers and covered entities is the most important factor in ensuring that collected information is accurate, comparable, and suitable for program oversight and evaluation. Once standardized fields and definitions are established, the Beacon Rebate Model platform is already designed to operationalize these requirements in a structured and straightforward manner.

Because the underlying data elements align with information already maintained by covered entities for purposes of 340B compliance and existing claims processing workflows, the combination of HRSA-defined standards and platform-based validation would significantly reduce variability in submissions.

At present, policymakers lack comprehensive visibility into how 340B pricing, MDPNP rebates, and Medicaid rebate structures interact at the claim level. A unified, structured data collection

would enable HRSA and CMS to assess whether statutory goals of each program are being achieved in practice, including whether discounts and rebates are appropriately applied and how these programs collectively influence net drug spending across federal healthcare programs.

Utility of Manufacturer Reporting for Program Oversight and Evaluation

To support effective oversight of a potential 340B Rebate Model Pilot Program, HRSA should require manufacturers to submit standardized reporting on a monthly basis, consistent with the agency's February 26 Information Collection Request indicating that such data would be used to evaluate program integrity and improve transparency.[8]

With respect to the content of reporting, HRSA could align requirements with data elements established under the prior Rebate Model Pilot design by requiring manufacturers to submit minimally necessary claims level data fields and a set of standardized data aggregations. The transaction-level extract would enable HRSA to assess individual rebate determinations. In parallel, aggregated reporting would provide a program-level view of performance and compliance trends, including metrics such as aggregated sales by covered entity type, average time from claim submission to rebate payment, the number of rebates paid beyond established timeframes, and the volume and reasons for denied rebates.

Together, these reporting elements would allow HRSA to monitor the operational performance of a Rebate Model Pilot Program while providing the agency with greater oversight into program use and patterns. Comprehensive reporting of 340B claims has the potential to streamline HRSA's workflows related to covered entity audits, ADR matters, engagement with other federal agencies, and general program monitoring. HRSA could further enhance transparency by publicly reporting selected aggregated metrics derived from manufacturer submissions on a periodic basis, such as quarterly or annual publication. To mitigate the risk of disclosing competitively sensitive information, any public reporting should be aggregated across manufacturers and structured to avoid the identification of individual manufacturer-specific sales or pricing data. Maintaining consistent reporting requirements for the full duration of the Rebate Model Pilot will enable HRSA to assess program performance over time. This approach would balance the goals of transparency and accountability with the need to protect sensitive commercial information, while providing stakeholders with meaningful insight into the operation and outcomes of the pilot program.

Please feel free to contact Ellie Blalock at eblalock@thinkbrg.com if there is any further information we can provide or if you have any questions about our comments.

[8] Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906-NEW, February 2026, available at: https://www.federalregister.gov/documents/2026/02/26/2026-03833/agency-information-collection-activities-proposed-collection-public-comment-request-information.

Sincerely,

/s/
Ellie Blalock
Vice President, Strategy & Policy
Second Sight Solutions, LLC

Information Collection Request: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation